Petitioner's Environmental Report for Dicamba-Tolerant Soybean MON 87708 and Dicamba- and Glufosinate-Tolerant Cotton MON 88701

The undersigned submits this petition under 7 CFR §340.6 to request that the Administrator make a determination that the article should not be regulated under 7 CFR Part 340

November 22, 2013

OECD Unique Identifiers: MON-877Ø8-9 (soybean) and MON-887Ø1-3 (cotton)
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Release of Information

Monsanto is submitting the information in this petition for review by the USDA as part of the regulatory process. By submitting this information, Monsanto does not authorize its release to any third party. In the event the USDA receives a Freedom of Information Act request, pursuant to 5 U.S.C. § 552, and 7 CFR Part 1, covering all or some of this information, Monsanto expects that, in advance of the release of the document(s), USDA will provide Monsanto with a copy of the material proposed to be released and the opportunity to object to the release of any information based on appropriate legal grounds, *e.g.*, responsiveness, confidentiality, and/or competitive concerns. Monsanto understands that a copy of this information may be made available to the public in a reading room and upon individual request as part of a public comment period. Except in accordance with the foregoing, Monsanto does not authorize the release, publication or other distribution of this information (including website posting) without Monsanto's prior notice and consent.

Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this report includes all information and views on which to base a determination, and that it includes all relevant data and information known to the petitioner that are unfavorable to the petition.

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TABLE OF CONTENTS

TABLE OF TABLES

TABLE OF FIGURES

I. PURPOSE AND NEED

Monsanto has developed a new biotechnology-derived soybean (*Glycine max*), designated as event MON 87708 ("DT soybean"), that is tolerant to dicamba herbicide, and a new biotechnology-derived cotton (*Gossypium* spp.), designated as event MON 88701 ("DGT cotton"), that is tolerant to dicamba and glufosinate herbicides. Monsanto submitted petitions for determinations of nonregulated status for DT soybean and DGT cotton three and one years ago, respectively. At the time of the initial submissions, Monsanto provided the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) with lengthy scientific materials and Environmental Reports. In the years that followed, APHIS has reviewed those materials in detail. The appropriate framework for APHIS's review of such petitions is the Plant Protection Act (PPA) and associated regulations at 7 CFR Part 340. For more than two decades, through many dozens of Environmental Assessments, two Environmental Impact Statements (EIS), and in multiple litigation matters, APHIS has explained that its regulatory role in the Coordinated Framework under the PPA is limited to assessing whether the subject organisms present a "plant pest risk." See Section I.B.1.

From 2007-2013, litigation in the U.S. District Court for the Northern District of California and appellate proceedings in the U.S. Court of Appeals for the Ninth Circuit focused on the scope of APHIS's authority under the PPA and APHIS's related obligations, if any, under the National Environmental Policy Act (NEPA) and the Endangered Species Act (ESA). One of the principal questions in those suits was whether APHIS has a responsibility under NEPA or ESA to examine the effects of herbicide uses in connection with the genetically engineered (GE) crop at issue, or instead whether the U.S. Environmental Protection Agency (EPA) has such responsibility. Monsanto intervened in that litigation, and together Monsanto and APHIS succeeded in winning both at the district court level and before the appellate court. See Section I.B.4 for more discussion. The court decision left no doubt that APHIS's traditional interpretation of its authority under the PPA was indeed correct, and that APHIS was not required by the PPA, NEPA or the ESA to address such herbicide uses in the manner plaintiffs in the litigation alleged. However, just days before the ultimate conclusion of that litigation APHIS issued a notice announcing that it would indeed prepare an EIS related, at least in part, to such herbicide uses.

Monsanto does not believe that the type of EIS described by APHIS's May 16, 2013, Notice of Intent (NOI) to prepare an EIS addressing herbicide uses is necessary or appropriate, particularly in light of these recent litigation decisions. Indeed, such an EIS could duplicate many of the analyses to be performed by EPA under its authorities. Both DT soybean and DGT cotton are needed by American farmers as soon as possible, and Monsanto has found it difficult to justify a delay in review of these technologies simply to perform duplicative analyses.

That said, Monsanto is consolidating information in this updated Environmental Report to ensure that there is no doubt the record is complete, and so that APHIS can refer to this material and can finish its intended EIS for DT soybean and DGT cotton as soon as possible. Accordingly, this updated Environmental Report for both technologies integrates and supplements the materials previously provided to APHIS on July 2010 (for DT soybean petition and Environmental Report), October 2012 (supplemental NEPA analysis for DT soybean), December 2012 (supplemental NEPA analysis for DT soybean), January 2013 (supplemental NEPA analysis for DT soybean), July 2012 (for DGT cotton petition), and May 2013 (for DGT cotton Environmental Report).

I.A. PURPOSE OF MON 87708 SOYBEAN (DT SOYBEAN) AND MON 88701 COTTON (DGT COTTON)

Monsanto has developed a new biotechnology-derived soybean (*Glycine max*), designated as event MON 87708 ("DT soybean"), that is tolerant to dicamba herbicide, and a new biotechnology-derived cotton (*Gossypium* spp.), designated as event MON 88701 ("DGT cotton"), that is tolerant to dicamba and glufosinate herbicides. DT soybean and DGT cotton are genetically engineered to be resistant to dicamba through the insertion of a gene (from *Stenotrophomonas maltophilia*) that expresses a mono-oxygenase enzyme that rapidly demethylates dicamba and renders it inactive, thereby conferring tolerance to dicamba. DGT cotton also contains a bialaphos resistance (*bar*) gene (from *Streptomyces hygroscopicus*) that expresses the phosphinothricin N-acetyltransferase (PAT) protein to confer tolerance to glufosinate herbicide. Both DT soybean and DGT cotton combined will be combined with glyphosate-tolerance traits utilizing traditional breeding techniques.

The in-crop use of dicamba for soybean and dicamba and glufosinate herbicides for cotton, in addition to glyphosate herbicide, provides enhanced weed management options in soybean and cotton cultivation to control a broad spectrum of grass and broadleaf weed species. These uses of dicamba and glufosinate also provide effective control of weeds resistant to several herbicide families, where such weeds may occur. Effective weed management practices in agricultural systems helps ensure that herbicide-resistant weeds do not become a limiting factor in crop production. One of the most recommended weed management practices by weed scientists is the use of multiple herbicide modes-of-action when appropriate, especially to mitigate the evolution and development of herbicide resistant weeds. Successful integration of DT soybean and DGT cotton can enhance weed management systems by providing additional in-crop herbicide modes-of-action, while fostering growers' use of established production practices, reduced tillage systems, and the same planting and harvesting machinery. DT soybean and DGT cotton will also help growers maintain yield and quality to meet the growing need for food, feed and fiber, both domestically and for export markets.

I.B. REGULATORY AUTHORITY

Since 1986, the U.S. Government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (U.S. FDA 1986; 1992). Under the Coordinated Framework, the responsibility for regulatory oversight falls on three federal agencies: the U.S. Food and Drug Administration (FDA), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA), and the U.S. Environmental Protection Agency (EPA). The FDA reviews the safety of food consumed by humans and animals under the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. §§ 301 *et seq.*); APHIS examines whether a plant itself presents a "plant pest" risk under the Plant Protection Act (PPA) (7 U.S.C. §§ 7701 *et seq.*); and EPA regulates potential environmental and human-health concerns regarding pesticide use by setting maximum permissible pesticide residues on crops under the FFDCA and prescribing the conditions under which associated herbicides and other pesticides can be used under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. §§ 136 *et seq.*).

I.B.1. USDA-APHIS Authority

APHIS regulates GE crops under its "plant pest" PPA authority. Under the PPA, to constitute a plant pest under the PPA, defined by 7 U.S.C. §7702(14), an organism must (1) fall within certain enumerated categories of living things and (2) injure or cause disease in plants. To meet the first requirement, an organism must be:

> [the] living stage of any of the following … (A) A protozoan. (B) A nonhuman animal. (C) A parasitic plant. (D) A bacterium. (E) A fungus. (F) A virus or viroid. (G) An infectious agent or other pathogen. (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

7 U.S.C. §7702(14).

Facially, GE plants do not satisfy this first requirement. The only type of plant that can even be a plant pest is a parasitic one (*i.e.,* a plant that depends on other plants for sustenance). The genetic elements used in many GE plants, however, are derived from (or inserted into target plants using) bacteria or viruses—organisms that may qualify as plant pests. It is therefore theoretically possible for a GE plant to present a plant-pest risk, and for that reason APHIS presumes under its governing GE/plant-pest regulations that these GE crops pose plant-pest risks.

As to the second requirement, APHIS has never considered potential gene flow between commercial crops to constitute the sort of "injury" or "disease" for purposes of the definition of "plant pest." That interpretation is based in part on the fact that cross-pollination is a natural reproductive process that has no effect on existing plants. Instead, any such "effect" would only be to the character of the offspring and is not in any ordinary sense considered injurious. APHIS has also never considered the pesticides applied to a crop—which are separately regulated by EPA—to be relevant to the analysis of the plant-pest risk of a GE plant. APHIS's interpretations of its plant-pest authority have been upheld by federal courts. *Center for Food Safety v. Vilsack*, 718 F.3d 829 (9th Cir. 2013); *Center for Food Safety v. Vilsack,* 844 F. Supp. 2d 1006 (N.D. Cal. 2012).); *see also* Brief for Federal Appellees at 17-18, *Vilsack*, 718 F.3d 829 (June 6, 2013) *available at* 2012 WL 2313232 ("The harms cited by plaintiffs [*i.e.*, herbicide impacts and potential cross-pollination] have never been treated as APHIS's statutory justification for regulation under its plant pest authority, and APHIS reasonably concluded that they do not qualify as plant pest risks pursuant to the Plant Protection Act."); *id.* at 29-30 ("Herbicides are not plant pests. Moreover, risks from glyphosate do not qualify as plant pest risks because glyphosate application does not result from Roundup Ready Alfalfa itself, but rather from independent human action." (citations omitted)); *id.* at 30 (APHIS "has not considered increased herbicide use to be a plant pest harm in its analyses of other genetically engineered herbicide resistant crops.").

In contrast to gene flow, the types of injuries that typically fall within USDA plant-pest authority are substantial threats to plants from organisms such as insects and mites (like the Asian Longhorned Beetle and Mediterranean fruit fly) and viruses and bacteria (like the potato virus and *Ralstonia*), which can devastate entire crops and forests.[1]

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1 See APHIS, *Plant Health*, http://www.aphis.usda.gov/plant_health/plant_pest_info/ (listing plant pests); 7 U.S.C. §7702(14); APHIS, *About APHIS*, http://www.aphis.usda.gov/about_aphis/.

APHIS's GE crop/plant-pest regulations are found at 7 CFR Part 340. Those regulations were promulgated pursuant to APHIS authority under statutes that were ultimately recodified as the PPA. Specifically, Congress enacted the PPA in 2000 to replace and supersede the Plant Quarantine Act, the Federal Plant Pest Act, and the Federal Noxious Weed Act. *See* Pub. L. No. 106-224, 114 Stat. 438 (codified at 42 U.S.C. § 7701 *et seq.*); *see also Ctr. for Food Safety v. Vilsack*, 844 F. Supp. 2d 1006, 1013 (N.D. Cal. 2012). "The PPA's definition of 'plant pest' is materially the same as the 1957 Federal Plant Pest Act's definition of plant pest," however. *Ctr. for Food Safety v. Vilsack*, 718 F.3d 829, 834 (9th Cir. 2013). In addition, Congress expressly provided that APHIS's preexisting regulations "shall remain in effect until" APHIS replaces them. 7 U.S.C. §7758(c). APHIS has not amended its Part 340 regulations since enactment of the PPA and thus the PPA expressly provides that they shall continue to govern.

Under the PPA, APHIS has authority to regulate the introduction (importation, interstate movement, or release into the environment) of certain plants pests and products. Certain GE organisms are initially presumed to be regulated articles by regulation if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and the donor, recipient, or vector organism is considered a plant pest, or its plant pest status is unknown.

Any person may petition the agency for a determination that a regulated article is unlikely to pose a plant pest risk and, therefore, should be no longer regulated under the plant pest provisions of the PPA or the regulations at 7 CFR Part 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the PPA when APHIS reaches a final determination that it is unlikely to pose a plant pest risk and grants a petition for nonregulated status. In such a case, APHIS authorizations—including permits and modifications—are no longer required for the environmental release, importation, or interstate movement of the nonregulated article or its progeny.

It was pursuant to these APHIS regulations that Monsanto submitted in 2010 a petition for a determination of nonregulated status for DT soybean,[2] and in 2012 a petition for a determination of nonregulated status for DGT cotton.[3] Monsanto's petitions also sought determinations of nonregulated status for any progeny derived from crosses between DT soybean and conventional soybean, DGT cotton and conventional cotton, and any progeny derived from crosses of DT

[2] Petition for the Determination of Nonregulated Status for Dicamba-Tolerant Soybean MON 87708, Monsanto Petition Number: 10-SY-201U (July 6, 2010) ; Supplemental Information to Support the NEPA Analysis for the Determination of Nonregulated Status of Dicamba-Tolerant Soybean MON 87708, Petition # 10-188-01p (Oct. 11, 2012); Supplemental Information to Support the NEPA Analysis for the Determination of Nonregulated Status of Dicamba-Tolerant Soybean MON 87708, Petition # 10-188-01p (Dec. 14, 2012); Supplemental Information to Support the NEPA Analysis for the Determination of Nonregulated Status of Dicamba-Tolerant Soybean MON 87708, Petition # 10-188-01p (Jan. 31, 2013).

[3] Petition for the Determination of Nonregulated Status for Dicamba and Glufosinate-Tolerant Cotton MON 88701, Monsanto Petition Number: 12-CT-244U (July 2, 2012); Petitioner's Environmental Report for Dicamba and Glufosinate-Tolerant Cotton MON 88701, Monsanto Petition Number: 12-CT-244U-S (USDA Petition #12-185-01p_al) (May 6, 2013).

soybean and DGT cotton with other biotechnology-derived soybean and cotton that has been granted nonregulated status under 7 CFR Part 340.

I.B.2. FDA Authority

The FDA regulates GE organisms under the authority of the FFDCA. The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those developed through genetic engineering such as DT soybean and DGT cotton. All foods and feeds, whether imported or domestic and whether derived from plants modified by conventional breeding techniques or by genetic engineering techniques, must meet the same rigorous safety standards. Under the FFDCA, food and feed manufacturers are responsible for ensuring that the products they market are safe and properly labeled. In addition, the FDA must approve the use of any food additives, including those introduced into food or feed through plant breeding, before marketing. To help developers of GE plants that can used for food and feed comply with their obligations under the FFDCA, the FDA encourages them to participate in a voluntary, pre-market consultation process. In that process, developers submit to FDA a summary of data and information that provide the basis for a conclusion that a food and feed derived from GE plants is as safe as comparable non-GE food in the food supply. The goal of the consultation process is to ensure that human food and animal feed safety issues or other regulatory issues (*e.g.*, labeling) are resolved prior to commercial distribution of food or feed derived from GE plants.

Monsanto completed the biotechnology consultation process with FDA for the safety and nutritional assessment of food and feed derived from DT soybean on October 11, 2011 (BNF No. 00125, Monsanto, 2011). As part of its evaluation, the FDA reviewed information on the identity, function, and characterization of the genes, including expression of the gene products in DT soybean, as well as information on the safety of the dicamba monooxygenase (DMO) protein and DT soybean itself, including a dietary risk assessment. Monsanto also submitted a summary of its safety and nutritional assessment of genetically engineered DGT cotton to FDA on April 6, 2012, and supplemented its submission with additional information on May 22, July 18, and September 10, 2012. The FDA issued its Biotechnology Consultation Agency Response Letter on April 24, 2013, finalizing the consultation (BNF No. 000135, Monsanto, 2013). As part of its evaluation, the FDA reviewed information on the identity, function, and characterization of the genes, including expression of the gene products in DGT cotton, as well as information on the safety of the DMO protein and DGT cotton, including a dietary risk assessment (BNF No. 000135, Monsanto, 2013).

I.B.3. EPA Authority

EPA regulates under FIFRA the pesticides (including herbicides) that are used with crops, including GE herbicide-tolerant crops like DT soybean and DGT cotton. FIFRA requires all pesticides to be registered before distribution or sale, unless they are exempted. Under FIFRA, EPA must approve each distinct pesticide product, each distinct use pattern, and each distinct use site. Each crop for example, consititues a unique use site and no registered pesticide may be applied to any crop unless EPA has approved that specific pesticide/crop use.

Each pesticide must be labeled with enforceable directions for use on a crop by crop basis. It is a violation of FIFRA to use any registered pesticide in a manner inconsistent with its labeling, subject to criminal and civil penalty. [4] For that reason, an approved herbicide cannot be lawfully used on a corresponding herbicide-tolerant crop, unless EPA approves a label amendment for such use.

Before EPA can approve any pesticide registration or label amendment, EPA must determine there will be no "unreasonable adverse effects on humans and the environment." *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 438 (2005). In addition, if EPA finds that an approved herbicide use presents "unreasonable hazard to … species declared endangered or threatened by the [Endangered Species Act]," EPA may immediately suspend the pesticide's registration. 7 U.S.C. §§136(l), 136d(c). In deciding whether to register a pesticide, EPA also analyzes whether consulation under §7 of the ESA is warranted. *See generally See Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1031-34 (9th Cir. 2005).

In addition to EPA's FIFRA authority, EPA also regulates potential human-health impacts from pesticides under the FFDCA. EPA does so by establishing "tolerance levels" (*i.e.*, "the amount of pesticide that may remain on food products") under the FFDCA. *CropLife Am. v. EPA*, 329 F.3d 876, 879 (D.C. Cir. 2003). The FFDCA "defines pesticide tolerances as 'safe' when there is 'a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.'" *Id.* (quoting 21 U.S.C. §346a(b)(2)(A)(ii)).

In summary, in order to approve any use of a herbicide EPA must conclude that the herbicide, when used according to the label, does not pose an unreasonable adverse effect to humans or the environment, and, in order to establish a tolerance for the use of a herbicide on a food or feed crop, find there is a reasonable certainty of no harm to human health from non-occupational (food, water and residential/recreational) exposures to the herbicide. Therefore, all herbicides approved for use in soybean and cotton production can be used safely, and do not pose an unreasonable risk to humans or the environment.

In 2010, Monsanto has submitted to an application to amend Registration Number 524-582 to register a new use pattern for dicamba on DT soybean that facilitates a wider window of application, allowing dicamba to be applied pre-emergence through crop emergence and in-crop post-emergence through the early R1 reproductive phase, subject to a number of application requirements on the proposed label, which is currently pending before EPA, and the establishment of new tolerances for dicamba in soybean forage and hay. EPA has reviewed the safety of dicamba and the primary metabolite of dicamba (3.6-dichlorosalicylic acid or "DCSA"), during the reregistration of dicamba in 2006. EPA concluded in the 2006 dicamba Reregistration Eligibility Decision (RED) document that risks to human health and the environment associated with exposure to dicamba and its metabolites, including DCSA, were below the Agency's level of concern for all registered uses of dicamba, including conventional soybean (U.S. EPA 2009d).

Monsanto has also submitted (in July 2012) an amendment to its dicamba label to register a new use pattern for dicamba on DGT cotton that facilitates a wider window of application by removing all existing preemergence planting restrictions and allowing in-crop postemergence applications

[4] FIFRA §12(a)(2)(G) and §14

through seven days prior to harvest. This application also requests the establishment of a tolerance for cotton gin by-products, and the inclusion of DCSA in the residue definitions for both cottonseed and gin by-products.

The use pattern and rate of glufosinate on DGT cotton will follow the existing glufosinate-tolerant cotton uses outlined on the glufosinate herbicide label. The glufosinate residues in DGT cotton treated with commercial glufosinate rates are below the established pesticide residue tolerances for both cottonseed and gin by-products. Currently, glufosinate is undergoing registration review at EPA, which is expected to conclude by the end of 2013. It is expected that EPA will affirm the continued use of glufinsate in the marketplace upon completion of the registration review process. Therefore, Monsanto will not seek any changes in the glufosinate label or the established tolerances for its use on DGT cotton.

I.B.4. *Center for Food Safety v. Vilsack* and APHIS's Regulatory Authority

On May 16, 2013, APHIS announced its intention to prepare a full Environmental Impact Statement (EIS) not only to address jurisdictional plant pest issues under the PPA, but also to examine the possible environmental impacts of dicamba herbicide uses, including the selection of herbicide-resistant weeds.[5] The PPA does not give APHIS regulatory authority over herbicide uses. Indeed, Congress has expressly transferred regulatory authority over herbicides from APHIS to EPA over four decades ago, and APHIS itself has long recognized the strict limits on its PPA authority.[6] EPA's authority to regulate herbicides under FIFRA includes an evaluation of, and measures to address, the development of herbicide resistance in weeds associated with the use of those products.[7] Further, EPA's review under FIFRA has been held to be the "functional equivalent" of NEPA review by multiple federal courts.[8] Accordingly, APHIS has no jurisdiction over herbicides or the development of herbicide resistance in weeds that may be associated with herbicide use, and no authority to consider herbicide impacts under the PPA. Nor does APHIS have any obligation under NEPA to consider the environmental impacts of dicamba or glufosinate use, or alternatives to

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5 78 Fed. Reg. 28796.

6 *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991(1984) (observing that "the Department of Agriculture's FIFRA responsibilities were transferred to the then newly created Environmental Protection Agency…."); *see also* Pub.L. No. 92-516, 86 Stat. 973 (1972).

7 *See, e.g.,* EPA, Pesticide Registration (PR) Notice 2001-5, "Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling," p. 2 (2001), available at http://www.epa.gov/PR_Notices/pr2001-5.pdf (labeling measures to assist in pesticide resistance management). Additionally, pesticide registrants must report resistance to EPA as an adverse effect in order to ensure the pesticide continues to meet FIFRA requirements for registration. 40 C.F.R. § 159.188(c).

8 *Envtl. Def. Fund, Inc. v EPA*, 489 F.2d 1247, 1256 (D.C. Cir. 1973) (holding that FIFRA's standard and processes are the "functional equivalent of a NEPA investigation" and that "[t]he law requires no more"); *Envtl. Def. Fund, Inc. v. Blum*, 458 F. Supp. 650, 662 n.6 (D.D.C. 1978) ("If the 'functional equivalent' requirement means anything, it surely means that the EPA [in conducting analysis under FIFRA] did not have to follow the detailed procedural requirements laid out by NEPA."); *Douglas Cnty. v. Babbitt*, 48 F.3d 1495, 1502-03 (9th Cir. 1995) ("FIFRA procedures … displace[] NEPA's procedural and informational requirements" because "Congress did not intend for NEPA to apply to FIFRA."); *Merrell v. Thomas*, 807 F.2d 776, 782 (9th Cir. 1986) ("FIFRA's review provisions do afford the public some opportunity to participate in pesticide registration decisions…. [And while that] opportunity would be greater if NEPA [also] applied[,] Congress has made its choice [not to do so].").

deregulation since there is no reasonable alternative to deregulation once APHIS finds DT soybean and DGT cotton do not pose a pose a greater plant pest risk than their conventional counterparts.[9]

The Ninth Circuit recently addressed APHIS' authority under the PPA in *Center for Food Safety v. Vilsack* and concluded that APHIS does not have authority to regulate herbicide issues pertaining to GE crops.[10] That case involved a challenge to the Record of Decision (ROD) and supporting EIS APHIS issued unconditionally deregulating Roundup Ready® Alfalfa (RRA) on the ground that RRA was not a "plant pest" within the meaning of the PPA.[11] This litigation has a lengthy history.

That ROD and EIS were prepared as a result of prior litigation, which resulted in APHIS's initial deregulation of RRA being vacated. Monsanto and Forage Genetics filed a petition in April 2004 seeking a determination that RRA is not a plant pest.[12] In response to the petition, APHIS considered whether RRA caused any plant pest harms and concluded that RRA is not a plant pest, and therefore should not be regulated.[13] APHIS also prepared an Environmental Assessment (EA) under NEPA and issued a Finding of No Significant Impact (FONSI).[14] The agency accordingly did not prepare an Environmental Impact Statement (EIS) in support of its initial deregulation decision. On June 14, 2005, APHIS unconditionally deregulated RRA.

Plaintiffs sued the agency in the United States District Court for the Northern District of California to challenge the June 2005 deregulation, contending that APHIS violated the PPA, the Endangered Species Act (ESA), and NEPA.[15] The district court initially found APHIS's initial deregulation violated NEPA, vacated that deregulation, and enjoined APHIS from deregulating RRA in any manner, and any further planting of RRA, pending completion of an EIS addressing the environmental effects of gene flow, glyphosate-resistant weeds, and other potential issues.[16] The Ninth Circuit affirmed the district court's order.[17] The Supreme Court, however, granted certiorari

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9 *DOT v. Public Citizen*, 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform).

10 718 F.3d 829, 832-33 (9th Cir. 2013).

11 *Id.* at 832.

12 *See* 70 Fed. Reg. 36917.

13 *Id.* at 36917-18.

14 *Id.* at 36919.

15 *Geertson Seed Farms v. Johanns*, No. C06-01075, 2007 U.S. Dist. LEXIS 14533 at *10-12 (N.D. Cal. Feb. 13, 2007).

16 *Geertson Seed Farms v. Johanns*, 2007 U.S. Dist. LEXIS 21491 at *2-3 (N.D. Cal. Mar. 12, 2007); *Geertson Farms v. Johanns*, 2007 U.S. Dist. LEXIS 32701 at *9 (N.D. Cal. May 3, 2007).

17 *Geertson Seed Farms v. Johanns*, 570 F.3d 1130, 1133-34 (9th Cir. 2009).

and reversed, and remanded, holding that the injunction prohibiting partial deregulation and/or further RRA planting was an abuse of discretion and must be dissolved in its entirety.[18]

APHIS released its final EIS for RRA in December 2010. APHIS explained in the ROD that it was required under the PPA to deregulate RRA because RRA was not a plant pest and APHIS accordingly lacked authority to continue to regulate it as such.

Plaintiffs then filed another action in U.S. District Court for the Northern District of California, challenging APHIS's 2011 unconditional deregulation of RRA.[19] The district court rejected plaintiffs' challenges entirely. The court held that the alleged impacts of gene flow from GE crops and increased glyphosate usage are not plant pest harms under the PPA.[20] Once APHIS correctly concluded that it no longer had jurisdiction to regulate RRA as a plant pest, the regulation of RRA was a nondiscretionary act that did not obligate the agency to consult with the U.S. Fish and Wildlife Service (USFWS) under the ESA regarding the potential impacts on threatened and endangered species from glyphosate use.[21] The district court held that APHIS' EIS satisfied NEPA's procedural requirements and entered summary judgment in favor of defendants on all claims.[22] Plaintiffs appealed to the Ninth Circuit, challenging the district court's conclusion that gene flow and the impacts associated with increased herbicide use are not plant pest harms under the PPA, and that RRA was therefore not a "plant pest" within the agency's regulatory jurisdiction.[23] The Ninth Circuit unanimously affirmed the district court's ruling, concluding that the PPA does not regulate the types of alleged harms of which the plaintiffs complained.[24] Plaintiffs sought rehearing and rehearing *en banc*, but their petition was denied.

Specifically, the Ninth Circuit concurred with the Government's position that APHIS does not have general authority over agricultural issues, and instead only possesses specific, narrow authority to reduce the risk of dissemination of plant pests or noxious weeds.[25] The Ninth Circuit also agreed with the Government that risks from herbicide uses do not constitute plant pest risks because herbicide use does not result from the GE organism itself, but instead from independent human action.[26] Indeed, the Court specifically held that APHIS "has … never considered the possible consequences associated with increased herbicide use, including creation of herbicide-resistant

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18 *Monsanto Co. v. Geertson* Se*ed Farms*, 130 S. Ct. 2743, 2761-62, 177 L. Ed. 2d 461 (2010).

19 *Ctr. for Food Safety v. Vilsack*, 844 F. Supp. 2d 1006 (N.D. Cal. Jan. 5, 2012).

20 *Id.* at 1017.

21 *Id.* at 1020-21.

22 *Id.* at 1024-25.

23 Ctr. for Food Safety v. Vilsack, 718 F.3d at 839.

24 *Id.* at 832.

25 *Id.* at 834-35.

26 Id.

weeds, to be 'plant pest' injuries," and that APHIS's interpretation is "the best interpretation of this particular statutory language."[27] Accordingly, the Ninth Circuit held that APHIS has no regulatory authority or discretion to deny the petition for nonregulated status because of alleged herbicide impacts or harms.[28]

Because the Ninth Circuit upheld APHIS' determination that RRA is not a plant pest under the meaning of the term in the PPA and the accompanying regulations, APHIS no longer had jurisdiction to regulate RRA, and accordingly had no obligation to consult with the USFWS under the Endangered Species Act (ESA) or to consider the effects of glyphosate use in RRA or other glyphosate tolerant crops in its EIS. Nor did APHIS have an obligation to consider alternatives to unconditional regulation under NEPA because APHIS's limited plant-pest authority denied APHIS any discretion to continue regulating RRA as a plant pest.

Likewise, APHIS has no obligation here under NEPA to prepare an EIS to consider the potential environmental impacts of dicamba (or glufosinate) use on DT soybean or DGT cotton crops because APHIS lacks authority (and hence discretion) to regulate herbicide uses under the PPA or other APHIS authority. Monsanto is nevertheless including a limited discussion of herbicide use and effects in this Environmental Report and its Appendices to address statements made and questions raised by APHIS about herbicide uses in its May 2013 Notice of Intent (NOI), even though Monsanto believes the NOI seeks information beyond the scope of APHIS' statutory authority under the PPA.

I.B.5. Threatened and Endangered Species

Section 7(a)(2) of the ESA requires that the Federal action agency, in consultation with the USFWS or the National Marine Fisheries Service (NMFS), ensure that any discretionary action the agency authorizes, funds, or carries out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. A species is added to the list of threatened and endangered plant and wildlife species when the USFWS/NMFS determines that it is threatened or endangered because of any of the following factors: the present or threatened destruction, modification, or curtailment of its habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease or predation; the inadequacy of existing regulatory mechanisms; and the natural or manmade factors affecting its survival. Once an animal or plant is added to the list, protective measures under the ESA apply to the species and its habitat—including protection from adverse effects of discretionary Federal activities. The agency taking the discretionary action must assess the effects of its action and consult with the USFWS or NMFS if it determines the action "may affect" listed species or critical habitat.

APHIS' regulatory authority over certain GE organisms under the PPA is limited to those GE organisms which it has reason to believe might be a plant pest or those for which APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk. APHIS does not have statutory authority to authorize or regulate the use of herbicides. Instead,

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27 *Alfalfa II*, 2013 U.S. App. LEXIS 9920, at *29-30 (9th Cir. May 17, 2013).

28 Id.

EPA has the sole authority to regulate the use of any herbicide, including dicamba, glufosinate, and glyphosate. APHIS' ESA responsibilities thus are limited to ensuring that the plant for which nonregulated status is sought (here, DT soybean and DGT cotton) will not itself affect listed species or critical habitat.

As part of the NEPA process, APHIS met with USFWS officials on June 15, 2011, to discuss whether APHIS has any obligations under the ESA to analyze the impacts of herbicide use associated with all GE crops on threatened and endangered species (TES). As a result of those discussions, the USFWS and APHIS agreed that it is not necessary for APHIS to perform an ESA effects analysis on herbicide use associated with GE crops. Again, EPA has the sole authority to authorize or regulate the use of dicamba, or any other herbicide, by growers. Under 7 CFR Part 340, APHIS only has the authority to regulate GE organisms if the agency believes the organism may pose a plant pest risk. The Ninth Circuit in *Center for Food Safety v. Vilsack* confirmed this point specifically regarding herbicide uses, concluding that the ESA's consultation duty is triggered only when the agency has authority to take action and discretion to decide what action to take.[29] In that case, APHIS had reached an ESA "no effect" conclusion as to the plant specifically, which was not challenged. The plaintiffs contended however that APHIS was required to perform an ESA consultation as to the herbicide. But APHIS lacked authority over the herbicide uses. Once APHIS concluded that RRA was not a plant pest, the agency had no jurisdiction to continue regulating the crop as a plant pest.[30] The agency's deregulation of RRA was thus a nondiscretionary act that did not trigger the agency's duty to consult under the ESA regarding herbicide uses.[31] In this instance, APHIS has no obligation under NEPA or the ESA to consider the effects on TES of herbicide use associated with DT soybean or DGT cotton crops. Nor does APHIS have an obligation to consult with the USFWS under the ESA given that the GE crops do not constitute plant pest risks.

In this Environmental Report, Monsanto has supplied information demonstrating that the biology of DT soybean and DGT cotton and the agricultural practices associated with their cultivation will have no impacts on TES and their critical habitats.[32] Additionally, though not required by law, Monsanto has provided in Appendix F information also available to the EPA in the context of the dicamba herbicide that addresses the potential indirect effects of dicamba application on TES associated with either the introduction or non-introduction of DT soybean and DGT cotton.

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29 Ctr. for Food Safety v. Vilsack, 718 F.3d at 842.

30 *Id.*

31 *Id.*

32 Petition for the Determination of Nonregulated Status for Dicamba-Tolerant Soybean MON 87708, Monsanto Petition Number: 10-SY-201U (July 6, 2010); Petitioner's Environmental Report for Dicamba and Glufosinate-Tolerant Cotton MON 88701, Monsanto Petition Number: 12-CT-244U-S (USDA Petition #12-185-01p_al) (May 6, 2013).

I.C. PURPOSE AND NEED FOR APHIS ACTION

The National Environmental Policy Act (NEPA) requires federal agencies to examine the potential environmental impacts of any proposed major federal action that may significantly affect the quality of the human environment. The federal action being considered here is the potential deregulation of DT soybean and DGT cotton. These products provide improved weed management options in soybean and cotton cultivation to control a broad spectrum of grass and broadleaf weed species. These uses of dicamba and glufosinate also provide effective control of herbicide resistant weeds that have arisen in certain areas of the U.S. which are impacting both conventional and existing GE crops. Existing GE crops have provided enormous benefits to farmers in recent decades, including improved yields, lower costs, decreased emissions from farm equipment, increased use of conservation tillage and associated environmental benefits, and the ability to use herbicides with a more benign human health and environmental profile. These new soybean and cotton GE crop products will provide another tool for farmers in certain areas of the U.S. who are encountering weed resistance and other weed management challenges, but seek to maintain yield and quality while using established production practices and conservation tillage.

Under the authority of the plant pest provisions of the PPA and 7 CFR Part 340, APHIS has issued regulations for the safe development and use of GE organisms. Any party can petition APHIS to deregulate an organism that is regulated under 7 CFR Part 340 by documenting the evidence that the GE organism is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived. As required by 7 CFR § 340.6, APHIS must respond to a petitioner that requests a determination of the regulated status of GE organisms, including GE plants such as DT soybean and DGT cotton. To do so, APHIS must conduct a Plant Pest Risk Assessment (PPRA) to determine whether the GE organism is likely to pose a plant pest risk. If APHIS concludes that the GE organism is unlikely to pose a plant pest risk, APHIS must grant the petition for nonregulated status, and the GE organism is no longer subject to the plant pest provisions of the PPA and 7 CFR Part 340. Here, APHIS must respond to the July 2010 petition from Monsanto requesting a determination of nonregulated status of DT soybean, and the July 2012 petition from Monsanto requesting a determination of nonregulated status of DGT cotton.

I.D. SCOPING FOR THE ENVIRONMENTAL REPORT

Public scoping is required under NEPA, as amended, Council on Environmental Quality (CEQ) regulations for implementing NEPA, the USDA regulations implementing NEPA, and the APHIS Implementing Procedures. Scoping for this environmental report began on May 16, 2013, when APHIS gave notice in the Federal Register (78 Fed. Reg. 28796-28798) of its intent to prepare a draft EIS.

The Federal Register notice solicited public involvement in the form of written comments regarding the above issues and alternatives for regulatory action. Written comments were accepted from the public during a comment period, which lasted until June 17, 2013.

Critically, *all* of the issues on which APHIS solicited comment relate to the herbicide—and not to the plants (DT soybean and DGT cotton) for which Monsanto has sought nonregulated status from APHIS. As discussed above, Congress transferred regulatory authority over herbicides from APHIS to EPA. Accordingly, APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider herbicide impacts under the PPA. Monsanto believes that APHIS has no legal obligation under NEPA to consider herbicide impacts or herbicide resistance in any Environmental

Impact Statement or Environmental Assessment. *See DOT v. Public Citizen*, 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform). *See also Center for Food Safety v. Vilsack*, No. 12-15052, 2013 U.S. App. LEXIS 9920, at *16-17 (9th Cir. 2013) ("If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests."). Nonetheless, because APHIS has announced its intention to address these herbicide-related issues in an Environmental Impact Statement, this Environmental Report similarly includes discussion of these issues. In addition, however, this report also addresses the key questions posed by the petitions for nonregulated status that *are* within APHIS' jurisdiction, *i.e.,* issues specifically related to potential plant pest risks or impacts, as well as issues related to potential impacts on agricultural production of soybeans and cotton, socioeconomic impacts and potential impacts on biological resources.

The alternatives that are discussed in Section III and analyzed in this Environmental Report result directly from this scoping effort.

II. AFFECTED ENVIRONMENT

II.A. INTRODUCTION

For the purpose of this environmental report, the affected environment for DT soybean and DGT cotton grown in the United States is described in the context of the production practices used to farm and process soybean and cotton, specifically the practices related to, among other things, pest management (including weed control) and the genetic environment that could potentially be influenced by gene flow from DT soybean and DGT cotton. These practices and conditions are described in this chapter to set the stage for the chapter IV (Environmental Consequences) discussion of how the different action alternatives may change activities and potentially have impacts on the human environment. The production practices under each alternative also determine how the various "resource areas" of the affected environment are affected by the decisions of growers and producers. Those resource areas have been grouped into the physical environment (land use, soil, water, air quality, and climate change), biological resources (wildlife and ecosystems), human health, animal health, and socioeconomics.

As discussed elsewhere in this report, Congress transferred regulatory authority over herbicides from USDA to EPA several decades ago. Accordingly, USDA-APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider herbicide impacts under the PPA. Nonetheless, because APHIS indicated in its Notice of Intent to Prepare an Environmental Impact Statement (78 Fed. Reg. 28796, May 16, 2013) that it would be considering herbicide effects and herbicide resistance as part of the NEPA process, Monsanto has included a limited discussion of herbicide impacts in the following sections and has provided detailed herbicide information in an Appendix to this report. Importantly, however, Monsanto believes that APHIS has no legal obligation under NEPA to consider herbicide impacts or herbicide resistance in any Environmental Impact Statement or Environmental Assessment. See *DOT v. Public Citizen*, 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform). See also *Center for Food Safety v. Vilsack*, No. 12-15052, 2013 U.S. App. LEXIS 9920, at

*16-17 (9th Cir. 2013) ("If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests.").

This chapter is organized into six main sections, as follows:

Section II.B, *Agricultural Production of Soybean & Cotton*, describes how soybean and cotton are farmed, including an overview of how the crops are used (*e.g.*, food, feed, fiber). Section II.B also discusses weed management practices in soybean and cotton farming because the DT and DGT traits may influence weed management options.

Section II.C, *Physical Environment*, describes how soybean and cotton farming practices (*e.g.*, tillage and herbicide usage) impact land uses, and how they interact with soil, air, and water bodies.

Section II.D, *Biological Resources*, describes how soybean and cotton, and the practices related to soybean and cotton production, interact with living organisms in ecological and agricultural settings. The biological resources are divided into animal communities, plant communities, and microorganisms. Section II.D also discusses gene flow and weediness, including the potential for hybridization with cultivated soybean and cotton plants, as well as with feral species. Section II.D also considers the potential impacts on adjacent agricultural crops and non-agricultural plants from the offsite movement of herbicides.

Section II.E, *Human Health*, describes both consumer and worker health and safety with respect to the production and use of soybean, cotton, and related products, and the use of pesticides that are applied before or during the production of soybean and cotton. Section II.E. addresses the direct ingestion of the products of soybean and cotton, such as cooking oils, food additives, and nutritional supplements, as well as the potential for inhalation of cotton dust by workers during cotton handling and processing.

Section II.F, *Animal Health*, describes the use of soybean, cotton, and derivative products in animal agriculture, and in particular in the animal feed industry. Section II.F also describes the biotechnology consultation process with FDA for soybean and cotton, and the dicamba tolerance assessment of the dicamba herbicide conducted by EPA.

Section II.G, *Socioeconomics*, describes the domestic economic environments of soybean and cotton, the trade economic environments of soybean and cotton, and public perceptions regarding genetically modified ingredients in food. These markets are described from seed to consumer.

II.B. AGRICULTURAL PRODUCTION OF SOYBEANS & COTTON

II.B.1. Agricultural Production of Soybeans

II.B.1.a. Crop Use and Biology

Soybean: Soybean belongs to the genus *Glycine*, which has approximately nine species, with commercial soybean (*G. max*) being placed in the subgenus *Soja* along with one other species, G. soja. *G. max* is sexually compatible only with *G. soja* and no other *Glycine* species. Wild soybean species are endemic throughout much of Asia, but do not exist naturally in North America (OECD 2000b). G. max is the only Glycine species located in the United States. *G. soja* is found in China, Taiwan, Japan, Korea, and Russia and can hybridize naturally with the cultivated soybean, *G. max* (Hymowitz 2004; Lu 2004).

Soybean Biology: Soybean is a "short day plant", meaning it flowers more quickly when day length is shorter. As a result, day length is important in determining areas of cultivar adaptation. Soybean cultivars are identified based on bands of adaptation (maturity groups) that run east-west, determined by latitude and day length. In the Americas north of the equator, there are 13 maturity groups (MG), from MG 000 at approximately 45 degrees latitude to MG X near the equator (OECD 2000b).

The soybean plant is a member of the legume family like alfalfa and clover and fixes a significant portion of its own nitrogen through the symbiotic relationship with the nitrogen-fixing Bradyrhizobia bacteria (*Bradyrhizobium japonicum*) that live in the nodules on its roots. Bradyrhizobia are unicellar, microscopic bacteria that invade the soybean plant through its root hairs (Hoeft, et al. 2000a; b). The plant responds to this invasion by forming nodules which contain colonies of bacteria. Once established on the soybean root, bacteria in the nodule take gaseous nitrogen from the atmosphere and fix it in forms easily used by the soybean plant. These bacteria can provide up to 50% of nitrogen needed by soybean (Pedersen 2007).

Soybean is considered a self-pollinating species, propagated commercially by seed. The anthers mature in the bud and directly pollinate the stigma of the same flower (OECD 2000b). Cross pollination is very rare, usually less than one percent (Caviness 1966).

The soybean plant is not weedy in character and in North America is not found outside of cultivation (OECD 2000b).

Soybean Use: Soybean is grown as a commercial crop in over 35 countries and is one of the most valued agricultural commodities because of its high protein and oil content. In 2011, soybean represented 56% of world oilseed production (ASA 2012), and approximately 41% of those soybeans were produced in the U.S. (USDA-FAS 2013a).

Approximately 95% of the world's soybean seed supply was crushed to produce soybean meal and oil in 2011 (Soyatech 2013), and the majority was used to supply the feed industry for livestock use or the food industry for edible vegetable oil and soybean protein isolates.

II.B.1.b. Land Use

Soybean Production: The productivity of soybean is highly dependent upon soil and climatic conditions. In the U.S., the soil and climatic requirements for growing soybean are very similar to corn. Planted acres by county are shown in Figure II.B-1. The soils and climate in the Midwestern, Eastern, and portions of the Great Plains regions of the U.S. provide sufficient water under normal climatic conditions to produce a soybean crop.

The U.S. soybean acreage in the past thirteen years has varied from approximately 64.7 to 77.5 million acres, with the lowest acreage recorded in 2007 and the highest in 2009 (Table II.B-1). Average soybean yields have varied from 33.9 to 44.0 bushels per acre over this same time period. Annual soybean production ranged from 2.5-3.4 billion bushels over the past thirteen years. According to data from USDA-NASS (2013b), soybean was planted on approximately 77.2 million acres in the U.S. in 2012, producing 3.0 billion bushels of soybean (Table II.B-1).

In 2013, 93% of soybean planted in the U.S. was genetically engineered (GE) to be herbicide tolerant. USDA listed no other types of GE soybean (USDA-ERS 2013). There is no indication that the introduction and widespread adoption of GE-derived crops in general has resulted in a significant change to the total U.S. acreage devoted to agricultural production. The cumulative land area in the U.S. planted to principal crops, which include corn, sorghum, oats, barley, winter wheat, rye, durum, spring wheat, rice, soybean, peanuts, sunflower, cotton, dry edible beans, potatoes, canola, proso millet, and sugar beets, has remained relatively constant over the past 27 years. From 1982 to 1995, the average yearly acreage of principal crops was 323 million. This average is essentially unchanged at 326 million acres since the introduction of GE-derived crops in 1996 (USDA-NASS 1984; 1990; 1992; 1995; 1998; 2000; 2003; 2006).

For purposes of this discussion, soybean production is divided into four major soybean growing regions: Midwest region (IL, IN, IA, KS, KY, MI, MN, MO, NE, ND, OH, SD, and WI), Southeast region (AL, AR, FL, GA, LA, MS, NC, SC, and TN), Eastern Coastal region (DE, MD, NJ, NY, PA, VA, and WV), and Plains region (OK and TX) (Table II.B.-2). The vast majority of soybean was grown in the Midwest region, representing 83.3% of the total U.S. acreage. The Southeast, Eastern Coastal, and Plains regions represented 13.1%, 92.9%, and 0.7% of the acreage, respectively.

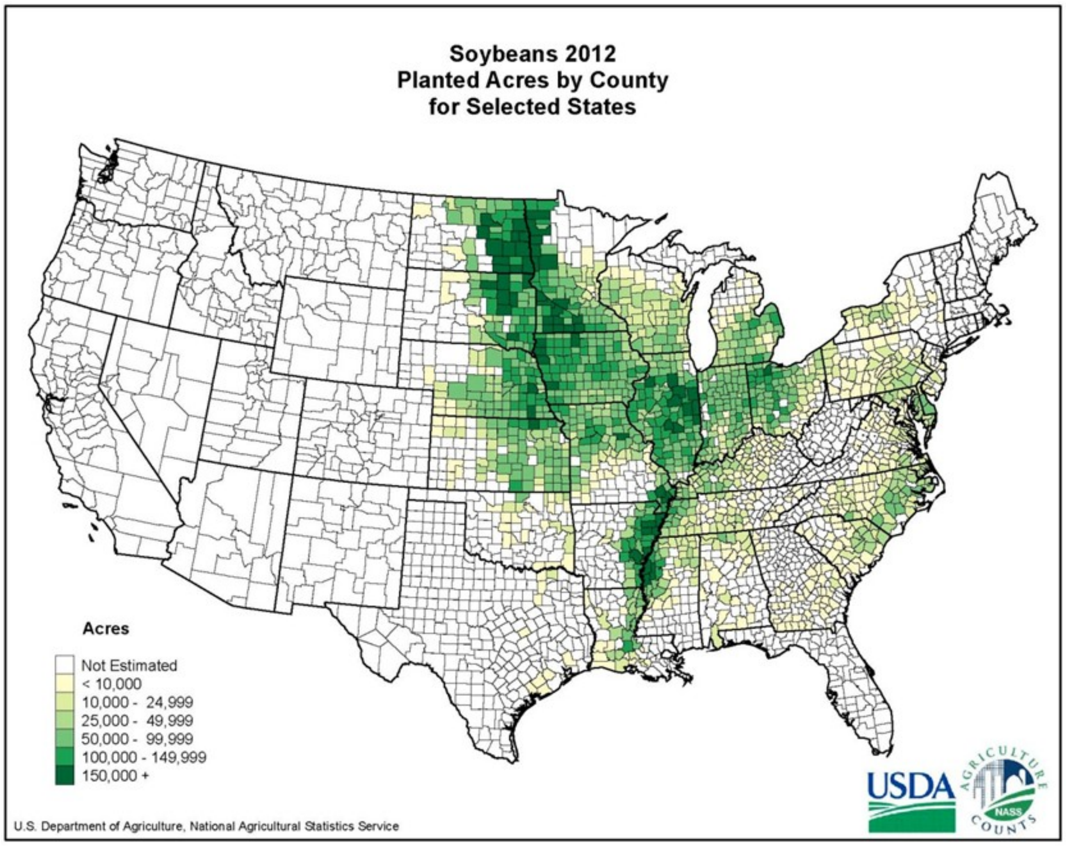

Figure II.B-1. Planted Soybean Acres by County in the U.S. in 2012.

Source: (USDA-NASS 2012f).

Table II.B-1 Soybean Production in the U.S., 1999 – 2012[1]

Year	Acres Planted (×1000)	Acres Harvested (×1000)	Average Yield (bushels/acre)	Total Production (×1000 bushels)	Value (billions $)
2012	77,198	76,104	39.6	3,014,998	43.19
2011	75,046	73,776	41.9	3,093,524	38.50
2010	77,404	76,610	43.5	3,329,181	37.55
2009	77,451	76,372	44.0	3,359,011	32.15
2008	75,718	74,681	39.7	2,967,007	29.46
2007	64,741	64,146	41.7	2,677,117	26.97
2006	75,522	74,602	42.9	3,196,726	20.47
2005	72,032	71,251	43.1	3,068,342	17.30
2004	75,208	73,958	42.2	3,123,790	17.90
2003	73,404	72,476	33.9	2,453,845	18.02
2002	73,963	72,497	38.0	2,756,147	15.25
2001	74,075	72,975	39.6	2,890,682	12.61
2000	74,266	72,408	38.1	2,757,810	12.47
Ave.	74,310	73,220	40.6	2,976,014	24.76

[1] Source is (USDA-NASS 2012f)

Table II.B-2. U.S. Soybean Production by Region and State in 2012[1]

Region/State	Acres Planted (thousands)	Acres Harvested (thousands)	Average Yield (bushels/acre)	Total Production (×1000 bushels)	Value (billions $)
Midwest Region					
Illinois	9,050	8,920	43.0	383,560	5.60
Indiana	5,150	5,140	43.5	223,590	3.26
Iowa	9,350	9,300	44.5	413,850	5.92
Kansas	4,000	3,810	22.0	83,820	1.20
Kentucky	1,480	1,470	40.0	58,800	0.85
Michigan	2,000	1,990	43.0	85,570	1.20
Minnesota	7,050	6,990	43.0	300,570	4.27
Missouri	5,400	5,260	29.5	155,170	2.25
Nebraska	5,050	4,990	41.5	207,085	2.90
North Dakota	4,750	4,730	34.0	160,820	2.28
Ohio	4,600	4,580	45.0	206,100	2.99
South Dakota	4,750	4,710	30.0	141,300	1.99
Wisconsin	1,710	1,700	41.5	70,550	0.98
Region Totals	64,340	63,590	39.2	2,490,785	35.69
Southeast Region					
Alabama	340	335	45.0	15,075	0.22
Arkansas	3,200	3,160	43.0	135,880	1.96
Florida	21	20	39.0	780	0.01
Georgia	220	215	37.0	7,955	0.12
Louisiana	1,130	1,115	46.0	51,290	0.75
Mississippi	1,970	1,950	45.0	87,750	1.26
North Carolina	1,590	1,580	39.0	61,620	0.86
South Carolina	380	370	34.0	12,580	0.18
Tennessee	1,260	1,230	38.0	46,740	0.68
Region Totals	10,111	9,975	42.1	419,670	6.04
Eastern Coastal Region					
Delaware	170	168	42.5	7,140	0.10
Maryland	480	475	47.0	22,325	0.32
New Jersey	96	94	39.0	3,666	0.05
New York	315	312	46.0	14,352	0.20
Pennsylvania	530	520	48.0	24,960	0.35
Virginia	590	580	42.0	24,360	0.33
West Virginia	21	20	49.0	980	0.01
Region Totals	2,202	2,169	45.1	97,783	1.36

Table II.B-2 (continued). U.S. Soybean Production by Region and State in 2012

Region/State	Acres Planted (thousands)	Acres Harvested (thousands)	Average Yield (bushels/acre)	Total Production (×1000 bushels)	Value (billions $)
Plains Region					
Oklahoma	420	260	15.0	3,900	0.06
Texas	125	110	26.0	2,860	0.04
Region Totals	545	370	18.3	6,760	0.10
U.S. Totals	77,198	76,104	39.6	3,014,998	43.19

[1] Source: (USDA 2013).

Seed Production Areas: Soybean seed is produced throughout most of the U.S. soybean-growing regions by companies that produce and sell seed, and by toll seed producers, or tollers, which are companies that produce certified seed for other companies pursuant to a contract. Seeds for a given maturity group are produced within the same geographic area where they will be planted for commercial production.

II.B.1.c. General Agronomic Practices

Below is a summary of information pertaining to the agronomic practices and management of soybean.

Life Cycle: Soybean is generally planted from early to mid-May and harvested in the fall. Soybean is photoperiod sensitive, which means that it transitions from vegetative to flowering stage in direct response to length of daylight (Scott and Aldrich 1970). Soybean can be harvested when the moisture content of the seed drops below 15%. (Scott and Aldrich 1970). Timely harvest when the moisture content is 13 to 14% also will minimize losses.

Soybean is considered a self-pollinating species, propagated commercially by seed. The anthers mature in the bud and directly pollinate the stigma of the same flower (OECD 2000b).

Varieties: Hundreds of soybean varieties are tested each year in performance trials conducted by universities and private companies in all the major soybean growing states. The following properties can typically be obtained from the results of variety trials, and considered by growers in variety selection: maturity group, disease resistance, insecticide seed treatment, yield, maturity date, percent lodging (plant fallen over on the ground), height, and herbicide resistance (Tylka, et al. 2010). In different parts of the country and/or in other trials, additional properties may be identified, such as iron deficiency tolerance or protein or oil content (Pedersen 2008b).

Water Use: The general water requirement for a high-yielding soybean crop is approximately 20 inches of water during the growing season (Hoeft et al. 2000a; b). Soil texture and structure are key components determining water availability in soils, where medium-textured soils hold more water, allowing soybean roots to penetrate deeper in medium-textured soils than in clay soils. Supplemental irrigation is used on approximately 7% of U.S. soybean acreage, primarily in the western and southern soybean growing regions (USDA-NASS 2008b). The highest concentrations of irrigated soybeans are in the sandy soils of eastern Nebraska and the Mississippi River Delta region of Arkansas and neighboring states (USDA-NASS 2009b). In 2006, an average of 8.4 inches of water per acre was applied to irrigated fields. Groundwater was the source for 92% of irrigated acres and surface water for the remainder (USDA-ERS 2012f).

Yields: Planting date has the greatest impact on yield, according to research conducted in the Northern states (Hoeft et al. 2000a; b). Highest yields are generally obtained when planting in early to mid-May. Yields begin to decline quite rapidly when planting is delayed until late May. Average U.S. soybean yields in the past ten years (2003 to 2012) have varied from 33.9 to 43.5 bushels per acre. Soybean production ranged from 2.45 to 3.36 billion bushels over the past ten years, with 2009 being the largest production year on record. Soybean yield (39.6 bushels per acre) and production (3.0 billion bushels) in 2012 was down slightly from the record level in 2009, mainly as a result of drought conditions in the Midwest and South regions (USDA-NASS 2013b). Average crop yield on irrigated land was 51.4 bushels per acre (USDA-ERS 2012f).

Crop Nutrition: The three most important soil-supplied nutrients are nitrogen, phosphate, and potash. Other nutrients important for plant growth such as calcium, magnesium, iron, boron, manganese, zinc, copper, and molybdenum are needed at much lower concentrations and are limiting only in certain environments (Pedersen 2007). Approximately half the nitrogen need of soybean is obtained from the soil and half from the air (Pedersen 2007). One bushel of soybean contains approximately 4.0 lb of nitrogen, 0.8 lb of phosphate, and 1.4 lbs of potash (Purdue Extension 2012).

Crop Rotation: The well-established farming practice of crop rotation is a key management tool for soybean growers. The purposes of growing soybean in rotation include:

- improving yield and profitability of one or both crops over time;
- decreasing the need for nitrogen fertilizer on the crop following soybean;
- mitigating or breaking disease, insect, and weed cycles;
- improving soil tilth and soil physical properties;
- increasing residue cover;
- reducing soil erosion;
- increasing soil organic matter; and
- reducing runoff of nutrients, herbicides, and insecticides (Al-Kaisi, et al. 2003; Boerma, et al. 2004; Heatherly and Elmore 2004).

According to USDA Economic Research Service, 95% of the soybean-planted acreage has been in some form of a crop rotation system since 1991 (USDA-ERS 2001). Corn- and wheat-planted acreage has been rotated at a slightly lower level of 75% and 70%, respectively. Although the benefits of crop rotations can be substantial, growers must make cropping decisions by evaluating agronomics, economic returns of various cropping systems, and other related factors. Crop rotations also afford growers the opportunity to diversify farm production in order to minimize market risks.

Agronomic practices such as rotation patterns for soybean vary from state to state. However, there are similarities among states within certain growing regions. The majority of the U.S. soybean acreage (68.6%) is rotated to corn, with approximately 14.5% of the soybean acreage rotated back to soybean the following year. Wheat follows soybean on approximately 11.2% of the U.S. soybean acreage.

Continuous soybean production is uncommon in the Midwest. Soybean extension specialists encourage growers to avoid the practice as a way to reduce the risk of damage from diseases and nematodes (Al-Kaisi et al. 2003; Hoeft et al. 2000a; b). Corn and soybean occupy more than 80% of the farmland in many of the Midwestern states, and the two-year cropping sequence of soybean-corn is used most extensively in this region. However, a soybean crop sometimes is grown after soybean and then rotated to corn in a 3-year rotation sequence (soybean-soybean-corn) in the Midwest. Compared to corn, soybean shows a greater yield response to being grown after a number of years without soybean. The yield of both corn and soybean is approximately 10% higher when grown in rotation than when either crop is grown continuously (Hoeft et al. 2000a; b).

A combination of conservation tillage practices and crop rotation has been shown to be very effective in improving soil physical properties. Long-term studies in the Midwest indicate that the corn-soybean rotation improves yield potential of no-till systems compared to continuous corn production (Al-Kaisi 2001).

Soil Types: The productivity of soybean is highly dependent upon soil and climatic conditions. In the U.S., the soil and climatic requirements for growing soybean are very similar to corn. Soil texture and structure are key components determining water availability in soils, where medium-textured soils hold more water, allowing soybean roots to penetrate deeper in medium-textured soils than in clay soils (USDA-ERS 2008).

Tillage: Tillage in soybean production systems is used to prepare a seedbed, address soil compaction, incorporate fertilizers and herbicides, manage water movement both within and out of a production field, and control weeds (CAST 2009), depending on tillage type. The benefits of conservation tillage or no-till systems relative to conventional tillage are well documented and include reduced soil erosion, reduced fuel and labor costs, conservation of soil moisture, improvement of soil structure, reduction of soil compaction and improvement of soil organic matter content. In 2008, approximately 30.1 million acres (41.3 %) of soybean were planted in a no-till system (CTIC 2008).

Conventional tillage is associated with intensive plowing and less than 15% crop residue at the soil surface; reduced tillage is associated with 15 to 30% crop residue; and conservation tillage, including no-till practices, is associated with at least 30% crop residue and substantially less soil erosion than other tillage practices (CTIC 2010; U.S. EPA 2010a). In 2011, over 65% of U.S. soybean acres used some form of conservation tillage (USB 2011c). The decision to plant soybean in a conservation tillage or no-till system is made long before planting as it may require special equipment. In addition, this decision is usually a long-term commitment, provided the system is successful.

Slow soybean emergence and growth, plus lower yields, have been some of the concerns associated with adoption of conservation tillage systems in soybean, especially no-till. Research in Wisconsin and Minnesota shows that soil temperatures can be four to five degrees colder in no-till systems than in conventional tillage systems, which can slow emergence, but have little effect on soybean yield (Pedersen 2008a). Improved planters for establishment of good soybean populations and planting glyphosate-tolerant soybean varieties to effectively control weeds in no-till fields have made no-till a more viable production system for soybean. In 1995, before the introduction of glyphosate-tolerant soybean, approximately 27% of the U.S. soybean acres used no-till production. In 2004, nine years after the introduction of glyphosate-tolerant soybean, no-till acreage increased to 36% of the total soybean acres (Sankula 2006). Using a data set covering 12 states and 11 years, Fernandez-Cornejo, et al. (2013) found that herbicide tolerant soybean adoption leads to a significant increase in the adoption of conservation tillage. The most recent surveys indicate that 41% of the soybean acres are produced using no-till methods (CTIC 2008). Researchers still recommend some spring tillage on fine-textured and poorly drained soils for proper seedbed preparation (Pedersen 2008a).

II.B.1.d. Pest Management

The use of pesticides, including fungicides, herbicides, and insecticides, is a key component of an integrated pest management (IPM) system in soybean. The various pesticides used in soybean, along with other IPM elements, are addressed in the two subsections below.

Disease Management: More than 100 pathogens are known to affect soybean, of which 35 are considered to be of economic importance (Bowers and Russin 1999). The estimated yield losses to soybean diseases in the U.S. were 12.5, 13.2, and 13.0 million metric tons in 2008, 2009, and 2010, respectively (Wrather and Koenning 2011), which equates to 15.5%, 14.4% and 14.4% losses of total soybean production, respectively (ASA 2011). Pathogens can affect all parts of the soybean plant, resulting in reduced quality and yield. The extent of losses depends upon the pathogen, the state of plant development and health when infection occurs, the severity of the disease on individual plants, and the number of plants affected (Bowers and Russin 1999).

According to field surveys conducted in fifteen soybean-producing states during 1996 to 2010, soybean cyst nematode (*Heterodera glycines*) caused the greatest soybean yield losses (Wrather and Koenning 2011). Phytophthora root and stem rot (*Phytophthora sojae*), brown spot (*Septoria glycines*), charcoal rot (*Macrophomina phaseolina*), sclerotinia stem rot (*Sclerotinia sclerotiorum*), seedling diseases, and sudden death syndrome (*Fusarium solani f.sp. glycines*) followed in economic importance (Wrather and Koenning 2011).

Selecting resistant varieties is the primary tool growers have for disease control (Bowers and Russin 1999). Resistant varieties may have morphological or physiological characteristics that provide immunity, resistance, tolerance or avoidance to certain pathogens. Cultural practices can also play an important role in disease management by reducing initial inoculums or reducing the rate of disease development (Bowers and Russin 1999). Rotation with non-host crops can help break disease cycles, particularly for soybean cyst nematode (Pederson, undated). High-quality seed is essential for controlling seedling diseases. Treating soybean seed with a fungicide (*e.g.*, metalaxyl or mefenoxam) is effective against damping-off disease (seedling blight) caused by common soil fungi, such as *Phytophthora* and *Pythium*. Fungicide seed treatments are recommended where there is a history of these seedling diseases.

Management of Insects: Although insects are rated as less problematic than weeds in U.S. soybean production, management of insect pests during the growth and development of soybean is important for protecting the yield of soybean (Aref and Pike 1998). Understanding the impact of insects on soybean growth is essential for proper management (Higley 1994; Steffey, et al. 1994; Way 1994; Yeargan 1994). It is also important to understand the way that insects injure soybean as well as how the soybean plant responds to insect injury. Insect injury can impact yield, plant maturity, or seed quality. The ultimate impact of injury is damage, as a measurable reduction in plant growth, development or reproduction. Insect injury in soybean seldom reaches levels to cause an economic loss in the primary soybean production areas, as indicated by the low percentage (16%) of soybean acreage that receives an insecticide treatment (USDA-NASS 2008c).

Characterizing soybean responses to insect injury is essential in establishing economic injury levels (Higley 1994; Steffey et al. 1994; Way 1994; Yeargan 1994). Most often, soybean insects pests are categorized or defined by the plant parts they injure, namely root-feeding, stem-feeding, leaf-feeding, or pod-feeding insects. The root- and stem-feeding insect groups are often the hardest to scout and typically are not detected until after they have caused their damage. The leaf-feeding insects comprise the biggest group of soybean insect pests, but not necessarily the most economically damaging insects. Recent research on defoliation has determined that a major effect of leaf injury is to reduce light interception by the soybean canopy which in turn can have a significant effect on yield (Higley 1994; Steffey et al. 1994; Way 1994; Yeargan 1994). Soybean, however, has an extraordinary capacity to withstand considerable defoliation early in the season without significant yield loss. By contrast, defoliation during the flowering and pod filling stages poses a greater threat to yield, because the soybean plant has less time to compensate for injury compared to other growth stages. Research indicates that the soybean plant can sustain a 35% leaf loss prior to the pre-bloom period without lowering yield (NDSU 2002). However, from pod-set to maturity, the plant can tolerate only a 20% defoliation level before yield is impacted.

Weeds in Soybeans: Annual weeds are perceived to be the greatest pest problem in soybean production, followed by perennial weeds (Aref and Pike 1998). Weed control in soybean is essential to optimizing yields because weeds compete with soybean for light, nutrients, and soil moisture. Weeds can also harbor insects and diseases, and can interfere with harvest, causing extra wear on harvest equipment.

Foxtail spp. (*Setaria spp.*), pigweed (*Amaranthus spp.*), velvetleaf (*Abutilon theophrasti*), lambsquarters (*Chenopodium album*), and cocklebur (*Xanthium strumarium*) are common weeds in Midwest corn and soybean fields. Certain growers in Indiana have reported giant ragweed (*Ambrosia artemisiifolia*), lambsquarters, Canada thistle (*Cirsium arvense*), cocklebur, and velvetleaf to be difficult-to-control weeds in corn and soybean (Nice and Johnson 2005). Giant and/or common ragweed are also common and problematic in Minnesota, Missouri, Arkansas, Wisconsin and Illinois (Anderson 2012; Boerboom and Owen 2006; Iowa State University 2003). In a 2005-2006 survey of 1,200 growers of glyphosate-tolerant crops (soybean, corn and cotton) in six Midwestern and southern states, growers in Illinois and Iowa, the two leading soybean-producing states, most frequently named common waterhemp (*Amaranthus tuberculatus*) as most difficult to control (Kruger, et al. 2009). Waterhemp is also reported to be a problematic in Minnesota, Indiana, Nebraska, Wisconsin and Missouri (Anderson 2012; Boerboom and Owen 2006; Iowa State University 2003; Kruger et al. 2009; Legleiter, et al. 2009). Horseweed (*Conyza canadensis*, also called marestail) has been reported to be problematic in Ohio, Arkansas, Tennessee, Kansas, Wisconsin and Illinois (Boerboom and Owen 2006; Mueller, et al. 2005; Peterson and Shoup 2012).

Tables II.B-3 through II.B-5 summarize the most common weeds for the three primary major soybean growing regions (Midwest, Southeast and Eastern Coastal). The Plains region is not discussed due to the low levels of soybean cultivation, < 1% U.S. soybean acres.

Table II.B-3. Common Weeds in Soybean Production: Midwest Region

Foxtail spp. (12)[1]	Ragweed, giant (3)	Dandelion (1)
Pigweed spp. (11)	Shattercane (3)	Johnson grass (1)
Velvetleaf (11)	Quackgrass (3)	Milkweed, honeyvine (1)
Lambsquarters (10)	Buckwheat, wild (2)	Nightshade, hairy (1)
Cocklebur (9)	Crabgrass spp. (2)	Oats, wild (1)
Ragweed, common (7)	Kochia (2)	Pokeweed, common (1)
Smartweed spp. (6)	Mustard, wild (2)	Prickly sida (1)
Morningglory spp. (5)	Nightshade, Eastern black (2)	Proso millet, wild (1)
Sunflower, spp. (5)	Palmer pigweed (2)	Sandbur, field (1)
Waterhemp spp. (5)	Canada thistle (1)	Venice mallow (1)
Horseweed (marestail) (3)	Chickweed (1)	Volunteer cereal (1)
Panicum, fall (3)	Cupgrass, woolly (1)	Volunteer corn (1)

[1] Number provided in parenthesis is the number of states out of the thirteen total states in the Midwest region reporting each weed as a common weed.
Sources:
IL: University of Illinois (2002) and Aaron Hager, Extension Weed Specialist, University of Illinois - Personal Communication (2006).
IN: 2003-2005 Statewide Purdue Horseweed Weed Survey, Special database query and personal communication (2006), Bill Johnson, Extension Weed Specialist, Purdue University.
IA, MN, OH, WI: (WSSA 1992).
KS: Dallas Petersen, Extension Weed Specialist, Kansas State - Personal communication (2006).
KY, MO: (Webster, et al. 2005).
MI: (Davis, et al. 2005).
NE: Alex Martin, Extension Weed Specialist, University of Nebraska – Personal communication (2006).
ND: (Zollinger and Lym 2000).
SD: Michael Moechnig, Extension Weed Specialist, South Dakota State University – Personal communication (2006).

Table II.B-4. Common Weeds in Soybean Production: Southeast Region

Morningglory spp. (8)[1]	Goosegrass (3)	Cutleaf evening-primrose (1)
Crabgrass spp. (6)	Johnsongrass (3)	Groundcherry (1)
Prickly sida (6)	Ragweed, common (3)	Henbit (1)
Nutsedge spp. (6)	Cocklebur (2)	Lambsquarters (1)
Sicklepod (5)	Florida beggarweed (2)	Ragweed, giant (1)
Signalgrass, broadleaf (5)	Hemp sesbania (2)	Smartweed (1)
Palmer pigweed (4)	Horseweed (marestail) (2)	Spurge, nodding/hyssop (1)
Pigweed spp. (4)	Texas millet (2)	Spurge, Prostrate (1)
Barnyard grass (3)	Browntop millet (1)	Tropic croton (1)
Florida pusely (3)	Copperleaf, hophorn (1)	

[1] Number provided in parenthesis is the number of states out of the eight total states in the Southeast region reporting each weed as a common weed.
Sources:
AL, AR, GA, LA, NC, SC: (Webster, et al. 2009).
MS, TN: (Webster et al. 2005).

Table II.B-5. Common Weeds in Soybean Production: Eastern Coastal Region

Foxtail spp. (6)[1]	Morningglory spp. (4)	Dandelion (1)
Ragweed, common (6)	Panicum, fall (4)	Goosegrass (1)
Velvetleaf (6)	Crabgrass spp. (3)	Johnson grass (1)
Lambsquarters (5)	Nutsedge spp. (3)	Nightshade, Eastern black (1)
Pigweed spp. (5)	Quackgrass (2)	Prickly sida (1)
Cocklebur (4)	Canada thistle (1)	Shattercane (1)
Jimson weed (4)	Burcucumber (1)	Smartweed spp. (1)

[1] Number provided in parenthesis is the number of states out of the six total states in the Eastern Coastal region reporting each weed as a common weed. Data were not available for DE in soybean.
Sources:
DE, MD, NJ, PA: (WSSA 1992).
NY: Russell Hahn, Extension Weed Specialist, Cornell University – Personal Communication (2006).
VA: (Webster et al. 2009).

Benefits of Herbicide Use in Agriculture: A study by CropLife America demonstrated that in 2005 the use of herbicides saved U.S. farmers 337 million gallons of fuel, produced $16 billion in crop yield increases, and cut weed control costs by $10 billion as compared to production without the use of herbicides (Gianessi and Reigner 2006). Additionally, without herbicides growers would have to abandon no-till or other conservation tillage production practices, which reduce soil erosion. If U.S. growers stopped using herbicides and resumed tillage on the number of acres not tilled in 2005, an additional 356 billion pounds of sediments would be deposited in streams and rivers, resulting in an estimated $1.4 billion in downstream damage (Gianessi and Reigner 2006).

Weed Management in Soybean: The factors that affect a potential yield loss in soybean from weed competition are the weed species, weed density, and the duration of the competition. When weeds are left to compete with soybean for the entire growing season, yield losses can exceed 75% (Dalley, et al. 2001). Generally, the competition between crops and weeds increases with increasing weed density. The time period that weeds compete with the soybean crop influences the level of yield loss. In general, the later the weeds emerge, the less impact the weeds will have on yield. Soybean plants withstand early-season weed competition longer than corn, and the canopy generally closes earlier in soybean than corn (i.e., plants in adjacent rows grow to a sufficient size such that their foliage touches between the rows blocking the sunlight from reaching the ground and prevents weed seeds from germinating). In addition, canopy closure is much sooner when soybean is planted in narrow rows.

The most effective weed management programs in soybean use a combination of cultural, mechanical, and/or herbicide control practices, hereafter called diversified weed management practices, instead of relying on one particular method of weed control (Beckie, et al. 2011; University of California 2009; Vargas, et al. 1996). Herbicide application practices that are compatible with diversified weed management practices include the use of several herbicides with different modes of action, either within or across seasons, applying herbicides at the labeled rate at the correct timing, and proper application of the herbicide. Cultural and mechanical practices can also be important components of an effective diversified weed management program (Ashigh, et al. 2012). Cultural practices such as crop rotation, narrow row spacing and planting date are a few of the crop management practices that are implemented to provide the crop with a competitive edge over weeds. Mechanical methods of weed control, including tillage, have been used for centuries to control weeds in crop production. Spring or fall preplant tillage and in-crop shallow cultivation can effectively reduce the competitive ability of weeds by burying the plants, disturbing or weakening their root systems, or causing sufficient physical injury to kill the plants. A consequence of in-crop cultivation for weed control is that it can injure crop roots and cause moisture loss. The planting of winter cover crops is another cultural practice that can also be utilized. The planting of cover crops, such as grasses, legumes or small grains, can protect and improve soil quality, help reduce erosion, and can serve as surface mulch in no-till cropping practices (Mannering, et al. 2007). Although in recent years there has been a resurgence in interest by crop experts and academics in the use of cover crops, the planting of a cover crop incurs additional costs to the grower and therefore is not currently a major weed management practice in major soybean growing areas (Singer 2006).

The use of herbicides has become an important part of managing weeds in soybean. Approximately 98 percent of the soybean acreage received an herbicide application in 2012 (USDA-NASS 2012d). The availability of herbicide-tolerant soybean products is an important aspect of weed management in U.S. soybean production. Herbicide-tolerant soybean was introduced to provide growers with additional options by improving crop safety (no herbicide damage to the crop) and improving weed control. In 2013, 93% of the U.S. soybean crop was herbicide-tolerant (USDA-ERS 2013); almost all is glyphosate-tolerant. As a result and as shown by the 2012 use data shown in Appendix A, Table A-8, glyphosate is the most widely used herbicide, being applied on 98 percent of the soybean acreage in 2012, including for preplant burndown and postemergence in crop applications (USDA-NASS 2012d). In 2012, dicamba-treated acres in soybean accounted for only 87 thousand acres, or 0.07% of the total preemergent treated acres (USDA-NASS 2012d). This is primarily because dicamba is phytotoxic to current soybean varieties and is therefore currently only labeled for application at timings that avoid contact with the growing plant, such as preplant treatments prior to planting, depending on rate and rainfall.

Over 35 different herbicide active ingredients are registered and available for use by soybean growers to control weeds. The ten most widely used alternative herbicides in soybean are listed in Table II.B-6. Alternative soybean herbicide use has almost doubled between 2009 and 2012. Integration of DT soybean into the glyphosate-tolerant soybean system and the subsequent use of dicamba will result in the displacement of some currently used, or foreseeable future use, non-glyphosate herbicides. Some non-glyphosate alternative herbicides have less benign human health and environmental characteristics as compared to dicamba, and reduced agronomic flexibility due to soybean planting restrictions, rotational crop planting restrictions, the need for adequate soil moisture for activation, or the need to apply prior to planting to minimize crop injury.[33] The properties of these alternative herbicides are summarized in Appendices A and C to provide a baseline for comparison to dicamba use on DT soybean.

Herbicide weed control programs in conventional soybean consist of preemergence herbicides used alone or in mixtures. Mixtures of two preemergence herbicides are used to broaden the spectrum of control to both grasses and broadleaf weed species. Preemergence herbicides are followed by

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[33] In order to approve a new use of a herbicide EPA must conclude that the herbicide, when used according to the label, does not pose an unreasonable adverse effect to humans or the environment, and, in order to establish a tolerance for the use of a herbicide on a food or feed crop, find there is a reasonable certainty of no harm to human health from non-occupational (food, water and residential/recreational) exposures to the herbicide. Therefore, all alternative herbicides used in soybean production can be used safely, and do not pose an unreasonable risk to humans or the environment.

postemergence applications to control weeds that emerge later in the crop. Total postemergence weed control programs were seldom used in conventional soybean prior to 1995 when glyphosate-tolerant soybean was first introduced. Prior to glyphosate-tolerant soybean, soybean planted in a no-till system would receive a preplant burndown herbicide application for broad-spectrum control of existing weeds at time of planting, followed by different soil residual herbicides at planting and possibly still other herbicides applied postemergence to the crop and the weeds. In conventional soybeans, the typical herbicide program consisted of multiple soil residual herbicides applied preemergence to the crop and weeds and, possibly, other herbicides applied postemergence to the crop and weeds. Therefore, multiple herbicides and/or multiple applications were generally used in conventional and no-till non-glyphosate-tolerant soybean. The average number of herbicide applications per acre in soybean rose from 1.5 in 1990 to 1.7 applications in 1995, reflecting the use of at-plant and postemergence applications or two postemergence applications (Gianessi, et al. 2002).

Table II.B-6. Ten Most Widely Used Alternative Herbicides in U.S. Soybean Production in 2012

Herbicide	Treated Acres (millions)[1]	Pounds Applied
2,4-D (acid, salts, and esters,	11.58	6.02
Flumioxazin	8.49	1.56
Imazethapyr	3.86	1.35
cloransulam-methyl	3.09	0.60
chlorimuron-ethyl	8.49	0.52
Fomesafen	6.18	0.22
Clethodim	6.95	0.19
pendimethalin	1.54	0.08
Tribenuron	0.77	0.04
flumiclorac-pentyl	0.77	0.01

[1] (USDA-NASS 2012d)

Selective herbicides are designed to kill specific types of plants, usually grasses or broadleaf weeds, and have proven effective to reduce in-crop tillage or cultivation to control weeds in soybean production. The development of selective herbicides has progressed since the introduction of the first herbicide (2,4-D) for weed control in corn in early 1940s. Although the primary purpose of tillage is for seedbed preparation, tillage still is used to supplement weed control with selective herbicides in soybean production. Refer to Appendix A for details on alternative herbicides used in soybean production.

Dicamba Herbicide Use: Dicamba is a broadleaf selective herbicide that was approved by the U.S. Environmental Protection Agency (EPA) for agricultural application uses in 1967 (U.S. EPA 2009d). Dicamba is formulated as a standalone herbicide product and marketed by several companies under various trade names such as Banvel®, Clarity®, Diablo®, Rifle®, Sterling®, and Vision®. These dicamba products can also be tank-mixed with one or more active ingredients depending on the crop to be treated. For example, Clarity® can be tank mixed with over 75 herbicide products in labeled crops. Additionally, dicamba is currently formulated as a premix product with one or more other herbicide active ingredients, including glyphosate, 2,4-D, diflufenzopyr, atrazine, nicosulfuron, metsulfuron, primsulfuron, triazulfuron, rimsulfuron, and halosulfuron.

Dicamba is currently labeled for weed control in corn, soybean, cotton, sorghum, wheat, barley, oats, millet, pasture, rangeland, asparagus, sugarcane, turf, grass grown for seed, conservation reserve programs, and fallow croplands. Dicamba-treated acreage has ranged from 17.4 to 36.3 million acres between 1990 and 2011. Usage of dicamba peaked during the period of 1994 through 1997, where 1994 was the peak year when 36 million crop acres were treated with 9.4 million pounds of dicamba. Since then, the use of dicamba has steadily declined to 17.4 million treated acres with 2.7 million pounds applied in 2006. The reduction in dicamba use has been attributed to the competitive market introductions of sulfonylurea herbicides (chlorsulfuron, metsulfuron-methyl, and thifensulfuron-methyl) in wheat, new broadleaf herbicide active ingredients in corn, and introduction of glyphosate-tolerant corn. More recently, however, dicamba-treated acres have been on the rise and have increased by as much as 7.9 million acres between 2006 to 2011; see Appendix A, Table A-1 for additional details. Most of this increase has occurred in fallow, pastureland, sorghum, and cotton (preplant) (Monsanto 2012).

Based on farm survey data generated in 2011 by a private market research company, dicamba application rates across agricultural row crops ranged from 0.07 to 0.27 pounds per acre with the average number of applications ranging from 1 to 1.4 applications per cropping season (Monsanto 2012). Dicamba rates (pounds per acre) are lowest in spring wheat where more than one application is typically made per cropping season.

Dicamba is currently labeled for use in conventional or glyphosate-tolerant soybean, although dicamba use is extremely limited because applications are restricted to very early preplant and/or preharvest applications due to soybean (crop) injury concerns. The dicamba-treated acreage in 2008 soybean production was approximately 872,000 acres, representing 1.2 % of the total soybean acreage (Monsanto 2009); see Appendix A, Table A-2 for additional details.

Dicamba belongs to the auxin class of herbicides, which is the oldest class of known synthetic herbicides. This class includes 2,4-D, 2,4-DB, mecoprop, MCPA, clopyralid, and several other active ingredients, and is WSSA Herbicide Group Number 4 (HRAC 2009).[34] On the basis of their structural and chemical properties, auxinic herbicides have been classified into several sub-groups, viz., phenoxyalkanoic acids (e.g., 2,4-D, MCPA), benzoic acids (e.g., dicamba, chloramben), pyridines (e.g., picloram, clopyralid), and quinolinecarboxylic acids (e.g., quinclorac, quinmerac). Generally, auxinic herbicides are effective against broadleaf (dicotyledonous) plant species, allowing them to often be used in production of narrow leaf (monocotyledonous) crops. Refer to Appendix A for details on dicamba herbicide.

Herbicide Resistance: Herbicide resistance is "the inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type" (WSSA 1998). In the mid-1950s, Harper (1957) theorized that annual, repeated use of a herbicide could potentially lead to shifts in weed species composition within a crop-weed community if other weed

[34] There are several systems of herbicide mode-of action classification. Among the most widely used are those of the Herbicide Resistance Action Committee (HRAC) and the Weed Science Society of America.

management methods are not utilized. Similarly, Bandeen et al. (1982) suggested that a normal variability in response to herbicides exists among plant species and tolerance can increase with repeated use of a herbicide in the absence of other weed management methods. To simplify, herbicide resistance in weeds is a result of natural selection. Plants of a given species are not all identical, but are made up of "biotypes" with various genetic traits. The repeated use of a herbicide may potentially lead to the selection of weed biotypes resistant to that herbicide, particularly when the herbicide is not used as part of a diversified weed management program. Within a weed species, individuals may possess an inherent ability to withstand the effects of a particular herbicide. Repeated use of that herbicide in the absence of other weed control herbicides or practices has the potential to expose the weed population to a "selection pressure," which may potentially lead to an increase in the number of surviving resistant individuals in the population (HRAC 2011). With repeated application of the same herbicide over time and no other appropriate herbicide or weed management practices, the resistant biotypes have the potential to become the dominant biotype in that weed community. As of April 2013, 400 herbicide-resistant weed biotypes have been reported to be resistant to 21 different herbicide modes-of-action worldwide (Heap 2013b). Glyphosate-resistant weeds account for approximately 6% of the herbicide-resistant biotypes while weeds resistant to herbicides that inhibit acetolactate synthase (ALS) account for 32% of the herbicide-resistant biotypes. Dicamba-resistant and glufosinate-resistant weeds account for <1% and 0.5% of resistant biotypes respectively (Heap 2012c; d; 2013b). See Appendix B of this environmental report for details of effects of weed resistance.

For as long as herbicide resistance has been a known phenomenon, public-sector weed scientists, private-sector weed scientists, and growers have been identifying methods to address the problem. For instance, when a farmer uses multiple weed control tools, resistant biotypes generally will not become the dominant biotype within a population (Gunsolus 2008). By contrast, there is a great potential for weed resistance in areas where there is a sole reliance on a single herbicide used repeatedly over multiple crop generations for the management of a specific weed spectrum, and where appropriate weed management practices are not utilized.

On agricultural land which contains a weed biotype that is resistant to a particular herbicide, the grower must use alternate methods of weed control. Management practices that can be used to mitigate the potential for development of resistance include herbicide mixtures, herbicide rotation, and crop rotation. Since many soybean farmers practice conservation tillage and some may choose to plant soybeans repeatedly on the same land, the use of multiple herbicide modes of action with overlapping effectiveness on the targeted weed spectrum will be an important method recommended, and there are an increasing number of farmers who are following such recommendations. The WSSA reports: "Weed scientists know that the best defense against weed resistance is to proactively use a combination of agronomic practices, including the judicious use of herbicides with alternative modes-of-action either concurrently or sequentially" (WSSA 2010). Studies have demonstrated that using the same combination of herbicides with multiple modes of action and overlapping effectiveness over multiple seasons is an effective way to proactively manage resistance (Beckie and Reboud 2009; Neve, et al. 2011).

Due to the broad spectrum activity of glyphosate, it has been possible for growers to rely on glyphosate for weed management without utilizing other weed management practices such as crop rotation, cultivation, or use of multiple herbicide modes of action; these practices have resulted in the selection of certain glyphosate-resistant weed biotypes in certain areas of the U.S.

As with other herbicide-resistant weeds that have developed, the emergence of herbicide-resistant weeds over the past decade, including glyphosate-resistant weed biotypes in certain areas of the U.S. has meant that growers have needed to adapt and implement various weed management strategies. Glyphosate-resistant weed biotypes that can be found in soybean fields in certain areas of the U.S., include Palmer pigweed (*Amaranthus palmeri*), spiny pigweed (*Amaranthus spinosus*), tall waterhemp (*Amaranthus tuberculatus*), common ragweed (*Ambrosia artemisiifolia*), giant ragweed (*Ambrosia trifida*), horseweed (*Conyza canadensis*), kochia (*Kochia scoparia*), goosegrass (*Eleusine indica*), Italian ryegrass (*Lolium multifloru*), and Johnsongrass (*Sorghum halepe*) (Heap, 2013).

Tables II.B-9 and II.B-10 summarize known resistance among the major weed species present in soybean within each of the key soybean herbicide groups and herbicide classes active on broadleaf weeds (Heap 2013b). Resistance to the ALS group of herbicides is present in most of the major broadleaf weed species commonly found in soybeans. For common ragweed and waterhemp there is known resistance to at least one member for several of the major soybean herbicide chemistry classes. While many effective options exist for managing common ragweed, waterhemp, Palmer pigweed and other key broadleaf weeds, the availability of additional herbicide modes-of-action will help mitigate the potential for development of future resistance in soybeans and manage existing herbicide-resistant weed populations. There has also been an increase in the detection of weed populations with multiple resistance (i.e., resistance to multiple herbicide modes-of-action) in certain weed species, for example, *Amaranthus* spp. (Tranel, et al. 2010). The emergence of these resistant biotypes demonstrates the continued need to utilize diversified weed management practices, including the need for additional herbicide modes-of-action in major crops such as soybeans.

The relative occurrence of herbicide-resistant weeds varies between the different sub-groups of auxinic (phenoxy in Tables II.B.9 and II.B-10) herbicides. Considering that auxin herbicides have been widely used in agriculture for more than 60 years, weed resistance to this class is relatively low (29 species, to date, worldwide) and its development has been slow, especially when compared to the speed of appearance of resistance to ALS inhibitors (107 species) or triazine-resistant populations (68 species) (Heap 2012d). The relatively low incidence of auxinic herbicide resistance is believed to be attributable to the fact that there are multiple target sites for these herbicides (Gressel and Segel 1982; Morrison and Devine 1993).

Monsanto scientists and academics recommend the use of multiple herbicide modes-of-action for glyphosate-tolerant soybean regardless of whether glyphosate-resistant or hard –to-control broadleaf weeds are present. Monsanto specifically recommends the use of a soil residual as part of the weed management system. Growers may also choose to switch to other weed management systems in their soybean fields. APHIS has approved other herbicide tolerant soybean including phosphinothricin-tolerant, ALS-tolerant and HPPD tolerant soybean events (Table II.B-11). For growers who choose to use glyphosate-tolerant soybean, Monsanto and university extension agents provide recommended control options for glyphosate-resistant weeds. These options include the use of residual and postemergent herbicides such as synthetic auxins (2,4-D), ACCase inhibitors (clethodim, sethoxydim), PPO inhibitors (lactofen, fomesafen), and ALS inhibitors (cloransulam).[35]

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35 Monsanto Technology Use Guide; www.weedresistancemanagement.com.

These herbicides alone or combinations of these herbicides as well as traditional tillage methods are and will continue to be used to control glyphosate-resistant or hard-to-control broadleaf weeds.

While the utilization of additional weed management practices has occurred particularly in glyphosate-tolerant corn and cotton, such practices are also occurring in glyphosate-tolerant soybeans. In a 2005 survey of growers in six states, 15 to 21% of growers applied non-glyphosate herbicides in addition to glyphosate for weed control in glyphosate-tolerant soybean (Givens, et al. 2009a). These non-glyphosate herbicides were applied prior to planting, at planting and/or postemergence in soybean. In another grower survey conducted at the end of the 2009 growing season, in certain areas of the U.S., the percent of growers applying non-glyphosate herbicides rose to 33% for those growing continuous glyphosate-tolerant soybean, and to 33% and 52% for growers growing glyphosate-tolerant soybean in rotation with only glyphosate-tolerant corn and only cotton, respectively (personal communication from Dr. David Shaw, December 2011). More recently, a survey indicated that approximately 30 and 43% of glyphosate-tolerant soybean planted acres are using non-glyphosate postemergence and soil applied residual herbicides, respectively, in addition to glyphosate in 2011 (See Appendix A, Table A-12 and A-13) (Monsanto 2009). These data indicate a trend towards increased diversification of weed management practices in glyphosate-tolerant crops.

Further evidence of increased adoption of diversified weed management practices, including incorporation of multiple herbicide modes-of-action, across glyphosate-tolerant corn, cotton and soybean is presented by Prince et. al. (2011b). Furthermore, researchers report that approximately 40 to 50% of the growers utilizing glyphosate-tolerant crops in major soy- and cotton-growing areas indicate that rotating herbicides or tank mixing glyphosate with other herbicides is an effective management practice to minimize the development of glyphosate resistance (Beckie 2006; Beckie and Reboud 2009; Diggle, et al. 2003; Powles, et al. 1996). Indeed, as described in detail below, a prominent strategy to mitigate the potential for development of herbicide-resistant weeds is to increase the diversity of weed management options in agriculture, including use of herbicides with different modes-of-action in a grower's weed management program (Duke and Powles 2009). Refer to Appendix B for details on herbicide resistance.

Table II.B-9. Known Weed Resistance in the Southern U.S.[1]

Most Common Broadleaf Weeds (# states where listed as a top weed)	Resistance Group [2]	ALS (Group 2)			PPO (Group 14)		PS II (Group 5)	Glycine (Group 9)	Phenoxy (Group 4)	
	Chemistry Class [2]	Sulfonyl Urea	Imidazolinones	Triazoles	Diphenyl ether	N-phenyl thalimide	Triazinones	-	Phenoxy	Benzoic acid
	Example	chlorimuron	imazethapyr	chloransulam	lactofen fomesafen	flumioxazin	metribuzin	glyphosate	2,4 D	dicamba
Morning glory (5)										
Sida (prickly sida (5)			X							
Sicklepod (4)										
Hemp sesbania (3)										
Pigweed spp. [3] (3)		X	X	X	X		X	X	X	
Palmer pigweed (2)		X	X	X				X		
Cocklebur (1)		X	X	X						
Horseweed (marestail) (1)		X		X				X		

1 Source: www.weedscience.org
2 Cross resistance is possible within a resistance group and/or chemistry class
3 Includes redroot pigweed, common waterhemp, spiny amaranth and smooth pigweed

Table II.B-10. Known Weed Resistance in the Midwest U.S. [1]

Most Common Broadleaf Weeds (# states where listed as a top weed)	Resistance Group [2]	ALS (Group 2)			PPO (Group 14)		PS II (Group 5)	Glycine (Group 9)		Phenoxy (Group 4)
	Chemistry Class [2]	Sulfonyl Urea	Imidazolinones	Triazoles	Diphenyl ether	N-phenyl thalimide	Triazinones	-	Phenoxy	Benzoic acid
	Example	chlorimuron	imazethapyr	chloransulam	lactofen fomesafen	flumioxazin	metribuzin	glyphosate	2,4 D	dicamba
Pigweed spp. [3] (12)		X	X	X	X		X			
Velvetleaf (11)										
Lambsquarters (10)		X	X				X			
Cocklebur (9)		X	X	X						
Common ragweed (7)		X	X	X	X	X		X		
Smartweed spp. (6)										
Morning glory (5)										
Waterhemp (5)		X	X	X	X			X	X	
Horesweed (marestail) (3)		X		X				X		
Giant ragweed (3)		X	X	X				X		
Kochia (2)		X	X					X		X

1 Source: www.weedscience.org
2 Cross resistance is possible within a resistance group and/or chemistry class
3 Includes redroot pigweed and smooth pigweed

Table II.B-11. Deregulated Biotechnology-derived Soybean Products[1]

Phenotype	Event	Institution	Date Deregulated
Herbicide-tolerant (Glyphosate/*Isoxaflutole)*	FG72	Bayer Crop Sciences	August, 2013
Omega 3 Fatty Acid	MON 87769	Monsanto	July, 2013
High Oleic Acid, Low Saturated Fat	MON 87705	Monsanto	December, 2011
Lepidopteran Resistant	MON 87701	Monsanto	June, 2011
High Oleic Acid	DP-3Ø5423-1	Pioneer	June, 2010
Glyphosate- and ALS-tolerant	DP-356043-5	Pioneer	July, 2008
Glyphosate-tolerant	MON 89788	Monsanto	February, 2007
Phosphinothricin-tolerant	GU262	AgrEvo	October, 1998
Phosphinothricin-tolerant	A5547-127	AgrEvo	May, 1998
Altered Oil Profile	G94-1, G94-19, G-168	DuPont	May, 1997
Phosphinothricin-tolerant	W62, W98, A2704-12, A2704-21, A5547-35	AgrEvo	August, 1996
Glyphosate-tolerant	40-3-2	Monsanto	May, 1994

[1] (USDA-APHIS 2013b)

II.B.1.e. Organic Production Practices

National Organic Program and Organic Soybean Farming: In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS 2010). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

In accordance with NOP, an accredited organic certifying agent conducts an annual review of the certified operation's organic system plan and makes on-site inspections of the certified operation and its records. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards.

The NOP regulations preclude the use of excluded methods. The NOP provides the following guidance under 7 CFR § 205.105:

> "…to be sold or labeled as '100 percent organic', 'organic' or 'made with organic (specified ingredients or group(s)),' the product must be produced and handled without the use of:

> (a) Synthetic substances and ingredients,…
>
> (e) Excluded methods,…"

Synthetic Substances are defined in 7 CFR § 205.2 as:

> "A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes." This includes synthetic herbicides, insecticides, and fertilizers.

Finally, excluded methods are defined as:

> "A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production…"

Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances and excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the avoidance of use of prohibited substances and excluded methods (USDA-AMS 2010).

Most EPA-registered synthetic pesticides are prohibited in organic production; however, there is the potential for inadvertent or indirect contact from neighboring conventional farms or shared handling facilities. As long as the operator has not directly applied prohibited pesticides and has documented efforts to minimize exposure to them, the USDA organic regulations allow for residues of prohibited pesticides at or below 5 percent of the EPA tolerance. (USDA-AMS 2012b).

Although the National Organic Standards preclude the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS 2011). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (USDA-AMS 2011).

Organic soybean producers use production practices designed to prevent commingling of their value-added crop with neighboring crops treated with herbicides and other pesticides or that may be using plant varieties produced by excluded methods. In addition, steps are taken to avoid spray drift from neighboring fields. These well-established practices include isolation zones, use of buffer rows surrounding the organic crop, adjusted planting dates, and varietal selection (Kuepper 2006).

The efficacy of management practices utilized to avoid pollen movement from a GE crop to organic soybean production operations is facilitated by the nature of soybean pollination. Soybean is a highly self-pollinated species and exhibits a very low level of outcrossing (see Section II.D.1.c) Outcrossing most commonly results from cross-pollination. Since soybean is highly self-pollinating, organic or conventional soybean producers can and have effectively implemented practices (e.g., isolation during the growing season, equipment cleaning during harvest, and post-harvest separation of harvested seed) that allow them to reasonably avoid biotechnology-derived soybean and maintain organic or conventional production status (Brookes and Barfoot 2004).

U.S. Organic Soybean Production: Organic soybean was produced on 96,080 acres in 2011 and yielded 2.9 million bushels, equal to approximately 0.09% of U.S. soybean production (USDA-NASS 2013b). The average yield was 30 bushels per acre. Major production states are Iowa, Minnesota, Michigan, New York, Illinois, Nebraska, and Wisconsin (USDA-NASS 2012d). Based upon recent trend information, the presence of GE soybean varieties on the market has not affected the ability of organic production systems to maintain their market share.

Organic soybean production practices include crop rotation, use of cover crops, green and animal manures, application of rock minerals such as lime, other soil additives, mechanical weed control, biological control of pests, and disease control primarily through management practices (CAST 2009; Kuepper 2003; USDA-AMS 2011).

II.B.1.f. Other Specialty Market Production

Other specialty soybean include those used for specific food products (e.g., fermented soy food, tofu, soymilk, sprouts, soy nuts [roasted seed] and edamame [green seed]), those grown for special oil or seed traits (e.g., reduced linolenic acid, high oleic acid, and high protein) and non-GE soybean (Lee and Herbek 2004; University of Kentucky 2009). These specialty soybeans are typically grown under contract for a specific market.

Specialty soybean are grown on fewer acres than commercial or commodity soybean and are grown, harvested and handled separately from commodity soybean. Specialty soybean must be segregated from other soybean throughout the production, storage and shipping process to preserve its identity.

II.B.1.g. Seed Production Services

Seed quality (including genetic purity, vigor, and presence of weed seed, seed-borne diseases, and inert materials such as dirt) is a major factor in crop yields. If natural variability in seed production is not carefully controlled, the value of a new variety or cultivar may be lost (Hartmann, et al. 1975). Genetic purity in commercial seed production is generally regulated through a system of seed certification which is intended to ensure that the desired traits in the seed are maintained throughout all stages in cultivation (Hartmann et al. 1975).

States have developed seed laws and certification agencies to ensure that purchasers who received certified seed can be assured that the seed meets established seed quality standards (Bradford 2006). The U.S. Federal Seed Act of 1939 recognizes seed certification and official certifying agencies. Implementing regulations further recognize land history, field isolation, and varietal purity standards for Foundation, Registered, and Certified seed.

In a seed certification program, classes of seed are identified to designate the seed generation from the original breeder source (Hartmann et al. 1975). Foundation seed, Registered seed, and Certified seed production is controlled by public or private seed certification programs (AOSCA 2009a). The original seed breeder seed stock is controlled by the developer of the variety (Adam 2005; Hartmann et al. 1975). The breeder stock is used to produce Foundation seed stock (Adam 2005). The institution associated with the breeder controls the production of Foundation seed stock. Foundation seed stock, in turn, is used to produce Registered seed for distribution to licensees, such as seed companies (Adam 2005). Registered seed is used by seed companies to produce large quantities of Certified seed (Adam 2005; Hartmann et al. 1975). The Certified (or Select) seed is then sold to growers through commercial channels (Adam 2005; Hartmann et al. 1975).

Seed certification cultivation practices commonly include recommendations for minimum isolation distances between various seed lines and planting border or barrier rows to prevent pollen movement (Hartmann et al. 1975; Wozniak and Martinez 2011). The isolation distance for Foundation, Registered, and Certified seeds, as dictated by the USDA Agricultural Marketing Service's (AMS) Federal Seed Act, is 1,320, 1,320, and 660 feet, respectively (7 CFR Part 201.76). During the growing season, seed certification agencies will monitor the fields for off-types, other crops, weeds, and disease (Wozniak and Martinez 2011). These certifying agencies also establish seed handling standards to reduce the likelihood of seed source mixing during production stages, including planting, harvesting, transporting, storage, cleaning, and ginning (Wozniak and Martinez 2011). Further discussion of cross-pollination, gene transfer, and weediness is presented in Section II.D.1.c.

II.B.2. Agricultural Production of Cotton

II.B.2.a. Crop Use and Biology

Cotton: Cotton belongs to the genus *Gossypium*, which currently encompasses approximately 50 species widely cultivated in tropical and subtropical regions around the world (OECD 2008; Percival, et al. 1999). There are four cultivated species, two diploid species *G. arboretum* and *G. herbaceum*, which evolved from Africa and the Middle East, and two allotetraploid species *G. hirsutum* and *G. barbadense*, which evolved in the Americas (Brubaker, et al. 1999). Upland cotton (*G. hirsutum*) and Pima cotton (*G. barbadense*) species account for more than 95% of world cotton production.

Improved modern varieties of *G. hirsutum* and *G. barbadense* are currently cultivated in the southern U.S., with *G. barbadense* grown primarily in the western states of Arizona, California, New Mexico, and Texas. *G. hirsutum* is produced throughout the 17 states comprising the U.S. cotton growing region.

Commercial cotton, including *G. hirsutum* and *G. barbadense*, has a long history of agricultural production (Lee 1984; USDA-AMS 2001; USDA-NASS 2012c). The extra-long staple lint produced from G. barbadense is segregated and classed separately from G. hirsutum and is sold at a premium (USDA-AMS 2001). However, cottonseed and cottonseed by-products (e.g., oil and meal) are not generally distinguished by species (OECD 2008; USDA-FAS 2005).

Cotton Biology and Weed Management: In contrast to other crops, including corn and soybean, cotton emergence and above ground growth is relatively slow during the first few weeks after planting. The slow early growth of cotton does not permit the crop to aggressively compete against weed species that often grow more rapidly (Smith and Cothren 1999). Weeds in cotton are controlled through the diversified use of various cultural, mechanical, and chemical methods (Hake, et al. 1996b). Historically, mechanical tillage and hand-weeding were the most important tools in cotton weed control due to the limited application window afforded to most chemical applications. Today with the advent of GE cotton, approximately 38% of the total cotton acres are post-plant cultivated. In fields classified as employing conventional tillage systems, over 50% cotton acres are cultivated for weed control (USDA-ERS 2012c).

Due to the biology and planting practices of cotton, in the U.S., whereby complete crop canopy closure is at times never achieved, herbicides are used at multiple intervals throughout the entire growing season on essentially all (>99%) the cotton acres in the U.S. (Brookes and Barfoot 2012; Monsanto 2012). Weed management and herbicide use are discussed in Section II.B.2.d.

Cotton Use: Cotton is a crop that produces two main commodities: fiber and seed. Fiber (lint) accounts for approximately 85% of the crop value. The development of the mechanized cotton gin in 1793 greatly contributed to the value of cotton as a crop by separating the fiber from the seed and by removing objectionable foreign matter, while generally preserving the inherent qualities of the fiber and seed (Smith and Cothren 1999). Approximately 57% of the cotton fiber produced is used in the manufacture of apparel, 36% is used in home furnishings, and 7% is used in industrial products (NCCA 2010a). For every 100 pounds of fiber produced by the cotton plant, it also produces approximately 162 pounds of cottonseed (NCCA 2010b). Roughly one-third of the cottonseed is crushed for oil and meal used in food products and in livestock feed. The extracted oil from cottonseed is further processed to produce cooking oil, salad dressing, shortening and margarine. Limited quantities of the cottonseed oil are used in soaps, pharmaceuticals, cosmetics, textile finishes, and other products.

II.B.2.b. Land Use

Cotton Production: Cotton is a warm-season plant. Successful production requires 200 frost-free days and more than 160 days above 15°C. Thus, continental U.S. production is limited to the southern portions of the country (Waddle 1984). Two species of cotton (genus *Gossypium*) are grown in the U.S.: upland cotton (*G. hirsutum*), which comprises the vast majority of U.S. cotton production with nearly 11 million acres planted and 18 million bales harvested, and Pima cotton (*G. barbadense*), which accounted for approximately 200,000 acres and half a million bales in 2010 (USDA-NASS 2011b). Planted acres by county are shown in Figures II.B-2 (upland cotton) and II.B-3 (Pima cotton).

U.S. upland cotton production occurs in 17 states, primarily across the southern portion of the U.S. where the climate is warmer and the season is longer (USDA-NASS 2010a). In the U.S., Pima cotton is grown primarily in California with small acreages in Arizona, New Mexico, and Texas (USDA-NASS 2013c). Cotton can be grown adjacent to or near large acre crops such as corn, soybeans, sorghum, wheat, peanuts, and other cotton; near vegetables, orchards, and pastures; and adjacent to non-agricultural lands, such as forests, grasslands, streams, lakes, and rivers; and occasionally near urban areas. Cotton fields are typically highly managed agricultural areas that can be expected to be dedicated to crop production for many years.

Total U.S. cotton acreage since 2000 has varied from approximately 9 to 16 million planted acres, with the lowest acreage recorded in 2009 and the highest in 2001 (Table II.B-12). Average cotton yields have varied from 632 to 879 pounds per acre over this same time period (Table II.B-12).

Approximately 7.6 million acres of cotton were planted in Texas in 2011, representing roughly 50% of the total U.S. cotton acres. Georgia was the second largest state for cotton acreage, with 1.6 million total acres (Table II.B-13). The variations observed in cotton acreage and production are primarily driven by current market conditions, rather than agronomic considerations.

Herbicide-tolerant cotton was grown on 73% of U.S. cotton acres in 2011 (USDA-NASS 2013b). Only 3% was planted to glufosinate-tolerant cotton (USDA-NASS 2010a). GE-derived varieties of cotton, containing either a herbicide tolerance, insect resistance, or both traits, comprise 90% of all cotton acreage in 2011 (USDA-NASS 2010a; 2013b). There is no indication that the introduction and widespread adoption of GE-derived crops in general has resulted in a significant change to the total U.S. acreage devoted to agricultural production. The cumulative land area in the U.S. planted to principal crops, which include corn, sorghum, oats, barley, winter wheat, rye, durum, spring wheat, rice, soybean, peanuts, sunflower, cotton, dry edible beans, potatoes, canola, proso millet, and sugar beets, has remained relatively constant over the past 27 years. From 1982 to 1995, the average yearly acreage of principal crops was 323 million. This average is essentially unchanged at 326 million acres since the introduction of GE-derived crops in 1996 (USDA-NASS 1984; 1990; 1992; 1995; 1998; 2000; 2003; 2006; 2009a).

For the purposes of this environmental report, cotton production is divided into four major cotton-growing regions: Southeast (AL, FL, GA, NC, SC, and VA), Midsouth (AR, LA, MS, MO, and TN), Southwest (KS, NM, OK, and TX), and West (AZ and CA) (Table II.B-13).

Seed Production Areas: Seed is produced in the same general areas as the cotton crop. The majority of the cotton seed crop is produced in Texas, with significant quantities produced in Arizona, Arkansas, California, and Mississippi (McDonald and Copeland 1997). Seed companies minimize the risk of crop loss due to weather events by producing seed in multiple regions.

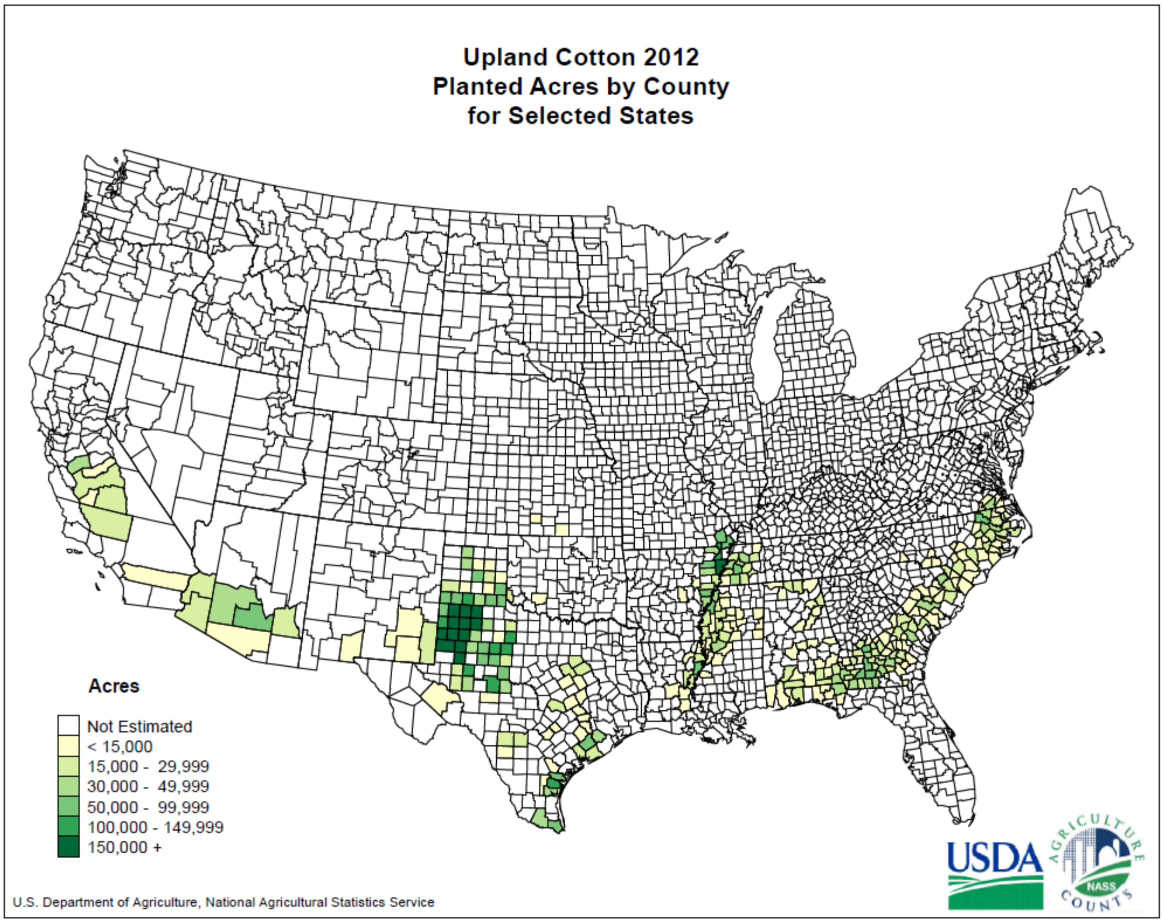

Figure II.B-2. Planted Upland Cotton Acres by County in the U.S. in 2012

(USDA-NASS 2013d).

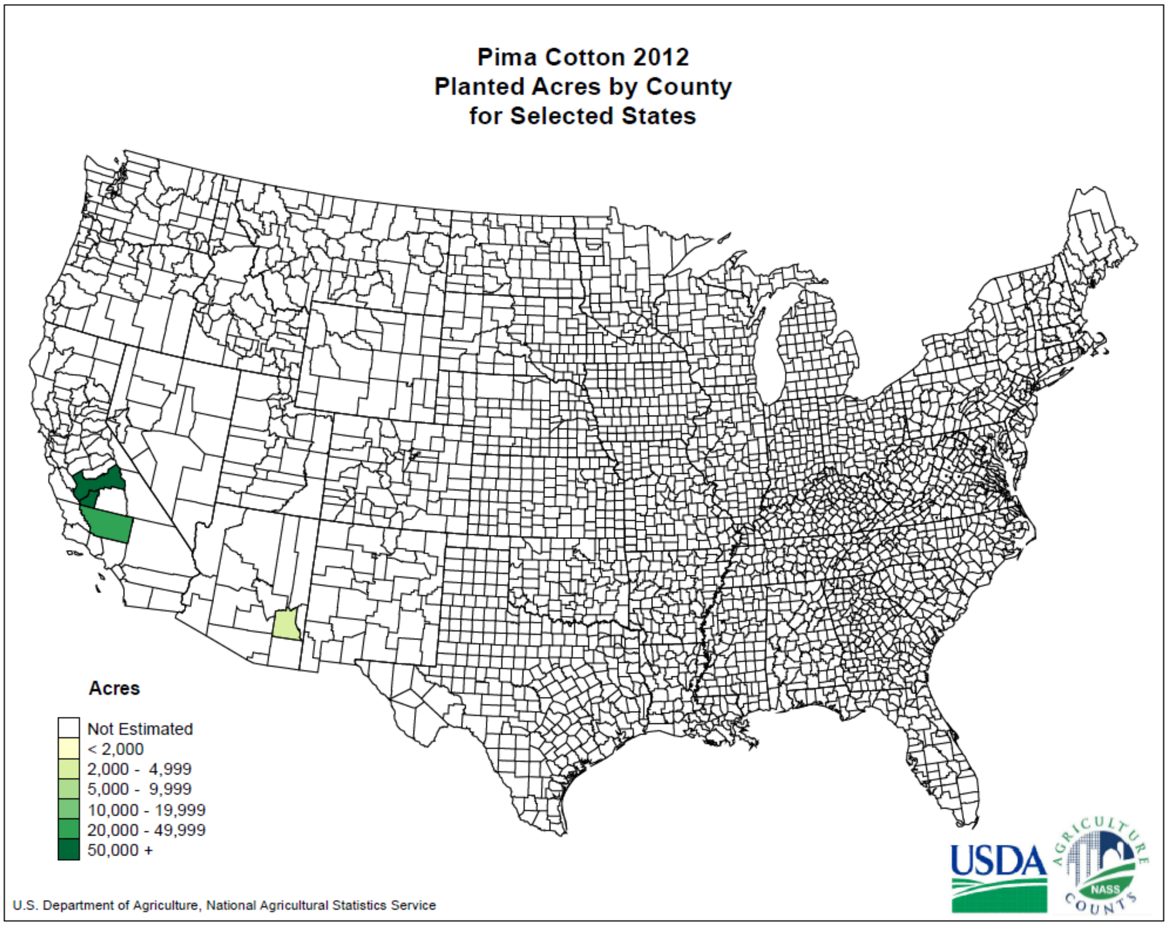

Figure II.B-3. Planted Pima Cotton Acres by County in the U.S. in 2012

(USDA-NASS 2013c).

Table II.B-12. Cotton Production in the U.S., 2000-2011[1]

Year	Acres Planted (×1000)	Acres Harvested (×1000)	Average Yield (lbs/acre)	Total Production (480 lb bales)	Value (billions $)
2011[2]	14,735	9,461	790	15,573,200	7.262
2010	10,973	10,707	821	18,314,500	7.318
2009	9,150	7,529	777	12,187,500	3.788
2008	9,471	7,569	813	12,815,300	3.021
2007	10,827	10,489	879	19,206,900	5.653
2006	15,274	12,732	814	21,587,800	5.013
2005	14,245	13,803	831	23,890,200	5.695
2004	13,659	13,057	855	23,250,700	4.994
2003	13,480	12,003	730	18,255,200	5.517
2002	13,958	12,417	665	17,208,600	3.777
2001	15,769	13,828	705	20,302,800	3.122
2000	15,517	13,053	632	17,188,300	4.260

[1](USDA-NASS 2011e).

[2](USDA-NASS 2012b).

Table II.B-13. U.S. Cotton Production by Region and State in 2011[1]

Region/State	Acres Planted (thousands)	Acres Harvested (thousands)	Average Yield (pounds/acre)
Alabama	460	447	762
Florida	122	120	660
Georgia	1,600	1,520	805
North Carolina	805	800	630
South Carolina	303	301	773
Virginia	116	115	689
Region Totals	3,406	3,303	720
Arkansas	680	660	938
Louisiana	295	290	852
Mississippi	630	605	968
Missouri	375	367	961
Tennessee	495	490	813
Region Totals	2,475	2,412	906
Kansas	80	68	494
New Mexico	68	62	1,084
Oklahoma	415	70	432
Texas	7,550	3,100	542
Region Totals	8,113	3,300	638
Arizona	250	248	1,526
California	637	634	1,399
Region Totals	887	882	1,463
U.S. Total	14,881	9,897	932

[1](USDA-NASS 2012b).

II.B.2.c. General Agronomic Practices

Life Cycle: Botanically, cotton is a perennial that is cultivated as an annual (Smith and Cothren 1999). Depending on the region and variety, cotton is planted in the U.S. between April and June and harvested between September and December (USDA-NASS 2010b). Cotton is normally considered to be a self-pollinating crop (Niles and Feaster 1984), although a low level of natural outcrossing has the potential to occur. Cotton pollen movement by wind is very limited due to it is large and sticky nature; several studies have demonstrated that cross-pollination, even in the presence of high pollinator activity, is limited by distance (OECD 2008) (see Subsection II.D.2.c for additional details).

Varieties: In a given year, more than 100 different cotton varieties are grown in the U.S. (USDA-AMS 2012a), with new varieties introduced every year. Varieties are evaluated in performance tests (variety trials) that are conducted across the cotton-growing region. Lint (fiber) yield potential has generally been the most important factor considered by growers in variety selection (Smith and

Cothren 1999). Growers also consider properties such as fiber length and strength, cold tolerance, seedling vigor, heat tolerance, leaf hairiness, insect and disease resistance, herbicide tolerance, storm resistance, maturity, and a number of other factors when selecting commercial varieties.

Water Use: Depending upon the U.S. cotton growing region and access to supplemental irrigation the water requirement for cotton to produce high yields varies. The humid Southeast region of the U.S. requires a minimum of 18 inches of water per year to produce maximum yields (Bednarz, et al. 2002). The desert Southwest region requires a maximum of roughly 40 inches of water per year (Hunsaker 1999). The water requirements of cotton are greater than the annual rainfall in the U.S. west of Central Texas; irrigation is a key component of the cotton production system to maximize yield. Approximately 45% of the cotton production in the U.S. is irrigated (USDA-ERS 2007).

Yields: The yield potential of a cotton crop is determined in the first 30 to 40 days after seed is placed in the ground (Deterling and El-Zik 1982). Planting date management is an important step to getting the crop established, achieving early fruit set, and establishing a strong yield potential (Smith and Cothren 1999). Cotton should be planted into prepared seedbeds that are firm, warm, and moist. Early season insect and mite damage, or damage to the terminal bud from hail, insects, or equipment, can negatively impact yields. The period between first bloom and the cessation of vegetative growth is the period when the greatest potential in crop yield is either gained or lost. Approximately 85% of the total bolls that are harvested come from floral buds (squares) set during the first four to five weeks of squaring (Deterling and El-Zik 1982). Production practices are optimized to favor reproductive growth at the expense of vegetative growth. Available options to influence cotton plant growth include the use of a plant growth regulator(s) such as mepiquat chloride, fertility management (primarily nitrogen and potassium), and overall water management. In addition, insect pest control is important throughout the growing season as pest populations exceed economic thresholds which dramatically decrease both square and immature boll retention. Weed control is equally important throughout the growing season to maximize yields by eliminating weeds that complete for available light, water, and nutrients.

Average 2011 cotton yields across the four cotton-growing regions ranged from 638 to 1463 pounds of cotton lint per acre, with the highest yields in the West with full irrigation, and the lowest yields in areas such as Kansas, Oklahoma, and Texas, where little to no irrigation is available (Table II.B-13).

Crop Nutrition: Thirteen essential minerals and nutrients are needed for cotton growth and development. Nitrogen is the nutrient to which cotton most consistently responds (Mullins and Burmester 2010). The key to management of nitrogen in the soil is to provide adequate amounts to correct deficiencies, but not excess amounts. Excess nitrogen fertilization can promote excess vegetative growth (at the expense of fruiting) and delayed maturity, which results in lower yields (Smith and Cothren 1999). In the Southwest and West regions, monitoring soil salinity is of additional importance because cotton is most sensitive to salts during the germination and seedling growth stage (Hake et al. 1996b). Soil salinity will severely delay emergence, which can make the plants more vulnerable to seedling disease. Pre-season soil test results for nitrogen, phosphorus, and potassium, determination of pH, and previous cropping and fertilization history determine the fertilizer and liming needs for the upcoming cotton crop.

Use of Plant Growth Regulators: Cotton is a perennial and has an indeterminate growth pattern (i.e. flowering and fruiting does not occur all at once, but rather it is an ongoing process that continues until harvest or frost). A consequence of this growth habit is that vegetative and reproductive growth occur at the same time and thus compete for photosynthetic products (Norton and Silvertooth 2000). Cotton growers commonly used mepiquat chloride and other plant growth regulators to control vegetative growth and thereby enhance reproductive growth (Norton and Silvertooth 2000).

Crop Rotation: Cotton rotation with other crops on a regular basis can help maintain soil productivity and reduce the incidence of various weeds, insect pests, or diseases (Hake et al. 1996b). Rotating cotton with monocot crops, such as corn, can help to reduce the soil inoculum level of the seedling disease fungi *Pythium* and *Rhizoctonia*. These seedling diseases can increase in continuous cotton cropping systems (Smith and Cothren 1999). However, production costs, relative rate of return, and the current market conditions dictate which crops to rotate with cotton or whether to grow continuous cotton. These economic factors may outweigh the agronomic benefits of crop rotation. In 2003, the USDA reported that cotton was grown in a continuous cropping system on 73% of the acreage in the major cotton-growing states (Norton and Silvertooth 2000; USDA-ERS 2006). However, more recent state-specific information from interviews with university extension crop production specialists and extension weed control specialists indicates that the percentage of cotton acres in continuous cropping is decreasing across the Cotton Belt. Based on interviews conducted by Monsanto in 2010, approximately 54% of U.S. cotton acres are followed by cotton in the crop rotation sequence. By region, this percent is highest in the Southwest (61%) and lowest in the West (30%). Only in the West region is cotton rotated to another crop, wheat, on the majority of cotton acres. Corn (16%), wheat (9%), soybean (8%), sorghum (8%), and peanuts (4%) are the other crops most frequently following cotton. When rotational crops are planted, the most common rotation crops by region are as follows: Southeast, soybean; Midsouth, corn; Southwest, sorghum; and West, wheat.

Winter cover crops are also utilized in cotton production. These cover crops are used to provide winter soil cover and protection, build soil nitrogen and organic matter, reduce nitrogen leaching, suppress weeds, and provide a habitat for beneficial predatory and parasitic insects and spiders (Guerena and Sullivan 2003).

Soil Types: Cotton has broad adaptability to a wide range of soil types, provided that sufficient nutrition and moisture are available through the growing season (Hake and Kerby 1996). In general, where annual rainfall is less than 20 inches, fine-textured soils (loam and clay loam) will be more productive because of their ability to store water in the soil profile. Where rainfall exceeds 30 inches per year, coarse-textured soil provides better internal drainage and greater productivity.

Preharvest and Harvest: Defoliants are applied prior to harvesting, as the complete removal or desiccation of leaf tissue in preparation for harvest is a necessity with machine harvesting (Hake, et al. 1996a). An additional objective of defoliation is to control or desiccate weeds that can reduce harvest efficiency, contribute to the weed seed bank, and reduce both the quality and value of the lint because of staining by vegetation (University of Georgia 2012).

Tillage: Tillage is used for seedbed preparation and may also be used for weed control. The primary purposes of preplant tillage are to incorporate residue from the previous crop, reduce wheel traffic compaction from the previous season, improve water filtration and soil aeration, control weeds, loosen the soil for root penetration, and provide a suitable environment for the planting and germination of cottonseed (Hake et al. 1996b). Decreased profitability in cotton production, as well as soil erosion concerns, have increased interest in conservation tillage systems. The benefits of conservation tillage or no-till systems are well documented and include reduced soil erosion, reduced fuel and labor costs, improved soil tilth (including structure improvement and reduction in compaction), increased organic matter, improved water quality, and conservation of soil moisture (CTIC 2011).

Conventional tillage is associated with intensive plowing and less than 15% crop residue at the soil surface; reduced tillage is associated with 15 to 30% crop residue; and conservation tillage, including no-till practices, is associated with at least 30% crop residue and substantially less soil erosion than other tillage practices (CTIC 2010; U.S. EPA 2010a). As of 2008, approximately 21% of cotton acres were planted in a conservation tillage system, which included no-tillage, mulch-till, and reduced tillage systems (CTIC 2010). Over 17% of the cotton acres were in no-tillage systems which rely solely on chemical means for weed control. The adoption of glyphosate-tolerant cotton has facilitated the transition from conventional tillage to conservation tillage systems over the last decade (Givens, et al. 2009b). Increases in total acres dedicated to conservation tillage have been attributed to increased planting of herbicide-tolerant cotton, which reduces the need for mechanical weed control (McClelland, et al. 2000; Towery and Werblow 2010).

Some growers have been slow to transition to conservation tillage systems because of equipment costs, compaction, flooding or poor drainage, delays in planting because fields are too wet or too cold, or carryover of diseases or pests in crop residue (Shurley 2006). However, in a 2000-2004 USDA Mississippi study that compared net economic returns with five different tillage methods, the no-till treatment regime (without cover crops) resulted in the highest returns per acre, primarily due to the reduction in the number of trips across the field (Perry 2009).

As a result of weed shifts and the existence of weeds resistant to glyphosate and other herbicides in certain areas of the U.S., there is the potential for the loss of soil conservation gains resulting from conservation tillage, because of the need to manage such weeds through additional means, including tillage. For example, mechanical methods (machine tillage or hand-weeding) have been found to be one of the few consistent control options for Palmer amaranth, which has become a frequent hard-to-control weed in certain areas of southeastern cotton production (CAST 2012).

II.B.2.d. Pest Management

The use of pesticides, including fungicides, herbicides, and insecticides, is a key component of an integrated pest management (IPM) system in cotton. The various pesticides used in cotton, along with other IPM elements, are addressed in the two subsections below.

Disease Management: Plant pathologists have estimated that diseases cause annual losses in U.S. cotton production of 1.8 million bales, which represents a yield reduction of approximately 9.0% (Blasingame, et al. 2008). Cotton must be protected from diseases during the early period of slow growth to prevent yield loses (Smith and Cothren 1999).

The major seedling diseases are caused by fungal pathogens that occur on or in cottonseed prior to planting and soil-borne pathogens that reside in soil (Smith and Cothren 1999). The soil-borne pathogens are the most important causes of seedling disease and the most difficult to control. Other fungal pathogens cause wilt diseases, resulting in yield losses. *Verticillium* and *Fusarium* wilt are the two major fungal wilt diseases which result in yield loss in cotton production. *Phymatotrichum* root rot, macrophomina root rot, *Agrobacterium* root rot, and root gall are the primary pathogens that may attack the roots of older cotton plants (Smith and Cothren 1999). The foliar diseases are caused by fungal and bacterial pathogens that infect leaves, stems, bolls, and occasionally seedling roots.

Bacterial blight, boll rot, fungal leaf spots, fungal boll rots, viran, and mycoplasmal make up the primary foliar diseases.

An integrated management system, utilizing agronomic and cultural practices, is the best means of controlling disease in cotton, including the selection of resistant varieties, and applications of biocontrol agents (Smith and Cothren 1999). The single most important practice for minimizing damage from seedling diseases is selection of high-quality planting seed that has minimal seed coat damage and high germination rates (Smith and Cothren 1999). Seedbed conditions that encourage rapid germination and emergence will minimize seedling disease losses (NCCA 2007). Various cultural practices such as crop rotation, proper fertility and water management, clean tillage systems, early planting, eliminating weeds (which are host plants to the pathogen), and practices that increase decomposition of crop residues can reduce the severity of diseases (Smith and Cothren 1999). Cottonseed is normally treated with a mixture of fungicides and biological control agents to protect seeds and seedlings from seed- and soil-borne pathogens during their first few weeks of growth. Fungicides are also used to prevent spread of foliar diseases when these infestations approach economically damaging levels. An average of three fungicide treatments were made in cotton in 2007 (USDA-ERS 2012a). Foliar fungicides are applied to approximately 3% of the cotton acreage (USDA-NASS 2008c).

Management of Insect and Other Pests: Insect and mite pests, which can result in decreased yield and reduced quality, are a common and continuous threat to cotton production in all regions where it is produced in the U.S. Nearly every stage of cotton growth is susceptible to injury; as a consequence, cotton fields must be monitored regularly. Insects caused yield losses of approximately 986 thousand bales of cotton in 2010, equating to a 3.9% yield loss (Williams 2010). Lepidopteran pests, specifically tobacco budworm and cotton bollworm result in the greatest yield reductions followed by stink bugs and lygus insects.

Successful and economical management of insect pests in cotton is accomplished through an integrated pest management approach of variety selection and implementation of cultural, biological, and chemical strategies (University of Georgia 2011). Preplant tillage and crop rotation are important agronomic and cultural practices utilized to reduce insect populations prior to planting cotton. Other agronomic practices are utilized to promote early maturity and reduce that period of time the crop is susceptible to insect and mite pests, and to increase the probability that an acceptable yield can be produced before insect pest densities exceed economic threshold levels (Smith and Cothren 1999). Selection of short-season determinate varieties, adherence to optimum planting periods, and early season insect and disease management strategies can shorten the production season and limit crop exposure to late season insect pressure. In addition, implementation of conservation tillage systems usually provide timely planting and crop management, to promote an earlier-maturing crop. Conservation tillage systems mediate soil moisture and temperature conditions to decrease the probability of delays in planting caused by adverse weather conditions (Smith and Cothren 1999). Biological control involves the importation, conservation, and/or augmentation of natural enemies (predators, parasites, and pathogens) of insect pests of cotton and is a major component of integrated pest management programs in cotton production (Smith and Cothren 1999).

The annual application of insecticide to cotton has decreased from 10-20 insect treatments per year to four to five treatments since the successful elimination of the boll weevil as an economic pest and the commercialization of insect-protected Bt cotton varieties in 1996 (University of Georgia 2012).

GE insect-protected cotton varieties were used on approximately 65% of the planted acres of cotton in 2011 (USDA-NASS 2012e).

Insecticides were applied to 66% of the U.S. cotton acreage in 2007, with an average of three insecticide treatments per treated acre (USDA-NASS 2008c).

In addition to cotton insect and mite pests, nematodes are present throughout the Cotton Belt and cause significant loss of yield and impact fiber quality. Nematodes are microscopic, wormlike animals that feed on cotton roots. Yield losses in cotton from nematodes exceed $400 million annually in the U.S (NCCA 2007). Management options are primarily pre-season and include planting tolerant or resistant cotton varieties, crop rotation, cultural practices and the use of a nematicide (NCCA 2007).

Weeds in Cotton: Across the Cotton Belt many annual and perennial weeds occur, resulting in economic damage to cotton yield, fiber quality, and economic returns. Barnyardgrass, crabgrass, pigweed spp. (including Palmer amaranth), morningglory spp., common cocklebur, and common lambsquarters are common annual weed species in almost all cotton-growing regions. Johnsongrass, bermudagrass, and nutsedge are common perennial weed species. Nightshade spp. and groundcherry are more common in the Southwest and West regions. Palmer amaranth, morningglory spp., and nutsedge spp. have been frequently reported as hard-to-control weed species in cotton (Webster et al. 2009). Tables II.B-14 through II.B-17 summarize the most common weeds for each of the four major cotton growing regions (Southeast, Midsouth, Southwest and West).

Table II.B-14. Common weeds in Cotton Production in the Southeast Region of the U.S.[1,2]

Crabgrass spp. (6)	Pigweed spp (3)	Crowfootgrass (1)
Morningglory spp (6)	Common cocklebur (2)	Horseweed (marestail) (1)
Prickly sida (5)	Common lambsquarters (2)	Jimsonweed (1)
Florida pusley (4)	Common ragweed (2)	Johnsongrass (1)
Nutsedge spp. (4)	Florida beggarweed (2)	Smartweed spp. (1)
Sicklepod (4)	Palmer amaranth (2)	Spurge spp (1)
Broadleaf signalgrass (3)	Texas millet (2)	Volunteer peanut (1)
Goosegrass (3)	Bermudagrass (1)	

1 Source: (Webster et al. 2009).
2 Number provided in parenthesis is the number of states out of the six total states (AL, FL, GA, NC, SC, & VA) in the Southeast Region reporting each weed as one of the ten most common weeds.

Table II.B-15. Common weeds in Cotton Production in the Midsouth Region of the U.S.[1,2]

Morningglory spp (5)	Velvetleaf (3)	Common cockleburr (1)
Broadleaf signalgrass (4)	Barnyardgrass (2)	Cutleaf evening-primrose (1)
Crabgrass spp (4)	Horseweed (marestail) (2)	Goosegrass (1)
Nutsedge spp (4)	Johnsongrass (2)	Hemp sesbania (1)
Prickly sida (4)	Palmer amaranth (2)	Henbit (1)
Spurge spp (4)	Bermudagrass (1)	Spurred anoda (1)
Pigweed spp (3)	Browntop millet (1)	

1 Source: (Webster et al. 2005; Webster et al. 2009) Webster et al., 2005 (MS & TN); Webster et al., 2009 (AR, LA, & MO).
2 Number provided in parenthesis is the number of states out of the five total states (AR, LA, MS, MO, & TN) in the Midsouth Region reporting each weed as one of the ten most common weeds.

Table II.B-16. Common weeds in Cotton Production in the Southwest Region of the U.S.[1,2]

Johnsongrass (4)	Pigweed spp (2)	Smartweed (1)
Nutsedge spp (4)	Russian thistle (2)	Smellmelon (1)
Common cockleburr (3)	Barnyardgrass (1)	Spurred anoda (1)
Palmer amaranth (3)	Bermudagrass (1)	Red Sprangletop (1)
Silverleaf Nightshade (3)	Bindweed, field (1)	Sunflower (1)
Common lambsquarters (2)	Foxtail spp (1)	Texas blueweed (1)
Large Crabgrass (2)	Groundcherry spp (1)	Texas millet (2)
Devil's claw (2)	Kochia (1)	Velvetleaf (1)
Morningglory spp (2)	Horseweed (marestail) (1)	Woolyleaf bursage (1)
Mustard spp (2)	Shepardspurse (1)	

1 Source: OK - Webster et al., 2009; KS – Dr. Stewart Duncan, Kansas State University – Personal Communication 11/4/2010; NM – Dr. Jamshid Ashigh, New Mexico State University – Personal Communications 11/12/2010; TX – Dr. Wayne Keeling and Dr. Gaylon Morgan, Texas A&M University - Personal communications 11/4/2010.
2 Number provided in parenthesis is the number of states out of the four total states (KS, OK, TX, & NM) in the Southwest Region reporting each weed as one of the ten most common weeds.

Table II.B-17. Common weeds in Cotton Production in the West Region of the U.S.[1,2]

Barnyardgrass (2)	Common lambsquarters (1)	Silverleaf Nightshade (1)
Morningglory spp (2)	Johnsongrass (1)	Palmer amaranth (1)
Sprangletop (2)	Junglerice (1)	Common Purslane (1)
Bermudagrass (1)	Nutsedge spp (1)	Horse Purslane (1)
Field Bindweed (1)	Pigweed spp (1)	Volunteer corn (1)
Cupgrass, southwestern (1)	Black Nightshade (1)	
Groundcherry spp (1)	Hairy Nightshade (1)	

1 Source: AZ – Bill McCloskey, University of Arizona – Personal Communication 11/5/2010; CA – Steven Wright, University of California - Personal Communication 11/16/2010.

[2] Number provided in parenthesis is the number of states out of the two total states (AZ & CA) in the West Region reporting each weed as one of the ten most common weeds.

Benefits of Herbicide Use in Agriculture: A study by CropLife America demonstrated that in 2005 the use of herbicides saved U.S. farmers 337 million gallons of fuel, produced $16 billion in crop yield increases, and cut weed control costs by $10 billion as compared to production without the use of herbicides (Gianessi and Reigner 2006). Additionally, without herbicides growers would have to abandon no-till production practices, which reduce soil erosion. If U.S. growers stopped using herbicides and resumed tillage on the number of acres not tilled in 2005, an additional 356 billion pounds of sediments would be deposited in streams and rivers, resulting in an estimated $1.4 billion in downstream damage (Gianessi and Reigner 2006).

Weed Management in Cotton: Weed control in cotton is essential to maximize both yield and quality of cotton fiber. The slow early growth of cotton does not permit the crop to aggressively compete against weed species that often grow more rapidly and utilize the available water, nutrients, light, and other resources for growth (Smith and Cothren 1999). Cotton yields can be reduced substantially if weeds are uncontrolled. Palmer amaranth has been reported to cause yield losses as high as 54% (Morgan, et al. 2001) and johnsongrass and barnyardgrass have been reported to reduce yields by 90% and 98%, respectively (Vargas et al. 1996). Based on 2005 data, not using herbicides in cotton would result in an increased production cost of approximately $2.3 billion annually and an estimated yield loss of 27% (Gianessi and Reigner 2006).

Weed-crop competition studies have demonstrated that the control of weeds during the first four to eight weeks after cotton planting is critical as weeds compete against the crop for water, nutrients, light and other resources necessary for growth (Smith and Cothren 1999). The primary weed competition factors affecting yield loss potential are the weed species, weed density, and the timing/duration of weed competition. Cotton emergence and above ground growth is relatively slow during the first few weeks after planting, and does not permit the crop to aggressively compete against often more rapidly developing weed species (Smith and Cothren 1999). In addition, cotton is primarily planted using wide row spacing which delays crop canopy closure until layby stage of cotton and extends the window of weed-crop competition.

While late-season infestations may not impact yield, they reduce harvesting efficiency, contribute to the weed seed bank and lower the lint grade (McWhorter and Bryson 1992; Vargas et al. 1996). Weeds can also increase cotton disease and insect management issues because certain weed species can be a host for pathogens, such as *Rhizoctonia* and *Verticillium*, and harbor insects such as lygus bugs.

The most effective weed management programs in cotton use diversified weed management practices, a combination of cultural, mechanical, and/or herbicide control practices, instead of relying on one particular method of weed control (Beckie et al. 2011; Norsworthy, et al. 2012; University of California 2009; Vargas et al. 1996). Herbicide application practices that are compatible with diversified weed management include the use of several herbicides with different modes-of-action, either within or across seasons, applying herbicides at the labeled rate at the correct timing, and proper application of the herbicide. Cultural and mechanical practices can also be important components of an effective diversified weed management program (Ashigh et al. 2012). Cultural practices such as crop rotation, use of optimal planting dates, and the use of cover crops, when implemented, can increase the crop's ability to compete with weeds. Crop rotation (limiting continuous cotton planting), in conjunction with other weed control methods, can play a role in the overall weed spectrum and can drastically reduce the overall weed population observed (Smith and Cothren 1999). Approximately 38% of the total cotton acres are post-plant cultivated for weed control and in conventional tillage systems, and over 50% of cotton acres are cultivated for weed control with as many as five tillage operations occurring after emergence to harvest (USDA-ERS 2012c). Spring preplant or fall postplant tillage and in-crop shallow cultivation can effectively reduce the competitive ability of weeds. A consequence of in-crop cultivation for weed control is that tillage equipment can damage crop roots or apical meristem, cause soil moisture loss. More recently, cotton growers have begun utilizing more hand-weeding to control glyphosate-resistant Palmer amaranth in fields. For example, Georgia cotton growers have increased hand-weeding from 17% of the state cotton acreage in 2000-2005 to 52% of the acreage in 2006-2010. Hand-weeding has current cost of $23 per acre (Sosnoskie and Culpepper 2012). A survey of Georgia cotton growers conducted in 2010 found that 92% of growers spent $16 million on hand-weeding 53% of the total Georgia cotton crop; similarly, at least 20% of the cotton acres in Tennessee were hand-weeded at cost of more than $3 million (Culpepper, et al. 2011).

The planting of winter cover crops can be utilized as part of a diversified weed management strategy. The planting of cover crops, such as grasses, legumes, or small grains can protect and improve soil quality, help reduce erosion, serve as surface mulch in no-till cropping practices, and provide habitat for beneficial insects (Guerena and Sullivan 2003; Hitt and Roos 2007; Mannering et al. 2007). Small grain crops such as rye are commonly used as a cover crop; incorporating rye or oats as a cover crop have been shown to suppress Palmer amaranth germination and growth (Price, et al. 2011). However the planting of cover crops in general incurs additional costs to the grower and therefore cover crops are not presently a major weed management practice utilized in cotton production systems (Singer 2006).

Herbicides are used on essentially all (>99%) cotton acres, and in 2011 approximately 39 million pounds of herbicides were applied pre- or postemergence in cotton production (Brookes and Barfoot 2012; Monsanto 2012). According to 2010 market data[36], there were approximately 46.3 million herbicide-treated cotton acres. Herbicides were applied to 21.8 million acres prior to the planting or emergence of cotton (preemergent) and to 24.5 million acres after the emergence of cotton (postemergent). For clarification, the market survey data counts one treated acre as the application of one active ingredient (a.i.) one time to an acre. If the same a.i. is applied a second time to that same acre or if two a.i.s are applied, it counts as two treated acres. USDA reports that 11.0 million acres of cotton were planted in 2010,[37] so that the 46.3 million herbicide-treated cotton acres means that on average each planted acre received at least 4 herbicide treatments. Cotton acres also received on average four treatments with herbicides during the 2011 growing season (USDA-ERS 2012a).

Of these treatments, 50% (23.3 million acres) were made with glyphosate herbicides, and the remaining 50% of treatments were made with more than 25 other active ingredients. The number of

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36 Monsanto Company. 2011. Farmer Survey Data. St. Louis, MO.

37 USDA Statistics for crops and geographic regions are available at http://www.nass.usda.gov/index.asp.

glyphosate applications on an average cotton acre was between 2 and 3 applications per year at an average rate of 2.0 pounds acid equivalent (a.e.) of glyphosate active ingredient per acre per crop year.

Herbicide-tolerant cotton is planted on the majority of U.S. cotton acres (73% in 2011), which allows for the postemergence in-crop use of glyphosate for control a broad spectrum of weeds. Glyphosate is the most widely used herbicide in cotton, applied on 91% of cotton acres with an average of 2.4 applications per growing season (Monsanto 2012). In 2010, between 49 and 76% of the growers who plant glyphosate-tolerant (GT) cotton applied non-glyphosate herbicides prior to planting, at planting, or postemergence. Percentages varied among cropping systems, with 76% of GT cotton in a rotation system with GT soybean receiving non-glyphosate herbicide applications, whereas non-glyphosate herbicides were only applied 49% of the time in continuous cotton cropping systems (Prince, et al. 2011a). Non-glyphosate herbicides with different modes-of-action are also frequently used to provide residual weed control, improve control on certain weed species, and extend weed control or control resistant weed species (Prince et al. 2011a). The non-glyphosate herbicides applied, on cotton in 2011, included ALS inhibitors (trifloxysulfuron, pyrithiobac), longchain fatty acid inhibitors (acetochlor, metolachlor), microtubule inhibitors (pendimethalin, trifluralin), PSII inhibitors (prometryn, fluometuron, diuron), PPO inhibitors (flumioxazin, fomesafen), synthetic auxins (2,4-D, dicamba), glufosinate, MSMA and paraquat (Monsanto 2012).

In 2010, dicamba-treated acres in cotton accounted for only 0.85 million acres, or 3.9% of the total preemergent treated acres.[38] This is primarily because dicamba is phytotoxic to current cotton varieties and is currently only labeled for application at timings that avoid contact with the growing plant, such as preplant treatments prior to planting, depending on rate and rainfall.

Over 30 different herbicide active ingredients are registered and available for use by cotton growers to control weeds. The ten most widely used alternative herbicides in cotton in 2010 are listed in Table II.B-18, compared to 2007 use. Integration of DGT cotton into the glyphosate-tolerant cotton system and the subsequent use of dicamba will result in the displacement of some currently used, or foreseeable future use herbicides, and therefore the properties of these alternative herbicides are summarized in this section to provide a baseline for comparison to dicamba use on DGT cotton. Some non-glyphosate alternative herbicides have a less benign human health and environmental characteristics compared to dicamba, and reduced agronomic flexibility due to cotton planting restrictions, rotational crop planting restrictions, the need for adequate soil moisture for activation, and the need to apply prior to planting or with hooded sprayers in-crop to minimize crop injury.[39]

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38 Monsanto Company. 2011. Farmer Survey Data. St. Louis, MO.

39 In order to approve a new use of a herbicide EPA must conclude that the herbicide, when used according to the label, does not pose an unreasonable adverse effect to humans or the environment, and, in order to establish a tolerance for the use of a herbicide on a food or feed crop, find there is a reasonable certainty of no harm to human health from non-occupational (food, water and residential/recreational) exposures to the herbicide. Therefore, all alternative herbicides used in cotton production can be used safely, and do not pose an unreasonable risk to humans or the environment.

Table II.B-18. Ten Most Widely Used Alternative Herbicides in U.S. Cotton Production

Herbicide	2007 Applications (million lbs)[1]	2010 Applications (million lbs)[1]
Trifluralin	2.8	3.1
Diuron	1.3	1.3
Pendimenthalin	1.3	1.2
S-metolachlor	0.6	1.1
Prometryn	0.6	0.4
2,4D, dimethylamine salt	0.3	0.4
Fluormeturon	0.3	0.4
MSMA	0.4	0.3
Fomesafen	0.05	0.2
2,4-D, ethylhexyl ester	0.1	0.1

[1](USDA-NASS 2012d)

Soil residual herbicides play an important role in cotton weed management by providing control of a number of weeds species that continuously germinate in cotton prior to canopy closure (Wilcut, et al. 2003). Soil residual herbicides, such as pendimethalin, trifluralin, diuron, fluometuron, acetochlor, and metolachlor, are applied to more than 40% of the current cotton acres (Monsanto 2012). In addition, many of the soil residual herbicides are limited by application restrictions, plant-back restrictions, the need for adequate soil moisture for activation, and the need to apply prior to planting or with hooded sprayers in-crop to minimize crop injury. Approximately 20% of growers applied a fall residual herbicide to control weeds prior to planting the following spring, and 60% (continuous cotton system) to 75% (GR cotton/GR soybean rotation) applied a mixture of glyphosate and a synthetic auxin herbicide (2,4-D or dicamba) as a spring burndown application (Prince et al. 2011a). Post emergent residual herbicides, such as metolachlor and acetochlor, were applied on over 25% of cotton acres in 2010 (Monsanto 2012).

Further details on the use of non-glyphosate herbicides in cotton producing states can be found in Prince et al. (2011a; 2011c), where it is reported that approximately 50% of surveyed growers who did not have glyphosate-resistant weeds on their farm used a non-glyphosate residual and/or postemergence herbicide in the 2009 growing season. For growers who have on-farm herbicide-resistant weed populations, the percentage of growers was higher, with 72% to 75% reporting the use of non-glyphosate herbicides. Older studies report that approximately 40 to 50% of the growers utilizing glyphosate-tolerant crops indicate that applying herbicides with different modes-of-action in sequence, rotating herbicides with different modes-of-action across the season, or tank mixing glyphosate with other herbicide modes-of-action are effective management practices to minimize the evolution and/or development of glyphosate resistance (Beckie 2006; Beckie and Reboud 2009; Diggle et al. 2003; Powles et al. 1996). The use of non-glyphosate herbicides in cotton production is expected to continue to increase as more growers adopt more diversified weed management strategies. Refer to Appendix A for details on alternative herbicides used in cotton production.

Dicamba Herbicide Use: Dicamba is a broadleaf selective herbicide that was approved by the U.S. Environmental Protection Agency (EPA) for agricultural application uses in 1967 (U.S. EPA 2009d). Dicamba is formulated as a standalone herbicide product and marketed by several companies under various trade names such as Banvel®, Clarity®, Diablo®, Rifle®, Sterling®, and Vision®. These dicamba products can also be tank-mixed with one or more active ingredients depending on the treated crop. For example, Clarity® can be tank mixed with over 75 herbicide products in labeled crops. Additionally, dicamba is currently formulated as a premix product with one or more other herbicide active ingredients, including glyphosate, 2,4-D, diflufenzopyr, atrazine, nicosulfuron, metsulfuron, primsulfuron, triazulfuron, rimsulfuron, and halosulfuron.

Dicamba is currently labeled for weed control in corn, soybean, cotton, sorghum, wheat, barley, oats, millet, pasture, rangeland, asparagus, sugarcane, turf, grass grown for seed, conservation reserve programs, and fallow croplands. Dicamba-treated acreage has ranged from 17.4 to 36.3 million acres between 1990 and 2011. Usage of dicamba peaked during the period of 1994 through 1997, where 1994 was the peak year when 36 million crop acres were treated with 9.4 million pounds of dicamba. Since then, the use of dicamba has steadily declined to 17.4 million treated acres with 2.7 million pounds applied in 2006. The reduction in dicamba use has been attributed to the competitive market introductions of sulfonylurea herbicides (chlorsulfuron, metsulfuron-methyl, and thifensulfuron-methyl) in wheat, new broadleaf herbicide active ingredients in corn, and introduction of glyphosate-tolerant corn. More recently, however, dicamba-treated acres have been on the rise and have increased by as much as 7.9 million acres from 2006 to 2011. Most of this increase has occurred in fallow, pastureland, sorghum, and cotton (preplant) (Monsanto 2012).

Based on farm survey data generated in 2011 by a private market research company, dicamba application rates across agricultural row crops ranged from 0.07 to 0.27 pounds per acre with the average number of applications ranging from 1 to 1.4 applications per cropping season (Monsanto 2012). Dicamba rates (pounds per acre) are lowest in spring wheat where more than one application is typically made per cropping season.

Dicamba is currently labeled for use in cotton although its use is limited to preplant applications due to cotton's susceptibility to dicamba. Consequently, the average application rate preplant in cotton is 0.26 pounds of dicamba per acre with one application per season. Dicamba preplant use in cotton has been on the rise in recent years, increasing from 140,000 acres in 2004, to 590,000 acres in 2008, and 1.4 million acres, or 9.6% of U.S. cotton acres, in 2011 (Monsanto 2012). This is primarily because it is a leading recommended herbicide for control of glyphosate-resistant marestail and Palmer amaranth in the Southeast and Midsouth region (AgWatch 2011; McClelland, et al. 2006; University of Georgia 2012).

Dicamba belongs to the auxin class of herbicides, which is the oldest class of known synthetic herbicides. This class includes 2,4-D, 2,4-DB, mecoprop, MCPA, clopyralid, and several other active ingredients, and is WSSA Herbicide Group Number 4 (HRAC 2009).[40] On the basis of their structural and chemical properties, auxinic herbicides have been classified into several sub-groups, viz., phenoxyalkanoic acids (*e.g.*, 2,4-D, MCPA), benzoic acids (*e.g.*, dicamba, chloramben), pyridines (*e.g.*, picloram, clopyralid), and quinolinecarboxylic acids (*e.g.*, quinclorac, quinmerac). Generally, auxinic herbicides are effective against broadleaf (dicotyledonous) plant species, allowing them to

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40 There are several systems of herbicide mode-of action classification. Among the most widely used are those of the Herbicide Resistance Action Committee (HRAC) and the Weed Science Society of America.

often be used in production of narrow leaf (monocotyledonous) crops. Refer to Appendix A for details on dicamba herbicide.

Glufosinate Herbicide Use: Glufosinate was approved by the U.S. EPA for agricultural uses in 1989 (U.S. EPA 2013b). Glufosinate is a non-selective foliar herbicide that is used for preplant and postemergence control of grass and broadleaf weeds. Glufosinate is formulated as a stand-alone herbicide product and marketed under the trade names Liberty®, Ignite™, Ignite®280, Rely™ 200, and Rely®280. All products contain either 1.67 or 2.34 lbs per gallon of glufosinate-ammonium. Glufosinate (Rely®280 and Ignite®280) is used for postemergence weed control in canola, corn, cotton, and soybean varieties that are glufosinate-tolerant. Glufosinate may be used for weed control in non-glufosinate-tolerant cotton when applied with a hood sprayer in-crop. It may also be applied as a preplant burndown application in commercial varieties of canola, corn, cotton, soybean, or sugar beet. In addition, glufosinate (Rely®200 and Rely®280) may be used for postemergence weed control in apples, berries, grapes, tree nuts, and applied for potato vine desiccation. Glufosinate products can be tank mixed with other active ingredients depending on the treated crop. For example, Ignite™ can be tank mixed with metolachlor or fluometuron for in-crop applications in glufosinate-tolerant cotton. However, reduced weed control has been observed when glufosinate is tank mixed with glyphosate (Dotray, et al. 2011b; Reed, et al. 2011; Reed, et al. 2012).

Glufosinate-treated acreage across all crops has steadily increased from 1.6 million acres in 1998 to 7.0 million acres in 2011. Increased weed resistance is one factor responsible for the increased use of glufosinate (Roberson 2012). Glufosinate is currently labeled for in-crop application on glufosinate-tolerant cotton from emergence through early bloom growth stage at 0.402 to 0.530 lbs a.i. per acre, seasonal maximum of 1.59 lbs a.i. per acre (Bayer Crop Science 2007). The average application rate in cotton is 0.39 pounds of glufosinate per acre with an average of 1.5 applications per season.

Herbicide Resistance: Herbicide resistance is "the inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type" (WSSA 1998). In the mid-1950s, Harper (1957) theorized that annual, repeated use of a herbicide could potentially lead to shifts in weed species composition within a crop-weed community if other weed management methods are not utilized. Similarly, Bandeen et al. (1982) suggested that a normal variability in response to herbicides exists among plant species and tolerance can increase with repeated use of a herbicide in the absence of other weed management methods. To simplify, herbicide resistance in weeds is a result of natural selection. Plants of a given species are not identical, but are made up of "biotypes" with various genetic traits. The repeated use of a herbicide may potentially lead to the selection of weed biotypes resistant to that herbicide, particularly when the herbicide is not used as part of a diversified weed management program. Within a weed species, individuals may possess an inherent ability to withstand the effects of a particular herbicide. Repeated use of that herbicide in the absence of other weed control herbicides or practices has the potential to expose the weed population to a "selection pressure," which may potentially lead to an increase in the number of surviving resistant individuals in the population (HRAC 2011). With repeated application of the same herbicide over time and no other appropriate herbicide or weed management practices, the resistant biotypes have the potential to become the dominant biotype in that weed community. As of April 2013, 400 herbicide-resistant weed biotypes have been reported to be resistant to 21 different herbicide modes-of-action worldwide (Heap 2013b). Glyphosate-resistant weeds account for approximately 6% of the herbicide-resistant biotypes while weeds resistant to herbicides that inhibit acetolactate synthase (ALS) account for 32% of the herbicide-resistant biotypes. Dicamba-resistant and glufosinate-resistant weeds account for $<1\%$ and 0.5% of resistant biotypes respectively (Heap 2012c; d; 2013b). See Appendix B for details of effects of weed resistance in agricultural systems.

For as long as herbicide resistance has been a known phenomenon, public-sector weed scientists, private-sector weed scientists, and growers have been identifying methods to address the problem. For instance, when a farmer uses multiple weed control tools, resistant biotypes generally will not become the dominant biotype within a population (Gunsolus 2008). By contrast, there is a greater potential for weed resistance in areas where there is a sole reliance on a single herbicide used repeatedly over multiple crop generations for the management of a specific weed spectrum and where other appropriate weed management practices are not utilized.

On agricultural land which contains a weed biotype that is resistant to a particular herbicide, the grower must use alternate methods of weed control. Management practices that can be used to mitigate the potential for development of resistance include, among other things, herbicide mixtures, herbicide rotation, and crop rotation. The WSSA reports: "Weed scientists know that the best defense against weed resistance is to proactively use a combination of agronomic practices, including the judicious use of herbicides with alternative modes-of-action either concurrently or sequentially" (WSSA 2010). Studies have demonstrated that using the same combination of herbicides with multiple modes of action and overlapping effectiveness over multiple seasons is an effective way to proactively manage weed resistance (Beckie and Reboud 2009; Neve et al. 2011).

Due to the broad spectrum activity of glyphosate, it has been possible for growers to rely on glyphosate for weed management without utilizing other weed management practices such as crop rotation, cultivation, or use of multiple herbicide modes-of-action; these practices have resulted in the selection of certain glyphosate-resistant weed biotypes.

Glyphosate-resistant weed biotypes that can be found in cotton fields in certain areas of the U.S. may include broadleaf biotypes of Palmer amaranth, waterhemp, common ragweed, giant ragweed, marestail, spiny amaranth (*Amaranthus spinosus*), and grass biotypes of ryegress, Johnsongrass (*Sorghum halapense*) and goosegrass (*Elusine indica*) (Heap 2012e). As with other herbicide-resistant weeds that have developed, the existence of herbicide-resistant weeds, including glyphosate-resistant weed biotypes, over the past decade has required growers to adapt and implement diversified weed management strategies.

The occurrence of weed-resistant biotypes varies across the cotton growing regions, with more resistance issues observed more frequently in the Southeast and Midsouth cotton growing regions. Table II.B-19 summarizes known resistance among the major weed species present in the southern U.S. for each of the key herbicide groups and herbicide classes that are efficacious on broadleaf weeds (Heap 2013b). *Amaranthus* spp., in particular Palmer amaranth, are weeds that present challenges in the mid-south and southeastern U.S. Palmer amaranth is considered to be one of the hard-to-control of the *Amaranthus* spp. because of its rapid growth and prolific seed production. In addition, it has developed resistance to multiple herbicide classes (glycines, ALS, and dinitroanilines) (Culpepper et al. 2011; Heap 2013a). Managing herbicide-resistant Palmer amaranth has proven to be challenging due to the biology of this particular weed, including its dioecious nature (the male and female flowers occur on separate plants), which leads to greater genetic diversity in the plant population and increases the potential for spreading herbicide resistance (Sosnoskie, et al. 2011).

Resistance to the ALS group of herbicides is present in most of the major broadleaf weed species commonly found in cotton. For *Amaranthus* spp. and *Ambrosia* spp., there is known resistance to at least one member for several of the major herbicide chemistry classes. In an effort to manage glyphosate-resistant Palmer amaranth, certain non-glyphosate herbicides have been reported as being used in conditions and practices that have the potential to result in increased selection of resistant biotypes to those herbicides, thereby putting certain agricultural herbicides in some major herbicide classes at risk (Nichols, et al. 2010; Prostko 2011a; b) (Dr. Larry Steckel and Dr. Stanley Culpepper, personal communications, August 2012). While effective options for managing *Ambrosia* spp., and *Amaranthus* spp., including Palmer amaranth and other key broadleaf weeds exist, there is a need for additional herbicide modes-of-action to mitigate potential future resistance of the key herbicides needed for weed management in cotton. In addition, there has been an increase in the detection of weed populations with multiple resistances (*i.e.*, resistance to multiple herbicide modes-of-action) in certain weed species, for example, *Amaranthus* spp. (Tranel et al. 2010). The emergence of these resistant biotypes demonstrates the continued need to utilize diversified weed management practices, including the need for additional herbicide modes-of-action that are effective in major crops.

The relative occurrence of herbicide-resistant weeds varies between the different sub-groups of auxinic (phenoxy in Table II.B-19) herbicides. Considering that auxin herbicides have been widely used in agriculture for more than 60 years, weed resistance to this class is relatively low (29 species, to date, worldwide) and its development has been slow especially when compared to the speed of appearance of resistance to ALS inhibitors (107 species) or triazine-resistant populations (68 species) (Heap 2012d). The relatively low incidence of auxinic herbicide resistance is believed to be attributable to the fact that there are multiple target sites for these herbicides (Gressel and Segel 1982; Morrison and Devine 1993).

Specific weed management recommendations by area or farm are often made by local experts versed in effective methods for both proactive and reactive resistance management. Since more than 53.4% of cotton is repeatedly grown on the same land the use of multiple herbicide modes-of-action with overlapping effectiveness on the targeted weed spectrum is an important method recommended and employed for weed resistance management. Studies have shown that using the same combination of herbicides with multiple modes-of-action and overlapping effectiveness over multiple seasons can effectively manage resistance (Beckie and Reboud 2009). Monsanto and the weed scientist community recommend the use of multiple herbicide modes-of-action in herbicide-tolerant cotton systems regardless of whether glyphosate-resistant or hard-to-control broadleaf weeds are present (University of Georgia 2012; University of Tennessee 2012). APHIS has deregulated multiple herbicide-tolerant cotton traits (Table II.B-20), and the use of diversified weed management systems with these traits helps ensure sustained profitable cotton production across the Cotton Belt. For growers using the herbicide-tolerant cotton systems, Monsanto and university extension weed scientists provide recommended control options for herbicide-resistant weeds[41] (Bond, et al. 2011; Culpepper, et al. 2013; Ferrell, et al. 2012; Jordan, et al. 2011; Monsanto Company 2012b; Norsworthy et al. 2012; Price et al. 2011; Prostko 2011b; University of Tennessee 2012). These options include the use of residual and postemergence herbicides such as microtubule inhibitors (pendimethalin, trifluralin), PSII inhibitors (diuron, fluometuron, prometryn), PPO inhibitors (flumioxazin, fomesafen), long-chain fatty acid inhibitors (acetochlor, metolachlor),

[41] https://www.roundupreadyplus.com

synthetic auxins (2,4-D, dicamba), and ALS inhibitors (pyrithiobac).[42] These herbicides alone or in combinations, as well as traditional tillage methods, are and will continue to be used to control herbicide-resistant or hard-to-control broadleaf weeds. Refer to Appendix B for details on weed resistance.

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42 Monsanto Technology Use Guide; www.weedresistancemanagement.com.

Table II.B-19. Known Weed Resistance in the Southern U.S. in 2012[1]

Resistance (Group) [2]	ALS (Group 2)	PPO (Group 14)		PSI (Group 22)	PS II (Group 5)	PS II (Group 7)	Organo-arsenicals (Group 25)	Microtubule Assembly Inhibitors (Group 3)	Glycine (Group 9)	Phenoxy (Group 4)	
Chemistry Class [2]	sulfonylurea	diphenyl ether	N-phenyl thalimide	bipyridiliums	triazine	ureas	organo-arsenicals	dinitroaniline	glycine	phenoxy	benzoic acid
Cotton Herbicide Examples	Trifloxy-sulfuron	Fomesafen	Flumioxazin	Paraquat	Prometryn	Diuron Fluometuron	MSMA	Trifluralin	Glyphosate	2,4 D	Dicamba
Most Common Broadleaf Weeds in Southeast / Midsouth (# of states listing as a top weed)											
morningglory (11) *Ipomoea spp.*											
prickly sida (9) *Sida spinosa*											
pigweed spp. (6) *Amaranthus* spp.[3]	X	X			X	X			X		
Palmer amaranth (4) *Amaranthus palmeri*	X				X			X	X		
Florida Pusley (4) *Richardia scabra*											
sicklepod (4) *Senna obtusifolia*											
cocklebur (3) *Xanthium strumarium*	X						X				
horseweed (marestail) (3) *Conyza canadensis*	X			X	X	X			X		
Ragweed spp. (2) *Ambrosia* spp.	X	X	X						X		
Florida Beggarweed (2) *Desmodium tortuosum*											

1 Source: (Heap 2012e), www.weedscience.org
2 Cross resistance is possible within a resistance group and/or chemistry class.
3 Includes redroot pigweed, smooth pigweed and common waterhemp.
Note: Blank boxes indicate no resistant biotypes for weed species/ herbicide combination in Southern U.S.

Table II.B-20. Deregulated Biotechnology-derived Cotton Products[1]

Phenotype	Event	Institution	Deregulation Effective Date
Glufosinate tolerant, Lepidopteran resistant	T303-3XGHB119	Bayer CropScience	August, 2012
Glufosinate tolerant, Lepidopteran resistant	T304-40XGHB119	Bayer CropScience	October, 2011
Lepidopteran resistant	COT 67B	Syngenta	September, 2011
Glyphosate tolerant	GHB614	Bayer CropScience	May, 2009
Glyphosate tolerant	MON 88913	Monsanto	December, 2004
Lepidopteran resistant	COT 102	Syngenta	July, 2005
Lepidopteran resistant	281-24-236	Mycogen/Dow	July, 2004
Lepidopteran resistant	3006-210-23	Mycogen/Dow	July, 2004
Phosphinothricin tolerant[2]	LLCotton25	Aventis	March, 2003
Lepidopteran resistant	Cotton 15985	Monsanto	November, 2002
Bromoxynil tolerant and lepidopteran resistant	31807 and 31808	Calgene	April, 1997
Sulfonylurea tolerant	19-51a	DuPont	January, 1996
Glyphosate tolerant	1445, 1698	Monsanto	July, 1995
Lepidopteran resistant	531, 757, 1076	Monsanto	June, 1995
Bromoxynil tolerant	BXN	Calgene	February, 1994

[1] (USDA-APHIS 2013b).

[2] Glufosinate tolerant.

II.B.2.e. Organic Production Practices

National Organic Program and Organic Cotton Farming: In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS 2010). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

In accordance with NOP, an accredited organic certifying agent conducts an annual review of the certified operation's organic system plan and makes on-site inspections of the certified operation and its records. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards.

The NOP regulations preclude the use of excluded methods. The NOP provides the following guidance under 7 CFR § 205.105:

> "…to be sold or labeled as '100 percent organic', 'organic' or 'made with organic (specified ingredients or group(s)),' the product must be produced and handled without the use of:
>
> (a) Synthetic substances and ingredients,…
>
> (e) Excluded methods,…"

Synthetic Substances are defined in 7 CFR § 205.2 as:

> "A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes." This includes synthetic herbicides, insecticides, and fertilizers.

Finally, Excluded methods are defined as:

> "A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production…"

Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances and excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the avoidance of use of prohibited substances and excluded methods (USDA-AMS 2010).

Most EPA-registered pesticides are prohibited in organic production; however, there is the potential for inadvertent or indirect contact from neighboring conventional farms or shared handling facilities. As long as the operator has not directly applied prohibited pesticides and has documented efforts to minimize exposure to them, the USDA organic regulations allow for residues of prohibited pesticides at or below 5 percent of the EPA tolerance. (USDA-AMS 2012b).

Although the National Organic Standards preclude the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS 2011). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (USDA-AMS 2011).

Organic cotton producers use production practices designed to prevent commingling of their value-added crop with neighboring crops treated with herbicides and other pesticides or that may be using plant varieties produced by excluded methods. In addition, steps are taken to avoid spray drift from neighboring fields. These well-established practices include isolation zones, use of buffer rows surrounding the organic crop, adjusted planting dates, and varietal selection (Kuepper 2006).

The efficacy of management practices utilized to avoid pollen movement from a GE crop to organic cotton production operations is facilitated by the nature of cotton pollination. Cotton is a self-pollinated species and exhibits a low level of outcrossing (Section II.D.2.c).

U.S. Organic Cotton Production: The USDA census of organic agriculture reported organic cotton farming on 30 farms in the U.S. in 2008, two in Arizona, three in New Mexico, four in California, and 21 in Texas (USDA-NASS 2008a). Texas (66%) and New Mexico (20%) together accounted for approximately 86% of the production. Based on USDA-ERS data, between 1997 and 2008, organic cotton acreage ranged from 9,213 acres in 2004 to 15,377 acres in 2008 (USDA-ERS 2008). In 2008 about 0.16% of the total 9.41 million acres of cotton was produced organically (USDA-ERS 2008). In recent years, small and sporadic acreages of organic cotton production have been cultivated in other states, including Missouri, Illinois, Kansas, Tennessee, and Colorado (USDA-ERS 2010c). Based upon recent trend information, the presence of GE cotton varieties on the market has not affected the ability of organic production systems to maintain their market share. Between 2000 and 2008, although 11 GE cotton events were no longer subject to regulation under the Plant Protection Act and 7 CFR Part 340, the acreage of organic cotton production remained at approximately 15,000 acres (USDA-APHIS 2013a; USDA-ERS 2008).

The South Plains area of Texas is one of the primary regions for organic cotton production (TOCMC 2011b). Features that make the South Plains well-suited for organic cotton production include cold enough winter temperatures to limit insect pressure and to provide a hard freeze to defoliate the cotton plants prior to harvesting, and a sunny climate and quick-drying soils to facilitate timely mechanical weed control. As many of these farmers do not irrigate, yields are heavily dependent upon rainfall (TOCMC 2011b).

Organic cotton growing practices include the use of natural defoliants; beneficial insects for pest control; compost, manure, and crop rotations for fertilizers; and hand-weeding, mechanical cultivation, cover crops and mulching for weed control. The same gins and spinning mills used for non-organic cotton are also used for organic cotton; however, they must be shut down and cleaned before processing the organic cotton, which adds to production costs (TOCMC 2011a).

Most U.S. organic cotton growers sell their cotton products through a marketing cooperative, the largest of which is the TOCMC, with approximately 30 members (OTA 2012; TOCMC 2011b). Cottonseed is marketed to organic dairies for feed (TOCMC 2011b). According to a survey conducted by OTA, organic cotton growers' biggest barriers to planting more organic cotton are finding a market willing to pay the added costs of organic products, production challenges such as weed and insect control, and labor costs. "Growers also cited competition from international organic cotton producers, as well as the cost of transition to organic." (OTA 2010).

II.B.2.f. Other Specialty Market Production

Production systems designed prior to the introduction of GE-derived cotton have allowed for production of cotton to meet varied customer demands. In addition to the market segments that produce organic cotton and non-GE cotton, distinct identity-preserved specialty cotton has also been grown and successfully marketed for many years.

Specialty cottons cultivated in the U.S. include organic cotton (discussed above), non-GE cotton, and naturally colored cotton (Lee 2007). Naturally colored cotton acreage is grown on between 5,000 and 7,000 acres, according to 1995 estimates (Lee 2007).

Specialty crop growers employ practices and standards for seed production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with other cotton crops (which includes GE crops) (Bradford 2006). These management practices include maintaining isolation distances to prevent pollen movement from other cotton sources, planting border or barrier rows to intercept pollen, and employing natural barriers to pollen (Bradford 2006; Kuepper 2006; Wozniak and Martinez 2011). These management practices allow the grower to meet standards for the production of specialty crop seed, maintain genetic purity, and protect the genetic diversity of cotton (Bradford 2006).

II.B.2.g. Seed Production Practices

On an annual basis, the supply of certified seed of all varieties of cotton combined must be able to plant over 10 million acres in the U.S. alone (NCPA 2013; USDA-NASS 2010a). This requires between 60,000 and 70,000 short tons of planting seed (NCPA 2011).

The majority of the cotton seed crop is produced in Texas, with significant quantities produced in Arizona, Arkansas, California, and Mississippi (McDonald and Copeland 1997). Seed companies minimize the risk of crop loss due to weather events by producing seed in multiple regions.

Seed quality (including genetic purity, vigor, and presence of weed seed, seed-borne diseases, and inert materials such as dirt) is a major factor in crop yields. If natural variability in seed production is not carefully controlled, the value of a new variety or cultivar may be lost (Hartmann et al. 1975). Genetic purity in commercial seed production is generally regulated through a system of seed certification which is intended to ensure that the desired traits in the seed are maintained throughout all stages in cultivation (Hartmann et al. 1975).

States have developed seed laws and certification agencies to ensure that purchasers who received certified seed can be assured that the seed meets established seed quality standards (Bradford 2006). The U.S. Federal Seed Act of 1939 recognizes seed certification and official certifying agencies. Implementing regulations further recognize land history, field isolation, and varietal purity standards for Foundation, Registered, and Certified seed.

In a seed certification program, classes of seed are identified to designate the seed generation from the original breeder source (Hartmann et al. 1975). Foundation seed, Registered seed, and Certified seed production is controlled by public or private seed certification programs (AOSCA 2009a). The original seed breeder seed stock is controlled by the developer of the variety (Adam 2005; Hartmann et al. 1975). The breeder stock is used to produce Foundation seed stock (Adam 2005). The institution associated with the breeder controls the production of Foundation seed stock. Foundation seed stock, in turn, is used to produce Registered seed for distribution to licensees, such as seed companies (Adam 2005). Registered seed is used by seed companies to produce large quantities of Certified seed (Adam 2005; Hartmann et al. 1975). The Certified (or Select) seed is then sold to growers through commercial channels (Adam 2005; Hartmann et al. 1975).

Seed certification cultivation practices commonly include recommendations for minimum isolation distances between various seed lines and planting border or barrier rows to prevent pollen movement (Hartmann et al. 1975; Wozniak and Martinez 2011). The isolation distance for Foundation, Registered, and Certified seeds, as dictated by the USDA Agricultural Marketing Service's (AMS) Federal Seed Act, is 1,320, 1,320, and 660 feet, respectively (7 CFR Part 201.76). During the growing season, seed certification agencies will monitor the fields for off-types, other crops, weeds, and disease (Wozniak and Martinez 2011). These certifying agencies also establish seed handling standards to reduce the likelihood of seed source mixing during production stages, including planting, harvesting, transporting, storage, cleaning, and ginning (Wozniak and Martinez 2011). Further discussion of cross-pollination, gene transfer, and weediness is presented in Subsection II.D.2.c.

II.C. PHYSICAL ENVIRONMENT

II.C.1. Land Use and Soil Quality

The cumulative land area in the U.S. planted to principal crops, which include corn, sorghum, oats, barley, winter wheat, rye, durum, spring wheat, rice, soybean, peanuts, sunflower, cotton, dry edible beans, potatoes, canola, proso millet, and sugar beets, has remained relatively constant over the past 27 years. From 1982 to 1995, the average yearly acreage of principal crops was 323 million. This average is essentially unchanged at 326 million acres since the introduction of biotechnology-derived crops in 1996 (USDA-NASS 1984; 1990; 1992; 1995; 1998; 2000; 2003; 2006; 2009a). Thus, there is no indication that the introduction and widespread adoption of biotechnology-derived crops in general has resulted in a significant change to the total U.S. acreage devoted to agricultural production.

Soil consists of solids (minerals and organic matter), liquids, and gases. This body of inorganic and organic matter is home to a wide variety of fungi, bacteria, and arthropods, as well as the growth medium for terrestrial plant life (USDA-NRCS 2003). Soil is characterized by its layers that can be distinguished from the initial parent material due to additions, losses, transfers, and transformations of energy and matter. It is further distinguished by its ability to support rooted plants in a natural environment. Soil plays a key role in determining the capacity of a site for biomass vigor and production in terms of physical support, air, water, temperature moderation, protection from toxins, and nutrient availability. Soils also determine a site's susceptibility to erosion by wind and water, and flood attenuation capacity.

Cultivation and tillage practices can directly impact soil, including its physical and biological properties. Conventional tillage traditionally requires that the producer remove all plant residues and weeds from the soil surface prior to planting, and then continue to cultivate the soil while the crop is growing in order to control late emerging weeds (Cotton Inc. 2010a). This practice results in soil loss due to wind and water erosion. Microbial populations and associated biochemical processes are critical to maintaining soil health and quality. Conservation practices developed to reduce field tillage have reduced the corresponding soil loss (USDA-NRCS 2005).

Conservation practices cause increases in soil organic matter that help bind soil nutrients and significantly reduce the loss of cropland soil from runoff, erosion, and leaching over time (Leep, et al. 2003; USDA-NRCS 2005). Total soil loss on highly erodible croplands and non-highly erodible croplands decreased from 3.06 billion tons per year in 1982 to 1.7 billion tons per year in 2007, or by 43% (USDA-NRCS 2010). This decrease in soil erosion accompanies a corresponding decrease in non-point source pollution of surface water by fertilizer and pesticides (Reicosky 2008). Soil tillage can also affect water resources and air quality.

The introduction of glyphosate-tolerant crops accelerated the growth of conservation tillage in the U.S., in large part because of the broad spectrum postemergence control offered by glyphosate (Price et al. 2011).

By definition, conservation tillage leaves at least 30% of the soil covered by crop residue (Peet 2001). The new crop is planted into the plant residue or in narrow strips of tilled soil. This is in comparison to conventional tillage where the seedbed is prepared through plowing (to turn the soil surface over), disking (to reduce the size of soil clods created by plowing), and harrowing (to reduce the size of clods left by disking) (Peet 2001). Benefits of reduced tillage practices include maintenance of soil organic matter and beneficial insects, increased soil water-holding capacity, less soil and nutrient loss from the field, reduced soil compaction, and less time and labor required to prepare the field for planting (Peet 2001). Weed control in conservation tillage crops is primarily through the use of herbicides (ACES 1996). Winter and cover crops are also utilized in conservation tillage for the purpose of suppressing weeds (Alabama Cooperative Extension System, 1996).

Although soil erosion rates are dependent on numerous local conditions such as soil texture and crop, a comparison of 39 studies contrasting conventional and no-till practices illustrates that, on average, no-till practices reduce erosion 488 times over conventional tillage (Montgomery 2007). This reduction is enough to bring soil production more in line with losses from erosion. From 1982 through 2003, erosion on U.S. cropland dropped from 3.1 billion tons per year to 1.7 billion tons per year (USDA-NRCS 2006a). This can partially be attributed to the increased effectiveness of weed control through the use of herbicides and the corresponding reduction in the need for mechanical weed control (Carpenter, et al. 2002). Conservation tillage also minimizes soil compaction due to the reduced number of tillage trips.

In some regions, conservation tillage is required. Farmers producing crops on highly erodible land are required by law to maintain a soil conservation plan approved by the USDA National Resources Conservation Service (NRCS) (USDA-ERS 2010a). These soil conservation plans are prepared by the grower pursuant to the 1985 Food Security Act Conservation Compliance and Sodbuster programs to minimize soil erosion (USDA-ERS 2010a).

While conservation tillage does have several benefits for soil health, some management concerns are associated with its use. Under no-till practices, soil compaction may become a problem as tillage is useful for breaking up compacted areas (USDA-NRCS 1996). Likewise, not all soils (such as wet and heavy clay soils) are suited for no-till. Also, no-till practices may lead to increased pest occurrences that conventional tillage is better suited to managing (NRC 2010). Other methods to improve soil quality include careful management of fertilizers and pesticides; use of cover crops to increase plant diversity and limit the time soil is exposed to wind and rain; and, increased landscape diversity with buffer strips, contour strips, wind breaks, crop rotations, and varying tillage practices (USDA-NRCS 2006b).

Soybeans

In 2012, soybean was grown as a commercial crop on over 77 million acres in at least 31 states in the U.S. (USDA-NASS 2013b). Soybean acreage in the past five years has been relatively stable, varying from 75.0 million to 77.5 million acres with a 10-year average of 74.3 million acres. Soybean fields are typically highly managed and are dedicated to crop production for many years. However, small fluctuations in soybean acreage do occur because of environmental, agronomic and economic factors, as well as government programs such as the conservation reserve program (CRP).

Approximately 93% of the soybean acreage in the U.S. is planted with GE herbicide-tolerant soybean varieties (USDA-ERS 2012b), and the Glyphosate-tolerant soybean system has become the standard weed control program in U.S. soybean production.

Soybean is cultivated across a wide variety of soils in the U.S. but grows best in a loose, well-drained loam (NSRL 2013). Cultivation and tillage practices can directly impact the attributes of soil, including its physical and biological properties. Microbial populations and associated biochemical processes are critical to maintaining soil health and quality. Additionally, maintaining soil pH in the range of 6.0 to 7.0 will enhance the availability of inherent and fertilizer nutrients, reduce the availability of toxic elements – particularly aluminum and manganese – and enhance microbial activity (Hoeft, et al. 2000b; c; Hoeft et al. 2000a; Hoeft, et al. 2000a; Hoeft et al. 2000b). The increased microbial activity that is associated with the optimum pH level results in oxidation of organic matter and increased release of nutrients from the organic matter. Soybeans need a variety of macronutrients, such as nitrogen, phosphorus, potassium, calcium, magnesium, and sulfur, at various levels (NSRL 2013). They also require smaller amounts of micronutrients such as iron, zinc, copper, boron, manganese, molybdenum, cobalt, and chlorine. These micronutrients may be deficient in poor, weathered soils, sandy soils, alkaline soils, or soils excessively high in organic matter.

In 2008, approximately 30.1 million acres (46.3%) of soybean were planted in a no-till system (CTIC 2008). In 2011, approximately 65% of U.S. soybean acres used some form of conservation tillage (ASA 2011; CTIC 2008).

Cotton

Cotton is cultivated in a wide variety of soils, but develops best in deep, arable soils with good drainage, high organic content, and a high moisture-retention capacity (OECD 2008). Irrigation allows cultivation in poor-quality soils with necessary nutrients provided in the irrigation water (OECD 2008).

Tillage is the aspect of cotton farming that has the greatest potential impact on soil. Glyphosate-tolerant cotton has facilitated the growth of conservation tillage systems in cotton production (Baldwin and Baldwin 2002; Carpenter and Gianessi 2001). As of 2008, conservation tillage systems are used on approximately 21% of the U.S. cotton acres (CTIC 2008). Wheat and rye are commonly employed as cover crops because of their ease in killing prior to cotton planting. The use of herbicide-resistant cotton has allowed cotton growers to more readily adopt soil conservation practices because it provides an economical, effective means of controlling weeds in post-plant cotton (ACES 1996; McClelland et al. 2000)

II.C.2. Water Resources

The principal law governing pollution of the nation's water resources is the Federal Water Pollution Control Act of 1972, better known as the Clean Water Act (CWA). The Act utilizes water quality standards, permitting requirements, and monitoring to protect water quality. The EPA sets the standards for water pollution abatement for all waters of the U.S. under the programs contained in the CWA, but, in most cases, gives qualified states the authority to issue and enforce permits. Drinking water is protected under the Safe Drinking Water Act of 1974 (Public Law 93-523, 42 U.S.C. 300 et seq.).

Surface water in rivers, streams, creeks, lakes, and reservoirs supports everyday life through the provision of water for drinking and other public uses, irrigation, and industry. Surface runoff from rain, snowmelt, or irrigation water can affect surface water quality by depositing sediment, minerals, or contaminants into surface water bodies. Surface runoff is influenced by meteorological factors such as rainfall intensity and duration, and physical factors such as vegetation, soil type, and topography.

Groundwater is the water that flows underground and is stored in natural geologic formations called aquifers. It sustains ecosystems by releasing a constant supply of water into wetlands and contributes a sizeable amount of flow to permanent streams and rivers. Based on 2005 data, the largest use of groundwater in the U.S. is irrigation, representing approximately 67.2% of all the groundwater pumped each day (McCray 2009). Approximately 47% of the U.S. population depends on groundwater for its drinking water supply. The EPA defines a sole source aquifer

(SSA) as an aquifer that supplies at least 50% of the drinking water consumed in the area overlying the aquifer. An SSA designation is one tool to protect drinking water supplies in areas where there are few or no alternative sources to the groundwater resource. There are 77 designated SSAs in the U.S. and its territories (U.S. EPA 2011a).

Unlike a point source, which is a "discernible, confined and discrete conveyance", nonpoint source pollution (NSP) comes from many diffuse sources. Rainfall or snowmelt moving over the ground, also known as runoff, picks up and carries away natural and human-made pollutants, creating NSP. The pollutants may eventually be transported by runoff into lakes, rivers, wetlands, coastal waters and ground waters. Agricultural NPS pollution includes agricultural sediments transported by erosion that may also include pesticides, fertilizers, and sometimes fuel and pathogens. Cotton and soybean production may impact groundwater due to movement of pesticides and fertilizers vertically through soil. Surface water may also be impacted from production by runoff from fields that carries soil particles, nutrients, and herbicides or other pesticides to streams, rivers, lakes, wetlands and other water bodies.

Pesticides are a relatively minor contributor to impairment of surface water in the U.S., according to an analysis of states' water quality reports to EPA, which EPA makes available through its National Assessment Database (U.S. EPA 2008a). As discussed below, based on existing data, the soil component of runoff is a much more important contributor to surface water impacts than is the pesticide component.

Dicamba has been widely used in agriculture over the last four decades with dicamba's peak use occurring in 1994 (see Appendix A of this Environmental Report for more detail). In the dicamba Reregistration Eligibility Decision (RED) document, EPA considered potential risks associated with dicamba use, and its degradate DCSA when appropriate, to surface or ground water using screening level (high-end exposure) models to estimate environmental concentrations. The EPA then compared these exposure estimates to appropriate endpoints from mammalian and aquatic animal and plant ecotoxicity studies to determine potential impacts on human health and the environment. The EPA used the models PRZM/EXAMS and SCIGROW to estimate levels of dicamba in surface and ground water, respectively, using the physical, chemical, and environmental fate properties, and subsequently concluded that all uses of dicamba, including high-end use patterns, were eligible for continued registration (see Appendix C of this Environmental Report for more detail).

While pesticides are relatively minor contributors to surface water impairment, existing data indicates that soil runoff is a more important contributor to surface water impacts. Tillage causes widespread soil disturbance; increased tillage therefore likely causes increased erosion, topsoil loss, sedimentation and turbidity. EPA has identified sedimentation and turbidity as two of the top ten causes of surface water impairment in general and sedimentation/siltation as a leading cause of impairment to rivers and streams in particular (U.S. EPA 2007a; 2009b).

Tillage causes widespread soil disturbance. Vegetative residues protect the soil surface from the impact of raindrops and slow the movement of water, reducing its load-carrying potential. Slower moving water leads to water absorption and less runoff. Runoff may carry soil particles, nutrients and pesticides away from fields to water bodies. Even as little as 30% residue cover typically reduces soil erosion rates by >50 % compared to bare ground (University of Missouri 1993). Typical soil loss from a field with a 93% residue cover may be only 2% of the loss from a field with 0% residue cover (Hill and Mannering 1995). Thus, erosion of topsoil, nutrient loss, and the resulting sedimentation, turbidity, and transport of nutrients to streams are likely to increase with increased tillage. Sediments and nutrients, primarily from agricultural crops, are the second and third leading causes of impairment in U.S. streams and rivers (pathogens are the leading cause), accounting for 21% and 20% of the miles of impaired streams and rivers, respectively. By comparison, pesticides account for 3% of miles of impaired streams and rivers, and these are primarily persistent pesticides such as DDT, chlordane, and DDE, which are no longer used in the U.S. (U.S. EPA 2012b; 2013c). EPA has projected conservation tillage to be "the major soil protection method and candidate best management practice for improving surface water quality" (U.S. EPA 2002). EPA identifies conservation tillage as the first of its CORE4 agricultural management practices for water quality protection (U.S. EPA 2013d). Growth of conservation tillage in the U.S. was greatly accelerated with the introduction of glyphosate-tolerant crops, in large part because of the broad spectrum postemergence control offered by glyphosate (Price et al. 2011). By 2008 conservation tillage (no-till, reduced till and other conservation tillage methods) was employed on approximately 63% of the crop acres, compared to 48% in 1994 prior to the introduction of herbicide-tolerant crops (CTIC 2008). As noted above, conservation tillage systems are used on approximately 21% of U.S. cotton acres (CTIC 2008).

Soybeans

In regions of the U.S. that experience low amounts of rainfall during the growing season or during drought, soybean yields benefit from proper irrigation. Soybeans require approximately 20-25 inches of water during the growing season to produce a relatively high yield of 40-50 bushels per acre (University of Arkansas 2006). In 2006 and 2008, approximately 9% of the planted acres of soybeans in the U.S. were irrigated (USDA-ERS 2011b; USDA-NASS 2008b; 2010c). A majority (approximately 73%) of irrigated soybean farms occur in the Missouri and Lower Mississippi Water Resource Regions, with soybean farms in the states of Nebraska, Arkansas, Mississippi, Missouri, and Kansas accounting for 85% of all irrigated acres (USDA-NASS 2008b). In 2006, approximately 8.4 inches of water per irrigated acre was used, producing an average of over 51 bushels per irrigated acre (USDA-ERS 2011b). This yield was approximately 19.8% higher than the national average (42.9 bushels per acre) for that year (USDA-NASS 2010c). The soils and climate in the Midwestern, Eastern and portions of the Great Plains regions of the U.S. provide sufficient water under normal climatic conditions to produce a soybean crop.

Pesticides accounted for less than one percent of reported causes of surface water impairment in all but four of the 17 leading U.S. soybean-producing states. In those four states, pesticides accounted for two to eight percent of reported causes of impairment. Of the pesticides that were reported as contributing to impairment among the 17 leading soybean-producing states, almost all are highly persistent chemicals that are no longer registered for use in the U.S. (U.S. EPA 2008a). Dicamba is not included on this list.

Cotton

Cotton has been developed as a drought-tolerant crop. Cotton's global water footprint represents about 2.6% of the world's water use and is lower than soybeans, maize, wheat, and rice (Cotton Inc. 2010b). Cotton production water use varies according to the growing environment (Cotton Inc. 2010b). Successful cultivation of dryland (non-irrigated) cotton requires at least 500 millimeters (mm) (40 inches) of rainfall during the growing season (OECD 2008). Cotton cultivated in the southwestern region of the U.S., including west Texas, southern New Mexico, southern Arizona, and southern California, requires irrigation (USDA-APHIS 2010a). Where irrigation water is needed (approximately 35% of the U.S. cotton grown), cotton yields are also much higher (Cotton Inc. 2010b). The desert southwest requires a maximum of 40 inches of irrigation per year, although the humid southeast may only require about 18 inches of irrigation per year (Cotton Inc. 2010b). Carefully timing the application of irrigation water optimizes the plant's vegetative growth, flowering, and boll production (OECD 2008). The lack of affordable water has been noted as one factor in the reduction of acres of cotton grown in California, Arizona, and New Mexico in the past decade (Cotton Inc. 2010b). In these areas, cotton has been displaced by higher value crops and land uses (Cotton Inc. 2010b).

II.C.3. Air Quality

The Clean Air Act (CAA) requires the attainment and maintenance of National Ambient Air Quality Standards (NAAQS) in all areas of the U.S. The NAAQS, developed by the EPA to protect public health, establish limits for six criteria pollutants: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO2), lead (Pb), and inhalable particulates (coarse particulate matter [PM] greater than 2.5 micrometers and less than 10 micrometers in diameter [PM_{10}] and fine particles less than 2.5 micrometers in diameter [$PM_{2.5}$]). The CAA requires states to achieve and maintain the NAAQS within their jurisdiction. Each state may adopt requirements stricter than those of the national standard and each is also required by EPA to prepare a State Implementation Plan (SIP) containing strategies to achieve and maintain the national standard of air quality within the state. Areas that violate air quality standards are designated as non-attainment areas for the criteria pollutant(s), whereas areas that comply with air quality standards are designated as attainment areas.

Primary sources of emissions associated with crop production include vehicle exhaust from motorized equipment such as tractors and irrigation equipment, suspended soil particulates from tillage and wind induced erosion, smoke from burning of fields, drift from sprayed herbicides and other pesticides, and nitrous oxide emissions from the use of nitrogen fertilizer (Aneja, et al. 2009; Hoeft et al. 2000a; b; U.S. EPA 2011c; USDA-NRCS 2006a).

Volatilization of fertilizers, herbicides and other pesticides from soil and plant surfaces also introduces certain chemicals to the air (Vogel, et al. 2008). A substance is volatile if it is likely to vaporize at atmospheric pressure. The USDA Agricultural Research Service (ARS) is conducting a long-term study to identify factors that affect pesticide levels in the Chesapeake Bay region airshed (USDA-ARS 2011). This study has determined volatilization is highly dependent upon exposure of disturbed unconsolidated soils and variability in measured compound levels is correlated with temperature and wind conditions. Another ARS study of volatilization of certain herbicides after application to fields has found moisture in dew and soils in higher temperature regimes significantly increases volatilization rates (USDA-ARS 2011). For example, low-volatility forumations can reduce volatility and offsite movement. The DGA salt formulation of dicamba, which is one low-volatility formulation, has been proposed for use on DT soybean and DGT cotton. For example, side-by-side field experiments have indicated that a formulation of the diglycolamine (DGA) salt of dicamba volatilized significantly less than a similar formulation of the DMA salt form (Egan and

Mortensen 2012). In the publication, the authors state, "Our data demonstrate that the diglycolamine formulation has a dramatic effect on reducing dicamba vapor drift. Estimates of total g acid equivalent vapor drift outside of the treated area were reduced 94% relative to the dimethylamine formulation, and the dose-distance curves indicate that predicted mean exposures drop close to zero only short distances away from the treated area." Measured air concentrations when using the DGA salt, for example, were 30- to 50-fold lower than those in the potassium and DMA salt laboratory studies EFED evaluated, even though the application rate was twice that of DMA (Mueller 2010). See Appendix D for additional details.

Pesticide spraying may impact air quality from drift. EPA defines drift as "the movement of pesticide through air at the time of application or soon thereafter, to any site other than that intended for application" (U.S. EPA 2000). Factors affecting drift include application equipment and method, weather conditions, topography, and the type of crop being sprayed (U.S. EPA 2000). EPA's Office of Pesticide Programs (OPP), which regulates pesticides in the U.S., encourages pesticide applicators to use all feasible means available to them to minimize drift. The Agency has introduced several initiatives to help address and prevent the problems associated with drift. Currently, EPA is evaluating new regulations for pesticide drift labeling and the identification of best management practices to control such drift (U.S. EPA 2009e), as well as identifying scientific issues surrounding field volatility of conventional pesticides (U.S. EPA 2010b). Additionally, OPP and EPA's Office of Research and Development are developing a new voluntary program, the Drift Reduction Technology (DRT) Program, which encourages the development, marketing and use of application technologies verified to significantly reduce spray drift (U.S. EPA 2009e).

Depending upon the herbicide being used, factors for managing the potential for spray drift include the selectivity and sensitivity of the herbicide, local weather conditions at the time of application (wind, temperature, humidity, inversion potential), droplet size distribution, application volume, boom height (height of the application equipment above the crop canopy), sprayer speed, and distance from the edge of the application area (Felsot, et al. 2010; SDTF 1997). The minimization of droplets less than 150 microns is important in reducing any potential for spray drift. Droplet size can be increased by requiring the use of certain nozzle types, increasing volume per minute spray rates, and by specifying an application volume per acre rate of at least 10 gallons. (SDTF 1997; TeeJet Technologies 2011). Arvidsson et al. (2011) investigated meteorological and technical factors affecting total spray drift and determined that boom height and wind speed were the primary factors affecting the potential for spray drift among those tested, followed by air temperature, driving speed and vapor pressure deficit. Arvidsson et al. (2011) demonstrated that drift increased with driving speed. This increase was attributed to either air flows associated with the forward movement of the sprayer or to increased vertical boom movement. Aerial application of pesticides may cause air quality impacts from drift and diffusion; however, aerial applications would not be permissible under Monsanto's proposed dicamba label amendment application—currently pending before EPA—for both DT soybean or DGT cotton, so there will be no issues with aerial application of pesticides potentially causing air quality impacts from drift and diffusion.

Soybeans

The majority of soybean grown in the U.S. is rotated with corn on a two-year rotation. Soybean fields typically are tilled and the new crop rotation planted in the following year. Use of herbicide-tolerant soybeans has facilitated conservation tillage and/or no-till soybean production, as it diminishes the need to till for weed control. Longer intervals between rotating crops and minimized earth disturbance from decreased tillage reduce the use of emission-producing equipment. This is demonstrated by the NRCS Energy Estimator: Tillage Tool (USDA-NRCS 2011). For example, the tool estimates potential fuel savings of 3,010 gallons or 60% savings per year based upon producing 1,000 acres of no-till soybean compared to conventional till soybean in the Urbana, Illinois postal code. NRCS is careful to note that this estimate is only approximate, as many variables could affect an individual operation's actual savings. Reduced tillage also generates fewer particulates (dust) and potentially contributes to lower rates of wind erosion releasing soil particulates into the air, benefitting air quality (Towery and Werblow 2010).

Cotton

Cotton ginning produces particulate matter, such as lint, dust, fine leaves and other trash that affect air quality (EPA AP-42 chapter 9). The effects of cotton ginning on air quality are being assessed in a comprehensive four-year cotton gin dust sampling study by USDA and cotton academics (USDA-ARS 2013a; b).

II.C.4. Climate Change

Climate change represents a statistical change in climate conditions, and may be measured across both time and space. Agriculture may influence climate change through various facets of the production process. Combustion of fossil fuels in mechanized farm equipment, fertilizer application, and decomposition of agricultural waste products may all contribute greenhouse gases to the atmosphere. Greenhouse gases collectively function as retainers of solar radiation, and agriculture-related activities are recognized as both direct (*e.g.*, exhaust from equipment) and indirect (*e.g.*, agricultural-related soil disturbance) sources of carbon dioxide (CO_2), methane (CH_4), and N_2O.

The major sources of GHG emissions associated with crop production are soil N_2O emissions, soil CO_2 and CH_4 fluxes, and CO_2 emissions associated with agricultural inputs and farm equipment operation (Adler, et al. 2007; Del Grosso, et al. 2002; Robertson, et al. 2000; West and Marland 2002). Over the twenty-year period of 1990 to 2009, total emissions from the agricultural sector grew by 8.7%, with 7% of the total U.S. GHG emissions in 2009 generated from this sector (U.S. EPA 2011d). Agriculture, including land-use changes for farming, is responsible for an estimated 17% to 32% of all human-induced GHG emissions worldwide (USDA Petition Number 09-082-01p). Generation of GHGs may have long term impacts on climate change as they function as retainers of solar radiation.

CH_4 and N_2O are the primary GHGs emitted by agricultural activities. Emissions from intestinal (enteric) fermentation and manure management represent about 20% and 7% of total CH_4 emissions from anthropogenic activities, respectively. Agricultural soil management activities including fertilizer application and cropping practices were the largest source of N_2O emissions, accounting for 69% of all U.S. N_2O emissions (U.S. EPA 2011d).

Tillage contributes to the release of greenhouse gases (GHG) because of the loss of carbon dioxide to the atmosphere and the exposure and oxidation of soil organic matter (Baker, et al., 2005). In general, conservation tillage strategies are associated with more stable and increased carbon sequestration due to a net reduction in CO_2 emissions (Lal and Bruce 1999; West and Marland 2002). Conservation tillage is also associated with reduced CO_2 emissions from lower farm equipment operations. Herro (Herro 2008) proposes that if agriculture practices were modified, significant reductions in the release of GHGs could be achieved.

Global climate change may also affect agricultural crop production (Karl, et al. 2009). These potential impacts on the agro-environment and individual crops may be direct, including changing patterns in precipitation, temperature, and duration of growing season, or may cause indirect impacts influencing weed and pest pressure (Rosenzweig, et al. 2001; Schmidhuber and Tubiello 2007). The impacts of GE crop varieties on climate change are unclear, though it is likely dependent on cropping systems, production practices, geographic distribution of activities, and individual grower decisions. The potential impact of climate change on agricultural output, however, has been examined in more detail. A recent Intergovernmental Panel on Climate Change (IPCC) forecast (2007) for aggregate North American impacts on agriculture from climate change actually projects yield increases of 5 to 20 percent for this century. The IPCC report notes that certain regions of the U.S. will be more heavily impacted because water resources may be substantially reduced. While agricultural impacts on existing crops may be substantial, North American production is expected to adapt with improved cultivars and responsive farm management (2007).

II.D. BIOLOGICAL RESOURCES

II.D.1. Biological Resources - Soybean

II.D.1.a. Animal Communities

Soybean production systems in agriculture are host to many animal species including deer, groundhogs, rabbits, raccoons, geese and small rodents. Mammals and birds, including migratory mammals and birds, may seasonally consume grain (Galle, et al. 2009), and invertebrates can feed on the plant during the entire growing season. Management of insects in soybean production fields is discussed in Section II.B.1.d. Animals protected as threatened or endangered species are discussed in Section VI.

Animals that feed primarily on soybean are seed-feeding insects and rodents found in agricultural fields. Crop pest insects are considered less problematic than weeds in U.S. soybean production as indicated by the low percentage (14%) of soybean acreage that receives insecticide treatment (USDA-NASS 2007). Some rodents, such as mice or squirrels, may seasonally feed exclusively on soybean seeds. Thus, these animals may have a diet containing significant amounts of soybean seeds. Deer may also browse in soybean fields on the forage and on seed left after harvest.

Intensive agricultural lands, such as those used in crop production, usually have low levels of biodiversity compared with adjacent natural areas (Lovett, et al. 2003). Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest result in limited habitat and a correspondingly limited diversity of plants and animals on agricultural land (Lovett et al. 2003). However, the implementation of cropland management strategies can increase the value of crop fields to wildlife (Sharpe 2010). Some of these strategies include:

- Conservation tillage and no-till practices have a positive impact on wildlife (Towery and Werblow 2010). Benefits include improved water quality, retention of cover, availability of waste grain on the soil surface for feed, and increased populations of invertebrates as a food source for turkey, quail, and songbirds (Sharpe 2010).

- Crop rotations can reduce the likelihood of crop disease, insect pests, weed pests, and the need for pesticides (University of California 2008).

Beneficial insects within and near a soybean field include a wide variety of predators, which catch and eat smaller insects and parasitic insects that live on or in the body of other insects during at least one stage of their life cycle. Pollinators are important for some crops; however, soybean generally is not a preferred plant for pollinators (Abrams, et al. 1978; Erickson 1975; Jaycox 1970a; c; b). Other beneficial organisms, including earthworms, termites, ants, beetles, millipedes, and others contribute to the decay of organic matter and the cycling of soil nutrients (Ruiz, et al. 2008).

Animals that feed outside soybean fields are also considered in this section. The environment surrounding a soybean field, which may vary in plant composition depending on the region, may serve as a food source and habitat for mammals, birds, fish and insects. In certain areas, soybean fields may be bordered by other soybean, corn, or other crops; soybean fields may also be surrounded by woods and/or pasture/grassland areas, as well as aquatic environments. Therefore, the types of vegetation, including weeds, around a soybean field depend on the area where the soybean is planted. Fertilizers and/or water containing pesticides have the potential to run off into adjacent lands, pesticides also have the potential to move outside of the agroecosystem from drift and offsite movement. Regardless of the agricultural operation, animals and insects outside the field have the potential to be impacted directly from the use of fertilizers, pesticides, and erosion caused from agricultural operations, or indirectly, both positively and negatively, from effects on the plant community outside the soybean field.

II.D.1.b. Plant Communities

The affected environment for growing soybean plants can generally be considered the agroecosystem (managed agricultural fields) plus some area extending beyond intended plantings. Plants, extraneous to the crop, which grow in planted fields can be considered weeds and are addressed in Section II.B.1.d. Animals protected as threatened or endangered species are discussed in Section VI.

Plants growing outside soybean fields are considered in this section. The environment surrounding a soybean field varies in plant composition depending on the region. In certain areas, soybean fields may be bordered by other soybean, corn, or other crops; fields may also be surrounded by woods and/or pasture/grassland areas, as well as aquatic environments. Therefore, the types of vegetation, including weeds, around a soybean field depend on the area where the soybean is planted. A variety of weeds and other vegetation dwell in and around soybean fields; those species may also vary depending on the region where the soybean is planted. These plants may be found in ditches, hedge rows, fence rows, wind breaks, yards, and other uncultivated areas, and may be annuals, biennials or perennials. Regardless of the agricultural operation, these plants may be impacted, both positively and negatively, by agricultural operations. Fertilizers and/or water have the potential to run off into adjacent lands, resulting in increased plant growth outside the agroecosystem. Herbicides are commonly used in the production of soybean; a more detailed discussion of their use can be found in Section II.B.1.d and in Appendix A. Impacts on adjacent agricultural crops and non-agricultural plants can occur from offsite movement of any herbicide. These impacts are actively managed by farmers and applicators trained to use such products consistent with product labels and other state or local restrictions. Depending upon the herbicide, factors for managing the potential for drift and offsite movement include the selectivity and sensitivity of the herbicide, local weather conditions at the time of application (*e.g.*, wind, temperature, humidity, inversion potential), droplet size distribution, application volume, boom height (*i.e.*, height of the application equipment above the crop canopy), sprayer speed, and distance from the edge of the application area (Felsot et al. 2010; SDTF 1997). A variety of measures can be employed to effectively control the potential for spray drift and offsite movement, including nozzle selection and application techniques and restrictions.

Another potential component of herbicide offsite movement is volatility, which is primarily a function of the physicochemical properties of the chemical, (*e.g.*, vapor pressure, Henry's Law constant, etc.), method of application (*e.g.*, soil-incorporated or not), and the local environmental conditions (*e.g.*, temperature, humidity, wind speed). Low-volatility forumations can reduce volatility and offsite movement. For example, side-by-side field experiments have indicated that a formulation of the diglycolamine (DGA) salt of dicamba volatilized significantly less than a similar formulation of the DMA salt form (Egan and Mortensen 2012). Measured air concentrations when using the DGA salt were 30- to 50-fold lower than concentrations of the potassium and DMA salts of dicamba from laboratory studies EFED evaluated, even though the application rate was twice that of DMA (Mueller 2010).

Additionally, pesticide registrants must report drift incidents to EPA as an adverse effect in order to ensure the pesticide continues to meet FIFRA requirements for registration. 40 C.F.R. § 159.195(a)(2). Before any registered herbicide can be applied to any new use site (including any deregulated GE-derived crop), EPA must approve a label amendment setting out the use pattern and specific application requirements for that new use site. Specifically, in order to approve a new use of a pesticide , EPA must conclude that no unreasonable adverse effects will result from the new use when applied according to label directions, which includes potential offsite movement. Offsite impacts are diminished when herbicides are applied in accordance with label instructions. Registered herbicides, including dicamba and glufosinate, are assessed by EPA for potential risks to non-target plants. A detailed discussion of the use of dicamba herbicide in the U.S. can be found in Appendix A.

Finally, soybeans infrequently occur as a volunteer when soybean seeds remain in a field following harvesting and may be considered a weed in the subsequent crop. Volunteer soybean in rotational crops is not a concern in the Midwest region because the soybean seed is typically not viable after the winter period (Carpenter et al. 2002; OECD 2000b). In southern soybean growing areas of the U.S. where the winter temperatures are milder, it is possible for soybean seed to remain viable over the winter and germinate the following spring. If volunteer soybean should emerge after planting, shallow cultivation and/or use of another herbicide will control volunteers and effectively reduce competition with the crop. Several postemergence herbicides are also available to control volunteer soybean (either conventional or herbicide-tolerant soybean) in each of the major soybean rotational crops. Therefore, due to the availability of adequate control measures for volunteer soybean, volunteer soybean normally is not a concern in rotational crops, such as corn, cotton, rice and small grains (e.g., wheat, barley, sorghum and oats), which are the primary rotational crops following soybean (Carpenter et al. 2002; OECD 2000b).

II.D.1.c. Gene Flow and Weediness

Gene introgression is a process whereby one or more genes successfully integrate into the genome of a recipient plant population. Introgression is affected by many factors, including the frequency of the initial pollination event, environmental factors, sexual compatibility of pollen donor and recipient plants, pollination biology, flowering phenology, hybrid stability and fertility, selection, and the ability to backcross repeatedly. Because gene introgression is a natural biological process, it does not constitute an environmental risk in and of itself (Sutherland and Poppy 2005). Gene introgression must be considered in the context of the transgene(s) inserted into the biotechnology-derived plant, and the likelihood that the presence of the transgene(s) and their subsequent transfer to recipient plants will result in increased plant pest potential. The potential for gene introgression from DT soybean is discussed below.

The assessment for gene introgression from DT soybean with other cultivated or wild relatives of soybean, discussed in detail below, indicates that DT soybean is no more likely to become a weed than conventional soybean, and DT soybean is expected to be similar to conventional soybean regarding its potential for and impacts from gene flow. Soybean lacks sexually-compatible relatives in the U.S.; therefore, the only pollen-mediated gene flow would be within cultivated soybean.

Hybridization with Cultivated Soybean: Although soybean is largely a self-pollinated species, low levels of natural cross-pollination can occur (Caviness 1966; OECD 2000b; Ray, et al. 2003; Yoshimura, et al. 2006). In studies with cultivated soybean, where conditions have been optimized to ensure close proximity and flowering synchrony, natural cross-pollination generally has been found to be very low. Most outcrossing occurred with surrounding plants, and cross-pollination frequencies varied depending on growing season and genotype. Insect activity does increase the outcrossing rate, but soybean generally is not a preferred plant for pollinators (Abrams et al. 1978; Erickson 1975; Jaycox 1970a; c; b).

Numerous studies on soybean cross-pollination have been conducted, and the published results, with and without supplemental pollinators, are summarized in Table II.D-1. Under natural conditions, cross-pollination among adjacent plants in a row or among plants in adjacent rows ranged from 0 to 6.3%. In experiments where supplemental pollinators (usually bees) were added to the experimental area, cross-pollination ranged from 0.5 to 7.74% in adjacent plants or adjacent rows. However, cross-pollination does not occur at these levels over long distances. Cross-pollination rates decrease to less than 1.5% beyond one meter from the pollen source, and rapidly decrease with greater distances from the source. The following cross-pollination rates at extended distances have been reported: 0.05% at 5.4 meters (Ray et al. 2003), 0% at 6.5 meters (Abud, et al. 2003), 0% at 10.5 m (Yoshimura et al. 2006), and 0.004% at 13.7 meters of separation (Caviness 1966).

The potential for cross-pollination in soybean is limited. This is recognized in certified seed regulations for foundation seed in the U.S., which permit any distance between different soybean cultivars in the field as long as the distance is adequate to prevent mechanical mixing (USDA-APHIS 2006).

The consequence of introgression of the dicamba tolerance trait from DT soybean into other soybean is negligible since soybean gene flow is naturally low; therefore the dicamba tolerance trait confers no increased plant pest potential to cultivated soybean.

Table II.D-1. Summary of Published Literature on Soybean Cross Pollination

Distance from Pollen Source (meters)	Cross-Pollination (%)	Comments	Reference
0.3	0.04 (estimated per pod)	Interspaced plants within a row. Experiment conducted in a single year. Single male and female parental varieties. Percent outcrossing calculated per pod rather than per seed.	(Woodworth 1922)
0.8	0.07 to 0.18	Adjacent rows. Experiment conducted over two years. Several male and female parental varieties.	(Garber and Odland 1926)
0.1	0.38 to 2.43	Adjacent plants within a row. Experiment conducted in a single year. Several male and female parental varieties.	(Cutler 1934)
0.1	0.2 to 1.2	Adjacent plants within a row. Experiment conducted in single year at two locations. Several male and female parental varieties.	(Weber and Hanson 1961)
0.9 2.7–4.6 6.4–8.2 10–15.5	0.03 to 0.44 0.007 to 0.06 0 to 0.02 0 to 0.01	Frequency by distance was investigated. Experiment conducted over three years. Single male and female parental varieties.	(Caviness 1966)
0.8 m	0.3 to 3.62	Various arrangements within and among adjacent rows. Experiment conducted over three years. Several male and female parental varieties.	(Beard and Knowles 1971)
One row (undefined)	1.15 to 7.74	Bee pollination of single-row, small-plots of pollen receptor surrounded by large fields (several acres) of pollen donor soybean. Soybean is not a preferred flower for alfalfa leafcutting bees.	(Abrams et al. 1978)
0.1–0.6	0.5 to 1.03 (depending on planting design)	Bee pollination of soybean grown in various spatial arrangements. Experiment conducted over four years. Several soybean cultivars.	(Chiang and Kiang 1987)
1.0	0.09 to 1.63	Adjacent rows. Experiment conducted over two years. Several male and female parental varieties.	(Ahrent and Caviness 1994)
0.5 1.0 6.5	0.44 to 0.45 0.04 to 0.14 none detected	Frequency by distance was investigated. Experiment conducted in a single year. Single male and female parental varieties.	(Abud et al. 2003)
0.9 5.4	0.29 to 0.41 0.03 to 0.05	Frequency by distance was investigated. Experiment conducted in a single year. Single male and female parental varieties.	(Ray et al. 2003)
0.15	0.65 to 6.32 (avg. 1.8)	Interspaced plants within a row. Experiment conducted in a single year. Single male and female parental varieties.	(Ray et al. 2003)
0.7 1.4 2.1 2.8 3.5 7.0 10.5	0 to 0.19 0 to 0.04 0 to 0.05 0 to 0.08 0 to 0.04 0 to 0.04 0	Interspaced plants within a row arranged in small plots. Experiment conducted in a four year period. Single male and two female parental varieties.	(Yoshimura et al. 2006)

Hybridization with Wild Species of *Glycine* Subgenus: As discussed in Section II.B.1.1, wild (native) *Glycine* species are endemic throughout much of Asia, but do not exist naturally in North America (OECD 2000b). Therefore, there is no potential for hybridization of soybean with wild species in the Americas.

The subgenus *Soja* includes the cultivated soybean *Glycine max* and the wild annual species *Glycine soja*. *Glycine soja* is found in China, Taiwan, Japan, Korea, and Russia and can hybridize naturally with the cultivated soybean, *G. max* (Hymowitz 2004; Lu 2004). However, Abe et al. (1999) note that "natural hybrids between *G. max* and *G. soja* are rare and hybrid swarms involving both species have never been reported." This is also supported by work from Kuroda et al. (2008) in which molecular markers were used and no gene flow from *G. max* to *G. soja* was detected. Many barriers to natural hybridization exist between soybean and wild relatives, including the highly selfing nature of both plants, required proximity of wild soybean to cultivated soybean, synchrony of flowering, and presence of pollinators. As such, it is highly unlikely that naturally occurring, pollen-mediated gene flow and transgene introgression into wild soybean relatives from incidentally released biotechnology-derived soybean will occur at any meaningful frequency.

Hybridization with Feral Species of *Glycine* Subgenus: Cultivated soybean seed rarely displays any dormancy characteristics and only under certain environmental conditions grows as a volunteer in the year following cultivation. If this should occur, volunteers do not compete well with the succeeding crop, and can easily be controlled mechanically or chemically. The soybean plant is not weedy in character. In North America, it is not found outside of cultivation. In managed ecosystems, soybean does not effectively compete with other cultivated plants or primary colonizers (OECD 2000a).

II.D.1.d. Microorganisms

Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil (Garbeva, et al. 2004). These microorganisms also suppress soil-borne plant diseases and promote plant growth (Doran, et al. 1996). The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, application of herbicide and fertilizer, and irrigation) (Garbeva et al. 2004). The occurrence and abundance of soil microorganisms are affected by 1) soil characteristics like tilth, organic matter, nutrient content, and moisture capacity, 2) typical physico-chemical factors such as temperature, pH, and redox potential, and 3) soil management practices. Agricultural practices such as fertilization and cultivation may also have profound effects on soil microbial populations, species composition, colonization, and associated biochemical processes (Buckley and Schmidt 2001; Buckley and Schmidt 2003). Consequently, significant variation in microbial populations is expected in agricultural fields.

Members of the bacterial family *Rhizobiaceae* and *Bradyrhizobiaceae* form a highly complex and specific symbiotic relationship with leguminous plants, including soybean (Gage 2004). The nitrogen-fixing plant-microbe symbiosis results in the formation of root nodules, which provide an environment in which differentiated bacteria called bacteroids are capable of reducing or "fixing" atmospheric nitrogen. The product of nitrogen fixation, ammonia, can then be utilized by the plant. As a result of this relationship, nitrogen inputs are typically not necessary for agricultural production of soybeans.

II.D.1.e. Biodiversity

Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest may all limit the diversity of plants and animals on agricultural land (Lovett et al. 2003). Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas. Herbicide use in agricultural fields can indirectly impact biodiversity by decreasing weed species present in the field and those insects, birds and mammals that potentially rely on these weeds.

Conservation tillage practices can have a positive impact on wildlife, including beneficial arthropods (Landis, et al. 2005; Towery and Werblow 2010). Conservation tillage practices benefit biodiversity on agricultural land due to decreased soil erosion, improved surface water quality, retention of vegetative cover, increased food sources from crop residues and increased populations of invertebrates (Landis et al. 2005; Sharpe 2010).

Species diversity and abundance in soybean agroecosystems may differ between non-GE, GE, and organic production systems. Many studies over the last ten years have investigated the differences in biological diversity and abundance between GE and non-GE fields, particularly those GE crops that are resistant to insects (*e.g.*, *Bt* crops) or herbicides (*e.g.*, glyphosate-tolerant or glufosinate-tolerant crops). Among the numerous studies, conflicting results are often reported. The literature has demonstrated decreases in biological diversity or abundance due to GE crops engineered to accumulate insecticidal proteins or tolerate herbicide application for weed management (Pilcher, et al. 2005). Alternatively, other studies of GE crops, such as *Bt* corn, when compared to non-GE crops sprayed with insecticides, demonstrate that GE crops do not cause any changes in arthropod abundance or diversity (Romeis, et al. 2004; Torres and Ruberson 2005; Wolfenbarger, et al. 2008). Some reports show that GE crops may even increase biological diversity in agroecosystems (Marvier, et al. 2007; Romeis, et al. 2006). Due to the multiple definitions of biological diversity, the determination of the level of biological diversity in any crop is complex; consensus on the measurement of diversity can be difficult to achieve. It can likewise be difficult in biodiversity studies to separate expected impacts from indirect ones. For example, reductions of biological control organisms are seen in some *Bt*-expressing GE crops, but are caused by reduction of the pest population following cultivation of the insect-resistant GE crop plant.

II.D.2. Biological Resources – Cotton

Modern conservation practices incorporated in cotton cultivation have brought a positive impact to animal and plant communities through reduced tillage, more carefully controlled and targeted chemical placement (fertilizers and pesticides), and better control of irrigation systems (CCI 2013; Cotton Inc. 2013). GE-based crop systems provide opportunities to optimize the introduction and implementation of many of these practices. For example, herbicide tolerance allows cultivation with minimal tillage required to control volunteers and weeds (Towery and Werblow 2010). This subsection provides an overview of the relationships of these practices to the biotic community.

II.D.2.a. Animal Communities

Cotton production systems in agriculture are host to many animal species. Mammals and birds may use cotton fields and the surrounding vegetation for food and habitat throughout the year. Invertebrates can feed on cotton plants or prey upon other insects living on cotton plants, as well as in the vegetation surrounding cotton fields. Insects considered pests to cotton area addressed in Section II.B.2.d. Animals protected as threatened or endangered species are discussed in Section VI.

Intensive agricultural lands, such as those used in crop production, usually have low levels of biodiversity compared with adjacent natural areas (Lovett et al. 2003). Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest result in limited habitat and a correspondingly limited diversity of plants and animals on agricultural land (Lovett et al. 2003). However, the implementation of cropland management strategies can increase the value of crop fields to wildlife (Sharpe 2010). Some of these strategies include:

- Conservation tillage and no-till practices have a positive impact on wildlife (Towery and Werblow 2010). Benefits include improved water quality, retention of cover, availability of waste grain on the soil surface for feed and increased populations of invertebrates as a food source for turkey, quail, and songbirds (Sharpe 2010).

- Crop rotations reduce the likelihood of crop disease, insect pests, weed pests, and the need for pesticides (University of California 2008).

Although many of the invertebrate organisms found in or near cotton production fields are considered pests, such as the cotton bollworm and tobacco budworm, most invertebrates are considered beneficial (University of Arkansas 2006). Beneficial insects include a wide variety of predators, which catch and eat smaller insects and parasitic insects that live on or in the body of other insects during at least one stage of their life cycle. Other beneficial insects function as pollinators. Major pollinators of *G. hirsutum* are bumble bees (*Bombus* spp.), black bees (*Melissodes* spp.), and honey bees (*Apis mellifera*) (McGregor 1976). Other beneficial organisms, including earthworms, termites, ants, beetles, millipedes, and others contribute to the decay of organic matter and the cycling of soil nutrients (Ruiz et al. 2008).

Since the mid-1990s, GE herbicide-tolerant cotton lines have been commercialized without substantiated reports of significant deleterious impacts on non-target organisms (OECD 2007; U.S. EPA 2008a; USDA-APHIS 2010b).

II.D.2.b. Plant Communities

The affected environment for growing cotton plants can generally be considered the agroecosystem (managed agricultural fields), plus some area extending beyond intended plantings. Plants, extraneous to the crops that grow in planted fields, can be considered weeds and are addressed in Section II.B.2.d. Plants protected as threatened or endangered species are discussed in Section VI.

The landscape surrounding a cotton field varies depending on the region. In certain areas, cotton fields may be bordered by other cotton (or other crop) fields or may also be surrounded by woodland, rangelands, and/or pasture/grassland areas. These plant communities may be natural or managed plant habitats for the control of soil and wind erosion and serve as wildlife habitats.

Surrounding plants may be impacted, both positively and negatively, by agricultural operations. Fertilizers and/or water may run off into adjacent lands, resulting in increased plant growth outside the field margins.

Herbicides are commonly used in the production of cotton; a more detailed discussion of their use can be found in Section II.B.2.d and Appendix A. Impacts on adjacent agricultural crops and non-agricultural plants can occur from offsite movement of any herbicide. These impacts are actively managed by farmers and applicators trained to use such products consistent with product labels and other state or local restrictions. Depending upon the herbicide, factors for managing the potential for drift and offsite movement include the selectivity and sensitivity of the herbicide, local weather conditions at the time of application (*e.g.*, wind, temperature, humidity, inversion potential), droplet size distribution, application volume, boom height (*i.e.*, height of the application equipment above the crop canopy), sprayer speed, and distance from the edge of the application area (Felsot et al. 2010; SDTF 1997). A variety of measures can be employed to effectively control the potential for spray drift and offsite movement, including nozzle selection and application techniques and restrictions, see Appendix D for additional detail.

Another potential component of herbicide offsite movement is volatility, which is primarily a function of the physicochemical properties of the chemical, (*e.g.*, vapor pressure, Henry's Law constant, etc.), method of application (*e.g.*, soil-incorporated or not), and the local environmental conditions (*e.g.*, temperature, humidity, wind speed). Low-volatility forumations can reduce volatility and offsite movement. For example, side-by-side field experiments have indicated that a formulation of the diglycolamine (DGA) salt of dicamba volatilized significantly less than a similar formulation of the DMA salt form (Egan and Mortensen 2012). Measured air concentrations when using the DGA salt were 30- to 50-fold lower than those in the potassium and DMA salt laboratory studies EFED evaluated, even though the application rate was twice that of DMA (Mueller 2010).

EPA considers possible effects from offsite movement as part of the pesticide registration process required under FIFRA. Additionally, pesticide registrants must report drift incidents to EPA as an adverse effect in order to ensure the pesticide continues to meet FIFRA requirements for registration. 40 C.F.R. § 159.195(a)(2). Before any registered herbicide can be applied to any new use site (including any deregulated GE-derived crop), EPA must approve a label amendment setting out the use pattern and specific application requirementsfor that new use site. Specifically, in order to approve a new use of a pesticide , EPA must conclude that no unreasonable adverse effects will result from the new use when applied according to label directions, which includes potential offsite movement. Offsite impacts are diminished when herbicides are applied in accordance with label instructions. Registered herbicides, including dicamba and glufosinate, are reassessed by EPA for potential risks to non-target plants. A detailed discussion of the use of dicamba and glufosinate herbicides in the U.S. can be found in Section II.B.2.d.

II.D.2.c. Gene Flow and Weediness

Gene flow is a biological process that facilitates the production of hybrid plants, introgression of novel alleles (*i.e.*, versions of a gene) into a population, and the evolution of new plant genotypes. Gene flow to and from an agro-ecosystem can occur on both spatial and temporal scales. In general, plant pollen tends to represent the major reproductive method for moving across areas, while both seed and vegetative propagation tend to promote the movement of genes across time and space.

The rate and success of gene flow is dependent on numerous external factors in addition to the donor/recipient plant. General external factors related to pollen-mediated gene flow include the presence/abundance/distance of sexually-compatible plant species; overlap of flowering phenology between populations; the method of pollination; the biology and amount of pollen produced; and weather conditions, including temperature, wind, and humidity (Mallory-Smith and Zapiola 2008). Seed-mediated gene flow also depends on many factors, including the absence/presence/magnitude of seed dormancy; contribution and participation in various dispersal pathways; and environmental conditions and events.

Hybridization with Cultivated Cotton: Although natural outcrossing can occur, cotton is normally considered to be a self-pollinating crop (Niles and Feaster 1984; OECD 2008). There are no morphological barriers to cross-pollination based on flower structure. However, the pollen is heavy and sticky, and transfer by wind is limited. Pollen is transferred instead by insects, and particularly by various wild bees, bumble bees (*Bombus* spp.), and honeybees (*Apis mellifera*). Numerous studies on cotton cross-pollination have been conducted, and the published results, with and without supplemental pollinators, are summarized in Table II.D-2. The recent cotton literature discussed below shows that the frequency of cross-pollination decreases with distance from the pollen source. McGregor (1976) traced movement of pollen by means of fluorescent particles and found that, even among flowers located only 150 to 200 feet from a cotton field that was surrounded by a large number of bee colonies to ensure ample opportunity for transfer of pollen, fluorescent particles were detected on only 1.6% of the flowers. In a 1996 study with various field designs, Llewellyn and Fitt (1996) also found low levels of cross-pollination in cotton. At one meter from the source they observed cross-pollination frequencies of 0.15 to 0.4%, decreasing to below 0.3% at 16 meters from the source. Umbeck et al. (1991) used a selectable marker to examine cross-pollination from a 30 x 136 meter source of GE-derived cotton. Cross-pollination decreased from five to less than one percent from one to seven meters, respectively, away from the source plot. A low level of cross-pollination (less than one percent) was sporadically detected to the furthest sampling distance of 25 meters. Berkey et al. (2002) reported that cross pollination between fields separated by a 13 foot road decreased from 1.89% in the row nearest the source to zero percent in the 24th row. Van Deynze et al. (2005) conducted a two year study on pollen-mediated gene flow with high and low pollinator activity. In the presence of high pollinator activity, the pollination frequency was 7.65% at 0.3 meters and less than 1% at greater than nine meters, whereas the pollination frequency with low pollinator activity was below 1% at just over a meter. In a 2008 study pollination frequencies of 5.00% and 0.00% were demonstrated at 1 and 8 meters, respectively (Kairichi, et al. 2008). By comparison, the isolation distances for Foundation, Registered, and Certified seeds in 7 CFR Part 201 are 1320, 1320, and 660 feet, respectively(USDA-AMS 2010).

Table II.D-2. Summary of Published Literature on Cotton Cross Pollination

Distance from Pollen Source (meters)	Cross-Pollination (%)	Comments	Reference
45-61	1.60%	Used fluorescent particles to follow pollinator movement in cotton fields over one season.	(McGregor 1976)
1 4 16	0.15-0.4% <0.08% <0.03%	Used a selectable marker to examine cross-pollination in the progeny of buffer row plants over one season.	(Llewellyn and Fitt 1996)
1 1-25	5% <1%	Used a selectable marker to examine cross-pollination from a 20 x 136 meter source of biotechnology-derived cotton over one season.	(Umbeck et al. 1991)
5 10.5 17 25	1.89% 0.77% 0.13% 0.00%	Used herbicide bioefficacy to examine pollen flow between fields separated by a 13 foot road over one season.	(Berkey et al. 2002)
0.3 >9 >1 1625	7.65% * < 1% * < 1% ** 0.04% **	Used herbicide bioefficacy confirmed by DNA testing to measured pollen-mediated gene flowing in four directions over 2 years.	(Van Deynze et al. 2005)
1 2-7 8	5.00% 2.00% 0.00%	Used ELISA strips to examine pollen-mediated gene flow in four directions from Bt source over a period of one season.	(Kairichi et al. 2008)

* High pollinator activity

** Low pollinator activity

Hybridization with Wild *Gossypium* Species: Only two 'wild' (native) *Gossypium* species related to cultivated cotton are known to be present in the U.S.: *G. thurberi* Todaro, which is found in Arizona (Fryxell 1984) and *G. tomentosum*, which is endemic to Hawaii. Based on cytological evidence, seven genomic types, A through G, many with subtypes, have been identified for the genus *Gossypium* (Endrizzi, et al. 1984). The domesticated species *G. hirsutum* and *G. barbadense* are allotetraploid (AADD, 2n=4x=52), while *G. thurberi* is a diploid (DD, 2n=2x=26), and *G. tomentosum* is an allotetraploid (AADD, 2n=4x=52). Only *G. tomentosum* is considered to be capable of crossing with domesticated cotton to produce fertile offspring (Waghmare, et al. 2005).

However, domesticated cotton is not grown commercially in Hawaii, with the exception of potential counter-season breeding nurseries where appropriate isolation distances and practices are utilized (Bates 1990). Thus, the potential for gene flow to these wild relatives is limited.

Hybridization with Feral *Gossypium* Species: The inability of plants or seeds of either *G. hirsutum* or *G. barbadense* to survive freezing temperatures restricts their persistence as perennials or recurrent annuals to tropical areas (U.S. EPA 2013e), where cotton is not grown. Feral *G. hirsutum* occurs in parts of southern Florida in the Everglades National Park and the Florida Keys and in Puerto Rico, several hundred miles from commercial cotton production areas (Brubaker et al. 1999; U.S. EPA 2013e).

II.D.2.d. Microorganisms

Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil (Garbeva et al. 2004). These microorganisms also suppress soil-borne plant diseases and promote plant growth (Doran et al. 1996). The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, application of herbicide and fertilizer, and irrigation) (Garbeva et al. 2004). Plant roots, including those of cotton, release a variety of compounds into the soil, creating a unique environment for microorganisms in the rhizosphere. Microbial diversity in the rhizosphere may be extensive and differs from the microbial community in the bulk soil (Garbeva et al. 2004).

The occurrence and abundance of soil microorganisms are affected by 1) soil characteristics like tilth, organic matter, nutrient content, and moisture capacity, 2) typical physico-chemical factors such as temperature, pH, and redox potential, and 3) soil management practices. Agricultural practices such as fertilization and cultivation may also have profound effects on soil microbial populations, species composition, colonization, and associated biochemical processes (Buckley and Schmidt 2001; Buckley and Schmidt 2003). Consequently, significant variation in microbial populations is expected in agricultural fields. Agricultural practices such as fertilization and cultivation may also have profound effects on soil microbial populations, species composition, colonization, and associated biochemical processes (Buckley and Schmidt 2001; Buckley and Schmidt 2003). Consequently, significant variation in microbial populations is expected in agricultural fields.

II.D.2.e. Biodiversity

Biodiversity is strongly impacted by agricultural practices, including the type of cultivated plant and its associated management practices. Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas.

Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest may all limit the diversity of plants and animals on agricultural land (Lovett et al. 2003). Herbicide use in agricultural fields can indirectly impact biodiversity by decreasing weed species present in the field and those insects, birds and mammals that potentially rely on these weeds.

Conservation tillage practices can have a positive impact on wildlife, including beneficial arthropods (Landis et al. 2005; Towery and Werblow 2010). Conservation tillage practices benefit biodiversity due to decreased soil erosion, improved surface water quality, retention of vegetative cover, increased food sources from crop residues and increased populations of invertebrates (Landis et al. 2005; Sharpe 2010).

Species diversity and abundance in cotton agroecosystems may differ between non-GE, GE, and organic production systems. Many studies over the last ten years have investigated the differences in biological diversity and abundance between GE and non-GE fields, particularly those GE crops that are resistant to insects (*e.g.*, *Bt* crops) or herbicides (*e.g.*, glyphosate-tolerant or glufosinate-tolerant crops). Among the numerous studies, conflicting results are often reported. The literature has demonstrated decreases in biological diversity or abundance due to GE crops engineered to accumulate insecticidal proteins or tolerate herbicide application for weed management (Pilcher et al. 2005)). Alternatively, other studies of GE crops, such as *Bt* corn, when compared to non-GE crops sprayed with insecticides, demonstrate that GE crops do not cause any changes in arthropod abundance or diversity (Romeis et al. 2004; Torres and Ruberson 2005; Wolfenbarger et al. 2008). Some reports show that GE crops may even increase biological diversity in agroecosystems (Marvier et al. 2007; Romeis et al. 2006). Insect-resistant cotton, when compared to non-GE cotton production, may not result in changes in non-target arthropod abundance and may increase species diversity during different times of the year (Carpenter 2011; Sisterson, et al. 2007). Due to the multiple definitions of biological diversity, the determination of the level of biological diversity in any crop is complex; consensus on the measurement of diversity can be difficult to achieve. It can likewise be difficult in biodiversity studies to separate expected impacts from indirect ones. For example, reductions of biological control organisms are seen in some *Bt*-expressing GE crops, but are caused by reduction of the pest population following cultivation of the insect-resistant GE crop plant.

II.E. HUMAN HEALTH

The affected environment in terms of human health and safety related to soybeans and cotton includes all aspects of direct and indirect human contact with soybeans and cotton. Pesticide use on soybean and cotton products is also relevant both from a human consumption and worker safety standpoint.

As discussed elsewhere in this report, Congress transferred regulatory authority over herbicides from USDA to EPA. Accordingly, USDA-APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider herbicide impacts under the PPA. APHIS indicated in its Notice of Intent to Prepare an Environmental Impact Statement (78 Fed. Reg. 28796, May 16, 2013) that it would be considering herbicide effects and herbicide resistance as part of the NEPA process, however Monsanto believes that APHIS has no legal obligation under NEPA to consider herbicide impacts or herbicide resistance in any Environmental Impact Statement or Environmental Assessment. See *DOT v. Public Citizen,* 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform). See *also Center for Food Safety v. Vilsack*, No. 12-15052, 2013 U.S. App. LEXIS 9920, at *16-17 (9th Cir. 2013) ("If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests."). Nonetheless, because APHIS indicated its intention to address herbicide-related impacts, Monsanto has included a discussion of herbicide impacts in Appendix F.

II.E.1. Consumer Health

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), it is the responsibility of food manufacturers to ensure that the ingredients and products they market are safe and properly labeled. Food and feeds derived from GE cotton and GE soybeans must be in compliance with all applicable legal and regulatory requirements. GE crops used for food or feed purposes undergo a voluntary consultation process with the FDA prior to release onto the market (21 CFR Parts 192 and 592) (U.S. FDA 2001b). Although this consultation is a voluntary process, thus far developers who intend to commercialize a GE crop that will be used for food or feed have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a GE crop meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the food and feed derived from that crop. The developer then submits to FDA a scientific and regulatory assessment summary of the food and feed safety of the product. FDA evaluates the submission and responds to the developer by letter (U.S. FDA 2010). All GE cotton and soybean products on the market today have satisfactorily completed the FDA consultation process established to review the safety of foods and feeds derived from GE crops for human and animal consumption. Several international agencies also review food safety associated with GE-derived food items, including the European Food Safety Agency (EFSA) and the Food Standards Australia and New Zealand (FSANZ). Food safety reviews frequently will compare the compositional characteristics of the GE crop with nontransgenic, conventional varieties of that crop (Aumaitre, et al. 2002; Codex Alimentarius 2009). Moreover, this comparison also evaluates the composition of the modified crop under actual agronomic conditions, including various agronomic inputs. Composition characteristics evaluated in these comparative tests include moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and antinutrients.

As noted by the National Research Council (NRC), compositional changes can arise with all forms of genetic modification, including both traditional breeding and genetic engineering (NRC 2004). However, the NRC also noted that no adverse health effects attributed to genetic engineering had been documented in the human population. Reviews on the nutritional quality of GE-derived foods have generally concluded that there are no significant nutritional differences in conventional versus GE-derived plants for food or animal feed (Faust 2002; Flachowsky, et al. 2005).

II.E.1.a. Soybeans

Humans consume soybeans and have done so for thousands of years. Soybean is a highly versatile crop which can be processed into a wide variety of food products. Soybean protein is used to enhance nutrition in a wide variety of food products, such as breakfast cereals and pasta. Soybean protein is also an important component in baked goods, alternative meat products, soups, energy bars, nutritional beverages, infant formula and dairy replacement products (USB 2011a). Soybean oil constitutes the majority (68%) of consumed edible fats and oils in the U.S. (ASA 2011). It is present in numerous food products including cooking oils, shortening, margarine, mayonnaise, salad dressings and a wide variety of fat or oil-based products (USB 2011a). Soybean improved with new traits produced by biotechnology pose no unique risks relative to other soybean developed using traditional breeding methods. Biotechnology-derived soybean is evaluated extensively prior to commercial introduction.

II.E.1.b. Cotton

Cotton fiber is most often used in the manufacture of a variety of textiles, and processed cotton fibers are used in pharmaceutical and medical applications because of their low capacity to cause irritation (OECD 2008). The highest grade linters, highly processed fiber, can also be used in the manufacturing of absorbent cotton, medical pads, and gauze (NCPA 2002). After ginning to remove fibers for textile manufacturing, cottonseed is processed into four major products: oil, meal, hulls, and linters. Processing of cottonseed typically yields (by weight): 16% oil, 45% meal, 26% hulls, and 9% linters, with 4% lost during processing (Cherry 1983). Due to the presence of anti-nutrients in cottonseed, including gossypol, and cyclopropenoid fatty acids, only highly refined products (refined, bleached, and deodorized (RBD) oil and linters) are suitable for human consumption. The levels of these anti-nutrients are drastically reduced during processing (AOCS 2009; Harris 1981; NCPA 1993).

Approximately 56% of cottonseed oil is used for salad or cooking oil, 36% for baking and frying fats, and the remaining 8% goes into margarine and other uses (OECD 2009). In addition, linters or cotton fiber may be minor ingredients in processed meats (sausage casing), ice cream, salad oil and other foods (OECD 2009). Approximately 835 million pounds of cottonseed oil was produced in the U.S. in 2010/2011. By comparison, U.S. production of soybean oil for the same period was 19 billion pounds (Ash 2013). RBD oil contains undetectable amounts of protein (Reeves and Weihrauch 1979) and linters are a highly processed product composed of nearly pure (i.e., >99.9%) cellulose (NCPA 2002; Nida, et al. 1996). Food and food ingredients derived from cotton have been used safely for human food for more than 100 years in most cotton producing countries (NCPA 1993).

II.E.1.c. Pesticide Exposure

Pesticides have been used extensively in the production of cotton and soybeans (see Appendix A of this Environmental Report). Consumers of cotton and soybean-derived food products may be exposed to residual levels of pesticides in those foods or from the consumption of animal-based food products containing residual levels of pesticides. Consumer exposure to pesticides used in cotton and soybean production may also potentially occur through ingestion of drinking water with residual levels of pesticides, and through contact with pesticides when applying them for residential purposes, such as through contact with lawns or other targets of consumer pesticide application (see Appendix E of this Environmental Report).

The use of pesticides is regulated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The purpose of the Agency's review is to ensure that the pesticide, "when used in accordance with widespread and commonly recognized practice," will not cause "unreasonable adverse effects on the environment." FIFRA 3(c)(5)(D).

If the pesticide may be used on food or feed crops, EPA ensures the safety of the food supply by establishing the amount of each pesticide that may safely remain in or on foods. These maximum pesticide residue levels (called "tolerances") limit the amount of the pesticide residue that can legally remain in or on foods. EPA undertakes this analysis under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), and must conclude that such tolerances will be safe, meaning that there is a reasonable certainty that no harm will result from aggregate (food, water and non-occupational residential/recreational) exposure to the pesticide residues. (U.S. EPA 2013a). In addition, when multiple pesticides affect the same target organs through the same toxicological mode- of-action, EPA considers the cumulative effect of those pesticides. In addition, the FDA and the USDA monitor foods for pesticide residues and work with the EPA to enforce these tolerances (USDA-AMS 2013).

The use of registered pesticides is further governed by labels, which are legally enforceable and define maximum application rates, total annual application limits, methods of application, and other use restrictions. The FIFRA registration process is discussed in more detail in Appendix E of this Environmental Report.

To register a new pesticide product, EPA evaluates potential risks to humans and the environment, and typically requires applicants to submit more than 100 different scientific studies conducted according to EPA guidelines. The data required by EPA are used to evaluate whether a pesticide has the potential to cause adverse effects on humans (including acute, chronic, reproductive, and carcinogenic risk), wildlife, fish, and plants (including endangered species and other non-target organisms, *i.e.*, organisms against which the pesticide is not intended to act). FIFRA was amended in 1988 to require the reregistration of products with active ingredients registered prior to November 1, 1984. In 1996, FIFRA was amended by the FQPA to require reevaluation of all pesticide active ingredient at fifteen year (or shorter) intervals thereafter (a process called Registration Review). The amendments called for the development and submission of data to support the continued registration of the active ingredient, as well as a review of all data submitted to the EPA. During the reregistration and registration review processes, EPA thoroughly reviews the scientific database since a pesticide's original registration.

Dicamba: EPA has evaluated dicamba and has concluded that it has a complete and comprehensive regulatory database (toxicity, environmental fate, and ecological toxicity). EPA completed the reregistration process for dicamba and a Registration Eligibility Decision (RED) was issued in 2006 and subsequently amended in 2008 and 2009 (U.S. EPA 2009d). EPA concluded there is a reasonable certainty that no harm will result to the general population, or to infants and children, as a result of aggregate (combined) exposure to dicamba residues; and that the available data submitted for dicamba are complete and adequate to support the continued registration of dicamba products and uses including current uses on commercial cotton and soybean. Part of EPA's risk assessment included exposure to drinking water using a conservative modeled scenario that assumed that essentially all (87%) crop acres within the watershed were treated with dicamba (U.S. EPA 2009d; 2011b).

Dicamba residue levels in soybean seed harvested from DT soybean treated with dicamba at more than twice the anticipated commercial in-crop application rate were less than 0.1 ppm, which is well below the established 10 ppm pesticide residue tolerance supporting dicamba use on commercial soybean. Soybean forage and hay, which can be feed to livestock, have no established tolerance, for that reason Monsanto is also petitioning (Pesticide Petition # 0F7725) the agency for the establishment of new tolerances on forage (45 ppm) and hay (70 ppm).

Dicamba residue levels in cottonseed harvested from DGT cotton treated with dicamba at the anticipated commercial in-crop application rate, and were 0.54 ppm, which is greater than the established 0.2 ppm pesticide residue tolerance supporting dicamba use on commercial cotton (40 CFR § 180.227) which is for the combined residues of parent dicamba and its metabolite 5-hydroxy dicamba. Cotton gin by-products, which serve as a ruminant feed supplement, have no established dicamba tolerance PP 2F8067 for the expanded use of dicamba on MON 88701, an increase in the dicamba residue tolerance from 0.2 ppm to 3 ppm for cottonseed, the establishment of a tolerance of 70 ppm for cotton gin by-products, and the inclusion of DCSA in the residue definitions for cottonseed and gin by-products.

Glufosinate: The safety of glufosinate use on many crops, including cotton, was reviewed by the EPA as part of the food, feed, and environmental safety reassessment in 2000 (U.S. EPA 2003). In addition, glufosinate has been used for in-crop application in glufosinate-tolerant crops since 1995 with no significant adverse effects reported. Glufosinate is currently labeled for in-crop application with glufosinate-tolerant cotton from emergence through early bloom growth stage. Currently glufosinate is undergoing Registration Review at EPA with a decision expected by the end of 2013 (U.S. EPA 2008b). It is expected that EPA will affirm the safety and efficacy of glufosinate and approve its continued use in the marketplace upon completion of the registration process.

The EPA-established glufosinate residue tolerances are 4.0 ppm and 15.0 ppm for cottonseed and gin by-products, respectively (40 CFR 180.473). Both of these tolerances include the combined residues of parent glufosinate and its metabolites N-acetyl glufosinate and 3-methylphosphinico-propionic acid.

II.E.2. Worker Health

Agriculture is a relatively hazardous industry, with machinery-related injuries – often from tilling equipment – as the primary hazard. Other fairly common hazards in agriculture include injuries related to animal contact, motor vehicles, and falls (CDC 2010).

Pesticides have been used extensively in cotton and soybean production; see Appendix A for details on current pesticide use. In the agricultural production of soybeans and cotton, growers and workers may be exposed to pesticides applied to soybeans and cotton by mixing, loading, or applying chemicals, or by entering a previously treated site. EPA conducts a comprehensive occupational worker safety evaluation and risk assessment of pesticides to assess the risk to agricultural workers during mixing, loading, and applying. See Appendix E for additional information on worker health characteristics of current cotton and soybean herbicides.

Dicamba: EPA evaluated occupational risk to workers as a part of the dicamba RED and concluded that worker exposure to dicamba for all registered agricultural uses – including exposures associated with current cotton and soybean uses – meet the "no unreasonable adverse effects" criteria of FIFRA (U.S. EPA 2009d).

Glufosinate: EPA evaluated risk to workers as a part of the food, feed, and environmental safety reassessment of glufosinate in 2000 (U.S. EPA 2003) and EPA is expected to provide a Registration Review by the end of 2013. In addition, glufosinate is currently labeled for in-crop application with glufosinate-tolerant cotton from emergence through early bloom growth stage.

In addition, the Worker Protection Standard (WPS) provides additional regulatory protections to agricultural workers and pesticide applicators.[43] The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment (PPE), restricted-entry intervals (REI) after pesticide application, decontamination supplies, and emergency medical assistance. Under the WPS, EPA requires the pesticide label to specify PPE and REI that will provide an appropriate level of protection, based on the properties of the pesticide product.

II.E.2.a. Soybean

The grain handling and processing operations are a highly hazardous work environment. Workers can be exposed to a number of serious hazards including fires and explosions from dust accumulation, suffocation from entrapment, falls, and crushing/amputating injuries. OSHA has developed specific guidance for grain processors and handlers to reduce these risks to workers (OSHA 2013). No unique soybean-specific worker hazards currently exist.

II.E.2.b. Cotton

A worker health hazard specific to cotton production is the cotton dust generated during cotton handing and processing, which has been identified as a chemical hazard by the National Institute for Occupational Safety and Health (NIOSH) (CDC 2013). The inhalation of cotton dust by mill workers can lead to asthma-like conditions called byssinosis (Salvaggio, et al. 1986).

Adverse health effects, such as ergonomic injuries, may potentially occur as a result of hand-weeding due to the repetitive nature and prolonged exertions of the hands (OSHA 2013). In some cases, farmers have had to resort to hand-weeding in order to achieve satisfactory control of Palmer amaranth. Georgia cotton growers have increased hand-weeding on 17% of the acreage in 2000-2005 to 52% of the acreage in 2006-2010 (Sosnoskie and Culpepper 2012). Similarly, in 2010, at least 20% of the cotton acres in Tennessee were hand-weeded (Culpepper et al. 2011).

II.F. ANIMAL HEALTH

II.F.1. Animal Feed: Soybean

Soybean meal is the most valuable component obtained from processing soybean, accounting for roughly 50-75% of its overall value (USDA-ERS 2005). Soybean meal is a substantial part of animal feed rations in the United States. Animal agriculture consumes 98% of the U.S.

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[43] 40 CFR 170, http://www.epa.gov/pesticides/safety/workers/PART170.htm

soybean meal produced (Soyatech 2013) and 70% of soybeans worldwide (USB 2011b). In 2011, approximately 39 million tons of soybean meal were produced, 27.3 million tons of which were marketed for animal feed, with the largest volumes consumed by poultry (48 percent), swine (26 percent), and beef (12 percent) (ASA 2012). Soybean meal can serve as an excellent protein source that can complement the limited amino acid profile of feeds derived from corn (Kerley and Allee 2003).

Dairy and livestock producers also use soybean forage as feed. Soybean forage is an inexpensive, readily available, on-farm source of high-quality, high-protein forage adapted to growth during the summer months when other forage legume species typically are restricted in growth (USDA-ARS, 2006). Soybean forage can be used as hay or to produce silage (MAFRI, 2004). An additional use of soybean for feed can be full-fat (whole) soybean for dairy cattle and swine, but for swine it is limited to a maximum of 20% of the total diet due to the high oil content (Yacentiuk, 2008).

II.F.2. Animal Feed: Cotton

Seed residue remaining after fiber removal for textile production (cottonseed meal and hulls) is marketed as cottonseed meal, cottonseed hulls, and whole cottonseed and utilized in the animal feed industry as sources of protein, fiber and energy (NCPA 2002; OECD 2009). The value of cottonseed as animal feed represents a substantial portion of the grower's income from cotton (Blasi and Drouillard 2002).

Cottonseed meal, which makes up over a third of the value of cottonseed, is an excellent source of protein for ruminant animals and is widely used in animal feed (Blasi and Drouillard 2002; Calhoun 2011). As mentioned in Section II.E.1.b, cottonseed contains the anti-nutrients gossypol and cyclopropenoid fatty acids. Gossypol helps protect the cotton plant from pathogens, but is an anti-nutrient for which sensitivity is species-dependent. Gossypol is also toxic to some species (Gadberry 2011).

Cottonseed is typically fed to ruminants (*i.e.*, cattle), because they have a relatively low sensitivity to gossypol and can tolerate moderate gossypol inclusion in their diets. Highly processed cottonseed meal is also fed to non-ruminant farm animals in limited quantities (OECD 2009). Cyclopropenoid fatty acids interfere with the metabolism of saturated fats (Cao, et al. 1993; Rolph, et al. 1990) and reportedly have adverse effects on egg yolk discoloration and reduced hatchability in chickens (Lordelo, et al. 2007; OECD 2004; 2008).

The hull is the tough, protective covering of the cottonseed that is removed prior to processing the seed for oil and meal. It is used as feed for livestock and can be an economical roughage that provides fiber, as well as serving as a good carrier for cottonseed meal and grain (NCPA 2002). Gin by-products, the dried plant material cleaned from the fiber during ginning, is also used as a source of roughage for livestock feeds.

Cottonseed is an animal food source most commonly in the form of cottonseed meal. Non-GE cotton varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for feed safety prior to release in the market.

II.F.3. FDA Consultation Process

Under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE soybean and cotton must comply with all applicable legal and regulatory requirements, which are designed to protect human health. GE crops used for food or feed purposes undergo a voluntary consultation process with the FDA prior to release onto the market (U.S. FDA 2001b). Although this consultation is a voluntary process, thus far developers who intend to commercialize a GE crop that will be used for food or feed have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a GE crop meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the food and feed derived from that crop. The developer then submits to FDA a scientific and regulatory assessment summary of the food and feed safety of the product. FDA evaluates the submission and responds to the developer by letter (U.S. FDA 2010).

II.F.3.a. FDA Consultation Process: Soybean

Monsanto has completed the biotechnology consultation process with FDA for the safety and nutritional assessment of food and feed derived from DT soybean on October 11, 2011 (BNF No. 00125, Monsanto, 2011). As a part of its evaluation, FDA reviewed information on the identity, function, and characterization of the genes, including expression of the gene products in DT soybean , as well as information on the safety of the MON 87708 DMO and DT soybean including a dietary risk assessment.

II.F.3.b. FDA Consultation Process: Cotton

Monsanto has completed the biotechnology consultation process with FDA for the safety and nutritional assessment of food and feed derived from DGT Cotton on April 24, 2013 (FDA 2013). As a part of its evaluation, FDA reviewed information on the identity, function, and characterization of the genes, including expression of the gene products in DGT cotton, as well as information on the safety of DGT Cotton including a dietary risk assessment.

II.F.4. EPA Dicamba Tolerance Assessment

As discussed elsewhere in this report, Congress transferred regulatory authority over pesticides from USDA to EPA. Accordingly, USDA-APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider herbicide impacts under the PPA.

EPA has responsibility to regulate the use of pesticides (including herbicides) that may be used on feed crops, and must establish pesticide tolerances (maximum pesticide residue levels) for the amount of pesticide residue that can legally remain in or on the feed crop. EPA undertakes this analysis under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA), and must conclude that such tolerances will be safe, meaning that there is a "reasonable certainty that no harm" to human health will result from the use of the pesticide. This finding of reasonable certainty of no harm is obligated under the FFDCA, as amended by the FQPA of 1996. Similar to the establishment of pesticide tolerances for food, the EPA will consider the toxicity of the pesticide and its break-down products, pesticide use rate and frequency of application; and how much of the pesticide (i.e., the residue) remains in or on food by the time is it marketed and prepared in its establishment of tolerance for animal feed (U.S. EPA 2013a).

DT Soybean: EPA reassessed all dicamba pesticide food and feed tolerances as part of the dicamba RED, including the 10 ppm soybean seed tolerance supporting the existing use in conventional soybean (U.S. EPA 2009d). A complete listing of dicamba feed tolerances can be found at 40 CFR § 180.227. Monsanto has requested a registration of an expanded use of a low-volatility DGA dicamba formulation on DT soybean, and petitioned (Pesticide Petition # 0F7725) the EPA to establish new feed tolerances on soybean forage (45 ppm) and soybean hay (70 ppm). Tolerances for soybean forage and hay for current dicamba uses in conventional soybean were not previously established because the current preharvest application is made past the stage where the crop would be useful as forage or hay. No other revisions to dicamba pesticide residue tolerances are needed including animal products such as meat or milk.

DGT cotton: Monsanto has requested a registration from U.S. EPA for the expanded use of a low-volatility DGA dicamba formulation on DGT cotton, an increase in the dicamba residue tolerance from 0.2 ppm to 3 ppm for cottonseed, the establishment of a tolerance of 70 ppm for cotton gin by-products, and the inclusion of DCSA in the residue definitions for cottonseed and gin by-products. No other revisions to dicamba pesticide residue tolerances are needed including animal products such as meat or milk.

II.G. SOCIOECONOMICS

This section addresses: (1) the domestic economic environment of soybean and cotton; (2) the trade economic environments of soybean and cotton; and (3) public perceptions regarding genetically modified ingredients in food.

The economics of cotton and soybean are presented below, divided into discussion of: (1) soybean market overview; (2) soybean production costs and revenue, including a discussion of the impacts of genetically-engineered (GE) soybean; (3) U.S. cotton market overview; (4) cotton production costs and revenue, including a discussion of GE cotton production; and (5) the organic market segments.

II.G.1. Domestic Economic Environments of Soybean and Cotton

II.G.1.a. Domestic Economic Environment: Soybean

In 2012, 77 million acres of soybeans were cultivated in the United States (USDA-NASS 2012e), yielding approximately 3.0 billion bushels at a value of 43.2 billion U.S. dollars0020(USDA-NASS 2013a). Total 2012 U.S. inventory (2011 remaining stocks plus 2012 production) totaled 3.2 billion bushels, with 43 percent of U.S. soybean destined for the export market (Ash 2013). The remaining 57 percent of U.S. soybean inventory was primarily utilized to produce soybean meal intended for feed, with lesser amounts processed for soybean oil intended for industrial or consumption purposes; seed and residuals; or ending stock for storage. The majority of domestic soybean use in the United States is used for animal feed or secondary industrial products, with only a small proportion of the soybean crop being consumed directly by humans.

Almost all of the U.S. soybean supply (95.6% in 2009/10) comes from domestic production and almost all of this supply (96.8%) is either exported or crushed for meal and oil (Table II.G-1). In any given year, the resulting meal and oil is modestly supplemented with carryover stocks and imports before being consumed domestically or exported. In the U.S., almost all of the soybean meal is used for animal feed (97.5% in 2002/03) (SMIC 2006). The vast majority of the oil (86% in 2010) is used for human consumption, with the balance going to industrial products (Figure II.G-1). Soybean oil represents almost 70% of the oils consumed by U.S. households. It is notable that higher petroleum prices and an increased interest in biofuels are increasing the demand for soybean-based biodiesel. From 1999 to 2009, the consumption of soybean biodiesel has increased from 0.5 to 545 million gallons (Soy Stats 2010).

The top ten soybean producing states (Iowa, Illinois, Minnesota, Indiana, Nebraska, Ohio, Missouri, South Dakota, Kansas, and North Dakota) accounted for more than 80% of this production (Table II.G-2). These states are located in the USDA-ERS's Heartland (Iowa, Illinois, Indiana, Minnesota, Missouri, Nebraska, Ohio, and South Dakota), Northern Crescent (Minnesota and Ohio), Northern Great Plains (Nebraska, Minnesota, North Dakota, and South Dakota), Prairie Gateway (Kansas and Nebraska), and Eastern Uplands (Missouri and Ohio) resource regions (Fernandez-Cornejo and McBride 2002), which vary in terms of land productivity and cost of production (Figure II.G-2). The most productive of these regions are the Heartland and Northern Crescent. While these regions have higher production cost, their higher productivity still results in greater profitability. In 2010, the U.S. total gross average value of soybean production per planted acre was $449.32 and the average price of a bushel of soybeans at harvest was $9.56 (USDA-ERS 2012b).

The domestic soybean industry is primarily composed of commodity production businesses and the users of soybean products (Figure II.G-3). Ultimately, the profitability of a soybean field is dependent on the suitability of a soybean harvest for its target market and the production costs for that particular harvest.

Because domestic utilization of soybean is focused on animal feed and oil production, the chemical composition of a soybean at harvest is important. Soy meal typically contains about 50 percent protein by dry weight, and is the most important product of soybean production. Of the domestically crushed soybean, 53 percent of soybean by weight produces meal and 19 percent produces oil (USB, 2011a). Changes in the fatty acid profile may impact food and industrial uses of the soybean oil. Fatty acid composition of the soybean oil affects melting point, oxidative stability, and chemical functionality, and changes in any of these can impact the market sector of the product (APAG, 2011). These fatty acid properties influence the market applications for the oil, and various foods and industrial products are formulated to take these properties into consideration (Cahoon 2003; Cargill 2011; USB 2011a)

Table II.G-1. U.S. soybean supply and disappearance[1] 2009/10.

	Soybeans	Soybean Meal (Million Metric Tons)	Soybean Oil
Total	95.58	38.19	10.24
	------------Supply------------		
Beginning Stocks	3.76	0.21	1.3
Production	91.42	37.83	8.90
Imports	0,40	0.15	0.05
	------------Disappearance------------		
Crush	47.67	--[2]	--
Feed, Seed & Residual	2.95	--	--
Domestic	--	27.78	7.20
Exports	40.85	10.14	7.54
Ending Stocks	4.11	0.27	1.53

Source: USDA-ERS (USDA-ERS 2011e)
[1] Disappearance is the consumed supply
[2] No data

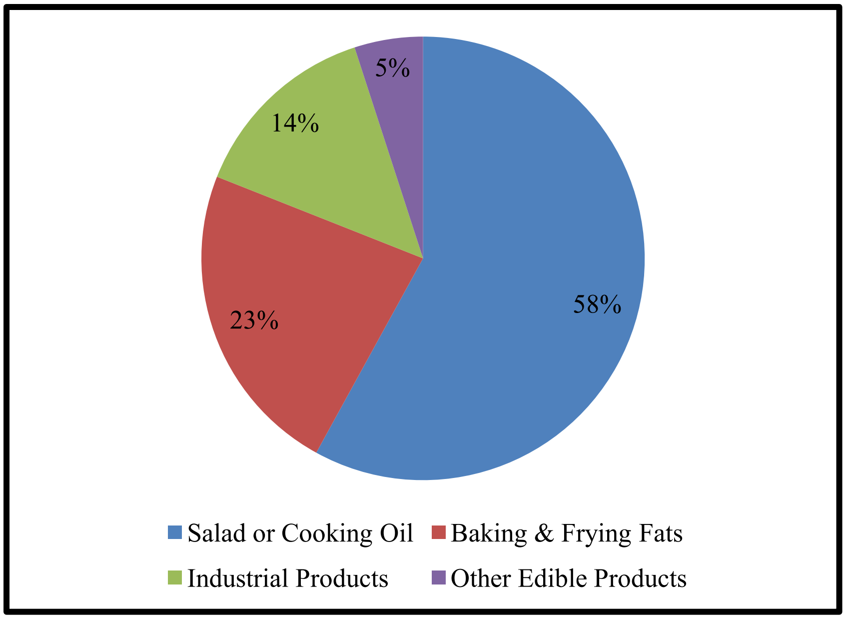


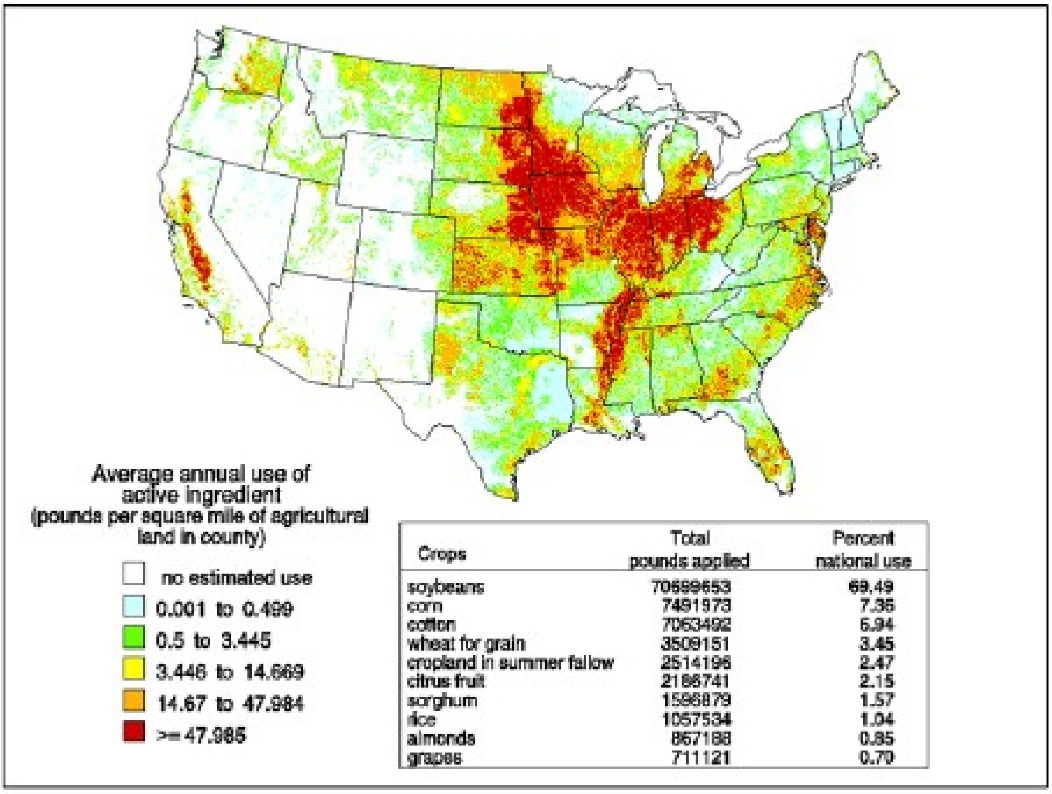
Figure II.G-1. Distribution of U.S. Soybean Oil Consumption in 2010.

Source: (ASA 2011)

Table II.G-2. Soybean crop value by state[1].

State	Crop Value ($ millions)			Percent of Total Soybean Crop Value		
	2008	2009	2010	2008	2009	2010
Alabama	126	172	100	0.4	0.5	0.3
Arkansas	1,191	1,185	1,246	4.0	3.7	3.2
Delaware	50	74	66	0.2	0.2	0.2
Florida	9	12	8	0.03	0.04	0.02
Georgia	122	155	76	0.4	0.5	0.2
Illinois	4,372	4,215	5,779	14.8	13.1	14.9
Indiana	2,492	2,612	3,050	8.5	8.1	7.8
Iowa	4,586	4,627	5,806	15.6	14.4	14.9
Kansas	1,129	1,506	1,658	3.8	4.7	4.3
Kentucky	476	675	572	1.6	2.1	1.5
Louisiana	298	354	456	1.0	1.1	1.2
Maryland	134	190	188	0.5	0.6	0.5
Michigan	687	759	1,012	2.3	2.4	2.6
Minnesota	2,675	2,674	3,717	9.1	8.3	9.6
Mississippi	728	713	846	2.5	2.2	2.2
Missouri	1,862	2,216	2,546	6.3	6.9	6.5
Nebraska	2,212	2,459	3,026	7.5	7.7	7.8
New Jersey	26	34	25	0.1	0.1	0.1
New York	107	99	147	0.4	0.3	0.4
North Carolina	514	571	496	1.7	1.8	1.3
North Dakota	1,022	1,075	1,564	3.5	3.3	4.0

[1] (USDA-NASS 2011a)



Crops	Total pounds applied	Percent national use
soybeans	70699653	69.49
corn	7491973	7.36
cotton	7063492	6.94
wheat for grain	3509151	3.45
cropland in summer fallow	2514196	2.47
citrus fruit	2186741	2.15
sorghum	1596879	1.57
rice	1057534	1.04
almonds	867188	0.85
grapes	711121	0.70

Figure II.G-2. Planted Soybean Acreage by County in the U.S. in 2012[1]

[1]Source is USDA-NASS (2012f).

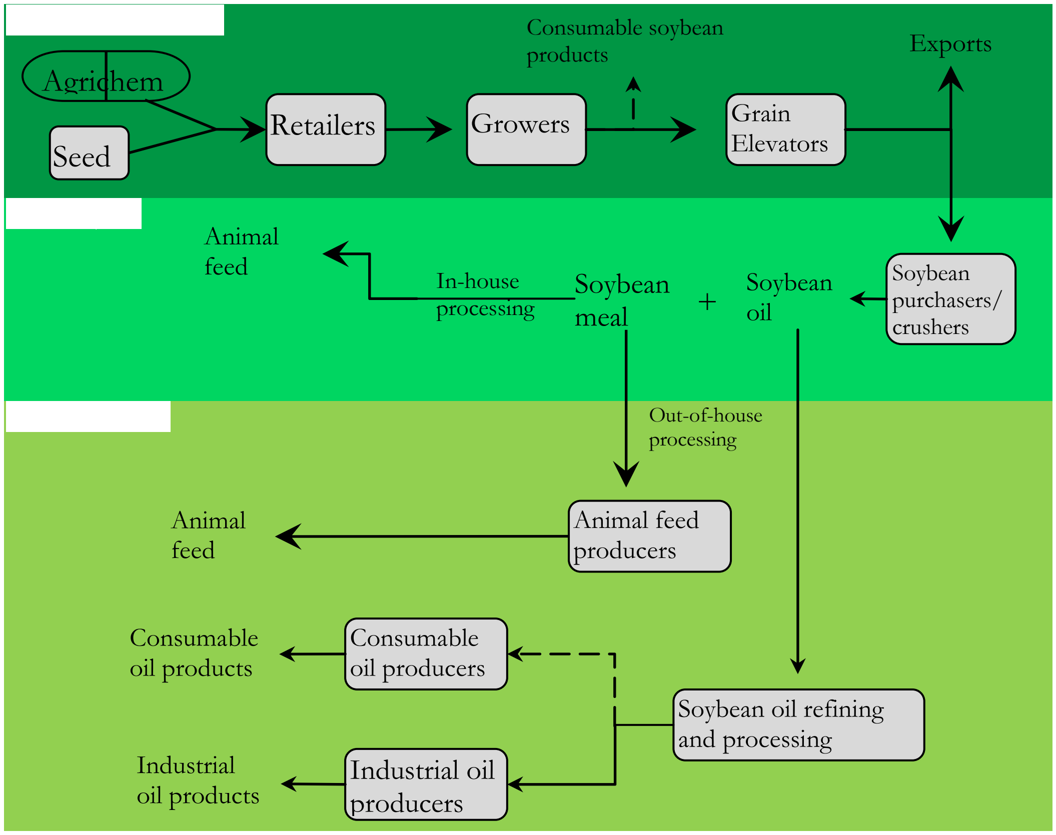


Figure II.G-3. General flow of U.S. soybean commodities.

Size of directional arrows is approximately proportional to use. For example, bold arrows represent the primary path of soybean commodities, whereas dashed arrows represent paths of soybean use that are relatively minor. Businesses are boxed in gray, while commodities are unboxed.

II.G.1.a.(1) Soybean Production Costs and Revenue

Managing input costs is a major component to the economics of producing a soybean crop (Helsel and Minor 1993). Key decisions on input costs include choosing what soybean varieties to plant, amounts of fertilizer to apply, and what herbicide program to use.

Production cost data are provided by USDA-ERS and collected in surveys conducted every four to eight years for each commodity as part of the annual ARMS (USDA-ERS 2011c). In general, operating costs represented 26% ($137/acre) of soybean farm gross income and may include expenses related to seed purchases, agronomic inputs (e.g., fertilizers, irrigation, and pesticides), and the maintenance of farm equipment. Allocated overhead costs, on the other hand, represented approximately 49% ($260/acre) of soybean farm gross income and include expenses related to labor, acquisition of farming equipment, land rental rates, taxes, and insurance premiums (USDA-ERS 2011c).

Gross value of production on a typical U.S. soybean farm in 2011 was approximately $525/acre (Table II.G-3). In total, net profit of a typical U.S. soybean farm, minus operating and overhead costs, was $129/acre in 2011 (USDA-ERS 2011c).

Table II.G-3. Soybean commodity costs and returns, 2011.

Soybean Cost/Return per Planted Acre	($ USD)
Gross value of production	
Primary Product	525.36
Total, gross value of production	525.36
Operating costs:	
Seed	55.55
Fertilizer	22.84
Chemicals	16.42
Custom operations	7.18
Fuel, lube, and electricity	20.98
Repairs	13.68
Purchased irrigation water	0.15
Interest on operating capital	0.07
Total, operating costs	136.87
Allocated overhead	
Hired labor	2.07
Opportunity cost of unpaid labor	17.09
Capital recovery of machinery and equipment	81.34
Taxes and insurance	134.30
General farm overhead	9.93
Total, allocated overhead	15.10
Total costs listed	259.83
Value of production less total costs listed	128.66
Value of production less operating costs	388.49

Source: USDA-ERS (2012c)

Soybean production practices and economic related to weed control have changed over the past fifteen years following the commercial release of Roundup Ready® soybean varieties in 1996 and LibertyLink® soybean varieties in 2009. Roundup Ready® soybeans are genetically engineered to be tolerant to glyphosate, while LibertyLink® soybeans are engineered to be tolerant to glufosinate. GE soybeans were planted on 94% of U.S. soybean acreage in 2011 (see Table II.G-4). In terms of weed control costs, Johnson et al. (2008) estimated a $1.562 billion reduction in production costs associated with grower's adoption of herbicide-tolerant soybeans in 2006. A more recent study found a $17.75 net cost saving per U.S. GE soybean acre in 2008 (Brookes and Barfoot 2012).

As of the 2010 growing season, there were 10 different weed species with glyphosate-resistant populations ranging across 25 different U.S. states (Table II.G-5) (Heap 2011). Resistant weed populations have been found in all but 1 (South Dakota) of the 10 major soybean producing states. Surveys show that farmers expect glyphosate resistance will or has increased the cost of weed control from $10.87 to $16.30 per acre (Foresman and Glasgow 2008; Hurley, et al. 2009b), and that farmers prefer to address the problem by using additional herbicides with different modes of action

(Foresman and Glasgow 2008; Johnson and Gibson 2006; Johnson, et al. 2009; Scott and VanGessel 2007).

In response to the increased incidence of glyphosate-resistant weeds, herbicide manufacturers and distributors offer incentive programs and promote diversified weed management practices. One example of such a program is the Roundup Ready PLUS ™ program that builds on the continued benefits of the Roundup Ready weed management system with glyphosate-based agricultural herbicides, but also promotes and incentives the use of additional registered herbicides to target hard to control and glyphosate-resistant weeds in soybean and cotton. The Roundup Ready PLUS program was developed by Monsanto in conjunction with academics and industry partners to help farmers improve their weed control. Herbicide providers included in the Roundup Ready PLUS program are Monsanto, Valent, Syngenta, FMC Agricultural Products, AMVAC Chemical Corporation and Makhteshim Agan of North America, Inc. (www.roundupreadyplus.com/Pages/Home.aspx)

There is consistent evidence that farmers obtain substantial financial and non-financial benefits as a result of adoption of GE crops. These benefits include an opportunity to increase income from off-farm labor; increased flexibility and simplicity in the application of pesticides; an ability to adopt more environmentally friendly farming practices; increased consistency of weed control; increased human safety; equipment savings; and labor savings (Duke and Powles 2009; Fernandez-Cornejo, et al. 2005; Fernandez-Cornejo and McBride 2002; Fernandez-Cornejo and W.D. McBride 2000; Hurley, et al. 2009a; Marra, et al. 2004).

Table II.G-4. Percentage of soybean acreage planted with GE herbicide-tolerant soybean varieties by state and for the U.S.

State	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Arkansas	43	60	68	84	92	92	92	92	94	94	96	95
Illinois	44	64	71	77	81	81	87	88	87	90	89	92
Indiana	63	78	83	88	87	89	92	94	96	94	95	96
Iowa	59	73	75	84	89	91	91	94	95	94	96	97
Kansas	66	80	83	87	87	90	85	92	95	94	95	96
Michigan	50	59	72	73	75	76	81	87	84	83	85	91
Minnesota	46	63	71	79	82	83	88	92	91	92	93	95
Mississippi	48	63	80	89	93	96	96	96	97	94	98	98
Missouri	62	69	72	83	87	89	93	91	92	89	94	91
Nebraska	72	76	85	86	92	91	90	96	97	96	94	97
North Dakota	22	49	61	74	82	89	90	92	94	94	94	94
Ohio	48	64	73	74	76	77	82	87	89	83	86	85
South Dakota	68	80	89	91	95	95	93	97	97	98	98	98
Wisconsin	51	63	78	84	82	84	85	88	90	85	88	91
Other[1] States	54	64	70	76	82	84	86	86	87	87	90	92
U.S.	54	68	75	81	85	87	89	91	92	91	93	94

Source: USDA-ERS (2011a)

[1] Includes all other states in the soybean estimating program.

Table II.G-5. Common U.S. Glyphosate-Resistant Weeds[1]

Genus and Species (Common Name)	1st Report Country (Year)	U.S. Occurrence (Year Reported)
Glycine (G/9) Resistant (i.e., glyphosate and sulfosate)		
Amaranthus palmeri (Palmer Amaranth)	U.S. (2005)	Georgia & North Carolina (2005) Arkansas & Tennessee (2006) New Mexico (2007) Mississippi & Missouri (2008) Louisiana (2010)
Amaranthus tuberculatus (Common Waterhemp)	U.S. (2005)	Missouri (2005) Illinois & Kansas (2006) Minnesota (2007) Indiana & Iowa (2009) Mississippi (2010)
Ambrosia artemisiifolia (Common Ragweed)	U.S. (2004)	Arkansas & Missouri (2004) Ohio (2006) Indiana, Kansas & North Dakota (2007) Minnesota (2008)
Ambrosia trifida (Giant Ragweed)	U.S. (2004)	Ohio (2004) Arkansas & Indiana (2005) Kansas & Minnesota (2006) Tennessee (2007) Iowa & Missouri (2009) Mississippi 2010)
Conyza canadensis (Horseweed)	U.S. (2000)	Delaware (2000) Kentucky & Tennessee (2001) Indiana, Maryland, Missouri, New Jersey & Ohio (2002) Arkansas, Mississippi, North Carolina & Pennsylvania (2003) California, Illinois & Kansas (2005) Nebraska (2006) Michigan (2007) Oklahoma (2009)

[1] Heap, 2011

II.G.1.b.

II.G.1.b.(1) Organic Soybean Production

Organic soybean was produced on 96,080 acres in 2011 and yielded 2.9 million bushels, equal to approximately 0.09% of U.S. soybean production (USDA-NASS 2012a). The average yield was 30 bushels per acre. Major production states are Iowa, Minnesota, Michigan, New York, Illinois, Nebraska, and Wisconsin (USDA-NASS 2012d). Organic soybean production acreage has ranged from 96,080 to 136,000 acres since 2000 (USDA-ERS 2010d). Organic farming operations as described by the National Organic Program, which is administered by USDA's Agricultural Marketing Service (AMS), requires organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances or products of excluded methods from adjoining land that is not under an organic production management plan. Organic production operations must also develop and maintain an organic production system plan approved by an accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition of the use of excluded methods. Excluded methods include a variety of methods used to genetically engineer organisms or influence their growth and development by means that are not possible under natural conditions or processes. The use of biotechnology such as that used to produce MON 87708 is an excluded method under the National Organic Program.

Organic certification involves oversight by an accredited certifying agent of the materials and practices used to produce or handle an organic agricultural product. This oversight includes an annual review of the certified operation's organic system plan and on-site inspections of the certified operation and its records. Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS 2010). The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in an approved organic system plan. Organic certification indicates that organic production and handling processes have been followed, not that the product itself is "free" from any particular substance.

Organic soybean producers use production practices designed to prevent commingling of their crop with neighboring crops treated with herbicides and other pesticides (spray drift), or that may be using plant varieties produced by excluded methods (pollen movement). These well established practices include isolation zones, use of buffer rows surrounding the organic crop, adjusted planting dates, and varietal selection. The implementation of management practices to avoid pollen from a biotechnology-derived crop in organic or conventional soybean production operations is facilitated by the nature of soybean pollination. Soybean is a highly self-pollinated species and exhibits a very low level of outcrossing (see Section IX.D). Outcrossing is the genetic transmission of a defined heritable characteristic from one group of individuals (population, crop variety) to another. Outcrossing most commonly results from cross-pollination. Since soybean is highly self-pollinating, organic or conventional soybean producers can and have effectively implemented practices (e.g., isolation during the growing season, equipment cleaning during harvest, and post-harvest separation of harvested seed) that allow them to reasonably avoid biotechnology-derived soybean and maintain organic or conventional production status (Brookes 2004). Information about the National Organic Program, organic standards, and practices can be viewed on line (USDA-AMS 2010).

II.G.1.c. Domestic Economic Environment: Cotton

In 2010/2011, most of the world's cotton production (116.40 million bales annually) was grown in China (30.5 million bales), India (26.4 million bales), the United States (18.1 million bales), Pakistan (8.6 million bales) and Brazil (9.0 million). In 2010/2011, the U.S. supplied over 14 million bales of the world's cotton exports, accounting for approximately 40% of the total world export market for cotton (USDA-FAS 2011b). China, Bangladesh, Indonesia, and Turkey are major importers of cotton. The largest customers for U.S. cotton are Asian countries and Mexico, due to the prevalence of textile manufacturing (NCCA 2010a; b). Cottonseed production currently results in approximately 10% of the world's oilseed production (USDA-FAS 2011a), and is exceeded by soybean (58%) and rapeseed (13%).

Gossypium hirsutum (upland cotton) cultivars account for more than 90% of the world's annual cotton crop and 97% of the U.S. cotton production (Smith and Cothren 1999; USDA-NASS 2012c). *G. barbadense*, known as extra-long staple, Pima, or Egyptian cotton, is also grown in the U.S, and accounts for approximately 3% of U.S. acreage (USDA-NASS 2012c). The long, strong, fine fibers produced by Pima are ideal for specialized uses, but due to the geographic limitation for optimum production in the U.S., it is economically less viable than the *G. hirsutum* cultivars. Pima cotton requires a longer growing season than upland cotton, and production is limited to the Southwestern states.

Cotton is a crop that produces two commodities: fiber and seed. The modern cotton gin has enhanced the value of cotton commodities by separating the fiber from the seed and by removing foreign matter, while preserving the inherent qualities of the fiber and seed (Smith and Cothren 1999). The fiber is the more valuable product of the crop, normally accounting for approximately 85% of the value of the harvested cotton. For every 100 pounds of fiber produced by the cotton plant, it also produces about 162 pounds of cottonseed (NCCA 2010a; b). Approximately one-third of the cottonseed is crushed for oil and meal used in both food products and in livestock feed. The oil is the most valuable by-product of cottonseed (NCCA 2010a). The extracted oil from cottonseed is further processed to produce cooking oil, salad dressing, shortening, and margarine. Limited quantities of the oil are used in soaps, pharmaceuticals, cosmetics, textile finishes, and other products.

II.G.1.c.(1) Cotton Production Costs and Revenue

The value of cotton production reached $7.27 billion in the U.S. in 2011 (USDA-NASS 2012a). In comparison, corn and soybean production values in 2011 were $76.46 and $35.78 billion, respectively (USDA-NASS 2012a).

The average operating cost for producing cotton in the U.S. was $465 per planted acre in 2011. The return or the value of the production less operating cost was reported to be $123 per planted acre in 2011 (USDA-ERS 2012e). The fluctuation in cotton price is the main factor contributing to the variation in value of cotton production from year to year. See Table II.G-6. These production returns for cotton do not include revenue from government program payments, which would significantly improve the return values presented for cotton. Comparable operating costs for producing corn and soybean in 2011 were $332 and $137 per acre, respectfully (USDA-ERS 2012d; b). Comparable returns for producing corn and soybean were $505 and $388 per acre, respectively.

Revenue, cost, and returns vary among cotton growing regions (Table II.G-7). The cotton growing area in Missouri ("Heartland") had the highest 2011 return per acre with $397. This region also had one of the highest average cotton and cottonseed yields (941 and 1522 pounds/planted acre, respectively). Operating costs were the highest in the Fruitful Rim region primarily due to the higher ginning costs. In the Prairie Gateway region, which is the largest cotton growing region (Kansas, New Mexico, Oklahoma, and Northern Texas), the returns on cotton were -$61 per acre in 2011. The negative returns in the Prairie Gateway region are the result of the severe drought conditions in Texas, which caused many growers not to harvest their fields.

In the Southeast, many farmers have implemented additional manual labor, such as hand-weeding, in order to achieve satisfactory control of Palmer amaranth. Georgia cotton growers have increased hand-weeding from 17% of the state cotton acreage in 2000-2005 to 52% of the acreage in 2006-2010. Hand-weeding has a current cost of $23 per acre (Sosnoskie and Culpepper 2012). A survey of Georgia cotton growers conducted in 2010 found that 92% of growers spent $16 million on hand-weeding 53% of the total Georgia cotton crop. Similarly, at least 20% of the cotton acres in Tennessee were hand-weeded at cost of more than $3 million.

The cotton industry continues to face many of the supply and demand concerns confronting other field crops. However, because cotton is used primarily in manufactured products, such as clothing and home furnishings, the industry faces additional challenges associated with the economic well-being of downstream manufacturing industries, as well as the general economic well-being of the final consumer (USDA-ERS 2009).

Table II.G-6. U.S. Cotton Production Costs and Returns From 2006 to 2011[1]

Production Cost or Return Category/ Itemized Costs	Cotton Cost/Return per Planted Acre ($ USD) 2006	2007	2008	2009	2010	2011
Gross Value of Production (cotton and cottonseed)	384.61	637.2	491.78	444.28	740.82	588.01
Operating Costs:						
Seed	61.69	60.34	64.78	73.17	80.98	96.61
Fertilizer[2]	44.55	62.81	98.25	90.77	72.86	95.06
Chemicals	62.99	63.35	62.68	67.93	67.12	66.72
Ginning	91.65	137.17	96.24	99.30	129.88	80.85
Other[3]	95.58	113.19	121.68	99.89	113.06	125.79
Total, operating costs	356.46	436.9	443.63	431.06	463.90	465.03
Allocated overhead[4]	198.61	229.5	244.57	259.43	269.34	283.82
Total cost listed	555.07	666.4	688.2	690.5	733.24	748.85
Value of production less total cost listed	-170.5	-29.2	-196.4	-246.2	7.58	-160.8
Value of production less operating costs	28.15	200.3	48.15	13.22	276.92	122.98
Supporting Information:						
Cotton yield: lbs/planted acre	686	911	632	618	780	496
Price: $/pound	0.47	0.57	0.6	0.59	0.82	0.96
Cottonseed yield: lbs./planted acre	1,113	1,474	1,023	999	1,262	802
Price: $/pound	0.06	0.08	0.11	0.08	0.08	0.14
Enterprise size (planted acres)	740	687	687	687	687	687
Production Practices:						
Irrigated (%)	31	43	43	43	43	43
Dryland (%)	69	57	57	57	57	57

[1](USDA-ERS 2012f)

[2]Commercial fertilizer, soil conditioners, and manure.

[3]Custom operations, fuel, lube, electricity, repairs, purchased irrigation water, and interest on operating costs.

[4]Hired labor, opportunity cost of unpaid labor, capital recovery of machinery and equipment, opportunity cost of land, taxes and insurance and general farm overhead.

Table II.G-7. Regional U.S. Cotton Production Costs and Returns in 2011[1]

Production Cost or Return Category/ Itemized Costs	Cotton Cost/Return per Planted Acre ($ USD)				
	Heartland	Prairie Gateway	Southern Seaboard	Fruitful Rim	Mississippi Portal
Gross Value of Production (cotton and cottonseed)	1,062.10	266.40	776.23	1,074.31	982.26
Operating Costs:					
Seed	159.42	74.72	108.38	99.98	135.96
Fertilizer[2]	119.06	54.67	147.84	123.74	126.38
Chemicals	87.03	41.14	88.13	95.41	101.85
Ginning	149.58	38.21	101.04	137.56	143.55
Other[3]	126.02	110.75	112.92	259.09	121.86
Total, operating costs	641.11	319.49	558.31	715.78	629.60
Allocated overhead[4]	375.44	235.46	296.37	393.22	348.02
Total cost listed	1,016.55	554.46	854.68	1,109.00	977.62
Value of production less total cost listed	45.55	-288.55	-78.45	-34.69	4.64
Value of production less operating costs	420.99	-53.09	217.92	358.53	352.66
Supporting Information:					
Cotton yield: lbs/planted acre	948	224	711	671	869
Price: $/pound	0.91	0.93	0.93	1.31	0.92
Cottonseed yield: lbs./planted acre	1,534	363	1,150	1,085	1,406
Price: $/pound	0.13	0.16	0.10	0.18	0.13
Enterprise size (planted acres)	861	770	453	507	954
Production Practices:					
Irrigated (%)	61	46	28	57	45
Dryland (%)	39	54	72	43	55

1 (USDA-ERS 2012e). Production regions are Farm Resource Regions defined by USDA-ERS. Heartland region includes MO cotton; Prairie Gateway includes KS, NM, OK, and Northern TX cotton; Southern Seaboard includes AL, GA, NC, SC, and VA cotton; Fruitful Rim includes AZ, CA, FL, Southern TX, Mississippi Portal includes AR, LA, MS, and TN cotton.

2 Commercial fertilizer, soil conditioners, and manure.

3 Custom operations, fuel, lube, electricity, repairs, purchased irrigation water, and interest on operating costs.

4 Hired labor, opportunity cost of unpaid labor, capital recovery of machinery and equipment, opportunity cost of land, taxes and insurance and general farm overhead.

Cotton (*Gossypium* spp.) is grown in the U.S. across southern states where the climate is warmer and the season is longer (see Figures II.B-2 and II.B-3). The total U.S. cotton acreage in the past 10 years has varied from approximately 9.15 to 15.77 million planted acres, with the lowest acreage recorded in 2009 and the highest in 2001 (Table II.G-8).

Average cotton yields have varied from 632 to 879 pounds per acre over this same time period. Total annual cotton production ranged from 12.19 to 23.89 million bales (480 pounds/bale) over the past ten years. The variations observed in cotton acreage and production is driven by current market conditions, rather than agronomic considerations. According to data from USDA-NASS (USDA-NASS, 2011b), cotton was planted on approximately 11 million acres in the U.S. in 2010, producing approximately 18 million bales of cotton (Table II.G-8). The value of cotton production reached $7.32 billion in the U.S. in 2010 (USDA-NASS, 2011b).

U.S. cotton production is divided into the following four major cotton growing regions, which span the southern and southwestern states: Southeast region (AL, FL, GA, NC, SC, and VA), Midsouth region (AR, LA, MS, MO, and TN), Southwest region (KS, NM, OK, and TX), and West region (AZ and CA) (Table II.G-9). Cotton planting and production figures for these regions in 2010 are shown in Table II.G-9 and discussed below (USDANASS, 2011e). Approximately 5.6 million acres of cotton were planted in Texas, representing about 51% of the total U.S. cotton acres. Texas produced 8.1 million bales (480 pounds/bale) of cotton, which represents approximately 44% of the U.S. cotton production. The second largest production state for cotton was Georgia with approximately 12% of U.S. cotton production. Average cotton yields across the four cotton growing regions ranged from 727 to 1416 pounds cotton lint per acre, with the highest yields in the West with full irrigation, and the lowest yields in areas such as Alabama, Oklahoma, and Texas, where little to no irrigation is employed (Table II.G-9). The average cotton yield across all regions is 821 pounds cotton lint per acre. The value of the cotton lint production among the four regions ranged from $0.86 billion in the West region to $3.35 billion in the Southwest region. The total value of the cottonseed production in the U.S. in 2010 was $1 billion with the value among the regions ranging from $134 million in the West region to $461 million in the Southwest region.

II.G.1.c.(2) Organic Cotton Production

The USDA census of organic agriculture reported organic cotton farming on 30 farms in the U.S. in 2008, two in Arizona, three in New Mexico, four in California, and 21 in Texas (USDA-NASS 2008a). Texas (66%) and New Mexico (20%) together accounted for approximately 86% of the production. Based on USDA-ERS data, between 1997 and 2008, organic cotton acreage ranged from 9,213 acres in 2004 to 15,377 acres in 2008 (USDA-ERS 2008). In 2008 about 0.16% of the total 9.41 million acres of cotton was produced organically (USDA-ERS 2008). In recent years, small and sporadic acreages of organic cotton production have been cultivated in other states, including Missouri, Illinois, Kansas, Tennessee, and Colorado (USDA-ERS 2010c). Based upon recent trend information, the presence of GE cotton varieties on the market has not affected the ability of organic production systems to maintain their market share. Between 2000 and 2008, although 11 GE cotton events were deregulated and the percent of GE cotton in the market was near or above 90% and the acreage of organic cotton production remained at approximately 15,000 acres (USDA-APHIS 2013c; USDA-ERS 2008).

The South Plains area of Texas is one of the primary regions for organic cotton production (TOCMC 2011b). Features that make the South Plains well-suited for organic cotton production include cold enough winter temperatures to limit insect pressure and to provide a hard freeze to defoliate the cotton plants prior to harvesting, and a sunny climate and quick-drying soils to facilitate timely mechanical weed control. As many of these farmers do not irrigate, yields are heavily dependent upon rainfall (TOCMC 2011b).

Organic cotton growing practices include the use of natural defoliants; beneficial insects for pest control; compost, manure, and crop rotations for fertilizers; and hand-weeding, mechanical cultivation, cover crops and mulching for weed control. The same gins and spinning mills used for non-organic cotton are also used for organic cotton; however, they must be shut down and cleaned before processing the organic cotton, which adds to production costs (TOCMC 2011a).

Most U.S. organic cotton growers sell their cotton products through a marketing cooperative, the largest of which is the TOCMC, with approximately 30 members (OTA 2012; TOCMC 2011b). Cottonseed is marketed to organic dairies for feed (TOCMC 2011b). According to a survey conducted by OTA, organic cotton growers' biggest barriers to planting more organic cotton are finding a market willing to pay the added costs of organic products, production challenges such as weed and insect control, and labor costs. "Growers also cited competition from international organic cotton producers, as well as the cost of transition to organic" (OTA 2010).

Table II.G-8. Cotton Production in the U.S., 2000-2010[1]

Year	Acres Planted (×1000)	Acres Harvested (×1000)	Average Yield (lbs/acre)	Total Production (480 lb bales)	Value (billions $)
2010	10,973	10,707	821	18,314,500	7.318
2009	9,150	7,691	777	12,187,500	3.788
2008	9,471	7,569	813	12,815,300	3.021
2007	10,872	10,489	879	19,206,900	5.653
2006	15,274	12,732	814	21,587,800	5.013
2005	14,245	13,803	831	23,890,200	5.695
2004	13,659	13,057	855	23,250,700	4.853
2003	13,480	12,003	730	18,255,200	5.517
2002	13,958	12,417	665	17,208,600	3.777
2001	15,769	13,828	705	20,302,800	3.122
2000	15,517	13,053	632	17,188,300	4.260

[1] (USDA-NASS 2011d)

Table II.G-9. U.S. Cotton Production by Region and State in 2010[1]

Region/State	Acres Planted (thousands)	Acres Harvested (thousands)	Average Yield (pounds/acre)	Total Production (thousand bales)	Cotton Lint $ Value (thousands)	Cottonseed $ Value (thousands)
Southeast Region						
Alabama	340	337	684	480	199,066	20,856
Florida	92	89	809	150	54,792	5,720
Georgia	1,330	1,320	811	2,230	926,966	91,120
North Carolina	550	545	854	970	338,957	44,992
South Carolina	202	201	872	365	136,656	16,756
Virginia	83	82	685	117	46,051	6,300
Region Totals	2,597	2,574	804	4312	1,702,488	185,744
Midsouth Region						
Arkansas	545	540	1,049	1,180	395,914	71,400
Louisiana	255	250	864	450	174,960	24,024
Mississippi	420	415	983	850	308,856	44,616
Missouri	310	308	1,068	685	226,214	40,630
Tennessee	390	387	843	680	275,482	42,180
Region Totals	1,920	1,900	971	3,845	1,381,426	222,850
Southwest Region						
Kansas	51	49	784	80	34,675	3,712
New Mexico	50	49	1,084	110	46,721	7,215
Oklahoma	285	270	738	415	180,276	20,727
Texas	5,567	5,367	723	8,082	3,083,472	429,814
Region Totals	5,953	5,734	727	8,687	3,345,144	461,468
West						
Arizona	198	196	1,460	595	246384	46,200
California	306	303	1,388	876	610042	87,599
Region Totals	504	499	1,416	1,471	856,426	133,799
U.S. Total	10,973	10,707	821	18,315	7,317,704	1,003,861

[1] (USDA-NASS 2011e)

II.G.2. Trade Economic Environments of Soybean and Cotton

II.G.2.a. Trade Economic Environment: Soybean

The United States produces approximately one-third of the global soybean supply (ASA 2012). In 2011, the U.S. exported 1.3 billion bushels of soybean, which accounted for 37 percent of the world's soybean exports. In total, the U.S. exported $30.7 billion worth of soybean and soybean products globally in 2012 (ASA 2011; USDA-FAS 2013a). China is the largest export market for U.S. soybean with purchases totaling $15 billion. Mexico is the second largest export market with sales of $1.9 billion in the same year (Table II.G-10). Other important markets include Japan and the EU.

The U.S., along with Brazil, Argentina, Paraguay, and Canada, account for 97% of the bulk soybean exported, while Argentina, Brazil, the U.S., India, and Paraguay account for 94.1% of the soybean meal exported (Table II.G-11). Argentina, the U.S., and Brazil are the dominant countries in terms of soybean oil exports accounting for 80.2% (Table II.G-11). Table II.G-12 presents the top ten U.S. export markets for soybean by volume for 2010 and 2011, during which China, Mexico, and the European Union's 27 member countries (EU-27) were the top 3 importers (USDA-ERS 2011d). As of March 2011, U.S. exports of soybean valued $13.79 billion, soybean meal approximately $2.1 billion, and soybean oil approximately $1.2 billion (USDA-ERS-FAS 2011). China, the EU-27, Mexico, and Japan are the major importers of world bulk soybean, accounting for 80.1% of total imports, whereas the EU-27, Vietnam, Thailand, Indonesia, and Japan are the largest importers of soybean meal with a world share of 57.6% (USDA-FAS, 2011a). For soybean oil, China and India are the major importers with a world share of 35.8% (USDA-FAS 2011a). U.S. soybean exports are projected to increase to approximately 1.5 billion bushels (33.2 million metric tons) in 2020 (USDA 2011).

Approximately 94% of the world's soybean seed supply was crushed to produce soybean meal and oil in 2008 (Soyatech 2010), and the majority was used to supply the feed industry for livestock use or the food industry for edible vegetable oil and soybean protein isolates.

Soybean exports in the form of bulk beans, meal, and oil are a major share of the total agricultural exports for the U.S., representing 20.1% of the total value of U.S. exports. The value of U.S. agricultural exports was $108.67 billion in 2010 (USDA-ERS 2011c). Bulk soybeans accounted for $16.9 billion of this total, ranking first among all agricultural commodities, while soybean meal, at a value of $3.78 billion, and soybean oil, at a value of $1.35 billion, ranked 6th and 16th, respectively (USDA-ERS 2011c). The U.S. was responsible for 44.0% of the world's bulk soybean exports, 18.2% of the world's soybean meal exports, and 16.8% of the world's soybean oil exports (Tables II.G-13, II.G-14).

Soybean meal represented 68% of the protein meal produced worldwide, though soybean ranked behind palm in terms of worldwide vegetable oil production (USDA-FAS 2011c). Similarly, soybean held the largest share of protein meal consumed worldwide, mainly as animal feed (USDA-FAS 2011c), with soybean oil again coming in second behind palm oil in terms of worldwide vegetable oil consumption (USDA-FAS 2011c).

Table II.G-10. U.S. Export Markets for Soybean and Soybean Products.

Top Ten U.S. Export Customers 2012 (millions of dollars)*					
Soybean Exports		Soybean Meal Exports		Soybean Oil Exports	
China	14,973	Mexico	654	China	265
Mexico	1,862	Philippines	599	Mexico	209
Japan	1,127	Canada	485	Morocco	162
Indonesia	994	Venezuela	348	India	96
Germany	867	Ecuador	258	Nicaragua	60
Taiwan	768	Morocco	218	Venezuela	54
Egypt	739	Egypt	212	Canada	39
Turkey	457	Dominican Republic	194	Colombia	34
Thailand	407	Guatemala	150	Jamaica	32
South Korea	395	Japan	149	Domican Republic	27
Other	2,116	Other	1,589	Other	181
Total	24,705	Total	4,856	Total	1,159

*Values of exports are listed in millions of dollars

Source: (USDA-FAS 2013b)

Table II.G-11. World Soybean Exports in 2009/2010.

Location	Soybean Bulk	Soybean Meal	Soybean Oil
	(million metric tons)		
Argentina	13.09	24.91	4.45
Bolivia	--[1]	--	0.26
Brazil	28.58	12.99	1.45
Canada	2.25	--	--
EU-27[2]	--	--	0.38
India	--	3.15	--
Paraguay	5.35	1.12	0.24
Russia	--	--	0.17
United States	40.85	10.14	1.52
Other	2.53	3.29	0.79

Source: USDA-FAS (2011c).

[1] -- = No Data

[2] European Union 27 member countries

Table II.G-12. Top 10 U.S. Soybean Export Markets in 2010/2011.

Location	January-October 2010	January-October 2011	October 2010	October 2011
	(million metric tons)			
China	15.65	13.86	5.58	3.88
Mexico	3.02	2.76	0.56	0.51
EU-27[1]	1.30	1.41	0.99	0.12
Japan	2.03	1.39	0.24	0.11
Taiwan	2.03	1.32	0.44	0.067
Indonesia	1.18	1.11	0.16	0.081
Egypt	0.86	0.57	0.12	0.14
Turkey	0.58	0.42	0.17	0.0029
South Korea	0.26	0.31	0.036	0.012
Syria	0.14	0.23	0.039	0.018
World Total	29.92	25.26	8.00	5.26

Source: (USDA-ERS 2011d)

[1] European Union 27 member countries

Table II.G-13. U.S. and Rest of World (ROW) Soybean Supply and Disappearance[1] 2009/10.

	Soybeans		Soybean Meal		Soybean Oil	
	U.S.	ROW	U.S.	ROW	U.S.	ROW
	(Million Metric Tons)					
Total	95.58	294.71	38.19	184.03	10.24	40.13
	-----Supply-----					
Beginning Stocks	3.76	38.82	0.21	4.20	1.30	1.62
Production	91.42	168.85	37.83	127.45	8.90	29.87
Imports	0.40	87.04	0.15	52.38	0.05	8.64
	-----Disappearance-----					
Crush	47.67	161.84	--[2]	--	--	--
Feed, Seed & Residual	2.95	26.09	--	--	--	--
Domestic	--	--	27.78	132.84	7.20	31.06
Exports	40.85	51.89	10.14	45.56	1.52	7.54
Ending Stocks	4.11	54.89	0.27	5.63	1.52	1.53

Source: USDA-ERS (USDA-ERS 2011e).

[1] Disappearance is the consumed supply [2]No data

Table II.G-14. World Soybean Production in 2009/2010.

Location	Soybean	Soybean Meal	Soybean Oil
	(million metric tons)		
Argentina	55	26.62	6.48
Brazil	69	26.12	6.47
Canada	4	--[1]	--
China	15	38.64	8.73
EU-27[2]	--	9.88	2.28
India	10	5.99	1.34
Mexico	--	2.83	0.64
Paraguay	7	--	--
United States	91	37.83	8.90
Other	11	17.37	4.06

Source: USDA-FAS (2011c).

[1]-- = No Data

[2] European Union 27 member countries

II.G.2.b. Trade Economic Environment: Cotton

Cotton is a crop that is primarily grown for fiber used in textiles. After ginning of the primary commodity, fiber, the cottonseed and cottonseed by-products (meal, hulls, linters, and oil) are utilized for various feed and industrial components.

Cottonseed currently comprises 10% of the world's oilseed production (USDA-FAS 2010), exceeded only by soybean (58%) and rapeseed (13%). Cottonseed is processed into four major by-products: oil, meal, hulls, and linters. Cottonseed oil is used as a primary source of vegetable oil, in the United States, and is utilized in many food applications. Cottonseed meal, hulls and whole cottonseed are natural sources of protein, fiber, and energy. Cottonseed meal can be used in both ruminant and monogastric rations while hulls serves as a source of roughage for ruminant feeds and fiber for monogastric rations. In addition, cottonseed is concentrated as feed, providing protein and energy for ruminant rations. Consequently, cottonseed and cottonseed by-products are primarily used domestically with approximate volumes of 1.3% of whole cottonseed, 10.8% of meal, 28.7% oil from US production being exported (Monsanto 2013).

Trade of cotton lint or fiber is particularly important for cotton. About 38% of the world's consumption of cotton fiber, a larger share than for wheat, corn, soybeans, or rice, crosses international borders before processing (Meyer, et al. 2007). Through trade in yarn, fabric, and clothing, much of the world's cotton again crosses international borders at least once more before reaching the final consumer (Meyer et al. 2007).

Starting in the 1930s, the U.S., Canada, and Europe entered into trade agreements that set limits on the amount of foreign-made apparel and textiles that could be imported into the U.S. The last of these agreements, the Multifibre Arrangement (MFA), ended in 2005 (Meyer et al. 2007). Consumption of cotton by U.S. textile mills peaked in 1997. Since then, U.S. mill use of cotton has dropped by approximately 50% in 2005 and by nearly 70% in 2009 (USDA-ERS 2009). This change in foreign-made textile imports resulted in increased global competition for import and export of raw cotton, as well as finished textiles (Meyer et al. 2007). U.S. consumer demand for cotton products remains strong, but imported clothing now accounts for most purchases by U.S. consumers (USDA-ERS 2009). The USDA-ERS reports that U.S. cotton mills consumed 60% of the domestic cotton through the 1990s, but not long after the end of MFA quotas, 70% of the U.S. cotton lint was exported (Meyer et al. 2007).

The cotton industry continues to face many of the supply and demand concerns confronting other field crops. However, because cotton is used primarily in manufactured products, such as clothing and home furnishings, the industry faces additional challenges associated with the economic well-being of downstream manufacturing industries, as well as the general economic well-being of the final consumer (USDA-ERS 2009).

II.G.3. Public Perceptions of Genetically Engineered Crops in Food

Growing urbanization over the last century and a half has left the American population geographically and generationally removed from the farm. Fewer than 2% of the American population live and work on farms. Surveys indicate that consumers understand very little about the food they consume (Godwin, et al. 2005; Lusk 2011).

The food production system is complex, comprised of a number of actors and institutions along an extensive value chain. The system increasingly relies on scientifically and technically complex production methods and inputs to achieve production efficiencies to meet demand (Lang 2013). These rapid technological changes create uncertainties for the public (Arnot 2011; 2013; Ryan and Doerksen 2013). Rapid growth in internet usage and rapid adoption of mobile devices and use of social media offers the consumer immediate access to an information-rich environment. The role of mass media and the rise of citizen journalist as well as the influence of celebrity have created an environment where distorted or misleading information about food and the food production system rapidly circulates. This has led to staunch and vocal opposition to products of genetic engineering (Chassy 2007) which in turn has had an impact on the general public's perception of genetically engineered (also referred to as GM) crops. This shift in consumer perceptions also plays out in other ways economically and politically. In recent years, there have been a number of state ballot initiatives in the US that would require mandatory labeling of genetically engineered-derived products. For example, California's Proposition 37, which would have required labeling of GM foods, was presented and defeated on the November 2012 ballot. Proposition 37 has spurred another two dozen state and municipal level initiatives (Clark, et al. 2013). The FDA provides guidelines on voluntary labeling of foods derived from genetically engineered crops (U.S. FDA 2001a; 2013).

Studies on consumer preferences of food derived from genetically engineered crops ("GM food") have been conducted in over 20 countries based on a number of factors including willingness to pay (Colson, et al. 2011). Yet, consumer preferences of GM food play out in different ways under different survey conditions which speak to "wildly differing results" of studies (Colson et al. 2011). Results are significantly influenced by the methods used to elicit those preferences, e.g., mail, phone surveys, experimental auctions, in-person surveys (Lusk 2011). Given the differing results, it is difficult to draw any definitive conclusions on consumer perceptions about GM foods (Lusk 2011). It has been reported, however, that US consumers are more accepting of GM foods that their European counterparts (Lusk 2011). This has been confirmed through economic experiments involving real food and real money by Lusk et al (2006).

Although scientific literacy, overall, has been rising in the United States, the level of public confusion is greatest in the area of the life sciences. Public understanding of biotechnology and food, in general, is very low (The Mellman Group 2006). Lusk (2011) reports on a survey by the Pew Initiative on Food and Biotechnology (The Mellman Group 2006). Only 26% of consumers surveyed believe that they had consumed a GM food and 74% indicated that they had little to no knowledge about the government regulation of food. Lusk et al (2006) conducted a meta-analysis where 82% of the 57 studies demonstrated a willingness to pay a premium to avoid non-GM foods. Other results of the meta-analysis suggest that consumers are most averse to the use of genetic engineering in meat product and least averse to its use in oil (Lusk 2011). Despite 'stated' low to no preference for GM foods, the market for "GM-free" food remains quite small in the United States (Lusk 2011).

While some studies reveal that information can shift consumer preferences (Colson et al. 2011; Huffman, et al. 2003). Others suggest that top-down, fact-focused approaches are a flawed approach to influencing consumer perceptions (Ryan 2013; Sapp, et al. 2009). Public opinion or consumer preferences are clearly not formed on scientific evidence alone. In a world of uncertainties, choices in the marketplace are influenced not only by preferences but also by beliefs (Lusk 2011).[44]

III. ALTERNATIVES

III.A. INTRODUCTION & DESCRIPTION OF ALTERNATIVES

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for regulating the introduction (importation, interstate movement, and environmental release) of genetically engineered (GE) organisms that are known to, or could, pose a plant pest risk. GE organisms are considered to be regulated articles if the donor organism, recipient organism, vector, or vector agent used in their creation is a member of a taxonomic group listed in the regulations in 7 CFR Part 340 and is known to be a plant pest, or the plant pest status of that organism is not known. A person may petition APHIS to evaluate submitted data and assess whether a particular regulated article is unlikely to pose a plant pest risk and, therefore, should no longer be subject to the regulations in 7 CFR Part 340. Pursuant to 7 CFR § 340.6, the petitioner is required to provide information related to plant pest risk that the agency uses to assess whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. If, based on this information, the agency concludes that the article is unlikely to pose a greater plant pest risk, the agency may make a determination to approve the petition and confer nonregulated status on the regulated article. Thereafter, APHIS would no longer require permits or notifications for the introduction of the GE organism.

This assessment considers whether to approve two petitions seeking a determination of nonregulated status for soybean and cotton cultivars genetically engineered to be resistant to herbicides. The first petition, APHIS Petition Number 10-188-01p, seeks a determination of nonregulated status of soybean (*Glycine max*) designated as event Dicamba Tolerant Soybean MON 87708 (hereinafter referred to as DT soybean), which has been genetically engineered for tolerance to the herbicide dicamba. The second petition, APHIS Petition Number 12-185-01p, seeks a determination of nonregulated status of cotton (*Gossypium* spp.) designated as event Dicamba Glufosinate Tolerant Cotton MON 87701 (hereinafter referred to as DGT cotton), which has been genetically engineered for tolerance to the herbicides dicamba and glufosinate.

This assessment concludes that both DT soybean and DGT cotton are no more likely to pose a plant pest risk than other soybean or cotton varieties. This assessment also addresses the potential impacts on the human environment of DT soybean and DGT cotton use in American agriculture—including the potential selection of dicamba resistant weeds as a potential effect of altered herbicide use— if DT soybean and DGT cotton are granted nonregulated status. These effects are considered in four reasonable alternatives discussed in greater detail below. The alternatives represent a full range of reasonable alternatives in reference to the petitions for nonregulated status, and are framed to highlight the issues associated with the cultivation of DT soybean and DGT cotton if each

[44] Lusk (2011) suggests that consumer beliefs have not been studied in a theoretically consistent manner by economists.

determined to have met the criteria to be deregulated. These alternatives vary in their feasibility based on regulatory and economic considerations. The four reasonable and appropriate alternatives include:

- Deny both petitions for determination of nonregulated status (No Action Alternative);
- Approve the petition for determination of nonregulated status of DT soybean, and deny the petition for determination of nonregulated status of DGT cotton; and
- Approve the petition for determination of nonregulated status of DGT cotton, and deny the petition for determination of nonregulated status of DT soybean;
- Grant both petitions for determination of nonregulated status (full deregulation of DT soybean and DGT cotton) (preferred alternative).

Additional alternatives (described in Section III.F) were considered but eliminated from further consideration because they were either unreasonable or inappropriate since they failed to meet the regulatory program's legally authorized purpose and need.

III.B. ALTERNATIVE 1 – DENY BOTH PETITIONS FOR DETERMINATION OF NONREGULATED STATUS (NO ACTION ALTERNATIVE)

Under Alternative 1, the petitions seeking a determination of nonregulated status of DT soybean and DGT cotton would be denied. DT soybean and DGT cotton would accordingly remain regulated articles under 7 CFR Part 340, and all environmental releases and interstate movements of DT soybean and DGT cotton would continue to be subject to APHIS' biotechnology regulations and the requirements of 7 CFR Part 340. Because DT soybean and DGT cotton and progeny derived from DT soybean and DGT cotton would remain regulated articles under 7 CFR Part 340, Alternative 1 would maintain the status quo. Alternative 1 therefore constitutes the No Action Alternative. Notifications or permits with conditions specified by APHIS would be required to move viable plant material and to plant DT soybean or DGT cotton outdoors, and measures to ensure physical and reproductive confinement would continue to be implemented. Deregulation of DT soybean and DGT cotton would not be permitted under Alternative 1.

This alternative is not the preferred alternative because, as demonstrated in the petitions for deregulation and Appendix G of this Environmental Report DT soybean and DGT cotton are unlikely to present a greater plant pest risk than the conventional counterparts. Choosing this alternative therefore would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status. Under the no-action alternative, growers will likely continue to use biotechnology-derived herbicide-tolerant soybean and cotton products that have been deregulated by APHIS, as well as herbicides to control weeds in soybean and cotton fields. Biotechnology-derived herbicide-tolerant varieties currently account for approximately 94% of soybean production and 73% percent of cotton production in the United States. Deregulated varieties would continue to be available commercially, and would be expected to continue to be widely grown, under this alternative. Because of existing resistance to currently available herbicides used in soybean and cotton production, and in the absence of new herbicide options, the number of weed populations and species with multiple resistances in soybean and cotton production areas may increase. So too may resistance to herbicide classes that are being relied on to manage current levels of resistance to glyphosate and other herbicides.

III.C. ALTERNATIVE 2 - APPROVE THE PETITION FOR DETERMINATION OF NONREGULATED STATUS OF DT SOYBEAN, AND DENY THE PETITION FOR DETERMINATION OF NONREGULATED STATUS OF DGT COTTON

Under Alternative 2, the petition seeking a determination of nonregulated status of DT soybean would be granted, and DT soybean and its progeny would no longer be regulated articles under 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of DT soybean, and growers could freely move and plant DT soybean without further oversight from the agency. The petition seeking a determination of nonregulated status of DGT cotton, however, would be denied, and DGT cotton and its progeny would remain regulated articles under 7 CFR Part 340. All environmental releases and interstate movements of DGT cotton would continue to be subject to APHIS' biotechnology regulations and the requirements of 7 CFR Part 340. Notifications or permits with conditions specified by APHIS would be required to move viable plant material and to plant DGT cotton outdoors, and measures to ensure physical and reproductive confinement would continue to be implemented.

As demonstrated in the petitions for deregulation and Appendix G of this Environmental Report, DT soybean is unlikely to pose a greater plant pest risk than its conventional counterpart. Accordingly, it would be appropriate to conclude that a determination of nonregulated status of DT soybean is consistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR Part 340, and the biotechnology regulatory policies in the Coordinated Framework. Approving the petition for DT soybean is also consistent with recent Ninth Circuit precedent, which provides that once a GE organism is determined not to pose a plant pest risk, it can no longer be subject to the plant pest provisions of the PPA or regulation under 7 CFR Part 340.[45]

However, this alternative is not the preferred alternative because, as demonstrated in the petitions for deregulation and Appendix G of this Environmental Report, DGT cotton is unlikely to pose a greater plant pest risk than its conventional counterpart. It would therefore be appropriate to conclude that choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status. The plant pest provisions of the PPA and the regulations at 7 CFR Part 340 do not justify denying a petition for determination of nonregulated status of DGT cotton where DGT cotton has not been found to pose a greater plant pest risk than its conventional counterpart. Moreover, under this alternative, growers will continue to use biotechnology-derived herbicide-tolerant cotton products that have been deregulated by APHIS, as well as herbicides to control weeds in cotton fields. Biotechnology-derived herbicide-tolerant varieties currently account for approximately 73% of cotton production in the United States. Deregulated varieties would continue to be available commercially, and would be expected to continue to be widely grown, under this alternative. Because of existing resistance to currently available herbicides used in cotton production, and in the

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[45] *Id.*

absence of new herbicide options, the number of weed populations and species with multiple resistance in cotton production areas may increase. So too may resistance to herbicide classes that are being relied on to manage current levels of resistance to glyphosate and other herbicides.

III.D. ALTERNATIVE 3 - APPROVE THE PETITION FOR DETERMINATION OF NONREGULATED STATUS OF DGT COTTON, AND DENY THE PETITION FOR DETERMINATION OF NONREGULATED STATUS OF DT SOYBEAN

Under Alternative 3, the petition seeking a determination of nonregulated status of DGT cotton would be granted, and DGT cotton and its progeny would no longer be regulated articles under 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of DGT cotton, and growers could freely move and plant DGT cotton without further oversight from the agency. The petition seeking a determination of nonregulated status of DT soybean, however, would be denied, and DT soybean and its progeny would remain regulated articles under 7 CFR Part 340. All environmental releases and interstate movements of DT soybean would continue to be subject to APHIS' biotechnology regulations and the requirements of 7 CFR Part 340. Notifications or permits with conditions specified by APHIS would be required to move viable plant material and to plant DT soybean outdoors, and measures to ensure physical and reproductive confinement would continue to be implemented.

DGT cotton is unlikely to pose a greater plant pest risk than conventional cotton, as demonstrated in the petitions for deregulation and Appendix G of this Environmental Report. Accordingly, it would be appropriate to determine that nonregulated status of DGT cotton is consistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR Part 340, and the biotechnology regulatory policies in the Coordinated Framework. A determination of nonregulated status is also consistent with recent Ninth Circuit precedent, which provides that once a GE organism is determined not to pose a plant pest risk, it can no longer be subject to the plant pest provisions of the PPA or regulation under 7 CFR Part 340.[46]

However, this alternative is not the preferred alternative because as demonstrated in the petitions for deregulation DT soybean is unlikely to present a greater plant pest risk than the unmodified parental organism. Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status. The plant pest provisions of the PPA and the regulations at 7 CFR Part 340 do not justify denying a petition for determination of nonregulated status of DT soybean where DT soybean has not been found to pose a greater plant pest risk than conventional soybean. Moreover, under this alternative, growers will continue to use biotechnology-derived herbicide-tolerant soybean products that have been deregulated by APHIS, as well as herbicides to control weeds in soybean fields. Biotechnology-derived herbicide-tolerant varieties currently account for approximately 94% of soybean production in the United States. Deregulated varieties would continue to be available commercially, and would be expected to continue to be widely grown, under this alternative. Because of existing resistance to currently available herbicides used in soybean productions, and in

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[46] *Id.*

the absence of new herbicide options, the number of weed populations and species with multiple resistance in soybean production areas may increase. So too may resistance to herbicide classes that are being relied on to manage current levels of resistance to glyphosate and other herbicides.

III.E. ALTERNATIVE 4 – GRANT BOTH PETITIONS FOR DETERMINATION OF NONREGULATED STATUS (FULL DEREGULATION OF DT SOYBEAN AND DGT COTTON)

Under Alternative 4, the petitions seeking a determination of nonregulated status of DT soybean and DGT cotton, and all progeny derived from each, would be granted, and DT soybean and DGT cotton would no longer be regulated articles under 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of DT soybean and DGT cotton. Growers could therefore freely move and plant DT soybean and DGT cotton without further oversight from APHIS. It would be appropriate to conclude that this alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements of 7 CFR Part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act (PPA). Because, as demonstrated in the petitions for deregulation and Appendix G of this Environmental Report, DT soybean and DGT cotton are unlikely to pose a greater plant pest risk than their conventional counterparts, a determination of nonregulated status of DT soybean and DGT cotton is a response that is consistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR Part 340, and the biotechnology regulatory policies in the Coordinated Framework. This alternative is also consistent with recent Ninth Circuit precedent, which provides that once a GE organism is determined not to pose a plant pest risk, it can no longer subject to the plant pest provisions of the PPA or regulation under 7 CFR Part 340.[47]

Under this alternative, growers may have future access to DT soybean and DGT cotton and progeny derived from these events if the developer decides to commercialize DT soybean and DGT cotton. With the approval by EPA for the use of dicamba on DT soybean and DGT cotton[48], and the integration of DT soybean and DGT cotton into the glyphosate-tolerant soybean and cotton systems through traditional breeding, the combined crop-tolerances to glyphosate, dicamba, and, for DGT cotton, glufosinate, would allow growers to utilize glyphosate, dicamba, and glufosinate herbicides in their weed management systems, as well as other herbicides currently registered for use in soybean and cotton.

47 See Ctr. for Food Safety v. Vilsack, 718 F.3d 829 (9th Cir. 2013).

48 EPA has previously approved the use of glufosinate over the top of glufosinate tolerant cotton.

III.F. ALTERNATIVES CONSIDERED BUT ELIMINATED FROM DETAILED EVALUATION

III.F.1. Approve Both Petitions For Determination of Nonregulated Status Only in Part (Isolation Distances, Geographic Restrictions, and Other Restrictions On Use)

In response to public concerns of gene flow between GE and non-GE plants, this analysis considered requiring an isolation distance separating DT soybean and DGT cotton from non-GE soybean and non-GE cotton production, respectively. Given that the petitions for deregulation DT soybean and DGT cotton demonstrate that they are unlikely to present a greater plant pest risk than their conventional counterparts, an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR Part 340.

This analysis also considered geographically restricting the production of DT soybean and/ or DGT cotton based on the location of production of non-DT soybean and non-DGT cotton in organic production systems or production systems for GE-sensitive markets. However, there are no geographic differences associated with any identifiable plant pest risks for DT soybean and DGT cotton. This alternative was rejected and not analyzed in detail because this analysis has concluded that DT soybean and DGT cotton do not pose a greater plant pest risk than their conventional counterparts, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with the statutory authority conferred by the plant pest provisions of the PPA and regulations in 7 CFR Part 340, as well as the biotechnology regulatory policies embodied in the Coordinated Framework.

The imposition of isolation distances or geographic restrictions would not meet the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements of 7 CFR Part 340 and the plant pest provisions of the PPA. Nor would deregulating (approval whole) DT soybean and DGT cotton only in part, under certain circumstances, absent a finding that DT soybean and DGT cotton pose a greater plant pest risk than their conventional counterparts. Consideration of a partial approval alternative is dependent upon a finding that the products in question have the potential to pose a plant pest risk in certain geographies or under certain conditions. It may then be appropriate to impose conditions upon the cultivation or use of the products in specific geographies or under conditions that mitigate the potential plant pest risk. However, DT soybean and DGT cotton have been thoroughly characterized, and extensive information has been presented demonstrating that DT soybean and DGT cotton do not present a plant pest risk under any circumstance. (See DT Soybean Petition for Deregulation #10-188-01p; DGT Cotton Petition for Deregulation #12-185-01p_1a; and Appendix G of this Environmental Report Therefore, from a plant pest risk perspective, there is no basis for imposing geographic or other restrictions on DT soybean and DGT cotton.

Moreover, the use of dicamba for agricultural purposes was first established in 1967, and, with the reregistration in 2006, the U.S. Environmental Protection Agency (EPA) recently reaffirmed that its use presents no unreasonable adverse effectswhen applied according to label directions, including in soybean and cotton production. The authority to determine whether and how dicamba may be used belongs solely to EPA; no other agency has the regulatory authority to restrict the use of pesticides or impose measures to mitigate their risk. Monsanto has applied for a label amendment for use of dicamba on DT soybean and DGT cotton. EPA will review the proposed label amendments and assess if the requested use pattern and use instructions meet the FIFRA standard of no unreasonable adverse effects. On the basis of this analysis demonstrating that there is no plant pest risk consideration or other risk that would lead to approval in part, and because only EPA has authority to regulate pesticides like dicamba and glufosinate, the alternative of approval in part was not considered further in this analysis. Any request to consider the effects of herbicide drift on downwind crops should properly be directed to EPA, which is the sole agency with authority to regulate pesticides.

III.F.2. Require Testing for DT Soybean and DGT Cotton

This analysis considered the appropriateness of requiring or providing testing for GE products in non-GE production systems. However, there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because DT soybean and DGT cotton do not pose a pose a greater plant pest risk than their conventional counterparts, the imposition of any type of testing requirement is inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR Part 340, and the biotechnology regulatory policies embodied in the Coordinated Framework. Moreover, this alternative is outside the scope of the decision being made by APHIS, which is whether or not to grant the petitions for nonregulated status of DT soybean and DGT cotton. An alternative with testing for GE products in non-GE production systems would be a regulatory program and not an alternative to full deregulation. Moreover, requiring testing of non-GE organisms would burden growers of conventional soybean and cotton crops who are not currently subject to the regulations of 7 CFR Part 340. Such a requirement would have no bearing on the introduction and dissemination of plant pests, and it is inconsistent with an equitable coexistence policy. Imposing such a requirement for DT soybean and DGT cotton, therefore, would not meet the purpose and need to respond appropriately to the petitions in accordance with regulatory authorities.

III.F.3. Ban All Planting of DT Soybean and DGT Cotton

Another alternative considered but rejected was to prohibit the growth of DT soybean and DGT cotton in the United States. This alternative would require current planting of DT soybean and DGT cotton to be removed from fields. Current seed stores would also need to be destroyed or shipped to countries that permit the use of these products. Non-DT soybean and non-DGT cotton varieties would not be available to growers who wish to grow soybean and cotton. Research and development of DT soybean and DGT cotton varieties would not be permitted.

This analysis rejected this alternative from further consideration because it does not meet the purpose and need to respond appropriately to the petitions in accordance with regulatory authorities. APHIS currently regulates DT soybean and DGT cotton under 7 CFR Part 340. Under this alternative, APHIS would not be able to authorize their introduction even with permits and notifications, which is currently done under the regulations. APHIS has issued many of these regulatory authorizations in the past and has not identified any plant pest-related justification to discontinue issuing permits or acknowledging notifications for DT soybean and DGT cotton. To prohibit all planting and growth of DT soybean and DGT cotton would be inconsistent with the government's policies to allow the safe development of GE organisms. Further, this alternative would be inconsistent with the government's policy and need to support the coexistence of GE and non-GE production systems.

III.G. COMPARISON OF IMPACTS BY ALTERNATIVE MATRIX

Table III.G-1 below summarizes the environmental impacts of the proposed action and alternatives by resource area.

Table III.G-1 Summary of Impacts of Each Alternative

	No Action Alternative For Both	**Approval in Whole of DT Soybean But Not DGT Cotton**	**Approval in Whole of DGT Cotton But Not DT Soybean**	**Approval in Whole of Both**
Agricultural Production				
Crops Use & Biology	The use of herbicides in soybean and cotton production is expected to continue to increase as more growers in certain areas of the U.S. adopt diversified weed management strategies to combat hard-to-control herbicide-resistant weeds. Some of the available herbicides may pose greater potential risks to animals or insects than dicamba. Conventional tillage practices may increase; increased use of tillage could have a small	Effects to mammals that consume DT soybean seed would be no different than those possible from the consumption of commercially cultivated soybean. The impact to birds or other animals, including migratory birds and animals that may consume soybean forage or seed from DT soybean would be no different than possible impacts from commercially cultivated soybean.	Effects to mammals that consume DGT cotton seed would be no different than those possible from the consumption of commercially cultivated cotton. The impact to birds or other animals, including migratory birds and animals that may consume seed from DGT cotton would be no different than possible impacts from commercially cultivated cotton. Use of herbicides is expected to increase as	No effects to animals are anticipated from consumption of DT soybean or DGT cotton seed or forage. Use of herbicides is expected to increase as more growers adopt diversified weed management strategies to combat hard-to-control and herbicide-resistant weeds, but dicamba is expected to displace some herbicides that would otherwise be used, and which could have a more significant environmental footprint. The increased ability to

	adverse impact on wildlife, as the crop residues that remain with the use of conservation tillage may provide shelter and food for wildlife, such as game birds and small animals.	Use of herbicides is expected to increase as more growers adopt diversified weed management strategies to combat hard-to-control and an increased number of herbicide-resistant weeds, but dicamba is expected to displace some herbicides that would otherwise be used, and which could have a more significant environmental footprint. The increased ability to sustain use of conservation tillage is expected to result in a small positive impact on wildlife, as the crop residues that remain with the use of conservation tillage may provide shelter and food for wildlife, such as game birds and small animals.	more growers adopt diversified weed management strategies to combat hard-to-control and an increased number of herbicide-resistant weeds, but dicamba is expected to displace some herbicides that would otherwise be used, and which could have a more significant environmental footprint. The increased ability to sustain use of conservation tillage is expected to result in a small positive impact on wildlife, as the crop residues that remain with the use of conservation tillage may provide shelter and food for wildlife, such as game birds and small animals.	sustain use of conservation tillage is expected to result in a small positive impact on wildlife, as the crop residues that remain with the use of conservation tillage may provide shelter and food for wildlife, such as game birds and small animals.
General Agronomic Practices	Unchanged	Unchanged	Unchanged	Unchanged
Tillage	Increased tillage is likely to control problematic herbicide-resistant weeds	Conservation tillage levels should be preserved on soybean	Conservation tillage levels should be preserved on cotton	Conservation tillage levels should be preserved on soybean

		acres because dicamba will provide an additional mode-of-action herbicide to combat resistant weeds	acres because dicamba will provide an additional mode-of-action herbicide to combat resistant weeds	and cotton acres because dicamba will provide an additional mode-of-action herbicide to combat resistant weeds
Pest Management	Unchanged	Unchanged	Unchanged	Unchanged
Weed Management	Growers would continue to use the glyphosate-tolerant soybean system for broad spectrum weed control, other registered alternative herbicides alone or in combination with other herbicide-tolerant soybean and/or cotton varieties for targeted hard-to-control weeds, and/or incorporate tillage into their practices. The inability to integrate DT soybean or DGT cotton into the glyphosate-tolerant soybean and cotton systems could increase the potential for herbicide-resistant weed populations to evolve and spread in certain soybean- and cotton- producing	Conservation tillage practices are expected to be sustained and potentially increase, and the DT soybean system will provide soybean growers with a more flexible and reliable weed management options and an additional mode-of-action herbicide to combat resistant weeds. Hand weeding is expected to decrease as a result of the effective and reliable weed management option provided by DT soybean. Cotton growers in certain areas of the U.S. would continue to experience weed control challenges with hard-to-control (e.g., morningglory) and	Conservation tillage practices are expected to be sustained and potentially increase, and the DT soybean system will provide soybean growers with a more flexible and reliable weed management options and an additional mode-of-action herbicide to combat resistant weeds. Hand weeding is expected to decrease as a result of the effective and reliable weed management option provided by DGT cotton. Soybean growers in certain areas of the U.S. would continue to experience weed control challenges with hard-to-	Soybean and cotton growers would have the option of using dicamba for treatment of hard-to-control and glyphosate-resistant weeds, providing an alternative mode-of-action with a more benign toxicity profile as compared to some alternative herbicides. Use of dicamba can mitigate the potential for development of resistance to other herbicides on soybean and cotton acres because of its broad activity on broadleaf weeds and low level of weed resistance. Conservation tillage practices on soybean and cotton acreage are

	areas of the U.S., resulting in the need for increased tillage, with corresponding adverse effects. Growers in certain areas of the U.S. would continue to experience weed control challenges with hard-to-control (e.g., morningglory) and resistant weed species (eg., Palmer amaranth and waterhemp); the number of acres with resistant weeds is projected to increase due to lack of adequate weed control solutions. The use of herbicides in soybean and cotton production is expected to continue to increase as more growers adopt diversified weed management strategies to combat hard-to-control and an increased number of herbicide-resistant weeds. Some of the available herbicides may pose	resistant weed species (eg., Palmer amaranth); the number of acres with resistant weeds is projected to increase due to lack of adequate weed control solutions. Soybean growers would have the option of using dicamba for treatment of hard-to-control (e.g., morningglory) and resistant weed species (eg., waterhemp);, providing an alternative mode-of-action with a more benign toxicity profile as compared to some alternative herbicides. Use of dicamba can mitigate the potential for development of resistance to other herbicides because of its broad activity on broadleaf weeds and low level of weed resistance, specifically on the summer spectrum of weeds known to infest soybean acres.	control and resistant weed species; the number of acres with resistant weeds is projected to increase due to lack of adequate weed control solutions. Cotton growers would have the option of using dicamba for treatment of hard-to-control weeds, providing an alternative mode-of-action with a more benign toxicity profile as compared to some alternative herbicides. Use of dicamba can mitigate the potential for development of resistance to other herbicides on cotton acres because of its broad activity on broadleaf weeds and low level of weed resistance. Conservation tillage practices on cotton acreage are expected to be sustained and potentially increase, and	expected to be sustained and potentially increase, and the DT soybean and DGT cotton systems will provide growers with more flexible and reliable weed management options. Hand weeding is expected to decrease as a result of the effective and reliable weed management option provided by DT soybean and DGT cotton.

	greater potential risks to animals or insects than dicamba.		the DGT cotton system will provide cotton growers with more flexible and reliable weed management options.	
Weed Resistance	Growers would continue to cultivate available herbicide-tolerant GE and non-GE soybean and cotton, using glyphosate alone or in combination with other non-glyphosate herbicides (including glufosinate) for weed management. For soybean and cotton in certain areas of the U.S., there is a potential for glyphosate-resistant weed populations to evolve and develop, as well as the potential resistant populations to other alternative soybean herbicides to evolve and develop. The use of existing herbicides presents challenges to the grower's ability to effectively achieve consistent control of problematic weeds in	Growers would continue to cultivate available herbicide-tolerant GE and non-GE cotton, using glyphosate alone or in combination with other non-glyphosate herbicides (including glufosinate) for weed management. The use of existing herbicides presents challenges to the grower's ability to effectively achieve consistent control of problematic weeds in cotton such as Palmer amaranth. Thus, it is foreseeable that under the No Action Alternative, the inability to cultivate cotton varieties containing DGT cotton combined with the glyphosate tolerance trait could increase the potential for glyphosate-	Growers would continue to cultivate available herbicide-tolerant GE and non-GE soybeans, using glyphosate alone or in combination with other non-glyphosate herbicides for weed management, but additional weed resistance could develop in certain soybean acreage of the U.S. With respect to cotton, the ability to cultivate cotton varieties containing DGT cotton combined with the glyphosate tolerance trait could offer significant benefits in the effort to achieve consistent control of problematic weeds in cotton, such as Palmer amaranth. Even though dicamba has been used extensively on millions of acres for	For soybean and cotton, the ability to cultivate varieties containing DT soybean and DGT cotton combined with the glyphosate tolerance trait could offer significant benefits in the effort to achieve consistent control of problematic weeds in cotton, such as Palmer amaranth and waterhemp. DT soybean and DGT cotton combined with glyphosate-tolerant soybean would provide the tools to directly mitigate the development of glyphosate- and other herbicide-resistant weeds. Even though dicamba has been used extensively on millions of acres for over 40 years, to date

	cotton such as Palmer amaranth. Thus, it is foreseeable that under the No Action Alternative, the inability to cultivate varieties containing DT soybean and DGT cotton combined with the glyphosate tolerance trait could increase the potential for glyphosate-resistant weed populations to evolve and spread in certain cotton producing areas of the U.S.	resistant weed populations to evolve and spread in certain cotton producing areas of the U.S. DT soybean combined with glyphosate-tolerant soybean would provide the tools to directly mitigate the development of glyphosate- and other herbicide-resistant weeds. Even though dicamba has been used extensively on millions of acres for over 40 years, to date there are only four species in North America with known biotypes that are resistant to dicamba. Thus, DT soybean offer an excellent option to mitigate the development of herbicide-resistant weeds, or to manage weeds that are resistant to other herbicides.	over 40 years, to date there are only four species in North America with known biotypes that are resistant to dicamba. Thus, DGT cotton offers an excellent option to mitigate the development of herbicide-resistant weeds, or to manage weeds that are resistant to other herbicides.	there are only four species in North America with known biotypes that are resistant to dicamba. Thus, DT soybean and DGT cotton offer excellent options to mitigate the development of herbicide-resistant weeds, or to manage weeds that are resistant to other herbicides.
Organic Production	Unchanged	Unchanged	Unchanged	Unchanged
Other Specialty Markets	Unchanged	Unchanged	Unchanged	Unchanged

Seed Production	Unchanged	Unchanged	Unchanged	Unchanged
Physical Environment				
Land Use Impacts	Unchanged	Unchanged	Unchanged	Unchanged
Soil Quality Impacts	An increase in tillage, which is likely under the No Action Alternative, would negate many of the benefits of conservation tillage to soil, including improvement of soil structure, reduction of soil compaction, conservation of soil moisture, reduction of soil erosion and improvement of soil organic matter content.	Conservation tillage acres are likely to remain the same, or potentially increase, on soybean acreage owing to the introduction of DT soybean combined with the glyphosate tolerance trait. Conservation tillage improves soil structure, reduces soil compaction, conserves soil moisture, reduces soil erosion and improves soil organic matter content. An increase in tillage is likely in cotton acreage, with corresponding adverse impacts on soil quality.	Conservation tillage acres are likely to remain the same, or potentially increase, on cotton acreage owing to the introduction of DGT cotton combined with the glyphosate tolerance trait. Conservation tillage improves soil structure, reduces soil compaction, conserves soil moisture, reduces soil erosion and improves soil organic matter content. An increase in tillage is likely in soybean acreage, with corresponding adverse impacts on soil quality.	Conservation tillage acres are likely to remain the same, or potentially increase, on soybean and cotton acreage owing to the introduction of DT soybean and DGT cotton combined with the glyphosate tolerance trait.. Conservation tillage improves soil structure, reduces soil compaction, conserves soil moisture, reduces soil erosion and improves soil organic matter content.
Water Quality Impacts	An increase in tillage, which is likely under the No Action Alternative, would result in increased transport of sediments, nutrients and pesticides into surface water bodies,	Conservation tillage acres are likely to remain the same, or potentially increase, on soybean acreage owing to the introduction of DT soybean combined with	Conservation tillage acres are likely to remain the same, or potentially increase, on cotton acreage owing to the introduction of DGT cotton combined with	Conservation tillage acres are likely to remain the same, or potentially increase, on soybean and cotton acreage owing to the introduction of DT soybean and DGT

	resulting in overall adverse surface water impacts.	the glyphosate tolerance trait., with corresponding benefits to surface water. An increase in tillage is likely in cotton acreage, with corresponding adverse impacts on water quality.	the glyphosate tolerance trait., with corresponding benefits to surface water. An increase in tillage is likely in soybean acreage, with corresponding adverse impacts on water quality.	cotton combined with the glyphosate tolerance trait., with corresponding benefits to surface water.
Air Quality Impacts	The no action alternative may result in increased tillage, which could cause some adverse air quality impacts compared with full deregulation, but the differences may not be significant. Emissions from farm equipment, airborne soil erosion and pesticide drift, as well as indirect air quality effects, e.g., nitrous oxide emissions associated with the use of nitrogen fertilizers, may also result under the no action alternative.	Not deregulating DGT cotton may result in increased tillage on cotton acreage, which could cause some adverse air quality impacts compared with full deregulation, but the differences may not be significant. Emissions may also be higher on cotton acreage from farm equipment, airborne soil erosion and pesticide drift, as well as indirect air quality effects, e.g., nitrous oxide emissions associated with the use of nitrogen fertilizers, under the no action alternative. Air quality impacts are expected to be reduced	Not deregulating DT soybean may result in increased tillage on soybean acreage, which could cause some adverse air quality impacts compared with full deregulation, but the differences may not be significant. Emissions may also be higher on soybean acreage from farm equipment, airborne soil erosion and pesticide drift, as well as indirect air quality effects, e.g., nitrous oxide emissions associated with the use of nitrogen fertilizers, under the no action alternative. Air quality impacts are	Air quality impacts are expected to be reduced on soybean and cotton acres as a result of deregulation, but the differences may not be significant.

		on soybean acres as a result of deregulation, but the differences may not be significant.	expected to be reduced on cotton acres as a result of deregulation, but the differences may not be significant.	
Climate Change Impacts	The no action alternative may result in increased tillage, which could cause some adverse climate impacts compared with full deregulation owing to reduced carbon emissions from lower farm equipment operations and increased carbon sequestration in the soil, but the differences are difficult to quantify.	Not deregulating DGT cotton may result in increased tillage, which could cause some adverse climate impacts compared with full deregulation owing to reduced carbon emissions from lower farm equipment operations and increased carbon sequestration in the soil, but the differences are difficult to quantify. Climate change impacts on soybean acreage are expected to be improved after introduction of DT soybean combined with the glyphosate tolerance trait., but the differences are difficult to quantify.	Not deregulating DT soybean may result in increased tillage, which could cause some adverse climate impacts compared with full deregulation owing to reduced carbon emissions from lower farm equipment operations and increased carbon sequestration in the soil, but the differences are difficult to quantify. Climate change impacts on cotton acreage are expected to be improved after introduction of DGT cotton combined with the glyphosate tolerance trait., but the differences are difficult to quantify.	Reduced tillage may provide climate change benefits, including reduced carbon emissions from lower farm equipment operations and increased carbon sequestration in the soil. Thus, climate change impacts on soybean and cotton acreage are expected to be improved after introduction of DT soybean and DGT cotton combined with the glyphosate tolerance trait., but the differences are difficult to quantify.

Biological Impacts				
Animal Communities	Increased use of tillage could have a small adverse impact on wildlife, as the crop residues that remain with the use of conservation tillage may provide shelter and food for wildlife, such as game birds and small animals.	Reduced tillage on DT soybean acreage could have a small beneficial impact on wildlife. Potential impacts from dietary exposure to DT soybean are not expected to have any impact on animal communities.	Reduced tillage on DGT cotton acreage could have a small beneficial impact on wildlife. Potential impacts from dietary exposure to DGT cotton are not expected to have any impact on animal communities.	Reduced tillage on DT soybean and DGT cotton acreage could have a small beneficial impact on wildlife. Potential impacts from dietary exposure to DT soybean or DGT cotton are not expected to have any impact on animal communities.
Plant Communities	Unchanged	Unchanged; there is no expectation that the introduction of DT soybean will alter the geographical range of commercial soybean cultivation and the potential environmental consequences of pollen transfer from DT soybean to other soybean or related *Glycine* species is considered to be negligible because of the safety of the introduced proteins and lack of any selective advantage by the dicamba trait that might be conferred on the recipient feral soybean or	Unchanged; there is no expectation that the introduction of DGT cotton will alter the geographical range of commercial cotton cultivation and the potential environmental consequences of pollen transfer from DGT cotton to other cotton or related Gossypium species is considered to be negligible because there are no native species of Gossypium found in cotton-growing areas, and because of the safety of the introduced proteins and lack of any selective advantage by	Unchanged; introduction of DT soybean and DGT cotton are not expected to the geographical range of commercial soybean or cotton cultivation, or to pose significant risk of gene transfer. EPA regulates the use of herbicides and has concluded that dicamba and glufosinate offsite movement from labeled uses do not pose unreasonable adverse effects to non-target vegetation.

		wild relatives. EPA regulates the use of herbicides and has concluded that dicamba offsite movement from labeled uses do not pose unreasonable adverse effects to non-target vegetation.	the dicamba and glufosinate traits that might be conferred on the recipient feral cotton or wild relatives. EPA regulates the use of herbicides and has concluded that dicamba and glufosinate offsite movement from labeled uses do not pose unreasonable adverse effects to non-target vegetation.	
Gene Flow & Weediness	Unchanged	Unchanged	Unchanged	Unchanged
Microorganisms	Unchanged	Unchanged	Unchanged	Unchanged
Biodiversity	Unchanged	Unchanged	Unchanged	Unchanged
Human Health				
Consumer Health	Unchanged	Unchanged; FDA has assessed the safety and nutritional characteristics of food and feed derived from DT soybean and concluded that it does not differ from conventional soybeans. EPA has set the tolerances of dicamba on food and feed to ensure a reasonable certainty of	Unchanged; FDA has assessed the safety and nutritional characteristics of food and feed derived from DGT cotton and concluded that it does not differ from conventional cotton. EPA has set the tolerances of dicamba on food and feed to ensure a reasonable certainty of	Unchanged; FDA has assessed the safety and nutritional characteristics of food and feed derived from DT soybean and DGT cotton and concluded that they do not differ from conventional soybeans or cotton. EPA has set the tolerances of dicamba on food and

		no harm.	no harm.	feed to ensure a reasonable certainty of no harm.
Worker Health	Use of increased tillage may represent a small increase in risk for workers, as the major hazard for agricultural workers is injury related to machinery. Increased use of hand weeding represents an increase in risks for workers.	Reduced tillage on DT soybean acreage could have a small beneficial impact on workers. Decreased reliance on hand weeding on DT soybean acreage would have a positive benefit on worker health Unchanged, or potential slight improvement on soybean acreage to the extent that dicamba may reduce the use of herbicides with less benign toxicity profiles. Not deregulating DGT cotton may result in increased tillage and hand weeding, which could cause adverse impact on worker health.	Reduced tillage on DGT cotton acreage could have a small beneficial impact on workers. Decreased reliance on hand weeding on DGT cotton acreage would have a positive benefit on worker health Unchanged, or potential slight improvement on cotton acreage to the extent that dicamba may reduce the use of herbicides with less benign toxicity profiles. Not deregulating DT soybean may result in increased tillage and hand weeding, which could cause adverse impact on worker health.	Reduced tillage on DT soybean and DGT cotton acreage could have a small beneficial impact on workers. Decreased reliance on hand weeding on DT soybean and DGT cotton acreage would have a positive benefit on worker health. Unchanged, or potential slight improvement on soybean and cotton acreage to the extent that dicamba may reduce the use of herbicides with less benign toxicity profiles.
Animal Feed & Animal Health				
	Unchanged	Unchanged; FDA has assessed the safety and nutritional characteristics of food and feed derived	Unchanged; FDA has assessed the safety and nutritional characteristics of food and feed derived	Unchanged; FDA has assessed the safety and nutritional characteristics of food and feed derived

		from DT soybean and concluded that it does differ from conventional soybeans. EPA has set the tolerances of dicamba on food and feed to ensure a reasonable certainty of no harm.	from DGT cotton and concluded that it does differ from conventional cotton. EPA has set the tolerances of dicamba on food and feed to ensure a reasonable certainty of no harm.	from DT soybean and DGT cotton and concluded that they do not differ from conventional soybeans or cotton. EPA has set the tolerances of dicamba on food and feed to ensure a reasonable certainty of no harm.
Socioeconomic Impacts				
Domestic Economic Environment	The lack of effective weed management programs combined with the potential for additional herbicide-resistant weeds to develop in certain areas in the U.S. could adversely impact the overall profitability and sustainability of U.S. soybean and cotton production.	Unchanged	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged	Unchanged	Unchanged
Organic and Specialty Segments	Unchanged	Unchanged	Unchanged	Unchanged

Notes: GT = glyphosate tolerant; GR = glyphosate resistant; GE = genetically engineered; T&E = threatened and endangered; NOP = National Organic Program; EIQ = environmental impact quotient

IV. ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impacts to the human environment from the regulatory alternatives discussed in this environmental report. Potential environmental impacts from the No Action Alternative and different action alternatives for DT soybean and DGT cotton are described in detail throughout this section.

An environmental impact would be a change, positive or negative, from the existing conditions of the affected environment, described for each resource area in Section II. Impacts may be categorized as direct, indirect, or cumulative. A direct impact is an effect that results solely from a proposed action without intermediate steps or processes. Possible examples include soil disturbance, air emissions, and water use. An indirect impact may be an effect that is related to but removed from a proposed action by an intermediate step or process. Potential examples include surface water quality changes resulting from soil erosion due to increased tillage, and worker safety impacts resulting from a change in herbicide use.

The production practices under each alternative determine how the various "resource areas" of the affected environment are affected by the decisions of the growers and producers. Those resource areas have been grouped into the physical environment (land use, soil, water, and air quality, and climate change), biological resources (wildlife and ecosystems), human health, animal health, and socioeconomics. For all alternatives discussed in each of the resources areas below, the terms DT soybean and DGT cotton are inclusive of the single GE events, any progeny derived from crosses between DT soybean or DGT cotton and conventional varieties, and crosses of DT soybean and DGT cotton with other GE-derived varieties that have previously been previously deregulated by APHIS.

As discussed elsewhere in this report, Congress transferred regulatory authority over herbicides from USDA to EPA. Accordingly, USDA-APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider direct, indirect, or cumulative herbicide impacts under the PPA, that may be associated with the deregulation and use of DT soybean or DGT cotton. Nonetheless, because APHIS indicated in its Notice of Intent to Prepare an Environmental Impact Statement (78 Fed. Reg. 28796, May 16, 2013) that it would be considering herbicide effects and herbicide resistance as part of the NEPA process, this document includes a discussion of herbicide impacts in the following sections, with more details in an Appendix. Importantly, however, Monsanto believes that APHIS has no legal obligation under NEPA to consider direct, indirect, or cumulative herbicide impacts or herbicide resistance in any Environmental Impact Statement or Environmental Assessment. See *DOT v. Public Citizen*, 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform). See also *Center for Food Safety v. Vilsack*, No. 12-15052, 2013 U.S. App. LEXIS 9920, at *16-17 (9th Cir. 2013) ("If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests.").

This chapter is organized into nine main sections, as follows:

Section IV.A, *Methodologies and Assumptions Used in the Analysis*, describes the methodology and assumptions used in analyses of environmental impacts of DT soybean and DGT cotton.

Section IV.B, *Agricultural Production of Soybeans and Cotton*, discusses the potential impacts of the No Action Alternative and different action alternatives for DT soybean and DGT cotton on how soybean and cotton are farmed. The analysis considers potential impacts on crop use and biology, land use, agronomic practices, and tillage. The analysis also addresses potential impacts to weed management, pest management, and weed resistance, although considered out of scope of the authority of USDA as stated above. Section IV.C. also discusses potential impacts on organic production, specialty market production, and seed production.

Section IV.C, *Physical Environment*, discusses the potential impacts of the No Action Alternative and different action alternatives for DT soybean and DGT cotton on the physical environment, including impacts on land use, soil quality, water quality, air quality and climate change. In addition to discussing the potential impacts of the plants themselves, this section also discusses potential impacts associated with the use of dicamba, although considered out of scope of the authority of USDA as stated above.

Section IV.D, *Biological Resources*, discusses the potential impacts of the No Action Alternative and different action alternatives for DT soybean and DGT cotton on living organisms in ecological and agricultural settings. The biological resources are divided into animal communities, plant communities, and microorganisms. Section IV.E also discusses potential impacts related to gene flow and weediness, as well as hybridization with cultivated soybean and cotton plants, and hybridization with feral species. Section IV.E also considers the impacts on adjacent agricultural crops and non-agricultural plants of the offsite movement of herbicides, although considered out of scope of the authority of USDA as stated above.

Section IV.E, *Human Health*, discusses the potential impacts of the No Action Alternative and different action alternatives for DT soybean and DGT cotton on consumer and worker health and safety. Section IV.F. also addresses potential impacts on human health from the use of pesticides that are applied before or during the production of soybean and cotton. Section IV.F. discusses potential impacts to human health from the direct ingestion of the products of DT soybean and DGT cotton, such as cooking oils, food additives, and nutritional supplements, as well as the inhalation of cotton dust by workers during cotton handling and processing.

Section IV.F, *Animal Feed and Animal Health*, discusses the potential impacts of the No Action Alternative and different action alternatives for DT soybean and DGT cotton on animal agriculture, and in particular in the animal feed industry. Section IV.G also addresses potential impacts of herbicide residues on animal feed, although considered out of scope of the authority of USDA as stated above.

Section IV.G, *Socioeconomics*, discusses the potential impacts of the No Action Alternative and different action alternatives for DT soybean and DGT cotton on the domestic economic environments of soybean and cotton and the trade economic environments of soybean and cotton. Section IV.H also discusses potential impacts on organic cotton production and organic soybean production.

Section IV.H, Other Impacts and Mitigation Measures discusses other potential impacts associated with the implementation of the alternatives, including unavoidable impacts; short-term versus long-term productivity of the environment; and irreversible/irretrievable commitment of resources. The section also describes potential mitigation measures, as applicable, beyond what is already built into the alternatives.

IV.A. METHODOLOGIES AND ASSUMPTIONS USED IN THE ANALYSIS

IV.A.1. Methodology and Assumptions Used for DT Soybean

Area of Proposed Use. DT soybean is a crop with a trait that will have intended utility across all of the acreage upon which soybean is currently grown and could be widely available in soybean varieties sold to growers.

Over the past decade, glyphosate-tolerant soybean varieties have been widely adopted in the marketplace. In most cases, glyphosate was applied to control narrowleaf and broadleaf weeds in U.S. soybean fields, where glyphosate provided excellent control of most weeds. In recent years, the development, in certain areas of the U.S., of glyphosate-resistant weeds and shifts in broadleaf weed populations to species that are inherently more tolerant to glyphosate have increased the use of additional herbicides that work through a different mode-of-action to achieve an acceptable level of weed control. As a result of the ongoing need to control weed species present in soybean fields, additional herbicides are being used, and multiple herbicide-tolerance traits are being developed to provide growers with additional weed control options that will compete with DT soybean. If USDA were to deregulate DT soybean, these herbicides and traits will likely continue to be available at the time DT soybean is introduced to the marketplace; thus, DT soybean would compete for market share with established products, like glyphosate-tolerant soybean 40-3-2 first introduced in 1996, Roundup Ready 2 Yield soybean, and other new herbicide-tolerance traits that would be available in the foreseeable future. Growers will ultimately select weed control systems that fit the needs for their individual farming operation, such that some proportion of growers will choose to use DT soybean integrated into the glyphosate-tolerant soybean system.

Summary of Genetic Modification. DT soybean was developed through *Agrobacterium*-mediated transformation of conventional soybean tissue based on well-established published methods. DT soybean contains a gene from *Stenotrophomonas maltophilia* that expresses a dicamba mono-oxygenase (DMO) protein to confer tolerance to dicamba herbicide. DMO protein rapidly demethylates dicamba to the inactive metabolite 3,6-dichlorosalicylic acid (DCSA), a known metabolite of dicamba in non-GE soybean, cotton, livestock and soil. The genetic modification is described in detail in Appendix G of this Environmental Report.

Basis for Discussion of Pesticide Impacts. As discussed elsewhere in this report, Congress transferred regulatory authority over herbicides from USDA to EPA. Accordingly, USDA-APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider herbicide impacts under the PPA. Nonetheless, because APHIS indicated in its Notice of Intent to Prepare an Environmental Impact Statement (78 Fed. Reg. 28796, May 16, 2013) that it would be considering herbicide effects and herbicide resistance as part of the NEPA process, Monsanto has included a discussion of herbicide impacts in the following section. Importantly, however, Monsanto believes that APHIS has no legal obligation under NEPA to consider herbicide impacts or herbicide resistance in any Environmental Impact Statement or Environmental Assessment. See

DOT v. Public Citizen, 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform). See *also Center for Food Safety v. Vilsack*, No. 12-15052, 2013 U.S. App. LEXIS 9920, at *16-17 (9th Cir. 2013) ("If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests.")..

Use of Low-Volatility DGA Salt of Dicamba – Proposed Changes in Dicamba Registration: Monsanto has submitted to EPA an application to amend EPA Reg. No. 524-582 to register a new use pattern for dicamba on DT soybean. The current and proposed uses are summarized in Table IV.A-1.

In the pending application to EPA, Monsanto requested approval only for the low volatility DGA salt formulation of dicamba (U.S. EPA Reg. No. 524-582) for use on DT soybean, and has proposed that dicamba applications be limited to ground applications only (*i.e.*, no aerial spraying), as well as proposing additional enforceable directions for use. Monsanto has also requested the establishment of a tolerance for soybean forage and hay; no other revisions to the dicamba residue tolerances are necessary, including animal products such as meat and milk. The use of dicamba on DT soybean does not present any new environmental exposure scenarios not previously evaluated in the RED and deemed acceptable by EPA.

Table IV.A-1. Summary of Dicamba Uses on Soybean

	Current Approved Uses		Proposed Uses on DT soybean	
Application Timing	Maximum Single Application Rate (lbs a.e./acre)	Maximum Annual Application Rate (lbs a.e./acre)	Maximum Single Application Rate (lbs a.e./acre)	Maximum Annual Application Rate (lbs a.e./acre)
Preemergence	0.50[1]	2.0	1.0[2]	2.0
Post-emergence	Not labeled		**0.50** (V3) + **0.50** (R1/R2)[3]	
Pre-harvest (7 days prior to harvest)	1.0		Not labeled	

[1] 14-28 day planting interval based on product application rate

[2] No planting interval

[3] In-crop application through V3 with a sequential application through R1/R2 growth stage as needed. Total of all in-crop applications from emergence up to R1/R2 is 1.0 lb a.e./acre.

Combination with Glyphosate-Tolerant Soybean. DT soybean is intended to be combined with glyphosate-tolerant soybean utilizing traditional breeding techniques. Soybean containing both DT soybean and glyphosate tolerance will allow the use of glyphosate and dicamba herbicides in a diversified weed management program, which includes the use of residual herbicides or other cultural practices, to control a broad spectrum of grasses and broadleaf weed species, and to sustain and complement the benefits and value of the glyphosate use in the glyphosate-tolerant systems. The combined system will support long-term sustainability of weed management in soybean and, in turn, support sustained, economic soybean production.

Inclusion of Potential Impacts from Herbicide Use: As discussed above, it is EPA's regulatory authority under FIFRA to register pesticide products for their intended uses. EPA has sole authority to regulate the use of any herbicide. Nonetheless, for the reasons discussed above, this environmental report evaluates potential impacts of dicamba use associated with DT soybean on the human environment.

Anticipated Weed Management Recommendations for DT Soybean: Monsanto's weed management system recommendations are shown in(Table IV.A-2. The recommended use patterns for dicamba on DT soybean will vary across U.S. soybean growing regions based on differences in growth habits and competitiveness of certain glyphosate-resistant weed species. Option 1 would be recommended for more aggressive glyphosate-resistant weed species, such as Palmer amaranth (*Amaranthus palmeri*) and waterhemp (*Amaranthus rudis*). These weed species are very fast growing, highly competitive with crops, high seed producers, very densely populated, and germinate and emerge throughout the growing season (Fast, et al. 2009; Keeley, et al. 1987; Nordby, et al. 2007; Sprague 2012). Two sequential postemergence applications will generally be required to control late-season emergence of these weed species. However, low rainfall conditions and/or early crop canopy closure that can be associated with narrow row spacing of soybean can reduce late-season weed emergence and potentially reduce the number of dicamba postemergence applications. Option 2 would be used for less aggressive glyphosate resistant weed species, such as horseweed (*Conyza canadensis*), common ragweed (*Ambrosia artemisiifolia*) and giant ragweed (*Ambrosia trifida*).

These weed management system recommendations represent a high-end proposal for dicamba use associated with DT soybean when combined with glyphosate-tolerant soybean. The actual number of applications and timing of applications of dicamba or glyphosate that the grower will make will vary depending on the specific weed spectrum, weed infestation levels, and the agronomic situation of the individual soybean field. Applying a residual herbicide preemergence in sequence with glyphosate plus dicamba postemergence, or tank mixing a residual herbicide with glyphosate plus dicamba postemergence could be considered as an alternative to two postemergence applications of glyphosate plus dicamba for season long weed control.

Table IV.A-2. Proposed Weed Management System Recommendations for DT Soybean Combined with Glyphosate-Tolerant Soybean.

Application Timing	Conventional Tillage[1]			Conservation Tillage (No-till or reduced till) [1]		
	No GR Weeds	GR Weeds or Suspected GR Weeds[2]		No GR Weeds	GR Weeds or Suspected GR Weeds[2]	
		Option 1[4]	Option 2[5]		Option 1[4]	Option 2[5]
Preemergence/ Preplant Burndown[3]	Residual	Residual	Residual	Residual plus Glyphosate plus Dicamba	Residual plus Glyphosate plus Dicamba	Residual plus Glyphosate plus Dicamba
Postemergence 1 (V1-V3)	Glyphosate plus Dicamba	Glyphosate plus Dicamba	Glyphosate plus Dicamba	Glyphosate plus Dicamba	Glyphosate plus Dicamba	Glyphosate plus Dicamba
Postemergence 2 (V4-R1)	---	Glyphosate plus Dicamba	---	---	Glyphosate plus Dicamba	---

[1] Anticipated average rate for dicamba is 0.38 pound a.e. per acre except for fields with glyphosate resistant (GR) species where a 0.5 pound a.e. per acre postemergence application rate will be recommended in most situations. See Appendix A.

[2] GR indicates glyphosate-resistant

[3] Monsanto and academics recommend the use of soil residuals as part of a comprehensive weed resistance management program to ensure that at least two effective herbicide modes-of-action are used in soybean and to provide protection against additional resistance development to existing herbicides used in soybean production. When a residual plus glyphosate plus dicamba is recommended the residual may be applied separately or in tank mixture with glyphosate plus dicamba.

[4] Option 1 would be used for more aggressive glyphosate resistant weed species, such as *Amaranthus spp*.

[5] Option 2 would be used for less aggressive glyphosate resistant weed species, such as horseweed.

Potential Additional Dicamba Use. It is impossible to determine the exact amount of acreage on which DT soybean may be grown if deregulated. Projections on the annual application of dicamba used on DT soybean are based on market adoption rates and the dicamba use pattern on DT soybean. The maximum possible annual application of dicamba on DT soybean, based on 100% adoption of across all U.S. soybean acreage (75 million acres) and applications of dicamba at the maximum labeled rates (proposed at 2.0 lbs a.e. per acre per year), would be 150 million pounds dicamba (as acid equivalent or a.e.). However, as discussed below, the actual total anticipated application will be much lower.

For the purposes of this assessment, it is assumed that DT soybean will occupy 40% of the U.S. soybean acreage at peak penetration. This estimate is based on a number of factors: 1) the percentage of non-glyphosate herbicides currently used in glyphosate-tolerant soybean, 2) current and historical use of dicamba in corn, 3) the development of glyphosate-resistant weeds in soybean cultivation areas, 4) the effectiveness of other non-glyphosate herbicides used in glyphosate-tolerant soybean, s; and 5) the foreseeable future introduction of new competitive biotechnology-derived traits in soybean.

Similarly the anticipated use patterns for dicamba on DT soybean will vary across U.S. soybean growing regions. This variability is dictated by growth habits and competitiveness of certain glyphosate-resistant weed species. As discussed above in *Anticipated Weed Management Recommendations for DT Soybean*, weed management recommendations will vary based on cultivation practices (i.e., tillage) and spectrum of glyphosate-resistant weeds present in the field. Based on weed management trials conducted across regions and weed spectrum a single early season in-crop application per year of dicamba at 0.38 lb a.e. per acre is expected on the majority of DT soybean acres. However, in no-till or conservation tillage soybean systems, an additional preplant application at 0.50 lb a.e. per acre could also be common practice, and in areas where glyphosate resistant weeds, especially *Ambrosia and Amaranthus* species, are present two in-crop applications at 0.5 lb a.e. each may be needed in some situations. See Appendix A for additional information supporting these anticipated use patterns.

Based on the anticipate dicamba application and use rate analysis summarized above, use of DT soybean on 40% of U.S. soybean acres would result in approximately 20.5 million lbs a.e. of dicamba applied to DT soybean annually (including preplant, preemergence and in-crop applications), see Table IV.A-3 . Currently 233,000 lbs a.e. of dicamba are applied preplant to commercially available soybean (Monsanto 2012).

The potential increase in dicamba usage associated with DT soybean production is expected to displace, in part, some of the current herbicides used in soybean today. Dicamba offers a relative reduction of risk potential in comparison to some of the alternative non-glyphosate herbicides currently available to soybean growers (see Appendices E and F) to this environmental report. Dicamba could be expected to conservatively replace approximately 21% of the projected total acres treated (TAT)[49] for all non-glyphosate herbicides used in preplant/preemergence application timing and 56% of the projected TAT for all non-glyphosate herbicides used in postemergence application timing at peak dicamba use based on a projection that 40% of total planted soybean acres may be treated with dicamba following the introduction of DT soybean. At projected peak penetration of dicamba use in DT soybean, an increase in both total soybean acres treated and total pounds of non-glyphosate herbicides applied to soybean is projected, however estimated increases are 12% or less of the total herbicide use projections if DT soybean is not commercialized.

49 The use of TAT provides a way to look at herbicide use that is independent of the various use rates of herbicides. If a herbicide is used more than once on an acre the TAT will reflect this multiple use, and consequently the TAT may exceed the number of crop acres planted. This provides a more complete view of herbicide use.

Table IV.A-3. Projected Dicamba Use on DT Soybean

Use Scenario[a]	Dicamba Treated MON 87708 Acres (000,000)	# PRE applications	PRE application rate (lb/acre a.e.)	# POST applications (V3 or V3 & R1)	POST application rate (lb/acre a.e.)	Total lbs of Dicamba (000,000)[b]	Total Annual lbs of Dicamba
Maximum labeled use pattern, 100% adoption							
	75	1	1.0	2	0.50	150	150
Anticipated use pattern, 100% adoption							
no-till acres [c]	30	1	0.5	1	0.38	26.4	
conventional tillage acres[d]	45			1	0.38	17.1	
							44
Anticipated use pattern, anticipated peak adoption of dicamba-treated MON 87708 acres							
no-till acres [c]	12[e]	1	0.5	1	0.38	10.6	
conventional tillage acres[d]	18[e]			1	0.38	6.8	
Resistant Amaranthus spp. Acres [f]	5[a]			2	0.31[g]	3.1	
							20.5[h]

[a] See Section *Anticipated Weed Management Recommendations for DT Soybean* and Appendix A for additional details regarding projected use pattern scenarios for dicamba on DT soybean.
[b] Total lbs dicamba is calculated combining the lbs of dicamba PRE and POST, where the lbs dicamba used either PRE or POST is calculated by multiplying the number of applications by the application rate for the respective application timing.
[c] No-tillage is practiced on 40% of the U.S. soybean acres (CTIC 2007).
[d] Conventional tillage acres also includes acres where reduced or minimum tillage is practiced and where it is assumed that a preemergent application of dicamba will be needed for weed control.
[e] Monsanto projects dicamba to be used on 40% of U.S. soybean acres (i.e., 30 million acres).
[f] These acres are a subset of the no-till and conventional tillage acres.

[g] Monsanto anticipates that two POST applications at 0.5 lb/acre a.e. each will be needed on acres resistant with A*maranthus spp*. Since these acres are a subset of the no-till and conventional tillage acres where a single POST application at 0.38 lb/acre dicamba a.e. has already been accounted for, the POST application rate is adjusted to avoid double counting of dicamba use on this subset of acres (i.e., adjusted POST application rate = 0.5 lb/acre – (0.38÷2) lb/acre).
[h] This figure is slightly less than the estimate of 22 million pounds described in Section VIII.H of the petition because it subtracts out the single 0.38 lb/acre a.e. application already accounted for in the no-till and conventional tillage calculations.

IV.A.2. Methodology and Assumptions Used for DGT Cotton

Area of Proposed Use: The DGT cotton herbicide tolerance traits are intended to have utility across all of the acreage upon which cotton is currently grown. If deregulated, varieties containing DGT cotton would be widely available to cotton growers.

Summary of Genetic Modification: DGT cotton was developed through *Agrobacterium*-mediated transformation of cotton tissue based on well-established published methods. A description of the genetic modification is included in Appendix G to this Environmental Report. DGT cotton contains a demethylase gene from *Stenotrophomonas maltophilia* that expresses a dicamba mono-oxygenase (DMO) protein to confer tolerance to dicamba herbicide and a bialaphos resistance (*bar*) gene from *Streptomyces hygroscopicus* that expresses the phosphinothricin N-acetyltransferase [PAT (*bar*)] protein to confer tolerance to glufosinate herbicide. DMO protein rapidly demethylates dicamba to the inactive metabolite 3,6-dichlorosalicylic acid (DCSA), a known metabolite of dicamba in non-GE cotton, soybean, livestock and soil. The PAT (*bar*) protein acetylates the free amino group of glufosinate to produce non-herbicidal N-acetyl glufosinate, a known metabolite in glufosinate-tolerant plants (OECD 2002).

Basis for Discussion of Pesticide Impacts. As discussed elsewhere in this report, Congress transferred regulatory authority over herbicides from USDA to EPA. Accordingly, USDA-APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider herbicide impacts under the PPA. Nonetheless, because APHIS indicated in its Notice of Intent to Prepare an Environmental Impact Statement (78 Fed. Reg. 28796, May 16, 2013) that it would be considering herbicide effects and herbicide resistance as part of the NEPA process, Monsanto has included a discussion of herbicide impacts in the following section. Importantly, however, Monsanto believes that APHIS has no legal obligation under NEPA to consider herbicide impacts or herbicide resistance in any Environmental Impact Statement or Environmental Assessment. See *DOT v. Public Citizen*, 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform). See *also Center for Food Safety v. Vilsack*, No. 12-15052, 2013 U.S. App. LEXIS 9920, at *16-17 (9th Cir. 2013) ("If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests.").

Use of Low-Volatility DGA Salt of Dicamba – Proposed Changes in Dicamba Registration: Monsanto has requested a registration from U.S. EPA for the expanded use of a low volatility diglycolamine (DGA) salt of dicamba on DGT cotton, limited dicamba application to ground application equipment, as well as proposing additional stewardship measures. Monsanto plans to further address the use of dicamba on DGT cotton with U.S. EPA to evaluate whether any additional measures may be appropriate to further address potential drift and offsite movement. Monsanto has also requested an increase in the dicamba residue tolerance for cottonseed, the establishment of a tolerance for cotton gin by-products, and the inclusion of DCSA in the residue definitions for both cottonseed and gin by-products.

Monsanto submitted an application to EPA to amend Registration number 524-582, a low-volatility DGA salt formulation, to remove all existing preemergence planting restrictions (application intervals, rainfall, and geographic) and to allow in-crop postemergence dicamba applications to DGT cotton containing varieties.[50] Before any application of dicamba can be made onto commercially cultivated DGT cotton, the EPA must first approve a label describing the conditions of use of the herbicide on DGT cotton – including the appropriate application rates and timing, and other measures necessary to address potential impacts of dicamba drift and offsite movement. Dicamba can currently be applied to cotton in the U.S. as a preplant application, at least 21 days prior to planting. Following EPA approval of the dicamba label amendment, growers would be authorized to apply dicamba alone or in mixtures with glyphosate, glufosinate, or other registered herbicides for preplant or postemergence in-crop applications on DGT cotton. If the proposed label is approved by EPA, dicamba would be authorized to be applied up to 1.0 lb a.e. per acre any time prior to cotton emergence, and postemergence in-crop up to 0.5 lbs a.e. per acre per application up through seven days prior to harvest. Maximum application amounts for dicamba would be 1.0 lb a.e. per acre for preplant/preemergence applications and 0.5 lb a.e. per acre per in-crop application with the combined total not to exceed 2.0 lbs a.e. dicamba per year for all applications. The proposed application rates on DGT cotton would be less than or equivalent to rates for dicamba established for other uses in the dicamba RED including the 2.0 lbs a.e. dicamba per year for all applications (U.S. EPA 2009a). Based on Monsanto's proposed dicamba label, aerial applications of dicamba will not be allowed on DGT cotton, thereby reducing spray drift potential (BASF 2008). Monsanto has requested a registration from U.S. EPA for the expanded use of dicamba on DGT cotton, an increase in the dicamba residue tolerance from 0.2 ppm to 3 ppm for cottonseed, the establishment of a tolerance of 70 ppm for cotton gin by-products, and the inclusion of DCSA in the residue definitions for cottonseed and gin by-products. No other revisions to the dicamba residue tolerances are necessary, including animal products such as meat and milk. Furthermore, the use of dicamba on DGT cotton does not present any new environmental exposure scenarios not previously evaluated in the RED and deemed acceptable by EPA.

Use of Glufosinate – No Changes in Registration: The PAT (*bar*) protein acetylates the free amino group of glufosinate to produce non-herbicidal N-acetyl glufosinate, a known metabolite in glufosinate-tolerant plants (OECD 2002). The use pattern and rate of glufosinate application on DGT cotton will follow the existing glufosinate-tolerant cotton uses outlined on the existing glufosinate herbicide label (Bayer Crop Science 2007) and Monsanto has confirmed that glufosinate residues on DGT cotton treated with commercial glufosinate rates are below the established pesticide residue tolerances established by U.S. EPA for both cottonseed and gin by-products (40 CFR 180.473). Consequently, Monsanto has not and will not pursue any changes in the glufosinate label or the established tolerances for its use on DGT cotton. Because there will be no changes in the use pattern and rate of glufosinate on DGT cotton

50 The current dicamba label approved by EPA prohibits dicamba preplant application on cotton west of the Rockies due to the potential for direct crop injury caused by dicamba in conjuction with the environmental conditions in this area. This restriction will not be included on the amended label for application of dicamba on DGT cotton since DGT cotton is tolerant to dicamba.

from the current baseline, these aspects related to the associated use of glufosinate on DGT cotton are not discussed in detail in this analysis.

Combination with Glyphosate-Tolerant Cotton. DGT cotton is intended to be combined with glyphosate-tolerant cotton utilizing traditional breeding techniques. Cotton containing both DGT cotton and glyphosate tolerance will allow the use of glyphosate, dicamba, and glufosinate herbicides in a diversified weed management program, which includes the use of residual herbicides or other cultural practices, to control a broad spectrum of grasses and broadleaf weed species, and to sustain and complement the benefits and value of the glyphosate use in the glyphosate-tolerant systems. The combined system will support long term sustainability of weed management in cotton and, in turn, support sustained, economic cotton production.

Use of Multiple Herbicide-Tolerant Traits. In recent years, the development, in certain areas of the U.S., of glyphosate-resistant weeds, as well as shifts in broadleaf weed populations to species that are inherently more tolerant to glyphosate, have increased the use of non-glyphosate herbicides that work through different modes-of-action to achieve an acceptable level of weed control. As a result, multiple herbicide-tolerant traits are and have been developed to provide cotton growers with additional weed control options that will compete with DGT cotton. These herbicides and traits will be available at the time DGT cotton is introduced to the marketplace; thus, DGT cotton will compete for market share with approved herbicide tolerance traits, including LibertyLink®, GlyTol®, and TwinLink® combined-trait products, and new herbicide-tolerance traits that will be available in the foreseeable future. Growers will ultimately select weed control systems that fit the needs for their individual farming operation, such that some proportion of growers will choose to use DGT cotton-containing varieties integrated into glyphosate-tolerant cotton systems.

Anticipated Weed Management Recommendations for DGT Cotton: The expected use patterns for dicamba and glufosinate on DGT cotton will vary across U.S. cotton growing regions. This variability is dictated by the environment and weed spectrum variations across these regions. Monsanto's recommendations for the Midsouth and Southeast regions are shown in (Table IV.A-4). In these regions, conventional tillage planted acres are expected to receive a single in-crop application per season of dicamba at 0.5 lbs a.e. per acre and conservation tillage or no-tillage acres are expected to receive two applications (one preplant application at 0.375 lbs a.e. per acre and one in-crop application at 0.50 lbs a.e. per acre). All acres in this region where glyphosate-resistant weeds are present, regardless of tillage, are expected to receive a single in-crop application of glufosinate as 0.53 lbs a.i. per acre. For the remaining acres where glyphosate-resistant weeds are not present, glyphosate will likely be used for control of late-emerging weeds. Dicamba and glufosinate use in eastern Texas and California is expected to be similar to that described for the Midsouth and Southeast regions.

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Table IV.A-4. Anticipated Weed Management Recommendations for DGT Cotton Combined with Glyphosate-Tolerant Cotton Systems for MO, AR, TN, AL, FL, GA, NC, SC, VA, LA, MS, eastern TX and CA.[1,2]

Application Timing	Conventional Tillage	Conservation Tillage (No-till or reduced till)
Preplant burndown and/or Preemergence	Residual	Dicamba + Glyphosate + Residual
Postemergence 1	Dicamba + Glyphosate + Residual[3]	Dicamba + Glyphosate + Residual
Postemergence 2	Glyphosate OR Glufosinate[4,5]	Glyphosate OR Glufosinate + Residual[5,6]

[1] Recommendations modified from those presented in Petition 12-185-01p_a1.
[2] Monsanto and academics recommend the use of soil residuals as part of a comprehensive weed resistance management program to ensure that two effective herbicide modes-of-action are used in cotton and to provide protections against additional resistance development to existing herbicides used in cotton production.
[3] Residual recommended if GR weeds present.
[4] Glyphosate recommended if no GR weeds present, glufosinate recommended in the presence of GR weeds.
[5] Tank mixes of glyphosate and glufosinate will not be recommended, because reduced weed control has been observed with the glyphosate and glufosinate tank mix as compared to each individual herbicide (Dotray, et al. 2011a; Reed et al. 2011; Reed et al. 2012).
[6] Glyphosate only if no GR weeds present, glufosinate and residual recommended in the presence of GR weeds.

In western Texas, New Mexico, Kansas, Oklahoma, and Arizona, dicamba is expected to be utilized more extensively than glufosinate for management of hard-to-control and/or glyphosate-resistant weeds in DGT cotton. Glufosinate is considered less effective on the weed spectrum under the high temperature and low humidity environmental conditions in these regions (Bayer CropScience 2011). The recommendations for these cotton growing areas are shown in Table IV.A-5. All acres are expected to receive one preplant application of dicamba (0.375 lbs a.e. per acre). Areas with glyphosate-resistant weeds are also expected to receive two in-crop applications of dicamba (0. 50 lbs a.e./acre) per season, whereas areas without glyphosate-resistant weeds will only receive one in-crop application of dicamba (0.50 lbs a.e./acre).

Table IV.A-5. Anticipated Weed Management Recommendations for DGT Cotton Combined with Glyphosate-Tolerant Cotton Systems for western TX, NM, KS, OK, and AZ [1,2]

Application Timing	Conventional Tillage	Conservation Tillage (No-till or reduced till)
Preplant burndown and/or Preemergence	Dicamba + Glyphosate + Residual	Dicamba + Glyphosate + Residual
Postemergence 1	Dicamba + Glyphosate	Dicamba + Glyphosate
Postemergence 2	Glyphosate ± Dicamba[3]	Glyphosate ± Dicamba[3]

[1] Recommendations modified from those presented in Petition 12-185-01p_a1.
[2] Monsanto and academics recommend the use of soil residuals as part of a comprehensive weed resistance management program to ensure that two effective herbicide modes-of-action are used in cotton and to provide protections against additional resistance development to existing herbicides used in cotton production.
[3] Dicamba recommended when GR weeds present.

Inclusion of Potential Impacts from Herbicide Use: As discussed above, it is EPA's regulatory authority under FIFRA to register pesticide products for their intended uses. EPA has sole authority to regulate the use of any herbicide. Nonetheless, for the reasons discussed above, this environmental report evaluates potential impacts of dicamba use associated with DGT cotton on the human environment. Glufosinate will not be discussed in detail because glufosinate use on DGT cotton is equivalent to currently deregulated glufosinate-tolerant cotton and will be considered baseline.

Potential Additional Dicamba Use: The maximum possible annual application of dicamba on cotton, with 100% adoption of DGT cotton across all U.S. upland cotton acreage (14.8 million acres)[51] and applications of dicamba at the maximum labeled rates (proposed at 2.0 lbs a.e. per acre per year), would be 29.6 million pounds a.e. However, as discussed below, the actual total anticipated application will be much lower and will not likely be additive with the current application of herbicides currently used on cotton, as dicamba will displace some of the current herbicide usage in cotton.

As discussed above, in the Midsouth, and Southeast regions, conventional tillage-planted acres are expected to receive a single in-crop application per season of dicamba at 0.5 lbs a.e. per acre and conservation tillage or no-tillage acres are expected to receive two applications (one preplant application at 0.375 lbs a.e. per acre and one in-crop application at 0.50 lbs a.e. per acre). Dicamba use in East Texas and California is expected to be similar to that described for

[51] Based on approximately 14.8 million acres planted to cotton in 2011, see Table II.B-12.

the Midsouth and Southeast regions. In West Texas, Kansas, Oklahoma, New Mexico, and Arizona dicamba is expected to be utilized more extensively than glufosinate for management of troublesome and/or glyphosate-resistant weeds. Glufosinate is considered less effective on the weed spectrum under the high temperature and low humidity environmental conditions in these regions (Bayer CropScience 2011). In West Texas, Kansas, Oklahoma, New Mexico, and Arizona conventional tillage acres are expected to receive two in-crop applications of dicamba per season at 0.50 lbs a.e. per acre. No-till or conservation tillage cotton acres will realistically receive three applications per season (one preplant application at 0.375 lbs a.e. per acre and two in-crop applications at 0.50 lbs a.e. per acre. Assuming these anticipated applications and use rates of dicamba, and using the assumption that DGT cotton has 100% adoption across all U.S. cotton acres and conservation tillage systems are used on approximately 21% of the U.S. cotton acres (CTIC 2008), dicamba use on DGT cotton would total approximately 10.5 million pounds.

It is impossible to determine the exact amount of acreage on which DGT cotton may be grown if deregulated. A 100% adoption rate of DGT cotton among cotton growers is unrealistic. Monsanto estimates dicamba-treated acres could eventually reach 50% of the total U.S. cotton acres. Growers will ultimately select weed control systems that fit the needs for their individual farming operations such that some proportion of growers will choose to use DGT cotton integrated into the glyphosate-tolerant cotton systems. As discussed in Section II.B.2.d, growers produced herbicide-tolerant cotton on approximately 73% of U.S. cotton acres in 2011, with almost all of this cotton being glyphosate-tolerant and approximately 3% being glufosinate tolerant. Growers currently producing herbicide-tolerant cotton are the growers most likely to adopt DGT cotton. Some of these growers may continue to grow the currently-available types of herbicide-tolerant cotton, and use other herbicides for hard-to-control weeds. For example, approximately 53 to 64% of growers of glyphosate-tolerant cotton used a non-glyphosate herbicide in addition to glyphosate in their cotton crops in 2005 (Givens et al. 2009a). An additional factor influencing the number of dicamba-treated cotton acres in the future will be the introduction of competing herbicide-tolerant traits in cotton.

Based on the dicamba application and use rate analysis summarized above, use of DGT cotton on 50% of U.S. cotton acres would result in approximately 5.2 million lbs a.e. of dicamba applied to DGT cotton annually (including preplant, preemergence and in-crop applications). Currently 364,000 lbs a.e. of dicamba are applied preplant to commercially available cotton (Monsanto 2012).

It is anticipated that dicamba applications will continue for all other currently labeled crops at the current annual level of approximately 3.8 million pounds (Monsanto 2012). Therefore, the addition of the estimated 5.2 million pounds of dicamba that would be applied to DGT cotton would result in a total estimated U.S. dicamba use of approximately 9.0 million pounds annually. This does not include the additional amount from DT soybean (Section IV.A.1).

The potential increase in dicamba usage associated with DGT cotton production is expected to displace a number of the current herbicides used in cotton today, particularly applications of fluometuron, fomesafen, MSMA, and paraquat. Dicamba offers a relative reduction of risk potential in comparison to some of the alternative non-glyphosate herbicides currently available to cotton growers (see Appendices E and F. Dicamba could be expected to conservatively replace approximately 34% of the projected total acres treated (TAT)[52] for all non-glyphosate herbicides used in preplant/preemergence application timing and 37% of the projected TAT for all non-glyphosate herbicides used in postemergence application timing at peak dicamba use based on a projection that 50% of total planted cotton acres may be treated with dicamba following the introduction of DGT cotton. At projected peak penetration of dicamba use in DGT cotton an increase in both total cotton acres treated and total pounds of non-glyphosate herbicide active ingredient applied to cotton is projected, however estimated increases are 16% or less of the total herbicide use projections (16% for TAT and 12% of total pounds of active ingredient) if DGT cotton is not commercialized.

IV.B. AGRICULTURAL PRODUCTION OF SOYBEANS & COTTON

IV.B.1. Crop Use and Biology

IV.B.1.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) soybean and cotton are expected to remain the same under the No Action Alternative. Under this alternative DT soybean and DGT cotton would not become integrated into the glyphosate-tolerant soybean and cotton systems, respectively, and dicamba use would likely remain similar to today's use pattern in soybean and cotton. Adding alternative herbicides with different modes-of-action into the glyphosate-tolerant systems to manage the development of glyphosate-resistant weeds and control glyphosate-resistant weeds would continue to remain an option. Additionally, conventional tillage may increase in some instances as an additional means to control problematic weeds.

Currently herbicides are used on nearly all (~98%) soybean acres, and over 35 different herbicide active ingredients are registered and available for use by soybean growers to control weeds. (See Section II.B.1.d); herbicides are used on nearly all (>99%) cotton acres, and approximately 39 million pounds of 30 different herbicides are applied pre- or postemergence in cotton production (Monsanto 2012) (See Section II.B.2.d). The use of herbicides in soybean and cotton production is expected to continue to increase as more growers adopt, in certain areas of the U.S., diversified weed management strategies to combat hard-to-control and herbicide-resistant weeds. Some of the available herbicides may pose greater potential risks to humans, and wildlife than dicamba; and conventional tillage practices may increase. Increased use of tillage could have a small adverse impact on wildlife, as the crop residues that remain with the use of conservation tillage may provide shelter and food for wildlife, such as game birds and small animals, and soil erosion associated with tillage can increase sedimentation and turbidity in surface water bodies and impact aquatic wildlife (CTIC 2011).

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52 The use of TAT provides a way to look at herbicide use that is independent of the various use rates of herbicides. If a herbicide is used more than once on an acre the TAT will reflect this multiple use, and consequently the TAT may exceed the number of crop acres planted. This provides a more complete view of herbicide use.

IV.B.1.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, the No Action Alternative for DGT cotton is not expected to result in significant changes to crop use and biology.

The Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. As discussed in Section IV.B.1, under the Deregulation in Whole Alternative, the cultivation of DT soybean is not expected to impact soybean agronomic practices, with the exception of a change in herbicide use pattern. Cultivation of DT soybean would not alter agronomic inputs or the number of soybean acres under cultivation, and will help maintain current levels of conservation tillage adoption and may have a small positive effect on the use of conservation tillage.

Potential Impacts from the Genetic Modification. Potential impacts from dietary exposure to DT soybean are discussed in detail in Sections IV.E.1 and IV.F. All the information in Sections IV.E.1 and IV.F.1 is relevant to dietary exposure for any animal that may consume DT soybean. As discussed in those sections, there is no meaningful risk to animal or human health from dietary exposure to the MON 87708 DMO protein and there are no known toxic properties associated with MON 87708 DMO protein. Furthermore, the seed produced by DT soybean is compositionally equivalent to commercially cultivated soybean, whether or not it is treated with dicamba. This information on the safety of MON 87708 DMO protein and the composition of DT soybean seed and forage, as detailed in Appendices F and H to this environmental report, indicate that the effects to mammals that consume DT soybean forage or seed would be no different than those from the consumption of commercially cultivated soybean. Similarly, the impact to birds or other animals, including migratory birds and animals that may consume soybean forage or seed from DT soybean would be no different than possible impacts from commercially cultivated soybean. During field trials with DT soybean, no biologically relevant changes in arthropod feeding damage were observed (see Appendix G) indicating similar arthropod susceptibility for DT soybean compared to commercially cultivated soybean. DT soybean exhibits no differences in toxic effects on insects or other animals as compared to commercially cultivated soybean. In addition, the cultivation of DT soybean does not impact the nutritional quality, safety, or availability of animal feed derived from DT soybean (see Section IV.F.).

Potential Impacts from Dicamba. To support the introduction of DT soybean, Monsanto has submitted to EPA an application to amend EPA Reg. No. 524-582, a low-volatility DGA salt formulation, to register a new use pattern for dicamba on DT soybean. The current and proposed uses are summarized in Table IV.A-1 (see Section IV.A.1). However, a comprehensive safety evaluation and risk assessment conducted by EPA concluded that dicamba has low toxicity to mammals, is not a carcinogen, does not adversely affect reproduction and development, and does not bioaccumulate in mammals (U.S. EPA 2009a; d). Similarly, an ecotoxicological risk assessment concluded that the use of dicamba does not pose an unreasonable risk of adverse effects to non-target species, such as birds and fish, when used according to label directions, nor does it pose an unreasonable risk of adverse effects to insects outside of the application area (U.S. EPA 2009a; d). Furthermore, outside the cultivated soybean field, dicamba is unlikely to affect forbs and beneficial arthropods that are dependent on plants for survival (U.S. EPA 2009a; d).

In summary, in terms of potential impacts to animal communities, including insects, beneficial arthropods, and all other animals that live in or near soybean fields containing DT soybean, the difference between the No Action and Deregulation in Whole Alternatives is primarily the difference in the types of herbicides that may be used. EPA has determined that when herbicides are used in accordance with their labels, no unreasonable adverse impacts will result. As discussed above, EPA's conclusions are based on comprehensive safety evaluations and risk assessments. Compared to the Deregulation in Whole Alternative, the No Action Alternative may pose a small increase in adverse impact on animal communities if it results in increased tillage, as crop residue provides shelter and food for wildlife, such as game birds and small animals, and soil erosion associated with tillage can increase sedimentation and turbidity in surface water bodies and impact aquatic wildlife (CTIC 2011).

IV.B.1.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed in Section IV.B.1.a, the No Action Alternative for DT soybean is not expected to result in significant changes to crop use and biology.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. As discussed in IV.B.2, the cultivation of DGT cotton is not expected to impact cotton agronomic practices, with the exception of a change in herbicide use pattern. Cultivation of DGT cotton would not alter agronomic inputs or the number of cotton acres under cultivation, and will help maintain current levels of conservation tillage adoption and may have a small positive effect on the use of conservation tillage.

Potential Impacts from the Genetic Modification. Potential impacts from dietary exposure to DGT cotton are discussed in detail in Sections IV.E.1 and IV.F. Except for the discussion specific to cottonseed oil and linters in Section IV.F.2, all the information in Sections IV.E.1 and IV.F is relevant to dietary exposure for any animals that may consume DGT cotton. As discussed in those sections, there is no meaningful risk to animal or human health from dietary exposure to MON 88701 DMO or PAT (*bar*). There are no known toxic properties associated with MON 88701 DMO or PAT (*bar*). Furthermore, the seed produced by DGT cotton is compositionally equivalent to commercially cultivated cotton, whether or not it is treated with dicamba and/or glufosinate. This information on the safety of MON 88701 DMO and PAT (*bar*) and composition of DGT cottonseed, as detailed Appendices F and H to this environmental report, indicate that the effects to mammals that consume DGT cotton seed would be no different than those possible from the consumption of commercially cultivated cotton. Similarly, the impact to birds or other animals, including migratory birds and animals that may consume cotton forage or cottonseed from DGT cotton would be no different than possible impacts from commercially cultivated cotton. During field trials with DGT cotton, no biologically relevant changes in arthropod feeding damage were observed (see Appendix G) indicating similar arthropod susceptibility for DGT cotton compared to commercially cultivated cotton. DGT cotton exhibits no differences in toxic effects on insects or other animals as compared to commercially cultivated cotton. In addition, the cultivation of DGT cotton does not impact the nutritional quality, safety, or availability of animal feed derived from DGT cotton (see Section IV.F).

Potential Impacts from Dicamba. To support the introduction of DGT cotton, Monsanto has submitted an application to EPA to amend Registration number 524-582, a low-volatility DGA salt formulation, to remove all preemergence planting restrictions (application intervals, rainfall, and geographic) and to allow in-crop postemergence dicamba applications to DGT cotton. However, a comprehensive safety evaluation and risk assessment conducted by EPA concluded that dicamba has low toxicity to mammals, is not a carcinogen, does not adversely affect reproduction and development, and does not bioaccumulate in mammals (U.S. EPA 2009a; d). Similarly, an ecotoxicological risk assessment concluded that the use of dicamba does not pose an unreasonable risk of adverse effects to non-target species, such as birds and fish, when used according to label directions, nor does it pose an unreasonable risk of adverse effects to insects outside of the application area (U.S. EPA 2009a; d). Furthermore, outside the cultivated cotton field, dicamba is unlikely to affect forbs and beneficial arthropods that are dependent on plants for survival (U.S. EPA 2009a; d).

Glufosinate has been used over-the-top of glufosinate-tolerant crops since 1995. Glufosinate is currently labeled for in-crop application with glufosinate-tolerant cotton from emergence through early bloom growth stage. The use pattern and rate of glufosinate on DGT cotton will follow the existing glufosinate-tolerant cotton uses outlined on the glufosinate herbicide label.

In summary, in terms of potential impacts to animal communities, including insects, beneficial arthropods, and all other animals that live in or near cotton fields containing DGT cotton, the difference between the No Action and Deregulation in Whole Alternatives is primarily the difference in the types of herbicides that may be used. EPA has determined that when herbicides are used in accordance with their labels, no unreasonable adverse impacts will result. As discussed above, EPA's conclusions are based on comprehensive safety evaluations and risk assessments. Compared to the Deregulation in Whole Alternative, the No Action Alternative may pose a small increase in adverse impact on animal communities if it results in increased tillage, as crop residue provides shelter and food for wildlife, such as game birds and small animals, and soil erosion can increase sedimentation and turbidity in surface water bodies and impact aquatic wildlife, and soil erosion associated with tillage can increase sedimentation and turbidity in surface water bodies and impact aquatic wildlife (CTIC 2011).

IV.B.1.d. Approval in Whole of DT Soybean and DGT Cotton.

As discussed in detail above, in terms of potential impacts to animal communities, including insects, beneficial arthropods, and all other animals that live in or near soybean and cotton fields containing DT soybean / DGT cotton, the difference between the No Action and Deregulation in Whole Alternatives is primarily the difference in the types of herbicides that may be used. EPA has determined that when herbicides are used in accordance with their labels, no unreasonable adverse impacts will result. As discussed above, EPA's conclusions are based on comprehensive safety evaluations and risk assessments. Further discussion of the difference in the types of herbicides used and associated impacts is included at Appendix A. Compared to the Deregulation in Whole Alternative for DT Soybean and DGT Cotton, the No Action Alternative may pose a small increase in adverse impact on animal communities if it results in increased tillage, as crop residue provides shelter and food for wildlife, such as game birds and small animals, and soil erosion can increase sedimentation and turbidity in surface water bodies and impact aquatic wildlife, and soil erosion associated with tillage can increase sedimentation and turbidity in surface water bodies and impact aquatic wildlife (CTIC 2011).

IV.B.2. General Agronomic Practices

IV.B.2.a. No Action Alternative for Both DT Soybean and DGT Cotton.

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) soybean and cotton are expected to remain the same under the No Action Alternative. General agronomic practices such as planting and harvesting times, crop nutrition, use of plant growth regulators, and preharvest and harvest practices are expected to remain the same as described in Section II.B.1.c. Specialized agronomic practices such as row spacing, the use of cover crops and crop rotation practices, as well as adoption of precision agriculture may change over time. There is a potential for increased use of non-glyphosate herbicides and potential increased use of tillage for weed control or hand-weeding. There may be increased potential for development of herbicide-resistant weeds in certain areas of the U.S.

IV.B.2.b. Approval in Whole of DT Soybean, but not DGT Cotton.

As discussed above, the No Action Alternative for DGT cotton is not expected to result in significant changes in general agronomic practices except for a potential for increased use of non-glyphosate herbicides and potential increased use of tillage or hand-weeding for weed control. There may be increased potential for development of herbicide-resistant weeds in certain areas of the U.S.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. As discussed in Appendix G, with the exception of the tolerance to dicamba, DT soybean is phenotypically and agronomically unchanged from other commercially cultivated soybean. No impact on agronomic practices and attributes such as planting and harvesting times, crop nutrition, use of plant growth regulators, preharvest and harvest practices, row spacing, use of cover crops, crop rotation, yield and introduction of new varieties would be anticipated. Therefore, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on general agronomic practices, with the exception of potential increased use of non-glyphosate herbicides and increased use of tillage or hand-weeding for weed control under the No Action Alternative. There may also be increased potential for development of herbicide-resistant weeds in certain areas of the U.S. under the No Action Alternative.

IV.B.2.c. Approval In Whole of DGT Cotton, but not DT Soybean

As discussed above, under the No Action Alternative for DT soybean, there is a potential for increased use of non-glyphosate herbicides and potential increased use of tillage or hand-weeding for weed control. There may be increased potential for development of herbicide-resistant weeds in certain areas of the U.S.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. As discussed in Appendix G, with the exception of the tolerances to both dicamba and glufosinate, DGT cotton is phenotypically and agronomically unchanged from other commercially cultivated cotton. No impact on agronomic practices and attributes such as planting and harvesting times, crop nutrition, use of plant growth regulators, preharvest and harvest practices, row spacing, use of cover crops, crop rotation, yield and introduction of new varieties would be anticipated. Therefore, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on general agronomic practices, with the exception of potential increased use of non-glyphosate herbicides and increased use of tillage or hand-weeding for weed control under the No Action Alternative. There may also be increased potential for development of herbicide-resistant weeds in certain areas of the U.S. under the No Action Alternative.

IV.B.2.d. Approval In Whole of DT Soybean and DGT Cotton.

As discussed above, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques, and of dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. As discussed in Appendix G, with the exception of the tolerance to both dicamba (and glufosinate in the case of DGT cotton) DT soybean and DGT cotton are phenotypically and agronomically unchanged from other commercially cultivated soybean and cotton. No impact on agronomic practices and attributes such as planting and harvesting times, crop nutrition, use of plant growth regulators, preharvest and harvest practices, row spacing, use of cover crops, crop rotation, yield and introduction of new varieties would be anticipated. Therefore, the Deregulation in Whole of DT soybean and DGT cotton and No Action Alternatives are the same regarding their potential impact on general agronomic practices, with the exception of potential increased use of non-glyphosate herbicides and increased use of tillage or hand-weeding for weed control under the No Action Alternative. There may also be increased potential for development of herbicide-resistant weeds in certain areas of the U.S. under the No Action Alternative.

IV.B.3. Tillage

IV.B.3.a. No Action Alternative for Both DT Soybean and DGT Cotton.

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. Current availability and usage of commercially available (both GE and non-GE) soybean and cotton are expected to remain the same under the No Action Alternative. Soybean and cotton growers will not have access to DT soybean and DGT cotton and some combination of herbicides already used in soybean and cotton production acres, in certain areas of the U.S., and possibly increased tillage or hand-weeding may be used to control problematic weeds, including glyphosate-resistant weeds. Increased tillage would negate many of the benefits of conservation tillage to soil including improvement of soil structure, reduction of soil compaction, conservation of soil moisture, reduction of soil erosion and the inherent benefits to water resources, and improvement of soil organic matter content (CTIC 2011; U.S. EPA 2008c).

IV.B.3.b. Approval In Whole of DT Soybean, but Not DGT Cotton.

As discussed above, under the No Action Alternative for DGT cotton, it is possible that increased tillage or hand-weeding may be used to control problematic weeds, including glyphosate-resistant weeds. Increased tillage would negate many of the benefits of conservation tillage to soil including improvement of soil structure, reduction of soil compaction, conservation of soil moisture, reduction of soil erosion and the inherent benefits to water resources, and improvement of soil organic matter content (CTIC 2011; U.S. EPA 2008c).

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. DT soybean would allow the additional use of dicamba herbicide in a diversified weed management program to control a broad spectrum of grasses and broadleaf weed species, including glyphosate-resistant biotypes of Palmer amaranth, marestail, common ragweed, giant ragweed, and waterhemp. The availability of DT soybean should help preserve the current acreage of soybean grown using conservation tillage and potentially help increase conservation tillage acreage. As discussed in Appendix B, increases in total soybean acres dedicated to conservation tillage have been attributed to an increased use of herbicide-tolerant soybean that reduces the need for mechanical weed control. Dicamba would provide additional modes-of-action for managing herbicide-resistant species. Therefore, the Deregulation in Whole Alternative would better sustain and potentially increase the use of conservation tillage practices as compared to the No Action Alternative.

IV.B.3.c. Approval In Whole of DGT Cotton, but Not DT Soybean.

As discussed above, under the No Action Alternative for DT soybean, it is possible that increased tillage may be used to control problematic weeds, including glyphosate-resistant weeds. Increased tillage would negate many of the benefits of conservation tillage to soil including improvement of soil structure, reduction of soil compaction, conservation of soil moisture, reduction of soil erosion and the inherent benefits to water resources, and improvement of soil organic matter content (CTIC 2011; U.S. EPA 2008c).

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. DGT cotton would allow the additional use of dicamba herbicide in a diversified weed management program to control a broad spectrum of grasses and broadleaf weed species, including glyphosate-resistant biotypes of Palmer amaranth, marestail, common ragweed, giant ragweed, and waterhemp. The availability of DGT cotton should help preserve the current acreage of cotton grown using conservation tillage and potentially help increase conservation tillage acreage, and reduce need for hand-weeding. As discussed in Appendix B, increases in total cotton acres dedicated to conservation tillage have been attributed to an increased use of herbicide-tolerant cotton that reduces the need for mechanical weed control. Dicamba would provide additional modes-of-action for managing herbicide-resistant species. Therefore, the Deregulation in Whole Alternative would better sustain and potentially increase the use of conservation tillage practices as compared to the No Action Alternative.

IV.B.3.d. Approval In Whole of DT Soybean and DGT Cotton.

As discussed above, Deregulation in Whole of DT soybean and DGT cotton would result in the gradual integration of the dicamba-tolerant event DT soybean and the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant soybean systems using traditional breeding techniques. DT soybean and DGT cotton would allow the additional use of dicamba herbicide (and glufosinate in the case of cotton) in a diversified weed management program to control a broad spectrum of grasses and broadleaf weed species, including glyphosate-resistant biotypes of Palmer amaranth, marestail, common ragweed, giant ragweed, and waterhemp. The availability of DT soybean and DGT cotton should help preserve the current acreage of soybean and cotton grown using conservation tillage and potentially help increase conservation tillage acreage. As discussed in Appendix B, increases in total soybean and cotton acres dedicated to conservation tillage have been attributed to an increased use of herbicide-tolerant soybean and cotton that reduce the need for mechanical weed control or hand-weeding. Dicamba would provide additional modes-of-action for managing herbicide-resistant species. Therefore, the Deregulation in Whole Alternatives would better sustain and potentially increase the use of conservation tillage practices as compared to the No Action Alternative.

IV.B.4. Pest Management

IV.B.4.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. Current availability and usage of commercially available (both GE and non-GE) soybean and cotton are expected to remain the same under the No Action Alternative. While specific diseases and pests in soybean and cotton change in significance over time and geography, the general management practices summarized in Section II.B.1.c would be expected to continue under the No Action Alternative.

IV.B.4.b. Approval of DT Soybean, but not DGT Cotton

As discussed above, under the No Action Alternative for DGT cotton, general pest management practices would be expected to continue under the No Action Alternative.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. As discussed in Appendix G, with the exception of the tolerance to dicamba, DT soybean is phenotypically, agronomically and compositionally unchanged from other commercially cultivated soybean. Phenotypic and agronomic information collected from field trials in 2008 using the same agricultural inputs showed no biologically meaningful differences between DT soybean and the conventional control. In an individual-site assessment of disease damage conducted in the field trials, no differences were observed between DT soybean and the conventional control for any of the comparisons for the assessed diseases among all observations across the U.S. In an assessment of arthropod-related damage, no statistically significant differences (5% level of significance) were detected between DT soybean and the conventional control for any of the comparisons for the assessed arthropods. See Appendix G for details. The lack of significant biological differences in plant responses to disease damage and arthropod-related damage for DT soybean support the conclusion that the Deregulation in Whole Alternative is the same as the No Action Alternative in terms of impacts on disease and pest management.

IV.B.4.c. Approval of DGT Cotton, but not DT Soybean

As discussed above, under the No Action Alternative for DT soybean, general pest management practices would be expected to continue under the No Action Alternative.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. As discussed in Appendix G, with the exception of the tolerances to both dicamba and glufosinate, DGT cotton is phenotypically, agronomically and compositionally unchanged from other commercially cultivated cotton. Phenotypic and agronomic information collected from field trials conducted in 2010 using the same agricultural inputs showed no biologically meaningful differences between DGT cotton and the conventional control. In an individual-site assessment of disease damage conducted in the 2010 field trials, no differences were observed between DGT cotton and the conventional control for any of the comparisons for the assessed diseases among all observations across the U.S. In an assessment of arthropod-related damage, no statistically significant differences (5% level of significance) were detected between DGT cotton and the conventional control for any of the 288 comparisons for the assessed arthropods. See Appendix G for details. The lack of significant biological differences in plant responses to disease damage and arthropod-related damage for DGT cotton support the conclusion that the Deregulation in Whole Alternative is the same as the No Action Alternative in terms of impacts on disease and pest management.

IV.B.4.d. Approval in Whole of DT Soybean and DGT Cotton

As discussed above, field trials demonstrate that are no significant biological differences in plant responses to disease damage and arthropod-related damage in DT soybean and DGT cotton as compared to conventional controls. Thus, the Deregulation in Whole Alternative for DT soybean and DGT cotton is the same as the No Action Alternative in terms of impacts on disease and pest management.

IV.B.5. Weed Management

IV.B.5.a. No Action Alternative for DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean would continue to be regulated by APHIS. Under this alternative DT soybean combined with glyphosate-tolerant soybean would not be available. Growers would continue to cultivate available GE and non-GE soybean, using glyphosate alone or in combination with other non-glyphosate herbicides used in soybean production for weed management, and/or incorporating mechanical tillage into their cultural practices. Under this alternative dicamba herbicide would not become integrated into the glyphosate-tolerant soybean system and dicamba use would likely remain similar to today's use pattern in soybean. Growers would continue to use the glyphosate-tolerant soybean system for broad spectrum weed control, other registered non-glyphosate herbicides alone or in combination with other herbicide-tolerant soybean for management of hard-to-control and/or glyphosate-resistant weeds, and/or incorporate tillage into their practices. Some non-glyphosate alternative herbicides have a less benign human health and environmental profile compared to dicamba, and reduced agronomic flexibility due to soybean planting restrictions, rotational crop planting restrictions, the need for adequate soil moisture for activation, and the need to apply prior to planting to minimize crop injury (See Section II.B.1.d for additional information).[53]

Integration of DT soybean into the glyphosate-tolerant soybean system has the potential to mitigate the evolution and development of herbicide-resistant weeds (see Appendix B for additional detail). The use of dicamba in conjunction with glyphosate and other residual herbicides provides growers with an herbicide system with two to three different modes of action with activity on the major target weeds including biotypes with resistance to glyphosate. Thus, it is foreseeable that under the No Action Alternative, the inability to integrate DT soybean into the glyphosate-tolerant soybean system could increase the potential for glyphosate-resistant weed populations to evolve and spread in soybean producing areas in certain parts of the U.S. In addition, the potential for resistance to evolve and spread in certain parts of the U.S. for other herbicides used in soybean production could also potentially increase in these areas where growers do not use multiple modes-of-action or other weed management methods. Also under the No Action Alternative, increased use of other non-glyphosate alternative herbicides, some with a less benign human health and environmental characteristics compared to dicamba, and reduced flexibility for the grower (e.g., restricted plant-back intervals, rotational crop restrictions) would be expected (Tables II.B-7 and II.B-8). A number of weeds commonly found in the Midwestern and southern portions of the U.S. already display resistance to many of these alternative herbicides (Tables II.B-9 and II.B-10), while only four broadleaf weed species have been confirmed to be resistant to dicamba in North the U.S./Canada, even though dicamba has been widely in use for over 40 years. Increasing the number of weed management options available to soybean growers, including other herbicide tolerant traits pending deregulation, is an important element to mitigate evolution and development of resistant weed populations.

Given these observations, the No Action Alternative for DT soybean and corresponding lack of effective alternative modes of action may lead to an increase in weed resistant populations for these alternative herbicides in some areas of the U.S. Herbicides are a critical element of conservation tillage practices. Since weed management is a primary reason for tillage, herbicides are the primary tool to replace tillage and thus are critical to the sustainability of conservation tillage practices. Under the No Action Alternative, increased use of traditional tillage methods for management of hard-to-control and/or glyphosate-resistant weeds may occur in some situations and result in the potential loss of many of the benefits of conservation tillage. Growers would continue to use the glyphosate-tolerant soybean system for broad spectrum weed control, other registered non-glyphosate herbicides, including dicamba, alone or in combination with other herbicide-tolerant soybean for management of hard-to-control and/or glyphosate-resistant weeds, and/or incorporate tillage into their practices.

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53 As previously discussed, all alternative herbicides used in soybean production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category (e.g., aquatic plant risk). In other instances dicamba presents a similar risk potential compared to some alternatives. In a few cases, dicamba presents a greater risk potential compared to some alternatives. This comparative assessment serves to demonstrate that the use of dicamba on DT soybean is unlikely to result in a significant impact/risk to human health or the environment compared to current herbicide agronomic practices, and in some instances its use may impart additional benefits as described in this Environmental Report.

Under the No Action Alternative, DGT cotton would continue to be regulated by APHIS. Under this alternative DGT cotton combined with glyphosate-tolerant cotton would not be available. Growers would continue to cultivate available GE and non-GE cotton, using glyphosate alone or in combination with other non-glyphosate herbicides used in cotton production, including glufosinate, for weed management, and/or incorporating mechanical tillage or hand-weeding into their cultural practices. Dicamba will continue to be applied preplant for control of broadleaf weeds. The use of alternative non-glyphosate herbicides, tillage practices or hand-weeding is expected to continue to increase as growers in certain areas of the U.S. seek additional herbicide or cultural options to manage hard-to-control and/or herbicide-resistant weeds in their fields (CAST 2012; Sosnoskie and Culpepper 2012). While all pesticides must meet the FIFRA standard ensuring that they do not pose unreasonable adverse effects to humans or the environment before they can be registered, some non-glyphosate alternative herbicides have less favorable human health and environmental characteristics compared to dicamba, and may have more restrictive application requirements or use rates to mitigate human health or environmental hazards. In addition, some non-glyphosate alternative herbicides have reduced agronomic flexibility due to cotton planting restrictions, rotational crop planting restrictions, the need for adequate soil moisture for activation, and the need to apply prior to planting or with hooded sprayers in-crop to minimize crop injury, as compared to dicamba. (See Section II.B.2.d and Appendix A for additional information.).[54] Growers in certain parts of the U.S. would continue to experience weed control challenges with hard-to-control and resistant weed species, such as morningglory and glyphosate-resistant Palmer amaranth; the number of acres with resistant weeds is projected to increase due to lack of adequate weed control solutions (Hartzler 2013; Owen 2006). Growers will continue to use alternative non-glyphosate herbicides that do not provide consistent or adequate control of resistant broadleaf weeds, likely leading to the development, in certain areas of the U.S., of new resistant weed populations to alternative herbicides such as glufosinate, ALS inhibitors and PPO inhibitors (Prostko 2011b; Sosnoskie and Culpepper 2012) (Dr. Larry Steckel and Dr. Stanley Culpepper, personal communications, August 2012). The lack of effective weed management programs combined with the potential for additional herbicide-resistant weeds to develop in certain areas in the U.S. can adversely impact the overall profitability and sustainability of U.S. cotton production (Culpepper, et al. 2008; Jordan et al. 2011; Nichols et al. 2010). Growers would continue to use the glyphosate-tolerant cotton system for broad spectrum weed control, other registered non-glyphosate herbicides, including dicamba, alone or in combination with other herbicide-tolerant cotton for management of hard-to-control and/or glyphosate-resistant weeds, and/or incorporate tillage or hand-weeding into their practices.

[54] As previously discussed, all alternative herbicides used in cotton production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category (e.g., aquatic plant risk). In other instances dicamba presents a similar risk potential compared to some alternatives. In a few cases, dicamba presents a greater risk potential compared to some alternatives. This comparative assessment serves to demonstrate that the use of dicamba on DGT cotton is unlikely to result in a significant impact/risk to human health or the environment compared to current herbicide agronomic practices, and in some instances its use may impart additional benefits as described in this Environmental Report.

IV.B.5.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, Under the No Action Alternative, DGT cotton combined with glyphosate-tolerant cotton would not be available. Growers would continue to cultivate available GE and non-GE cotton, using glyphosate alone or in combination with other non-glyphosate herbicides used in cotton production, including glufosinate, for weed management, and/or incorporating mechanical tillage or hand-weeding into their cultural practices. Dicamba will continue to be applied preplant for control of broadleaf weeds. The use of alternative non-glyphosate herbicides or tillage practices/hand-weeding is expected to continue to increase as growers in certain areas of the U.S. seek additional herbicide or cultural options to manage hard-to-control and/or herbicide-resistant weeds in their fields (CAST 2012; Sosnoskie and Culpepper 2012). Some non-glyphosate alternative herbicides have a less benign human health and the environment profile compared to dicamba, and reduced agronomic flexibility due to cotton planting restrictions, rotational crop planting restrictions, the need for adequate soil moisture for activation, and the need to apply prior to planting or with hooded sprayers in-crop to minimize crop injury (See Section II.B.2.d and Appendix A for additional information).[55] Cotton growers in certain areas of the U.S. would continue to experience weed control challenges with hard-to-control and resistant weed species, such as morningglory and glyphosate-resistant Palmer amaranth; the number of acres with resistant weeds is projected to increase due to lack of adequate weed control solutions (Hartzler 2013; Owen 2006). Cotton growers will continue to use alternative non-glyphosate herbicides that do not provide consistent or adequate control of resistant broadleaf weeds, likely leading to the development, in certain areas of the U.S., of new resistant weed populations to alternative herbicides such as glufosinate, ALS inhibitors and PPO inhibitors (Prostko 2011b; Sosnoskie and Culpepper 2012) (Dr. Larry Steckel and Dr. Stanley Culpepper, personal communications, August 2012). The lack of effective weed management programs combined with the potential for additional herbicide-resistant weeds to develop in certain areas in the U.S. can adversely impact the overall profitability and sustainability of U.S. cotton production (Culpepper et al. 2008; Jordan et al. 2011; Nichols et al. 2010).

With respect to DT soybean, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. DT soybean would allow the expanded use of dicamba in a diversified weed management program to control a broad spectrum of grasses and broadleaf weed species including glyphosate-resistant biotypes of Palmer amaranth, marestail, common ragweed, giant ragweed and waterhemp. Under the Deregulation in Whole Alternative, soybean growers will have the option to cultivate soybean containing the combination of dicamba and glyphosate tolerance traits.

Under the Deregulation in Whole Alternative, soybean growers would have the option of a wider window for treating their soybean crop with dicamba pending U.S. EPA approval of the

55 As previously discussed, all alternative herbicides used in cotton production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category (e.g., aquatic plant risk).

new use pattern. As discussed in detail in Section IV.A.1, Monsanto submitted an application to U.S. EPA to amend Registration number 524-582, a low-volatility DGA salt formulation, to remove all existing preemergence planting restrictions and to allow in-crop postemergence dicamba applications to DT soybean. Before any application of dicamba can be made onto commercially cultivated DT soybean, the EPA must first approve a label describing the conditions of use of the herbicide in connection with DT soybean – including the appropriate application rates and timing, and other measures necessary to address potential impacts of dicamba offsite movement. The number of acres upon which dicamba is used will likely increase under this alternative. As described in Section IV.A.1, DT soybean could eventually occupy 40% of U.S. soybean acres at peak penetration. The potential use of dicamba on DT soybean would result in a total of 50.2 million acres treated with dicamba. Similarly, the total amount of dicamba applied in overall agriculture would also increase. Based upon an upper-end estimation of the anticipated commercial use pattern for dicamba in DT soybean, an additional 20.5 million pounds of dicamba is estimated (high-end) to be added to U.S. soybean fields each season. According to NASS statistics, approximately 103 million pounds of herbicides were used on soybean in 2006, and more recently 133 million pounds of herbicides in 2012, demonstrating the trend towards increasing herbicide use for the management of problematic weeds including resistant populations as well as the incorporation of diversified weed management practices in soybean growing areas (USDA-NASS 2012d). As discussed previously, dicamba will displace in part the use of some existing herbicides used in soybean production.

Dicamba has a more benign human health and environmental profile in comparison to some of the alternative non-glyphosate herbicides currently available to soybean growers. The rationale and supporting information for the comparative alternative analysis is summarized below, additional details are presented in Appendices A:

Dicamba has a more favorable toxicity profile and poses a lower health risk potential to applicators and consumers compared to some alternative herbicides;

Dicamba has lower toxicity to aquatic animals and plants and poses lower risk potential to aquatic organisms compared to some alternative herbicides;

Dicamba when used in conjunction with glyphosate integrated into the glyphosate-tolerant soybean system provides growers with a more flexible and reliable weed management system (Peterson, et al. 2011).

Dicamba could be expected to conservatively replace approximately 14% of the projected total acres treated (TAT) for all non-glyphosate herbicides used in preplant/preemergence application timing and 15% of the projected TAT for all non-glyphosate herbicides used in postemergence application timing at peak dicamba use based on the 40% of total planted soybean acres where dicamba is projected to be used. At projected peak penetration of dicamba use in DT soybean an increase in both total acres treated and total pounds of herbicide active ingredient applied is projected, however estimated increases are 12% or less of the total herbicide use projections (11% for TAT and 12% of total pounds of active ingredient) if DT soybean is not commercialized.

Dicamba is an excellent option to mitigate the potential for development of resistance to other herbicides because of its broad activity on broadleaf weeds and low level of weed resistance, specifically on the summer spectrum of weeds known to infest soybean acres.

In summary, with the cultivation of DT soybean and the associated use of dicamba, shifts in herbicide use will occur, with dicamba displacing some of the alternative herbicides currently used by growers. Conservation tillage practices are expected to be sustained and potentially increase, and the DT soybean system will provide soybean growers with a more flexible and reliable weed management options. On the basis of the above analysis, the Deregulation in Whole and No Action Alternatives are similar regarding weed management for soybean growers. However, the No Action Alternative would not provide as many options to manage weeds and address the potential for the development of herbicide-resistant weeds, and would not take advantage of DT soybean to help sustain the long-term agronomic, environmental, and economic value and benefits of glyphosate as a weed control tool in soybean.

IV.B.5.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, under the No Action Alternative, DT soybean would continue to be regulated by APHIS. Under this alternative DT soybean combined with glyphosate-tolerant soybean would not be available. Growers would continue to cultivate available GE and non-GE soybean, using glyphosate alone or in combination with other non-glyphosate herbicides used in soybean production for weed management, and/or incorporating mechanical tillage into their cultural practices. Under this alternative dicamba herbicide would not become integrated into the glyphosate-tolerant soybean system and dicamba use would likely remain similar to today's use pattern in soybean. Growers would continue to use the glyphosate-tolerant soybean system for broad spectrum weed control, other registered alternative herbicides alone or in combination with other herbicide-tolerant soybean for targeted hard-to-control weeds, and/or incorporate tillage into their practices.

Integration of DT soybean into the glyphosate-tolerant soybean system has the potential to mitigate the evolution and development of glyphosate- and other herbicide-resistant weeds (see Appendix B for additional detail). For soybean, the use of dicamba in conjunction with glyphosate and other residual herbicides provides growers with an herbicide system with two to three different modes of action with activity on the major target weeds including biotypes with resistance to glyphosate. Thus, it is foreseeable that under the No Action Alternative, the inability to integrate DT soybean into the glyphosate-tolerant soybean system could increase, in certain areas of the U.S., the potential for glyphosate-resistant weed populations to evolve and spread in soybean producing areas. In addition, the potential for resistance to evolve and spread for other herbicides used in soybean production could also increase in these areas where growers do not use multiple modes-of-action or other weed management methods. Also under the No Action Alternative, increased use of other non-glyphosate alternative herbicides, some with a less benign human health and environmental profile compared to dicamba, and reduced flexibility for the grower (e.g., restricted plant-back intervals, rotational crop restrictions) would be expected (See Section II.B.1.d and Appendices A & B).[56] A number of weeds commonly found in the Midwestern and southern portions of the U.S. already display resistance to many of these alternative herbicides (Tables II.B-9 and II.B-10), while only four broadleaf weed species have been confirmed to be resistant to dicamba in the U.S./Canada, even though dicamba has been widely in use for over 40 years. Increasing the number of weed management options available to soybean growers, including other herbicide tolerant traits pending deregulation, is an important element to mitigate evolution and development of resistant weed populations.

Given these observations, the No Action Alternative for DT soybean and corresponding lack of effective alternative modes of action may, in some areas of the U.S., lead to an increase in weed resistant populations for these alternative herbicides. Herbicides are a critical element of conservation tillage practices. Since weed management is a primary reason for tillage, herbicides are the primary tool to replace tillage and thus are critical to the sustainability of conservation tillage practices. Under the No Action Alternative for DT soybean, increased use of traditional tillage methods for the control of problematic weeds may occur in some situations and result in the potential loss of many of the benefits of conservation tillage.

With respect to cotton, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. DGT cotton would allow the expanded use of dicamba, along with glufosinate herbicide in a diversified weed management program to control a broad spectrum of grasses and broadleaf weed species including glyphosate-resistant biotypes of Palmer amaranth, marestail, common ragweed, giant ragweed and waterhemp. Under the Deregulation in Whole Alternative growers will have the option to cultivate cotton containing the combination of dicamba, glufosinate, and glyphosate tolerance traits. Monsanto is not seeking changes to the current labeled use pattern for glufosinate with glufosinate-tolerant cotton, thus the deregulation of DGT cotton will only result in changes in the dicamba use pattern on cotton. For those acres where glyphosate-resistant broadleaf weeds may already be present and where dicamba could be used for control of resistant or hard-to-control broadleaf weeds, the cultivation of cotton containing the DGT cotton traits would be a new option for growers. With the exception of its tolerance to both dicamba and glufosinate, DGT cotton has been shown to be no different from commercially available (both GE and non-GE) cotton in its agronomic characteristics. A summary of current cotton agronomic practices is presented in Section II.B.2.c.

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56 All alternative herbicides used in soybean production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category (e.g., aquatic plant risk). In other instances dicamba presents a similar risk potential compared to some alternatives. In a few cases, dicamba presents a greater risk potential compared to some alternatives. This comparative assessment serves to demonstrate that the use of dicamba on DT soybean is unlikely to result in a significant impact/risk to human health or the environment compared to current herbicide agronomic practices, and in some instances its use may impart additional benefits as described in this Environmental Report.

The cultivation of DGT cotton combined with glyphosate tolerant cotton will provide growers with the ability to use dicamba, glufosinate and glyphosate as part of an effective diversified weed management system. Dicamba tolerance provides an important tool for the management of hard-to-control and resistant weed species, in particular glyphosate-resistant Amaranthus species such as Palmer amaranth, which pose major weed control challenges in cotton production and threaten cotton quality and yield (CAST 2012). Soil residual herbicides will continue to be recommended by academics and Monsanto, especially in fields where glyphosate-resistant Amaranthus species such as Palmer amaranth and waterhemp may be present to aid in the control of these weed species, which are prolific seed producers, fast growing, highly competitive with cotton, densely populated, and germinate and emerge throughout the growing season (Chandi, et al. 2013; Jha 2008; Liu, et al. 2012; New Mexico State University 2013; Nordby et al. 2007; Sosnoskie et al. 2011). Dicamba, when used in conjunction with DGT cotton combined with glyphosate-tolerant cotton and proper management practices, would provide growers with a more flexible and reliable weed management system (Marshall 2012; York, et al. 2012). Combining DGT cotton with glyphosate-tolerant cotton would allow for in-season application of glyphosate, glufosinate, and/or dicamba, and increase the diversity of in-crop herbicide control options which, in turn, supports the long term sustainability of glyphosate-tolerant cotton.

In addition, the availability of DGT cotton combined with glyphosate-tolerant cotton is expected to help preserve the current acreage of cotton grown using conservation tillage and potentially help increase conservation tillage acreage. As discussed in Section II.B.2.c, 3.1.3, increases in total acres dedicated to conservation tillage have been attributed to an increased use of herbicide-tolerant cotton which reduces the need for mechanical weed control, such as tillage and hand-weeding (McClelland et al. 2000; Towery and Werblow 2010).

Under the Deregulation in Whole Alternative, growers would have expanded dicamba use options pending U.S. EPA approval of the new use pattern. As discussed in detail in Section IV.A.2, Monsanto submitted an application to U.S. EPA to amend Registration number 524-582, a low-volatility DGA salt formulation, to remove all existing preemergence planting restrictions (application intervals, rainfall, and geographic) and to allow in-crop postemergence dicamba applications to DGT cotton. Before any application of dicamba can be made onto commercially cultivated DGT cotton, the EPA must first approve a label describing the conditions of use of the herbicide in connection with DGT cotton – including the appropriate application rates and timing, and other measures necessary to address potential impacts of dicamba offsite movement. As described in Section IV.A.2, the number of cotton acres treated with dicamba will likely increase under this Alternative; Monsanto estimates as much as 50% of cotton acres could eventually be treated with dicamba herbicide. Based on the analysis described in Section IV.A.2., use of DGT cotton on 50% of U.S. cotton acres would result in approximately 5.2 million lbs a.e. of dicamba applied to DGT cotton annually (including preplant, preemergence and in-crop applications). Currently 364,000 lbs a.e. of dicamba are applied preplant to commercially available cotton (Monsanto 2012). With this potential addition of dicamba applied to DGT cotton, the total U.S. dicamba use is estimated to be 9.0 million pounds annually.

In comparison, approximately 39 million pounds of herbicides were used on over 99% of cotton acres in 2011 (see Section II.B.2.d), and herbicide usage in cotton has been trending up due to the growth and spread of problematic weeds, including herbicide-resistant populations and the implementation of diversified weed management practices (see Section II.B.2.d and Appendix A for additional details regarding recent trends). Additionally, dicamba will displace the use of some existing herbicides used in cotton production, which may have a less benign human health and the environment profile compared to dicamba.[57] In addition, many of the registered alternative herbicides are limited by application restrictions, plant back restrictions, the need for adequate soil moisture for activation, and the need to apply prior to planting or with hooded sprayers in-crop to minimize crop injury (See Tables II.B-179 and II.B-2018 for additional information).

Dicamba could be expected to conservatively replace approximately 34% of the projected total acres treated (TAT) for all non-glyphosate herbicides used in preplant/preemergence application timing and 37% of the projected TAT for all non-glyphosate herbicides used in postemergence application timing at peak dicamba use based on the 50% of total planted cotton acres where dicamba is projected to be used. At projected peak penetration of dicamba use in DGT cotton an increase in both total acres treated and total pounds of herbicide active ingredient applied is projected, however estimated increases are 16% or less of the total herbicide use projections (16% for TAT and 12% of total pounds of active ingredient) if DGT cotton is not commercialized.

In summary, with the cultivation of DGT cotton and the associated use of dicamba, shifts in herbicide use will occur, with dicamba displacing some of the alternative herbicides currently used by growers. Conservation tillage practices are expected to be sustained and potentially increase, and the DGT cotton system will provide cotton growers with a more flexible and reliable weed management options. On the basis of the above analysis, the Deregulation in Whole and No Action Alternatives are similar regarding weed management for cotton growers. However, the No Action Alternative would not provide as many options to manage weeds and address the development of herbicide-resistant weeds, and would not take advantage of DGT cotton to help sustain the long-term agronomic, environmental, and economic value and benefits of glyphosate as a weed control tool in cotton.

IV.B.5.d. Approval in Whole of DT Soybean and DGT Cotton

As discussed above, the cultivation of DT soybean and DGT cotton and the associated use of dicamba, shifts in herbicide use will occur, with dicamba displacing some of the alternative herbicides currently used by growers. Conservation tillage practices are expected to be sustained and potentially increase, and the DT soybean and DGT cotton systems will provide growers with a more flexible and reliable weed management options. On the basis of the above analysis, the Deregulation in Whole and No Action Alternatives are similar regarding weed

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57 All alternative herbicides used in soybean production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category (e.g., aquatic plant risk). In other instances dicamba presents a similar risk potential compared to some alternatives. In a few cases, dicamba presents a greater risk potential compared to some alternatives. This comparative assessment serves to demonstrate that the use of dicamba on DT soybean is unlikely to result in a significant impact/risk to human health or the environment compared to current herbicide agronomic practices, and in some instances its use may impart additional benefits as described in this Environmental Report.

management for cotton growers. However, the No Action Alternative would not provide as many options to manage weeds and address the development of herbicide-resistant weeds, and would not take advantage of DGT cotton to help sustain the long-term agronomic, environmental, and economic value and benefits of glyphosate as a weed control tool in cotton. Additional discussion of weed management impacts is set forth at Cumulative Impacts Section V.I. and Appendix B.

IV.B.6. Weed Resistance

IV.B.6.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. Under this alternative, DT soybean and DGT cotton combined with glyphosate-tolerant soybean would not be available. Growers would continue to cultivate available herbicide-tolerant GE and non-GE soybean and cotton, using glyphosate alone or in combination with other non-glyphosate herbicides (including glufosinate) for weed management.

Growers would continue to use the glyphosate-tolerant soybean system for broad spectrum weed control, other registered alternative herbicides alone or in combination with other herbicide-tolerant soybean, and/or incorporate tillage into their practices. The use of existing herbicide options presents increasing challenges to the grower's ability to achieve consistent control of problematic weeds such as glyphosate-resistant waterhemp and Palmer amaranth. It is foreseeable that under the No Action Alternative, there is a potential for an increase in the evolution and development of glyphosate-resistant weed populations in soybean cultivation areas, as well as the potential for the evolution and development of resistant populations to other alternative herbicides used in soybean production (see Appendix B for additional details).

With respect to cotton, the use of existing herbicides presents challenges to the grower's ability to effectively achieve consistent control of problematic weeds in cotton such as Palmer amaranth. Thus, it is foreseeable that under the No Action Alternative, the inability to cultivate cotton varieties containing DGT cotton combined with the glyphosate tolerance trait could increase the potential for glyphosate-resistant weed populations to evolve and spread in certain cotton producing areas of the U.S. In addition, the potential for resistance to continue to evolve and spread for other popular herbicides used in cotton production, such as ALS and PPO herbicides, could also increase in these areas where growers do not use multiple effective modes of action (Prostko 2011a) (Dr. Larry Steckel and Dr. Stanley Culpepper, personal communications, August 2012).

Monsanto and the weed scientist community recommend the use of multiple herbicide modes-of-action in herbicide-tolerant soybean and cotton systems regardless of whether glyphosate-resistant or hard to control broadleaf weeds are present (Jordan et al. 2011; Monsanto Company 2012a; Price et al. 2011; Prostko 2011b; University of Tennessee 2012). These options include the use of residual and postemergence herbicides such as microtubule inhibitors (pendimethalin, trifluralin), PPO inhibitors (flumioxazin, fomesafen), long chain fatty acid inhibitors (metolachlor), synthetic auxins (2,4-D, dicamba), ALS inhibitors (thifensulfuron), and PSII inhibitors (metribuzin, sulfentrazone- soybean; diuron, fluometuron, prometryn- cotton). Monsanto's Roundup Ready PLUS program, which encourages soybean and cotton growers to use multiple herbicide modes-of-action in their weed management programs, will continue under the No Action Alternative.

Academics recommend that all cotton acres in the South and Midsouth be treated as though there are existing glyphosate-resistant Palmer amaranth weed populations present (University of Georgia 2012; University of Tennessee 2012). This is because the spread of glyphosate resistance alleles via outcrossing among Palmer amaranth populations is highly probable. Additionally, a number of weeds commonly found in the cotton production areas of the U.S. already display resistance to several alternative non-glyphosate herbicides used in cotton production, which are commonly recommended to control glyphosate-resistant Amaranthus species, specifically the ALS and PPO inhibitors. In the absence o a diversified weed management system that employs multiple herbicide modes-of-action, new resistant weed biotypes, including biotypes resistant to multiple herbicides, are likely to evolve and increase leading to fewer herbicide options available for control of key weed species in cotton. The more extensive use and, in some situations, use in the absence of other herbicide modes-of-action effective at controlling Palmer amaranth, raises the risk level for additional resistance to develop. In addition, a number of current herbicides used in cotton today are limited by application restrictions, plant back restrictions, the need for adequate soil moisture for activation, and the need to apply prior to planting or with hooded sprayers in-crop to minimize crop injury (See Appendices A & B for additional details).

The evolution and development of resistance to alternative herbicides can be mitigated through the use of diversified weed resistance management strategies that utilize different mechanisms of control as part of weed management practices, such as mechanical tillage or other cultural practices.

IV.B.6.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, it is foreseeable that under the No Action Alternative, the inability to cultivate cotton varieties containing DGT cotton combined with the glyphosate tolerance trait could increase the potential for glyphosate-resistant weed populations to evolve and spread in certain cotton producing areas of the U.S. In addition, the potential for resistance to continue to evolve and spread for other popular herbicides used in cotton production, such as ALS and PPO herbicides, could also increase in these areas where growers do not use multiple effective modes of action (Prostko 2011a) (Dr. Larry Steckel and Dr. Stanley Culpepper, personal communications, August 2012).

With respect to DT soybean, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. For those acres where glyphosate-resistant broadleaf weeds may already be present and where dicamba could be used for control of resistant or hard-to-control broadleaf weeds, the cultivation of soybean containing the DT soybean traits would be an option for growers. DT soybean combined with glyphosate-tolerant soybean would provide the tools to directly manage the development of glyphosate- and other herbicide-resistant weeds (see Section II.B.2.d and Appendices B and C for more detail). The use of dicamba in conjunction with glyphosate and residual herbicides provides growers with an effective herbicide system with two to three distinct modes-of-action with activity on the major target weeds including biotypes with resistance to glyphosate.

To support the introduction of varieties containing DT soybean, Monsanto will use multiple methods to distribute technical and stewardship information to growers, academics and grower advisors regarding the use of the product as part of a diversified weed management system. Growers who purchase Monsanto varieties containing DT soybean sign a limited use license known as the Monsanto Technology Stewardship Agreement (MTSA). The MTSA obligates growers to comply with certain requirements, including the Monsanto Technology Use Guide (TUG). The TUG will set forth the requirements and best practices for the cultivation of DT soybean including recommendations on weed resistance management practices.

The weed resistance management practices that are designed to minimize the potential for the development of herbicide-resistant weeds will be articulated in the TUG and also be broadly communicated to growers and retailers. These practices will be communicated through a variety of means, including direct communications to each grower authorized to purchase and plant a soybean variety containing DT soybean, a public website, and reports in farm media publications. The overall weed resistance management program will be reinforced through collaborations with U.S. academics, who will provide their recommendations for appropriate stewardship of dicamba and glyphosate in soybean production, as well as by collaboration with crop commodity groups who have launched web-based weed resistance educational modules.

Dicamba has been used extensively on millions of acres for over 40 years. To date, there are four species with known resistant biotypes to dicamba in the U.S./Canada: common hempnettle, kochia, prickly lettuce, and wild mustard (Heap 2012a). Additionally, a population of common lambsquarters has been confirmed to be resistant in New Zealand, for a total of five species worldwide with confirmed resistant biotypes to dicamba. See Appendix B for additional information on dicamba-resistant biotypes. However, the introduction of DT soybean is not likely to result in a substantial risk for the development of dicamba-resistant weeds for several reasons:

- The use of glyphosate in addition to dicamba would provide multiple herbicide modes-of-action on key broadleaf weeds which would diminish the chance for selection of dicamba-resistant broadleaf weeds when species are not resistant to glyphosate;

- In fields where glyphosate-resistant broadleaf weeds are present or suspected, glyphosate plus dicamba will be recommended. In addition, Monsanto will recommend an additional herbicide with a 3rd mode-of-action that also has activity on the glyphosate-resistant broadleaf weed, thereby providing two effective modes-of-action to control glyphosate-resistant weeds; and

- The proposed dicamba herbicide label for DT soybean, existing glyphosate herbicide labels, and separate Monsanto weed management recommendations (e.g., Monsanto's annual TUG and publicly available websites) will specify the effective rate and timing of dicamba and glyphosate applications for optimal weed control, reducing the selection pressure for dicamba as well as glyphosate. The new use pattern and draft label for dicamba to be used on DT soybean are subject to regulatory approval by EPA.

DT soybean integrated into the glyphosate-tolerant cotton systems provides a simple, effective weed management system to control existing resistant weeds and allows for an easy way to incorporate multiple effective herbicide modes-of-action for effective weed resistance management. In the unlikely case that broadleaf weeds were to evolve or develop with resistance to dicamba, existing cultivation and alternative herbicide tools (see Section II.B.2.d for a description of alternative herbicides) would remain potential options to provide effective control (see Appendix A for a description of alternative herbicides). Furthermore, under the Deregulation in Whole Alternative, the potential for resistance to continue to evolve and spread for other popular herbicides used in soybean production, such as ALS and PPO herbicides, is expected to be reduced. However, the development of resistance to alternative herbicides can be managed through the use of diversified weed resistance management strategies that utilize different mechanisms of control as part of weed management practices, such as mechanical tillage or other cultural practices. On the basis of the above analysis, the Deregulation in Whole and No Action Alternatives are similar regarding potential increased costs and complexity in weed control for soybean growers. However, the No Action Alternative would not provide as many management options for addressing the development of herbicide-resistant weeds, and would not take advantage of DT soybean to help sustain the long-term agronomic, environmental and economic value and benefits of glyphosate-tolerant soybean.

IV.B.6.c. Approval in Whole of DGT Cotton, but not DT Soybean

Under the No Action Alternative, DT soybean would continue to be regulated by APHIS. Under this alternative DT soybean combined with glyphosate-tolerant soybean would not be available. Growers would continue to cultivate available herbicide-tolerant GE and non-GE soybean, using glyphosate alone or in combination with other non-glyphosate herbicides for weed management. Growers would continue to use the glyphosate-tolerant soybean system for broad spectrum weed control, other registered alternative herbicides alone or in combination with other herbicide-tolerant soybean, and/or incorporate tillage into their practices. There is a potential for glyphosate-resistant weed populations to increase and spread in soybean cultivation areas, as well as the potential for the development and spread of resistant populations to other alternative herbicides used in soybean production.

With respect to DGT cotton, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. For those acres where glyphosate-resistant broadleaf weeds may already be present and where dicamba could be used for control of resistant or hard-to-control broadleaf weeds, the cultivation of cotton containing the DGT cotton traits would be an option for growers. DGT cotton combined with glyphosate-tolerant cotton would provide the tools to manage dicamba-, glufosinate-, and glyphosate-resistant weeds and mitigate evolution and development of resistant weed populations (see Section II.B.2.d and Appendix B of this Environmental Report for more detail). The use of dicamba and glufosinate, plus residuals, in select situations in conjunction with glyphosate provides growers with an effective herbicide system with three distinct modes-of-action.

To support the introduction of varieties containing DGT cotton, Monsanto will use multiple methods to distribute technical and stewardship information to growers, academics and grower advisors regarding the use of the product as part of a diversified weed management system. Growers who purchase Monsanto varieties containing DGT cotton sign a limited use license known as the Monsanto Technology Stewardship Agreement (MTSA). The MTSA obligates growers to comply with certain requirements, including the Monsanto Technology Use Guide

(TUG). The TUG will set forth the requirements and best practices for the cultivation of DGT cotton including recommendations on weed resistance management practices.

The weed resistance management practices that are designed to minimize the potential for the development of herbicide-resistant weeds will be articulated in the TUG and also be broadly communicated to growers and retailers. These practices will be communicated through a variety of means, including direct communications to each grower authorized to purchase and plant a cotton variety containing DGT cotton, a public website, and reports in farm media publications. The overall weed resistance management program will be reinforced through collaborations with U.S. academics, who will provide their recommendations for appropriate stewardship of dicamba and glufosinate in cotton production, as well as by collaboration with crop commodity groups who have launched web-based weed resistance educational modules (WSSA 2012).

Dicamba has been used extensively on millions of acres for over 40 years. To date, there are four species with known resistant biotypes to dicamba in the U.S./Canada: common hempnettle, kochia, prickly lettuce, and wild mustard (Heap 2012d). Additionally, a population of common lambsquarters has been confirmed to be resistant in New Zealand, for a total of five species worldwide with confirmed resistant biotypes to dicamba. Glufosinate has been used since 1994 and, to date, there are two weed species with confirmed resistance to glufosinate: goosegrass in Malaysia and Italian ryegress in Oregon, U.S.(Heap 2012b). See Appendix B of this Environmental Report, for additional information on dicamba- and glufosinate-resistant biotypes. However, the introduction of DGT cotton is not likely to result in a substantial risk for the development of dicamba- or glufosinate-resistant weeds for several reasons:

The use of residuals in select situations, plus glyphosate or glufosinate, in addition to dicamba, would provide multiple modes-of-action on key broadleaf weeds which would diminish the chance for selection of dicamba- or glufosinate-resistant broadleaf weeds;

In fields where glyphosate-resistant broadleaf weeds are present or suspected, glyphosate plus dicamba and/or glufosinate will be recommended. In addition, it will be recommended that an additional herbicide with a 3rd mode-of-action that also has activity on the glyphosate-resistant broadleaf weed be used, thereby providing two effective modes-of-action to control glyphosate-resistant weeds; and

The proposed dicamba herbicide label for DGT cotton, existing glyphosate herbicide labels, and separate Monsanto weed management recommendations (e.g., Monsanto's annual TUG and publicly available websites) will specify the effective rate and timing of dicamba, glyphosate, and glufosinate applications for optimal weed control, reducing the selection pressure for dicamba as well as glyphosate and glufosinate. The new use pattern and draft label for dicamba to be used on DGT cotton are subject to regulatory approval by EPA.

DGT cotton integrated into the glyphosate-tolerant cotton systems provides a simple, effective weed management system to control existing resistant weeds and allows for an easy way to incorporate multiple effective herbicide modes-of-action for effective weed resistance management. In the unlikely case that broadleaf weeds were to evolve or develop resistance to dicamba or glufosinate, existing cultivation and alternative herbicide tools (see Section II.B.2.d for a description of alternative herbicides) would remain potential options to provide effective control. Furthermore, under the Deregulation in Whole Alternative, the potential for resistance to continue to evolve and develop for other popular herbicides used in cotton production, such as ALS and PPO herbicides, is expected to be reduced. However, the development of resistance to alternative herbicides can be managed through the use of diversified weed resistance management strategies that utilize different mechanisms of control as part of weed management practices, such as mechanical tillage or other cultural practices. On the basis of the above analysis, the Deregulation in Whole and No Action Alternatives are similar regarding potential increased costs and complexity in weed control for cotton growers. However, the No Action Alternative would not provide as many management options for addressing the development of herbicide-resistant weeds, and would not take advantage of DGT cotton to help sustain the long-term agronomic, environmental and economic value and benefits of glyphosate-tolerant cotton.

IV.B.6.d. Approval in Whole of DT Soybean and DGT Cotton

As discussed above, DT soybean and DGT cotton integrated into the glyphosate-tolerant soybean and cotton systems provides a simple, effective weed management system to control existing resistant weeds and allows for an easy way to incorporate multiple effective herbicide modes-of-action for effective weed resistance management. In the unlikely case that broadleaf weeds were to evolve or develop with resistance to dicamba, existing cultivation and alternative herbicide tools (see Appendix A for a description of alternative herbicides) would remain potential options to provide effective control. Furthermore, under the Deregulation in Whole Alternative, the potential for resistance to continue to evolve and develop for other popular herbicides used in soybean and cotton production, such as ALS and PPO herbicides, is expected to be reduced. However, the development of resistance to alternative herbicides can be managed through the use of diversified weed resistance management strategies that utilize different mechanisms of control as part of weed management practices, such as mechanical tillage or other cultural practices. On the basis of the above analysis, the Deregulation in Whole and No Action Alternatives are similar regarding potential increased costs and complexity in weed control for cotton growers. However, the No Action Alternative would not provide as many management options for addressing the development of herbicide-resistant weeds, and would not take advantage of DT soybean and DGT cotton to help sustain the long-term agronomic, environmental and economic value and benefits of glyphosate-tolerant soybean and cotton.

IV.B.7. Organic Production

IV.B.7.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT cotton would remain subject to the regulatory requirements of 7 CFR part 340 and the plant pest provisions of the Plant Protection Act. The availability of GE, non-GE and organic soybean and cotton would not change as a result of the continued regulation of DT soybean or DGT cotton. Organic seed producers would continue to utilize the same methods as applied in certified seed production systems designed to maintain soybean and cotton seed identity and meet National Organic Standards as established by the NOP.

As described in Section II.B., organic soybean production is a very small portion of the soybean market which would not be expected to change under the No Action Alternative. Also, agronomic practices employed to produce organic soybean would remain unaffected by selection of the No Action Alternative.

Acreage devoted to organic cotton production is small relative to that of total cotton acres, the majority of which is planted with GE varieties. Total organic cotton acres have remained relatively steady at ~15,000 acres between 2000 and 2008 (USDA-APHIS 2013). As described in Section II.B.2.e, organic cotton production is a very small portion of the cotton market which would not be expected to change under the No Action Alternative. Also, agronomic practices employed to produce organic cotton would remain unaffected by selection of the No Action Alternative.

It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods does not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche 2006; USDA-AMS 2010; 2011). However, certain markets or contracts may have defined thresholds regarding levels of GE presence (Non-GMO Project 2012).

IV.B.7.b. Approval in Whole of DT Soybean, but not DGT Cotton

As described above, the availability of GE, non-GE and organic cotton seed would not change as a result of the continued regulation of DGT cotton. Organic seed producers would continue to utilize the same methods as applied in certified seed production systems designed to maintain cotton seed identity and meet National Organic Standards as established by the NOP. Acreage devoted to organic cotton production is small relative to that of total cotton acres, the majority of which is planted with GE varieties. Total organic cotton acres have remained relatively steady at ~15,000 acres between 2000 and 2008 (USDA-APHIS 2013). As described in Section II.B., organic cotton production is a very small portion of the cotton market which would not be expected to change under the No Action Alternative. Also, agronomic practices employed to produce organic cotton would remain unaffected by selection of the No Action Alternative. It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods does not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche 2006; USDA-AMS 2010; 2011). However, certain markets or contracts may have defined thresholds regarding levels of GE presence (Non-GMO Project 2012).

With respect to DT soybean, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. GE herbicide-tolerant soybean lines are already extensively used by farmers, while organic soybean production represents a small percentage of the total U.S. soybean acreage. Similar to the No Action Alternative, organic soybean acreage is likely to remain small, regardless of whether new varieties of GE or non-GE soybean varieties, including DT soybean, become available for commercial soybean production.

When compared to other GE varieties of soybean, DT soybean should not present any new or different issues and impacts for organic and other specialty soybean producers and consumers. Organic producers employ a variety of measures to manage identity and preserve the integrity of organic production systems (Guerena and Sullivan 2003). Agronomic tests conducted by Monsanto found DT soybean to be substantially equivalent to the non-GE control variety; hence, pollination characteristics would be similar to other soybean varieties currently available to growers (Appendix G to this environmental report). Given the largely self-pollinating nature and the limited pollen movement of soybean, it is not likely that organic farmers will be substantially affected by a determination of nonregulated status of DT soybean when organic soybean is produced in accordance with agronomic practices designed to meet National Organic Standards. This is particularly the case given that 93% of all soybean acres currently are already GE. The Deregulation in Whole Alternative is not anticipated to increase the overall acreage of GE soybean, but rather is anticipated to be adopted by growers already using another GE variety, but who are interested in adopting an alternative mode-of-action herbicide to control herbicide-resistant or hard-to-control broadleaf weeds or to mitigate the potential for development of herbicide-resistant weeds.

The trend in the cultivation of GE soybean, non-GE, and organic soybean varieties, and the corresponding production systems to maintain varietal integrity are likely to remain the same as the No Action Alternative. Accordingly, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on organic soybean production.

IV.B.7.c. Approval in Whole of DGT Cotton, but not DT Soybean

As described above, the availability of GE, non-GE and organic soybean seed would not change as a result of the continued regulation of DT soybean. Organic seed producers would continue to utilize the same methods as applied in certified seed production systems designed to maintain soybean seed identity and meet National Organic Standards as established by the NOP. As described in Section II.B.1.e, organic soybean production is a very small portion of the soybean market which would not be expected to change under the No Action Alternative. Also, agronomic practices employed to produce organic soybean would remain unaffected by selection of the No Action Alternative. It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods does not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche 2006; USDA-AMS 2010; 2011). However, certain markets or contracts may have defined thresholds regarding levels of GE presence (Non-GMO Project 2012).

With respect to DGT cotton, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. GE herbicide-tolerant cotton lines are already extensively used by farmers, while organic cotton production represents a small percentage (less than 0.2%) of the total U.S. cotton acreage (USDA-ERS 2008). Similar to the No Action Alternative, organic cotton acreage is likely to remain small, regardless of whether new varieties of GE or non-GE cotton varieties, including DGT cotton, become available for commercial cotton production.

When compared to other GE varieties of cotton, DGT cotton should not present any new or different issues and impacts for organic cotton producers and consumers. Organic producers employ a variety of measures to manage identity and preserve the integrity of organic production systems (Guerena and Sullivan 2003). Agronomic tests conducted by Monsanto found DGT cotton substantially equivalent to the non-GE control variety; hence, pollination characteristics would be similar to other cotton varieties currently available to growers (see Appendix G). Given the largely self-pollinating nature and the limited pollen movement of cotton (Niles and Feaster 1984; OECD 2008), it is not likely that organic farmers will be substantially affected by a determination of nonregulated status of DGT cotton when organic cotton is produced in accordance with agronomic practices designed to meet National Organic Standards. This is particularly the case given that 90% of all cotton acres currently are already GE. The Deregulation in Whole Alternative is not anticipated to increase the overall acreage of GE cotton, but rather is anticipated to be adopted by growers already using another GE variety, but who are interested in adopting an alternative mode-of-action herbicide to control herbicide-resistant weeds or to mitigate the potential for development of herbicide-resistant weeds.

The trend in the cultivation of GE cotton, non-GE, and organic cotton varieties, and the corresponding production systems to maintain varietal integrity are likely to remain the same as the No Action Alternative. Accordingly, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on organic cotton production.

IV.B.7.d. Approval in Whole of DT Soybean and DGT Cotton

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of DT soybean and DGT cotton with the current glyphosate-tolerant soybean and cotton systems using traditional breeding techniques. GE herbicide-tolerant soybean and cotton varieties are already extensively used by farmers, while organic soybean and cotton production represents a small percentage of the total U.S. soybean and cotton acreage. Similar to the No Action Alternative, combined organic soybean and cotton acreage is likely to remain small, regardless of whether new varieties of GE or non-GE soybean varieties, including DT soybean and DGT cotton, become available for commercial production.

When compared to other GE varieties of soybean and cotton, DT soybean and DGT cotton should not present any new or different issues and impacts for organic and other specialty producers and consumers. Organic producers employ a variety of measures to manage identity and preserve the integrity of organic production systems (Guerena and Sullivan 2003). Agronomic tests conducted by Monsanto found DT soybean and DGT cotton to be substantially equivalent to the non-GE control variety; hence, pollination characteristics would be similar to other soybean varieties currently available to growers (Appendix G to this Environmental Report). Given the largely self-pollinating nature and the limited pollen movement of soybean and cotton (see Sections II.B.1.c and II.B.2.c), it is not likely that organic farmers will be substantially affected by a determination of nonregulated status of DT soybean and DGT cotton when organic soybean and cotton is produced in accordance with agronomic practices designed to meet National Organic Standards. This is particularly the case given that 93% of all soybean acres and 90% of all cotton acres currently are already GE. The Deregulation in Whole Alternative is not anticipated to increase the overall acreage of GE soybean and GE cotton, but rather is anticipated to be adopted by growers already using another GE variety, but who are interested in adopting an alternative mode-of-action herbicide to control herbicide-resistant weeds or to mitigate the potential for development of herbicide-resistant weeds.

The trend in the cultivation of GE, non-GE, and organic soybean and cotton varieties, and the corresponding production systems to maintain varietal integrity are likely to remain the same as the No Action Alternative. Accordingly, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on organic soybean and cotton production.

IV.B.8. Other Specialty Market Production

IV.B.8.a. No Action Alternative for DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. As discussed in Section II.B., specialty soybean and cotton is cultivated in the U.S. Current availability and usage of commercially cultivated (both GE and non-GE) soybean and cotton, as well as identity preserved specialty soybean and cotton, are expected to remain the same under the No Action Alternative. Under the No Action Alternative, specialty soybean and cotton production would be expected to continue much as it is currently, with continuing fluctuations in production based on supply and demand and other economic considerations.

IV.B.8.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, under the No Action Alternative, specialty cotton production would be expected to continue much as it is currently, with continuing fluctuations in production based on supply and demand and other economic considerations.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. As discussed in Section II.B, GE soybean lines are grown on approximately 93% of U.S. soybean acres. It is possible that DT soybean could be incorporated using conventional breeding with a range of specialty soybean products, including those which have been developed using biotechnology, such as high oleic soybean. Its use would not be expected to present any new or different issues or impacts for specialty soybean producers and consumers.

With the exception of its tolerance to dicamba, DT soybean has been shown to be no different from non-GE soybean in its agronomic and reproductive characteristics, including pollen diameter, viability and morphology (see Appendix G for details). Thus, DT soybean is expected to be no different from other soybean in its ability to cross-pollinate with other soybean; therefore, no additional means beyond those already used to produce GE-derived and specialty soybean will be needed if DT soybean were grown commercially.

A determination of nonregulated status of DT soybean would not change the availability and quality of seed for specialty soybean varieties. Conventional management practices and procedures, as described previously for soybean seed production and seed handling are in place to maintain the quality of various types of soybean. Soybean growers have utilized these methods effectively to meet the standards for the production of specialty crop seed. Therefore, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on specialty soybean growers.

IV.B.8.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, under the No Action Alternative, specialty soybean production would be expected to continue much as it is currently, with continuing fluctuations in production based on supply and demand and other economic considerations.

With respect to DGT cotton, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. As discussed in Section II.B., GE cotton lines are grown on approximately 90% of U.S. cotton acres. Like other GE traits to date, DGT cotton is not planned for incorporation into specialty cotton. Its use would not be expected to present any new or different issues or impacts for specialty cotton producers and consumers.

With the exception of its tolerances to both dicamba and glufosinate, DGT cotton has been shown to be no different from non-GE cotton in its agronomic and reproductive characteristics, including pollen diameter, viability and morphology (see Appendix G for details). Thus, DGT cotton is expected to be no different from other cotton in its ability to cross-pollinate with other cotton; therefore, no additional means beyond those already used to produce GE-derived and specialty cotton will be needed if DGT cotton were grown commercially.

A determination of nonregulated status of DGT cotton would not change the availability and quality of seed for specialty cotton varieties. Conventional management practices and procedures, as described previously for cotton seed production and seed handling are in place to maintain the quality of various types of cottonseed. Cotton growers have utilized these methods effectively to meet the standards for the production of specialty crop seed. Therefore, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on specialty cotton growers.

IV.B.8.d. Approval in Whole of DT Soybean and DGT Cotton

As discussed above, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of DT soybean and DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. As discussed in Section II.B.2.b, GE lines are grown on approximately 93% of U.S. soybean and 90% of U.S. cotton acres. DT soybean could be incorporated using conventional breeding with a range of specialty soybean products, including those which have been developed using biotechnology such as high oleic soybean. DGT cotton is not planned for incorporation into specialty cotton. Their use would not be expected to present any new or different issues or impacts for specialty producers and consumers.

With the exception of their tolerances to dicamba (and glufosinate in the case of cotton), DT soybean and DGT cotton have been shown to be no different from non-GE cotton in its agronomic and reproductive characteristics, including pollen diameter, viability and morphology (see Appendix G for details). Thus, DT soybean and DGT cotton are expected to be no different from other soybean and cotton in their ability to cross-pollinate with other soybean and cotton; therefore, no additional means beyond those already used to produce GE-derived and specialty soybean and cotton will be needed if DT soybean and DGT cotton were grown commercially.

A determination of nonregulated status of DT soybean and DGT cotton would not change the availability and quality of seed for specialty soybean and cotton varieties. Conventional management practices and procedures, as described previously for soybean and cotton seed production and seed handling are in place to maintain the quality of various types of soybean and cottonseed. Soybean and cotton growers have utilized these methods effectively to meet the standards for the production of specialty crop seed. Therefore, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on specialty soybean and cotton growers.

IV.B.9. Seed Production

IV.B.9.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) soybean and cotton are expected to remain the same under the No Action Alternative. DT soybean and DGT cotton would not be propagated to any extent by seed producers because there would be no commercial demand for seed containing DT soybean and DGT cotton. Under the No Action Alternative, current soybeans and cotton seed production practices are not expected to change.

IV.B.9.b. Approval in Whole of DT Soybean, but not DGT Cotton

As described above, under the No Action Alternative, current cotton seed production practices are not expected to change because DGT cotton would not be propagated to any extent by seed producers as there would be no commercial demand for seed containing DGT cotton.

With respect to DT soybean, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. Certified seed production is a carefully managed process (see Section II.B. for additional detail). DT soybean is not expected to impact certified seed production practices or production of specialty soybean seed for reasons described in this section.

If DT soybean is deregulated, seed production would occur within production systems previously developed by seed producers for certified soybean seed, using standards specified by AOSCA to assure compliance with the Federal Seed Act. DT soybean has been thoroughly characterized and (with the exception of its tolerances to dicamba) is not agronomically or phenotypically different from commercial soybean (as detailed in Appendix G). The difference between the Deregulation in Whole and the No Action Alternative is expected to be integration of DT soybean into glyphosate-tolerant soybean varieties using traditional breeding techniques. For those seed production acres where glyphosate-resistant weeds may already be present or where application of a herbicide with a different mode-of-action would aid in weed control or the implementation of weed resistant management practices, the cultivation of soybean containing the DT soybean traits would be an option for seed producers.

Certified soybean seed producers can and have effectively implemented practices (e.g., isolation distances during the growing season, equipment cleaning during harvest, and post-harvest separation of harvested seed) that allow them to maintain commercially acceptable levels of varietal purity. Achieving these purity standards is facilitated by the fact that soybean is a highly self-pollinated species that exhibits very low levels of outcrossing. Because DT soybean has been shown to be no different from commercial soybean relative to pollen morphology and viability, the cultivation of DT soybean will not impact the ability to implement production practices required for the production of certified seed. Therefore, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on certified seed production practices.

IV.B.9.c. Approval in Whole of DGT Cotton, but not DT Soybean

As described above, under the No Action Alternative, current soybean seed production practices are not expected to change because DT soybean would not be propagated to any extent by seed producers as there would be no commercial demand for seed containing DT soybean.

With respect to DGT cotton, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. Certified seed production is a carefully managed process (see Section II.B for additional detail). DGT cotton is not expected to impact certified seed production practices or production of specialty cottonseed for reasons described in this section.

If DGT cotton is deregulated, seed production would occur within production systems previously developed by seed producers for certified cotton seed, using standards specified by AOSCA to assure compliance with the Federal Seed Act. DGT cotton has been thoroughly characterized and (with the exception of its tolerances to both dicamba and glufosinate) is not agronomically or phenotypically different from commercial cotton (as detailed in Appendix G). The difference between the Deregulation in Whole and the No Action Alternative is expected to be integration of DGT cotton into glyphosate-tolerant cotton varieties using traditional breeding techniques. For those seed production acres where glyphosate-resistant weeds may already be present or where application of a herbicide with a different mode-of-action would aid in weed control or the implementation of weed resistant management practices, the cultivation of cotton containing the DGT cotton traits would be an option for seed producers.

Certified cotton seed producers can and have effectively implemented practices (e.g., isolation distances during the growing season, equipment cleaning during harvest, and post-harvest separation of harvested seed) that allow them to maintain commercially acceptable levels of varietal purity. Achieving these purity standards is facilitated by the fact that cotton is a self-pollinated species that exhibits low levels of outcrossing. Because DGT cotton has been shown to be no different from commercial cotton relative to pollen morphology and viability, the cultivation of DGT cotton will not impact the ability to implement production practices required for the production of certified seed. Therefore, the Deregulation in Whole and No

Action Alternatives are the same regarding their potential impact on certified seed production practices.

IV.B.9.d. Approval in Whole of DT Soybean and DGT Cotton

As discussed above, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of DT soybean and DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. Certified seed production is a carefully managed process (see Section II.B for additional detail). DT soybean and DGT cotton are not expected to impact certified seed production practices of soybean or cottonseed for reasons described in this section.

If DT soybean and DGT cotton are deregulated, seed production would occur within production systems previously developed by seed producers for certified cotton seed, using standards specified by AOSCA to assure compliance with the Federal Seed Act. DT soybean and DGT cotton have been thoroughly characterized and with the exception of their herbicide tolerances are not agronomically or phenotypically different from commercial soybean and cotton (as detailed in Appendix G). The difference between the Deregulation in Whole and the No Action Alternative is expected to be integration of DT soybean and DGT cotton into glyphosate-tolerant varieties using traditional breeding techniques. For those seed production acres where glyphosate-resistant weeds may already be present or where application of a herbicide with a different mode-of-action would aid in weed control or the implementation of weed resistant management practices, the cultivation of soybean and cotton containing the DT soybean and DGT cotton traits would be an option for seed producers.

Certified soybean and cotton seed producers can and have effectively implemented practices (e.g., isolation distances during the growing season, equipment cleaning during harvest, and post-harvest separation of harvested seed) that allow them to maintain commercially acceptable levels of varietal purity. Achieving these purity standards is facilitated by the fact that soybean and cotton are self-pollinated species that exhibits low levels of outcrossing. Because DT soybean and DGT cotton have been shown to be no different from commercial cotton relative to pollen morphology and viability, the cultivation of DT soybean and DGT cotton will not impact the ability to implement production practices required for the production of certified seed. Therefore, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on certified seed production practices.

IV.C. PHYSICAL ENVIRONMENT

The following section discusses the potential impacts of the No Action Alternative and Deregulation in Whole of either DT soybean, DGT cotton or both on the physical environment, including impacts on land use, soil quality, water quality, air quality and climate change. In addition to discussing the potential impacts of the plants themselves, this section also discusses potential impacts associated with the use of dicamba. As discussed elsewhere in this report, however, Congress transferred regulatory authority over herbicides from USDA to EPA. Accordingly, USDA-APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider herbicide impacts under the PPA. Nonetheless, because APHIS indicated in its Notice of Intent to Prepare an Environmental Impact Statement (78 Fed. Reg. 28796, May 16, 2013) that it would be considering herbicide effects and herbicide resistance as part of the NEPA process, Monsanto has included a discussion of herbicide impacts in the following section. Importantly, however, Monsanto believes that APHIS has no legal obligation under NEPA to consider herbicide impacts or herbicide resistance in any Environmental Impact Statement or Environmental Assessment. See DOT v. Public Citizen, 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform). See also Center for Food Safety v. Vilsack, No. 12-15052, 2013 U.S. App. LEXIS 9920, at *16-17 (9th Cir. 2013) ("If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests.").

IV.C.1. Land Use Impacts

IV.C.1.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated articles and would not be widely grown. Under this alternative, dicamba and glufosinate use would likely remain similar to today's use pattern. Land use changes would not be expected with the No Action Alternative. Relatively minor fluctuations in soybean and cotton acreage would be expected, resulting from environmental, agronomic, economic and governmental influences.

IV.C.1.b. Approval in Whole of DT Soybean, But Not DGT Cotton

As discussed above, the No Action Alternative for DGT cotton is not expected to result in significant changes to land use. Growers likely would continue to use glyphosate and glufosinate-tolerant cotton in the same areas and with the same weed control options as currently used.

With respect to DT soybean, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. For those acres where glyphosate-resistant weeds may already be present, where application of an herbicide with a different mode-of-action would aid in weed control, or for grower implementation of weed resistant management practices, the cultivation of soybeans containing the DT soybean trait would be an option for growers.

Herbicide-tolerant soybean has been deregulated and grown in the U.S. since 1996. Glyphosate-tolerant soybean currently occupies greater than 90% of total soybean acres. Fluctuations in total soybean acreage before and after herbicide-tolerant soybean was commercialized(USDA-NASS 2011d) indicates that factors unrelated to the availability of the herbicide-tolerant trait play a role in total soybean acres planted. Agricultural land use, and consequently crop production, is dictated by many factors, the most significant of which is commodity prices. Accordingly, growers may increase acres dedicated to soybean production to meet increased demand, but they do so in response to commodity prices and market demand, not in response to availability or adoption of biotechnology-derived traits.

With the exception of tolerance to dicamba, DT soybean is phenotypically and agronomically unchanged from conventional soybean. Phenotypic and agronomic information collected from field trials conducted in 2008 using the same agricultural inputs showed no meaningful changes between DT soybean and the conventional control (see Appendix G of this Environmental Report). Compared to conventional soybean, DT soybean does not display increased susceptibility to pests or diseases, and is not changed regarding crop emergence, growth development or yield. Additional laboratory and greenhouse-based experiments reached the same conclusion; DT soybean was unchanged compared to the conventional control for seed germination and symbiotic relationship parameters. Therefore, production management practices (*e.g.*, planting and harvest timing, fertilizer inputs, and pesticide use other than dicamba) are not expected to change with the introduction of DT soybean. Similarly, because there are no changes in growth and development or yield, there is no expectation that the introduction of DT soybean will significantly alter the geographical range of commercial soybean cultivation. Thus, the introduction of DT soybean is not anticipated to facilitate production of soybean in areas where it is not currently grown or have significant impact on total soybean production acres. Therefore, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on land use.

IV.C.1.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, the No Action Alternative for DT soybean is not expected to result in significant changes to land use.

With respect to DGT cotton, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. For those acres where glyphosate-resistant weeds may already be present, where application of an herbicide with a different mode-of-action would aid in weed control, or for grower implementation of weed resistant management practices, the cultivation of cotton containing the DGT cotton trait would be an option for growers.

Currently, herbicides are used on nearly all (>99%) U.S. cotton acres and GE cotton lines are grown on approximately 90% of U.S. cotton acres. Agricultural land use, and consequently crop production, is dictated by many factors, the most significant of which is commodity prices. Accordingly, growers may increase acres dedicated to cotton production to meet increased demand, but they do so in response to commodity prices and market demand, not in response to availability or adoption of biotechnology-derived traits.

With the exception of tolerance to dicamba and glufosinate, DGT cotton is phenotypically and agronomically unchanged from conventional cotton. Phenotypic and agronomic information collected from field trials conducted in 2010 using the same agricultural inputs showed no meaningful changes between DGT cotton and the conventional control (see Appendix G of this Environmental Report). Compared to conventional cotton, DGT cotton does not display increased susceptibility to pests or diseases, and is not changed regarding crop emergence, growth development or yield. Additional laboratory and greenhouse-based experiments reached the same conclusion; DGT cotton was unchanged compared to the conventional control for seed germination and symbiotic relationship parameters. Therefore, production management practices (*e.g.*, planting and harvest timing, fertilizer inputs, and pesticide use other than dicamba and glufosinate) are not expected to change with the introduction of DGT cotton. Similarly, because there are no changes in growth and development or yield, there is no expectation that the introduction of DGT cotton and its use in development of cotton varieties will significantly alter the geographical range of commercial soybean cultivation. Thus, the introduction of DGT cotton is not anticipated to facilitate production of cotton in areas where it is not currently grown or have significant impact on total cotton production acres. Therefore, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on land use.

IV.C.1.d. Approval in Whole of DT Soybean and DGT Cotton

Deregulation in Whole of DT soybean and DGT cotton is expected to result in the gradual integration of the dicamba tolerance with the current glyphosate-tolerant soybean and cotton systems using traditional breeding techniques. For those acres where glyphosate-resistant weeds may already be present, where application of an herbicide with a different mode-of-action would aid in weed control, or for grower implementation of weed resistant management practices, the cultivation of soybean or cotton containing the DT soybean or DGT cotton traits would be an option for growers.

Agricultural land use, and consequently crop production, is dictated by many factors, the most significant of which is commodity prices. Accordingly, growers may increase acres dedicated to soybean or cotton production to meet increased demand, but they do so in response to commodity prices and market demand, not in response to availability or adoption of biotechnology-derived traits.

With the exception of tolerance to dicamba (and glufosinate in the case of DGT cotton), DT soybean and DGT cotton are phenotypically and agronomically unchanged from conventional soybeans and cotton. Phenotypic and agronomic information collected from field trials conducted in 2008 and 2010, respectively for DT soybean and DGT cotton, using the same agricultural inputs showed no meaningful changes between DT soybean and DGT cotton and the conventional control. Compared to conventional soybeans and cotton, DT soybean and DGT cotton does not display increased susceptibility to pests or diseases, and is not changed regarding crop emergence, growth development or yield. Additional laboratory and greenhouse-based experiments reached the same conclusion; DT soybean and DGT cotton were unchanged compared to the conventional control for seed germination and symbiotic relationship parameters. Therefore, production management practices (*e.g.*, planting and harvest timing, fertilizer inputs, and pesticide use other than dicamba and glufosinate) are not expected to change with the introduction of DT soybean and DGT cotton. Similarly, because there are no changes in growth and development or yield, there is no expectation that the introduction of DT soybean and DGT cotton and their use in development of soybean and cotton varieties will significantly alter the geographical range of commercial soybean and cotton cultivation. Thus, the introduction of DT soybean and DGT cotton is not anticipated to facilitate production of soybean and cotton in areas where it is not currently grown or have significant impact on total soybean and cotton production acres. Therefore, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on land use.

IV.C.2. Soil Quality Impacts

IV.C.2.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, both DT soybean and DGT Cotton would continue to be regulated by APHIS. Agronomic practices currently utilized in the cultivation of soybeans and cotton would not be altered. However, some combination of herbicides already used in soybean and cotton production acres likely would continue to increase in order to control problematic weeds. Under the no-action alternative, some growers in certain areas of the U.S. may reincorporate the use of conventional tillage practices to manage problematic weed populations (NRC 2010). An increase in tillage would negate many of the benefits of conservation tillage to soil, including improvement of soil structure, reduction of soil compaction, conservation of soil moisture, reduction of soil erosion and improvement of soil organic matter content. DT soybean and DGT cotton have the potential to mitigate the evolution and development of glyphosate-resistant weeds because they provide growers with an herbicide system with multiple modes-of-action. Thus, it is foreseeable that under the No Action Alternative, the inability to integrate DT soybean and DGT cotton into the glyphosate-tolerant soybean and cotton systems could, in certain areas of the U.S., increase the potential for glyphosate-resistant weed populations to evolve and spread. Under the No Action Alternative, adding other herbicides with different modes-of-action into the glyphosate-tolerant systems to mitigate development of glyphosate-resistant weeds and control glyphosate-resistant weeds would continue to remain an option. Additionally, conventional tillage may increase in some instances as an additional means to control problematic weeds.

IV.C.2.b. Approval in Whole of DT Soybean, But Not DGT Cotton

As discussed above, the No Action Alternative for DGT cotton is expected to result in minimal changes to soil quality.

The difference between the Deregulation in Whole of DT soybean and the No Action Alternative is expected to be integration of DT soybean into the glyphosate-tolerant soybean system using traditional breeding techniques. For those acres where glyphosate-resistant weeds may already be present, where application of an herbicide with a different mode-of-action would aid in weed control, or for grower implementation of weed resistant management practices, the cultivation of soybean containing the DT soybean trait would be an option for growers. Approval of DT soybean is likely to encourage use of conservation tillage.

Other than changes associated with herbicide use, DT soybean will not alter the agronomic practices typically utilized in the cultivation of soybean. DT soybean has been found to be compositionally, agronomically and phenotypically equivalent to conventional soybean. Therefore, microbial populations and associated biochemical processes in soil are not expected to change with the introduction of DT soybean. The DT soybean-produced protein DMO (MON 87708 DMO) demonstrates a high level of substrate specificity and is not expected to persist in the environment. Studies have shown no impact to the symbiont interactions of DT soybean, or to NTOs such as beneficial and pest arthropods when exposed to MON87707 DMO in the field (*see* DT Soybean Petition and Appendix G of this Environmental Report). Based on these data, the cultivation of DT soybean is not expected to impact microbial populations and associated biochemical processes.

Multiple herbicides are already used in soybean production. Agricultural fields are purposefully managed to be weed-free resulting in greater economic benefit to the grower. A discussion of weed management practices is provided in Section II.B.1.d. In the U.S., 98% of soybean acreage was treated with an herbicide in 2006 (USDA-NASS 2007). Therefore, introduction of DT soybean and treatment with dicamba is unlikely to affect soil quality in commercial soybean production systems differently than those herbicides already used in soybean. Dicamba has been registered by the EPA for use on a wide range of agricultural uses since 1967 (see Appendices G and H of this Environmental Report). The EPA evaluated dicamba and its metabolites as part of the RED (U.S. EPA 2009d), and concluded that dicamba may accumulate with frequent and intensive use (2.0 and 2.8 lb per acre a.e. single application and 7.7 lb per acre a.e. annually). The EPA mandated reductions in dicamba use rates as part of dicamba's continued registration to effect these and other potential impacts (U.S. EPA 2009d). The proposed label submitted by Monsanto, which is currently pending before EPA for application of dicamba on DT soybean follows the reduced application rates set by EPA in 2009. Based on the proposed application rates (1.0 lb per acre a.e. with a maximum annual rate of 2.0 lb a.e. per acre), dicamba is unlikely accumulate or persist in the environment. In addition, results of standardized tests with, dicamba and dicamba formulations indicate no long-term effects on functional processes of soil microorganisms (carbon respiration and nitrogen transformation) at rates proposed for dicamba on DT soybean (EC 2008).

A reasonably foreseeable impact under full deregulation is mitigation of the evolution and development of glyphosate-resistant broadleaf weeds as well as weeds resistant to other soybean herbicide classes, such as PPO herbicides, in soybean producing areas. This is because growers will likely use dicamba together with glyphosate on the combined dicamba- and glyphosate-tolerant soybean product because of the excellent crop tolerance and compatibility of the two herbicides. In addition, other herbicides will be recommended and used by growers especially in areas in the U.S. where the grower is managing a weed population already resistant to glyphosate. This will further assist in mitigating the potential for resistance to dicamba and other herbicides used in the DT soybean system.

Dicamba is an excellent option to mitigate the potential for resistance to other herbicides because of its broad spectrum activity on broadleaf weeds and low level of weed resistance, specifically on the summer spectrum of weeds known to infest soybean acres. A prominent strategy to mitigate the evolution and development of herbicide-resistant weeds is to increase the diversity of weed management practices used in a particular cropping system. Diversified weed management practices use a combination of cultural (e.g., crop rotation), mechanical (e.g., cultivation), and herbicide control practices, including use of herbicides with different modes-of-action (Duke and Powles 2009). Thus, DT soybean integrated into the glyphosate-tolerant soybean system provides the opportunity to increase the diversity of in-crop herbicide control options for growers and, in turn, supports the long term sustainability of the glyphosate-tolerant soybean system with its established benefits.

Based on this analysis, conservation tillage acres are likely to remain the same, or potentially increase, with the introduction of DT soybean. Conservation tillage improves soil structure, reduces soil compaction, conserves soil moisture, reduces soil erosion and improves soil organic matter content. An increase in tillage is likely in cotton acreage, with corresponding adverse impacts on soil quality. Therefore, the approval in whole of DT soybean and No Action Alternatives are not significantly different regarding their impact on soil quality.

IV.C.2.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, the No Action Alternative for DT soybean is not expected to result in significant changes to soil quality.

The difference between the No Action and Deregulation in Whole Alternatives for DGT cotton would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. For those acres where glyphosate-resistant weeds may already be present, where application of a herbicide with a different mode-of-action would aid in weed control, or for grower implementation of weed resistant management practices, the cultivation of cotton containing the DGT cotton trait would be an option for growers.

DGT cotton will allow the additional use of dicamba and glufosinate herbicides in a diversified weed management program to control a broad spectrum of grasses and broadleaf weed species including glyphosate-resistant biotypes. The availability of DGT cotton could help preserve the current acreage of cotton grown using conservation tillage and potentially lead to increased conservation tillage adoption. As discussed in Section II.B.2.c of this Environmental Report, increases in total acres dedicated to conservation tillage have been attributed to an increased use of herbicide-tolerant cotton, which reduces the need for mechanical weed control (McClelland et al. 2000; Towery and Werblow 2010).

A reasonably foreseeable impact under full deregulation is the mitigation of the evolution and development of glyphosate-resistant broadleaf weeds as well as weeds resistant to other soybean herbicide classes, such as PPO herbicides, in soybean producing areas. This is because growers will likely use dicamba together with glyphosate on the combined dicamba- and glyphosate-tolerant cotton product because of the excellent crop tolerance and compatibility of the two herbicides. In addition, other herbicides will be recommended and used by growers especially in cetain areas in the U.S. where the grower is managing a weed population already resistant to glyphosate. This will further assist in mitigating the potential for resistance to dicamba and other herbicides used in the DGT cotton system.

Dicamba is an excellent option to mitigate the potential for resistance to other herbicides because of its broad spectrum activity on broadleaf weeds and low level of weed resistance, specifically on the summer spectrum of weeds known to infest soybean acres. A prominent strategy to mitigate the evolution and development of herbicide-resistant weeds is to increase the diversity of weed management practices used in a particular cropping system. Diversified weed management practices use a combination of cultural (e.g., crop rotation), mechanical (e.g., cultivation), and herbicide control practices, including use of herbicides with different modes-of-action (Duke and Powles 2009). Thus, DGT cotton integrated into the glyphosate-tolerant cotton system provides the opportunity to increase the diversity of in-crop herbicide control options for growers and, in turn, supports the long term sustainability of the glyphosate-tolerant cotton system with its established benefits.

DGT cotton has been found to be compositionally, agronomically, and phenotypically equivalent to commercially cultivated cotton (see Appendix G of this Environmental Report). Therefore the physiochemical characteristics of the soil are not expected to change with the introduction of DGT cotton. Field studies have shown that DGT cotton is no different than commercial cotton in terms of response to abiotic stress (such as compaction, drought, high winds, nutritional deficiency, etc.), disease damage, arthropod-related damage, and pest- and beneficial-arthropod abundance (see Appendix G of this Environmental Report). The donor organisms for the MON 88701 DMO and PAT (bar) protein coding sequences, *Stenotrophomonas maltophilia* and *Streptomyces hygroscopicus*, respectively, are bacteria that are ubiquitous in the environment, including in soil. Based on these data, the cultivation of DGT cotton is not expected to impact physiochemical characteristics of the soil. Impacts associated with DGT cotton are expected to be essentially the same as those associated with the No Action Alternative.

Multiple herbicides are already used in nearly all cotton production fields. Agricultural fields are purposefully managed for weed control, to provide economic benefit to the grower resulting from increased yields (see Section II.B.2.d) Herbicides are used on nearly all (>99%) the cotton acres in the U.S., and 30 herbicides, including dicamba and glufosinate, are registered for use on cotton (Table A-23).

Dicamba has been registered by the EPA for a wide range of agricultural uses since 1967 (see Appendix A). The EPA evaluated dicamba and its metabolites as part of the RED (U.S. EPA 2005a; b), and concluded that dicamba may accumulate in soil at the application rates registered for use at that time (2.0 and 2.8 lbs per acre a.e. single application and up to 7.7 lbs per acre a.e. annually). To prevent dicamba accumulation in soils and to minimize other potential impacts, the EPA mandated reductions in dicamba use rates (1.0 lb per acre a.e. with a maximum annual rate of 2.0 lbs a.e. per acre) as part of dicamba's continued registration (U.S. EPA 2009d). The proposed label submitted by Monsanto, which is currently pending before EPA for application of dicamba on DGT cotton, follows the reduced application rates set by EPA in 2009. In addition, results of standardized tests with dicamba and dicamba formulations indicate no long-term effects on functional processes of soil microorganisms (carbon respiration and nitrogen transformation) at rates proposed for dicamba on DGT cotton (EFSA 2007c).

Glufosinate use on DGT cotton is equivalent to currently deregulated glufosinate-tolerant cotton and is considered baseline. No changes in potential impacts of glufosinate on soil quality are anticipated.

Based on this analysis, conservation tillage acres are likely to remain the same, or potentially increase, with the introduction of DGT cotton. Conservation tillage improves soil structure, reduces soil compaction, conserves soil moisture, reduces soil erosion and improves soil organic matter content. An increase in tillage is likely in soybean acreage, with corresponding adverse impacts on soil quality. Based on this analysis, the approval in whole and No Action Alternatives are not significantly different regarding their impact on soil quality.

IV.C.2.d. Approval in Whole of both DT soybean and DGT cotton

Deregulation in Whole of both DT soybean and DGT cotton is expected result in the integration of DT soybean and DGT cotton into the glyphosate-tolerant soybean and cotton systems using traditional breeding techniques. For those acres where glyphosate-resistant weeds may already be present, where application of an herbicide with a different mode-of-action would aid in weed control, or for grower implementation of weed resistant management practices, the cultivation of soybeans or cotton containing the DT soybean or DGT cotton traits would be an option for growers.

Other than changes associated with herbicide use, DT soybean and DGT cotton will not alter the agronomic practices typically utilized in the cultivation of soybeans and cotton. DT soybean and DGT cotton have been found to be compositionally, agronomically and phenotypically equivalent to conventional soybean and cotton. Therefore, microbial populations and associated biochemical processes in soil are not expected to change with the introduction of DT soybean and DGT cotton. Approval of DT soybean and DGT cotton is likely to encourage use of conservation tillage.

Multiple herbicides are already used in soybean and cotton production. Agricultural fields are purposefully managed to be weed-free resulting in greater economic benefit to the grower. Introduction of DT soybean and DGT cotton and treatment with dicamba and glufosinate is unlikely to affect soil quality in commercial soybean and cotton production systems differently than those herbicides already used in soybean and cotton. Dicamba has been registered by the EPA for use on a wide range of agricultural uses since 1967. The EPA evaluated dicamba and its metabolites as part of the RED (U.S. EPA 2009d), and concluded that dicamba may accumulate with frequent and intensive use (2.0 and 2.8 lb per acre a.e. single application and 7.7 lb per acre a.e. annually). The EPA mandated reductions in dicamba use rates as part of dicamba's continued registration to effect these and other potential impacts (U.S. EPA 2009d). The proposed labels submitted by Monsanto, which are currently pending before EPA for application of dicamba on DT soybean and DGT cotton, follow the reduced application rates set by EPA in 2009. Based on the proposed application rates (1.0 lb per acre a.e. with a maximum annual rate of 2.0 lb a.e. per acre), dicamba is unlikely accumulate or persist in the environment. In addition, results of standardized tests with dicamba and dicamba formulations indicate no long-term effects on functional processes of soil microorganisms (carbon respiration and nitrogen transformation) at rates proposed for dicamba on DT soybean and DGT cotton (EC 2008; EFSA 2007c).

A reasonably foreseeable impact under full deregulation is mitigation of the evolution and development of glyphosate-resistant broadleaf weeds as well as weeds resistant to other soybean and cotton herbicide classes, such as PPO herbicides, in certain soybean and cotton producing areas of the U.S. This is because growers will likely use dicamba together with glyphosate on the combined dicamba- and glyphosate-tolerant soybean and cotton products because of the crop tolerance and compatibility of the two herbicides. In addition, other herbicides will be recommended and used by growers especially in cases where the grower is managing a weed population already resistant to glyphosate. This will further assist in mitigating the potential for resistance to dicamba and other herbicides used in the DT soybean and DGT cotton systems.

Dicamba is an excellent option to mitigate the potential for resistance to other herbicides because of its broad spectrum activity on broadleaf weeds and low level of weed resistance, specifically on the summer spectrum of weeds known to infest soybean acres. A prominent strategy to mitigate the evolution and development of herbicide-resistant weeds is to increase the diversity of weed management practices used in a particular cropping system. Diversified weed management practices use a combination of cultural (e.g., crop rotation), mechanical (e.g., cultivation), and herbicide control practices, including use of herbicides with different modes-of-action (Duke and Powles 2009). Thus, DT soybean and DGT cotton integrated into the glyphosate-tolerant soybean and cotton systems provide the opportunity to increase the diversity of in-crop herbicide control options for growers and, in turn, support the long term sustainability of the glyphosate-tolerant soybean and cotton systems with their established benefits.

Glufosinate use on DGT cotton is equivalent to currently deregulated glufosinate-tolerant cotton and is considered baseline. No changes in potential impacts of glufosinate on soil quality are anticipated.

Based on this analysis, conservation tillage acres are likely to remain the same, or potentially increase, on soybean and cotton acreage with the introduction of DT soybean and DGT cotton, as compared to the No Action Alternative. The potential increase in conservation tillage acres is the most likely under this scenario. Conservation tillage improves soil structure, reduces soil compaction, conserves soil moisture, reduces soil erosion and improves soil organic matter content. Based on this analysis, the approval in whole and No Action Alternatives for DT soybean and DGT cotton are not significantly different regarding their impact on soil quality.

IV.C.3. Water Quality Impacts

IV.C.3.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, both DT soybean and DGT Cotton would continue to be regulated by APHIS. Land acreage and agronomic practices (including irrigation) associated with soybean and cotton production would not be substantially impacted. Therefore, water resources and irrigation practices associated with soybean and cotton production are not likely to be substantially affected.

Surface water has the potential to be impacted from soybean and cotton production by runoff from soybean and cotton fields that may carry soil particles and herbicides or other pesticides to streams, rivers, lakes, wetlands and other water bodies. As discussed, based on existing data, the soil component of runoff is a much more important contributor to surface water impacts than is the pesticide component. Similarly, ground water has the potential to be impacted from soybean and cotton production due to the use of herbicides or other pesticides for weed management.

Growers will continue to choose certain pesticides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Farnham, 2001; Heiniger, 2000; University of Arkansas, 2008). Agricultural production of existing nonregulated herbicide-tolerant GE and non-GE soybean and cotton would continue to utilize EPA-registered pesticides, including glyphosate, dicamba and glufosinate for weed management. Dicamba would continue to be used as currently authorized by EPA for pre-plant applications. Glufosinate use is likely to continue to follow the recent trend of increased use associated with the adoption of glufosinate-tolerant soybeans and cotton. The environmental risks of pesticide use are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. Additionally, pesticide registrants must report to EPA the detection of certain amounts of pesticides in surface water, ground water, and drinking water as an adverse effect in order to ensure the pesticide continues to meet FIFRA requirements for registration. 40 C.F.R. § 159.178(b).

EPA's reregistration and registration review process ensures that each registered pesticide continues to meet the FIFRA registration standard, i.e., that pesticides will not cause unreasonable adverse effects when used as directed on product labels.

Under full deregulation, growers' use of dicamba and glufosinate for managing hard-to-control and herbicide-resistant broadleaf weeds in soybean and cotton fields would be expected to increase. Under the No Action Alternative, growers would need to use other practices for dealing with hard-to-control and herbicide-resistant broadleaf weeds. These practices would likely consist of some combination of herbicide use and traditional tillage. However, the specific combination of herbicides used would likely be different than with full deregulation, as dicamba would not be able to be used late preemergence or postemergence on DT soybean or DGT cotton. Growers would likely use some combination of herbicides currently in use for soybean and cotton (see Section II.B.1.d and II.B.2.d).

If the No Action Alternative resulted in increased use of conventional tillage practices for weed control, overall adverse surface water impacts may be greater under the No Action Alternative than under the full deregulation alternative. Tillage causes widespread soil disturbance. Thus, erosion, topsoil loss and the resulting sedimentation and turbidity in streams are likely to increase with increased tillage. Based on the states' water quality reports to EPA, which EPA makes available through its National Assessment Database, pesticides in general and herbicides in particular are a relatively minor contributor to impairment of surface water in the U.S., compared to sedimentation/siltation and turbidity (U.S. EPA 2012a). Pesticides accounted for less than one percent of reported causes of surface water impairment in all but four of the 17 leading U.S. soybean-producing states. In those four states, pesticides accounted for 2% to 8% of reported causes of impairment. Of the pesticides that were reported as contributing to impairment among the 17 leading soybean-producing states, almost all are highly persistent chemicals that are no longer registered for use in the U.S. Only one currently used herbicide, atrazine, was reported (U.S. EPA 2012a).

In summary, based on EPA data, herbicides in general are minor contributors to surface water impairment in the U.S., while sedimentation/siltation and turbidity are more significant contributors. The No Action, compared to Deregulation in Whole of DT soybean and DGT cotton, would likely result in a different combination of alternative herbicides being used and may result in increased tillage to obtain effective weed control. Weed management is a primary reason for tillage, and reduced herbicide options due to existing herbicide resistance, in some cases, may increase the need for tillage (CAST 2011). Increased tillage could contribute to adverse surface water impacts through increased runoff of soil particles to surface water bodies.

IV.C.3.b. Approval In Whole of DT Soybean, But Not DGT Cotton

As discussed above, approval of the No Action Alternative for DGT cotton is not expected to result in significant changes to water quality.

Land acreage and agronomic practices (including irrigation) associated with soybean production would not be substantially impacted by the Deregulation in Whole of DT soybean. Therefore, water resources and irrigation associated with soybean production are not likely to be substantially affected, and the impacts on water use of the Deregulation in Whole Alternative would be the same as the No Action Alternative.

The difference between the Deregulation in Whole and the No Action Alternative for DT soybean is expected to be integration of DT soybean into the glyphosate-tolerant soybean system using traditional breeding techniques. For those acres where glyphosate-resistant weeds may already be present, where application of an herbicide with a different mode-of-action would aid in weed control, or for grower implementation of weed resistant management practices, the cultivation of soybean containing the DT soybean trait would be an option for growers.

Water quality could be impacted either directly by DT soybean via plant material impacts on water resources, or indirectly via impacts from the use of dicamba or tillage practices associated with the planting of DT soybean. Conservation tillage, a system that leaves 30% or more of the previous crop residue covering the soil when planting another crop has been increasingly employed in commercial soybean acres, and helps minimize any impacts of soybean production on water quality by reducing soil erosion.

In terms of potential direct impacts on water quality, DT soybean has been shown to be compositionally, agronomically and phenotypically equivalent to conventional soybean and is therefore unlikely to have any significant impact on surface water quality. The DMO protein contained in DT soybean is a member of the larger family of oxygenase proteins that are ubiquitous in plants and bacteria in the environment. The mode-of-action of this family of proteins is well known, and the introduced DMO protein itself was derived from a common soil bacterium (*Stenotrophomonas maltophilia*). MON 87708 DMO has been shown to have a high level of substrate specificity, and characterization data provided in Appendix G of this Environmental Report demonstrate the safety of the MON 87708 DMO protein. Therefore, it is unlikely that the presence of MON 87708 DMO protein in DT soybean will have a significant impact on water quality.

Under full deregulation of DT soybean, there will be a decreased need for farmers employing conventional tillage practices in order to manage certain weed situations. There is a potential impact to soil conservation in those situations where tillage has been employed to manage resistant weeds (CAST 2011). Dicamba's complementary and supplementary postemergence activity to glyphosate will provide improved postemergence weed management options and thus support more sustainable conservation tillage practices because postemergence herbicide options are generally preferred by growers (Fawcett and Towery 2002). Tillage causes widespread soil disturbance causing erosion and topsoil loss, impacting the sedimentation and turbidity of streams. EPA identified sedimentation and turbidity as two of the top 10 causes of impairment to surface water in the U.S.; similarly in 2007, EPA identified sedimentation/siltation as a leading cause of impairment to rivers and streams in particular (U.S. EPA, 2007a; 2009a). EPA has projected conservation tillage to be "the major soil protection method and candidate best management practice for improving surface water quality" (U.S. EPA, 2002). EPA identifies conservation tillage as the first of its CORE4 agricultural management practices for water quality protection (U.S. EPA, 2008a). Therefore, the Deregulation in Whole and No Action Alternatives are not significantly different regarding the impact of the cultivation of DT soybean on water quality.

Under full deregulation of DT soybean, dicamba would be an additional weed management tool for managing hard-to-control and herbicide-resistant broadleaf weeds found in soybean fields. The use of dicamba on soybean would be expected to increase relative to current and historical levels of use, up to 2.6 times the maximum historical annual level in 1994. However, potential impacts associated with any increased use of dicamba from the cultivation of DT soybean have been adequately assessed by EPA as part of the dicamba Reregistration Eligibility Decision (RED); therefore it is reasonably foreseeable that EPA will register this specific use of dicamba under FIFRA. EPA considered potential risks associated with dicamba use, including its degradate DCSA when appropriate, on surface or ground water using screening level (high-end exposure) models to estimate environmental concentrations. The EPA then compared these exposure estimates to appropriate endpoints from mammalian, aquatic animal and plant ecotoxicity studies, and concluded dicamba meets the FIFRA standard for no unreasonable adverse effects on human health and the environment (see Appendices G and H of this Environmental Report. The EPA analysis, based on use patterns that exceed the proposed single and annual maximum use rates for dicamba on DT soybean, does not take into account normal variation in environmental concentrations that can occur, and assumes that greater than 85% of the watershed is treated with the herbicide at the maximum labeled rate on the same day. In addition, the EPA examined and considered available monitoring data as part of the dicamba RED, where concentrations of dicamba in ground and surface water were detected at levels up to 44 μg/L and 1.76 μg/L, respectively. Furthermore, potential impacts on ground and surface water from dicamba use on DT soybean will be considered by EPA as part of Monsanto's pending application to register the use of dicamba on DT soybean, and must meet the FIFRA standard for no unreasonable adverse effects on human health or the environment prior to approval.

It is foreseeable that the frequency of dicamba detections in ground and surface water could increase as a result of the cultivation of DT soybean; however, levels of dicamba in water are not expected to increase above the levels already evaluated and considered by EPA. Existing monitoring data provides additional support that water resources will not be impacted from any potential increase in dicamba use. Monsanto has compiled publicly available surface and ground water monitoring data from across the United States from 1990 through 2010, including sampling sites in areas where soybean and corn are grown and where dicamba use has historically been most intense (see Appendix C of this Environmental Report. Maximum labeled use rates during most of this timeframe (2.8 lb a.e. per acre single maximum and 7.7 lb a.e. per acre annual maximum) were much higher than presently allowed rates (1.0 lb a.e. per acre single maximum and 2.0 lb a.e. per acre annual maximum) and the rates proposed on Monsanto's dicamba label for use on DT soybean. Therefore, an examination of available surface and groundwater monitoring data in these areas during the mid-1990s would be indicative of the anticipated levels of dicamba that may occur from the use on DT soybean.

An evaluation of the compiled surface water data from 1994 through 1998 for the major soybean areas during the primary dicamba application months of April through July indicates that detected levels of dicamba (90th percentile concentration for all samples where dicamba was detected[58]) were less than 1 μg/L. Monitoring data from April through July were evaluated because these are the months where the majority of dicamba applications are made to soybean (preemergence) and corn (pre- and postemergence), and when surface water concentrations from with these applications would be expected to peak. The maximum level of dicamba in

58 EPA uses the 90th percentile as the relevant high-end endpoint when analyzing water monitoring data.

surface water during this same timeframe was 9.4 μg/L. Similarly, the evaluation of the groundwater data for major soybean growing areas from 1994 through 1998 indicates that detected levels of dicamba (90^{th} percentile concentration of all samples where dicamba was detected) were 0.25 μg/L or less. The maximum level of dicamba in groundwater during this same timeframe was 2.2 μg/L. Furthermore, dicamba has been used in crops grown in rotation with soybean (e.g., cotton and corn) for decades with no significant adverse effects reported.

Considering the available monitoring data for ground and surface water during the period of dicamba's most intensive use and when application rates were significantly higher than the rates proposed for use on DT soybean, it is reasonable to assume that levels in ground and surface water that may result from the use of dicamba on DT soybean would be below the levels (high-end exposure modeling and monitoring data) considered by the EPA in the dicamba RED, and where EPA concluded would no unreasonable adverse effects on human health or the environment.

Based on the above, the Deregulation in Whole and No Action Alternatives are similar regarding their potential impact on surface and ground water quality from the use of dicamba on DT soybean.

IV.C.3.c. Approval in Whole of DGT cotton, but not DT Soybean

As discussed above, the No Action Alternative for DT soybean is not expected to result in significant changes to water quality.

As discussed in Section IV.B.2.b, DGT cotton would not change cultivation practices for cotton production, nor would it increase the total acres and range of U.S. cotton production areas. Therefore, Deregulation in Whole of DGT cotton would not change the current use of irrigation practices in commercial cotton production, and the impacts on water use of the Deregulation in Whole Alternative would be the same as the No Action Alternative.

Conservation tillage has been increasingly employed on commercial herbicide-tolerant cotton acres and helps minimize the impact of cotton production on water quality by reducing erosion (Price et al. 2011). It is therefore anticipated that the introduction of DGT cotton will help maintain current levels of conservation tillage adoption and may further increase the number of cotton acres in conservation tillage, resulting in improved water quality.

Under full deregulation, dicamba would be an additional weed management tool for managing hard-to-control and herbicide-resistant broadleaf weeds found in cotton fields. As discussed in Section IV.A.2, the use of dicamba on cotton may increase by approximately 5.2 million pounds a.e. annually; combined with current crop uses of approximately 3.8 million pounds a.e. dicamba, the total would still be less than the maximum historical pounds of dicamba in 1994 (See Table A-7 in Appendix A). The increase in dicamba usage is expected to displace some of the current herbicide usage in cotton today, particularly applications of diuron, fomesafen, fluometuron, and paraquat. Dicamba offers a more benign human health and environmental profile in comparison to some of the alternative non-glyphosate herbicides currently available to cotton growers (see Appendix A).

If EPA approves the registration of dicamba for use on DGT cotton, then it will have reviewed the data and found no unreasonable adverse environmental impacts from that use. Dicamba use on DGT cotton will only be permitted following EPA approval. The EPA considered potential risks associated with dicamba use, including its degradate DCSA on surface or ground water using screening level (high-end theoretical exposure) models to estimate potential environmental concentrations of dicamba and DCSA. The EPA then compared these exposure estimates to appropriate endpoints from mammalian, aquatic animal and plant ecotoxicity studies conducted with dicamba, and concluded dicamba meets the FIFRA standard for no unreasonable adverse effects on human health and the environment. The EPA modeling predictions and the NAWQA monitoring results (see Appendices E and F of this Environmental Report) demonstrate that dicamba concentrations that might occur in drinking water are orders of magnitude below the lifetime Health Advisory Level (HAL) of 4000 ug/L for dicamba. Thus, confirming that the potential risk of dicamba leaching into groundwater or running off into surface water is low and does not threaten human health or acceptable water quality. In addition, dicamba has been used in crops grown in rotation with cotton (e.g., corn and soybean) for decades with no significant adverse effects reported.

Furthermore, potential impacts on ground and surface water from dicamba use on DGT cotton will be considered by EPA as part of Monsanto's pending application to register the use of a low volatility DGA dicamba formulation on DGT cotton, and must meet the FIFRA standard for no unreasonable adverse effects on human health or the environment prior to approval.

It is possible that the frequency of dicamba detections in ground and surface water could increase as a result of the cultivation of DGT cotton. However, the EPA models for dicamba movement and accumulation assume greater than 85% of the acres are treated with dicamba and the maximum use rates on DGT cotton would be less than or equal to rates previously evaluated by EPA. Therefore, the levels of dicamba in water following the introduction of DGT cotton may increase, but are not expected to increase above the levels already evaluated and considered acceptable by EPA. See Appendix C of this Environmental Report for additional information on the EPA models use to evaluate dicamba.

Considering the available monitoring data for levels of dicamba in ground and surface water during the period of dicamba's most intensive use (1994) and that application rates at that time were substantially higher than the rates proposed for use on DGT cotton, it is reasonable to conclude that levels of dicamba in ground and surface water that may result from the use of dicamba on DGT cotton would be below the levels (high-end exposure modeling and monitoring data) considered by the EPA in the dicamba RED. In the RED assessment, EPA concluded that all uses of dicamba contemplated would not result in an unreasonable adverse effect on human health or the environment.

Glufosinate use on DGT cotton is equivalent to currently deregulated glufosinate-tolerant cotton and is considered baseline. Glufosinate use on many crops, including cotton, was reviewed by the EPA as part of the food, feed, and environmental safety reassessment in 2000 (U.S. EPA 2003). In addition, glufosinate has been used over-the-top of glufosinate-tolerant crops since 1995 with no significant adverse effects reported. Glufosinate is currently labeled for in-crop application with glufosinate-tolerant cotton from emergence through early bloom growth stage (Bayer Crop Science 2007). The use pattern and rate of glufosinate on DGT cotton will follow the existing glufosinate-tolerant cotton uses outlined on the glufosinate herbicide label. Currently glufosinate is undergoing Registration Review at EPA with with a forthcoming final decision scheduled in 2013 (U.S. EPA 2009d). It is likely that EPA will approve the continued use of glufosinate in the marketplace upon completion of the Registration Review process.

Therefore, the Deregulation in Whole and No Action Alternatives are similar regarding their potential impact on ground water quality from the use of dicamba on DGT cotton.

IV.C.3.d. Approval in whole of both DT soybean and DGT cotton

The difference between the Deregulation in Whole and the No Action Alternative for DT soybean and DGT cotton is expected to be integration of DT soybean and DGT cotton into the glyphosate-tolerant soybean and cotton systems using traditional breeding techniques. For those acres where glyphosate-resistant weeds may already be present, where application of an herbicide with a different mode-of-action would aid in weed control, or for grower implementation of weed resistant management practices, the cultivation of soybean or cotton containing the DT soybean or DGT cotton traits would be an option for growers.

Approval in whole of DT soybean and DGT cotton would not change cultivation practices for soybean or cotton production, nor would it increase the total acres and range of U.S. soybean and cotton production areas. Therefore, Deregulation in Whole of DT soybean and DGT cotton would not change the current use of irrigation practices in commercial soybean and cotton production, and the impacts on water use of the Deregulation in Whole Alternative would be the same as the No Action Alternative.

Water quality could be impacted either directly by DT soybean and DGT cotton via plant material impacts on water resources, or indirectly via impacts from the use of dicamba or tillage practices associated with the planting of DT soybean and DGT cotton. Conservation tillage, a system that leaves 30% or more of the previous crop residue covering the soil when planting another crop has been increasingly employed in commercial soybean acres, and helps minimize any impacts of soybean production on water quality by reducing soil erosion.

In terms of potential direct impacts on water quality, DT soybean and DGT cotton have been shown to be compositionally, agronomically and phenotypically equivalent to conventional soybean and cotton and therefore are unlikely to have any significant impact on surface water quality.

Under full deregulation of DT soybean and DGT cotton, there will be a decreased need for farmers employing conventional tillage practices in order to manage certain weed situations. There is a potential impact to soil conservation in those situations where tillage has been employed to manage resistant weeds (CAST 2011). Dicamba's complementary and supplementary postemergence activity to glyphosate will provide improved postemergence weed management options and thus support more sustainable conservation tillage practices because postemergence herbicide options are generally preferred by growers (Fawcett and Towery 2002). Tillage causes widespread soil disturbance causing erosion and topsoil loss, impacting the sedimentation and turbidity of streams. EPA identified sedimentation and turbidity as two of the top 10 causes of impairment to surface water in the U.S.; similarly in 2007, EPA identified sedimentation/siltation as a leading cause of impairment to rivers and streams in particular (U.S. EPA 2007b; 2009c). EPA has projected conservation tillage to be "the major soil protection method and candidate best management practice for improving surface water quality" (U.S. EPA 2007a). EPA identifies conservation tillage as the first of its

CORE4 agricultural management practices for water quality protection (U.S. EPA 2013d). Therefore, the Deregulation in Whole and No Action Alternatives are not significantly different regarding the impact of the cultivation of DT soybean and DGT cotton on water quality.

Under full deregulation, dicamba would be an additional weed management tool for managing hard-to-control and herbicide-resistant broadleaf weeds found in soybean and cotton fields. The use of dicamba on soybean would be expected to increase relative to current and historical levels of use, and the use of dicamba on cotton would be expected to increase relative to current levels but stay below the historical maximum. Potential impacts associated with any increased use of dicamba from the cultivation of DT soybean and DGT cotton have been adequately assessed by EPA as part of the dicamba Reregistration Eligibility Decision (RED); therefore it is reasonably foreseeable that EPA will register this specific use of dicamba under FIFRA. EPA considered potential risks associated with dicamba use, including its degradate DCSA when appropriate, on surface or ground water using screening level (high-end exposure) models to estimate environmental concentrations. The EPA then compared these exposure estimates to appropriate endpoints from mammalian, aquatic animal and plant ecotoxicity studies, and concluded dicamba meets the FIFRA standard for no unreasonable adverse effects on human health and the environment. The EPA analysis, based on use patterns that exceed the proposed single and annual maximum use rates for dicamba, does not take into account normal variation in environmental concentrations that can occur, and assumes that greater than 85% of the water shed is treated with the herbicide at the maximum labeled rate on the same day. In addition, the EPA examined and considered available monitoring data as part of the dicamba RED, where concentrations of dicamba in ground and surface water were detected at levels up to 44 μg/L and 1.76 μg/L, respectively. Furthermore, potential impacts on ground and surface water from dicamba use on DT soybean and DGT cotton will be considered by EPA as part of Monsanto's pending application to register the use of dicamba on DT soybean and DGT cotton, and must meet the FIFRA standard for no unreasonable adverse effects on human health or the environment prior to approval.

It is foreseeable that the frequency of dicamba detections in ground and surface water could increase as a result of the cultivation of DT soybean and DGT cotton; however, levels of dicamba in water are not expected to increase above the levels already evaluated and considered by EPA. Existing monitoring data provides additional support that water resources will not be impacted from any potential increase in dicamba use. Monsanto has compiled publicly available surface and ground water monitoring data from across the United States from 1990 through 2010, including sampling sites in areas where soybean and corn are grown and where dicamba use has historically been most intense (see Appendices C and F of this Environmental Report). Maximum labeled use rates during most of this timeframe (2.8 lb a.e. per acre single maximum and 7.7 lb a.e. per acre annual maximum) were much higher than presently allowed rates (1.0 lb a.e. per acre single maximum and 2.0 lb a.e. per acre annual maximum) and the rates proposed on Monsanto's dicamba label for use on DT soybean and DGT cotton. Therefore, an examination of available surface and groundwater monitoring data in these areas during the mid-1990s would be indicative of the anticipated levels of dicamba that may occur from the use on DT soybean.

An evaluation of the compiled surface water data from 1994 through 1998 for the major soybean areas during the primary dicamba application months of April through July indicates that detected levels of dicamba (90^{th} percentile concentration for all samples where dicamba was detected[59]) were less than 1 μg/L. Monitoring data from April through July were evaluated because these are the months where the majority of dicamba applications are made to soybean (preemergence) and corn (pre- and postemergence), and when surface water concentrations from with these applications would be expected to peak. The maximum level of dicamba in surface water during this same timeframe was 9.4 μg/L. Similarly, the evaluation of the groundwater data for major soybean growing areas from 1994 through 1998 indicates that detected levels of dicamba (90th percentile concentration of all samples where dicamba was detected) were 0.25 μg/L or less. The maximum level of dicamba in groundwater during this same timeframe was 2.2 μg/L.

Considering the available monitoring data for ground and surface water during the period of dicamba's most intensive use and when application rates were significantly higher than the rates proposed for us on DT soybean, it is reasonable to assume that levels in ground and surface water that may result from the use of dicamba on DT soybean would be below the levels (high-end exposure modeling and monitoring data) considered by the EPA in the dicamba RED, and where EPA concluded would have no unreasonable adverse effects on human health or the environment. Compiled water monitoring data were not inclusive of cotton production areas, except for surface water sources in the Delta region, however the high-end modeling predicted concentrations evaluated by EPA included cropping scenarios representative of cotton growing region.

Glufosinate use on DGT cotton is equivalent to currently deregulated glufosinate-tolerant cotton and is considered baseline. Glufosinate use on many crops, including cotton, was reviewed by the Environmental Protection Agency (EPA) as part of the food, feed, and environmental safety reassessment in 2000 (U.S. EPA 2003). In addition, glufosinate has been used over-the-top of glufosinate-tolerant crops since 1995 with no significant adverse effects reported. Glufosinate is currently labeled for in-crop application with glufosinate-tolerant cotton from emergence through early bloom growth stage (Bayer Crop Science 2007; 2013). The use pattern and rate of glufosinate on DGT cotton will follow the existing glufosinate-tolerant cotton uses outlined on the glufosinate herbicide label. Currently glufosinate is undergoing Registration Review at EPA with a forthcoming final decision scheduled in 2013 (U.S. EPA 2008b; 2009d). It is likely that EPA will approve the continued use of glufosinate in the marketplace upon completion of the Registration Review process. Therefore, Monsanto will not pursue any changes in the glufosinate label, use pattern, or the established tolerances for its use on DGT cotton.

Because conservation tillage acres are likely to remain the same, or potentially increase, on soybean and cotton acreage with the introduction of DT soybean and DGT cotton, corresponding benefits to surface water are expected as compared to the No Action Alternative. Therefore, the approval in whole and No Action Alternatives are similar regarding their potential impact on surface and ground water quality from the use of dicamba on DT soybean and DGT cotton and glufosinate on DGT cotton.

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[59] EPA uses the 90th percentile as the relevant high-end endpoint when analyzing water monitoring data.

IV.C.4. Air Quality Impacts

IV.C.4.a. No action alternative for both DT soybean and DGT cotton

Under the No Action Alternative, both DT soybean and DGT Cotton would continue to be regulated by APHIS. Several agricultural practices have the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from agricultural burning, tillage, heavy equipment emissions, pesticide drift from spraying, and indirect emissions from carbon dioxide and nitrous oxide emissions from the use of nitrogen fertilizer and degradation of organic materials (Aneja et al. 2009; U.S. EPA 2010c; USDA-NRCS, 2006; U.S. EPA, 2011d).

As discussed above, compared with full deregulation of DT soybean and DGT cotton, the No Action Alternative may result in increased tillage, and decreases in conservation tillage. EPA reports conservation tillage as an agricultural practice that "increases carbon storage through enhanced soil sequestration" and that "may reduce energy-related CO_2 emissions from farm equipment" (U.S. EPA 2010a). When carbon is stored, it is not available to be emitted in the form of carbon dioxide (CO_2), a greenhouse gas. Thus, the No Action Alternative may result in increased tillage, which could cause some adverse air quality impacts compared with full deregulation.

Adoption of GE soybean and cotton varieties is expected to continue. To the extent that the adoption and cultivation of GE soybean and cotton varieties allows the grower to implement soil conservation practices, air quality improvements associated with these practices would be expected to follow. This would include both direct air quality effects, e.g., emissions from farm equipment, airborne soil erosion and pesticide drift, as well as indirect air quality effects, e.g., nitrous oxide emissions associated with the use of nitrogen fertilizers (Aneja et al. 2009; USDA-NRCS, 2006; EPA, 2011d). Under the No Action Alternative, growers would still likely practice conservation tillage, and in certain situations they would rely on tillage and/or other herbicides used in soybean and cotton production. Other herbicide-tolerant soybean and cotton events have been deregulated by APHIS or have been submitted to APHIS for deregulation. These events and their companion herbicides may be used to promote conservation tillage practices under the No Action Alternative. Therefore, the No Action and Deregulation in Whole Alternatives may not be significantly different regarding their potential impact on air quality.

IV.C.4.b. Approval in whole of DT soybean, but not DGT cotton

As discussed above, the No Action Alternative for DGT cotton is not expected to result in significant changes to air quality.

The difference between the Deregulation in Whole and the No Action Alternative is expected to be the integration of DT soybean into the glyphosate-tolerant soybean system using traditional breeding techniques. For those acres where glyphosate-resistant weeds may already be present, where application of an herbicide with a different mode-of-action would aid in weed control, or for grower implementation of weed resistant management practices, the cultivation of soybean containing the DT soybean trait would be an option for growers.

General management strategies currently employed to manage and mitigate herbicide drift and volatilization would not differ from those currently employed throughout the industry under the No Action Alternative. Depending upon the site-specific application requirements, growers would continue to select from a range of strategies to effectively reduce drift and volatilization currently provided and enforced on herbicide labels (see e.g., Monsanto, 2010; Bayer, 2011b).

Agricultural practices are not expected to change significantly with the introduction of DT soybean. A discussion of the agricultural practices associated with soybean production in the U.S. is provided in Section II.B.1.c, and includes discussion of cultural, mechanical and herbicide practices for weed management. Deregulation of DT soybean is expected to facilitate the trend toward increased adoption of conservation tillage methods by soybean growers because conservation tillage (specifically no-till) relies on the use of herbicides to control weeds that emerge in a field prior to or after planting the soybean seed into the previous crop stubble, thus avoiding disturbance of the soil. DT soybean would help to maintain existing conservation tillage practices and facilitate the adoption of conservation tillage practices by simplifying weed control options for growers utilizing a non-glyphosate herbicide or where there are glyphosate-resistant or hard-to-control broadleaf weeds present. Soybean represents the greatest number of acres of the major field crops utilizing conservation tillage and the highest percentage of total crop acres devoted to conservation tillage practices (CTIC 2007). Considerable benefits to the physical environment, including those related to air quality, are obtained from use of conservation tillage methods including (CTIC 2011; USDA-NRCS 2005):

- Dramatic reduction in soil erosion from wind and water;
- Less herbicide, water, and soil runoff from soils improving the quality of streams and lakes;
- Overall healthier soils;
- Increased carbon sequestration leading to reduced greenhouse gases;
- Decreased fuel emissions due to reduced use of tractors to plow fields;
- Reduced nitrogen applications (much of which is made from fossil fuels); and
- Less overall water usage for agricultural purposes.

While Deregulation in Whole of DT soybean may facilitate some trend towards increasing conservation tillage, it is not expected to significantly impact air quality. Therefore Deregulation in Whole and No Action Alternatives may not be significantly different regarding their impacts on air quality.

IV.C.4.c. Approval in whole of DGT cotton, but not DT soybean

As discussed above, the No Action Alternative for DT soybean is not expected to result in significant changes to air quality.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. For those acres where glyphosate-resistant weeds may already be present, where application of a herbicide with a different mode-of-action would aid in weed control, or for grower implementation of weed resistant management practices, the cultivation of cotton containing the DGT cotton traits would be an option for growers.

General management strategies currently employed to manage and mitigate herbicide drift and volatilization would not differ from those currently employed throughout the industry under the No Action Alternative. Depending upon the site-specific application requirements, growers would continue to select from a range of strategies to effectively reduce drift and volatilization currently provided and enforced on herbicide labels (see e.g., Monsanto, 2010; Bayer, 2011b).

Agricultural practices that may affect air quality are not expected to change substantially with the introduction of DGT cotton. Deregulation of DGT cotton is expected to sustain or possibly increase current adoption levels of conservation tillage methods by cotton growers because conservation tillage (in particular, no-till) relies on the use of herbicides to control weeds that emerge in a field prior to or after planting the cotton seed into the previous crop stubble, thus avoiding disturbance of the soil. DGT cotton would help to maintain existing conservation tillage practices and facilitate the adoption of conservation tillage practices by simplifying weed control options for growers utilizing a non-glyphosate herbicide where there are glyphosate-resistant or hard-to-control broadleaf weeds present. Considerable benefits to the physical environment, including those related to air quality, are obtained from use of conservation tillage methods including (CTIC 2011; USDA-NRCS 2005):

- Dramatic reduction in soil erosion from wind and water;
- Less herbicide, water, and soil runoff from soils improving the quality of streams and lakes;
- Overall healthier soils;
- Increased carbon sequestration leading to reduced greenhouse gases;
- Decreased fuel emissions due to reduced use of tractors to plow fields;
- Reduced nitrogen applications (much of which is made from fossil fuels); and
- Less overall water usage for agricultural purposes.

While Deregulation in Whole of DGT cotton may facilitate some trend towards increasing conservation tillage, it is not expected to significantly impact air quality. In summary, compared with the No Action Alternative, the Deregulation in Whole Alternative of the DGT cotton alternative is expected to result in localized and short-term increases in emissions from application of dicamba and glufosinate, and localized and short-term decreases in emissions of other herbicides used in cotton and/or decreases in emissions from vehicles and dust resulting from higher levels of conservation tillage. Thus, the Deregulation in Whole and No Action Alternatives may not be significantly different regarding their impacts on air quality.

IV.C.4.d. Approval in whole of both DT soybean and DGT cotton

The difference between the Deregulation in Whole and the No Action Alternative is expected to be the integration of DT soybean and DGT cotton into the glyphosate-tolerant soybean and cotton systems using traditional breeding techniques. For those acres where glyphosate-resistant weeds may already be present, where application of an herbicide with a different mode-of-action would aid in weed control, or for grower implementation of weed resistant management practices, the cultivation of soybean or cotton containing the DT soybean or DGT cotton traits would be an option for growers.

General management strategies currently employed to manage and mitigate herbicide drift and volatilization would not differ from those currently employed throughout the industry under the No Action Alternative. Depending upon the site-specific application requirements, growers would continue to select from a range of strategies to effectively reduce drift and volatilization currently provided and enforced on herbicide labels (see e.g., Monsanto, 2010; Bayer, 2011b).

Agricultural practices are not expected to change significantly with the introduction of DT soybean and DGT cotton. Deregulation of DT soybean and DGT cotton is expected to facilitate the trend toward increased adoption of conservation tillage methods by soybean and cotton growers because conservation tillage (specifically no-till) relies on the use of herbicides to control weeds that emerge in a field prior to or after planting the soybean seed into the previous crop stubble, thus avoiding disturbance of the soil. DT soybean and DGT cotton would help to maintain existing conservation tillage practices and facilitate the adoption of conservation tillage practices by simplifying weed control options for growers utilizing a non-glyphosate herbicide or where there are glyphosate-resistant or hard-to-control broadleaf weeds present. Considerable benefits to the physical environment, including those related to air quality, are obtained from use of conservation tillage methods including (CTIC 2011; USDA-NRCS 2005):

- Dramatic reduction in soil erosion from wind and water;
- Less herbicide, water, and soil runoff from soils improving the quality of streams and lakes;
- Overall healthier soils;
- Increased carbon sequestration leading to reduced greenhouse gases;
- Decreased fuel emissions due to reduced use of tractors to plow fields;
- Reduced nitrogen applications (much of which is made from fossil fuels); and
- Less overall water usage for agricultural purposes.

While Deregulation in Whole of DT soybean and DGT cotton may facilitate some trend towards increasing conservation tillage, it is not expected to significantly impact air quality. In summary, compared with the No Action Alternative, the Deregulation in Whole Alternative is expected to result in localized and short-term increases in emissions from application of dicamba and glufosinate, and localized and short-term decreases in emissions of other herbicides used in cotton and/or decreases in emissions from vehicles and dust resulting from higher levels of conservation tillage. Thus, the Deregulation in Whole and No Action Alternatives may not be significantly different regarding their impacts on air quality.

IV.C.5. Climate Change Impacts

IV.C.5.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) soybeans and cotton are expected to remain the same under the No Action Alternative.

Under the No Action Alternative, contributions of agriculture, including soybean and cotton production, to greenhouse gas emissions would be expected to continue. Climate change is likely to impact agriculture, including cotton production; however, the specific impacts are speculative.

Conservation tillage practices used in U.S. soybean and cotton production have been identified as providing climate change benefits (Brenner et al., 2001). Conservation tillage, in addition to providing benefits to soil quality, has the benefit of increasing carbon sequestration in soils. Conservation tillage is also associated with reduced carbon emissions from lower farm equipment operations. Switching from conventional tillage to a no-till corn-soybean rotation in Iowa, for example, has been estimated to increase carbon sequestration by 550 kg/hectare (485 lb./acre) per year (Towery and Werblow 2010; Paustian et al., 2000; Brenner et al., 2001).

Under the No Action Alternative, current impacts on climate change associated with soybean and cotton production would not be affected. Agronomic practices associated with soybean and cotton production such as tillage, cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment would continue on soybeans and cotton grown throughout the region.

IV.C.5.b. Approval in Whole of DT Soybean, But Not DGT Cotton

As discussed, approval of the No Action Alternative for DGT cotton is not expected to result in significant climate change impacts.

A determination of nonregulated status of DT soybean is not expected to result in changes in the current soybean cropping practices, with the exception of potential changes in the use of certain herbicides for weed management. DT soybean is essentially indistinguishable from other soybean varieties in terms of agronomic characteristics and cultivation practices. As DT soybean is essentially equivalent to other GE herbicide-tolerant and non-GE soybeans, no changes in agronomic practices (such as crop rotation), cultivation, geographic range, seasonality or insect susceptibility, are expected to occur. Based on individual grower needs, DT soybean could provide growers with an alternative to intensive tillage practices that may be used to address herbicide weed resistance challenges. This in turn could reduce the need for conventional tillage practices that may impact conservation tillage practices. The continued use of conservation tillage associated with GE crops may reduce GHG emissions as a result of increased carbon sequestration in soils, decreased fuel consumption, and the reduction of nitrogen soil amendments (Towery and Werblow 2010).

Based on the above information, the availability of DT soybean is not expected to change the cultivation or agronomic practices or agricultural land acreage associated with growing soybean. It may provide some benefit to reducing GHG contributions to climate change in the form of sustaining the adoption of conservation tillage practices, but overall the impacts to climate change is expected to be similar to the No Action Alternative.

IV.C.5.c. Approval in whole of DGT cotton, but not DT soybean

As discussed, approval of the No Action Alternative for DT soybean is not expected to result in significant climate change impacts.

A determination of nonregulated status of DGT cotton is not expected to result in changes in the current cotton cropping practices, with the exception of potential changes in the use of certain herbicides for weed management. DGT cotton is essentially indistinguishable from other cotton varieties in terms of agronomic characteristics and cultivation practices. As DGT cotton is essentially equivalent to other GE herbicide-tolerant and non-GE cotton, no changes in agronomic practices (such as crop rotation), cultivation, geographic range, seasonality or insect susceptibility, are expected to occur. Based on individual grower needs, DGT cotton could provide growers with an alternative to intensive tillage practices that may be used to address herbicide weed resistance challenges. This in turn this could reduce the need for conventional tillage practices that may impact conservation tillage practices. The continued use of conservation tillage associated with GE crops may reduce GHG emissions as a result of increased carbon sequestration in soils, decreased fuel consumption, and the reduction of nitrogen soil amendments (Towery and Werblow 2010).

Based on the above information, the availability of DGT cotton is not expected to change the cultivation or agronomic practices or agricultural land acreage associated with growing cotton. It may provide some benefit to reducing GHG contributions to climate change in the form of sustaining the adoption of conservation tillage practices, but overall the impacts to climate change is expected to be similar to the No Action Alternative.

IV.C.5.d. Approval in whole of both DT soybean and DGT cotton

A determination of nonregulated status of DT soybean and DGT cotton is not expected to result in changes in the current cotton cropping practices, with the exception of potential changes in the use of certain herbicides for weed management. DT soybean and DGT cotton are essentially indistinguishable from other soybean and cotton varieties in terms of agronomic characteristics and cultivation practices. As DT soybean and DGT cotton are essentially equivalent to other GE herbicide-tolerant and non-GE soybeans and cotton, no changes in agronomic practices (such as crop rotation), cultivation, geographic range, seasonality or insect susceptibility, are expected to occur. Based on individual grower needs, DT soybean and DGT cotton could provide growers with an alternative to intensive tillage practices that may be used to address herbicide weed resistance challenges. This in turn this could reduce the need for conventional tillage practices that may impact conservation tillage practices. The continued use of conservation tillage associated with GE crops may reduce GHG emissions as a result of increased carbon sequestration in soils, decreased fuel consumption, and the reduction of nitrogen soil amendments (Towery and Werblow 2010).

Based on the above information, the availability of DT soybean and DGT cotton is not expected to change the cultivation or agronomic practices or agricultural land acreage associated with growing soybeans and cotton. It may provide some benefit to reducing GHG contributions to climate change in the form of sustaining the adoption of conservation tillage practices, but overall the impacts to climate change is expected to be similar to the No Action Alternative.

IV.D. BIOLOGICAL IMPACTS FROM DT SOYBEAN & DGT COTTON

IV.D.1. Animal Communities

IV.D.1.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, both DT soybean and DGT Cotton would continue to be regulated by APHIS. The availability and usage of commercially cultivated (both GE and non-GE) soybean and cotton are expected to remain the same under the No Action Alternative. Under this alternative DT soybean and DGT Cotton would not become integrated into the glyphosate-tolerant soybean and cotton systems and dicamba use would likely remain similar to today's use pattern in soybean and cotton. Adding alternative herbicides with different modes-of-action into the glyphosate-tolerant systems to manage the development of glyphosate-resistant weeds and control glyphosate-resistant weeds would continue to remain an option. Additionally, conventional tillage may increase in some instances as an additional means to control problematic weeds.

Currently herbicides are used on nearly all (~98%) soybean acres, and over 35 different herbicide active ingredients are registered and available for use by soybean growers to control weeds (See Section II.B.1.d). Currently herbicides are used on nearly all (>99%) cotton acres, and approximately 39 million pounds of 30 different herbicides are applied pre- or postemergence in cotton production (Monsanto, 2012) (See Section II.B.2.d). The use of herbicides in both soybean and cotton production is expected to continue to increase as more growers adopt diversified weed management strategies to combat hard-to-control herbicide-resistant weeds. Although all herbicides must meet the FIFRA standard of no unreasonable adverse effects to humans or the environment, some available herbicides may pose greater potential risks to animals or insects than dicamba; moreover, conventional tillage practices may increase as a result of weed management challenges. Increased use of tillage could have a small adverse impact on wildlife, as the crop residues that remain with the use of conservation tillage may provide shelter and food for wildlife, such as game birds and small animals (CTIC 2011).

IV.D.1.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, the No Action Alternative for DGT cotton is not expected to result in significant changes to animal communities.

The difference between the No Action and the Deregulation in Whole Alternatives for DT soybean would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. As discussed in Section IV.B.1, under the Deregulation in Whole Alternative, the cultivation of DT soybean is not expected to impact soybean agronomic practices, with the exception of a change in herbicide use pattern. Cultivation of DT soybean would not alter agronomic inputs or the number of soybean acres under cultivation, and will help maintain current levels of conservation tillage adoption and may have a small positive effect on the use of conservation tillage.

Potential Impacts from the Genetic Modification. Potential impacts from dietary exposure to DT soybean are discussed in detail in Sections IV.E.1 and IV.F. All the information in Sections IV.E.1 and IV.F.1 is relevant to dietary exposure for any animals that may consume DT soybean. As discussed in those sections, there is no meaningful risk to animal or human health from dietary exposure to the MON 87708 DMO protein. There are no known toxic properties associated with the MON 87708 DMO protein. Furthermore, grain and forage produced by DT soybean is compositionally equivalent to commercially cultivated soybean, whether or not it is treated with dicamba. Additional information on the safety of the MON 87708 DMO protein and composition of DT soybean grain and forage, as detailed in Appendix G of this Environmental Report indicate that the effects to mammals that consume DT soybean seed would be no different than those possible from the consumption of commercially cultivated soybean. Similarly, the impact to birds or other animals, including migratory birds and animals that may consume soybean forage or seed from DT soybean would be no different than possible impacts from commercially cultivated soybean. During field trials with DT soybean, no biologically relevant changes in arthropod feeding damage were observed (see Appendix G of this Environmental Report) indicating similar arthropod susceptibility for DT soybean compared to commercially cultivated soybean. DT soybean exhibits no differences in toxic effects on insects or other animals as compared to commercially cultivated soybean. In addition, the cultivation of DT soybean does not impact the nutritional quality, safety, or availability of animal feed derived from DT soybean (see Section IV.F.).

Potential Impacts from Dicamba. To support the introduction of DT soybean, Monsanto has submitted to EPA an application to amend EPA Reg. No. 524-582, a low-volatility DGA salt formulation, to register a new use pattern for dicamba. The current and proposed uses are summarized in Table IV.A-1 (see Section IV.A.1). However, a comprehensive evaluation and risk assessment conducted by EPA concluded that dicamba has low toxicity to mammals, is not a carcinogen, does not adversely affect reproduction and development, and does not bioaccumulate in mammals (U.S. EPA 2009a; d). An ecotoxicological risk assessment concluded that the use of dicamba does not pose an unreasonable risk of adverse effects to non-target species, such as birds and fish, when used according to label directions, nor does it pose an unreasonable risk of adverse effects to insects outside of the application area (U.S. EPA 2009a; d). Furthermore, outside the cultivated cotton field, dicamba is unlikely to affect forbs and beneficial arthropods that are dependent on plants for survival (U.S. EPA 2009a; d).

In summary, in terms of potential impacts to animal communities, including insects, beneficial arthropods, and all other animals that live in or near soybean fields containing DT soybean, the difference between the No Action and Deregulation in Whole Alternatives is primarily the difference in the types of herbicides that may be used. As with the No Action Alternative, use of herbicides is expected to increase as more growers adopt diversified weed management strategies to combat hard-to-control and herbicide-resistant weeds, but dicamba is expected to displace some herbicides that would otherwise be used, and which could have a more significant environmental footprint. EPA has determined that when herbicides are used in accordance with their labels, no unreasonable adverse impacts will result. As discussed above, EPA's conclusions are based on comprehensive evaluations and risk assessments. Compared to the Deregulation in Whole Alternative, the No Action Alternative may pose a small increase in adverse impacts on animal communities if it results in increased tillage, because crop residue provides shelter and food for wildlife, such as game birds and small animals (CTIC 2011).

IV.D.1.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, the No Action Alternative for DT soybean is not expected to result in significant changes to animal communities.

The difference between the No Action and the Deregulation in Whole Alternatives for DGT cotton would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. As discussed in Section IV.B.2, the cultivation of DGT cotton is not expected to impact cotton agronomic practices, with the exception of a change in herbicide use pattern. Cultivation of DGT cotton would not alter agronomic inputs or the number of cotton acres under cultivation, and will help maintain current levels of conservation tillage adoption and may have a small positive effect on the use of conservation tillage.

Potential Impacts from the Genetic Modification. Potential impacts from dietary exposure to DGT cotton are discussed in detail in Sections IV.E.1 and IV.F. Except for the discussion specific to cottonseed oil and linters in Section IV.F.2, all the information in Sections IV.E.1 and IV.F is relevant to dietary exposure for any animals that may consume DGT cotton. As discussed in those sections, there is no meaningful risk to animal or human health from dietary exposure to MON 88701 DMO or PAT (bar). There are no known toxic properties associated with MON 88701 DMO or PAT (bar). Furthermore, the seed produced by DGT cotton is compositionally equivalent to commercially cultivated cotton, whether or not it is treated with dicamba and/or glufosinate. This information on the safety of MON 88701 DMO and PAT (bar) and composition of DGT cottonseed, as detailed in Appendix G of this Environmental Report, indicate that the effects to mammals that consume DGT cotton seed would be no different than those possible from the consumption of commercially cultivated cotton. Similarly, the impact to birds or other animals, including migratory birds and animals that may consume cottonseed from DGT cotton would be no different than possible impacts from commercially cultivated cotton. During field trials with DGT cotton, no biologically relevant changes in arthropod feeding damage were observed (see Appendix G of this Environmental Report) indicating similar arthropod susceptibility for DGT cotton compared to commercially cultivated cotton. DGT cotton exhibits no differences in toxic effects on insects or other animals as compared to commercially cultivated cotton. In addition, the cultivation of DGT cotton does not impact the nutritional quality, safety, or availability of animal feed derived from DGT cotton (see Section IV.F).

Potential Impacts from Dicamba. To support the introduction of DGT cotton, Monsanto has submitted an application to EPA to amend Registration number 524-582, a low-volatility DGA salt formulation, to remove all preemergence planting restrictions (application intervals, rainfall, and geographic) and to allow in-crop postemergence dicamba applications to DGT cotton. However, a comprehensive evaluation and risk assessment conducted by EPA concluded that dicamba has low toxicity to mammals, is not a carcinogen, does not adversely affect reproduction and development, and does not bioaccumulate in mammals (U.S. EPA 2009a; d). An ecotoxicological risk assessment concluded that the use of dicamba does not pose an unreasonable risk of adverse effects to non-target species, such as birds and fish, when used according to label directions, nor does it pose an unreasonable risk of adverse effects to insects outside of the application area (U.S. EPA 2009b; a). Furthermore, outside the cultivated cotton field, dicamba is unlikely to affect forbs and beneficial arthropods that are dependent on plants for survival (U.S. EPA 2009a; d). As with the No Action Alternative, use of herbicides is expected to increase as more growers adopt diversified weed management strategies to combat hard-to-control and herbicide-resistant weeds, but dicamba is expected to displace some herbicides that would otherwise be used, and which could have a more significant environmental footprint. Nonetheless, EPA has determined that when herbicides are used in accordance with their labels, no unreasonable adverse impacts will result. As discussed above, EPA's conclusions are based on comprehensive evaluations and risk assessments.

Glufosinate has been used over-the-top of glufosinate-tolerant crops since 1995. Glufosinate is currently labeled for in-crop application with glufosinate-tolerant cotton from emergence through early bloom growth stage. The use pattern and rate of glufosinate on DGT cotton will follow the existing glufosinate-tolerant cotton uses outlined on the glufosinate herbicide label.

In summary, in terms of potential impacts to animal communities, including insects, beneficial arthropods, and all other animals that live in or near cotton fields containing DGT cotton, the difference between the No Action and Deregulation in Whole Alternatives is primarily the difference in the types of herbicides that may be used. EPA has determined that when herbicides are used in accordance with their labels, no unreasonable adverse impacts will result. As discussed above, EPA's conclusions are based on comprehensive evaluations and risk assessments. Compared to the Deregulation in Whole Alternative, the No Action Alternative may pose a small increase in adverse impact on animal communities if it results in increased tillage, because crop residue provides shelter and food for wildlife, such as game birds and small animals (CTIC 2011).

IV.D.1.d. Approval in Whole of DT Soybean and DGT Cotton

As discussed in detail above, in terms of potential impacts to animal communities, including insects, beneficial arthropods, and all other animals that live in or near soybean and cotton fields containing DT soybean and DGT cotton, the difference between the No Action and Deregulation in Whole Alternatives is primarily the difference in the types of herbicides that may be used. EPA has determined that when herbicides are used in accordance with their labels, no unreasonable adverse impacts will result. As discussed above, EPA's conclusions are based on comprehensive evaluations and risk assessments. Compared to the Deregulation in Whole Alternative, the No Action Alternative may pose a small increase in adverse impact on animal communities if it results in increased tillage, as crop residue provides shelter and food for wildlife, such as game birds and small animals (CTIC 2011).

IV.D.2. Plant Communities

Consistent with the *Plant Communities* discussion in Section II.D.1.b, this discussion considers both agricultural and non-agricultural plants outside the soybean and cotton fields that may have the potential to be affected by the use of DT soybean and DGT cotton. Non-soybean and non-cotton plants within the field are considered weeds and are addressed in Section

II.B.1.d and Section II.B.2.d. Potential impacts to plant communities through gene flow and increased weediness characteristics are addressed in Section II.D.1.c and Section II.D.2.c.

Plants on adjacent land, including agricultural crops, have the potential to be affected by herbicide transported in surface water runoff and in air. A herbicide could undergo air transport from the intended application site either by particle drift during spray application or by post-application volatilization from treated surfaces if appropriate mitigation measures are not taken. Spray drift of herbicides is a familiar and well-studied phenomenon (Felsot et al. 2010). Aerial application is associated with increased drift potential compared to ground spray application because the herbicide is released at a greater distance above the crop canopy.

IV.D.2.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. Current availability and usage of commercially available (both GE and non-GE) soybean and commercially available (both GE and non-GE) cotton are expected to remain the same under the No Action Alternative. Under this alternative DT soybean and DGT cotton would not become integrated into the glyphosate-tolerant soybean or cotton systems and dicamba use would likely remain similar to today's use pattern in soybean and cotton.

As discussed under in Section II.D.1.c, cultivated soybean and cultivated cotton are largely self-pollinating, and no wild (native) or feral species of *Glycine* or *Gossypium* have been found in soybean-growing or cotton-growing areas in North America. Gene flow to sexually compatible plants and weediness are not concerns with existing commercial soybean and cotton, and would not be expected to be concerns with new varieties that may be introduced.

Currently herbicides are used on nearly all (~98%) soybean acres, and over 35 different herbicide active ingredients are approved for use in soybean (Section II.B.1.d). Currently herbicides are used on nearly all (>99%) cotton acres, and approximately 39 million pounds of 30 different herbicides are applied pre- or postemergence in cotton production (Monsanto, 2012) (Section II.B.2.d). The use of herbicides in soybean and cotton production is expected to continue to increase as more growers adopt diversified weed management strategies to combat hard-to-control weeds and herbicide-resistant biotypes. Adding additional herbicides with different modes-of-action into the soybean and cotton production systems to mitigate development of glyphosate-resistant weeds and control glyphosate-resistant weeds would continue to remain an option. Potential offsite impacts to adjacent plants from these alternative herbicides would vary, depending on active ingredients, weather conditions, formulations, application methods, and other factors.

IV.D.2.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, the No Action Alternative for DGT cotton is not expected to result in significant changes to plant communities.

The difference between the No Action and the Deregulation in Whole Alternatives for DT soybean would be the gradual integration of the dicamba-tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. As gene flow and weediness are not currently concerns in existing commercial soybean production, no concern would be expected under the Deregulation in Whole Alternative unless DT soybean has characteristics that make it more likely to cross-pollinate and introgress with cultivated soybean, establish feral populations in soybean-growing regions, or allow it to be commercially produced in areas where it is not currently grown.

Potential Impacts from the Genetic Modification. With the exception of its tolerance to dicamba, DT soybean has been shown to be no different from non-GE soybean in its phenotypic, agronomic, and ecological characteristics including pollen diameter, viability and morphology (see Appendix G of this Environmental Report). Thus, DT soybean is expected to be no different from other soybean in its ability to cross pollinate with other soybean. In addition, DT soybean is not different from non-GE soybean in terms of seed dormancy and germination, susceptibility to or tolerance of disease or insect pests, and response to abiotic stressors (such as compaction, drought, high winds, nutrient deficiency, etc.), and would therefore be no different than non-GE soybean in its potential for volunteers and feral populations. In particular, the lack of hard seed, a well-accepted characteristic often associated with plants that are weeds, supports a conclusion of no increased weediness of DT soybean compared to commercially cultivated soybean (see Appendix G of this Environmental Report).

Phenotypic and agronomic information collected from field trials conducted in 2008 using the same agricultural inputs showed no meaningful changes between DT soybean and the conventional control (see Appendix G of this Environmental Report). Information presented in the petition demonstrates that compared to other commercially cultivated soybean, DT soybean does not display increased susceptibility to pests or diseases, and is not changed regarding crop emergence, growth and development, or yield. Additional laboratory and greenhouse-based experiments reached the same conclusion. Therefore, there is no expectation that the introduction of DT soybean and its use in development of soybean varieties will alter the geographical range of commercial soybean cultivation. Thus, the introduction of DT soybean is not anticipated to facilitate production of soybean in areas where it is not currently grown or have a notable impact on total soybean production acres.

Importantly, the potential environmental consequences of pollen transfer from DT soybean to other soybean or related *Glycine* species is considered to be negligible because of the safety of the introduced proteins and lack of any selective advantage by the dicamba trait that might be conferred on the recipient feral soybean or wild relatives. Furthermore, no wild (native) or feral species of *Glycine* have been found in soybean-growing areas (Section II.D.1.c).

Based on these characteristics of DT soybean, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on other plants as a result of the genetic modification.

Potential Impacts from Dicamba. The Deregulation in Whole Alternative would likely result in an increase in dicamba use compared to current levels.

When proper mitigation measures and pesticide application techniques are utilized, offsite impacts to non-target vegetation as a result of offsite movement can be avoided. Such mitigation measures and techniques often focus on reducing potential impacts to non-target vegetation from offsite movement from particle (spray) and vapor (volatility). U.S. EPA considers possible effects from offsite movement as part of the pesticide registration process. In order to approve the use of a pesticide (herbicide) under FIFRA, U.S. EPA must conclude that no unreasonable adverse effects on non-target vegetation will result from offsite movement when the herbicide is used according to the product label.

A detailed discussion about offsite movement is provided in Appendix D to this Environmental Report. As discussed therein, experimental testing has shown that, in the absence of proper mitigation measures and pesticide techniques, offsite movement of dicamba can result in visual symptoms and/or injury to trees and certain sensitive crops, particularly beans (*e.g.*, dry and snap beans), cotton, flowers, fruit trees, grapes, ornamentals, peas, potatoes, soybean, sunflower, tobacco, tomatoes, and other broadleaf plants when contacting their roots, stems or foliage (BASF Corporation 2008; Jordan, et al. 2009). These plants are most sensitive to dicamba during their development or growing stage (BASF Corporation 2008).

However when herbicides are applied according to the FIFRA label application instructions, offsite impacts can be avoided. EPA concluded in the dicamba RED (U.S. EPA 2009a) that existing FIFRA label language to mitigate offsite movement was sufficient to reduce the potential risk of damage to adjacent vegetation. Because the proposed application rates for dicamba on DT soybean are less than or equivalent to rates for dicamba established for other uses in the dicamba RED, and because these uses were evaluated by EPA as part of the RED and the proposed label contains the offsite movement mitigation language, it is reasonable to conclude that the use of dicamba on DT soybean also meets the FIFRA no unreasonable effects standard for drift and offsite movement (U.S. EPA 2009a). Monsanto's request for the use of dicamba on DT soybean only for low-volatility salts such as the DGA salt formulation (U.S. EPA Reg. No. 524-582) is currently pending before EPA. The proposed FIFRA label's inclusion of specific application requirements, such as a no-spray buffer to protect dicamba-sensitive areas (see Appendix D of this Environmental Report for additional details), and/or any other measures imposed by EPA, will reduce dicamba offsite movement and potential impacts to adjacent sensitive areas. Furthermore, to further minimize potential impacts from post application volatilitzation, Monsanto will not allow growers to use dimethylamine salt (DMA) of dicamba and/or dicamba acid on DT soybean.

Growers and commercial applicators are aware of the sensitivity of certain crops to herbicides, including dicamba, and the extra precautions that should be taken in making applications when these crops are nearby. In addition, growers and commercial applicators follow label directions and restrictions, and growers are educated by university specialists and industry representatives on the proper application equipment, equipment setup, and climatic conditions to maximize herbicide performance and minimize offsite movement of herbicides. To provide growers with specific information for dicamba applications to dicamba-tolerant crops, Monsanto is implementing a robust stewardship program that will include a strong emphasis on grower and applicator training. In addition, U.S. EPA and state agencies have enforcement authority over the use of any registered pesticide in a manner inconsistent with its labeling.

In summary, EPA regulates the use of herbicides and has concluded that dicamba offsite movement from labeled uses similar to those proposed on DT soybean do not pose unreasonable adverse effects to non-target vegetation. Furthermore, as indicated above, when herbicides are applied in accordance with the FIFRA label application use instructions, which are legally enforceable, impacts on adjacent agricultural crops and non-agricultural plants can be avoided. Monsanto has submitted a proposed label to EPA for the use of dicamba on DT soybean, and EPA must approve the product label before any applications can be made. Thus, potential impacts to these adjacent areas due to deregulation of DT soybean and use of dicamba are similar when compared to the No Action Alternative. Therefore, the Deregulation in Whole and No Action Alternatives are similar regarding potential impacts on adjacent agricultural and non-agricultural areas.

IV.D.2.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, the No Action Alternative for DT soybean is not expected to result in significant changes to plant communities.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. As gene flow and weediness are not currently concerns in existing commercial cotton production, no concern would be expected under the Deregulation in Whole Alternative unless DGT cotton has characteristics that make it more likely to cross-pollinate and introgress with cultivated cotton, establish feral populations in cotton-growing regions, or allow it to be commercially produced in areas where it is not currently grown.

Potential Impacts from the Genetic Modification. With the exception of its tolerances to both dicamba and glufosinate, DGT cotton has been shown to be no different from non-GE cotton in its phenotypic, agronomic, and ecological characteristics including pollen diameter, viability and morphology (see Appendix G of this Environmental Report). Thus, DGT cotton is expected to be no different from other cotton in its ability to cross pollinate with other cotton. In addition, DGT cotton is not different from non-GE cotton in terms of seed dormancy and germination, susceptibility to or tolerance of disease or insect pests, and response to abiotic stressors (such as compaction, drought, high winds, nutrient deficiency, etc.), and would therefore be no different than non-GE cotton in its potential for volunteers and feral populations. In particular, the lack of hard seed, a well-accepted characteristic often associated with plants that are weeds, supports a conclusion of no increased weediness of DGT cotton compared to commercially cultivated cotton (see Appendix G of this Environmental Report).

Phenotypic and agronomic information collected from field trials conducted in 2010 using the same agricultural inputs showed no meaningful changes between DGT cotton and the conventional control (see Appendix G of this Environmental Report). Information presented in the petition demonstrates that compared to other commercially cultivated cotton, DGT cotton does not display increased susceptibility to pests or diseases, and is not changed regarding crop emergence, growth and development, or yield. Additional laboratory and greenhouse-based experiments reached the same conclusion. Therefore, there is no expectation that the introduction of DGT cotton and its use in development of cotton varieties will alter the geographical range of commercial cotton cultivation. Thus, the introduction of DGT cotton is not anticipated to facilitate production of cotton in areas where it is not currently grown or have a notable impact on total cotton production acres.

Importantly, the potential environmental consequences of pollen transfer from DGT cotton to other cotton or related *Gossypium* species is considered to be negligible because of the safety of the introduced proteins and lack of any selective advantage by the dicamba and glufosinate traits that might be conferred on the recipient feral cotton or wild relatives. Furthermore, no wild (native) or feral species of *Gossypium* have been found in cotton-growing areas (Fryxell 1984; Waghmare et al. 2005).

Based on these characteristics of DGT cotton, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on other plants as a result of the genetic modification.

Potential Impacts from Dicamba. The Deregulation in Whole Alternative would likely result in an increase in dicamba use in cotton compared to its current use. This discussion focuses on dicamba, as no changes to allowable glufosinate use on cotton are expected.

As discussed in *Approval in Whole of DT Soybean, but not DGT Cotton*, when herbicides are applied according to the FIFRA label application instructions, offsite impacts can be avoided. The proposed application rates for dicamba on DGT cotton are less than or equivalent to rates for dicamba established for other uses in the dicamba RED, and because these uses were evaluated by EPA as part of the RED and the proposed label contains the offsite movement mitigation language, discussed above, it is reasonable to conclude that the use of dicamba on DGT cotton also meets the FIFRA no unreasonable effects standard for drift and offsite movement (U.S. EPA 2009a; d). Monsanto's request for the use of dicamba on DGT cotton only for low-volatility salts such as the DGA salt formulation (U.S. EPA Reg. No. 524-582) is currently pending before EPA. The proposed FIFRA label's inclusion of specific application requirements, such as a no-spray buffer to protect dicamba-sensitive areas (see Appendix D of this Environmental Report for additional details), and/or any other measures imposed by EPA, will reduce dicamba offsite movement and potential impacts to adjacent sensitive areas. Furthermore, to further minimize potential impacts from post application volatilitzation, Monsanto will not allow growers to use dimethylamine salt (DMA) of dicamba and/or dicamba acid on DGT cotton.

In summary, EPA regulates the use of herbicides and has concluded that dicamba offsite movement from labeled uses similar to those proposed on DGT cotton do not pose unreasonable adverse effects to non-target vegetation. Furthermore, as indicated above, when herbicides are applied in accordance with the FIFRA label application use instructions, which are legally enforceable, impacts on adjacent agricultural crops and non-agricultural plants can be avoided. Monsanto has submitted a proposed label to EPA for the use of dicamba on DGT cotton, EPA must approve the product label before any applications can be made. Thus, potential impacts to these adjacent areas due to deregulation of DGT cotton and use of dicamba are similar when compared to the No Action Alternative. Therefore, the Deregulation in Whole and No Action Alternatives are similar regarding potential impacts on adjacent agricultural and non-agricultural areas.

IV.D.2.d. Approval in Whole of DT Soybean and DGT Cotton

As discussed in detail above, in terms of potential impacts to plant communities, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DT soybean and DGT cotton with the current glyphosate-tolerant soybean and cotton systems using traditional breeding techniques. Gene flow and weediness are not concerns in existing commercial soybean and cotton production. EPA regulates the use of herbicides and has concluded that dicamba offsite movement from labeled uses do not pose unreasonable adverse effects to non-target vegetation. Furthermore, as indicated above, when herbicides are applied in accordance with the FIFRA label application use instructions, which are legally enforceable, impacts on adjacent agricultural crops and non-agricultural plants can be avoided. Thus, potential impacts to these adjacent areas due to deregulation of DT soybean and use of dicamba are similar when compared to the No Action Alternative. Therefore, the Deregulation in Whole and No Action Alternatives are similar regarding potential impacts on adjacent agricultural and non-agricultural areas.

IV.D.3. Gene Flow and Weediness

IV.D.3.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT Cotton would continue to be regulated by APHIS. Current availability and usage of commercially available (both GE and non-GE) soybean and cotton are expected to remain the same under the No Action Alternative. Under this alternative DT soybean and DGT cotton would not become integrated into the glyphosate-tolerant soybean and cotton systems and dicamba use would likely remain similar to today's use pattern in soybean and cotton.

As discussed below in Section V.J, cultivated soybean and cotton are largely self-pollinating, and no wild (native) or feral species of *Glycine* or wild (native) or feral species of *Gossypium* have been found in soybean-growing or cotton-growing regions of the U.S. Gene flow to sexually compatible plants and weediness are not concerns with existing commercial soybeans or with existing commercial cotton, and would not be expected to be concerns with new varieties that may be introduced.

IV.D.3.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, No Action Alternatives for DGT cotton is not expected to result in significant changes to animal communities.

With the exception of its tolerance to dicamba, DT soybean has been shown to be no different from non-GE soybean in its phenotypic, agronomic, and ecological characteristics including pollen diameter, viability and morphology (see Appendix G of this Environmental Report). Thus, DT soybean is expected to be no different from other soybean in its ability to cross pollinate with other soybean. In addition, DT soybean is not different from non-GE soybean in terms of seed dormancy and germination, susceptibility to or tolerance of disease or insect pests, and response to abiotic stressors (such as compaction, drought, high winds, nutrient deficiency, etc.), and would therefore be no different than non-GE soybean in its potential for volunteers and feral populations. In particular, the lack of hard seed, a well-accepted characteristic often associated with plants that are weeds, supports a conclusion of no increased weediness of DT soybean compared to commercially cultivated soybean (see Appendix G of this Environmental Report).

Phenotypic and agronomic information collected from field trials conducted in 2008 using the same agricultural inputs showed no meaningful changes between DT soybean and the conventional control (see Appendix G of this Environmental Report). Information presented in the petition demonstrates that compared to other commercially cultivated soybean, DT soybean does not display increased susceptibility to pests or diseases, and is not changed regarding crop emergence, growth and development, or yield. Additional laboratory and greenhouse-based experiments reached the same conclusion. Therefore, there is no expectation that the introduction of DT soybean and its use in development of soybean varieties will alter the geographical range of commercial soybean cultivation. Thus, the introduction of DT soybean is not anticipated to facilitate production of soybean in areas where it is not currently grown or have a notable impact on total soybean production acres.

Importantly, the potential environmental consequences of pollen transfer from DT soybean to other soybean or related *Glycine* species is considered to be negligible because of the safety of the introduced proteins and lack of any selective advantage by the dicamba trait that might be conferred on the recipient feral soybean or wild relatives. Furthermore, no wild (native) or feral species of *Glycine* have been found in soybean-growing areas Section II.D.1.c.

Based on these characteristics of DT soybean, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on other plants as a result of the gene flow or weediness.

IV.D.3.c. Approval in Whole of DGT Cotton, but not DT Soybean

With the exception of its tolerances to both dicamba and glufosinate, DGT cotton has been shown to be no different from non-GE cotton in its phenotypic, agronomic, and ecological characteristics including pollen diameter, viability and morphology (see Appendix G of this Environmental Report for details). Thus, DGT cotton is expected to be no different from other cotton in its ability to cross pollinate with other cotton. In addition, DGT cotton is not different from non-GE cotton in terms of seed dormancy and germination, susceptibility to or tolerance of disease or insect pests, and response to abiotic stressors (such as compaction, drought, high winds, nutrient deficiency, etc.), and would therefore be no different than non-GE cotton in its potential for volunteers and feral populations. In particular, the lack of hard seed, a well-accepted characteristic often associated with plants that are weeds, supports a conclusion of no increased weediness of DGT cotton compared to commercially cultivated cotton (see Appendix G of this Environmental Report).

Phenotypic and agronomic information collected from field trials conducted in 2010 using the same agricultural inputs showed no meaningful changes between DGT cotton and the conventional control (see Appendix G of this Environmental Report). Information presented in the petition demonstrates that compared to other commercially cultivated cotton, DGT cotton does not display increased susceptibility to pests or diseases, and is not changed regarding crop emergence, growth and development, or yield. Additional laboratory and greenhouse-based experiments reached the same conclusion. Therefore, there is no expectation that the introduction of DGT cotton and its use in development of cotton varieties will alter the geographical range of commercial cotton cultivation. Thus, the introduction of DGT cotton is not anticipated to facilitate production of cotton in areas where it is not currently grown or have a notable impact on total cotton production acres.

Importantly, the potential environmental consequences of pollen transfer from DGT cotton to other cotton or related Gossypium species is considered to be negligible because of the safety of the introduced proteins and lack of any selective advantage by the dicamba and glufosinate traits that might be conferred on the recipient feral cotton or wild relatives. Furthermore, no wild (native) or feral species of *Gossypium* have been found in cotton-growing areas (Fryxell 1984; Waghmare et al. 2005). Additional details are provided in Section IV.D.2.c.

Based on these characteristics of DGT cotton, the Deregulation in Whole and No Action Alternatives are the same regarding their potential impact on gene flow and weediness.

IV.D.3.d. Approval in Whole of DT Soybean and DGT Cotton

As discussed in detail above, in terms of potential impacts to gene flow and weediness, there is no substantial difference between the No Action and Deregulation in Whole Alternatives for DT soybean and DGT cotton. EPA has determined that when herbicides are used in accordance with their labels, no unreasonable adverse impacts will result. As discussed above, EPA's conclusions are based on comprehensive evaluations and risk assessments. Further discussion of the difference in the types of herbicides used and associated impacts is included in Appendix A. Therefore, the Deregulation in Whole and the No Action Alternatives are similar regarding potential impacts on gene flow and weediness.

IV.D.4. Microorganisms

IV.D.4.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. Current availability and usage of commercially available (both GE and non-GE) soybean and cotton are expected to remain the same under the No Action Alternative. Under this alternative DT soybean and DGT cotton would not become integrated into the glyphosate-tolerant soybean and cotton systems and dicamba use would likely remain similar to today's use pattern in soybean and cotton.

Adding other herbicides with different modes-of-action into the glyphosate-tolerant systems to mitigate development of glyphosate-resistant weeds and control glyphosate-resistant weeds would continue to remain an option. Additionally, conventional tillage may increase in some instances as an additional means to control problematic weeds.

Agricultural practices such as pesticide applications and tillage are known to impact soil microbial populations, species composition, colonization, and associated biochemical processes. However, alternative herbicides are already available and are used in soybean and cotton, and would likely be used instead of dicamba under the No Action Alternative.

IV.D.4.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, No Action Alternatives for DGT cotton is not expected to result in significant changes to soil microorganisms.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba -tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. As discussed in Section II.B.1.c, DT soybean is not expected to alter the current agronomic practices for soybean cultivation. No adverse effects on soil microorganisms, including agronomically important rhizosphere-inhabiting soil bacteria such as *Bradyrhizobiaceae japonicum,* are associated with DT soybean or its cultivation, nor do the characteristics of the MON 87708 DMO protein pose any concern to soil microorganisms.

The use of dicamba for agricultural purposes was first established in 1967, and with the reregistration in 2006, EPA recently reaffirmed its conclusion that use of dicamba does not result in unreasonable adverse effects when applied according to label directions, including for soybean production (U.S. EPA 2009a). Impacts on soil microorganisms have not been raised as an important concern, and results of standardized tests with dicamba and dicamba formulations did not indicate any long term effects on soil microorganisms (Durkin and Bosch 2004). Results of standardized tests with dicamba and dicamba formulations indicate no long-term effects on functional processes of soil microorganisms (carbon respiration and nitrogen transformation) at rates proposed for dicamba on DT soybean.

On the basis of these observations and in conjunction with related phenotypic measurements for DT soybean, no impact on soil microorganisms is expected from the cultivation of DT soybean. Therefore, the Deregulation in Whole and No Action Alternatives are similar regarding potential impacts on soil microorganisms.

IV.D.4.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, No Action Alternatives for DT soybean is not expected to result in significant changes to soil microorganisms.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. As discussed in Section IV.B.2.c, DGT cotton is not expected to alter the current agronomic practices for cotton cultivation. No adverse effects on soil microorganisms are associated with DGT cotton or its cultivation, nor do the characteristics of the MON 88701 DMO or PAT (*bar*) pose any concern to soil microorganisms.

The use of dicamba for agricultural purposes was first established in 1967, and with the reregistration in 2006, EPA recently reaffirmed its conclusion that use of dicamba does not result in unreasonable adverse effects when applied according to label directions, including for cotton production (U.S. EPA 2009a). Impacts on soil microorganisms have not been raised as an important concern, and results of standardized tests with dicamba and dicamba formulations did not indicate any long term effects on soil microorganisms (Durkin and Bosch 2004). Results of standardized tests with dicamba and dicamba formulations indicate no long-term effects on functional processes of soil microorganisms (carbon respiration and nitrogen transformation) at rates proposed for dicamba on DGT cotton (EFSA 2007c). Glufosinate is currently used on cotton at the rates that would be the same as those used on DGT cotton.

On the basis of these observations and in conjunction with related phenotypic measurements for DGT cotton, no impact on soil microorganisms is expected from the cultivation of DGT cotton. Therefore, the Deregulation in Whole and No Action Alternatives are similar regarding potential impacts on soil microorganisms.

IV.D.4.d. Approval in Whole of DT Soybean and DGT Cotton

As discussed in detail above, in terms of potential impacts to soil microorganisms in or near soybean and cotton fields containing DT soybean or DGT cotton, the there is no substantial difference between the No Action and Deregulation in Whole Alternatives for potential impacts on soil microorganisms. No adverse effects on soil microorganisms are associated with DT soybean or its cultivation, nor do the characteristics of the MON 87708 DMO protein pose any concern to soil microorganisms. No adverse effects on soil microorganisms are associated with DGT cotton or its cultivation, nor do the characteristics of the MON 88701 DMO or PAT (bar) pose any concern to soil microorganisms. Therefore, the Deregulation in Whole of DT soybean and DGT cotton and No Action Alternatives are the same regarding their potential impact on soil microorganisms.

IV.D.5. Bioiversity

IV.D.5.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT Cotton would continue to be regulated by APHIS. Current availability and usage of commercially available (both GE and non-GE) soybean and cotton are expected to remain the same under the No Action Alternative. Under this alternative DT soybean and DGT cotton would not become integrated into the glyphosate-tolerant soybean and cotton systems and dicamba use would likely remain similar to today's use pattern in soybean and cotton. As discussed in Sections III.D.1.e and III.D.2.e, the use of herbicides in agricultural fields impacts biodiversity within the field by decreasing weed species. It is the grower's goal, for his economic well-being, to cultivate a single plant species in the field, to the exclusion of other species.

Currently 98% of soybean fields are treated with herbicides and 99% of cotton fields are treated with herbicides, averaging four applications per year. Soybean fields and cotton fields would be expected to continue to have low plant diversity, and associated low animal diversity.

IV.D.5.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, the No Action Alternative for DGT cotton is not expected to result in significant changes to plant or animal biodiversity.

For DT soybean, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba -tolerant event DT soybean with the current glyphosate-tolerant soybean systems using traditional breeding techniques. Except for tolerances to dicamba, DT soybean is phenotypically and agronomically the same as its non-GE counterpart (Appendix G of this Environmental Report). Therefore, DT soybean would not be expected to have direct impacts on biodiversity any different than other commercially available soybean.

U.S. soybean fields currently have low plant (and associated animal) diversity by intent and 98% of soybean fields are treated with herbicides. Therefore, introduction of DT soybean and treatment with dicamba and is unlikely to affect the animal or plant communities found in soybean fields differently than today's practices. Based on this analysis, it is concluded that the potential effect of Deregulation in Whole of DT soybean on biodiversity would not differ from impacts associated with current agricultural practices used for production of soybean. Therefore, the Deregulation in Whole and the No Action Alternatives are similar regarding potential impacts on biodiversity.

IV.D.5.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, the No Action Alternative for DT soybean is not expected to result in significant changes to plant or animal biodiversity.

With respect to DGT cotton, the difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. Except for tolerances to both dicamba and glufosinate, DGT cotton is phenotypically and agronomically the same as its non-GE counterpart (Appendix G to this Environmental Report). Therefore, DGT cotton would not be expected to have direct impacts on biodiversity any different than other commercially available cotton.

U.S. cotton fields currently have low plant (and associated animal) diversity by intent and over 99% of cotton fields are treated with herbicides, averaging four applications per year. Therefore, introduction of DGT cotton and treatment with dicamba and or glufosinate is unlikely to affect the animal or plant communities found in cotton fields differently than today's practices. Based on this analysis, it is concluded that the potential effect of Deregulation in Whole of DGT cotton on biodiversity would not differ from impacts associated with current agricultural practices used for production of cotton. Therefore, the Deregulation in Whole and the No Action Alternatives are similar regarding potential impacts on biodiversity.

IV.D.5.d. Approval in Whole of DT Soybean and DGT Cotton

As discussed in detail above, in terms of potential impacts to plant and animal diversity in or near soybean and cotton fields containing DT soybean or DGT cotton, there is no substantial difference between the No Action and Deregulation in Whole Alternatives for potential impacts on plant and animal diversity. U.S. soybean and cotton fields currently have low plant (and associated animal) diversity by intent and 98% of soybean fields are treated with herbicides and 99% of cotton fields are treated with herbicides, averaging four applications per year. Therefore, the Deregulation in Whole and the No Action Alternatives are similar regarding potential impacts on biodiversity.

IV.E. HUMAN HEALTH AND SAFETY IMPACTS

IV.E.1. Human Health

IV.E.1.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) soybeans and cotton would be expected to remain the same under the No Action Alternative. Thus, exposure to DT soybean and DGT cotton would also remain unchanged. Consumer exposure to existing conventional and GE soybeans and cotton would remain unchanged, with continued exposure to currently used herbicides in soybeans and cotton.

IV.E.1.b. Approval of DT Soybean, but not DGT Cotton

As discussed above, approval of the No Action Alternative for DGT cotton is not expected to have significant impacts on human health.

Under full deregulation, DT soybean could be grown broadly across the U.S. Soybean and forage produced from DT soybean would enter the food and feed chain and would be consumed by humans and animals. Agricultural workers would be exposed to DT soybean and its associated agricultural practices. Monsanto has completed the U.S. FDA consultation process for DT soybean, with FDA confirming the safety of DT soybean-derived food and feed on October 11, 2011.

The potential human health impacts associated with the introduction of DT soybean and increased applications of dicamba are separately discussed below. As discussed elsewhere in this report, however, Congress transferred regulatory authority over herbicides from USDA to EPA. Accordingly, USDA-APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider herbicide impacts under the PPA. Nonetheless, because APHIS indicated in its Notice of Intent to Prepare an Environmental Impact Statement (78 Fed. Reg. 28796, May 16, 2013) that it would be considering herbicide effects and herbicide resistance as part of the NEPA process, Monsanto has included a discussion of herbicide impacts in the following section. Importantly, however, Monsanto believes that APHIS has no legal obligation under NEPA to consider herbicide impacts or herbicide resistance in any Environmental Impact Statement or Environmental Assessment. See DOT v. Public Citizen, 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform). See also Center for Food Safety v. Vilsack, No. 12-15052, 2013 U.S. App. LEXIS 9920, at *16-17 (9th Cir. 2013) ("If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests.").

DT Soybean: DT soybean was developed through *Agrobacterium*-mediated transformation of soybean meristem tissue using the binary transformation plasmid PV-GMHT4355. DT soybean contains one copy of the insert at a single integration locus. No additional genetic elements from the transformation vector were detected in the genome of DT soybean, including backbone sequence from plasmid PV-GMHT4355. Additionally, the data confirm the organization and sequence of the insert, and demonstrate the stability of the insert over several generations. On the basis of these data, it is concluded that only the MON 87708 DMO is produced from the inserted DNA.

For DT soybean, the available data demonstrate that harvested seed is as safe as conventional soybean for food and feed uses; thus it is safe and wholesome for consumption. To assess the impact of the DMO protein in DT soybean on food and feed safety, bioinformatic analyses were used to establish the lack of both structurally and immunologically-relevant similarities between DT soybean and allergens or toxins, based on the amino acid sequence of MON 87708 DMO. Furthermore, digestive fate experiments conducted with MON 87707 DMO demonstrate rapid digestion in simulated gastric fluid (SGF), a characteristic shared among many proteins with a history of safe consumption. Rapid digestion of MON 87708 in

SGF indicates that it is highly unlikely that DT soybean DMO will reach absorptive cells of the intestinal mucosa. This, combined with the history of safe consumption of mono oxygenases (the class of enzymes to MON 87708 DMO belongs) and the lack of homology of the amino acid sequence to known allergens and toxins, supports a conclusion that MON 87708 DMO has low allergenic and toxic potential. Finally, a high dose of MON 87708 DMO in a mouse acute oral toxicity evaluation demonstrated that it is not acutely toxic, and does not cause any adverse effect. The safety assessment supports the conclusion that exposure to MON 87708 DMO poses no meaningful risk to human or animal health.

Extensive analysis of the composition of DT soybean seed and forage demonstrated that no biologically relevant changes were detectable. A detailed compositional assessment of soybean harvested seed and forage is presented in the DT Soybean Petition and Appendix G of this Environmental Report. The levels of key nutrients, anti-nutrients, and other components in DT soybean were examined and compared to that of the near-isogenic conventional soybean control, A3525, a conventional soybean variety with background genetics representative of DT soybean, but without the genetic modification. Additionally, tolerance intervals representing 99% of the values of each analyte for a commercial soybean population were established. Results demonstrate that the levels of key nutrients, anti-nutrients, and other components of DT soybean are compositionally equivalent to the conventional control and within the range of variability of commercial soybean that were grown concurrently in the same trial. Furthermore, FDA completed its consultation on the food, feed and nutritional safety assessment on DT soybean on October 11, 2011, confirming Monsanto's conclusion on the safety of DT soybean derived food and feed.

On the basis of the characteristics of MON 88701 DMO and the extensive compositional characterization of DT soybean harvested seed, no impacts to human health are expected from the Deregulation in Whole Alternative.

Dicamba: The toxicology or risk profile of dicamba has been extensively reviewed (U.S. EPA 2009a; d). Dicamba does not pose any unusual toxicological concerns and is not carcinogenic (Durkin and Bosch 2004; European Commission 2007; U.S. EPA 2009d). EPA completed the reregistration of dicamba in 2006. The Reregistration Eligibility Decision (RED) document for dicamba and its associated salts concluded that a high level of confidence exists for the dicamba hazard data base and the reliability of these data necessary to support the required finding for continued registration, including the pre-harvest use on commercial soybean. The dicamba RED document, and the related EPA Health Effects Division (HED) chapter (U.S. EPA 2005d), provide a detailed overview of the toxicological properties of dicamba. Dicamba's toxicity profile is presented in Appendix L of the DT Soybean Petition, and summarized in Appendices A and E of this Environmental Report.

EPA evaluated the potential risks to humans from the use of dicamba as a part of the dicamba RED, concluding that aggregate exposure to dicamba, defined as dietary (food and water) and non-occupational (residential and recreational) exposures, meet the FIFRA determination of no unreasonable adverse effects and the FFDCA determination for reasonable certainty of no harm to human health. EPA has conducted acute and chronic dietary (food and water) risk assessments for dicamba based on a theoretical worst case exposure estimate. For food, this estimate assumes that dicamba is used on 100 percent of all the crops on which the pesticide is currently approved for use. It further assumes that the resulting pesticide residues found on all harvested food and feed crops and derived animal food commodities (e.g., meat and milk) are at the level of the legally established tolerance (i.e., the maximum allowable pesticide residue level). Residues of dicamba are defined as dicamba and its metabolites 5-hydroxy dicamba and 3,6-dichlorosalicylic acid (DCSA) in soybean commodities, and as dicamba and DCSA in animal food commodities, as currently regulated in 40 CFR § 180.227. For water, EPA assumed that dicamba could potentially move offsite to adjacent surface water bodies as a result of drift or runoff, or move through soil to groundwater. Since the estimated concentrations in groundwater were significantly lower compared to surface water, surface water estimates were used in the worst case dietary assessments. Surface water estimates were generated with the conservative screening level models SCIGROW and PRZM/EXAM using an exaggerated application rate that is 2.8 times higher than the current 1.0 lb a.e./A maximum single application rate established in the dicamba RED (U.S. EPA 2005a; d; c; 2009d), and the maximum single application rate proposed for DT soybean . EPA mandated reductions in dicamba use rates as part of the dicamba RED (1 lb a.e./A and 2 lb a.e./A for a single application and for annual application, respectively) (See Appendices A and C of this Environmental Report for more detail on dicamba levels in water resources).

Based on the worst-case assumptions outlined above and in Appendix H, acute and chronic dietary exposure was well below the Agency's level of concern to satisfy the FIFRA and FFDCA standards (U.S. EPA 2009d).

Characterization of the nature of dicamba residues in DT soybean confirms no additional residues of concern are created in DT soybean, and the current soybean seed dicamba residue definition is applicable for DT soybean. Residue levels in soybean seed harvested from DT soybean treated with dicamba at the proposed maximum allowable application use pattern (1.0 pound a.e. per acre preemergence and two 0.5 pound a.e. per acre postemergence applications) were less than 0.1 ppm, well below the established 10 ppm tolerance supporting the current use of dicamba on conventional soybean. These dicamba residue data for DT soybean were submitted to the U.S. EPA on April 28, 2010 (OPP Decision Number: D-432753, Registration Number 524-582), along with a proposed label for the use of dicamba on DT soybean.

Presently, dicamba is applied to less than 1% of soybean acres using pre-plant and pre-harvest burndown applications (see Appendix A to this Environmental Report). Under the Deregulation in Whole Alternative, dicamba will be used on more soybean acres and a higher percentage of soybean and soybean-derived foods will contain dicamba residues; however, dicamba residue levels in DT soybean harvested seed or processed foods will be significantly lower compared to levels originating from the current pre-harvest soybean use (approximately 100-fold lower, based on <0.1 ppm. residue in DT soybean seed compared to established 10 ppm tolerance (see Section II.E.1.c). It is difficult to determine the exact impact on actual dietary exposure from the expanded use of dicamba on DT soybean; however, the EPA concluded that residues of dicamba up to 10 ppm in soybean seed are safe (reasonable certainty of no harm as defined by FFDCA) for human and animal consumption, based on the EPA's Tier 1 dietary and aggregate (dietary plus other non-occupational) exposure assessments which assume 100% of soybean foods contain dicamba residues at the 10 ppm tolerance level.

Additionally, Monsanto has petitioned the EPA to establish new feed tolerances for soybean forage and hay to allow DT soybean forage and hay to be fed to livestock, a practice that is presently prohibited for dicamba-treated commercial soybean. This practice is presently not allowed because the current preharvest application is made past the stage where the crop would be useful as forage or hay. Thus, there has been no reason for pursuing these tolerances until earlier in-crop applications of dicamba were possible, as with DT soybean. Dietary exposure to livestock from the feeding of DT soybean forage and hay does not result in an exceedance of the livestock maximum theoretical dietary burden established by the EPA, which is used to establish animal by-product commodity tolerances (*e.g.*, meat and milk). Therefore, the approval of soybean forage and hay tolerances does not result in a change to the current animal by-product commodity (food) tolerances and as a result does not increase potential dietary exposure of dicamba.

Since no changes to the current dicamba food tolerances (soybean seed and animal by-products) are needed, the dietary and aggregate risk assessments conducted in the RED are inclusive of the incremental exposure resulting from the use of dicamba on DT soybean. Therefore, the deregulation of DT soybean would not present a significant impact to human health, and the Deregulation in Whole and No Action Alternatives are the similar regarding potential impacts on human health.

IV.E.1.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, approval of the No Action Alternative for DT soybean is not expected to have significant impacts on human health.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. Prior to the introduction of a GE-derived crop product to the marketplace, Monsanto conducts tests to assure that the product is as safe as its conventional counterpart under the intended use conditions. GE-derived crops for food and feed use undergo a voluntary consultation process with the U.S. FDA prior to release into the market. Monsanto has completed the U.S. FDA consultation process for DGT cotton, with FDA confirming on April 24, 2013 the safety of food and feed derived from DGT cotton.

DGT Cotton: Under the Deregulation in Whole Alternative, consumers could be exposed to food products derived from DGT cotton. As discussed in the DGT Cotton Petition and Appendices H and I to this Environmental Report, the only human food currently produced from cottonseed is refined, bleached, and deodorized (RBD) oil, and to a smaller extent, linters. RBD oil and linters are processed fractions that contain negligible amounts of total protein and the DGT cotton DMO and PAT (*bar*) proteins represents a very small portion of the total protein in the cottonseed of DGT cotton; therefore no exposure to MON 88701 DMO or PAT (bar) proteins is anticipated for food uses of DGT cotton.

Assessment of DGT cotton included a molecular assessment of the genetic insert to verify that only the intended genetic changes occurred and that the insert is stable, an assessment of the safety of the inserted proteins, and a compositional analysis to assess the comparability of DGT cotton with existing commercial counterparts. The summaries below are from the petition and the food and feed safety and nutritional assessment of DGT cotton that Monsanto submitted to FDA in April 2012, petition BNF 135.

DGT cotton was developed through *Agrobacterium*-mediated transformation of cotton tissue. *Agrobacterium* is a soil microbe with the ability to transfer part of its DNA into a host plant. The *Agrobacterium* transformation system has been utilized in the development of a large number of genetically engineered plants in commercial production (IOM-NRC 2004). Molecular analyses demonstrated that DGT cotton contains one copy of the inserted transferred DNA at a single integration locus. No backbone sequences from the plasmid vector were detected in the genome of DGT cotton. Additionally, the data confirmed the organization and sequence of the insert and demonstrated the stability of the insert over several generations. These data demonstrated that there are no unintended changes in the DGT cotton genome as a result of the insertion of transferred DNA encoding the MON 88701 DMO and PAT (bar) proteins. On the basis of these data, it is concluded that only the MON 88701 DMO and PAT (*bar*) are produced from the inserted DNA. A description of the genetic modification is included in Appendix G of this Environmental Report.

Monsanto has provided the FDA with information on the identity, function, and characterization of the genes, including expression of the gene products MON 88701 DMO and PAT (*bar*). The submittal to the FDA included information on the safety of the MON 88701 DMO and PAT (*bar*) proteins, as well as the safety of DGT cotton, including a dietary risk assessment. Monsanto initiated the consultation process with FDA for the commercial distribution of DGT cotton and submitted a safety and nutritional assessment of food and feed derived from DGT cotton to the FDA in April 2012. FDA completed the consultation process for DGT cotton on April 24, 2013.

The safety of PAT proteins present in commercial GE-derived crops has been extensively assessed and in 1997 a tolerance exemption was issued for PAT proteins by U.S. EPA. Numerous glufosinate-tolerant products, including those in cotton, corn, soy, canola, sugarbeet, and rice, have been reviewed by the FDA with no concerns identified. MON 88701 DMO and PAT (*bar*) were fully characterized and the enzymatic activity of MON 88701 DMO was found to be specific for dicamba when tested using structurally similar cotton endogenous substrates (see Appendix G of this Environmental Report). The specificity of PAT proteins has been extensively documented in the literature. Neither protein has relevant amino acid sequence similarities to known allergens, toxins or other proteins that may have adverse effects on mammals. MON 88701 DMO and PAT (*bar*) were each rapidly digested in simulated gastric and intestinal fluids, a characteristic shared among many proteins with a history of safe consumption. Rapid digestion of MON 88701 DMO and PAT (*bar*) in simulated gastric and intestinal fluids indicates that it is highly unlikely that MON 88701 DMO or PAT (*bar*) would reach absorptive cells of the intestinal mucosa. Neither MON 88701 DMO nor PAT (*bar*) caused any observable adverse effects when tested in mouse acute oral toxicity analyses. In addition, the only fractions derived from cottonseed that are used in food applications are oil and linters, which contain undetectable and negligible amounts of protein, respectively. Therefore, MON 88701 DMO and PAT (*bar*) proteins comprise a very low, non-detectable portion of the total protein present in food derived from DGT cotton. The safety assessment supports the conclusion that exposure to MON 88701 DMO and PAT (*bar*) from DGT cotton poses no meaningful risk to human and animal health.

Detailed compositional analyses, in accordance with OECD guidelines, were conducted to assess whether levels of key nutrients and anti-nutrients in DGT cottonseed were comparable to levels in the conventional cotton control, Coker 130, and several commercial reference cotton varieties.

Cottonseed were harvested from eight sites in which DGT cotton (treated sequentially with glufosinate and dicamba herbicides), the conventional control and a range of commercial reference varieties were grown concurrently in the same field trial. The commercial reference varieties were used to establish a range of natural variability of the key nutrients and anti-nutrients in commercial cotton varieties that have a long history of safe consumption. Nutrients assessed in this analysis included proximates (ash, fat, moisture, protein, and carbohydrates by calculation), calories by calculation, acid detergent fiber, neutral detergent fiber, crude fiber, total dietary fiber, amino acids (18 components), fatty acids (C8-C22), minerals (calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium, and zinc) and vitamin E. The key anti-nutrients assessed included gossypol and cyclopropenoid fatty acids (CPFA).

Based on statistical analysis of the analyzed nutrient and anti-nutrient levels, herbicide-treated DGT cotton is compositionally equivalent to commercially cultivated cotton and therefore the food and feed safety and nutritional quality of this product is comparable to that of the commercially cultivated cotton. These results support the overall food and feed safety of DGT cotton.

Based on the overall assessment of DGT cotton as related to consumer health, including the integrity and stability of the inserted DNA, the safety of the inserted MON 88701 DMO and PAT(bar) proteins, and the compositional equivalence of DGT cotton to currently available commercial cotton, impacts on consumer health from the Deregulation in Whole Alternative are not expected to differ from those of the No Action Alternative.

Dicamba and Glufosinate: Under the Federal Food, Drug, and Cosmetic Act (FFDCA), pesticide residues in or on raw agricultural commodities or processed foods are allowed only after a tolerance or exemption from tolerance has been established. Residue tolerances and exemptions for pesticides are established by the U.S. EPA under the FFDCA. The U.S. FDA enforces the tolerances set by the U.S. EPA. The U.S. EPA also reviews the proposed use pattern for all herbicides and prior to approval and placement on herbicide labels determines that no unreasonable risk exists for the environment.

To support the introduction of DGT cotton, Monsanto submitted an application to EPA to amend Registration Number 524-582, a low-volatility DGA salt formulation, to remove all pre-emergence planting restrictions (application intervals, rainfall, and geographic) and to allow in-crop post-emergence dicamba applications to DGT cotton. The toxicology or risk profile of dicamba has been extensively reviewed (U.S. EPA 2009d). Dicamba does not pose any unusual toxicological concerns and is not carcinogenic (Durkin and Bosch 2004; EFSA 2007a; U.S. EPA 2009d). EPA completed the reregistration of dicamba in 2006. The RED document for dicamba and its associated salts concluded a high level of confidence exists for the dicamba hazard data base and the reliability of these data necessary to support the required finding for continued registration, including the preharvest use on commercial cotton. The dicamba RED document, and the related EPA Health Effects Division (HED) chapter (U.S. EPA 2005a; d), provide a detailed overview of the toxicological properties of dicamba. A summary of dicamba's toxicity profile is presented in Appendix A, Section A.4 of the DGT Cotton Petition and Appendix E of this Environmental Report.

EPA evaluated the potential risks to humans from the use of dicamba as a part of the dicamba RED, concluding that aggregate exposure to dicamba, defined as dietary (food and water) and non-occupational (residential and recreational) exposures, meet the FIFRA determination of no unreasonable adverse effect (see Appendix A, Sections A.3-A.4, of the DGT Cotton Petition and Appendix E of this Environmental Report) and the FFDCA determination for reasonable certainty of no harm to human health. EPA has conducted acute and chronic dietary (food and water) risk assessments for dicamba based on a theoretical worst case exposure estimate. For food, this estimate assumes that dicamba is used on 100 percent of all the crops on which the pesticide is currently approved for use. It further assumes that the resulting pesticide residues found on all harvested food and feed crops and derived animal food commodities (e.g., meat and milk) are at the level of the legally established tolerance (i.e., the maximum allowable pesticide residue level). Residues of dicamba are defined as dicamba and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid (5-hydroxy dicamba) in cottonseed commodities, as currently regulated in 40 CFR § 180.227. For water, EPA assumed that dicamba could potentially move offsite to adjacent surface water bodies as a result of drift or runoff, or move through soil to groundwater. Since the estimated concentrations in groundwater were significantly lower compared to surface water, surface water estimates were used in the worst case dietary assessments. Surface water estimates were generated with the conservative screening level models SCIGROW and PRZM/EXAM using an exaggerated application rate that is 2.8 times higher than the current 1.0 lb a.e./A maximum single application rate established in the dicamba RED (U.S. EPA 2005d; 2009d), and the maximum single application rate proposed for DT soybean . EPA mandated reductions in dicamba use rates as part of the dicamba RED (1 lb a.e./A and 2 lb a.e./A for a single application and for annual application, respectively). (See Appendices C and F of this Environmental Report for more detail on dicamba levels in water resources).

Based on the worst-case assumptions outlined above and in Appendix H, acute and chronic dietary exposure was well below the Agency's level of concern to satisfy the FIFRA and FFDCA standards (U.S. EPA 2009d).

Dicamba can currently be applied to cotton in the U.S. as a preplant application, at least 21 days prior to planting. The tolerance of DGT cotton to dicamba facilitates a wider window of application on cotton, allowing preemergence application of the herbicide up to the day of crop emergence and post-emergence in-crop applications through seven days preharvest. Monsanto has requested a registration from U.S. EPA for the expanded use of dicamba on DGT cotton, an increase in the dicamba residue tolerance for cottonseed, the establishment of a tolerance for cotton gin by-products, and the inclusion of DCSA in the residue definitions for both cottonseed and gin by-products. No other revisions to the dicamba pesticide residue tolerances are necessary, including animal products such as meat and milk. Furthermore, the use of dicamba on DGT cotton does not present any new environmental exposure scenarios not previously evaluated and deemed acceptable by EPA. The potential dietary exposure to dicamba associated with these proposed changes in cotton tolerances are minimal, because cottonseed-derived food (*i.e.*, oil and linters) goes through extensive processing, and consumption of cotton gin by-product by livestock will not result in a change to the current animal by-product commodity (food) tolerances.

The proposed use pattern for dicamba on DGT cotton falls within the use patterns evaluated by EPA in the dicamba RED; therefore, the proposed use of dicamba on DGT cotton does not present any new environmental exposure scenarios not previously evaluated and deemed acceptable by EPA, including estimates of drinking water exposure.

Glufosinate use on DGT cotton is equivalent to currently deregulated glufosinate-tolerant cotton and is considered baseline.

On the basis of the above analysis, the Deregulation in Whole and No Action Alternatives are similar regarding impacts on consumer health.

IV.E.1.d. Approval in Whole of DT Soybean and DGT Cotton

As discussed in detail above, there is no substantial difference for potential impacts to human health between the No Action and Deregulation in Whole Alternatives for DT soybean and DGT cotton.

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with current glyphosate-tolerant soybean systems and the dicamba and glufosinate-tolerant event DGT cotton with current glyphosate-tolerant cotton systems using traditional breeding techniques. Prior to the introduction of a GE-derived crop product to the marketplace, Monsanto conducts tests to assure that the product is as safe as its conventional counterpart under the intended use conditions. GE-derived crops for food and feed use undergo a voluntary consultation process with the U.S. FDA prior to release into the market. Monsanto completed the U.S. FDA consultation process for both DT soybean and DGT cotton.

On the basis of the characteristics of MON 87708 DMO, MON 88701 DMO, PAT (*bar*), the extensive compositional characterization of DT soybean and DGT cotton harvested seed, and the overall assessment of DT soybean and DGT cotton as related to human health, impacts on consumer health from the Deregulation in Whole Alternative are not expected to differ from those of the No Action Alternative.

Monsanto has submitted to EPA applications to amend EPA Reg. No. 524-582, a low-volatility DGA salt formulation, to register a new use patterns for dicamba on DT soybean and DGT cotton as mentioned above. The proposed use patterns fall within the use patterns evaluated by EPA in the dicamba RED, therefore the proposed use of dicamba on DT soybean and DGT cotton does not present any new environmental exposure scenarios not previously evaluated and deemed acceptable by EPA, including estimates of drinking water exposure.

Glufosinate use on DGT cotton is equivalent to currently deregulated glufosinate-tolerant cotton and is considered baseline.

On the basis of the above analysis, the Deregulation in Whole and No Action Alternatives for DT soybean and DGT cotton are similar regarding impacts on consumer health.

IV.E.2. Worker Health

IV.E.2.a. No action alternative

Under the No Action Alternative, DT soybean and DGT cotton would remain regulated articles and would not be commercially available to growers. It is likely that growers will continue to use herbicides in soybean and cotton production, and use the glyphosate-tolerant soybean and cotton systems along with additional herbicides where needed or recommended to control hard-to-control or glyphosate-resistant weeds. Growers may also choose to use other herbicide-tolerant soybean and cotton varieties, use a combination of alternative herbicides registered for use in soybean or cotton, use traditional tillage practices or use hand-weeding especially in cotton. The continued use of dicamba on a small number of soybean and cotton acres would also be expected. Therefore, agricultural workers will be exposed to residues of dicamba as well as other herbicides under the No Action Alternative. Use of increased tillage may represent a small increase in risk of machinery-related injury, if it results in increased trips across the field, and/or a small increase in strains and repetitive motion injury, if it results in increased hand-weeding, for agricultural workers. On the basis of the analysis above, the deregulation in whole and No Action Alternatives involve the continued use of herbicides for production of soybean and cotton. Thus the impacts to agricultural worker health for Deregulation in Whole and the No Action Alternative are not considered materially different.

IV.E.2.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, the No Action Alternative for DGT cotton is not expected to have significant impacts on worker health. Cotton farmers would continue to implement manual labor, such as hand-weeding, in order to achieve satisfactory control of Palmer amaranth.

It is expected that under the Deregulation in Whole Alternative for DT soybean, DT soybean will be integrated into the glyphosate-tolerant soybean system using traditional breeding techniques. DT soybean would be an option for growers where glyphosate-resistant weeds may already be present or where application of an herbicide with a different mode-of-action would aid in weed control or the implementation of weed resistant management practices.

There is no notable worker safety issue related directly to exposure to DT soybean. As described elsewhere, DT soybean is as safe as conventional soybean for use as food or feed. MON 88701 DMO has no safety concerns that would result in adverse effects to workers exposed to DT soybean plant tissues.

Agricultural workers can be exposed to dicamba during the herbicide application or upon re-entry into treated DT soybean fields. Under the proposed label, which is currently pending before EPA, dicamba could be applied as a preemergent treatment on DT soybean at rates up to 1 lb a.e. per acre and then again in two sequential 0.5 lb a.e. per acre postemergent treatments up to the R1/R2 growth stage using a ground application method. The EPA conducted a comprehensive occupational exposure assessment as part of the dicamba reregistration in 2006 and concluded no unreasonable risk to agricultural workers from ground and aerial dicamba applications to soybean at rates up to 2 lb a.e. per acre when required personal protective equipment is worn (U.S. EPA 2009d). The application scenario evaluated by EPA encompasses the application method and rates for dicamba applied to DT soybean. Therefore, the deregulation of DT soybean does not present a significant impact to the health of agricultural workers.

Overall, when compared to the Deregulation in Whole Alternative, the No Action Alternative may represent a small increase in risk of machinery-related injury, if it results in increased trips across the field, the No Action Alternative for DGT cotton and DT soybean may also result in a small increase in strains and repetitive motion injury, if it results in increased hand-weeding. The deregulation of DT soybean does not present a significant impact to the health of agricultural workers.

IV.E.2.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, the No Action Alternative for DT soybean is not expected to have significant impacts on worker health.

It is expected that under the Deregulation in Whole Alternative for DGT cotton, DGT cotton will be integrated into the current glyphosate-tolerant cotton systems using traditional breeding techniques. DGT cotton would be an option for growers where glyphosate-resistant weeds may already be present or where application of an herbicide with a different mode-of-action would aid in weed control or the implementation of weed resistant management practices.

As discussed above, DGT cotton is as safe as commercially cultivated cotton for use as food or feed. MON 88701 DMO and PAT (*bar*) have no safety concerns that would result in adverse effects to workers exposed to DGT cotton plant tissues.

Agricultural workers can be exposed to dicamba and/or glufosinate during the herbicide application or upon re-entry into treated DGT cotton fields. Pending EPA approval, dicamba would be authorized to be applied up to 1.0 lb a.e. per acre prior to planting up to the emergence of cotton, and post-emergence in-crop up to 0.5 lbs a.e. per acre per application, could be applied up through seven days prior to harvest. The EPA conducted a comprehensive occupational exposure assessment as part of the dicamba reregistration in 2006 and concluded no unreasonable risk to agricultural workers from ground and aerial dicamba applications at rates up to 2 lbs a.e. per acre when required personal protective equipment is worn (U.S. EPA 2009d). The application scenario evaluated by EPA encompasses the application method and rates for dicamba applied to DGT cotton. No label changes will be needed for glufosinate. Therefore, the deregulation of DGT cotton does not present a significant impact to the health of agricultural workers.

In summary, in terms of impacts to workers, the difference between the No Action and the Deregulation in Whole Alternatives is primarily the difference in the types of herbicides that may be used, tillage operations, and hand-weeding for DGT cotton. EPA has determined that when herbicides are used in accordance with their labels, no unreasonable adverse impacts will result. As discussed above, EPA's conclusions are based on comprehensive evaluations and risk assessments.

Overall, when compared to the Deregulation in Whole Alternative, the No Action Alternative may represent a small increase in risk of machinery-related injury, if it results in increased trips across the field, and/or a small increase in strains and repetitive motion injury, if it results in increased hand-weeding. The deregulation of DT soybean does not present a significant impact to the health of agricultural workers.

IV.E.2.d. Approval in whole of both DT soybean and DGT cotton

It is expected that under the Deregulation in Whole, DT and DGT cotton would be integrated into the glyphosate-tolerant soybean and cotton systems using traditional breeding techniques. DT soybean and DGT cotton would be options for growers where glyphosate-resistant weeds may already be present or where application of an herbicide with a different mode-of-action would aid in weed control or the implementation of weed resistant management practices.

As discussed above, DT soybean and DGT cotton are as safe as commercially cultivated soybeans and cotton for use as food or feed. MON 88701 DMO and PAT (*bar*) proteins have no safety concerns that would result in adverse effects to workers exposed to DT soybean or DGT cotton plant tissues.

Agricultural workers can be exposed to dicamba during the herbicide application or upon re-entry into treated DT soybean and DGT cotton fields. Monsanto has submitted to EPA applications to amend EPA Reg. No. 524-582, a low-volatility DGA salt formulation, to register a new use patterns for dicamba on DT soybean and DGT cotton as mentioned above. The proposed use patterns fall within the use patterns evaluated by EPA in the dicamba RED, therefore the proposed use of dicamba on DT soybean and DGT cotton does not present any worker health exposure scenarios not previously evaluated and deemed acceptable by EPA, including estimates of drinking water exposure.

Glufosinate use on DGT cotton is equivalent to currently deregulated glufosinate-tolerant cotton and is considered baseline.

In summary, in terms of impacts to workers, the difference between the No Action and the Deregulation in Whole Alternatives is primarily the difference in the types of herbicides that may be used, tillage practices and the use of hand-weeding. EPA has determined that when herbicides are used in accordance with their labels, no unreasonable adverse impacts will result. As discussed above, EPA's conclusions are based on comprehensive evaluations and risk assessments.

Overall, when compared to the Deregulation in Whole, the No Action Alternative may represent a small increase in risk of machinery-related injury, if it results in increased trips across the field. The No Action Alternative for DGT cotton and DT soybean may also result in a small increase in strains and repetitive motion injury, if it results in increased hand-weeding.

The deregulation of DT soybean and DGT cotton does not present a significant impact to the health of agricultural workers.

IV.F. ANIMAL FEED AND ANIMAL HEALTH

This section discusses the environmental consequences of deregulating DT soybean and/or DGT cotton or taking No Action. Potential impacts from the cultivation of DT soybean and DGT cotton occur from exposure to the inserted genes and proteins in DT soybean and DGT cotton and from dicamba residues in animal feed from the use of dicamba in soybean and cotton.

The potential impacts on animal feed associated with the introduction of DT soybean and DGT cotton and increased applications of dicamba are separately discussed below. However, as discussed elsewhere in this report, Congress transferred regulatory authority over herbicides from USDA to EPA. Accordingly, USDA-APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider herbicide impacts under the PPA. Nonetheless, because APHIS indicated in its Notice of Intent to Prepare an Environmental Impact Statement (78 Fed. Reg. 28796, May 16, 2013) that it would be considering herbicide effects and herbicide resistance as part of the NEPA process, Monsanto has included a discussion of herbicide impacts in the following section. Importantly, however, Monsanto believes that APHIS has no legal obligation under NEPA to consider herbicide impacts or herbicide resistance in any Environmental Impact Statement or Environmental Assessment. See *DOT v. Public Citizen,* 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform). See *also Center for Food Safety v. Vilsack,* No. 12-15052, 2013 U.S. App. LEXIS 9920, at *16-17 (9th Cir. 2013) ("If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests.").

IV.F.1. No Action Alternative for Both DGT Cotton and DT Soybean

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) soybean and cotton are expected to remain the same, and the use of dicamba herbicide in soybean and cotton would remain unchanged, including the pre-harvest treatments in soybean which result in dicamba residues in soybean seed up to the 10 ppm tolerance. Exposure to existing conventional and GE soybean and cotton products used for animal feed would remain unchanged (see Section II.F. for a description of the use of soybean and cotton-derived products for animal feed). Other herbicides are available and would be used in soybean and cotton as needed to control weeds in conventional and herbicide-tolerant soybean and cotton. The availability of safe and nutritional animal feed from existing soybean and cotton crops, including crops containing dicamba (soybean only) or other herbicide residues from currently established uses, will continue

IV.F.2. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, the No Action Alternative for DGT cotton is not expected to have significant impacts on animal feed or animal health.

The difference between the Deregulation in Whole and the No Action Alternative is expected to be integration of DT soybean into the glyphosate-tolerant soybean system using traditional breeding techniques. Under the Deregulation in Whole Alternative, there is potential for cultivation of soybean seed containing the DT trait to proactively manage and prevent the evolution and development of herbicide-resistant weeds. For those acres where glyphosate-resistant weeds may already be present or where application of an herbicide with a different mode-of-action would aid in weed control or the implementation of weed resistant management practices, the cultivation of soybean containing the DT trait would be an option for growers.

Potential impacts to the safety of animal feed from widespread cultivation of DT soybean would be primarily based on the possible effects of the introduced MON87708 DMO protein that provides tolerance to dicamba and the dicamba residues from the application of dicamba that would be present in animal feed. There is no meaningful risk to animal health from dietary exposure to MON 87708 DMO or toxic properties associated with MON 87708 DMO. Furthermore, the composition of the grain and forage produced by DT soybean is equivalent to conventional soybean. This information on the safety of MON 87708 DMO and composition of DT soybean seed as detailed in Appendix G indicate that there would be no negative impact on the safety or nutritional quality of animal feed from the cultivation of DT soybean.

Monsanto has completed the biotechnology consultation process with FDA for the safety and nutritional assessment of food and feed derived from DT soybean on October 11, 2011 (BNF No. 00125, Monsanto, 2011). As a part of its evaluation, FDA reviewed information on the identity, function, and characterization of the genes, including expression of the gene products in DT soybean, as well as information on the safety of MON 87708 DMO, including a dietary risk assessment.

Dicamba is presently applied to less than 1% of soybean acres using pre-plant and pre-harvest burn down applications. Under the Deregulation in Whole Alternative, dicamba will be used on more soybean acres and a higher percentage of soybean-derived animal feeds will contain dicamba residues. However, dicamba residue levels in DT soybean harvested seed or processed meal will be significantly lower compared to levels originating from the current pre-harvest soybean use (approximately 100-fold lower, based on <0.1 ppm residue in DT soybean seed compared to established 10 ppm tolerance - see Appendix E for residue levels in seed). As part of the pesticide tolerance setting process for dicamba (40 CFR 180.227), the EPA concluded that residues of dicamba up to 10 ppm in soybean seed (grain) are safe (reasonable certainty of no harm as defined by FFDCA) for animal consumption. Additionally, Monsanto has petitioned the EPA to establish new feed tolerances for soybean forage and hay to allow DT soybean forage and hay to be fed to livestock. Dietary exposure to livestock from the feeding of DT soybean forage and hay does not result in an increase in the maximum dietary (feed) exposure of dicamba evaluated and deemed safe by EPA.

DT soybean, MON 87708 DMO and dicamba residues in DT soybean-derived feed components do not affect the safety or nutritional quality of animal feed. The deregulation of DT soybean will not result in a significant impact on animal feed, and consequently to animal health. Therefore, the Deregulation in Whole and the No Action Alternatives are the same regarding their effects an animal feed.

IV.F.3. Approval In Whole of DGT Cotton, but not DT Soybean

As discussed above, the No Action Alternative for DT soybean is not expected to have significant impacts on animal feed or animal health.

The difference between the No Action and the Deregulation in Whole Alternatives for DGT cotton would be the gradual integration of the dicamba and glufosinate-tolerant event DGT cotton with the current glyphosate-tolerant cotton systems using traditional breeding techniques. Under the Deregulation in Whole Alternative, domestic animals, mainly ruminants, would be exposed to feed products derived from DGT cotton. As discussed in Section II.F, cottonseed meal is an excellent protein source for ruminants, and hulls and gin by-products may be used for roughage.

Potential impacts to the safety of animal feed from widespread cultivation of DGT cotton would be primarily based on the possible effects of the introduced MON 88701 DMO and PAT (*bar*) proteins that provide tolerance to dicamba and glufosinate, respectively and the dicamba and glufosinate residue that would be in animal feed.

Monsanto has completed the biotechnology consultation process with FDA for the safety and nutritional assessment of food and feed derived from DGT cotton in April 2013. As a part of its evaluation, FDA reviewed information on the safety of the MON 88701 DMO and PAT (bar) protein and DGT cotton seed, including a dietary risk assessment. MON 88701 DMO and PAT (*bar*) were fully characterized and the enzymatic activity of MON 88701 DMO was found to be specific for dicamba when tested using structurally similar cotton endogenous substrates (see Appendix G of this Environmental Report). The specificity of PAT proteins has been extensively documented in the literature. Neither protein has relevant amino acid sequence similarities to known allergens, toxins or other proteins that may have adverse effects on mammals. MON 88701 DMO and PAT (*bar*) were each rapidly digested in simulated gastric and intestinal fluids, a characteristic shared among many proteins with a history of safe consumption. Rapid digestion of MON 88701 DMO and PAT (*bar*) in simulated gastric and intestinal fluids indicates that it is highly unlikely that MON 88701 DMO or PAT (*bar*) would reach absorptive cells of the intestinal mucosa. Neither MON 88701 DMO nor PAT (*bar*) caused any observable adverse effects when tested in mouse acute oral toxicity analyses. Furthermore, detailed compositional analyses, in accordance with OECD guidelines, demonstrated that levels of key nutrients and anti-nutrients in DGT cottonseed are comparable to levels in the conventional cotton control, Coker 130, and several commercial reference cotton varieties. This information on the safety of DMO and composition of DGT cotton as detailed in Appendix G indicate that there would be no negative impact on the safety or nutritional quality of animal feed from the cultivation of DGT cotton.

The cultivation of DGT cotton will not change the number of cotton acres cultivated in the U.S., and the extent in which cotton acres are cultivated will continue to be based on the same market-based drivers that exist today.

The DMO protein allows for a broadened application window of dicamba to DGT cotton. The PAT (*bar)* protein is the same protein present in commercial glufosinate-tolerant cotton; and the use of glufosinate on DGT cotton is also the same as for existing commercial glufosinate-tolerant cotton varieties. Upon deregulation, DGT cottonseed produced for animal feed may contain dicamba and or glufosinate residues from the application of dicamba and/or glufosinate. Dicamba is presently applied to approximately 10% of cotton acres using pre-plant burn down applications. Under the Deregulation in Whole Alternative, dicamba will be used on more cotton acres and a higher percentage of cotton-derived animal feeds will contain dicamba residues.

Under the Deregulation in Whole Alternative, domestic animals, mainly ruminants, would be exposed to feed products derived from DGT cotton. DGT cotton, MON 88701 DMO, PAT (*bar*), as well as dicamba and glufosinate residues in DGT cotton-derived feed components do not affect the safety or nutritional quality of animal feed. The deregulation of DGT cotton will not result in a significant impact on animal feed, and consequently to animal health. Therefore, the Deregulation in Whole and the No Action Alternatives are the same regarding their effects an animal feed.

IV.F.4. Approval in Whole of DT Soybean and DGT Cotton

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with current glyphosate-tolerant soybean systems and the dicamba and glufosinate-tolerant event DGT cotton with current glyphosate-tolerant cotton systems using traditional breeding techniques. DT soybean and DGT cotton would be an option for growers where glyphosate-resistant weeds may already be present or where application of an herbicide with a different mode-of-action would aid in weed control or the implementation of weed resistant management practices.

As discussed above, DT soybean and DGT cotton are as safe as commercially cultivated soybeans and cotton for use as animal feed. Information on the safety of MON 87708 DMO, MON 88701, PAT (*bar*), and DT soybean and DGT cotton compositional analyses indicate that there would be no negative impact on the safety or nutritional quality of animal feed from the cultivation of DT soybean or DGT cotton. The deregulation of DT soybean and DGT cotton will not result in a significant impact on animal feed, and consequently to animal health. Therefore, the Deregulation in Whole and the No Action Alternatives are the same regarding their effects an animal feed.

IV.G. SOCIOECONOMIC IMPACTS

IV.G.1. Domestic Economic Environment: Soybean and Cotton

In 2012, 77 million acres of soybeans were cultivated in the U.S., yielding 3.0 billion bushels at a value of 43.2 billion U.S. dollars (USDA-NASS, 2013h). The majority of soybeans produced in the U.S. are utilized domestically for animal feed, with lesser amounts and by-products used for oil or fresh consumption (USDA-ERS, 2012b). Total acreage planted to soybeans in the US is projected to remain at 2012 levels in 2013, then falling slightly to 76 million acres for 2014 through 2021. Average yields are projected to increase from 44.5 bushels per acre in 2013 to 48.1 bushels/acre in 2021 (USDA-OCE, 2012).

The value of cotton production reached $7.27 billion in the U.S. in 2011 (USDA-NASS 2012a). In comparison, corn and soybean production values in 2011 were $76.46 and $35.78 billion, respectively (USDA-NASS 2012a).

Cotton producers in the U.S. are among the most technically advanced in the world, annually harvesting about 17 million bales or 7.2 billion pounds of cotton (US-EPA, 2009). The USDA ERS notes that U.S. cotton productivity has increased in recent years as a result of technological advancements, including biotechnology-derived varieties (Meyer et al. 2007). Herbicide-tolerant cotton is one of the most widely and rapidly adopted crops in the U.S., followed by insect-resistant cotton (Fernandez-Cornejo and Caswell 2006; USDA-ERS 2010b). By the adoption of new technologies, including agronomic traits delivered through biotechnology, the yields of cotton lint per acre in the U.S. ranks among the highest in the world (USDA-NASS 2011c). The adoption of postemergent herbicide-tolerant varieties provides opportunities to apply fewer herbicides and to reduce field cultivation (University of California 2009; USDA-NASS 2011c).

IV.G.1.a. No Action Alternative for Both DGT Cotton and DT Soybean

Under the No Action Alternative, DT soybean and DGT cotton would continue to be regulated. Growers and other parties who are involved in production, handling, processing, or consumption of soybean and cotton would not have access to DT soybean or DGT cotton, but would continue to have access to commercial soybean and cotton varieties, including GE soybean and cotton varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Domestic growers will continue to utilize conventional soybean and cotton varieties based upon availability and market demand.

Contemporary soybean and cotton crop management practices include specific measures to protect and preserve varietal identity, as well as a wide range of agronomic inputs. These management practices vary from grower to grower, and are unaffected by the No Action Alternative. Management practice considerations associated with the current cultivation of herbicide-tolerant soybeans would include adherence to label use restrictions for any herbicides applied to the crop. Growers adopting GE varieties incur a cost premium to acquire the seed (NRC 2010). These technology fees are imposed by the product developer to cover their research and development costs, and GE seeds are traditionally more expensive than conventional seed (NRC 2010).

Growers cultivating GE crops all pay such technology fees. The NRC suggests that the benefits associated with the adoption of GE crops, including a reduction in agronomic inputs and increases in yield outweigh the extra costs of the GE seed (NRC 2010). All growers adopting GE crops would incur these fees. These costs are unaffected by the No Action Alternative.

The existence of glyphosate-resistant weed biotypes has been identified as an economic concern (NRC 2010). In the areas of the U.S. where they occur, glyphosate-resistant weed biotypes have the potential to reduce the effectiveness and economic benefits of glyphosate-tolerant crop systems (Owen, et al. 2011) (Weirich, et al. 2011). However, growers continue to use glyphosate and build their weed management programs around glyphosate, because even in the presence of certain resistant weed biotypes, glyphosate continues to provide many benefits to farmers. Current research advocates using herbicides presenting multiple modes of action to manage these weeds (Owen et al. 2011). Growers would select other herbicides based on the targeted weed spectrum and types and level of herbicide resistance present in a particular field (Purdue Extension 2012). Dicamba is one such herbicide offering another mode-of-action to control glyphosate-resistant weeds.

Where necessary to manage herbicide-resistant weeds, growers in certain areas of the U.S. have increased herbicide application rates, increased the number of herbicide applications, and have returned to more traditional tillage practices (NRC 2010). The economic impacts of glyphosate-resistant weeds in certain areas of the U.S. are a direct result of increased inputs: additional herbicides are required to control the weeds; fuel costs increase as heavy equipment is used more frequently in the field for chemical application; and tillage and labor and management hours increase in association with the application of additional herbicides and machinery use (NRC 2010; Weirich et al. 2011). There is also the potential additional cost from the reduction in yield that can occur as a result of competition of the crop with the weeds (NRC 2010; Weirich et al. 2011).

Under the No Action Alternative, growers will continue to benefit from the adoption and cultivation of GE crops, including the commensurate reduction in costs associated with tillage and pesticide applications (Duke and Powles 2009). At the same time, those growers in certain areas of the U.S. managing herbicide-resistant weeds have the potential to incur increased costs to employ management techniques, which may include increased pesticide use and increased tillage. These trends are unaffected by the No Action Alternative.

IV.G.1.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, approval of the No Action Alternative for DGT cotton growers will continue to benefit from the adoption and cultivation of GE crops, including the commensurate reduction in costs associated with tillage and pesticide applications (Duke and Powles 2009). Those growers in certain areas of the U.S. managing herbicide-resistant weeds have the potential to incur increased costs to employ a wide range of management techniques, which may include increased pesticide use, increased tillage and/or hand-weeding.

It is expected that under the Deregulation in Whole Alternative for DT soybean, DT soybean will be integrated into the glyphosate-tolerant soybean system using traditional breeding techniques. DT soybean would be an option for growers where glyphosate-resistant weeds may already be present or where application of an herbicide with a different mode-of-action would aid in weed control or the implementation of weed resistant management practices.

The adoption of DT soybean is expected to help maintain the economic and non-pecuniary benefits growers have realized using the glyphosate-tolerant system. Adopters of DT soybean may realize savings in weed management costs through reduced expenditure on herbicides, reduced application costs for growers who reduce the number of trips across the field, and reduced tillage costs. In addition, growers who may be experiencing yield losses due to competition from glyphosate-resistant weeds may avoid these losses through improved weed control. The short term benefits of the introduction of the technology will be highly dependent on the price of the technology and herbicide to growers, which will also impact the extent of adoption. Other benefits include time and labor savings to growers through the simplicity and flexibility of the dicamba and glyphosate weed control system over alternative herbicides that are authorized for use in soybean production. In addition, the ability to use dicamba in combination with glyphosate will further preserve the benefits the glyphosate-tolerant system has provided in the form of increasing adoption of conservation tillage acres. Monsanto and academics recommend the use of a third herbicide mode-of-action with soil residual activity as part of a comprehensive weed resistance management program to assure that at least two effective modes-of-action are always used in the cultivated soybean field. The cultivation of DT soybean provides a method to mitigate the evolution and development of glyphosate-resistant weeds and resistance to other herbicide classes due to the use of multiple herbicide modes-of-action in the DT soybean weed management system. This benefit is expected to outweigh additional costs of controlling resistant weeds through the dicamba and glyphosate weed control system.

Monsanto anticipates that DT soybean could replace currently available soybean varieties and may be selected by growers of conventional soybean varieties making a change to a GE variety. The commercialization of DT Soybean, however, is unlikely to have significant impact on the total acreage planted to soybeans, since larger market forces that influence the price of soybeans are more influential in the planting decisions that growers make.

Soybean composition greatly affects its viability as a component of animal feed. Soybean meal generally contains 50 percent protein by dry weight and is an important component of soybean production. An additional 19 percent (by weight) of domestically produced soybeans are used to produce oil (USB, 2011a). The fatty acid content of soybean grain is important for the domestic soybean oil industry, as the soybean oil profile affects melting point, oxidative stability, and chemical functionality, ultimately determining the market value/marketability of the product (APAG 2011).

A determination of nonregulated status of DT soybean is expected to have similar impacts on the domestic economic environment as the No Action Alternative. Comparison of DT soybean with conventional soybean demonstrated no significant differences in fatty acid or crude protein content. Thus, market sector use of DT soybean under the Preferred Alternative is unlikely to be substantially different from market use of conventional soybean, as the primary factors of oil and protein content are not substantially different between the two soybean varieties.

Under the Approval in Whole Alternative, trends related to the domestic economic environment are unlikely to be substantially different than what would occur in the No Action Alternative.

IV.G.1.c. Approval in Whole of DGT Cotton, but not DT Soybean

Under the No Action Alternative, DT soybean and growers will continue to benefit from the adoption and cultivation of GE crops, including the commensurate reduction in costs associated with tillage and pesticide applications (Duke and Powles 2009). Those growers in certain areas of the U.S. managing herbicide-resistant weeds have the potential to incur increased costs to employ a wide range of management techniques, which may include increased pesticide use, increased tillage, and hand weeding.

The adoption of DGT cotton is expected to help maintain the economic and non-pecuniary benefits growers have realized using the glyphosate-tolerant system. Adopters of DGT cotton may realize savings in weed management costs through reduced expenditure on herbicides, reduced application costs for growers who reduce the number of trips across the field, and reduced tillage costs. In addition, growers in certain areas of the U.S. who are experiencing yield losses due to competition from glyphosate-resistant weeds may avoid these losses through improved weed control. The short term benefits of the introduction of the technology will be highly dependent on the price of the technology and herbicide to growers, which will also impact the extent of adoption. Other benefits include time and labor savings to growers through the simplicity and flexibility of the dicamba, glufosinate, and glyphosate weed control system over alternative herbicides that are authorized for use in cotton production. In addition, the ability to use dicamba in combination with glyphosate or glufosinate will further preserve the benefits the glyphosate-tolerant system has provided in the form of increasing adoption of conservation tillage acres. Monsanto and academics recommend the use of a third herbicide mode-of-action with soil residual activity as part of a comprehensive weed resistance management program to assure that at least two effective modes-of-action are always used in the cultivated cotton field. The cultivation of DGT cotton provides a method to mitigate the evolution and development of glyphosate-resistant weeds and resistance to other herbicide classes due to the use of multiple herbicide modes-of-action in the DT soybean weed management system. This benefit is expected to outweigh additional costs of controlling resistant weeds through the dicamba, glufosinate, and glyphosate weed control system.

Monsanto anticipates that DGT cotton could replace currently available cotton varieties and may be selected by growers of conventional cotton varieties making a change to a GE variety. However, availability of DGT cotton is not expected to result in an increase in cotton acreage;

as discussed in Section II.G.2. of this Environmental Report, global cotton prices are the main factor contributing to the variation in value of the cotton production from year to year—and thus is likely to be the primary determinant of cotton acreage.

While Monsanto anticipates that DGT cotton could replace existing GE cotton varieties currently in the market, specific economic projections are not provided. To the extent that the planting of DGT cotton results in a potential decrease in herbicide applications, farms adopting DGT cotton might experience an increase in net income. However, net income differentials cannot be projected. However, as Monsanto anticipates that DGT cotton would only replace existing GE cotton varieties and not result in increased cotton acreage, resulting socioeconomic impacts are expected to be similar to the No Action Alternative.

IV.G.1.d. Approval in Whole of Both DGT Cotton and DT Soybean

As discussed in detail above, in terms of potential impacts of DT soybean or DGT cotton on domestic economic factors, there is no substantial difference between the No Action and Deregulation in Whole Alternatives. While Monsanto anticipates that DT soybean and DGT cotton could replace existing GE soybean and cotton varieties currently in the market, specific economic projections are not provided. To the extent that the planting of DT soybean and DGT cotton results in a potential decrease in herbicide applications, farms adopting DT soybean and DGT cotton might experience an increase in net income. However, net income differentials cannot be projected. However, as Monsanto anticipates that DT soybean and DGT cotton would only replace existing GE soybean and cotton varieties and not result in increased soybean or cotton acreage, resulting socioeconomic impacts are expected to be similar to the No Action Alternative.

IV.G.2. Trade Economic Environment

The U.S. produces approximately one-third of the global soybean supply (ASA 2012). In 2011, the U.S. exported 1.3 billion bushels of soybean, which accounted for 37 percent of the world's soybean exports (USDA-FAS 2013b). The global demand for soybeans is expected to increase by a full third over 2011 consumption in the next ten years. China is expected to account for 91 percent of the increased demand (FAPRI 2012; Hartnell 2010). China is predicted to import 69 percent of the total soybean market by 2021/2022 (FAPRI, 2012). The USDA has predicted that U.S. exports will remain flat during much of this period, as a result of increase in domestic consumption and competition from South America (FAPRI 2012; USDA-ERS, 2013d).

Cotton is a crop that is primarily grown for fiber used in textiles. After ginning of the primary commodity, fiber, the cottonseed and cottonseed by-products (meal, hulls, linters, and oil) are utilized for various feed and industrial components. Data from 2010/2011 show that most of the world's cotton production (116.40 million bales annually) is grown in China (30.5 million bales), India (26.4 million bales), the United States (18.1 million bales), Brazil (9.0 million), and Pakistan (8.6 million bales)(USDA-FAS 2012) . In 2010/2011, the U.S. supplied over 14 million bales of the world's cotton exports, accounting for approximately 40% of the total world export market for cotton (USDA-FAS 2011b). China, Bangladesh, Indonesia, and Turkey are major importers of cotton fiber. The largest customers for U.S. cotton fiber are Asia and Mexico, due to the relatively large textile manufacturing industry in those areas (NCCA 2010a).

Starting in the 1930s, the U.S., Canada, and Europe entered into trade agreements that set limits on the amount of foreign-made apparel and textiles that could be imported into the U.S. The last of these agreements, the Multifibre Arrangement (MFA), ended in 2005 (Meyer et al. 2007). Consumption of cotton by U.S. textile mills peaked in 1997. Since then, U.S. mill use of cotton has dropped by approximately 50% in 2005 and by nearly 70% in 2009 (USDA-ERS 2009). This change in foreign-made textile imports resulted in increased global competition for import and export of raw cotton, as well as finished textiles (Meyer et al. 2007). U.S. consumer demand for cotton products remains strong, but imported clothing now accounts for most purchases by U.S. consumers (USDA-ERS 2009). The USDA-ERS reports that U.S. cotton mills consumed 60% of the domestic cotton through the 1990s, but not long after the end of MFA quotas, 70% of the U.S. cotton lint was exported (Meyer et al. 2007).

IV.G.2.a. No Action Alternative for Both DT Soybean and DGT Cotton

Under the No Action Alternative, there is unlikely to be any change to the current soybean or cotton markets. Most (91%) of the soybean varieties currently cultivated in the U.S. are GE varieties and it is predicted that this will not change substantially (USDA-ERS, 2012a). It is projected that approximately 90% of the cotton produced will continue to be planted with the currently available GE cotton (USDA-ERS, 2010c). Both U.S. soybean and cotton will continue to play a role in global production, and the U.S. will continue to be a supplier of soybeans and cotton in the international market but the extent of use will be subject to global market conditions.

Economic evidence shows that international trade and productivity is enhanced by the adoption of GE cotton and that these products can be channeled into suitable export markets. For example, increased global production of Bt cotton adoption led to a 3% reduction in the world cotton price (Frisvold and Reeves, 2007). This research also showed that individual countries obtained greater economic gains by adopting Bt cotton technology than if they did not adopt it, and further, found non-adopting regions to lose cotton market share to the adopting regions (Frisvold and Reeves, 2007). These conditions are not expected to change if DGT cotton remains a regulated article.

IV.G.2.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, the cropping and marketing decisions made by cotton growers are unlikely to be impacted by the No Action Alternative and it is expected that approximately 90% of the cotton produced will continue to be planted with the currently available GE cotton (USDA-ERS, 2010c). U.S. cotton will continue to play a role in global cotton production, and will continue to be a supplier in the international market but the extent of use will be subject to global market conditions.

A determination of nonregulated status of DT soybean is not expected to adversely impact international soybean markets. To the extent that adoption of DT soybean allows growers to reduce weed control costs, its introduction may enhance U.S. competitiveness in global markets. To support commercial introduction of DT soybean in the U.S., Monsanto requested import approval of DT soybean in key soybean export markets of the United States that have functioining regulatory systems. These include, but are not limited to: Canada, Mexico, Japan, the EU, South Korea, and China. Table IV.G-1 lists the current status of import approvals in key U.S. soybean export markets.

Table IV.G-1. Status of Import Approvals of DT Soybean in Key US Soybean Export Markets

	DT Soybean		DT Soybean Stack[1,2]	
Country	Submission	Approval	Submission	Approval
Canada	Nov. 2010	Oct. 2012	Nov. 2012	Jan. 2013
Mexico	Nov. 2011	July 2012	June 2012	Feb. 2013
Japan	March 2011	Oct 2013	Sept. 2012	In review
Korea	Feb. 2011	Oct. 2013	Jan. 2013	In review
Australia	May 2011	May 2012	NA	
EU	Jan. 2011	In review	March 2012	In review
China	Oct. 2012	In review	NA	
Taiwan	March 2011	April 2013	April 2013	In review
India	April 2013	In review	NA	

[1] DT soybean will be stacked with Roundup Ready 2 Yield (MON 89788).
[2] Progeny (breeding stacks) of GE crops are not regulated by APHIS.

In general, a global launch (i.e., commercialization) may not be undertaken until the proper regulatory approvals have been obtained (I. Coates, 2012, Personal Communication). Approval in these export countries is intended to mitigate global sensitivities to GE productions and work in accordance with international regulations. The trade economic impacts associated with a determination of nonregulated status of DT soybean are anticipated to be very similar to the No Action Alternative.

IV.G.2.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, under the No Action Alternative, there is unlikely to be any change to the current soybean market. Most (91 %) of the soybean varieties currently cultivated in the U.S. are GE varieties and it is predicted that this will not change substantially (USDA-ERS, 2012a). U.S. soybeans will continue to play a role in global soybean production, and the U.S. will continue to be a supplier in the international market.

A determination of nonregulated status of DGT cotton is not expected to adversely impact international cotton markets. To the extent that adoption of DGT cotton allows growers to reduce weed control costs, its introduction may enhance U.S. competitiveness in global markets. To support commercial introduction of DGT cotton in the U.S., Monsanto requested import approval of DGT cotton in key cotton export markets of the United States that have functioining regulatory systems. These include submissions to the relevant regulatory authorities in Canada, Mexico, the European Union (EU), and Japan, among others. Table IV.G-2 lists the current status of import approvals in U.S. cotton export markets.

Table IV.G-2. Status of Import Approvals of DGT Cotton in Key US Cotton Export Markets

	DGT Cotton		DGT Cotton Stacks[1,2]	
Country	Submission	Approval	Submission	Approval
Canada	June 2012	In review	Not yet submitted	-
Mexico	May 2013	In review	Not yet submitted	-
Japan	Nov. 2012	In review	June 2013	In review
Korea	Oct. 2012	In review	Not yet submitted	-
Australia	Jan. 2013	In review	NA	-
EU	Feb. 2013	In review	Not yet submitted	-
China	Not yet submitted	-	NA	
Philippines	Not yet submitted	-	Not yet submitted	-

[1] DGT will be stacked with Roundup Ready Flex Cotton and Bollgard II (MON 88913 and MON 15985).
[2] Progeny (breeding stacks) of GE crops are not regulated by APHIS.

A determination of nonregulated status of DGT cotton is not expected to adversely impact the trade economic environment and may potentially enhance it through the subsequent development and global adoption of DGT cotton could provide another herbicide-tolerant management choice for growers. A reduction in costs for domestic growers associated with the reduction herbicide use may make U.S. producers more competitive in the global market. The trade economic impacts associated with a determination of nonregulated status of DGT cotton are anticipated to be very similar to the No Action Alternative.

IV.G.2.d. Approval in Whole of Both DT Soybean and DGT Cotton

It is expected that under the Deregulation in Whole, DT soybean and DGT cotton would be integrated into the glyphosate-tolerant soybean and cotton systems using traditional breeding techniques. DT soybean and DGT cotton would be options for growers where glyphosate-resistant weeds may already be present or where application of an herbicide with a different mode-of-action would aid in weed control or the implementation of weed resistant management practices.

To the extent that adoption of DT soybean allows growers to reduce weed control costs, its introduction may enhance US competitiveness in global markets. To support commercial introduction of DT soybean and DGT cotton in the U.S., Monsanto intends to submit dossiers to request import approval of DT soybean and DGT cotton to the proper regulatory authorities of several countries that already have regulatory processes for GE soybean and cotton in place.

In general, a global launch (i.e., commercialization) may not be undertaken until the proper regulatory approvals have been obtained (I. Coates, 2012, Personal Communication). Approval in these export countries is intended to mitigate global sensitivities to GE productions and work in accordance with international regulations. The trade economic impacts associated with a determination of nonregulated status of DT soybean and DGT cotton are anticipated to be very similar to the No Action Alternative.

IV.G.3. The Organic Segment

IV.G.3.a. No Action Alternative for Both DT Soybean and DGT Cotton

Current availability, market demand, and acreage of organic soybean and cotton are anticipated to remain unchanged under the No Action Alternative. Similar to market trends for other U.S. organic products, demand of organic soybean and cotton is likely to increase (USDA-ERS, 2007). Despite this increasing demand, however, the share of U.S. organic soybean and cotton production remains relatively small and steady. While this flat production of U.S. organic soybean and cotton correlates with an increase in GE soybean adoption, there is little or no evidence to suggest a cause-and-effect relationship. These trends are expected to be unaffected by the No Action Alternative.

IV.G.3.b. Approval in Whole of DT Soybean, but not DGT Cotton

As discussed above, approval of the No Action Alternative for DGT cotton is not expected to impact organic cotton production.

In 2011, out of 77 million acres of total soybean production, there were approximately 96,000 acres of organic soybean produced across 1,203 farms in the United States (USDA-NASS 2012e). This represented about 0.13 percent of total U.S. soybean production in 2011 (USDA-NASS 2011b; 2012e). This proportion is not anticipated to substantially change in spite of rising domestic demand, due in part to increasing competition and imports from international organic soybean producers (USDA-ERS, 2007). Therefore, domestic demand for organic soybean and organic soybean products appear to be sustained by increasing imports from international organic soybean producers (USDA 2007)(USDA-ERS, 2007).

It is not likely that organic farmers will be substantially affected by a determination of nonregulated status of DT soybean. Soybean is primarily a self-pollinated plant (OECD 2010), and there is no reason to suspect that the biology of DT soybean will increase its potential to outcross with soybean varieties utilized in organic soybean production (USDA-APHIS, 2012d). As set forth in Monsanto's Petition for Nonregulated Status, field studies of DT soybean reproductive biology revealed no substantial differences in factors influencing reproductive potential, including pollen viability, date of emergence, date of 50 percent flowering, and date of maturity (See DT soybean petition).

It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in a product labeled organic (USDA-AMS 2010). The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods (Ronald and Fouche 2006; USDA-AMS 2010). However, certain markets or contracts may have defined thresholds (Non-GMO Project 2012).

A determination of nonregulated status of DT soybean is unlikely to substantially affect U.S. organic soybean market conditions. In contrast to other U.S. organic crops, U.S. organic soybean production has not kept pace with demand, as discussed above (USDA-ERS 2010d). The increased demand for organic soybean in the U.S. has generally been met by increasing imports from international organic soybean producers (USDA 2007; USDA-ERS, 2007).

IV.G.3.c. Approval in Whole of DGT Cotton, but not DT Soybean

As discussed above, approval of the No Action Alternative for DT soybean is not expected to impact organic cotton production.

The USDA census of organic agriculture reported organic cotton farming on 30 farms in the U.S. in 2008, two in Arizona, three in New Mexico, four in California, and 21 in Texas (USDA-NASS 2008a). Texas (66%) and New Mexico (20%) together accounted for approximately 86% of the production. Based on USDA-ERS data, between 1997 and 2008, organic cotton acreage ranged from 9,213 acres in 2004 to 15,377 acres in 2008 (USDA-ERS 2008). In 2008 about 0.16% of the total 9.41 million acres of cotton was produced organically (USDA-ERS 2008). In recent years, small and sporadic acreages of organic cotton production have been cultivated in other states, including Missouri, Illinois, Kansas, Tennessee, and Colorado (USDA-ERS 2010c). Based upon recent trend information, the presence of GE cotton varieties on the market has not affected the ability of organic production systems to maintain their market share. Between 2000 and 2008, although 11 GE cotton events were deregulated and the percent of GE cotton in the market was near or above 90% and the acreage of organic cotton production remained at approximately 15,000 acres (USDA-APHIS 2013c; USDA-ERS 2008).

Most U.S. organic cotton growers sell their cotton products through a marketing cooperative, the largest of which is the TOCMC, with approximately 30 members (OTA 2012; TOCMC 2011b). Cottonseed is marketed to organic dairies for feed (TOCMC 2011b). According to a survey conducted by OTA, organic cotton growers' biggest barriers to planting more organic cotton are finding a market willing to pay the added costs of organic products, production challenges such as weed and insect control, and labor costs. "Growers also cited competition from international organic cotton producers, as well as the cost of transition to organic" (OTA 2010).

It is not likely that organic farmers will be substantially affected by a determination of nonregulated status of DGT Cotton. Cotton is primarily a self-pollinated plant (OECD 2010), and there is no reason to suspect that the biology of DGT cotton will increase its potential to outcross with cotton varieties utilized in organic soybean production (USDA-APHIS, 2012d). As set forth in Monsanto's Petition for Nonregulated Status, field studies of DGT cotton reproductive biology revealed no substantial differences in factors influencing reproductive potential, including pollen viability, date of emergence, date of 50 percent flowering, and date of maturity (Monsanto, 2010).

It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in a product labeled organic (USDA-AMS

2010). The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods (Ronald and Fouche 2006; USDA-AMS 2010). However, certain markets or contracts may have defined thresholds (Non-GMO Project 2012).

A determination of nonregulated status of DGT cotton is unlikely to substantially affect U.S. organic cotton market conditions.

IV.G.3.d. Approval in Whole of Both DT Soybean and DGT Cotton

The difference between the No Action and the Deregulation in Whole Alternatives would be the gradual integration of the dicamba-tolerant event DT soybean with current glyphosate-tolerant soybean systems and the dicamba and glufosinate-tolerant event DGT cotton with current glyphosate-tolerant cotton systems using traditional breeding techniques. On the basis of the above information, the Deregulation in Whole and No Action Alternatives for DT soybean and DGT cotton are similar regarding impacts on organic production.

IV.H. OTHER IMPACTS AND MITIGATION MEASURES

This section describes other potential impacts associated with the implementation of the alternatives, including unavoidable impacts; short-term versus long-term productivity of the environment; and irreversible/irretrievable commitment of resources. This section also describes potential impact mitigation measures, as applicable, beyond what is already built into the alternatives.

IV.H.1. Unavoidable Impacts

Unavoidable impacts are any adverse environmental effects which cannot be avoided should the proposal be implemented (40 CFR § 1502.16).

IV.H.1.a. Production Management

In order to generally maintain economic feasibility, soybean and cotton production practices require herbicide usage. As a result, herbicide application is essentially unavoidable for all of the alternatives. Likewise, even though the adoption of DT soybean and DGT cotton is likely to increase the use of conservation tillage (including strip-till) methods, some degree of tillage and its resulting disturbance of soil is also unavoidable.

As discussed elsewhere in this report, due to the lack of sexually compatible species with soybean and cotton in the areas where these crops are grown and the very low levels of pollen transfer from those species, gene flow from DT soybean and/or DGT cotton to other species is not expected. A negligible level of gene flow to other varieties of the same species may be unavoidable but can be easily addressed with proper mitigation measures in place and existing technologies for removing unwanted volunteers.

IV.H.1.b. Biological Resources

While there are many mechanisms that can mitigate the potential for the occurrence of herbicide resistance in weed populations, depending on applicator choices, the selection of herbicide-resistant weeds in certain areas of the U.S. may be unavoidable under all four alternatives. Selection of herbicide-resistant weeds is greatly influenced by applicator choices such as weed control strategies. The selection of herbicide-resistant weeds can be mitigated to the extent that applicator behaviors can be influenced.

Under the No Action Alternative, growers are expected to continue using glyphosate-resistant soybean and cotton systems, and to use other registered alternative herbicides alone or in combination with other herbicide-tolerant soybean or cotton varieties for targeted hard-to-control weeds, and/or to incorporate tillage into their practices. Under this alternative growers will not have the additional option of applying dicamba to soybean, or dicamba and/or glufosinate to cotton in order to provide an additional herbicide with an alternative mode-of-action. Thus, although the selection of herbicide-resistant weeds may be unavoidable in certain areas of the U.S., this impact may be expected to be mitigated in part under the deregulation alternatives.

Under all scenarios, the application of non-glyphosate herbicides is expected. As discussed above, APHIS has no jurisdiction over risks resulting from the use of herbicides or other pesticides; these risks fall instead within the jurisdiction of EPA's oversight of pesticide usage. See Section I.B. Potential toxic effects from these herbicides on animals are likely to be prevented by adherence to the EPA-mandated label conditions, which are designed to ensure no unreasonable adverse effects on the environment. Moreover, none of the herbicides is expected to pose risks of population-level effects when used within label limits. Although unlikely, there could be a short-term loss of groundcover for those species using soy or cotton fields if farmers allow the land to go fallow for a few years. Potential impacts on aquatic species from conventional tillage include impaired habitat conditions from soil erosion.

Under the no-action alternative, comparatively greater conventional tillage practices could result in decreased microbial biomass and activity.

Application of herbicides according to EPA label requirements will ensure no unreasonable adverse effects to plant communities at the population level in the vicinity of treated crops, but there is the potential for presence of herbicides in unintended areas on some occasions and at some locations is possible under all the alternatives.

IV.H.1.c. Socioeconomic impacts

Under the no-action alternative soy and cotton seed growers would need to discard any DT soybean and DGT cotton seed grown for future expected crop production cycles. Returns to past investments in the development of these varieties that depend on production in the United States would no longer be realized. Also, soy and cotton growers and processors would not be able to benefit from any increased returns provided by DT soybean and DGT cotton as compared to alternate deregulated varieties.

IV.H.1.d. Physical environment

Under the no-action alternative, use of more intensive tillage practices (conventional/traditional tillage) by growers in certain areas in the U.S. in an attempt to manage glyphosate-resistant weeds would likely increase compared to practices used in planting of DT soybean and/or DGT cotton. Adoption of conventional tillage would be expected to result in greater soil erosion, loss of organic matter, soil compaction, and reduced moisture holding capacity, as compared to conservation or reduced tillage methods. This would lead to an increase in potential sedimentation and turbidity in nearby surface waters during rain and irrigation events. A return to more conventional tillage methods would also lead to more limited micro-organism diversity and possible elimination of some micro-organisms.

As discussed above, under all alternatives, growers would be expected to apply non-glyphosate herbicides. As discussed above, APHIS has no jurisdiction over risks resulting from the use of herbicides or other pesticides; these risks fall instead within the jurisdiction of EPA's oversight of pesticide usage. See Section I.B. Application of these herbicides could potentially impact micro-organisms in soil. This could limit micro-organism diversity or possibly eliminate some micro-organisms.

IV.H.1.e. Human Health

Under the no-action alternative, it is expected that the use of cultivation and other equipment would be greater than in the deregulation alternatives, which could increase adverse health effects from exposure to engine exhaust and fugitive soil particulates. Under all alternatives, growers would be expected to apply non-glyphosate herbicides. Workers would likely be exposed to a higher rate of potential equipment accidents due to the production practices associated with the no-action alternative, and they would be likely exposed to higher rates and amounts of engine emissions and soil particulates, as compared to practices used in growing DT soybean and DGT cotton. Also under the no-action alternative, the number of workers in the field would likely be greater, given the different production practices, which could increase the numbers exposed to equipment emissions, soil particulates, and pesticides.

IV.H.2. Short-term vs. Long-term Productivity of the Environment

Short-term uses and long-term productivity of the environment are linked, and opportunities that are acted upon have corollary opportunity costs in terms of foregone options and productivity could have continuing effects well into the future.

An issue with respect to long-term productivity is the extent to which herbicide-resistant weeds in certain areas of the U.S. will result from the agronomic practices related to each of the alternatives. These issues exist with respect to all herbicides used, including those used outside of glyphosate-tolerant cropping systems. That said, as glyphosate-resistant weeds have developed, the question of how to effectively control these weeds in glyphosate-tolerant cropping systems has emerged. Stacking DT soybean and/or DGT cotton with glyphosate-tolerant traits, as Monsanto has indicated that it intends to do, would enable use of a combination of different herbicide modes of action to be applied to these crops, an approach that is expected to mitigate the potential for future development of herbicide-resistant weeds (Duke and Powles, 2009). Based on individual grower needs, this approach may reduce the need to use conventional tillage to control glyphosate-resistant weeds (Owen et al. 2011), which could potentially lead to a reduction in crop residue and SOM (Towery and Werblow 2010). Increased tillage could subsequently decrease soil stability, soil structure, and infiltration and water holding capacity, as well as increase the potential for wind and water erosion (USDA-NRCS, 1996). By helping to manage glyphosate-resistant weeds in certain areas of the U.S., the deregulation alternatives may benefit the long-term productivity of the environment.

In addition, Best Management Practices can help control the development of herbicide-resistant weeds. These include: a) identifying weeds and monitoring for escapes to determine if current practices need to be modified to achieve acceptable levels of weed control; b) using proper herbicide rates and timing; c) using crop rotation to facilitate use of different modes of action over time; d) using agronomic management practices to supplement herbicide weed control; e) alternating herbicides with different modes of action; and f) tank mixing herbicides of different modes of action.

IV.H.3. Irreversible Resource Commitments

Irreversible resource commitments represent a loss of future options. It applies primarily to the use of nonrenewable resources and to factors that are renewable only over long time spans, or to adverse impacts that cannot be reversed once they are set in motion. An irretrievable commitment of resources represents opportunities that are foregone for the period of the proposed action.

No irreversible or irretrievable commitments of resources were identified with respect to production and management of soy or cotton crops and physical environmental resources for any alternative. It is expected that much of the land that would be used for DT soybean and/or DGT cotton production under the deregulation alternatives is already in use for soy and/or cotton production respectively, or for other agricultural production. Land currently used for soy or cotton production could be allowed to go fallow or could be used for crops other than soy or cotton. Acreage used for soy or cotton production does not represent an irreversible or irretrievable commitment of resources because the land can be easily converted to serve other purposes such as growing other crops or for commercial or residential use. Soil used for soy and/or cotton production does not represent an irreversible or irretrievable commitment of resources because the soil composition can be amended through changes in production management (e.g., tillage practices, chemical application) or converted to serve other purposes such as growing other crops or going fallow. Surface water and groundwater used for irrigation purposes would be replenished through the natural water cycle as long as sustainable use of water resources is practiced.

IV.H.4. Mitigation Measures

As defined in the CEQ regulations for implementing NEPA (40 CFR § 1508.20) mitigation includes:

- avoiding the impact altogether by not taking a certain action or parts of an action;
- minimizing impacts by limiting the degree or magnitude of the action and its implementation;
- rectifying the impact by repairing, rehabilitating, or restoring the affected environment;

- reducing or eliminating the impact over time by preservation and maintenance operations during the life of the action; and

- compensating for the impact by replacing or providing substitute resources or environments.

The measures listed below, if employed, would mitigate possible adverse impacts that may be associated with the deregulation alternatives. Whether these mitigation methods are required through a regulatory program or are used as part of industry led stewardship programs, they can be effective. A summary of mitigation measures are presented by resource area below. Note that not all mitigation measures would work for all users. The mitigation measures discussed below do not apply to the No Action Alternative because DT soybean and DGT cotton would be grown under the regulations in 7 CFR part 340. Conditions would be used to confine the plantings. Many of the recommendations below would be incorporated into the conditions. Any DT soy or DGT cotton grown under the No Action Alternative would be subject to conditions in the associated growing permit for the regulated biotechnology crops. The mitigation measures described below focus primarily on measures that are not built into the alternatives.

As discussed elsewhere in this report, Congress transferred regulatory authority over herbicides from USDA to EPA. Accordingly, USDA-APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider herbicide impacts under the PPA. Nonetheless, because APHIS indicated in its Notice of Intent to Prepare an Environmental Impact Statement (78 Fed. Reg. 28796, May 16, 2013) that it would be considering herbicide effects and herbicide resistance as part of the NEPA process, Monsanto has included a discussion of herbicide impacts in the following section. Importantly, however, Monsanto believes that APHIS has no legal obligation under NEPA to consider herbicide impacts or herbicide resistance in any Environmental Impact Statement or Environmental Assessment. See *DOT v. Public Citizen*, 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform). See *also Center for Food Safety v. Vilsack*, No. 12-15052, 2013 U.S. App. LEXIS 9920, at *16-17 (9th Cir. 2013) ("If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests.").

IV.H.4.a. Production Management

IV.H.4.a.(1) Measures to Mitigate Herbicide Impacts

Mitigation measures to oversee the proper usage of herbicides are determined by EPA and are disseminated to the herbicide users through EPA approved labels. Under the No-Action Alternative, glyphosate and non-glyphosate herbicides would continue to be used on soy and cotton crops, potentially at similar levels as prior to deregulation, but more likely at greater levels, as non-glyphosate pesticide applications are likely to increase in certain areas of the U.S. as efforts to control glyphosate-resistant weeds occur in such areas. Under the deregulation alternative, more dicamba and potentially glufosinate, but less of other herbicides, would be used than under the No-Action Alternative. Adhering to herbicide label requirements, including application rates and other requirements, following industry stewardship programs, and U.S. EPA's and the states' overnight of pesticides will largely minimize improper herbicide usage.

IV.H.4.a.(2) Measures to Mitigate Gene Flow to Other Crops

As discussed above, soybean lacks sexually-compatible relatives in the U.S.; therefore, the only pollen-mediated gene flow would be within cultivated soybean. Similarly, of the two "wild" (native) species of cotton that exist in the U.S., one cannot produce sexually fertile offspring when crossed with domesticated cotton, and the other is endemic to Hawaii, where domesticated cotton is not produced, with the exception of potential counter-season breeding nurseries where appropriate isolation distances and practices are utilized. As a result, gene flow to wild species of soy and/or cotton is not expected.

With respect to gene flow to other domesticated populations, as discussed above, this is unlikely due to the biology of the soybean and cotton plants. Under the No-Action Alternative, there would be no further commercial release of DT soybean and DGT cotton and existing DT soybean and DGT cotton plants would eventually be harvested. Research and development permits would not be affected by this alternative. Therefore, research and development plantings under APHIS permits could still occur. Those plantings would be subject to the permit conditions, which have gene flow mitigation stipulations.

Under the deregulation alternatives, DT soybean and/or DGT cotton could be grown by farmers across the country. Mitigation measures to reduce the potential impact of gene flow include geographic separation of seed production regions and isolation distances. Specialty crop growers employ practices and standards for seed production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with other soy or cotton crops (which includes GE crops) (Bradford 2006). These management practices include maintaining isolation distances to prevent pollen movement from other cotton sources, planting border or barrier rows to intercept pollen, equipment cleaning during harvest, post-harvest separation of harvested seed, and employing natural barriers to pollen (Bradford 2006; Kuepper 2006; Wozniak and Martinez 2011). These management practices allow the grower to meet standards for the production of specialty crop seed, maintain genetic purity, and protect the genetic diversity of soy and/or cotton (Bradford 2006). Similarly, seed certification cultivation practices commonly include recommendations for minimum isolation distances between various seed lines and planting border or barrier rows to prevent pollen movement (Hartmann et al. 1975; Wozniak and Martinez 2011). The isolation distance for Foundation, Registered, and Certified seeds, as dictated by the USDA Agricultural Marketing Service's (AMS) Federal Seed Act, is 1,320, 1,320, and 660 feet, respectively (7 CFR Part 201.76). During the growing season, seed certification agencies will monitor the fields for off-types, other crops, weeds, and disease (Wozniak and Martinez 2011). These certifying agencies also establish seed handling standards to reduce the likelihood of seed source mixing during production stages, including planting, harvesting, transporting, storage, cleaning, and ginning (Wozniak and Martinez 2011). Soybean seed fields are also mapped to ensure the seed field has the minimum federal isolation requirement of five feet as a physical barrier (AOSCA 2009b).

IV.H.4.a.(3) Measures to Mitigate Gene flow to Wild Soy and/or Cotton Populations

As discussed above, soybean does not grow in the wild in North America. Similarly, no feral species of Gossypium have been found in cotton-growing areas (Fryxell 1984; Waghmare et al. 2005). As a result, gene flow to wild soy and/or cotton populations is not expected.

IV.H.4.a.(4) Measures to Mitigate Volunteer DT Soybean and DGT cotton Plants

Correct application of herbicides would allow for control of volunteer DT soybean and/or DGT cotton plants. As discussed in Appendix A of this Environmental Report, a substantial number of alternative herbicides exist for the control of volunteer DT soybean and/or DGT cotton.

IV.H.4.b. Biological Resources

IV.H.4.b.(1) Measures to Minimize Impacts on Animals and Non-target Plants

Mitigation measures to minimize the potential impacts on animals, micro-organisms, and non-target plants under all of the alternatives include measures that already are a part of standard production practices for soybean and cotton. Complying with herbicide label instructions as required by EPA should minimize potential toxic effects from all alternatives. Unless EPA otherwise directs through the registration, Monsanto will take several steps to manage dicamba offsite movement including: the use of only low volatility dicamba formulations, for example the DGA salt of dicamba; requiring growers to consult a website like Pre-Serve.org to confirm whether threatened or endangered species may be in proximity to the application area; and specifying requirements on the product label intended to reduce the potential for drift, including a wind-directional no-spray buffer when sensitive areas including areas where threatened and endangered species may be present, to ensure protection of these sensitive areas. These restrictions, and/or any other measures imposed by EPA, will minimize the impact on animals and non-target plants from the use of dicamba on DT soybean and DGT cotton.

To mitigate potential adverse effects due to herbicide drift during applications, EPA imposes specific application requirements on product labels. Depending upon the herbicide, relevant factors in managing the potential for spray drift include the selectivity and sensitivity of the herbicide, local weather conditions at the time of application (wind, temperature, humidity, inversion potential), droplet size distribution, application volume, boom height (height of the application equipment above the crop canopy), sprayer speed, and distance from the edge of the application area (Felsot et al. 2010; SDTF 1997). A variety of measures can be employed to control the potential for spray drift and offsite movement, including nozzle selection and application techniques and restrictions. Additionally, ground-based application of herbicides minimizes the potential for spray drift to occur. Monsanto's proposed label for dicamba — which is currently pending before EPA—does not allow aerial application on DT soybean or DGT cotton. This label restriction, and/or other measures imposed by EPA, will minimize the potential for spray drift. For the deregulation alternatives, conservation tillage practices likely associated with DT soybean and DGT cotton production maximize retention of crop residues and minimize soil disturbance erosion, thereby minimizing potential adverse effects on micro-organisms from soil disturbance and crop residue removal, and minimizing potential adverse effects on aquatic plants and animals from sedimentation, turbidity, and chemical inputs from runoff.

IV.H.4.b.(2) Measures to Mitigate the Evolution and Development of Resistant Weeds

Glyphosate-resistant weeds have developed in some cropping systems in certain areas of the U.S. The deployment of several other practices by growers, including the use of herbicides with different mechanisms of action and BMPs (as discussed in Section IV.H) may also help mitigate selection of herbicide-resistant weeds. (Norsworthy et al. 2012). The deregulation alternatives are expected to expand growers' options to utilize weed control systems with different mechanisms of action.

As discussed elsewhere in this report, Congress transferred regulatory authority over herbicides from USDA to EPA. Accordingly, USDA-APHIS has no jurisdiction over herbicides or herbicide resistance, and no authority to consider direct, indirect, or cumulative herbicide impacts under the PPA that may be associated with the deregulation and use of DT soybean or DGT cotton. Nonetheless, because APHIS indicated in its Notice of Intent to Prepare an Environmental Impact Statement (78 Fed. Reg. 28796, May 16, 2013) that it would be considering herbicide effects and herbicide resistance as part of the NEPA process, this document includes a discussion of herbicide impacts in the following sections, with more details in the Appendices. Importantly, however, Monsanto believes that APHIS has no legal obligation under NEPA to consider direct, indirect, or cumulative herbicide impacts or herbicide resistance in any Environmental Impact Statement or Environmental Assessment. See *DOT v. Public Citizen*, 541 U.S. 752, 770, 769 (2004) (where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant "cause" of the effect, and is therefore not required to analyze the environmental impact of an action it could not refuse to perform). See also *Center for Food Safety v. Vilsack*, No. 12-15052, 2013 U.S. App. LEXIS 9920, at *16-17 (9th Cir. 2013) ("If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests.").

Once resistant weeds are observed, mechanisms that can help mitigate weed persistence include the implementation of diversified weed management systems (such as tillage) in addition to implementing other best management practices, such as field scouting and other management practices that can identify weeds that appear to have resisted the herbicide. Among growers there is increasing awareness of herbicide stewardship needs. Industry is providing more tools to help growers adopt the farming practices that will both mitigate the development of herbicide resistance where it exists and help control the spread of herbicide-resistant weeds. The likely future commercialization of DT soybean and DGT cotton varietals with stacked glyphosate tolerance is one such option.

As discussed further in Appendix B, DT soybean and DGT cotton combined with glyphosate-tolerant soybean and cotton will provide the tools to directly manage the development of dicamba-, glufosinate-, and glyphosate-resistant weeds. One of the most recommended weed management practices by experts is the use of multiple herbicide modes-of-action when appropriate. The WSSA reports: "Weed scientists know that the best defense against weed resistance is to proactively use a combination of agronomic practices, including the judicious use of herbicides with alternative modes-of-action either concurrently or sequentially" (WSSA 2010). Studies have demonstrated that using the same combination of herbicides with multiple modes of action and overlapping effectiveness over multiple seasons is an effective way to proactively manage resistance (Beckie and Reboud 2009). In soybeans, the use of dicamba in conjunction with glyphosate and other residual herbicides provides growers with an effective herbicide system with two to three distinct modes-of-action with activity on the major target weeds including biotypes with resistance to glyphosate. In cotton, the use of dicamba and glufosinate in conjunction with glyphosate provides growers with an effective herbicide system with three distinct modes-of-action.

To support the introduction of varieties containing DT soybean and DGT cotton, Monsanto will use multiple methods to distribute technical and stewardship information to growers, academics and grower advisors regarding the use of the product as part of a diversified weed management system. Monsanto's Technology Use Guide (TUG), which is signed by all growers that utilize traits like those in DT soybean and DGT cotton, will set forth the requirements and best practices for the cultivation including recommendations on weed resistance management practices. Growers who purchase varieties containing DT soybean and DGT cotton will be required to enter into a limited use license with Monsanto and must sign and comply with the Monsanto Technology Stewardship Agreement (MTSA), which requires the grower to follow the TUG.

The weed resistance management practices that are designed to minimize the potential for the development of herbicide-resistant weeds will be articulated in the TUG and also be broadly communicated to growers and retailers. These practices will be communicated through a variety of means, including direct communications to each grower authorized to purchase and plant a variety containing DT soybean and DGT cotton, a public website, and reports in farm media publications. The overall weed resistance management program will be reinforced through collaborations with U.S. academics, who will provide their recommendations for appropriate stewardship of dicamba in soybean production and dicamba and glufosinate in cotton production, as well as by collaboration with crop commodity groups who have launched web-based weed resistance educational modules (WSSA 2012).

IV.H.4.c. Socioeconomic Impacts

No options to mitigate any socioeconomic impacts have been identified.

IV.H.4.d. Physical Environment

In general, impacts on the physical environment from soy and cotton farming, as with any crop, are minimized through implementation of proper management practices for each agricultural activity, such as tillage, erosion control, and pesticide application.

As described in Section V.A, increases in the acreage of DT soybean and/or DGT cotton are expected under the deregulation alternatives. To the extent they are concerns, land use-related impacts such as potential for gene flow can be minimized by adherence to the management practices and isolation distances.

Impacts on soil quality are an expected consequence of farming in general. As described in Section V.D, soil impacts can vary with the tillage practices in use, and can be reduced through increased use of conservation and reduced tillage techniques. Adoption of DT soybean and/or DGT cotton would facilitate increased use of conservation and reduced tillage and thus would lead to reduced adverse impacts on soil quality.

As described in Section II.C.3, the use of tractors and other equipment to cultivate the soil and conduct other activities involved with growing soybean and/or cotton can result in engine emissions and fugitive soil particulates being carried by the wind to the neighboring public. These emissions and particulates are an expected consequence of farming in general, but they can be reduced by changes in farming practices. Under the deregulation alternatives, there is evidence that the increased use of conservation and reduced tillage associated with adoption of DT soybean and/or DGT cotton can decrease usage of fossil fuel-burning equipment, decrease soil erosion by wind, and decrease pesticide usage.

As with other agricultural crops, the effects of soybean and cotton farming on surface water and groundwater (e.g., lakes, streams, aquifers) depend on multiple factors or activities related to crop production, which can include soil preparation, planting and harvesting; tillage practices; tractor and other equipment use; the use of herbicides and fertilizers; and the frequency of irrigation necessary to produce a viable crop. Under the deregulation alternatives and as discussed in Section II.C.1, adoption of DT soybean and/or DGT cotton facilitates increased use of conservation and reduced tillage practices which, compared to typical tillage practices for conventional soybean and/or cotton, decreases soil erosion, reduces water runoff, and reduces contaminant levels in runoff, all of which lead to improved surface water and groundwater quality.

IV.H.4.e. Human Health

For the potential adverse effects to human health from the use of pesticides that may occur under all of the alternatives, mitigation measures include the handling and use requirements and precautionary statements on pesticide labels required by EPA. Pesticide labels convey the necessary information developed by EPA on how to handle, store, apply, and dispose of pesticides with a reasonable certainty of no harm to human health. Using a pesticide in a manner that is inconsistent with these directions on the label is a violation of FIFRA and EPA, and state regulatory bodies have enforcement authority over such misuse. For the potential higher equipment use under the No-Action Alternative, safety labels and equipment already are used and no additional mitigation measures could be identified.

V. CUMULATIVE IMPACTS

This section describes potential cumulative impacts in connection with deregulating DT soybean and DGT cotton. Below, this section considers potential direct and indirect impacts of the proposed action and alternatives in combination with the potential impacts of other relevant past, present, and reasonably foreseeable future actions that may have an impact on the same resources. These combined impacts are called cumulative impacts.

CEQ regulations (40 CFR § 1500 to 1508) that implement the procedural requirements of NEPA (42 U.S.C. § 4321 et seq.) require a cumulative impacts analysis of the action as part of the Environmental Impact Statement (EIS) process. CFR § 1508.7 defines cumulative impacts as:

> [T]he impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such

other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.

In this section, actions that could have effects that coincided in time and space with the effects from the proposed deregulation and associated activities, are identified and considered in combination with the impacts of other Federal, non-Federal, and private actions.

V.A. STRUCTURE OF THE CUMULATIVE IMPACTS ANALYSIS

For this report, the analysis of cumulative impacts follows the analysis steps described in *Considering Cumulative Effects Under the National Environmental Policy Act* (CEQ, 1997):

Specify the class of actions for which effects are to be analyzed.

Designate the appropriate time and space domain in which the relevant actions occur.

Identify and characterize the set of receptors to be assessed.

Determine the magnitude of effects on the receptors and whether those effects are accumulating.

V.B. CLASS OF ACTIONS TO BE ANALYZED

This analysis addresses large, regional, and national-scale trends and issues that have impacts that may accumulate with those of the Deregulation Alternative. This analysis does not evaluate site-specific cumulative impacts, primarily because DT soybean and DGT cotton are grown widely and are rotated with other crops in agricultural system. The decision to be made by APHIS does not dictate specific locations for planting; therefore, site specific analysis is not possible.

V.C. GEOGRAPHICAL AND TEMPORAL BOUNDARIES FOR THE ANALYSIS

The alternatives are discussed in Section III. For the Deregulation Alternative, Monsanto has requested the deregulation of DT soybean and DGT cotton without geographic restrictions. DT soybean and DGT cotton would be potentially cultivated throughout the continental U.S. Therefore, the spatial domain for past, present, and reasonably foreseeable future actions considers the entire nation and in some cases, has international implications. This analysis focuses more on geographic interaction of activities than timing of interactions because the actual timeframes for many of the reasonably foreseeable future actions are uncertain. Reasonably foreseeable actions are generally those future actions for which there is a reasonable expectation that the action could occur, such as a project that has already started or a future action that has obligated funding. Monsanto has identified activities relevant to the cumulative impacts analysis from reviews of information available from government agencies, such as Environmental Impact Statements, land-use and natural resource management plans, and from private organizations. Not all actions identified in this analysis would have cumulative impacts on all resource areas.

V.D. RESOURCES ANALYZED

Resources evaluated in this cumulative impacts analysis include the resource areas discussed in Sections II and IV: Land Use and Production Practices; Physical Environment; Biological; Human Health and Safety; and Socioeconomic. However, as discussed in Sections II and IV, resources that would experience impacts from the deregulation of DT soybean and DGT cotton in combination with other actions are described, and an analysis of the cumulative effects to the resource is presented below.

V.E. MAGNITUDE OF EFFECTS ON RESOURCES

The potential extent of the impacts of the deregulation alternatives combined with other actions, and the duration of those impacts are considered in determining the magnitude of cumulative effects that impact each resource area. When possible, the assessment of the effects on a resource is based on quantitative analysis; however, many effects are difficult to quantify. In these cases, a qualitative assessment of cumulative impacts is made. CEQ regulations at 40 CFR § 1502.22—incomplete or unavailable information, directs agencies on how to proceed when evaluating effects on the human environment in an EIS when there is incomplete or unavailable information. While information describing the characteristics and potential effects of other projects and activities within the time and space domain is primarily qualitative and in some cases is incomplete or unavailable, there is enough information to consider the cumulative effects of the deregulation of DT soybean and DGT cotton. This qualitative approach is used when necessary throughout this section and for each resource area. For this section if a topic is discussed qualitatively, further quantitative details about the topic are either incomplete or unavailable.

As suggested by the CEQ (1997) handbook, *Considering Cumulative Effects Under the National Environmental Policy Act,* this report considered the following basic types of cumulative effects that might occur due to the deregulation alternatives:

- *Additive* — loss of a resource from more than one incident.
- *Countervailing* — adverse effects are compensated by beneficial effects.
- *Synergistic* — total effect is greater than the sum of effects when considered independently.

In the following analysis, cumulative impacts should be considered additive unless designated as otherwise. In the case of most resources that may experience cumulative impacts, the Deregulation Alternative is only responsible for a contribution of an incremental portion the total impact on the resource. The past, present, and reasonably foreseeable connected actions typically contribute to the majority of impacts experienced by the resource, and would continue to have impacts on the resource even if the No Action Alternative were implemented.

V.F. ASSUMPTIONS USED FOR CUMULATIVE IMPACTS ANALYSIS

As described and analyzed throughout Section V, DT soybean and DGT cotton, if deregulated, are not expected to have direct effects on the environment that differ from current commercially cultivated soybeans and cotton, because they are phenotypically, agronomically and ecologically the same as current commercial cotton, except for their tolerances to dicamba and dicamba and glufosinate, respectively. The difference between the Deregulation in Whole and the No Action Alternative is expected to be integration of DT soybean and DGT cotton into the glyphosate-tolerant soybean cotton systems (GE-derived systems) using traditional breeding techniques. Therefore, the only foreseeable potential impacts are related to changes in weed management (herbicide use and tillage). Nevertheless, while the focus of this discussion is on potential cumulative impacts related to changes in weed management, it also addresses potential cumulative impacts related to combination of DT soybean and DGT cotton with crop varieties with different GE traits that are no longer subject to the regulatory requirements of 7 CFR part 340 (*i.e.*, "stacked" traits).

Cumulative effects have been analyzed for each environmental issue assessed in Section V. In this report, the cumulative effects analysis is focused on the incremental impacts of the deregulation of DT soybean and/or DGT cotton taken in consideration with related activities, including past, present, and reasonably foreseeable future actions. Certain aspects of these products and their cultivation would be no different from other conventional or previously deregulated variants of these crops; these instances are described below. In this analysis, if there are no direct or indirect impacts identified, then it is assumed that there can be no cumulative impacts. Where it is not possible to quantify impacts, a qualitative assessment of potential cumulative impacts is provided.

V.G. CONVENTIONAL BREEDING WITH OTHER GE-DERIVED OR NON-GE CROPS

Stacked soybean and cotton varieties may contain more than one GE trait as the result of crossing two GE plants. DT soybean and/or DGT cotton may be crossed with non-GE or GE varieties of those plants that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. APHIS regulations at 7 CFR Part 340 do not provide for Agency oversight of GE soybean and cotton varieties no longer subject to the requirement of Part 340 and the plant pest provisions of the Plant Protection Act, or over stacked varieties combining these GE varieties, unless it can be positively shown that such stacked varieties were to pose a likely plant pest risk. Monsanto has indicated that it will likely develop "stacked" hybrids with DT soybean and/or DGT cotton and other commercially available traits, expected to initially be GE glyphosate tolerance. In this process, the dicamba tolerance from DT soybean and the dicamba and glufosinate tolerance from DGT cotton will be combined with glyphosate tolerance from other varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Such a stacked variety could provide growers with the option to combine several herbicides with different modes of action for control of weeds. Therefore, this cumulative impacts analysis will assume that DT soybean and/or DGT cotton could be combined with commercially available glyphosate tolerant varietals as a reasonably foreseeable future action.

Deregulated GE glyphosate-tolerant (e.g., Roundup Ready®) crop varieties have been in the market since 1996, when glyphosate-tolerant soybean became commercially available. The potential effects from the cultivation of glyphosate-tolerant crops, with a corresponding analysis of the implications of the use of glyphosate, have been thoroughly evaluated in APHIS EAs since the 1993 introduction of the first glyphosate-tolerant crop product (see http://www.aphis.usda.gov/biotechnology/not_reg.html).

Several of these evaluations included crops conferring tolerance to multiple herbicides and have concluded there is no finding of significant impact from the deregulation in whole of the crop. Specific crop examples include:

- Sugar Beet, 2011. Monsanto and KWS SAAT AG Glyphosate-tolerant Sugar Beet (Petition No. 03-023-01p).
- Soybean, 2011. Monsanto Improved Fatty Acid Profile Soybean (which includes glyphosate tolerance) (Petition No. 09-201-01p).
- Alfalfa, 2011. Monsanto Glyphosate-tolerant Alfalfa (Petition 04-110-01p).
- Corn, 2009. Pioneer Glyphosate and Imadazolinone-tolerant Corn (Petition 07-152-01p).
- Cotton, 2009. Bayer Crop Science Glyphosate-tolerant Cotton (Petition 06-332-01p).
- Soybean, 2008. Pioneer Glyphosate and Acetolactate Synthase-tolerant Soybean (Petition No. 06-271-01p).
- Soybean, 2007. Monsanto Glyphosate-tolerant Soybean (Petition 06-178-01p).
- Cotton, 2005. Monsanto Glyphosate-tolerant Cotton (Petition 04-086-01p).
- Rapeseed 2001. Monsanto Glyphosate-tolerant Rapeseed (Petition 01-324-01p).
- Corn, 2000. Monsanto Glyphosate-tolerant Corn (Petitions No. 97-099-01p and 00-011-01p).
- Rapeseed 1998. Monsanto Glyphosate-tolerant Rapeseed (Petition 98-216-01p).
- Sugar Beet, 1998. Novartis Seeds and Monsanto Glyphosate-tolerant Sugar Beet (Petition No. 98-173-01p).
- Corn, 1997. Monsanto Glyphosate-tolerant Corn (Petition No. 97-099-01p).
- Corn, 1996. Monsanto Glyphosate-tolerant and European Corn Borer-resistant Corn (Petition No. 96-317-01p).
- Cotton, 1995. Monsanto Glyphosate-tolerant Cotton (Petition 95-045-01p).
- Soybean, 1993. Monsanto Glyphosate-tolerant Soybean (Petition 93-258-01p).

The first glyphosate-tolerant soybean became commercially available to growers in 1996 after Monsanto's Roundup Ready® Soybean (GTS 40-3-2) was determined to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (see APHIS Petition File 93-258-01p at http://www.aphis.usda.gov/biotechnology/not_reg.html). Similarly, the first glyphosate-tolerant cotton to be deregulated by APHIS was Roundup Ready® cotton lines 1445 and 1698, which were submitted as Petition 95-045-01p by Monsanto and deregulated by APHIS in July, 1995.

Other stacked varieties of either of these crops might also be developed at a later time which also derive tolerance to dicamba from the DT soybean or to dicamba and glufosinate from DGT cotton. Currently, all GE soybean varieties are herbicide-tolerant, namely to glyphosate, with a smaller (i.e., approximately 1.3% of planted acres in 2011) but growing number of glufosinate-tolerant varieties available since 2010. In addition to tolerance to glyphosate and glufosinate, other GE soybean traits no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act include lepidopteran resistance, high oleic acid content, and acetolactate synthase tolerance (see http://www.aphis.usda.gov/biotechnology/not_reg.html). Similarly, other GE cotton traits no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act include lepidopteran resistance, glufosinate tolerance, and phosphinothricin tolerance. Issues associated with potential future stacking, particularly cultivation of a stacked hybrid incorporating glyphosate resistance from varieties previously determined to be nonregulated, are presented and discussed in the cumulative effects analyses where appropriate.

APHIS has determined that none of the individual biotechnology-derived products it has previously deregulated displays increased plant pest characteristics or creates potentially significant impacts on the human environment. APHIS has also concluded that any progeny derived from crosses of these deregulated biotechnology-derived soybean products with conventional or previously deregulated biotechnology-derived soybean are unlikely to exhibit new plant pest properties. This presumption that combined trait biotechnology products are unlikely to exhibit new characteristics that would pose new plant pest risks or potential environmental impacts not observed in the single event biotech product is based upon several facts, including: 1) stability of the genetic inserts is confirmed in each single event product across multiple generations; 2) stability of each of the introduced traits is continually and repeatedly assessed as new combined trait varieties are created by plant breeders and tested over multiple seasons prior to commercial release; 3) combined trait products are developed using the well established process of conventional breeding that has been safely used for thousands of years to generate new varieties; and 4) in both principle and practical application in the field, it has been shown that two unrelated biotechnology traits combined together by conventional breeding, do not display new characteristics or properties distinct from those present in the single event biotech products. (Brookes and Barfoot 2012; James 2010; Lemaux 2008; Pilacinski, et al. 2011).

V.H. DEMONSTRATED GENETIC AND PHENOTYPIC STABILITY

An assessment of the stability of the genetic inserts in DT soybean and DGT cotton are discussed in Appendix G to this environmental report and are summarized here; refer to the Appendix for more detail. Generational stability analysis was assessed by Southern blot analysis and demonstrated that the genetic inserts present in DT soybean and DGT cotton were maintained across the five breeding generations evaluated. These data demonstrate that DT soybean and DGT cotton are stable in their progeny. Having established that the genetic material is stable and inherited in a Mendelian fashion, and based on experience with DT soybean and DGT cotton in Monsanto's plant breeding program over the course of many generations, it is concluded that the phenotypes of DT soybean and DGT cotton are likewise stable. There are numerous examples in the literature that confirm that GE events and their associated phenotypes and overall characteristics are stably inherited across generations and across genetic backgrounds, including when they are combined by conventional breeding to produce combined trait products (McCann, et al. 2005; Ridley, et al. 2011; Zhou, et al. 2011).

V.I. COMBINED TRAIT PRODUCT PERFORMANCE IN PRINCIPLE AND IN PRACTICE

Conventional plant breeding is routinely used to improve crop performance and is specifically employed to develop plant varieties that fit particular environments and production practices (Powell et al., 2003). The same biological and selective principles used for conventional and single GE event variety development are used to combine previously approved GE events. When conventional breeding is used to generate varieties with combined GE events, these varieties are screened over multiple generations and across diverse growing environments. Typically, product performance and agronomic features are evaluated and crop characteristics such as yield, field performance, and disease resistance are measured and tested to ensure that the traits are stable, heritable, and express the desired phenotype under a wide range of environmental conditions. The phenotypic characteristics evaluated during the screening of new combined GE event candidate varieties are the result of the plant's genotype and are the culmination of the complex metabolic pathways that are activated in response to environmental conditions. The evaluation of phenotypic characteristics allows breeders to assess and screen for potential unintended effects produced as a result of the various traits (both GE traits and other inherent traits) combined in the variety. Selection during the conventional breeding process is valuable in removing undesirable characteristics and thereby helps to maintain the safety and quality of the food and/or feed product (Cellini et al., 2004; NRC, 2004; WHO, 1995).

When assessing the safety of combined GE events, it is important to consider international guidance regarding conventional breeding and assessments of the substantial equivalence of GE events combined by conventional breeding. For example, the World Health Organization concludes that a substantial equivalence conclusion can be maintained in a combined GE trait variety if substantial equivalence had been demonstrated for each of the single event parents. Specifically, they argue that "...if substantial equivalence has been demonstrated both for a [genetically engineered] tomato with a gene producing a delayed ripening phenotype and for a [genetically engineered] tomato with a gene for herbicide resistance, then crossing these two varieties would result in a new variety that would be expected to be substantially equivalent to the parents" (WHO, 1995). Additional international groups, including the Food and Agriculture Organization/World Health Organization (FAO, 1996), International Seed Federation (ISF, 2005), and CropLife International (CLI, 2005) similarly advocate basing the safety of combined GE events on the safety of the parental GE events. The FDA has stated that "narrow crosses are unlikely to result in unintended changes to foods that raise safety or other regulatory questions" – "including narrow crosses between different rDNA-modified [GE] lines" (U.S. FDA, 2001).

Thus, the data packages that are developed for single GE events are useful in establishing the safety of the combined GE event product. Accordingly, single GE events previously assessed to be as safe as their conventional counterparts should continue to be safe when combined through conventional plant breeding. As a result, the rigorous safety assessments and plant pest risk assessments conducted on single GE events, which were deemed to pose no more risk than their conventional counterparts, also can be used to predict the safety and potential risk of the combined GE event product. As described below, this assertion is supported by direct experience gained through the commercial planting and utilization of combined GE event products as well as a body of information collected to support authorizations where combined GE event products require additional assessment.

There are many examples of combined trait biotech products that have been produced commercially on millions of acres without incident over the past decade in both the US and in other countries[60]. In the US, there are over 30 combined trait products that have been made commercially available. In 2011, 49% of the total corn acres planted (92 M acres) and 58% of total cotton planted (13M acres) contained multiple (2 or more) GE events (USDA-ERS, 2011).[61] Combined trait biotech products were planted on 40 million hectares or 25% of the global biotech area of 160 million hectares in 2011.[62] The safety of commercially available combined trait biotech products has been well-demonstrated in multiple independent reports that document the continually increasing acceptance and use of these products by farmers globally (Brookes and Barfoot, 2009; James, 2009; Lemaux, 2008; Sankula, 2006).

In addition, regulatory agencies in some countries request additional characterization of combined GE events and comparisons to single event parental controls and conventional comparators. These additional studies may include analysis of phenotype, molecular characteristics, protein characteristics, morphology and compositional evaluation. Analyses of combined GE events compared to parental controls have consistently revealed the following: no phenotypic differences from parental events; molecular characteristics that are the same as parental events with all events inherited stably; levels of introduced proteins comparable to the single event parents; no morphological differences compared to parental events; compositional equivalence based on nutrient and anti-nutrient evaluations, and no pleiotropic or toxic effects compared to the conventional non-GE crop (Pilacinski et al., 2011).

V.J. CUMULATIVE IMPACTS: ACREAGE AND AREA OF SOYBEAN AND COTTON PRODUCTION

Cumulative effects associated with a determination of nonregulated status of DT soybean to acreage and areas of soybean production are unlikely. Deregulation is not expected to directly cause a change in agricultural acreage devoted to conventional or GE soybean cultivation in the U.S. and there are no anticipated changes to the availability of GE and non-GE soybean varieties on the market. The potential future development and cultivation of a stacked soybean variety presenting tolerance to dicamba and glyphosate is not likely to change the current number of acres of soybean being treated with glyphosate, since currently more than 90% of

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[60] See http://www.biotradestatus.com for list of combined trait products that have previously been commercialized.

[61] See http://www.ers.usda.gov/data/biotechcrops/adoption.htm.

[62] http://www.isaaa.org/resources/publications/briefs/43/executivesummary/default.asp

soybean acres are planted with GE glyphosate-tolerant soybeans (USDA-ERS, 2011b). Rather, DT soybean is anticipated to be adopted by growers already using a GE variety, but who are interested in utilizing an herbicide with a different mode-of-action, either to control existing herbicide-resistant weeds, or to mitigate the potential for future development of herbicide-resistant weeds. Additionally, the availability of a stacked variety of DT soybean for commercial production is not expected to change the areas where soybean can be grown for soybean production in the U.S. since the agronomic characteristics of DT soybean are essentially indistinguishable from other available soybean varieties.

Similarly, cumulative effects associated with a determination of nonregulated status of DGT cotton to acreage and areas of cotton production are unlikely. Deregulation is not expected to directly cause a change in agricultural acreage devoted to conventional or GE cotton cultivation in the U.S. and there are no anticipated changes to the availability of GE and non-GE cotton varieties on the market. Rather, DGT cotton is anticipated to be adopted by growers already using a GE variety, but who are interested in utilizing an herbicide with a different mode-of-action, either to control existing herbicide-resistant weeds, or to mitigate the potential for future development of herbicide-resistant weeds. The potential future development and cultivation of a stacked cotton variety presenting tolerance to dicamba, glufosinate, and glyphosate is similarly not likely to change the areas where cotton can be grown for cotton production in the U.S. since the agronomic characteristics of DGT cotton are essentially indistinguishable from other available cotton varieties. Although total U.S. cotton acreage since 2000 has varied from approximately 9 to 16 million planted acres, the variations observed in cotton acreage and production are primarily driven by current market conditions, rather than agronomic considerations.

For these reasons, there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to impact soybean and cotton acreage and areas of production.

V.J.1. Cumulative Impacts: Agronomic Practices

A determination of nonregulated status of DT soybean and/or DGT cotton is not expected to result in changes in the current soybean and cotton cropping practices, with the exception of potential changes in the use of certain herbicides. As discussed above, potential impacts from changes to herbicide usage are addressed herein even though such impacts are outside the scope of APHIS's action and fall instead within the jurisdiction of EPA's oversight of pesticide usage.

V.J.2. Soybean

DT soybean would provide soybean growers with the option to use dicamba post-emergence. Similar to the current use of dicamba, the use of dicamba on soybean would be in accordance with the per application and per year rates approved by EPA. Studies conducted by Monsanto demonstrate that, in terms of agronomic characteristics and cultivation practices, DT soybean is essentially indistinguishable from other soybean varieties currently grown. Consequently, impacts to cropping practices associated with the adoption of DT soybean are not expected.

Monsanto has indicated its intention to develop a stacked hybrid with DT soybean and commercially available soybean varieties conferring glyphosate tolerance. If combined with a glyphosate tolerance trait, DT soybean would enable growers to use a combination of herbicides with different modes of action on soybean, an approach proposed to mitigate the future development of herbicide-resistant weeds (Duke and Powles, 2009). The future development and cultivation of a stacked DT soybean variety presenting the additional tolerance to glyphosate is not likely to increase the number of acres of soybean being treated with glyphosate, since, in 2011, more than 90% of soybean acres were planted with GE glyphosate-tolerant soybeans (USDA-ERS, 2011b). DT soybean, either alone or combined with other traits, would likely replace these other GE herbicide-tolerant soybeans currently being cultivated. Therefore, it is expected that combining other herbicide tolerance traits with those of DT soybean would not increase the overall number of acres that herbicide would be applied to. Herbicide use would be in accordance with per application and per year rates approved by EPA.

V.J.3. Cotton

A determination of nonregulated status of DGT cotton is not expected to result in changes in the current cotton cropping practices, with the exception of potential changes in the use of certain herbicides.

DGT cotton would provide cotton growers with the option to use dicamba post-emergence in addition to using glufosinate, which would provide different modes of action to control glyphosate-resistant weeds. Similar to the current use of dicamba and glufosinate, the use of dicamba and glufosinate on cotton would be in accordance with the per application and per year rates approved by EPA. Studies conducted by Monsanto demonstrate that, in terms of agronomic characteristics and cultivation practices, DGT cotton is essentially indistinguishable from other cotton varieties currently grown. Consequently, impacts to cropping practices associated with the adoption of DGT cotton are not expected.

Monsanto has indicated its intention to develop a stacked hybrid with DGT cotton and commercially available cotton varieties conferring glyphosate tolerance. If combined with a glyphosate tolerance trait, DGT cotton would enable growers to use a combination of herbicides with different modes of action on cotton, an approach proposed to mitigate the future development of herbicide-resistant weeds (Duke and Powles, 2009). The future development and cultivation of a stacked DGT cotton variety presenting the additional tolerance to glyphosate is not likely to increase the number of acres of cotton being treated with glyphosate. Glyphosate is the most widely used herbicide in cotton, applied on 91% of cotton acres with an average of 2.4 applications per growing season (Monsanto 2012). Therefore, it is expected that combining other herbicide tolerance traits with those of DGT cotton would not increase the overall number of acres to which herbicides would be applied. Herbicide use would be in accordance with per application and per year rates approved by EPA.

V.J.4. Cumulative Impacts of Herbicides

Based on the dicamba applications and use rate analysis discussed in Appendix A to this Environmental Report, use of DGT cotton on 50% of U.S. cotton acres would result in approximately 5.2 million lbs a.e. of dicamba applied to DGT cotton annually (including preplant, preemergence and in-crop applications). With respect to DT soybean, Monsanto estimates a potential increased use of dicamba by approximately 20.5 million pounds annually. Considering the adoption rates of DGT cotton (50%) and DT soybean (40%)[63] and the current use of 3.8 million lbs of dicamba per year, the total U.S. dicamba use would be approximately29.5 million pounds annually. This level of dicamba use would be approximately 3 times the historical peak levels experienced since dicamba's introduction in 1967. See Appendix A to this Environmental Report for additional details on projected dicamba use on DT soybean and DGT cotton.

However, dicamba (and glufosinate, in the case of cotton) are expected to replace the use of other herbicides in soybeans and cotton, such as fluometuron, fomesafen, MSMA, and paraquat. See Appendix A for a more comprehensive list of herbicides dicamba is expected to replace. The commercialization of soybean and cotton products containing dicamba-tolerance will allow for an increase in the use of dicamba for weed control in soybean and cotton due to the elimination of in-crop (POST segment) and preplant (PRE segment) crop safety concerns. With crop safety no longer a barrier, farmers will be able to incorporate dicamba into their weed management programs because of the advantages it offers versus other herbicides. The following are some of the most significant advantages dicamba offers over other alternative herbicides:

- Improved efficacy compared to other commercially available herbicides to control tough broadleaf weeds and weeds that are resistant to glyphosate and other herbicides used in soybean and production (Johnson et al., 2010)
- Greater convenience and flexibility due to the elimination of plant back and rotational crop restrictions
- Improved crop safety relative to other herbicide options
- Reduced handling restrictions relative to other herbicide options
- A more benign toxicity profile and lower risk potential to applicators, consumers, and aquatic organisms compared to some alternative herbicides (Appendix A).[64]

These advantages will translate into dicamba replacing certain non-glyphosate herbicides currently used preplant and/or postemergent in soybeans and cotton. In addition, the ability to use dicamba to manage existing resistant weeds will drive an overall reduction in herbicide use in some situations. For example, Monsanto and academics currently recommend that farmers with glyphosate resistant weeds apply a residual product, such as flumioxazin, or fomesafen preplant to the crop, followed by fluometuron preemergence, and followed by glyphosate plus

63 Monsanto projects dicamba to be conservatively used on 40% of U.S. soybean acres. This estimate was incorrectly listed as 50% in Tables VIII-21 through VIII-24 in petition 12-185-01p_a1.

64 In order to approve a new use of a herbicide EPA must conclude that the herbicide, when used according to the label, does not pose an unreasonable adverse effect to humans or the environment, and, in order to establish a tolerance for the use of a herbicide on a food or feed crop, find there is a reasonable certainty of no harm to human health from non-occupational (food, water and residential/recreational) exposures to the herbicide. Therefore, all alternative herbicides used in cotton production can be used safely, and do not pose an unreasonable risk to humans or the environment.

acetochlor or metolachlor after planting, and then conclude with hooded applications of paraquat and/or directed applications of MSMA or diruon to control escapes.[65] With the ability of farmers to use dicamba in crop, dicamba would replace the need for some of these products, and others currently being used, thus resulting in a shift and replacement of herbicide use and applications. Monsanto will continue to recommend the use of multiple herbicide modes-of-action in the dicamba systems, including residual herbicide products.

Glyphosate is not expected to be replaced by dicamba in either the PRE or the POST segment. Dicamba will primarily be used in combination with glyphosate and this combination will simply displace glyphosate combinations with other non-glyphosate herbicides and/or glyphosate herbicide used alone.

With respect to soybeans, the projected total pounds of herbicides in each application segment (PRE and POST) that would be replaced by dicamba were determined using the methodology and data source as the total area treated (TAT) analysis described in Appendix A. The same herbicide growth projections for the PRE and POST application segments (i.e., 101% and 132%) were applied to the 2011 pounds of herbicide applied data. Based on this analysis, we project that dicamba would replace an estimated 3.6 million pounds of PRE non-glyphosate herbicides and 1.6 million pounds of POST non-glyphosate herbicides in 2015 (See Appendix A to this Environmental Report).

With respect to cotton, the projected total pounds of herbicides in each application segment (PRE and POST) that would be replaced by dicamba were determined using the methodology and data source as used in the TAT analysis described in Appendix A. Based on this analysis, we project that dicamba would replace an estimated 1.35 million lbs of PRE non-glyphosate herbicides and 0.5 million lbs of POST non-glyphosate herbicides at peak market penetration. See Appendix A to this Environmental Report for details on DT soybean and DGT cotton herbicide use analysis.

V.K. NET IMPACT OF DT SOYBEAN AND DGT COTTON ON OVERALL HERBICIDE USE

The analysis set forth above and described in great detail in Appendix A, was completed to evaluate the assertions made in recent publications by Benbrook (2012) and Mortensen et al. (2012), which suggest the commercialization of dicamba-tolerant soybeans and associated use of dicamba will only be additive to current herbicide use and, according to Mortensen, could result in a 'profound' increase in overall herbicide use. The main reasons for their conclusions are (1) overall herbicide use in 2007 was projected to not change through 2013, and (2) dicamba use would be entirely additive to use of existing herbicides. However, the analysis above and in Appendix A highlight the inaccuracy of these conclusions and clearly demonstrates two key conclusions:

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65 www.roundupreadyplus.com. Warrant is a trademark of Monsanto Technology LLC. All other trademarks are the property of their respective owners.

(1) The overall use of non-glyphosate herbicides in soybean and cotton production has grown since 2007, and this growth is expected to continue and eventually plateau. The current and projected future growth is due in large part to the adoption of best management practices as recommended by public and private sector weed scientists and the development of weed resistance in certain areas of the U.S. This increase in non-glyphosate herbicide use would occur regardless of the commercialization of dicamba-tolerant soybeans and cotton, and

(2) When dicamba-tolerant soybean and cotton systems are available, dicamba would displace a significant amount of non-glyphosate herbicides used for weed management. Based on expectations by Monsanto and academic weed scientists that farmers will continue to implement diversified weed management programs that utilize multiple herbicide modes-of-action and dicamba would be an important weed management tool in future soybean and cotton production.

The deregulation and subsequent commercialization of dicamba-tolerant soybean and cotton will not alter the number of cultivated soybean or cotton acres or the geographical areas where soybean and cotton are cultivated in the U.S. Consequently, dicamba-tolerant soybeans and cotton will be grown on land that is already highly managed for agricultural crop production and where herbicides are widely used today. As described previously, the commercialization of dicamba-tolerant soybeans and cotton will result in a slight increase in herbicide use (treated acres and pounds of dicamba) on those acres where it is planted and the grower chooses to use dicamba in their weed management program. However the increase in dicamba relative to overall herbicide use in soybean and cotton production is relatively low, contributing less than 15% to the overall herbicide use in glyphosate-tolerant soybean production and 16 % to the overall herbicide use in glyphosate-tolerant cotton production.

While an increase in overall herbicide use in soybean and cotton growing areas is projected for the commercialization of DT soybean and DGT cotton, assuming growers adopt recommended weed management practices, these practices provide numerous economic and environmental benefits, which are detailed in Appendices A & B and summarized below.

- Effective tool for sustainable management of glyphosate resistant weeds where they exist
- Mitigate the evolution and development of weed resistance for all classes of herbicides used in soybean and cotton production
- Improved consistency of hard-to-control weeds thereby reducing the potential for new resistant biotypes to develop
- Increased application flexibility
- Preserve the benefits of the glyphosate-tolerant weed control system
- Preserve the many environmental and economic benefits of conservation tillage

Furthermore, the projected increase in the amount of dicamba used in soybean and cotton production is not expected to result in adverse impacts to human health or the environment. The U.S. EPA regulates pesticide use and under FIFRA must reach a conclusion of no unreasonable adverse effects to human health and the environment before dicamba can be approved for use with DT soybean and/or DGT cotton. Monsanto has submitted an application to EPA to approve the use of dicamba with DT soybean and DGT cotton. EPA concluded in the dicamba Reregistration Eligibility Decision document that all then-registered uses of dicamba can be used without resulting in unreasonable adverse effects (U.S. EPA, 2009). Because the use patterns for dicamba with DT soybean and DGT cotton are consistent with the use patterns and assumptions on herbicide use intensification evaluated in the RED, any projected increase in dicamba use from the commercialization of DT soybean and DGT cotton is not expected to result in potential adverse impacts to the human health or the environment, and EPA will reconfirm that dicamba's use does not result in unreasonable adverse effects as part of its review of the Monsanto application.

Due to the overlap of areas planted to cotton and soybeans there is the possibility for a crop rotation that includes both DT soy and DGT cotton. While this will increase selection pressure on dicamba the risk of resistance to dicamba will be effectively mitigated by the implementation of diversified weed management programs in both DT soy and DGT cotton. Field studies by Beckie and Reboud, 2009 and modeling studies by Neve et. al. (2011) both clearly demonstrate the effectiveness of repeated applications of the same herbicide or combinations of herbicides to retard the evolution of resistance when used in diversified weed management programs. In the case of both DT soy and DGT cotton, dicamba will be used in combinations with residual herbicides that are effective on targeted glyphosate resistant species and with glyphosate and/or glufosinate both of which would add an additional herbicide mode-of-action to control of certain weeds common in each crop.

Based on EPA's assessment, adverse impacts from cumulative effects of herbicide use are not expected under the Deregulation in Whole Alternative.

V.L. CUMULATIVE IMPACTS: SEED PRODUCTION

Based on current trends, GE products are likely to continue to dominate soybean and cotton production. GE soybean varieties were grown on more than 93% of soybean acres in 2011 (USDA-ERS, 2011b). Similarly, GE cotton lines are grown on approximately 90% of U.S. cotton acres. To the extent that growers see value in the traits offered by stacked DT soybean or stacked DGT cotton varieties, these varieties may replace existing soybean and cotton varieties. The availability of stacked DT soybean and DGT cotton are not anticipated to change cultivation areas for soybean and cotton production in the U.S. Because changes in the agronomic practices and locations for soybean and cotton seed production are not expected, there are no cumulative effects identified for either GE or non-GE seed production with the potential commercial availability of stacked DT soybean or DGT cotton.

V.M. CUMULATIVE IMPACTS: ORGANIC PRODUCTION

A determination of nonregulated status of DT soybean and/or DGT cotton is not expected to change the market demands for GE soybean and cotton or soybean and cotton produced using organic methods. Data from USDA-ERS indicates that in 2011, 93% of all soybean grown in the U.S. were GE varieties (USDA-ERS, 2011b). GE cotton lines are grown on approximately 90% of U.S. cotton acres. In 2008, organic soybean varieties were grown on less than 1% of the 75.2 million acres planted with soybean in the U.S. (USDA-ERS, 2010b), and organic cotton was grown on approximately 0.16% of the total 9.41 million acres planted with cotton (USDA-ERS 2008).

Based upon information on recent trends, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share. Since 1994, fourteen GE soybean events or lines and fifteen GE cotton events or lines have been determined by APHIS to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Organic production of soybeans grew from 82,143 acres in 1997 to a maximum of 174,467 acres in 2001. Since 2001, the total acreage of organic soybean production has experienced a slight decline in growth over time, with 125,621 acres planted in 2008 (USDA-ERS, 2010b). The decline of organic soybean acreage has been attributed to high prices being paid for conventional soybean and high fuel costs (McBride and Greene, 2008) and not the adoption rate of GE soybean. Organic cotton production has similarly maintained its market share. Based on USDA-ERS data, between 1997 and 2008, organic cotton acreage ranged from 9,213 acres in 2004 to a maximum of 15,377 acres in 2008 (USDA-ERS 2008). Based on the trends in the cultivation of GE, non-GE, and organic varieties, and the fact that the pressures on the corresponding production systems to maintain varietal integrity are likely to remain the same, there are no cumulative impacts to organic soybean and cotton production from a determination of nonregulated status of DT soybean and DGT cotton.

V.N. CUMULATIVE IMPACTS: SOIL QUALITY

No negative cumulative effects on soil quality have been identified associated with a determination of nonregulated status of DT soybean and/or DGT cotton. A determination of nonregulated status for DT soybean and/or DGT cotton would not change agronomic practices affecting the quality of soil cultivated in commercial soybean and/or cotton production. DT soybean and DGT cotton are not expected to result in changes in the current soybean or cotton cropping practices, with the exception of potential changes in the use of certain herbicides for weed management, and a potential decrease in conventional tillage practices. As discussed above, potential impacts from changes to herbicide usage are outside the scope of APHIS's action and fall instead within the jurisdiction of EPA's oversight of pesticide usage. See Section I.B.

If DT soybean and/or DGT cotton became commercially available and were stacked with other transgenic herbicide-tolerance traits, depending on the extent of adoption, they may contribute to sustaining conservation tillage in U.S. soybean and cotton production that both directly and indirectly impacts soil quality. The single most damaging effect on land due to agriculture is loss of soil caused by tillage. Tillage is primarily performed for seed bed preparation and has the added benefit as a weed control measure. Herbicide-tolerant crops have enabled significant implementation/adoption of no-till or reduced tillage methods for weed control (Duke and Powles 2009). As discussed in Section II.B.2.c, increases in total acres dedicated to conservation tillage have been attributed to an increased use of herbicide-tolerant cotton, which reduces the need for mechanical weed control (McClelland et al. 2000; Towery and Werblow 2010). DT soybean and DGT cotton would allow the additional use of dicamba and glufosinate herbicides in case of DGT cotton, in a diversified weed management program to control a broad spectrum of grasses and broadleaf weed species. As such, the availability of DT soybean and DGT cotton could help preserve the current acreage of cotton grown using conservation tillage and potentially help increase conservation tillage acreage. The Deregulation in Whole Alternative would provide another herbicide-tolerant crop option and thus could help continued adoption and preservation of conservation tillage methods, resulting in a small positive cumulative environmental impact.

As discussed above, use of herbicides alone or stacked with other herbicide-tolerant or other traits is not expected to increase the overall number of acres to which herbicide would be applied. See Sections V.A.2 and V.A.3. The total amount of the mix of herbicides that may be applied to DT soybean and/or DGT cotton or subsequent varieties derived therefrom would be used in accordance with per application and per year rates approved by EPA. EPA's reregistration and registration review process ensures that each registered pesticide continues to meet the FIFRA registration standard, i.e., that pesticides will not cause unreasonable adverse effects when used as directed on product labels.

Based on the above information, there are no past, present, or reasonably foreseeable actions that would aggregate with effects of deregulation that would have a negative impact on soil resources; rather, there may be slight beneficial cumulative impacts to soil quality from sustaining conservation tillage rates in soybean and cotton production.

V.O. CUMULATIVE IMPACTS: WATER RESOURCES

A determination of nonregulated status of DT soybean and/or DGT cotton is not expected to result in changes in the current cropping practices, with the exception of potential changes in the use of certain herbicides, and, as discussed above, a potential decrease in conventional tillage practices. As discussed above, potential impacts from changes to herbicide usage are outside the scope of APHIS's action and fall instead within the jurisdiction of EPA's oversight of pesticide usage. See Section I.B. No changes in water use or irrigation practices currently used in commercial soybean or cotton production are expected.

Monsanto has indicated its intention to stack DT soybean and/or DGT cotton with other nonregulated soy and cotton varieties, particularly varieties conferring tolerance to the herbicide glyphosate. Some glyphosate-tolerant crops have had nonregulated status since 1994 when glyphosate-tolerant soybean was determined to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (see http://www.aphis.usda.gov/biotechnology/not_reg.html) (USDA-APHIS, 1994). As discussed above, use of herbicides with DT soybean and/or DGT cotton alone or if stacked with other herbicide-tolerant or other traits is not expected to increase the overall number of acres to which herbicide would be applied. See Sections V.A.2 and V.A.3.

If DT soybean and/or DGT cotton became commercially available and were stacked with other transgenic herbicide-tolerance traits, depending on the extent of adoption, they may contribute to sustaining conservation tillage in U.S. soybean and cotton production that indirectly impacts water quality from soil erosion. The single most damaging effect on water quality due to agriculture is increased sedimentation and turbidity caused from erosion caused by tillage. Tillage is primarily performed for seed bed preparation and has the added benefit as a weed control measure. Herbicide-tolerant crops have enabled significant implementation/adoption of no-till or reduced tillage methods for weed control (Duke and Powles 2009). As discussed in Section II.B.2.c, increases in total acres dedicated to conservation tillage have been attributed to an increased use of herbicide-tolerant cotton, which reduces the need for mechanical weed control (McClelland et al. 2000; Towery and Werblow 2010). DT soybean and DGT cotton would allow the additional use of dicamba, and glufosinate herbicides in case of DGT cotton, in a diversified weed management program to control a broad spectrum of grasses and broadleaf weed species. As such, the availability of DT soybean and DGT cotton could help preserve the current acreage of soybean and cotton grown using conservation tillage and potentially help increase conservation tillage acreage. Further, based on individual grower needs, this approach may reduce the need to use conventional tillage to control glyphosate-resistant weeds (Owen, 2011), which could potentially lead to increased sedimentation and agricultural chemical pollutant offloading to surface water from soil erosion (Towery and Werblow, 2010). As a result, the Deregulation in Whole Alternative could help continued adoption and preservation of conservation tillage methods, resulting in a small positive cumulative environmental impact.

Glyphosate is already used on soybean and cotton in both conventional and GE varieties and the impacts of glyphosate use on water resources are well documented. Although glyphosate is very soluble in water, it is strongly adsorbed to soils; consequently, glyphosate is unlikely to leach into groundwater or surface water runoff following application (Giesy et al., 2000; US-EPA, 1993). Relying on toxicological data, bioaccumulation and biodegradation studies, and acute and chronic tests on fish and other aquatic organisms, EPA has determined that "the potential for environmental effects of glyphosate in surface water is minimal" (US-EPA, 2002b).

Dicamba has been widely used in agriculture over the last four decades with dicamba's peak use occurring in 1994. In the dicamba Reregistration Eligibility Decision (RED) document, EPA considered potential risks associated with dicamba use, and its degradate DCSA when appropriate, due to surface or ground water using screening level (high-end exposure) models to estimate environmental concentrations. The EPA then compared these exposure estimates to appropriate endpoints from mammalian, aquatic animal and plant ecotoxicity studies, and concluded dicamba meets the FIFRA standard for no unreasonable adverse effects on human health and the environment (see Appendices E and F to this Environmental Report). It is foreseeable that the frequency of dicamba detections in ground and surface water has the potential to increase as a result of the cultivation of DT soybean and DGT cotton; however, levels of dicamba in water are not expected to increase above the levels already evaluated and considered by EPA. Considering the available monitoring data for ground and surface water during the period of dicamba's most intensive use and when application rates were significantly higher than the rates proposed for us on DT soybean and DGT cotton, it is reasonable to assume that levels in ground and surface water that may result from the use of dicamba on DT soybean or DGT cotton would be below the levels (high-end exposure modeling and monitoring data) considered by the EPA in the dicamba RED, and where EPA concluded would have no unreasonable adverse effects on human health or the environment. The total amount of the mix of herbicides that may be applied to DT soybean, DGT cotton, or subsequent varieties derived therefrom would be used in accordance with per application and per year rates approved by EPA. EPA's reregistration and registration review process ensures that each registered pesticide continues to meet the FIFRA registration standard, i.e., that pesticides will not cause unreasonable adverse effects when used as directed on product labels.

The potential future cultivation of stacked soybean and/or cotton varieties and the associated use of glyphosate in addition to dicamba and glufosinate are not expected to result in cumulative effects to water resources. Therefore, there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have a negative impact on water resources.

V.P. CUMULATIVE IMPACTS: AIR QUALITY

A determination of nonregulated status of DT soybean and DGT cotton is not expected to result in changes in the current soybean and cotton cropping practices, with the exception of potential changes in the use of certain herbicides, and a potential decrease in tillage practices. As discussed above, potential impacts from changes to herbicide usage are outside the scope of APHIS's action and fall instead within the jurisdiction of EPA's oversight of pesticide usage. See Section I.B. As a result, no changes in air quality are anticipated.

Monsanto has indicated its intention to stack DT soybean and/or DGT cotton with other nonregulated soy and cotton varieties, particularly varieties conferring tolerance to the herbicide glyphosate. If combined with a glyphosate tolerance trait, DT soybean and/or DGT cotton would enable growers to use a combination of herbicides with different modes of action on soybean and/or cotton, an approach proposed to mitigate the future development of herbicide-resistant weeds (Duke and Powles, 2009). Based on individual grower needs, this approach may reduce the need to use conventional tillage to control glyphosate-resistant weeds that exist in certain areas of the U.S. (Owen, 2011), which could potentially impact conservation tillage. A decrease in tillage practices may have air quality benefits. As discussed above, use of herbicides on DT soybean and/or DGT cotton alone or if stacked with other herbicide-tolerant or other traits is not expected to increase the overall number of acres to which herbicide would be applied. It would be a violation of federal law to apply these pesticides at application rates or timing that are not approved by EPA.

Monsanto has sought approval of the DGA salt of dicamba only for use on DT soybean and/or DGT cotton. As discussed above, the formulation of the diglycolamine (DGA) salt of dicamba volatilized significantly less than a similar formulation of the DMA salt form (Egan and Mortensen 2012). Coupled with other label restrictions, and/or any other measures imposed by EPA, this will minimize the impact on air quality from spray drift. The use of low-volatility formulations, including the DGA salt of dicamba used on DT soybean or DGT cotton is not expected to result in predicted mean exposures "close to zero only short distances away from the treated area."(Egan and Mortensen 2012).

Monsanto has also indicated that its proposed dicamba product label would impose enforceable spray drift application requiremets that exceed requirements EPA deemed appropriate in the dicamba RED. EPA defines drift as "the movement of pesticide through air at the time of application or soon thereafter, to any site other than that intended for application" (US-EPA, 2000b). Factors affecting drift include application equipment and method, weather conditions, topography, and the type of crop being sprayed (US-EPA, 2000b). The proposed FIFRA label instructions would obligate the applicator to follow relevant spray-drift prevention measures such as: proper nozzle type to ensure larger droplet size, ground application, proper boom height, and awareness of wind direction and speed. These restrictions and/or any measures imposed by EPA would effectively prevent harm from spray drift.

V.Q. CUMULATIVE IMPACTS: CLIMATE CHANGE

A determination of nonregulated status for DT soybean and DGT cotton is not expected to result in changes in the current soybean and cotton cropping practices, with the exception of potential changes in the use of certain herbicides for weed management, and a potential decrease in conventional tillage practices. As discussed above, potential impacts from changes to herbicide usage are outside the scope of APHIS's action and fall instead within the jurisdiction of EPA's oversight of pesticide usage. See Section I.B.

Some agricultural practices, such as tillage, can contribute to climate change through releasing GHG emissions from soil and emissions from associated fuel-burning equipment (Brookes and Barfoot, 2006; CAST, 2009). Monsanto has indicated its intention to develop a stacked hybrid with DT soybean and/or DGT cotton and commercially available soybean and cotton varieties conferring glyphosate tolerance. If combined with a glyphosate tolerance trait, DT soybean and/or DGT cotton would enable growers to use a combination of herbicides with different modes-of-action on soybean and cotton, an approach proposed to mitigate the future development of herbicide-resistant weeds (Duke and Powles, 2009). Based on individual grower needs, this approach may reduce the need to use conventional tillage to control glyphosate-resistant weeds (Owen, 2011). The continued use of conservation tillage associated with GE crops may reduce GHG emissions as a result of increased carbon sequestration in soils, decreased fuel consumption, and the reduction of nitrogen soil amendments (Towery and Werblow, 2010).

As discussed above, use of herbicides on DT soybean and/or DGT cotton alone or if stacked with other herbicide-tolerant or other traits is not expected to increase the overall number of acres to which herbicide would be applied. It would be a violation of federal law to apply these pesticides at application rates or timing that are not approved by EPA.

There are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have a negative impact on climate change.

V.R. CUMULATIVE IMPACTS: ANIMAL COMMUNITIES

A determination of nonregulated status of DT soybean and/or DGT cotton is not expected to result in changes in the current soybean and cotton cropping practices, with the exception of potential changes in the use of certain herbicides for weed management, and a potential decrease in conventional tillage practices. As discussed above, potential impacts from changes to herbicide usage are outside the scope of APHIS's action and fall instead within the jurisdiction of EPA's oversight of pesticide usage. See Section I.B.

Monsanto has indicated its intention to stack DT soybean and/or DGT cotton with other nonregulated soy and cotton varieties, particularly varieties conferring tolerance to the herbicide glyphosate. If combined with a glyphosate tolerance trait, DT soybean and/or DGT cotton would enable growers to use a combination of herbicides with different modes of action on soybean and/or cotton, an approach proposed to mitigate the future development of herbicide-resistant weeds (Duke and Powles, 2009). Based on individual grower needs, this approach may reduce the need to use conventional tillage to control glyphosate-resistant weeds (Owen, 2011). Reduced tillage improves habitat value through increased water quality, availability of waste grain, retention of cover in fields, and increased populations of invertebrates (Brady, 2007; Sharpe, 2010).

Both DT soybean and DGT cotton have been shown to have no toxic effects to animals. The FDA has completed its consultations on the safety of DT soybean and/or DGT cotton as animal feed. Monsanto intends to stack DT soybean and DGT cotton with soybean and cotton lines containing the 5-enolpyruvylshikimate-3-phosphate synthase (cp4 epsps) gene encoding the CP4 EPSPS protein conferring glyphosate tolerance. FDA has previously evaluated the safety of the CP4 EPSPS protein for feed and found no toxic effects to animals (US-FDA, 1995).

Glyphosate is already used in soybean and cotton in both conventional and glyphosate-tolerant varieties. The herbicide has been previously reviewed by EPA for impacts on non-target organisms and is currently being evaluated as part of the registration review process, scheduled to be completed in 2015 (US-EPA, 1993, 2009a, 2009d). Likewise, dicamba is widely used in agriculture and has been reviewed by EPA for impacts on non-target organisms (U.S. EPA 2009b), and it would be a violation of federal law for any herbicide to be used by growers inconsistent with the EPA label application rate. The total amount of the herbicides that may be applied to DT soybean and DGT cotton or subsequent varieties derived therefrom would be determined in accordance with per application and per year rates approved by EPA. EPA's reregistration and registration review process ensures that each registered pesticide continues to meet the FIFRA registration standard, i.e., that pesticides will not cause unreasonable adverse effects when used as directed on product labels.

Monsanto is developing a stewardship program that would include technological advancements in application and off-target movement of dicamba for application to DT soybean and/or DGT cotton, with a strong emphasis on grower and applicator training. Monsanto is also seeking U.S. EPA registration of a low volatility dicamba formulation (DGA salt) for ground application only. Monsanto's proposed product label – which is currently pending before EPA – includes specific application requirements, including a no-spray buffer to protect adjacent dicamba-sensitive areas. To further minimize potential impacts from post application volatilitzation, Monsanto would not allow growers to use dimethylamine salt (DMA) of dicamba and/or dicamba acid on DT soybean. These measures, and/or others identified by EPA, will effectively address any potential impact of off-site movement of these herbicides.

As discussed above, use of herbicides on DT soybean and DGT cotton alone or if stacked with other herbicide-tolerant or other traits is not expected to increase the overall number of acres to which herbicide would be applied. It would be a violation of federal law to apply these pesticides at application rates or timing that are not approved by EPA.

There are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have an adverse impact on animal communities.

V.S. CUMULATIVE IMPACTS: PLANTS COMMUNITIES

A determination of nonregulated status of DT soybean and/or DGT cotton is not expected to result in changes in the current soybean or cotton cropping practices, with the exception of potential changes in the use of certain herbicides for weed management, and a potential decrease in conventional tillage practices. As discussed above, potential impacts from changes to herbicide usage are outside the scope of APHIS's action and fall instead within the jurisdiction of EPA's oversight of pesticide usage. See Section I.B.

Monsanto has indicated its intention to stack DT soybean and DGT cotton with other nonregulated soy and cotton varieties, particularly varieties conferring tolerance to the herbicide glyphosate. If combined with a glyphosate tolerance trait, DT soybean and DGT cotton would enable growers to use a combination of herbicides with different modes of action on soybean and/or cotton, an approach proposed to mitigate the future development of herbicide-resistant weeds (Duke and Powles, 2009). Based on individual grower needs, this approach may reduce the need to use conventional tillage to control glyphosate-resistant weeds (Owen, 2011), which could potentially impact conservation tillage. Reduced tillage improves soil quality and reduces soil erosion, sustaining both crop and non-crop plants.

Glyphosate is already used in soybean and cotton in both conventional and glyphosate-tolerant varieties. The herbicide has been previously reviewed by EPA for impacts on non-target organisms and is currently being evaluated as part of the registration review process, scheduled to be completed in 2015 (US-EPA, 1993, 2009a, 2009d). Likewise, dicamba is widely used in agriculture and has been reviewed by EPA for impacts on non-target organisms (EPA 2009b), and it would be a violation of federal law for any herbicide to be used by growers inconsistent with the EPA label application rate. Therefore, the total amount of the herbicides that may be applied to DT soybean and DGT cotton or subsequent varieties derived therefrom would be determined in accordance with per application and per year rates approved by EPA. EPA's reregistration and registration review process ensures that each registered pesticide continues to meet the FIFRA registration standard, i.e., that pesticides will not cause unreasonable adverse effects when used as directed on product labels.

DT soybean and DGT cotton would provide alternatives to glyphosate in weed management systems, as dicamba and/or glufosinate will control the already glyphosate-resistant and hard to control broadleaf weeds. Diversified weed management programs that use herbicides from different groups, as well as varying cropping systems, rotating crops, and using mechanical as well as chemical weed control methods will potentially mitigate the potential for selection of herbicide-resistant weed populations (Green and Owen, 2011; Gunsolus, 2002; Powles, 2008; Sellers et al., 2011).

To support the introduction of varieties containing DT soybean and DGT cotton, Monsanto will use multiple methods to distribute technical and stewardship information to growers, academics and grower advisors regarding the use of the product as part of a diversified weed management system. Growers who purchase Monsanto varieties containing DT soybean sign a limited use license known as the Monsanto Technology Stewardship Agreement (MTSA). The MTSA obligates growers to comply with certain requirements, including the Monsanto Technology Use Guide (TUG). The TUG will set forth the requirements and best practices for the cultivation of DT soybean including recommendations on weed resistance management practices.

The weed resistance management practices that are designed to minimize the potential for the development of herbicide-resistant weeds will be articulated in the TUG and also be broadly communicated to growers and retailers. These practices will be communicated through a variety of means, including direct communications to each grower authorized to purchase a soybean variety containing DT soybean or a cotton variety containing DGT cotton, a public website[66], and reports in farm media publications. The overall weed resistance management program will be reinforced through collaborations with U.S. academics, who will provide their recommendations for appropriate stewardship of dicamba and glufosinate in soybean and cotton production, as well as by collaboration with crop commodity groups who have launched web-based weed resistance educational modules (WSSA 2012).

As discussed above, use of herbicides on DT soybean and DGT cotton alone, or if stacked with other herbicide-tolerant or other traits, is not expected to increase the overall number of acres to which herbicide would be applied. It would be a violation of federal law to apply these pesticides at application rates or timing that are not approved by EPA.

There are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have an adverse impact on plant communities.

V.T. CUMULATIVE IMPACTS: GENE FLOW AND WEEDINESS

The reproductive characteristics of the DT soybean and DGT cotton are substantially equivalent to other GE and non-GE soybean varieties of the same crops. See Appendix G to this Environmental Report.

V.T.1. Soybean

Given the reproductive characteristics of soybean, the probability for cross-pollination is low (Caviness, 1966; Ray et al., 2003). While cross-pollination can occur between adjacent plants and adjacent rows, it is unlikely that DT soybean or potential future varieties of DT soybean stacked with other traits would be grown in the same fields as other soybean varieties. Methods commonly used to ensure seed purity such as isolation distances and rotation cycles that specify a minimum number of years between crops (Conner et al., 2003) would further minimize vertical gene transfer. Gene movement between sexually compatible soybean varieties would be no greater for a stacked DT soybean than it is for other non-GE or GE cultivars. The potential for horizontal gene flow to other unrelated organisms would be highly unlikely (USDA-APHIS, 2012).

As discussed elsewhere in this report, DT soybean does not have any substantial weediness characteristics. Similarly, a soybean variety including dicamba-tolerance with glyphosate tolerance traits would not be expected to exhibit any weediness characteristics that would pose a plant pest risk.

Soybeans seldom exhibit dormancy and require specific environmental conditions to grow the following year (OECD, 2000), although volunteer soybean has been known to occur in some of the warmer regions of the U.S. In addition, volunteer soybean do not compete well with other crops and are easily controlled with common agronomic practices. DT soybean stacked with other herbicide-tolerant traits may lead to the need to manage volunteer soybeans in certain regions, especially in crops with herbicide tolerance to the same mode(s) of action..

[66] http://www.monsanto.com/weedmanagement/Pages/default.aspx

Management of these volunteer soybeans may require the use of more narrow spectrum herbicides (such as atrazine in maize), or conventional mechanical control methods. While additional management practices for the control of volunteer stacked soybean varieties in rotation with other crops may be needed, these requirements are not expected to be anything beyond common agronomic practices.

V.T.2. Cotton

Although natural outcrossing can occur, cotton is normally considered to be a self-pollinating crop (Niles and Feaster 1984; OECD 2008). Research on cotton cross-pollination reveals that the frequency of cross-pollination falls off rapidly with distance from the pollen source (see Subsection II.D.2.c for additional details). Methods commonly used to ensure seed purity such as isolation distances and rotation cycles that specify a minimum number of years between crops (Conner et al., 2003) would further minimize vertical gene transfer. Gene movement between sexually compatible cotton varieties would be no greater for stacked DGT cotton than it is for other non-GE or GE cultivars. The potential for horizontal gene flow to other unrelated organisms would be highly unlikely (USDA-APHIS, 2012).

With the exception of its tolerances to both dicamba and glufosinate, DGT cotton has been shown to be no different from non-GE cotton in its phenotypic, agronomic, and ecological characteristics including pollen diameter, viability and morphology (see Section VII.C.3 of petition 12-185-01p_a1 for details). Thus, DGT cotton is expected to be no different from other cotton in its ability to cross pollinate with other cotton. In addition, DGT cotton is not different from non-GE cotton in terms of seed dormancy and germination, susceptibility to or tolerance of disease or insect pests, and response to abiotic stressors (such as compaction, drought, high winds, nutrient deficiency, etc.), and would therefore be no different than non-GE cotton in its potential for volunteers and feral populations. In particular, the lack of hard seed, a well-accepted characteristic often associated with plants that are weeds, supports a conclusion of no increased weediness of DGT cotton compared to commercially cultivated cotton (see Appendix G to this Environmental Report. Similarly, a cotton variety including DGT cotton herbicide-tolerance traits with glyphosate tolerance would not be expected to exhibit any weediness characteristics that would pose a plant pest risk.

DGT cotton stacked with other herbicide-tolerant traits may lead to the need to manage volunteer cotton in certain regions, especially in crops with herbicide tolerance to the same mode(s) of action. Management of this cotton may require the use of more narrow spectrum herbicides (such as atrazine in maize), or conventional mechanical control methods. While additional management practices for the control of volunteer stacked cotton varieties in rotation with other crops may be needed, these requirements are not expected to be anything beyond common agronomic practices.

V.T.3. Conclusion

No substantial cumulative effects on gene movement and weediness that would occur from a determination of nonregulated status to DT soybean or DGT cotton have been identified.

V.U. CUMULATIVE IMPACTS: MICROORGANISMS

The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva et al., 2004). A determination of nonregulated status for DT soybean and/or DGT cotton is not expected to result in changes in the current soybean and/or cotton cropping practices, with the exception of potential changes in the use of certain herbicides for weed management and a potential decrease in conventional tillage practices. If DT soybean and/or DGT cotton became commercially available and were stacked with other transgenic herbicide-tolerance traits, depending on the extent of its adoption, it may contribute to sustaining conservation tillage. Stacking DT soybean and/or DGT cotton with glyphosate would enable use of a combination of rates of different herbicide modes of action to be applied to soybean or cotton, an approach proposed to mitigate the future development of herbicide-resistant weeds (Duke and Powles, 2009). Based on individual grower needs, this approach may reduce the need to use conventional tillage to control glyphosate-resistant weeds (Owen, 2011), which could potentially lead to a reduction in crop residue and SOM (Towery and Werblow, 2010). Maintaining adequate residue in the first three inches of the surface provides for a cooler and moister environment, increasing substrates and food for microorganisms (USDA-NRCS, 1996).

Nor do the characteristics of the MON 87708 DMO, MON 88701 DMO or PAT (*bar*) pose any concern to soil microorganisms. The use of dicamba for agricultural purposes was first established in 1967, and EPA recently reaffirmed that the use of dicamba for agricultural purposes does not result in unreasonable adverse effects when applied according to label direction , including soybean and cotton production, with the reregistration in 2006 (U.S. EPA 2009a). Impacts on soil microorganisms have not been raised as an important concern, and results of standardized tests with dicamba and dicamba formulations did not indicate any long term effects on soil microorganisms (Durkin and Bosch 2004). Results of standardized tests with dicamba and dicamba formulations indicate no long-term effects on functional processes of soil microorganisms (carbon respiration and nitrogen transformation) at rates proposed for dicamba on DT soybean and DGT cotton (EFSA 2007b). Glufosinate is currently used on cotton at the rates that would be the same as those used on DGT cotton.

Glyphosate is already used in soybean and cotton in both conventional and glyphosate-tolerant varieties. The herbicide has been previously reviewed by EPA for impacts on the environment and is currently being evaluated as part of the registration review process, scheduled to be completed in 2015 (US-EPA, 1993, 2009a, 2009d). Investigations of the impact of glyphosate on microorganisms are mixed (Weaver et al., 2007). Haney et al. (2002) and Araujo et al. (2003) report that glyphosate is mineralized by microorganisms that leads to an increase in their population and activity, while Busse et al. (2001) and Weaver et al. (2007) found little evidence of changes to soil microorganism's population and activity and any declines recorded were small and not consistent throughout the season. It also has been reported that the use of glyphosate increases the colonization of soil borne fungal pathogens such as Fusarium spp. (Fernandez et al., 2009; Huber, 2010; Kremer and Means, 2009); however, peer reviewed research that report a direct correlation of glyphosate use to an increase in plant disease is limited and any connection to impacts on yield has not been established (Camberato et al., 2011). The total amount of the mix of herbicides that may be applied to DT soybean, DGT cotton or subsequent varieties derived therefrom would be determined in accordance with per application and per year rates approved by EPA. EPA's process ensures that each registered pesticide continues to meet the FIFRA registration standard for human health and the environmental safety. EPA's reregistration and registration review process ensures that each registered pesticide continues to meet the FIFRA registration standard, i.e., that pesticides will not cause unreasonable adverse effects when used as directed on product labels.

As discussed above, use of herbicides on DT soybean and/or DGT cotton alone or if stacked with other herbicide-tolerant or other traits is not expected to increase the overall number of acres to which herbicide would be applied. It would be a violation of federal law to apply these pesticides at application rates or timing that are not approved by EPA.

Based on the above information, there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have a negative impact on microorganisms; rather, there may be slight beneficial cumulative impacts from sustaining conservation tillage rates in soybean and cotton production.

V.V. CUMULATIVE IMPACTS: BIODIVERSITY

A determination of nonregulated status of DT soybean and DGT cotton is not expected to result in changes in the current soybean or cotton cropping practices, with the exception of potential changes in the use of certain herbicides for weed management, and a potential decrease in conventional tillage practices. As discussed above, potential impacts from changes to herbicide usage are outside the scope of APHIS's action and fall instead within the jurisdiction of EPA's oversight of pesticide usage. See Section I.B.

Monsanto has indicated its intention to stack DT soybean and DGT cotton with other nonregulated soy and cotton varieties, particularly varieties conferring tolerance to the herbicide glyphosate. If combined with a glyphosate tolerance trait, DT soybean and DGT cotton would enable growers to use a combination of herbicides with different modes of action on soybean and/or cotton, an approach proposed to mitigate the future development of herbicide-resistant weeds (Duke and Powles, 2009). Based on individual grower needs, this approach may reduce the need to use conventional tillage to control glyphosate-resistant weeds (Owen, 2011). Reduced tillage improves habitat value through increased water quality, availability of waste grain, retention of cover in fields, and increased populations of invertebrates (Brady, 2007; Sharpe, 2010). Incorporation of herbicide tolerance in the crop may facilitate the grower adoption of conservation and no-till strategies, thereby improving soil characteristics enhancing soil fauna and flora (Towery and Werblow, 2010), increasing the flexibility of crop rotation, and facilitating strip cropping (Fernandez-Cornejo et al., 2002), all contributing to the health of the faunal and floral communities in and around soybean fields that promotes biodiversity (Palmer et al., No Date; Sharpe, 2010).

Glyphosate is already used in soybean and cotton in both conventional and glyphosate-tolerant varieties. The herbicide has been previously reviewed by EPA for impacts on the environment and is currently being evaluated as part of the registration review process, scheduled to be completed in 2015 (US-EPA, 1993, 2009a, 2009d). Likewise, dicamba is widely used in agriculture and has been reviewed by EPA for impacts on non-target organisms (U.S. EPA 2009b). The total amount of the mix of herbicides that may be applied to DT soybean soybean, DGT cotton, or subsequent varieties derived therefrom would be used in accordance with per application and per year rates approved by EPA. EPA's reregistration and registration review process ensures that each registered pesticide continues to meet the FIFRA registration standard, i.e., that pesticides will not cause unreasonable adverse effects when used as directed on product labels.

Monsanto is developing a stewardship program that would include technological advancements in application and off-target movement of dicamba for application to DT soybean and/or DGT cotton, with a strong emphasis on grower and applicator training. Monsanto is also seeking U.S. EPA registration of a low volatility dicamba formulation (DGA salt) for ground application only. Monsanto's proposed product label – which is currently pending before EPA – includes specific application requirements, including a no-spray buffer to protect adjacent dicamba-sensitive areas. To further minimize potential impacts from post application volatilitzation, Monsanto would not allow growers to use dimethylamine salt (DMA) of dicamba and/or dicamba acid on DT soybean. These measures, and/or others identified by EPA, will effectively address any potential impact of off-site movement of these herbicides.

As discussed above, use of herbicides on DT soybean soybean and/or DGT cotton alone or if stacked with other herbicide-tolerant or other traits is not expected to increase the overall number of acres to which herbicide would be applied. It would be a violation of federal law to apply these pesticides at application rates or timing that are not approved by EPA.

Based on the above information, there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have an adverse impact on biodiversity.

V.W. CUMULATIVE IMPACTS: HUMAN HEALTH

A determination of nonregulated status of DT soybean and/or DGT cotton would have no adverse impact on human health. The FDA has completed its consultations on the safety of DT soybean and DGT cotton as food and animal feed. Monsanto intends to stack DT soybean and DGT cotton with soybean and cotton lines containing the 5-enolpyruvylshikimate-3-phosphate synthase (cp4 epsps) gene encoding the CP4 EPSPS protein conferring glyphosate tolerance. FDA has previously evaluated the safety of the CP4 EPSPS protein for feed and found no toxic effects to animals (US-FDA, 1995). As specified in 40 CFR §174.523, EPA has reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities (US-EPA, 2012b). This exemption is based on a safety assessment that included rapid digestion in simulated gastric fluids, lack of homology to known toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. The lack of any documented reports of adverse effects since the introduction of other glyphosate crops in 1993 suggests the safety of its use.

Worker safety is taken into consideration by EPA in the pesticide registration process and reregistration process. Pesticides are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. EPA's process ensures that each registered pesticide continues to meet the FIFRA registration standard for human health.

Glyphosate has been widely used on soybean since the first glyphosate-tolerant soybean variety in 1994 was determined to be no longer subject to the regulatory requirements of 7 CFR part

340 or the plant pest provisions of the Plant Protection Act (Heiniger 2000). The use of glyphosate herbicide in accordance with federal law does not result in adverse effects on development, reproduction, or endocrine systems in mammals. Under present and expected use conditions, and when used in accordance with the EPA label, glyphosate does not pose a human health risk. Pesticide residue tolerances for glyphosate are listed in 40 CFR § 180.364 and include acceptable concentrations for soybean seeds (US-EPA, 2011b).

Dicamba has been registered in the U.S. for use on food crops since 1967 (U.S. EPA 2009d) and has been widely used in agricultural production for over forty years. The EPA concluded there is reasonable certainty that no harm will result to the general population, or to infants and children, as a result of aggregate (all) exposure to dicamba residues. Established food and feed tolerances for dicamba are listed at 40 CFR 180.227, and in addition to the crop plants, they include residue limits for meat, milk, and meat by-products that may arise when livestock consume dicamba-treated commodities. The total amount of the mix of herbicides that may be applied to DT soybean, DGT cotton, or subsequent varieties derived therefrom would be used in accordance with per application and per year rates approved by EPA. When used in compliance with the EPA label, pesticides do not cause unreasonable adverse effects to human health and worker safety.

In light of the above information, there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have an adverse impact on human health.

V.X. CUMULATIVE IMPACTS: ANIMAL FEED

A determination of nonregulated status of DT soybean and/or DGT cotton would have no adverse impact on animal health. The FDA has completed its consultations on the safety of DT soybean and DGT cotton as animal feed. Monsanto intends to stack DT soybean and DGT cotton with soybean and cotton lines containing the 5-enolpyruvylshikimate-3-phosphate synthase (cp4 epsps) gene encoding the CP4 EPSPS protein conferring glyphosate tolerance. FDA has previously evaluated the safety of the CP4 EPSPS protein for feed and found no toxic effects to animals (US-FDA, 1995). As specified in 40 CFR §174.523, EPA has reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities (US-EPA, 2012b). This exemption is based on a safety assessment that included rapid digestion in simulated gastric fluids, lack of homology to known toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. The lack of any documented reports of adverse effects since the introduction of other glyphosate crops in 1996 suggests the safety of its use.

Glyphosate has been widely used on soybean since the first glyphosate-tolerant soybean variety was determined to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act in 1994. The use of glyphosate herbicide in accordance with federal law does not result in adverse effects on development, reproduction, or endocrine systems in mammals. Under present and expected use conditions, and when used in accordance with the EPA label, glyphosate does not pose a health risk to animals as an animal feed concern. Pesticide residue tolerances for glyphosate are listed in 40 CFR § 180.364 and include acceptable concentrations for soybean forage, hay, hulls, and seed (US-EPA, 2011b).

Dicamba has been registered in the U.S. for use on food crops since 1967 (U.S. EPA 2009d) and has been widely used in agricultural production for over forty years. A comprehensive safety evaluation and risk assessment conducted by EPA concluded that dicamba has low toxicity to mammals, is not a carcinogen, does not adversely affect reproduction and development, and does not bioaccumulate in mammals (U.S. EPA 2009d). An ecotoxicological risk assessment concluded that the use of dicamba does not pose an unreasonable risk of adverse effects to non-target species, such as birds and fish, when used according to label directions, nor does it pose an unreasonable risk of adverse effects to insects outside of the application area (U.S. EPA 2009d). Established food and feed tolerances for dicamba are listed at 40 CFR 180.227, and in addition to the crop plants, they include residue limits for meat, milk, and meat by-products that may arise when livestock consume dicamba-treated commodities.

The amount of different herbicides that may be applied to DT soybean, DGT cotton, or subsequent varieties derived therefrom would be used in accordance with per application and per year rates approved by EPA. EPA's reregistration and registration review process ensures that each registered pesticide continues to meet the FIFRA registration standard, i.e., that pesticides will not cause unreasonable adverse effects when used as directed on product labels.

In light of the above information, there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have an adverse impact on animal health.

V.Y. CUMULATIVE IMPACTS: DOMESTIC ECONOMIC ENVIRONMENT

There are potential implications of the change in herbicide use as a result of a determination of non-regulated status of DT soybean and/or DGT cotton, particularly with regard to the management of glyphosate-resistant weeds. As discussed above, potential impacts from changes to herbicide usage are outside the scope of APHIS's action and fall instead within the jurisdiction of EPA's oversight of pesticide usage. See Section I.B.

Monsanto has indicated its intention to stack DT soybean and DGT cotton with commercially available soybean and cotton varieties conferring glyphosate tolerance. These stacked varietals have the potential to improve grower management strategies for control of glyphosate-resistant weeds and also improve grower economics.

DT soybean stacked with glyphosate tolerance would enable farmers to choose dicamba, glyphosate, and a mixture of the two for post-emergence weed control. DGT cotton stacked with glyphosate tolerance would allow for the same options, plus the additional ability to apply glufosinate. This herbicide management strategy is anticipated to sustain the long-term viability of the glyphosate-tolerant cropping system and preserve the benefits it provides to growers, the agricultural industry, and society. The adoption of such a diverse weed management strategy, incorporating several herbicides with alternative modes of action, may initially cost more than the conventional single-herbicide approach, but these costs are likely to be offset by an increase in yields in those fields where the weed pressure has been reduced (Weirich et al. 2011).

As discussed previously, both glyphosate-tolerant soy and cotton were rapidly adopted following their introduction in the U.S. and now account for the majority of soy and cotton acres planted. Herbicide-tolerant crops, primarily glyphosate-tolerant, have affected agricultural production globally and similar adoption profiles have occurred in other geographies where glyphosate-tolerant crops have been introduced (*e.g.*, Argentina, Brazil, Canada). Early efforts to characterize the reasons that glyphosate-tolerant crops achieved such rapid adoption focused on profitability, yield, and costs (Carpenter and Gianessi 2001). Information from recent grower surveys cite other non-pecuniary advantages such as simplicity, convenience, flexibility and safety as some of the primary reasons for using glyphosate-tolerant crops (Hurley et al. 2009b). One of the biggest advantages of glyphosate-tolerant cropping systems has been the reduction in labor. The reduction in labor allowed growers more free time to pursue other activities and freed up farm management time for non-farm income.

The adoption of DT soybean and DGT cotton is expected to help maintain the economic and non-pecuniary benefits growers have realized using the glyphosate-tolerant system. These include time and labor savings to growers through the simplicity and flexibility of a dicamba, and glyphosate (and glufosinate for DGT cotton) weed control system over alternative herbicides that are authorized for use in soy and cotton production. In addition, the ability to use dicamba in combination with glyphosate (and glufosinate in the case of cotton) will further preserve the benefits the glyphosate-tolerant system has provided in the form of increasing adoption of conservation tillage acres. The cultivation of DT soybean DGT cotton provides a method to manage the development of glyphosate-, glufosinate- or dicamba-resistant weeds, as well as weeds resistant to other herbicide class of chemistries, and this benefit is expected to outweigh additional costs of controlling resistant weeds through the dicamba, glufosinate, and glyphosate weed control system.

Based on these factors, no net negative cumulative effects on domestic economics have been identified associated with the cultivation of DT soybean and/or DGT cotton. If growers adopt stacked varieties and take advantage of the weed management strategy incorporating herbicides with different modes of action to control glyphosate-resistant weeds, local farm economics may be positively impacted. In light of the above information, there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have an adverse impact on the domestic economic environment.

V.Z. CUMULATIVE IMPACTS: TRADE ECONOMIC ENVIRONMENT

A determination of nonregulated status of DT soybean and DGT cotton, including subsequent stacked herbicide tolerant varieties, are not expected to adversely impact the trade economic environment and may have a positive impact through increased yields in soybean or cotton areas of the U.S. affected by glyphosate-resistant weeds. Current and historic economic evidence indicates that herbicide-tolerant soybean and cotton technology has the potential to increase domestic production at lower cost. This trend of lower production costs could enhance international soybean trade by making U.S. products more competitive in the global market.

The subsequent development and global adoption of these stacked varieties could provide another herbicide-tolerant management choice for growers. As the value and benefits of these products are realized, particularly in areas of the U.S. where glyphosate-resistant weeds have emerged, DT soybean, DGT cotton, and subsequent stacked varieties may have potential for export as a seed product.

In light of the above, there are no past, present, or reasonable foreseeable actions that in aggregate with effects of the proposed action would negatively impact the trade economic environment.

VI. THREATENED AND ENDANGERED SPECIES ANALYSIS

Congress passed the Endangered Species Act (ESA) of 1973, as amended, to prevent extinctions facing many species of fish, wildlife, and plants. The purposes of the Endangered Species Act (ESA) are to provide a means for conserving the ecosystems upon which endangered and threatened species depend and a program for the conservation of such species.[67] To implement the ESA, the U.S. Fish and Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS); other Federal, State, and local agencies; Tribes; non-governmental organizations; and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal list of threatened and endangered wildlife and plants.

A species is added to the list when the USFWS and/or NMFS determined it to be endangered or threatened because of any of the following factors:

The present or threatened destruction, modification, or curtailment of its habitat or range;

Overutilization for commercial, recreational, scientific, or educational purposes;

Disease or predation;

The inadequacy of existing regulatory mechanisms; and

The natural or manmade factors affecting its survival.

In accordance with the ESA, once an animal or plant is added to the list, protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of its action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or critical habitat. To facilitate APHIS' ESA consultation process, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS' regulatory authority and effects analysis for petitions for nonregulated status, and developed a process for conducting an effects determination consistent with the Plant Protection Act of 2000 (Title IV of Public Law 106-224). This process is described in a decision tree document, which has been included in recent Environmental Assessments and the

[67] Endangered Species Act of 1973 (as amended through Public Law 107-136), Section 2(b)

Final Environmental Impact Statement for glyphosate-tolerant H7-1 sugar beet (USDA-APHIS 2011; 2012). APHIS has used this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for GE regulatory actions.

VI.A. POTENTIAL FOR GE PLANT TO AFFECT THREATENED OR ENDANGERED SPECIES

APHIS' regulatory authority over genetically engineered (GE) organisms under the PPA is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR 340.1). EPA has sole authority to regulate the use of any herbicide. After completing a plant pest risk analysis, if APHIS determines that the GE organism does not pose a plant pest risk, then the GE organism would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 and, therefore, APHIS will grant a determination of nonregulated status.

In accordance with the ESA, APHIS will review its action under the PPA relative to the GE organism to determine if its action may affect listed species or critical habitat just as EPA reviews and regulates herbicides to determine impact on threatened and endangered species and/or critical habitats. Monsanto has prepared the information in this Environmental Report to assist APHIS in making this determination from DT soybean and DGT cotton. In its review, for each GE plant, APHIS considers the following information, data, and questions (USDA-APHIS 2012):

A review of the biology and taxonomy of the crop plant and its sexually compatible relatives;

Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;

A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;

A review of the agronomic performance of the plant, including disease and pest susceptibilities, weediness potential, and agronomic and environmental impacts;

Determination of the concentrations of known plant toxicants (if any are known in the plant);

Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species or a host of any threatened or endangered plant or animal species; and

Any other information that may inform the potential for an organism to pose a plant pest risk.

VI.B. POTENTIAL FOR DT SOYBEAN TO AFFECT THREATENED OR ENDANGERED SPECIES

To identify any potential effects of DT soybean on threatened and endangered plant species, the potential for DT soybean to cross with a listed species was evaluated. Soybean is not native to the U.S., and DT soybean is not sexually compatible with any federally listed TES or a native species proposed for listing. Like other *G. max*, DT soybean will likely be a poor competitor with native vegetation and will not survive outside of cultivation (Baker 1965). Thus, DT soybean is not expected to interbreed with any plant species or displace natural vegetation in the U.S.

To identify potential effects on threatened and endangered animal species, the risks to threatened and endangered animals from consuming DT soybean or vegetative materials are considered. In this analysis, the biology of DT soybean and the agricultural practices associated with the cultivation of DT soybean have been considered for potential adverse impact on TES and their critical habitats. Bioinformatics analysis determined that MON 87708 DMO does not share amino acid sequence similarities with known allergens, gliadins, glutenins, or protein toxins. (See Appendix G to this Environmental Report) MON 87708 DMO was rapidly digested in *in vitro* assays using simulated gastric and intestinal fluids and did not show any adverse effects when administered to mice via oral gavage at levels far in excess of that reasonably expected to be consumed by humans or animals. Compared to commercially cultivated soybean, DT soybean does not express any additional proteins or natural toxicants that are known to directly or indirectly affect a listed TES or species proposed for listing by the U.S. Fish and Wildlife Service. Compositional analysis of DT soybean for nutrients and anti-nutrients indicated that the harvested seed and forage from DT soybean were compositionally equivalent to commercially cultivated soybean. Thus, DT soybean would not be expected to have any impacts on TES that would differ from commercially cultivated soybean.

The only TES animal listed that occupies habitat that is likely to include soybean fields and that might feed on soybean is the Federally Endangered Delmarva Peninsula Fox Squirrel, *Sciurus niger cinereus*, found in areas of the mid-Atlantic Eastern seaboard.[68] It is known to utilize certain agricultural lands readily, and its diet includes acorns, nuts/seeds of hickory, beech, walnut, and loblolly pine, buds and flowers of trees, fungi, insects, fruit, and an occasional bird egg. Given its varied diet, the safety of MON 87708 DMO, and the demonstrated compositional, agronomic and phenotypic equivalence of DT soybean to commercially cultivated soybean, it is concluded that no biologically significant changes to the habitat or diet of the Delmarva Peninsula Fox Squirrel are expected. Consequently, the planting of DT soybean is not expected to impact the Delmarva Peninsula Fox Squirrel.

As part of the analysis for TES and critical habitat, Monsanto considered whether DT soybean has any characteristics that may allow the plant to naturalize in the environment and potentially have an effect on TES. In doing so, Monsanto assessed whether DT soybean is any more likely to become a weed than commercially cultivated soybean. Weediness could potentially affect TES or critical habitat if DT soybean were to become naturalized in the environment. As discussed in Section II.D.1.c., cultivated soybean is largely self-pollinating, with minimal gene movement, and no wild (native) or feral species of *Glycine* are found in the U.S. With the exception of its tolerance to dicamba and, DT soybean has been shown to be no different from commercially cultivated soybean in its phenotypic, agronomic and ecological characteristics, including pollen diameter, viability, and morphology. In addition, DT soybean is not different from commercially cultivated soybean in terms of seed dormancy and germination,

[68] Source is from website: http://ecos.fws.gov/tess_public/SpeciesReport.do; [Accessed May 14, 2009].

susceptibility to or tolerance of disease or insect pests, and response to abiotic stressors (such as compaction, drought, high winds, nutrient deficiency, etc.), and would, therefore be no different than commercially cultivated soybean in its potential for volunteers and feral populations. In particular, the lack of hard seed, a well-accepted characteristic often associated with plants that are weeds, supports a conclusion of no increased weediness of DT soybean compared to commercially cultivated soybean. Collectively, this information indicates that DT soybean is no different from commercially cultivated soybean in its weediness potential.

In summary, no stressor associated with the introduction of DT soybean is expected to affect the reproduction, numbers, or distribution of a listed TES, candidate species, or species proposed for listing. As a result, a detailed site-specific (or spatially explicit) exposure analysis for individually listed TES is not necessary. Collectively, all the laboratory and field trial data on DT soybean support the conclusion that there would be no difference with cultivation of DT soybean from effects that would occur from the production of commercially cultivated soybean. Soybean is not native to the U.S., and DT soybean is not sexually compatible with any federally listed TES or a species proposed for listing. Like other *G. max*, DT soybean will likely be a poor competitor with native vegetation and will not survive outside of cultivation (Baker 1965). Thus, DT soybean is not expected to interbreed with any plant species or displace natural vegetation in the U.S.

VI.C. POTENTIAL FOR DGT COTTON TO AFFECT THREATENED OR ENDANGERED SPECIES

To identify any potential effects of DGT cotton on threatened and endangered plant species, the potential for DGT cotton to cross with a listed species was evaluated. Cotton is in the genus *Gossypium* and has the ability to cross with some other species of cotton in the same genus (OECD 2008). A review of the list of threatened and endangered plant species in the U.S. shows that DGT cotton would not be sexually compatible with any listed threatened or endangered plant species, species proposed for listing, or candidate species, as none of these listed, proposed, or candidate species are in the same genus or known to cross pollinate with species of the genus *Gossypium* (USFWS 2012; 2013). As discussed in Section II.D.2.c., there is only one native *Gossypium* species found in U.S. cotton-growing regions, in Arizona, and cross-pollination of th*at specie*s with commercial cotton would not produce fertile offspring (Fryxell 1984; Waghmare et al. 2005).

To identify potential effects on threatened and endangered animal species, the risks to threatened and endangered animals from consuming DGT cotton, cottonseed or vegetative materials are considered. As discussed in Appendix G to this Environmental Report, there is no difference in the composition and nutritional quality of DGT cottonseed compared with commercially cultivated cottonseed. The allergenicity and toxicity of the MON 88701 DMO and PAT(*bar*) proteins were also evaluated. The research summarized and referenced in Appendix G found no differences in allergenicity and toxicity compared to the analogous protein in commercially cultivated cotton. Both types of proteins are ubiquitous in nature and normally present in food and feeds derived from these plant and microbial sources. As discussed in Appendix G, during field trials with DGT cotton, no biologically relevant changes in arthropod feeding damage were observed, indicating similar arthropod susceptibility for DGT cotton compared to commercially cultivated cotton. As DGT cotton exhibits no toxic effects on insects or other animals it is concluded that they will not be affected. In addition, the cultivation of DGT cotton does not impact the nutritional quality, safety or availability of animal feed. Based on these results, no effects to any TES animal species (or candidate species, or species proposed for listing) that may feed on DGT cotton plant parts would be expected.

As part of the analysis for TES and critical habitat, Monsanto considered whether DGT cotton has any characteristics that may allow the plant to naturalize in the environment and potentially have an effect on TES. In doing so, Monsanto assessed whether DGT cotton is any more likely to become a weed than commercially cultivated cotton. Weediness could potentially affect TES or critical habitat if DGT cotton were to become naturalized in the environment. As discussed in Section II.D.2.c, cultivated cotton is largely self-pollinating, and no wild (native) or feral species of *Gossypium* have been found in cotton-growing areas. As discussed in Appendix G, with the exception of its tolerances to both dicamba and glufosinate, DGT cotton has been shown to be no different from commercially cultivated cotton in its phenotypic, agronomic and ecological characteristics, including pollen diameter, viability, and morphology. In addition, DGT cotton is not different from commercially cultivated cotton in terms of seed dormancy and germination, susceptibility to or tolerance of disease or insect pests, and response to abiotic stressors (such as compaction, drought, high winds, nutrient deficiency, etc.), and would, therefore be no different than commercially cultivated cotton in its potential for volunteers and feral populations. In particular, the lack of hard seed, a well-accepted characteristic often associated with plants that are weeds, supports a conclusion of no increased weediness of DGT cotton compared to commercially cultivated cotton. Collectively, this information indicates that DGT cotton is no different from commercially cultivated cotton in its weediness potential.

In summary, no stressor associated with the introduction of DGT cotton is expected to affect the reproduction, numbers, or distribution of a listed TES, candidate species, or species proposed for listing. As a result, a detailed site-specific (or spatially explicit) exposure analysis for individually listed TES is not necessary. Collectively, all the laboratory and field trial data on DGT cotton support the conclusion that there would be no difference with cultivation of DGT cotton from effects that would occur from the production of commercially cultivated cotton. Cotton is not sexually compatible with, nor does it serve as a host species for, any listed species, candidate species or species proposed for listing. Based on the characteristics of the introduced protein and comparative compositional assessments, consumption of DGT cotton by any listed species or species proposed for listing will not result in a toxic or allergic reaction.

VI.D. POTENTIAL IMPACTS OF DICAMBA USE ON THREATENED AND ENDANGERED SPECIES

As discussed above, APHIS met with USFWS officials on June 15, 2011 to discuss whether APHIS has any obligations under the ESA to analyze the impacts of herbicide use associated with all GE crops on TES. As a result of these joint discussions, the USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on herbicide use associated with GE crops. As discussed elsewhere in this document, EPA has the sole authority to authorize or regulate the use of dicamba, or any other herbicide, by soybean and cotton growers. Under 7 CFR 340, APHIS only has the authority to regulate DT soybean and DGT cotton or any GE organism if the agency believes it may pose a plant pest risk. The

Ninth Circuit in *Center for Food Safety v. Vilsack* confirmed this point specifically regarding herbicide uses, concluding that the ESA's consultation duty is triggered only when the agency has authority to take action and discretion to decide what action to take.[69] In that case, APHIS had reached an ESA "no effect" conclusion as to the plant specifically, which was not challenged. The plaintiffs contended, however, that APHIS was required to perform an ESA consultation as to the herbicide. But APHIS lacked authority over the herbicide uses. Once APHIS concluded that RRA was not a plant pest, the agency had no jurisdiction to continue regulating the crop as a plant pest.[70] The agency's deregulation of RRA was thus a nondiscretionary act that did not trigger the agency's duty to consult under the ESA regarding herbicide uses.[71] In this instance, APHIS has no obligation under NEPA or the ESA to consider the effects on TES of herbicide use associated with DT soybean or DGT cotton crops. Nor does APHIS have an obligation to consult with the USFWS under the ESA given that the GE crops do not constitute plant pest risks. EPA is responsible for evaluating the effects on TES of herbicides on cotton and soybean, and EPA will only approve the use of dicamba on DT soybean and DGT cotton if it determines that the uses will not affect threatened and endangered species. Details of EPA's Endangered Species Protection Program (ESPP) and TES evaluation program, as well as the ecological risks of dicamba are discussed in Appendices A and F to this Environmental Report.

It is important to note that the use of herbicides in the production of soybean and cotton would not be unique to the production of DT soybean and DGT cotton, and DT soybean and DGT cotton are not dependent on the use of dicamba for their production lifecycles. As noted in Section II.B.2.d, herbicides are used on over 99% of cotton acres. Various herbicides other than dicamba are typically used to control weeds during production of commercially cultivated cotton, and these herbicides could presumably be used in production of DGT cotton. An analysis of herbicide use in cotton and the associated risks are described in more detail in Appendices A and F to this Environmental Report.

Conservation tillage and no-till practices have a positive impact on wildlife (Towery and Werblow 2010). Benefits include decreased soil erosion and improved water quality in receiving waters, retention of cover, availability of waste grain on the soil surface for feed, and increased populations of invertebrates as a food source (Sharpe 2010). As described in Sections II.B.1.c and II.B.2.c, the use of herbicides, particularly with herbicide-tolerant crops, facilitates the use of conservation tillage practices.

Monsanto has requested approval of the use of a low-volatility DGA dicamba formulation on DT soybean and DGT cotton by amending the label for EPA Registration Number 524-582. In the EPA's review of this registration request, they will apply the same statutory-based regulatory requirements as they do to all pesticides. Because the proposed use of dicamba on DT soybean and DGT cotton falls within the use rate limits established by EPA in the 2006

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69 Ctr. for Food Safety v. Vilsack, 718 F.3d at 842.

70 *Id.*

71 *Id.*

RED, it can be concluded that risks to non-target organisms from the use of dicamba on DT soybean and DGT cotton have been assessed. Pending EPA approval, additional application requirements will be included in the FIFRA label to further limit dicamba offsite movement. In addition, Monsanto is implementing a robust stewardship program that will include a strong emphasis on grower and applicator training. Furthermore, prior to commercialization of DT soybeans and DGT cotton, Monsanto will implement an endangered species mitigation system for dicamba. The implemented system will either be an EPA-specific system and/or a web-based system, similar to that currently available for glyphosate at PreServe.org. This will facilitate applicator and grower implementation of use restrictions for protection of threatened and endangered non-monocotyledonous terrestrial plant species. Glufosinate is currently undergoing Registration Review at EPA, which will take into consideration glufosinate's potential impact on endangered species (U.S. EPA 2008b).

In addition to the web-based endangered species mitigation system for dicamba, Monsanto will take steps to manage dicamba offsite movement through inclusion of specific application requirements on the proposed FIFRA as EPA directs. The authority to restrict the use of pesticides or impose measures to mitigate their risk belongs solely to EPA; no other agency has the regulatory authority. For example, Monsanto's proposed label restrictions for in-crop use on DT soybean and DGT cotton—which are currently pending before EPA—include, but are not limited to: a ban on aerial applications; the use of low-volatility formulations; restrictions on spray nozzle use to ensure larger droplets are applied; restrictions on boom height for pesticide applications; and for certain limited use areas, buffers and other application limitations based on wind speed and other factors specifically designed to prevent spray drift from having any effect on threatened or endangered plants (or obligate plants or critical habitat relied on by a small number of endangered species). These label restrictions, and/or any other measures imposed by EPA, will ensure that there is no effect on threatened and endangered species from the use of dicamba on DT soybean and DGT cotton. Furthermore, to provide growers with specific information for dicamba applications to dicamba-tolerant crops, Monsanto is implementing a robust stewardship program that will include a strong emphasis on grower and applicator training.

In lengthy and detailed submissions to EPA over the past two years, Monsanto has established the scientific predicate for its conclusions that these specific measures will preclude the dicamba applications at issue from having an effect on threatened or endangered species. Specifically, Monsanto has submitted the following reports on the potential impacts on threatened and endangered species of dicamba use over the top of DT soybean:

- Determination of Dicamba Residue Decline in Forage after Application to Dicamba-Tolerant Soybean MON 87708 × MON 89788. Feb. 27, 2012
- Honegger, *Overview for Plant Taxa*, Dec. 20, 2012 ["Plant Overview"];
- Frank and Kemman, A County-Level Analysis for Plant Taxa, Dec. 20, 2012;
- Carr and Leopold, Sub-County Proximity Analysis for Listed Plants: Part 1 of 2: Western U.S. States and Hawaii, Dec. 20, 2012;

- Carr and Leopold, Sub-County Proximity Analysis for Listed Plants: Part 2 of 2: Eastern U.S. States, Dec. 20, 2012;
- Carr and Leopold, Sub-County Proximity Analysis for Listed Plants: Iowa, Apr 4, 2013;
- Wright, et. al, An Evaluation of Potential Exposure and Biological Effects, Jan. 25, 2013;
- Honegger, Overview of an Evaluation of Potential Exposure and Biological Effects, Mar. 12, 2013 [hereinafter "Overview"];
- Schuler, et. al, Refined Analysis for Terrestrial Animals, Mar. 12, 2013;
- Frank and Kemman, A County-Level Analysis for Animal Taxa (2013 Update), Mar. 12, 2013;
- Schuler, et. al., Indirect Effects Analysis for Terrestrial Animals, Apr. 4, 2013;
- Honegger, Overview of Proposed Approach to Address the Potential for Off-site Movement from Use of Dicamba on Dicamba-Tolerant Soybeans, Aug. 7, 2012;
- Orr, et. al., Concordance of MON 54140 Buffer Distances Determined using Field Spray Drift Studies and AgDRIFT®, Mar. 12, 2013;
- Wright, Potential Effects of MON 54140 on Soybean Plants when Applied at Low Application Rates in the Field, Aug. 7, 2012;
- Orr, et. al., Summary of Investigations of the Potential for Off-Site Movement through the Air of the Herbicide MON 54140 Following Ground Applications, Jul. 17, 2012; and
- Sall, et. al., Measurement of the Volatile Flux of Dicamba under Field Conditions using the Theoretical Profile Shape Method, April 22, 2013.

In addition, Monsanto has submitted the following reports on the potential impacts on threatened and endangered species of dicamba use over the top of DGT cotton:

Honegger et al., An Evaluation of Potential Exposure and Biological Effects. October 8, 2013.
Honegger, Overview of an Evaluation of Potential Exposure and Biological Effects to Animals October 8, 2013.
Carr and Orr, Potential Exposure and Effects for Listed Plants, October 8, 2013.
Schuler, et al., Indirect Effects Analysis for Terrestrial Animals, October 8, 2013.
Schuler, et al., Refined Analysis for Terrestrial Animals, October 8, 2013.

Frank and Kemman, A County-Level Analysis for Animal Taxa, October 8, 2013.
Frank and Kemman, A County-Level Analysis for Plant Taxa, October 8, 2013.

The reports describe the risk assessment process prescribed by EPA to carry out its particular duties with respect to the ESA, i.e., analyzing the risk of direct effects of dicamba to threatened and endangered species in association with DT soybean and DGT cotton cultivation. As described therein, for both TES animals and plants, Monsanto first conducted the type of screening-level analyses set forth in EPA's *Overview Document*. Using the maximum use pattern set out in the proposed label at issue, which is currently pending before EPA, Monsanto estimated exposure of designated animal and plant taxa using current EPA environmental exposure models. Monsanto then utilized these conservative exposure estimates, in conjunction with effects values for species of designated taxa derived from toxicity tests meeting EPA quality standards, to calculate risk quotients (RQs). If the RQ value, calculated by dividing the estimated exposure by the appropriate toxicity value, was less than the Level of Concern (LOC) for TES in the designated taxa, Monsanto concluded that risks to a taxonomic category could be excluded from concern because of the conservative nature of the screening-level assessment assumptions and, therefore, that there would be no effect on the relevant threatened or endangered species. Monsanto undertook a similar analysis at the screening level to evaluate potential indirect effects on threatened and endangered species and potential effects on critical habitat, thereby enabling Monsanto to exclude from concern such effects on certain species.

Again, following EPA's *Overview Document*, Monsanto next conducted a more detailed, county-level analysis for taxonomic groups (and associated listed species) that could not be excluded from concern at the screening level. This analysis identified: (i) all counties indicated as having soybean / cotton farms in the last three Ag. Census (1997, 2002, and 2007) as having "potential" for soybean production, and (ii) every endangered species within those counties in the taxonomic groups that had not been excluded from concern at the screening level. A "no effect" determination could then be made for species "co-occurrences" based on a number of exclusions (*e.g.*, product property, habitat, not of concern, proximity, diet, and feeding) or on state or federally recognized protections.

For animals, this analysis expressly recognized and took into account the fact that the animals at issue may move from location to location. Specifically, the feeding and diet exclusions for animals are based on inherent characteristics of the individual endangered species and are not in any way impacted by where the species is physically present. The "not of concern" designation is provided *only* where the species has not been reported in the county in the past 35 years, or where FWS does not include the county on the list of counties where the species is known or believed to occur in the county (or where the species has been delisted). The habitat exclusion applies only where the individual endangered species' habitat is not suitable for agricultural production. Finally, the proximity exclusion only applies when land relevant for soybean production is not within a relevant species' "home range" – *i.e.*, the area within which the species lives and travels, based on information from FWS and other sources.

For co-occurrences of listed plant species not excluded from concern based on the county level analysis, a refined sub-county analysis was undertaken to assess the proximity of reported species observations to relevant land use for soybean / cotton production. In addition, mitigation measures were proposed, where necessary, to prevent effects on such plant species in certain use limitation areas. For more details on Monsanto's ESA assessment for dicamba, see Appendix F to this Environmental Report. Based on these analyses, and any further analysis conducted by Monsanto and/or US EPA, U.S. EPA, who has the sole authority to authorize or regulate the use of dicamba, or any other herbicide, will be positioned to comply fully with its ESA obligations with respect to dicamba use on DT soybean and DGT cotton.

VII. CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS, AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

VII.A. EXECUTIVE ORDERS (EO) WITH DOMESTIC IMPLICATIONS

The following EOs require consideration of the potential impacts of the Federal action to various segments of the population.

> EO 12898 (US-NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.
>
> ***EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks,"*** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

The No Action and Deregulation in Whole Alternatives were analyzed with respect to EO 12898 and EO 13045. Neither alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

Available mammalian toxicity data associated with the MON 88701 DMO and PAT (*bar*) proteins establish the safety of DT soybean and DGT cotton and their products to humans, including minorities, low-income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken.

Based on the information submitted Monsanto, DT soybean and DGT cotton are agronomically, phenotypically, and biochemically comparable to conventional soybean and cotton except for the introduced DMOs (both DT soybean and DGT cotton) and PAT (*bar*)

(DGT cotton) proteins. The information provided in the petition indicates that the proteins, DMO and PAT (*bar*), expressed in DT soybean and/or DGT cotton are not expected to be allergenic, toxic, or pathogenic in mammals (USDA Petitions 10-188-01p and 12-185-01p). Also, FDA has completed biotechnology consultations on both proteins in the context of other food and feeds and indicated that they had no questions (Appendix I).

Human toxicity has also been thoroughly evaluated by the EPA in its development of pesticide labels for both dicamba (U.S. EPA 2009a; d). Pesticide labels include use precautions and restrictions intended to protect workers and their families from exposures.[72] APHIS assumes that growers will adhere to these legally-binding herbicide use precautions and restrictions. As discussed in Subsection IV.E, Human Health and Safety Impacts, the potential use of dicamba on DT soybean and dicamba and glufosinate on DGT cotton at the proposed application rates would be no more than that currently approved for other crops and found by the EPA not to have adverse impacts to human health when used in accordance with label instructions. It is expected that EPA and USDA ERS would monitor the use of DT soybean and DGT cotton to determine impacts on agricultural practices, such as chemical use, as they have done previously for herbicide-tolerant products.

Based on these factors, a determination of nonregulated status of DT soybean and DGT cotton is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

The following executive order addresses Federal responsibilities regarding the introduction and effects of invasive species:

> ***EO 1311 (US-NARA, 2010),"Invasive Species,"*** states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause.

Soybean and cotton are not listed in the U.S. as a noxious weed species by the Federal government nor are they listed as an invasive species by major invasive plant data bases. Cultivated soybean and cottonseed do not usually exhibit dormancy and requires specific environmental conditions to grow as a volunteer the following year (OECD 2000b; 2008). Any volunteers that may become established do not compete well with the planted crop and are easily managed using standard weed control practices. Soybean and cotton are not considered invasive species. Based on the information submitted by the applicant and assessed by APHIS, DT soybean and DGT cotton are agronomically, phenotypically, and biochemically comparable to conventional soybean and cotton except for the introduced DMO and PAT (*bar*) proteins.

72 In order to approve a new use of a herbicide EPA must conclude that the herbicide, when used according to the label, does not pose an unreasonable adverse effect to humans or the environment, including agricultural workers and bystanders (e.g., farm families). Furthermore, the Worker Protection Standard requires the inclusion of precautionary language in the **Agricultural Use Requirments** box on the pesticide label. This language includes directions for the use and handling of personal protective equipment (PPE) to manage exposure to the worker and also serves to reduce exposure to the farm family from contaiminated clothing.

Therefore, they would not be expected to have invasive characteristics different from commercially available soybean and cotton.

The following executive order requires the protection of migratory bird populations:

> ***EO 13186 (US-NARA, 2010), "Responsibilities of Federal Agencies to Protect Migratory Birds,"*** states that Federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Migratory birds may be found in soybean and cotton fields. While soybean and cotton do not meet the nutritional requirements for many migratory birds (Krapu et al., 2004), they may forage for insects and weed seeds found in and adjacent to soybean and cotton fields. As discussed in Sections IV.D.1.a and IV.D.2.a (Animal Communities) data submitted by the applicant has shown no difference in compositional and nutritional quality of DT soybean and DGT cotton compared with other GE or non-GE soybean and cotton, apart from the presence of the introduced proteins. DT soybean and DGT cotton are not expected to be allergenic, toxic, or pathogenic in mammals. The expressed proteins in DT soybean and DGT cotton have a history of safe consumption in the context of other food and feeds. The FDA has completed its food safety consultation on the MON 87708 DMO protein in DT soybean and the MON 88701 DMO and PAT (*bar*) protein in DGT cotton (Appendix I). Based on APHIS' assessment of DT soybean and DGT cotton, it is unlikely that a determination of nonregulated status of DT soybean and DGT cotton would have a negative effect on migratory bird populations. The environmental effects associated with dicamba are included in the EPA RED for the herbicide (U.S. EPA 2009a; d). Testing indicates that dicamba, when used as directed by the U.S. EPA label, does not pose an unreasonable risk of adverse effects to birds (U.S. EPA 2009a; d). Based on these factors, it is unlikely that the determination of nonregulated status of DT soybean and DGT cotton would have a negative effect on migratory bird populations.

VII.B. INTERNATIONAL IMPLICATIONS

EO 12114 (US-NARA, 2010), "Environmental Effects Abroad of Major Federal Actions," requires Federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken.

Significant environmental impacts outside the U.S. are not expected in the event of a determination of nonregulated status of DT soybean and DGT cotton. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new soybean and cotton cultivars internationally apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of DT soybean and/or DGT cotton subsequent to a determination of nonregulated status would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection

Convention (IPPC) (IPPC, 2010). The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). In April 2004, a standard for Pest Risk Analysis (PRA) of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through The Cartagena Protocol on Biosafety is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity of LMOs, which include those modified through biotechnology. The Protocol came into force on September 11, 2003, and 160 countries are Parties to it as of December 2010 (CBD, 2010). Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol and the required documentation. LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII, 2010). These data will be available to the Biosafety Clearinghouse.

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the OECD. NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures (RSPM) No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO, 2009).

APHIS also participates in the North American Biotechnology Initiative (NABI), a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico, and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including Argentina, Brazil, Japan, China, and Korea.

VII.C. IMPACTS ON UNIQUE CHARACTERISTICS OF GEOGRAPHIC AREAS

A determination of nonregulated status of DT soybean and DGT cotton is not expected to impact unique characteristics of geographic areas such as park lands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

Monsanto has presented results of agronomic field trials for DT soybean and DGT cotton (Appendix G). The results of these field trials demonstrate that there are no differences in agronomic practices in DT soybean and DGT cotton when compared to commercially available soybean and cotton. The common agricultural practices that would be carried out in the cultivation of DT soybean and DGT cotton are not expected to deviate from current practices, including the use of EPA-registered pesticides. There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of DT soybean and DGT cotton. This action would not convert land use to nonagricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted DT soybean and DGT cotton, including the use of EPA-registered pesticides. The adherence to EPA label use restrictions for all pesticides is expected to mitigate potential impacts to the human environment. With regard to pesticide use, a determination of nonregulated status of DT soybean and DGT cotton is likely to result in changes to the use of dicamba on soybean and cotton. The potential changes in herbicide use, including application rates and annual maximum allowable applications, are discussed in Section IV.A. Monsanto has submitted applications to EPA to provide for this change in use for dicamba on DT soybean and DGT cotton (there is no expected change in glufosinate use from the currently approved application rate for cotton). APHIS assumes that any new EPA label would provide for label use restrictions intended to mitigate potential impacts to the human environment, including potential impacts to unique geographic areas. As noted above, APHIS further assumes that the grower will closely adhere to EPA label use restrictions for all pesticides.

In 2009, the EPA completed a reregistration analysis for dicamba which considered human health risk and ecological risks associated with potential exposure to dicamba in multiple pathways (U.S. EPA 2009a; d). Although some risks were identified, the EPA determined that these risks could be mitigated by modifying the approved label application rates and spray droplet size (U.S. EPA 2005c). The EPA has also evaluated the potential effect of dicamba on salmon in eleven areas of California and Southern Oregon[73] in response to the consent agreement reached in the Washington Toxics lawsuit.[74] The conclusion of EPA's risk assessment is as follows:

[73] These areas are called Evolutionarily Significant Units based on the salmonid populations present in these areas.

[74] Washington Toxics Coalition v. Environmental Protection Agency, 413 F.3d 1024 (9th Cir. 2005).

"Regardless of the specific dicamba compounds, I conclude that dicamba compounds with currently registered uses will have "no effect" on listed Pacific salmon and steelhead and their critical habitat…" (U.S. EPA 2003).

Glufosinate-ammonium was first registered for home use with the EPA in 1993 (OSTP, 2001). It is currently labeled under the trade name Ignite® 280 SL by Bayer CropScience LP (Bayer Crop Science 2007). The EPA is currently conducting a Registration Review for glufosinate with a forthcoming final decision scheduled in 2013 (U.S. EPA 2008b). The Agency plans to conduct a comprehensive ecological risk assessment, including an endangered species assessment, for all glufosinate-ammonium uses. The Agency has requested additional aquatic nonvascular plant data to evaluate the extent of risk to aquatic plants imposed by the application of glufosinate-ammonium. The EPA's Final Work Plan for Registration Review (U.S. EPA 2008b) states:

"The planned ecological risk assessment will allow the Agency to determine whether glufosinate-ammonium use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitat. If the assessment indicates that glufosinate-ammonium "may affect" a listed species or its designated critical habitat, the assessment will be refined. The refined assessment will allow the Agency to determine whether use of glufosinate-ammonium is "likely to adversely affect" the species or critical habitat or "not likely to adversely affect" the species or critical habitat. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Services), as appropriate."

Submittals to this analysis can be found at the Regulations.gov website under docket designation EPA-HQ-OPP-2008-0190. Labeled uses of glufosinate are approved pending the outcome of the EPA's ecological risk analysis.

Based on these findings, including the assumption that label use restrictions are in place to protect unique geographic areas and that those label use restrictions are adhered to, a determination of nonregulated status DT soybean and DGT cotton is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

VII.D. NATIONAL HISTORIC PRESERVATION ACT (NHPA) OF 1966 AS AMENDED

The NHPA of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to:

> (1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties, and (2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

APHIS' proposed action, a determination of nonregulated status of DT soybean and DGT cotton is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; APHIS' Preferred Alternative would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of non-regulated status of DT soybean and DGT cotton. APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition, with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the soybean production regions. The cultivation of DT soybean and DGT cotton is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

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Appendix A: Dicamba Herbicide Usage, Herbicide Displacement, and Comparative Analysis of Alternative Registered Herbicides

TABLE OF CONTENTS

TABLES AND FIGURES

A.1. INTRODUCTION AND OVERVIEW

Herbicides have provided soybean and cotton growers with the most cost-effective way to manage weeds. Herbicides are used on 98% of soybean acres and more than 35 different herbicides are approved for use in soybean cultivation. Herbicides are also used on 99% of cotton acres and more than 45 different herbicides have been used in cotton from 2002-2011. Glyphosate is the most widely used soybean and cotton herbicide, and it is used on 97% of soybean acres and 91% of cotton acres (USDA-NASS, 2007; Monsanto, 2012).

Growers base their herbicide decisions on a number of factors including weed species, tillage practices, herbicide price and efficacy, and weed resistance considerations. Public and private sector weed scientists have recommended the use of multiple herbicide modes-of-action in agricultural crop production to provide broad spectrum weed control, to delay the evolution and development of weed resistance, and to control weeds that are already resistant to a particular herbicide or herbicide mode-of-action. Recent recommendations for the use of multiple modes-of-action in mixtures, sequences, and/or rotation are based on studies that have shown resistance can be mitigated, contained, and managed through good management practices (Beckie and Reboud 2009; Neve et al., 2011). In particular, simultaneously using two herbicides with different modes-of-action significantly reduces the probability of weeds developing resistance to either or both herbicides (Beckie and Reboud, 2009; Powles et al., 1996). Consequently, soybean and cotton growers have increasingly incorporated herbicides with other modes-of-action (*i.e.*, non-glyphosate herbicides) into their weed management practices. Current market research has demonstrated that growers are adopting weed management practices that utilize multiple herbicide modes-of-action (Givens et al., 2009; Hurley et al., 2009; Price et al., 2012).

The use of non-glyphosate herbicides is expected to continue to grow. In fact, it is reasonable to expect that the use of non-glyphosate herbicides with other modes-of-action will continue with or without the deregulation of dicamba-tolerant soybean, designated as event MON 87708 ("DT soybean"), or dicamba- and glufosinate-tolerant cotton, designated as event MON 88701("DGT cotton"). However, the deregulation of DT soybean and DGT cotton will provide growers with the ability to integrate new uses of dicamba into soybean and cotton weed management systems that include other herbicides and/or mechanical and cultural practices, all of which contribute to mitigating the evolution and development of herbicide resistance.

Recent publications by Mortensen et al. (2012) and Benbrook (2012) suggest that the commercialization of dicamba-tolerant soybean and associated use of dicamba will only be additive to current herbicide use. Additionally, Mortensen claims that this use could result in a "profound" increase in overall herbicide use (Mortensen et al., 2012). Contrary to these publications, the available data support the conclusion that dicamba will displace some herbicides currently used in soybean and cotton cultivation, and that the increase in total herbicide use when DT soybean and DGT cotton are commercialized will be consistent with weed resistance best management practices being recommended by public and private sector weed scientists with the desire to maintain optimum crop yields.

A.2. BACKGROUND ON DICAMBA USE IN THE U.S.

Dicamba was approved by the U.S. Environmental Protection Agency (EPA) for agricultural uses in 1967 (EPA 2009b). Dicamba is formulated as a stand-alone herbicide product and marketed by several companies under various trade names—including Banvel®, Clarity®, Diablo®, Rifle®, and Sterling®—that are various salt formulations of dicamba. These dicamba products can be tank mixed with one or more active ingredients depending on the treated crop. For example, Clarity® can be tank mixed with over 75 herbicide products in labeled crops. Additionally, dicamba is formulated as a registered premix product with one or more other herbicide active ingredients such as 2,4-D, atrazine, diflufenzopyr, glyphosate, halosulfuron, metsulfuron, nicosulfuron, primsulfuron, rimsulfuron, and triasulfuron. Dicamba herbicide (*e.g.*, Clarity® – diglycolamine [DGA] salt of dicamba) is currently labeled for weed control in soybean, corn, cotton, sorghum, wheat, barley, oats, millet, pasture, rangeland, asparagus, sugarcane, turf, grass grown for seed, conservation reserve programs, and fallow croplands.

Table A-1 provides a summary of dicamba-treated acres (*i.e.*, crop acreage that has dicamba applied to it) and the amount of dicamba acid equivalent applied for all labeled crops each year from 1990 through 2011. Dicamba-treated acreage has ranged from 17.4 to 36.3 million acres during this period. Usage of dicamba peaked during the period of 1994 through 1997 (1994 being the peak year, with 36.3 million acres treated with 9.4 million pounds of dicamba). After 1994, the use of dicamba steadily declined through 2006 to 17.4 million treated acres with 2.7 million pounds used, due to the competitive market introductions of sulfonylurea herbicides (chlorsulfuron, metsulfuron-methyl, and thifensulfuron-methyl) in wheat, new broadleaf herbicide active ingredients in corn, and glyphosate-tolerant corn. However, dicamba-treated acres have increased by as much as 4.0 million acres since 2006. Most of the increase in dicamba-treated acres has occurred in fallow, pastureland, sorghum, and cotton (Monsanto, 2012). Dicamba-treated acres have increased in cotton, in particular, because it is a common preplant herbicide recommendation for glyphosate-resistant marestail (horseweed) and Palmer amaranth in the Midsouth region (McClelland et al., 2006). Approximately 25.3 million acres of crops were treated with dicamba in 2011 (see Table A-2 for a summary of the dicamba-treated acres by crop in 2011). Based on USDA-NASS (2005, 2007, 2010, 2011, and 2012) statistics, dicamba application rates ranged from 0.07 to 0.24 pounds per acre with the average number of applications ranging from 1 to 1.9 applications per cropping season. Dicamba rates are lowest in barley, wheat and oats, where typically more than one application is made in these crops per cropping season (see Table A-3)

Table A-1. Dicamba Use in All Labeled Crops from 1990 to 2011[1]

Year	Treated Acres (000,000 acres)	Dicamba (a.e.) (000,000 lbs)
1990	26.8	6.7
1991	24.5	6.3
1992	30.3	7.4
1993	27.7	7.0
1994	36.3	9.4
1995	34.3	8.7
1996	33.3	8.2
1997	33.1	8.6
1998	32.2	8.0
1999	29.8	6.3
2000	29.4	5.4
2001	30.6	5.4
2002	29.4	5.0
2003	27.1	4.3
2004	22.3	3.9
2005	21.3	3.4
2006	17.4	2.7
2007	18.6	2.7
2008	20.2	2.7
2009	21.5	3.1
2010	20.3	3.3
2011	25.3	3.8

[1] Source is Monsanto (2012).

Shaded bar indicates the year with maximum dicamba-treated acres.

Table A-2. Dicamba-Treated Acres and Amounts Applied to Labeled Crops and Uses in 2011[1]

Crop	Total Crop Acres (000)	Dicamba-Treated Acres (000)	% U.S. Dicamba-Treated Acres[2]	% Crop Acres Treated with Dicamba[3]	Dicamba (a.e.) (000 lbs)
Asparagus	29	2	0.01	NA	<1
Barley	2,460	80	0.3	3.2	6
Corn	92,146	10,880	43.0	10.3	1,531
Cotton	14,533	1,416	5.6	9.6	364
Fallow	14,899	3,966	15.7	18.7	597
Pastureland	95,532	2,009	7.9	2.0	438
Sorghum	5,315	1,316	5.2	18.1	206
Soybean	74,835	872	3.4	1.2	233
Sugarcane	825	163	0.6	15.6	36
Wheat, all	53,223	4,532	17.9	7.4	418
All other uses	NA	65	0.3	NA	9
Total		**25,301**	**100.0**		**3,837**

NA denotes not applicable.
[1] Source is Monsanto (2012).
[2] The percentage of the total dicamba-treated acres for all labeled crops and uses.
[3] Percentages calculated from crop acres treated with dicamba (data not shown).

Table A-3. Dicamba Applications – Average Number and Rates to Labeled Crops[1]

Crop	# of Dicamba Applications	Rate of Dicamba per Application	Rate of Dicamba per Crop Year
Corn	1.2	0.209	0.249
Cotton	1.0	0.244	0.244
Sorghum	1.9	0.159	0.298
Soybean	1.0	0.223	0.223
Barley	1.0	0.112	0.112
Wheat, spring	-	0.110	0.113
Wheat, winter	1.7	0.149	0.247
Oats	1.00	0.066	0.066

[1]USDA-NASS, 2005 (oats), 2007 (cotton), 2010 (corn), 2011 (barley & sorghum), 2012 (soybean & wheat)

A.3. IMPACT OF DT SOYBEAN DEREGULATION

A.3.1. Impact of DT Soybean Deregulation on Dicamba Use

Monsanto has developed DT soybean to offer growers an expanded use of the herbicide dicamba in soybean production. DT soybean will facilitate a wider window of dicamba application in soybean, allowing preemergence application up to the day of crop emergence (cracking) and in-crop postemergence applications through the R1/R2 growth stage. DT soybean will be combined with glyphosate-tolerant soybean utilizing traditional breeding techniques. The combination of herbicide-tolerance traits will allow the pre- and postemergence use of both dicamba and glyphosate herbicides in a diversified weed management program to control a broad spectrum of grass and broadleaf weed species (Johnson et al., 2010). Increasing postemergence herbicide options is important, especially in conservation tillage situations, where the performance consistency of postemergence herbicides has generally been greater than that of soil active residual products. Dicamba will offer an effective control option for glyphosate-resistant broadleaf weed species, namely marestail, common ragweed, giant ragweed, palmer pigweed, and waterhemp, as well as improve control of glyphosate's hard-to-control broadleaf weeds (*e.g.*, common lambsquarters, hemp sesbania, morningglory species, nightshade, Pennsylvania smartweed, prickly sida, and wild buckwheat) (Johnson et al., 2010). Dicamba will also offer an effective control option for broadleaf species resistant to ALS and PPO chemistries. In the case of PPO resistance, a primary dicamba benefit will be to provide options for delaying the further spread of PPO resistant *Amaranthus* species (University of Tennessee, 2010).

A.3.2. Projections of dicamba use on DT Soybean

Current labeled uses of dicamba in soybean are limited to early preplant and late postemergence (preharvest) applications. Significant planting restrictions exist in soybean for preplant applications of dicamba, including a maximum application rate of 0.5 lbs a.e. per acre, a 28-day interval between application and planting soybean, and a minimum of one inch of rainfall must occur before planting soybean to avoid soybean injury. Monsanto has submitted an application to U.S. EPA to amend Registration Number 524-582, a low volatility DGA salt formulation, to remove all preemergence planting restrictions (intervals and rainfall) and to allow in-crop postemergence dicamba applications to DT soybean through the R1/R2 growth stage. Once approved, growers would be authorized to apply dicamba alone or in mixtures with glyphosate or other herbicides for preplant or in-crop postemergence applications on DT soybean. Dicamba would be authorized to be applied preemergence up to crop emergence as a single application or split applications up to a total of 1.0 lb a.e. per acre, and up to two postemergence applications up to 0.5 lb a.e. per acre each through the R1/R2 growth stage of soybean. The maximum annual application rate of dicamba on DT soybean is 2.0 lb dicamba a.e. per acre.

Furthermore, consistent with recommendations by academics and weed scientists, Monsanto will recommend the use of a third herbicide mode-of-action with soil residual activity as part of a comprehensive weed resistance management program to assure that at least two effective modes-of-action are always used in the cultivated soybean field. A summary of the anticipated weed control recommendations for the combined DT soybean and glyphosate-tolerant soybean system is provided in Table A-4.

In 2010, Monsanto conducted an informal survey of weed scientists across the country to estimate the number of crop acres with glyphosate resistant weed populations. Based upon this survey it was estimated that approximately 14-16 million acres of planted row-crops (i.e. corn, soybeans, cotton) had populations of glyphosate resistant weeds. Of these acres, the majority of acres (~ 10 million) are infested with glyphosate resistant marestail populations where a preplant application of dicamba and glyphosate described above will be effective for control. The remainder of resistant acres (~5 million) have resistant *Ambrosia* (common and giant ragweed) and *Amaranthus* (palmer pigweed and water hemp,) species present. A conservative estimate of 5 million resistant acres is assumed for this assessment, which overestimates current resistant acres in soybean producing areas and also accounts for potential increases in resistant acres because not all resistant crop acres would be planted to soybean in any given year.

Table A-4. Anticipated Weed Management Recommendations for DT Soybean Combined with Glyphosate-Tolerant Soybean [1]

Application Timing	Conventional Tillage[2]			Conservation Tillage [2] (No-till or reduced till)		
	No GR Weeds	GR Weeds or Suspected GR Weeds		No GR Weeds	GR Weeds or Suspected GR Weeds	
		Option 1[3]	Option 2[4]		Option 1[3]	Option 2[4]
Preemergence (burndown, at planting) [5]	Residual	Residual	Residual	Residual + Glyphosate + Dicamba	Residual + Glyphosate + Dicamba	Residual + Glyphosate + Dicamba
Postemergence [1] (V1-V3)	Glyphosate + Dicamba	Glyphosate + Dicamba	Glyphosate + Dicamba	Glyphosate + Dicamba	Glyphosate + Dicamba	Glyphosate + Dicamba
Postemergence [2] (V4-R2)	---	Glyphosate + Dicamba	---	---	Glyphosate + Dicamba	---

[1] The anticipated use patterns represent a high-end estimate for predicting dicamba use associated with DT soybean integrated with the glyphosate-tolerant soybean system. Actual weed control practices by growers will vary depending on the specific weed spectrum and agronomic situation of the individual soybean field, specifically dicamba use could be lower especially for the preemergence and second postemergence applications.

[2] Average rate for dicamba is 0.38 pound a.e. per acre except for fields with glyphosate resistant (GR) species where a 0.5 pound a.e. per acre postemergence application rate will be recommended. In some situations, the second postemergence application may not be needed. See Section III.A.1 for additional information supporting the anticipated use pattern.

[3] Option 1 would be used for more aggressive glyphosate resistant weed species, such as *Ambrosia* or *Amaranthus* species. See Section III.A.1 for additional information supporting the anticipated use pattern.

[4] Option 2 would be used for less aggressive glyphosate resistant weed species, such as marestail. See Section III.A.1 for additional information supporting the anticipated use pattern.

[5] Monsanto and academics recommend the use of soil residuals as part of a comprehensive weed resistance management program to ensure that two effective herbicide modes-of-action are used in soybean and to provide protections against additional resistance development to existing herbicides used on soybeans.

The potential increase in dicamba use in U.S. soybean production upon deregulation of DT soybean was assessed by estimating the total dicamba use across soybean acres. Assuming 100% adoption of DT soybean across all U.S. soybean acreage[75] and an application of dicamba at the maximum labeled use rate on all soybean acres, dicamba use on DT soybean could potentially total 150 million pounds. Assuming the anticipated use rate of 0.5 lb a.e. per acre dicamba for preemergence applications and 0.38 lb a.e. per acre dicamba for postemergence applications, and using a conservative assumption that DT soybean has 100% adoption across all U.S. geographies and conservation tillage systems are used on approximately 40% of the U.S. soybean acres (CTIC, 2007), dicamba use on DT soybean would total approximately 44 million pounds (See Table A-5).

In practice, however, a single early season in-crop application per year of dicamba at 0.38 lb a.e. per acre is expected on the majority of DT soybean planted acres. However, in no-till or conservation tillage soybean systems, an additional preplant application at 0.50 lb a.e. per acre could also be common practice, and in areas where more aggressive glyphosate resistant weeds, such as *Ambrosia* and *Amaranthus* species, are present two in-crop applications at 0.5 lb a.e. each may be needed in some situations. These anticipated use patterns represent a high-end estimate for predicting dicamba use associated with DT soybean integrated with the glyphosate-tolerant soybean system. Thus, when considering a more realistic adoption rate for DT soybean of 40%, dicamba use on DT soybean would total approximately 20.5 million pounds (See Table A-5).

It is anticipated that dicamba applications will continue for currently labeled crops at the dicamba-treated acreage levels and amounts presented in Table A-1, such that the dicamba treatment to DT soybean will thereby result in a total U.S. dicamba use of approximately 24.3 million pounds annually. This level of dicamba use would be approximately double the historical peak level experienced since dicamba's introduction in 1967.

Taking into consideration the above assessment, the potential dicamba-treated DT soybean acreage is estimated to be 40% of the U.S. soybean acres, and would represent approximately 30 million dicamba-treated soybean acres. Considering the acreage currently treated with dicamba (25.3 million acres of which 0.87 million acres are soybean in 2011; see Table A-1 and A-2), this would potentially result in a total of 55.3 million acres treated with dicamba. As presented previously, dicamba was used on approximately 36 million acres at its peak use in 1994.

[75] Based on approximately 75 million acres planted to soybean in 2011 (USDA-NASS, 2013).

Table A-5. Projected Dicamba Use on DT Soybean

Use Scenario	Dicamba Treated DT soybean Acres (000,000)	# PRE applications	PRE application rate (lb/acre a.e.)	# POST applications (V3 or V3 & R1)	POST application rate (lb/acre a.e.)	Total lbs of Dicamba (000,000)[a]	Total Annual lbs of Dicamba
Maximum labeled use pattern, 100% adoption							
	75	1	1.0	2	0.50	150	**150**
Anticipated use pattern, 100% adoption							
no-till acres [b]	30	1	0.5	1	0.38	26.4	
conventional tillage acres[c]	45			1	0.38	17.1	
							44
Anticipated use pattern, anticipated peak adoption of dicamba-treated DT soybean acres							
no-till acres [b]	12[d]	1	0.5	1	0.38	10.6	
conventional tillage acres[c]	18[d]			1	0.38	6.8	
Resistant *Amaranthus spp. Acres* [e]	5			2	0.31[f]	3.1	
							20.5[g]

[a] Total lbs dicamba is calculated combining the lbs of dicamba PRE and POST, where the lbs dicamba used either PRE or POST is calculated by multiplying the number of applications by the application rate for the respective application timing.

[b] No-tillage is practiced on 40% of the U.S. soybean acres (CTIC, 2007).

[c] Conventional tillage acres also includes acres where reduced or minimum tillage is practiced and where it is assumed that a preemergent application of dicamba will be needed for weed control.

[d] Monsanto projects dicamba to be used on 40% of U.S. soybean acres (i.e., 30 million acres).

[e] These acres are a subset of the no-till and conventional tillage acres.

[f] Monsanto anticipates that two POST applications at 0.5 lb/acre a.e. each will be needed on acres resistant with A*maranthus spp*. Since these acres are a subset of the no-till and conventional tillage acres where a single POST application at 0.38 lb/acre dicamba a.e. has already been accounted for, the POST application rate is adjusted to avoid double counting of dicamba use on this subset of acres (i.e., adjusted POST application rate = 0.5 lb/acre – (0.38÷2) lb/acre).

[g] This figure is slightly less than the estimate of 22 million pounds described in Section VIII.H of the petition because it subtracts out the single 0.38 lb/acre a.e. application already accounted for in the no-till and conventional tillage calculations.

A.3.3. Benefits of DT Soybean for Weed Management

Upon integration of DT soybean into the glyphosate-tolerant soybean system, dicamba will provide excellent control of numerous annual and perennial broadleaf weed species, including populations of broadleaf weeds that are resistant to ALS, atrazine, or glyphosate herbicides. Table A-6 shows weed control ratings for dicamba, glyphosate and several glyphosate tank mixtures when applied as a preplant burndown application to common broadleaf weed species found in soybean fields of the Midwest and Southeast regions. An application of dicamba alone provides effective control of a broad spectrum of winter and summer annual and perennial broadleaf weed species. In comparison, glyphosate alone provides excellent control of many grass species in addition to many of the annual and perennial broadleaf species listed. However, dicamba provides a higher level of control of certain broadleaf weeds including common lambsquarters, Pennsylvania smartweed, red clover, alfalfa, marestail, hairy vetch, and prickly lettuce. Dicamba will be very complementary in mixtures with glyphosate for weed control in a preplant application (Johnson et al, 2010) and will offer growers equal or superior weed control to other glyphosate mixtures because it offers reduced potential herbicide antagonism, improved efficacy and broader weed spectrum. See Appendix B, Section B.2.5 for detailed benefit analysis of DT soybean.

The dicamba tolerance trait in DT soybean will permit in-crop applications of dicamba to soybean with excellent crop safety (crop tolerance). Dicamba will also complement the weed control of in-crop applications of glyphosate when applied as a mixture or in sequence. Table A-7 shows common broadleaf weed responses to dicamba compared to glyphosate and several glyphosate labeled tank mixtures in soybean. Since dicamba is not currently labeled for in-crop applications in soybean, weed control ratings for dicamba were taken from labeled in-crop applications of dicamba in corn for comparison purposes. Glyphosate will continue to provide broad spectrum control of annual grasses and broadleaf weeds, while dicamba will provide improved control of common ragweed, giant ragweed, hemp sesbania, morningglory species, and prickly sida. As presented in Table A-6, dicamba is more effective in controlling marestail then glyphosate. Likewise, in comparison to glyphosate, dicamba is expected to also improve the control of lambsquarters, eastern black nightshade, kochia, palmer pigweed, and wild buckwheat. In addition to complementing the weed control of glyphosate, dicamba will provide another mode of action in the Roundup Ready soybean system to lower the potential risk of weeds developing resistance to glyphosate (see discussion later in this appendix). Furthermore, dicamba will provide an alternative mode of action for control of broadleaf weeds with populations known to be resistant to ALS and PPO classes of herbicides (see Table A-8 for herbicide listings).

Application of both dicamba and glyphosate to DT soybean combined with the glyphosate tolerant soybean system will provide effective control of both dicamba- and glyphosate-resistant broadleaf weeds (Johnson et al, 2010). In the U.S., kochia (*Kochia scoparia*) and prickly lettuce (*Lactula serriola*) are the only species with biotypes confirmed to be resistant to dicamba after 40+ years of use (Heap, 2009). Additionally, a population of lambsquarters (*Chenopodium album*) has been confirmed as resistant in New Zealand, and in Canada common hempnettle (*Galeopsis tetrahit*) and wild mustard (*Sinapis arvensis*) have been confirmed as resistant, for a total of five species worldwide with confirmed resistance to dicamba. Glyphosate has been shown to provide good to excellent control of all five of these broadleaf weeds. In addition, there are 3 species (spreading dayflower (*Commelina diffusa*), field bindweed (*Convolvulus arvensis*) and wild carrot (*Daucus carota*)) in the U.S. with confirmed resistance to 2,4-D. Of the dicamba and 2,4-D species with known resistance in the U.S. and Canada, cross resistance between dicamba and 2,4-D has only been documented in wild mustard. However, cross resistance within the other species can not be totally ruled out nor assumed to be present. Currently in the U.S., six grass species and seven broadleaf species have been confirmed to have resistance to glyphosate. Dicamba provides good to excellent control of all seven of these broadleaf species. None of these broadleaf weed biotypes have been shown to have populations that are resistant to both glyphosate and dicamba. However, there are known resistant populations of kochia that are either resistant to glyphosate or to dicamba, but no population with known resistance to both glyphosate and dicamba. Since there is no cross resistance between dicamba and glyphosate either product can be effective on kochia populations resistant to the other. A more detailed discussion regarding the potential development of dicamba resistance in weeds can be found in Appendix B of the Environmental Report.

Table A-6. Common Broadleaf Weed Responses to Preplant Burndown Herbicides

	Common Broadleaf Weeds[1,2]														
Herbicide/Application	LQ	CR	GR	SW	CC	M, SP	CT	RC	AL	HV	MT	PL	DN, HB	DL	CG
Spring Preplant Application															
2,4-D (0.5 lb/1.0 lb)	-	-	-	-	-	9	-/6	6/8	-/7	6/8	8/9	8/9	-/8	6/7	9/9
Dicamba	9	9	9	9	6	7	-	9	8	8	7	9	-	7	-
Dicamba + 2,4-D	9	9	9	9	6	9	6	9	8	9	9	9	-	8	9
Glyphosate	8	9	8	7	7	8	6	7	6	6	6	8	-	7	7
Glyphosate + 2,4-D	9	9	9	8	7	9	6	8	8	8	8+	9	6	8	9
Glyphosate + Canopy	8	9	9	9	7	8	6	7	6	6	8	8+	9	8+	9
Glyphosate + Canopy + 2,4-D	9	9	9	9	7	9	6	8	8	8	9	9	9	8+	9
Glyphosate + Gangster + 2,4-D	9	9	9	9	7	9	6	8	8	8	9	9	8	8	9
Glyphosate + Python + 2,4-D	9	9	9	8	7	9	6	8	8	8	9	9	6	8	9
Glyphosate + Scepter + 2,4-D	9	9	9	8	7	9	6	8	8	8	8+	9	6	8	9
Gly + Sonic/Authority First + 2,4-D	9	9	9	9	7	9	6	8	8	8	9	9	8	8	9
Glyphosate + Valor + 2,4-D	9	9	9	8	7	9	6	8	8	8	8+	9	8	7	9

[1]All weed control ratings are from the 2009 Weed Control Guide for Ohio and Indiana – Weed Responses to Burndown Herbicides, Ohio State University and Purdue University (Loux et al., 2009). Weed control ratings for weeds are: 9 = 90% to 100%, 8 = 80% to 90%, 7 = 70% to 80%, 6 = 60% to 70%, and - = less than 60% control, not recommended. Ratings assume the herbicides are applied in the manner suggested in the guidelines and according to the label under optimum growing conditions.
[2]Weed species: LQ = lambsquarters, CR = common ragweed, GR = giant ragweed, SW = annual smartweed, CC = common chickweed, M & SP = mustard and shephard's purse, CT = Canada thistle, RC = red clover, AL = alfalfa, HV = hairy vetch, MT = marestail, PL = prickly sida, DN & HB = deadnettle & henbit, DL = dandelion, and CG = crested groundsel

Table A-7. Common Broadleaf Weed Responses to Dicamba Compared to Labeled Postemergence Herbicides in Soybean Production

	Common Broadleaf Weeds[1,2]													
Herbicide/Application	BN	CB	CR	GR	HS	LQ	MG	PA	PW	PS	SP	SW	VL	WH
Postemergence														
Bentazon	-	9	7	6	4	7	2-9	4	-	8	0	9	8+	-
Chlorimuron	-	9	8	7+	8	-	8-9	6	9	2	7	8	8	-
Cloransulam	-	9	9	9	3	-	8-9	2	-	2	7	8	9	-
Chlorimuron/thifensulfuron	-	9	8	7+	NA	8	NA	NA	9	NA	NA	9	9	-
Dicamba[3]	8	9	9	9	9	8	9	9	8	8	8	8	7+	8
Flumiclorac	-	7	7	-	NA	7	NA	NA	7	NA	NA	-	9	7
Fomesafen	8	7	8+	8	9	-	8-9	8	9	2	3	7	6	9
Glyphosate	8	9	8+	8	7	8	7-9	9	9	7	8	8	8	8
Glyphosate/imazethapyr	9	9	8+	8+	NA	8+	NA	NA	9	NA	NA	9	9	8
Imazamox	9	8	7	8	NA	8	NA	NA	9	NA	NA	8	9	-
Imazethapyr	9	9	6	7	0	6	7-9	6	9	6	0	9	9	-
Lactofen	8+	8	9	8	9	-	8-9	8	9	8	5	6	7	9
Thifensulfuron	-	6	-	-	NA	8	NA	NA	9	NA	NA	8	9	-

[1]All weed control ratings except for HS, MG, PA, PS, and SP are from the 2009 Weed Control Guide for Ohio and Indiana – Ohio State University and Purdue University (Loux et al., 2009). Ratings for HS, MG, PA, PS, and SP are from the 2009 Weed Control Guidelines for Mississippi, Mississippi State University (MSU, 2010), except for dicamba ratings for PA are from the 2010 Weed Control Manual for Tennessee (University of Tennessee, 2010). Weed control ratings for weeds, except HS, MG, PA, PS, and SP, are: 9 = 90% to 100%, 8 = 80% to 90%, 7 = 70% to 80%, 6 = 60% to 70%, and - = less than 60% control, not recommended. Weed control ratings for HS, MG, PA, PS, and SP are: 9-10 = excellent, 7-8 = good, 4-6 = fair, 0-3 = none to slight. Ratings assume the herbicides are applied in the manner suggested in the guidelines and according to the label under optimum growing conditions. NA denotes not available.
[2]Weed species: BN = black nightshade, CB = cocklebur, CR = common ragweed, GR = giant ragweed, LQ = lambsquarters, MG = morningglory spp., HS = hemp sesbania, PA = palmer and spiny pigweed, PW = pigweed, PS= prickly sida, SP = sicklepod, SW = smartweed, VL = velvetleaf, and WH = waterhemp
[3]Weed control ratings for dicamba are from postemergence applications in corn.

Table A-8. Herbicide Use in Soybean Use in the U.S. in 2012[1]

Herbicide	Chemical Family	Mode-of-Action (MOA)	Percent-Treated Acres	Total Area Applied (Percent/MOA)	Quantity Applied (1000 lbs)	Total Quantity Applied (1000 lbs/MOA)
Glyphosate	glycine	EPSPS inhibitor	98	100	109,336	110,589
Sulfosate	glycine		3		1,253	
Pendimethalin	dinitroanaline	Tubulin inhibitor	2	4	1,559	2,865
Trifluralin	dinitroanaline		2		1,306	
Metribuzin	triazinone	PSII inhibitor	3	11	675	1,753
Sulfentrazone	triazolinone		8		1,078	
Chlorimuron-ethyl	sulfonylurea	ALS inhibitor	11	26	187	590
Cloransulam-methyl	triazolopyrimidine		4		83	
Flumetsulam	triazolopyrimidine		*		14	
Imazamox	imidazolinone		*		6	
Imazaquin	imidazolinone		*		34	
Imazethapyr	imidazolinone		5		221	
Rimsulfuron	Imidazolinone		*		4	
Thifensulfuron	sulfonylurea		5		31	
Tribenuron-methyl	sulfonylurea		1		10	
Acetochlor	chloroacetamide	Cell division inhibitor	1	9	635	6,553
Metolachlor	chloroacetamide		7		5,683	
Dimethenamid	chloroacetamide		1		235	
Paraquat	bipyridilium	PSI disruption	3	3	813	813

Table A-8 (continued). Herbicide Use in Soybean Use in the U.S. in 2012[1]

Herbicide	Chemical Family	Mode-of-Action (MOA)	Percent-Treated Acres	Total Area Applied (Percent/MOA)	Quantity Applied (1000 lbs)	Total Quantity Applied (1000 lbs/MOA)
Clethodim	cyclohexenone	ACCase inhibitor	9	14	524	907
Fenoxaprop	aryloxyphenoxy propionate		*		7	
Fluazifop-P-butyl	aryloxyphenoxy propionate		3		195	
Quizalofop-P-ethyl	aryloxyphenoxy propionate		2		118	
Sethoxydim	cyclohexenone		*		63	
Acifluorfen	diphenylether	PPO inhibitor	1	29	210	2,477
Carfentrazone-ethyl	triazolinones		*		1	
Fluthiacet	thiadiazole		2		10	
Flumiclorac-pentyl	N-phenylphthalimide		1		35	
Flumioxazin	N-phenylphthalimide		11		602	
Fomesafen	diphenylether		8		1,347	
Lactofen	diphenylether		2		192	
Saflufenacil	pyrimidinedione		4		80	
2,4-D	phenoxy	Synthetic auxin	15	15	6,021	6,108
Dicamba	benzoic acid		*		87	
					Total	**132,979**

* Area receiving application is less than 0.5 percent.

[1] Data derived from USDA-NASS (2013b). Planted acreage for the nineteen primary soybean production states was 72.9 million acres, which represented 96.5% of total planted acres

A.3.4. Herbicide Use Trends: Impact of DT Soybean on future herbicide use

The objective of this analysis is to provide information regarding: (1) the current and expected growth in use of non-glyphosate herbicides in glyphosate-tolerant soybean and cotton in the absence of DT soybean and DGT cotton; (2) the herbicides most likely to be replaced by dicamba, and the extent of this potential replacement when DT soybean and DGT cotton systems are commercialized; (3) the projected change in overall herbicide use when DT soybean and DGT cotton are commercialized; and (4) a comparative analysis of dicamba and alternative soybean and cotton herbicides, including an emphasis on herbicide risk profiles and comparative herbicide efficacy.

A.3.4.1. **Materials and Methods**

This analysis utilizes unpublished grower survey data obtained from an independent, private-market research company that provides farm-survey information on agricultural herbicide usage in the U.S. This information reflects the most current data available on U.S. herbicide usage, and presents data on glyphosate-tolerant soybean from 2002 through 2011 to represent herbicide use after widespread adoption of glyphosate-tolerant soybean and after glyphosate-resistant weeds had begun impacting weed control decisions in soybean cultivation. The majority of data are presented in terms of total acres treated (TAT), which is the number of acres treated with an herbicide. The use of TAT provides a way to look at herbicide use that is independent of the various use rates of herbicides. If an herbicide is used more than once on an acre, the TAT will reflect this multiple use, and consequently the TAT may exceed the number of crop acres planted. This method provides a more complete view of herbicide use.

This analysis organizes data in two broad usage sets (Table A-9): preplant/pre-emergence to the crop (PRE) and post-emergence in-crop use (POST). The PRE set are herbicides applied prior to planting the crop through planting of the crop, but before crop emergence regardless of their mode-of-activity. The POST set are herbicides applied after crop emergence regardless of their mode-of-activity. In glyphosate-tolerant soybean, a total of 53 different non-glyphosate herbicides had been used in the PRE timing, while 37 different non-glyphosate herbicides had been used in the POST timing (Table A-9). The total PRE and POST herbicides used in glyphosate-tolerant soybean acres from 2002 through 2011 are presented in Table A-10 and Table A-11 below, respectively.

To better understand how dicamba would impact overall herbicide use at peak penetration of dicamba-tolerant soybeans, projections of the growth of TAT for all herbicides including glyphosate after 2011 were developed using a four-parameter logistic regression model. The four-parameter logistic model is one of the most commonly used growth rate models because it has properties desirable for this analysis (*i.e.*, monotonically increasing, symmetric about an inflection point, and upper/lower asymptotes). For this analysis, a major consideration is the ability to estimate the limiting maximum value of TAT, which is mathematically referred to as an upper asymptote. This means that the model estimates a potential maximum value of TAT which will not be exceeded at any point in time. Based on expected grower practices, which are based upon weed management needs and the acceptable level of management generally applied to soybean weed-control practices, including herbicide and mechanical tillage costs, it was assumed that a grower would be expected to make, on average, 1.5 applications of PRE herbicides and 2 applications of POST herbicides in glyphosate-tolerant soybeans by 2015. Specifically, the 1.5 PRE timing applications were estimated based on: (1) approximately 50% of soybean acres utilizing conservation tillage and receiving at least

1 preplant burndown herbicide application (*e.g.*, glyphosate); and (2) all glyphosate-tolerant soybean acres receiving at least 1 herbicide application (soil residual or postemergence active) after planting but before crop emergence. Thus, 1.5 PRE herbicide applications are expected to be made on average across all glyphosate-tolerant soybean acres. Similarly, the estimate of 2 POST herbicide applications in glyphosate-tolerant soybeans was based on the expectation that, on average, glyphosate would be supplemented by either a postemergence grass or a postemergence broadleaf herbicide. These are projections for the average number of herbicide applications, for that reason, in some cases where aggressive glyphosate resistant weeds, such as Amaranthus spp., may be present an additional postemergence application of a non-glyphosate herbicide may be needed. Conversely, the non-glyphosate postemergence grass or broadleaf herbicide may not be needed in some cases based on the specific weed spectrum in the soybean field.

Growth modeling was conducted using existing TAT data for all herbicides in glyphosate-tolerant soybeans from 2002 through 2011 (Table A-10 and Table A-11) with an upper asymptote set at 109 million acres for the PRE timing (Figure A-1) and 145 million acres for the POST timing (Figure A-2). These asymptotes were estimated by multiplying the estimated maximum number of herbicide applications for each application timing (*i.e.*, PRE or POST) by the anticipated number of glyphosate-tolerant soybean acres. The number of glyphosate-tolerant soybean acres planted after 2011 was assumed to remain constant at 72.5 million acres, which was based on the average of 2008 through 2011 planted glyphosate-tolerant soybean acres. To derive estimates from the model, an assumption was made that the total number of treated acres would reach 99% of its limiting maximum value (or upper asymptote) by 2015 because herbicide use is expected to plateau in 2015 based on an aggressive adoption rate for diversified weed management practices. The projected TAT for the PRE and POST herbicides sets through 2020 are presented in Table A-10 and Table A-11, respectively.

Table A-9. Non-Glyphosate Herbicides Used in Glyphosate-Tolerant Soybeans from 2002 to 2011[a]

Preemergence (PRE) Active Ingredients		**Postemergence (POST) Active Ingredients**	
2,4-D	Iodosulfuron	2,4-D	Paraquat
2,4-DB	Lactofen	2,4-DB	Pelargonic acid
Acifluorfen	Linuron	Acetochlor	Pendimethalin
Alachlor	MCPA	Acifluorfen	Pyraflufen ethyl
Bentazone	Metolachlor	Alachlor	Quizalofop
Carfentrazone-ethyl	Metolachlor-S	Bentazone	Sethoxydim
Chlorimuron	Metribuzin	Carfentrazone-ethyl	Sulfosate
Chlorsulfuron	Metsulfuron	Chlorimuron	Thifensulfuron
Clethodim	MSMA	Clethodim	Tribenuron methyl
Clomazone	Nicosulfuron	Cloransulam-methyl	
Cloransulam-methyl	Norflurazon	Dicamba	
Dicamba	Paraquat	Dimethenamid	
Diflufenzopyr	Pelargonic acid	Dimethenamid-P	
Dimethenamid	Pendimethalin	Fenoxaprop	
Dimethenamid-P	Pyraflufen ethyl	Fluazifop	
Ethalfluralin	Quizalofop	Flumetsulam	
Fenoxaprop	Rimsulfuron	Flumiclorac	
Fluazifop	Saflufenacil	Flumioxazin	
Flufenacet	Sethoxydim	Fluthiacet-methyl	
Flumetsulam	Simazine	Fomesafen	
Flumiclorac	Sulfentrazone	Imazamox	
Flumioxazin	Sulfosate	Imazaquin	
Fluthiacet-methyl	Thifensulfuron	Imazethapyr	
Fomesafen	Tribenuron methyl	Lactofen	
Glufosinate	Trifluralin	Linuron	
Imazamox		Metolachlor	
Imazaquin		Metolachlor-S	
Imazethapyr		Naptalam	

[a] Unpublished market research data (Monsanto, 2011)

Table A-10. Total Acres Treated (TAT) for PRE Applications – Soybean

	Total Acres Treated Market Research Data[a]									
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
TAT non-glyphosate herbicides	13,193,707	14,840,690	14,668,394	13,212,012	15,174,490	14,638,461	22,202,786	26,395,565	29,864,690	40,536,350
% increase 2002-2007						**11%**				
% increase 2007-2011										**177%**
TAT for glyphosate only	15,717,762	14,961,613	15,786,481	18,506,336	20,714,073	21,483,177	29,008,410	28,038,773	25,344,134	24,895,051
Total TAT (non-glyphosate + glyphosate herbicides)	28,911,469	29,802,303	30,454,875	31,718,348	35,888,563	36,121,638	51,211,196	54,434,338	55,208,824	65,431,401
Planted GT Soybean acres	60,349,592	64,979,824	67,387,514	66,589,441	70,243,541	61,116,671	71,592,623	73,219,834	74,059,185	71,734,537

Table A-10 (continued). Total Acres Treated (TAT) for PRE Applications – Soybean

	Total Acres Treated Projected TAT Using Logistic Modeling to Estimate Growth								
	2012	2013	2014	2015	2016	2017	2018	2019	2020
TAT non-glyphosate herbicides	64,773,279	74,715,994	79,267,452	81,087,544	81,775,565	82,030,078	82,123,472	82,157,642	82,170,130
% increase 2011-2015				**100%**					
TAT for glyphosate only	26,800,000	26,800,000	26,800,000	26,800,000	26,800,000	26,800,000	26,800,000	26,800,000	26,800,000
Total TAT (non-glyphosate + glyphosate herbicides)	91,573,279	101,515,994	106,067,452	107,887,544	108,575,565	108,830,078	108,923,472	108,957,642	108,970,130
Planted GT Soybean acres[b]	72,500,000	72,500,000	72,500,000	72,500,000	72,500,000	72,500,000	72,500,000	72,500,000	72,500,000

[a] Unpublished market research data (Monsanto, 2011)
[b] Estimated

Table A-11: Total Acres Treated (TAT) for POST applications – Soybean

	Total Acres Treated									
	Market Research Data[a]									
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
TAT non-glyphosate herbicides	5,989,024	6,763,229	5,954,804	4,954,480	5,568,882	5,595,885	9,471,130	16,016,729	20,726,606	24,928,111
% increase 2002-2007						**-7%**				
% increase 2007-2011										**345%**
TAT for glyphosate only	69,983,206	78,770,855	81,581,659	78,442,879	73,746,629	69,000,104	85,111,702	86,217,950	92,455,945	86,782,777
Total TAT (non-glyphosate + glyphosate herbicides)	75,972,230	85,534,084	87,536,463	83,397,359	79,315,511	74,595,989	94,582,832	102,234,679	113,182,551	111,710,888
Planted GT Soybean acres	60,349,592	64,979,824	67,387,514	66,589,441	70,243,541	61,116,671	71,592,623	73,219,834	74,059,185	71,734,537

Table A-11 (continued). Total Acres Treated (TAT) for POST Applications – Soybean

	Total Acres Treated								
	Projected TAT Using Logistic Modeling to Estimate Growth								
	2012	2013	2014	2015	2016	2017	2018	2019	2020
TAT non-glyphosate herbicides	46,043,835	52,619,725	56,137,061	57,850,059	58,646,207	59,008,178	59,171,102	59,244,102	59,276,743
% increase 2007-2015				**132%**					
TAT for glyphosate only	86,000,000	86,000,000	86,000,000	86,000,000	86,000,000	86,000,000	86,000,000	86,000,000	86,000,000
Total TAT (non-glyphosate + glyphosate herbicides)	132,043,835	138,619,725	142,137,061	143,850,059	144,646,207	145,008,178	145,171,102	145,244,102	145,276,743
Planted GT Soybean acres[b]	72,500,000	72,500,000	72,500,000	72,500,000	72,500,000	72,500,000	72,500,000	72,500,000	72,500,000

[a] Unpublished market research data (Monsanto, 2011)
[b] Estimated

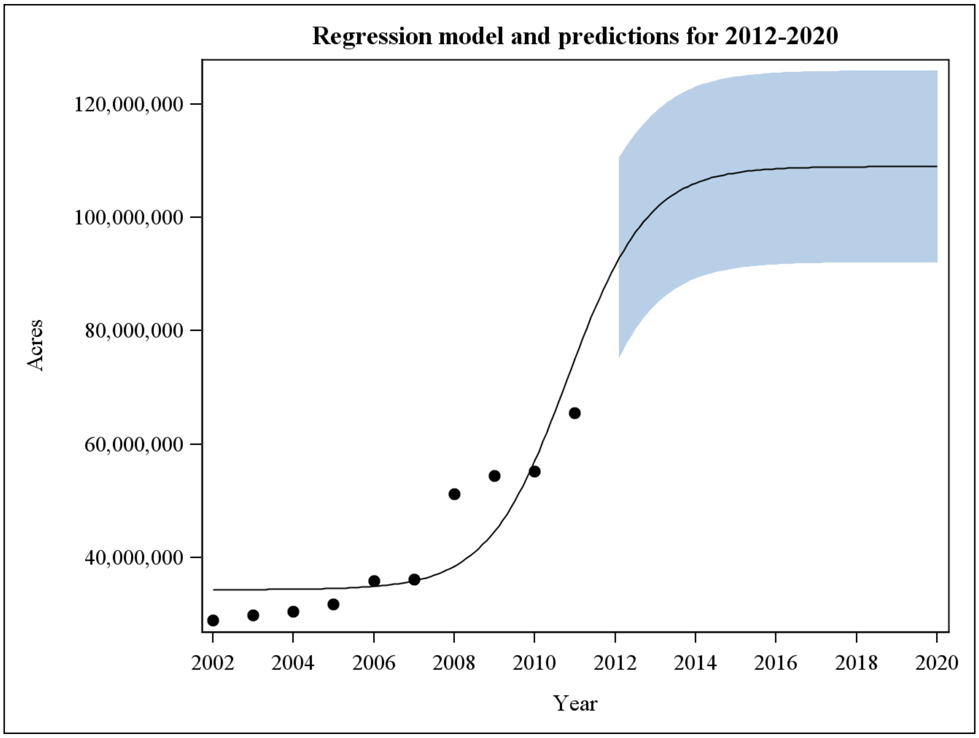

Figure A-1. Regression model and predictions for PRE non-glyphosate soybean herbicides
The shaded area represents the 95% confidence interval for the modeled projection.

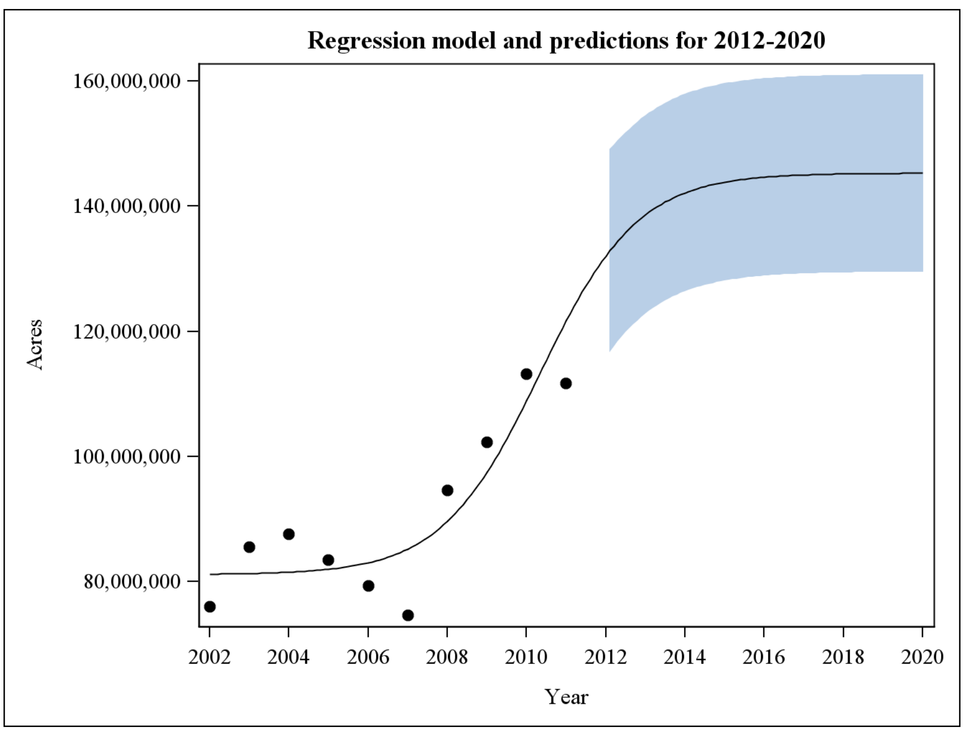

Figure A-2. Regression model and predictions for POST non-glyphosate soybean herbicides
The shaded area represents the 95% confidence interval for the modeled projections.

A.3.4.2. **Analysis of PRE Soybean Herbicide Use from 2002-2011**

The use of non-glyphosate herbicides included in the PRE set is influenced by use of conservation tillage (*i.e.*, reliance on herbicides to control emerged weeds prior to crop planting) and use of residual herbicides applied preplant and/or preemergent to crop emergence. The use of non-glyphosate PRE herbicides in glyphosate-tolerant soybeans was relatively flat from 2002 through 2007, with only an 11% increase in TAT between 2002 and 2007 (Table A-10). In 2007, glyphosate-tolerant soybeans were grown on 61 million acres. At that time, the primary non-glyphosate herbicides used were those providing postemergence control of broadleaf weeds. From 2008 to 2011, there was a 177% increase in the use of non-glyphosate herbicides in the glyphosate-tolerant soybean PRE segment. In 2011, glyphosate-tolerant soybeans were grown on 72 million acres, an 18% increase from 2007. It can be concluded from this data that the growth in non-glyphosate herbicide use was not driven just by an increase in the total planted acres of glyphosate-tolerant soybean. Instead, this increase in use of non-glyphosate herbicides in the 2008 through 2011 time period is consistent with the increased emphasis by the public and private sectors on promoting more diversified weed management and also the increase in glyphosate resistant weeds during this time period. Likewise, it can be concluded that non-glyphosate herbicide use will continue to increase and eventually plateau, regardless of the expected launch of dicamba-tolerant crops. Assuming no commercialization of dicamba-tolerant soybeans, the growth in PRE non-glyphosate TAT could be expected to increase to approximately 81 million acres by 2015, which is a further 100% increase in non-glyphosate herbicide use from 2011 (Table A-10). Of the planted glyphosate-tolerant soybean acres in 2011, approximately 43% received a non-glyphosate PRE herbicide application (Table A-12). The number of glyphosate applications in glyphosate-tolerant soybeans has been relatively flat since 2007 and is expected to remain flat in the foreseeable future regardless of the commercialization of dicamba-tolerant soybean (Table A-12).

Table A-12. Base acres and average number of applications for PRE segment – Soybean[a]

	Acres [a]										
	2002	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**Averages (2008-2011)**
Non-glyphosate herbicides											
Base acres[b]	19,516,983	17,903,463	16,760,037	15,406,031	15,420,411	14,290,515	19,622,747	23,552,933	26,610,180	31,144,934	
Base acres as percent of GT planted acres	32%	28%	25%	23%	22%	23%	27%	32%	36%	**43%**	
Avg # of non-glyphosate applications per treated acre[c]	1.19	1.24	1.24	1.20	1.19	1.17	1.23	1.25	1.26	1.39	
Glyphosate herbicides											
Base Acres[b]	14,967,089	14,123,133	15,013,484	17,446,790	19,509,232	19,800,590	25,978,778	25,660,098	24,190,709	23,414,531	
Base acres as percent of GT planted acres	25%	22%	22%	26%	28%	32%	36%	35%	33%	**33%**	
Avg # of glyphosate applications per treated acre[c]	1.05	1.06	1.05	1.06	1.06	1.08	1.12	1.09	1.05	1.06	
Planted soybean acres											
GT Soybean planted acres	60,349,592	64,979,824	67,387,514	66,589,441	70,243,541	61,116,671	71,592,623	73,219,834	74,059,185	71,734,537	72,651,545
Total soybeans planted acres	73,043,055	73,652,916	74,809,004	72,969,983	74,810,075	63,975,002	74,404,952	77,584,979	78,725,010	74,835,004	76,387,486

[a] Unpublished market research data (Monsanto, 2011).
[b] The base acre is the number of acres that receives at least 1 application of a herbicide.
[c] The reported average number of applications as tabulated in the market research data base does not allow values for individual segments (glyphosate and non-glyphosate herbicides) to be combined to generate a number representative of the total number of average applications in the segment (PRE or POST).

A.3.4.3. **Analysis of POST Soybean Herbicide Use from 2002-2011**

The use of herbicides at this timing is primarily influenced by the need to control weeds after they emerge in the crop or to extend the preemergence residual control of weeds longer into the growing season. As in the case of non-glyphosate PRE herbicides, the use of non-glyphosate POST herbicides applied in glyphosate-tolerant soybeans was flat from 2002 through 2007, with essentially no growth in TAT between 2002 and 2007 (Table A-11). However, from 2008 to 2011 there was a 345% increase in TAT for the use of non-glyphosate POST herbicides in the glyphosate-tolerant soybean. During the same time period, glyphosate-tolerant soybean acres grew approximately 18%. As in the case for the PRE herbicides, this data indicates that the increase in non-glyphosate herbicide use was not solely related to an increase in planted glyphosate-tolerant soybean acres. The increased use of non-glyphosate POST herbicides after 2008 is evidence of increased adoption of diversified weed management practices by farmers. These outcomes are consistent with farmer adoption of recommendations from the public and private sectors on how best to proactively and reactively manage resistance. Likewise, it can be concluded that non-glyphosate herbicide use will continue to increase and eventually plateau, regardless of the expected launch of dicamba-tolerant soybean. Assuming no commercialization of dicamba-tolerant soybean, the growth in TAT from non-glyphosate POST herbicides could be expected to increase to approximately 58 million acres by 2015, which is a 132% increase in non-glyphosate herbicide use from 2011 (Table A-11). In 2011 approximately 30% of glyphosate tolerant soybean acres received a non-glyphosate POST herbicide application (Table A-13). The number of glyphosate applications in glyphosate-tolerant soybean in the POST segment has been relatively flat since 2002 and is expected to remain at a stable rate in the future regardless of whether or not DT soybean is commercialized (Table A-13).

Table A-13. Base acres and average number of applications for POST segment – Soybean[a]

	Acres [a]										
	2002	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**Averages (2008-2011)**
Non-glyphosate herbicides											
Base acres[b]	5,112,506	5,825,154	5,428,650	4,491,573	4,996,258	4,921,061	8,485,432	14,085,236	17,177,978	21,455,105	
Base acres as percent of GT planted acres	8%	9%	8%	7%	7%	8%	12%	19%	23%	**30%**	
Avg # of non-glyphosate applications per treated acre[c]	1.17	1.16	1.10	1.10	1.11	1.14	1.12	1.14	1.21	1.16	
Glyphosate herbicides											
Base Acres[b]	58,357,957	62,808,659	65,942,923	63,966,600	65,823,639	59,949,798	69,491,079	71,727,511	71,962,333	68,739,858	
Base acres as percent of GT planted acres	97%	97%	98%	96%	94%	98%	97%	98%	97%	**96%**	
Avg # of glyphosate applications per treated acre[c]	1.20	1.25	1.24	1.23	1.12	1.15	1.22	1.20	1.28	1.26	
Planted soybean acres											
GT Soybean planted acres	60,349,592	64,979,824	67,387,514	66,589,441	70,243,541	61,116,671	71,592,623	73,219,834	74,059,185	71,734,537	72,651,545
Total soybeans planted acres	73,043,055	73,652,916	74,809,004	72,969,983	74,810,075	63,975,002	74,404,952	77,584,979	78,725,010	74,835,004	76,387,486

[a] Unpublished market research data (Monsanto, 2011).

[b] The base acre is the number of acres that receives at least 1 application of a herbicide.

[c] The reported average number of applications as tabulated in the market research data base does not allow values for individual segments (glyphosate and non-glyphosate herbicides) to be combined to generate a number representative of the total number of average applications in the segment (PRE or POST).

A.3.4.4. **Projected Dicamba Use (TAT and Total Pounds) on DT Soybean**

Based upon anticipated use patterns for dicamba on DT soybean as described in Section VIII.H of petition #10-188-01p (Monsanto, 2010), projections on the number of dicamba TAT and total pounds of dicamba used on DT soybean were determined for the combined PRE and POST application timing. The anticipated use projections represent a high-end estimate of the incremental dicamba use as described in the petition. Projected dicamba use at peak penetration (assumed to be 2015 for this analysis) is 47.1 million TAT and 20.5 million pounds (Table A-14).

Table A-14. Anticipated Total Acres Treated (TAT) for PRE and POST applications of dicamba on DT Soybean

Agronomic Practice	Projected acres where dicamba may be used[a]	Number of PRE dicamba applications[b]	Average PRE application rate (lb/acre a.e.)[b]	Number of POST dicamba applications[b]	Average POST application rate (lb/acre a.e.)[b]	Projected 2015 dicamba TAT[c]	Projected 2015 total lbs dicamba[d]
No-Tillage Acres	12,032,000	1	0.5	1	0.38	24,064,000	10,588,160
Conventional Tillage Acres	18,048,000	-		1	0.38	18,048,000	6,858,240
Resistant *Amaranthus spp.* Soybean Acres[e]	5,000,000	-		1[f]	0.62[g]	5,000,000	3,100,000
Total high-end projection on dicamba use						**47,112,000**	**20,546,400**[h]

[a] Soybean is projected to be grown on 75.2 million acres in 2015. Monsanto projects dicamba to be conservatively used on 40% of U.S. soybean acres (i.e., 30,080,000 acres). No-tillage is practiced on 40% of the U.S. soybean acres (CTIC, 2007). The remaining acres are conventional tillage.

[b] See Section VIII.H of the Dicamba-Tolerant Soybean MON 87708 petition #10-188-01p for details regarding the anticipated use pattern for dicamba on DT soybean.

[c] Projected TAT = (Projected Acres x Number of PRE Applications) + (Projected Acres x Number of POST Applications).

[d] Projected Total lbs = (Projected Acres x Number of PRE Applications x Avg. PRE rate) + (Projected Acres x Number of POST Applications x Avg. POST rate).

[e] These acres are a subset of the no-till and conventional tillage acres

[f] Monsanto anticipates that two POST applications at 0.5 lb/acre a.e. each will be needed on acres resistant with A*maranthus spp*. Since these acres are a subset of the no-till and conventional tillage acres where a single POST application has already been accounted for, the number of applications is adjusted to avoid double counting on this subset of acres.

[g] Monsanto anticipates that two POST applications at 0.5 lb/acre a.e. each will be needed on acres resistant with A*maranthus spp*. The average application rate on these acres is determined by subtracting the 0.38 lb/acre a.e. POST application already accounted for in the no-till and conventional tillage calculations (i.e., 0.5 + 0.5 - 0.38 lb/acre).

[h] This figure is slightly less than the estimate of 22 million pounds described in Section VIII.H of the petition because it subtracts out the single 0.38 lb/acre a.e. application already accounted for in the calculation

A.3.5. Displacement of Other Non-Glyphosate Herbicides by Dicamba Use Following Deregulation of DT Soybean

A.3.5.1. **Materials and Methods**

In order to estimate the amount of non-glyphosate herbicides that could be replaced by dicamba, Monsanto weed management scientists identified those herbicides most likely to be replaced by dicamba from the list of non-glyphosate herbicides currently being used in glyphosate-tolerant soybeans (Table A-9). These herbicides were selected based on criteria such as lower efficacy, carryover concerns, existing resistance, use restrictions, and/or crop safety. This exercise resulted in the selection of 7 and 15 non-glyphosate herbicides in the PRE and POST segments, respectively. The herbicides expected to be replaced by dicamba in the PRE set included imazethapyr, pendimethalin, metribuzin, trifluralin, 2,4-D, paraquat and glufosinate (Table A-15). The herbicides in the POST set included fomesafen, chlorimuron, fluthiacet-methyl, cloransulam-methyl, lactofen, flumiclorac, thifensulfuron, imazamox, acifluorfen, bentazone, imazethapyr, imazaquin, metolachlor-s, metolachlor and acetochlor (Table A-16). In addition, the percent replacement for each herbicide was estimated based upon a technical understanding of the herbicide products and the marketplace, and the herbicides were grouped based upon those estimates. The displacement analysis presented was conducted relative to the projected use of non-glyphosate herbicides in 2015 because that was estimated to be the year when non-glyphosate herbicide use would plateau in glyphosate-tolerant soybeans based on an aggressive adoption rate for diversified weed resistant management practices. Glyphosate use in glyphosate-tolerant soybean has remained relatively constant over the last decade and is not projected to increase in the future.

To obtain an accurate estimate of the amount of herbicide that dicamba would potentially displace, it was necessary to estimate the number of acres that would be planted to DT soybean and the number of DT soybean acres that would be treated with dicamba at peak market penetration. Monsanto estimated that DT soybean varieties could be planted on up to 50% of the U.S. soybean acres at peak penetration, and that dicamba would be used on up to 80% of those planted acres (*i.e.*, 40% of U.S. soybean acres). That value represents a high-end estimate of incremental dicamba use as described in more detail above. It is reasonable to conclude that the actual market penetration and associated dicamba use could likely be lower.

Additional analyses were conducted for each application timing segment to allow for a comparison of the projected pounds of herbicide applied in 2015 with and without the commercialization of DT soybean. These analyses utilized the same market research as the TAT analysis.

Table A-15. Projected Total Acres Treated (TAT) for PRE herbicides most likely to be displaced by dicamba – Soybean

Active Ingredients	Projected % Replacement	Primary Rationale	2011[a]		2015 (Projected)	
			TAT[a]	TAT Replaced[b]	TAT[c]	TAT Replaced[b]
2,4-D, Paraquat, glufosinate	60%	efficacy, carryover, and/or restricted use	11,441,812	2,746,035	22,883,624	5,492,070
metribuzin, trifluralin	30%	crop safety	4,026,148	483,138	8,052,296	966,276
imazethapyr, pendimethalin	10%	crop safety, carryover, and/or existing resistance	4,476,390	179,056	8,952,780	358,111
Total Projected TAT Replaced				**3,408,228**		**6,816,456**

[a] Unpublished market research data (Monsanto, 2011). TAT is only for those active ingredients within each herbicide grouping.
[b] TAT replaced = TAT x Projected % Replacement x 40%. Monsanto projects dicamba to be conservatively used on 40% of U.S. soybean acres at market penetration.
[c] 2015 TAT is based on the projected growth rate of 100% for non-glyphosate PRE herbicide use taken from Table A-10.

Table A-16. Projected Total Acres Treated (TAT) for POST herbicides most likely to be displaced by dicamba – Soybean

Active Ingredients	Projected % Replacement	Primary Rationale	2011		2015 (Projected)	
			TAT[a]	TAT Replaced[b]	TAT[c]	TAT Replaced[b]
fomesafen, chlorimuron, fluthiacet-methyl, cloransulam-methyl, lactofen flumiclorac, thifensulfuron, imazamox, acifluorfen, bentazone	80%	efficacy, carryover, crop safety, existing resistance	15,247,063	4,879,060	35,373,186	11,319,420
imazethapyr, imazaquin	50%	efficacy, carryover, existing resistance	2,969,428	593,886	6,889,073	1,377,815
metolachlor-s, metolachlor, acetochlor	10%	efficacy	4,110,272	164,411	9,535,831	381,433
Total Projected TAT Replaced				**5,637,357**		**13,078,667**

[a] Unpublished market research data (Monsanto, 2011). TAT is only for those active ingredients within each herbicide grouping.
[b] TAT replaced = TAT x Projected % Replacement x 40%. Monsanto projects dicamba to be conservatively used on 40% of U.S. soybean acres at market penetration.
[c] 2015 TAT is based on the projected growth rate of 132% for non-glyphosate POST herbicide use taken from Table A-11.

A.3.5.2. **Analysis of Displacement of Other Non-Glyphosate Herbicides by Dicamba Use Following Deregulation of DT Soybean**

The commercialization of a soybean product containing dicamba-tolerance will allow for an increase in the use of dicamba for weed control in soybean due to the elimination of in-crop (POST segment) and preplant (PRE segment) crop safety concerns. While dicamba is presently labeled for preplant uses in soybean, that use is currently limited because the application must be made more than 14 days prior to planting in order to address crop safety risks. With crop safety no longer a barrier, farmers can incorporate dicamba into their weed management programs because of the advantages it offers versus other herbicides.

Those advantages will translate into dicamba replacing certain non-glyphosate herbicides currently used preplant or postemergent in-crop in soybeans. In addition, the ability to use dicamba to manage existing resistant weeds will reduce the need for multiple residual herbicides and/or multiple postemergence herbicides in some situations. This will drive an overall reduction in herbicide use in some situations. For example, Monsanto and academics currently recommend that farmers with glyphosate-resistant weeds apply a residual product, such as Valor® (flumioxazin), Gangster® (flumioxazin/cloransulam) or Authority® First (Cloransulam-methyl/sulfentrazone), preemergence to the crop and then follow with glyphosate plus Warrant® (acetochlor) plus either Cobra® (lactofen) or Flexstar® (fomesafen). With the ability of farmers to use dicamba in-crop, dicamba would replace the need to use acetochlor, lactofen or fomesafen, thus reducing overall herbicide use and applications.

Glyphosate is not expected to be replaced by dicamba in either the PRE or the POST segment. Dicamba will primarily be used in combination with glyphosate and this combination will simply displace glyphosate combinations with other non-glyphosate herbicides and/or glyphosate used alone.

A.3.5.2.1. Projected TAT Estimates for Replacement of Currently Used PRE Herbicides by Dicamba

At peak use of DT soybean, dicamba is projected to be used on approximately 40% of total soybean acres. The projected 81.1 million TAT for all non-glyphosate PRE herbicides used in soybeans in 2015 (Table A-10) adjusted for the dicamba use projection of 40% results in a theoretical maximum of 32.4 million TAT that could potentially be displaced by dicamba. The non-glyphosate herbicides most likely to be displaced by dicamba are listed in Table A-15 and include active ingredients that can be used for burndown, residual, or residual and burndown control. These herbicides were selected because of the advantages dicamba would offer relative to each selected herbicide and expected farmer preferences towards dicamba use (*see* Table A-15 for specific advantages). A projected percent replacement was then estimated for each herbicide based on criteria such as lower efficacy, carryover concerns, existing resistance, use restrictions, and/or crop safety. Reductions in use of each herbicide were then estimated and herbicides with the same projected percent replacement were grouped. In the case of the PRE herbicides, the groupings were 10%, 30%, or 60%. Applying the projected percent reductions to the projected 2015 TAT for each reduction grouping provides an estimate for the number of treated acres that dicamba would replace. Based on these assumptions, it can be projected that dicamba would replace an estimated 6.8 million non-glyphosate PRE herbicide TAT in 2015 (Table A-15). Therefore, dicamba could be expected to conservatively replace approximately 21% of the projected TAT for all non-glyphosate herbicides used in PRE application timing in 2015 based on the 40% of total planted soybean acres where dicamba is projected to be used (*i.e.*, 32.4 million TAT). Note that 2015 is not selected based upon the expected year of introduction or peak use of dicamba tolerant soybeans; instead, it was based upon current trends and conservative projections on the growth and adoption of non-glyphosate herbicide use in glyphosate-tolerant soybeans.

A.3.5.2.2. Projected TAT Estimates for Replacement of Currently Used POST Herbicides by Dicamba

As stated previously, a high-end estimate of dicamba use on soybean is 40% of total soybean acres at peak use of DT soybeans. The projected 57.9 million TAT for all non-glyphosate POST herbicides used in soybeans in 2015 (Table A-11) adjusted for the dicamba use projection of 40% results in a theoretical maximum of 23.1 million TAT that could potentially be displaced by dicamba. The non-glyphosate herbicides most likely to be displaced by dicamba are listed in Table A-16 and include active ingredients that can be used for burndown, residual, or residual and burndown control. These herbicides were selected because of the advantages dicamba would offer relative to each selected herbicide and expected farmer preferences towards dicamba use (*see* Table A-16 for specific advantages). A projected percent replacement was then estimated for each herbicide based on criteria such as lower efficacy, carryover concerns, existing resistance, use restrictions, and/or crop safety. Reductions in use of each herbicide were then estimated and herbicides with the same projected percent replacement were grouped. In the case of the POST herbicides, the groupings were 10%, 50%, or 80%. Applying the projected percent reductions to the projected 2015 TAT for each herbicide grouping provides an estimate for the number of treated acres that dicamba would replace. Based on these assumptions, it can be projected that dicamba would replace an estimated 13.1 million non-glyphosate herbicide TAT in 2015. Therefore, dicamba could be expected to conservatively replace approximately 56% of the projected TAT for all non-glyphosate herbicides used in POST application timing in 2015 based upon the above assumption that dicamba will only be used on 40% of total planted soybean acres (i.e., 23.1 million TAT).

A.3.5.2.3. Projected Total Pound Estimates for Replacement of Currently Used Herbicides By Dicamba

The projected total pounds of herbicides in each application segment (PRE and POST) that would be replaced by dicamba were determined using the same methodology and data source as the TAT analysis described above. The same herbicide growth projections for the PRE and POST application segments (*i.e.*, 101% and 132%; see Table A-10 and Table A-11, respectively) were applied to the 2011 pounds of herbicide applied data. Based on this analysis, it can be projected that dicamba would replace an estimated 3.6 million pounds of PRE non-glyphosate herbicides and 1.6 million pounds of POST non-glyphosate herbicides in 2015 (Table A-17 and Table A-18, respectively).

Table A-17. Projected Total Pounds for PRE herbicides most likely to be displaced by dicamba – Soybean

Active Ingredients	Projected % Replacement	Primary Rationale	2011[a]		2015 (Projected)	
			Total Lbs[a]	Total Lbs Replaced[b]	Total Lbs[c]	Total Lbs. Replaced[b]
2,4-D, Paraquat, glufosinate	60%	efficacy, carryover, and/or restricted use	6,266,139	1,503,873	12,532,278	3,007,747
metribuzin, trifluralin	30%	crop safety	1,680,767	201,692	3,361,534	403,384
imazethapyr, pendimethalin	10%	crop safety, carryover, and/or existing resistance	2,564,019	102,561	5,128,038	205,122
Total Projected Pounds Replaced				**1,808,126**		**3,616,252**

[a] Unpublished market research data (Monsanto, 2011). Total Lbs is only for those active ingredients within each herbicide grouping.
[b] Total Lbs replaced = Total Lbs x Projected % Replacement x 40%. Monsanto projects dicamba to be conservatively used on 40% of U.S. soybean acres at market penetration.
[c] 2015 Total Lbs is based on the projected growth rate of 100% for non-glyphosate PRE herbicide use taken from Table A-10.

Table A-18. Projected Total Pounds for POST herbicides most likely to be displaced by dicamba – Soybean

Active Ingredients	Projected % Replacement	Primary Rationale	2011		2015 (Projected)	
			Total Lbs[a]	Total Lbs Replaced [b]	Total Lbs[c]	Total Lbs. Replaced [b]
fomesafen, chlorimuron, fluthiacet-methyl, cloransulam-methyl, lactofen flumiclorac, thifensulfuron, imazamox, acifluorfen, bentazone	80%	efficacy, carryover, crop safety, existing resistance	1,536,012	491,524	3,563,548	1,140,335
imazethapyr, imazaquin	50%	efficacy, carryover, existing resistance	160,245	32,049	371,768	74,354
metolachlor-s, metolachlor, acetochlor	10%	efficacy	4,113,250	164,530	9,542,740	381,710
Total Projected Pounds Replaced				**688,103**		**1,596,399**

[a] Unpublished market research data (Monsanto, 2011). Total Lbs is only for those active ingredients within each herbicide grouping.
[b] Total Lbs replaced = Total Lbs x Projected % Replacement x 40%. Monsanto projects dicamba to be conservatively used on 40% of U.S. soybean acres at market penetration.
[c] 2015 Total Lbs is based on the projected growth rate of 132% for non-glyphosate PRE herbicide use taken from Table A-11.

A.3.6. Net Impact of DT Soybean on Overall Herbicide Use

Table A-19 presents estimates of the net impact of DT soybean on future total acres treated and total pounds of active ingredients. At projected peak penetration of dicamba use in DT soybean, an increase in both total acres treated and total pounds of herbicide active ingredient applied is projected; however, estimated increases are less than 15% of the total herbicide use projections (TAT and pounds of active ingredient) if dicamba-tolerant soybean is not commercialized. The comprehensive analysis set forth in this appendix was completed to evaluate the assertions made in recent publications by Benbrook (2012) and Mortensen et al. (2012), which suggest that the commercialization of dicamba-tolerant soybeans and associated use of dicamba will only be additive to current herbicide use and, according to Mortensen, could result in a 'profound' increase in overall herbicide use. The main reasons for their conclusions are that: (1) overall herbicide use in 2007 was projected not to change through 2013; and (2) dicamba use would be entirely additive to use of existing herbicides. However, this analysis highlights the inaccuracy of these conclusions and clearly demonstrates two key conclusions:

> (1) The overall use of non-glyphosate herbicides in soybean production has significantly grown since 2007, and this growth is expected to continue and eventually plateau. The current and projected future growth is due in large part to the adoption of best management practices as recommended by public and private sector weed scientists and the development and spread of weed resistance. This increase in non-glyphosate herbicide use would occur regardless of the commercialization of DT soybeans, and
>
> (2) When a DT soybean system is available, dicamba would displace a significant amount of non-glyphosate herbicides used for weed management. This analysis conservatively projects that on acres where DT soybean is planted and dicamba is used, dicamba will replace approximately 21% of the projected PRE non-glyphosate herbicide TAT and 56% of the projected POST non-glyphosate herbicide TAT.

The deregulation and subsequent commercialization of DT soybean will not alter the number of cultivated soybean acres or the geographical areas where soybean is cultivated in the U.S. Consequently, DT soybean will be grown on land that is already highly managed for agricultural crop production and where herbicides are widely used today. As described previously, the commercialization of DT soybean will result in a slight increase in herbicide use (treated acres and pounds of dicamba) on those acres where it is planted and the grower chooses to use dicamba in their weed management program. However, the increase in dicamba relative to overall herbicide use in soybean production is relatively low, contributing less than 15% to the overall herbicide use in glyphosate-tolerant soybean production.

While an increase in overall herbicide use in soybean growing areas is projected for the commercialization of DT soybean, assuming growers adopt recommended weed management practices, these practices provide numerous economic and environmental benefits which are detailed in this Environmental Report and Appendices B, C, and F thereto, and summarized below:

- Providing an effective tool for sustainable management of glyphosate resistant weeds;

- Mitigating the potential for the evolution and development of weed resistance for all classes of herbicides used in soybean;
- Improving the consistency of control over hard-to-control weeds, thereby reducing the potential for new resistant biotypes to develop;
- Increasing application flexibility;
- Preserving the benefits of the glyphosate-tolerant weed control system; and
- Preserving the many environmental and economic benefits of conservation tillage

Furthermore, the projected increase in the amount of dicamba used in soybean production is not expected to result in adverse impacts to human health or the environment. The EPA regulates pesticide use and is required under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) to reach a conclusion of no unreasonable adverse effects to human health and the environment before any application of dicamba can be made on DT soybean (*see* Appendices E and F to this Environmental Report). Monsanto has submitted an application to EPA to approve the use of dicamba on DT soybean. EPA concluded in the dicamba Reregistration Eligibility Decision document that all then-registered uses of dicamba can be used without resulting in unreasonable adverse effects when used according to the approved legal label (EPA, 2009). Because the use pattern for dicamba on DT soybean is consistent with the use patterns and assumptions on herbicide use intensification evaluated in the RED, any projected increase in dicamba use from the commercialization of DT soybean is not expected to result in potential adverse impacts to the human health or the environment, and EPA is expected to reconfirm dicamba's safety as part of its review of the Monsanto application.

Table A-19. Net impact of Dicamba-Tolerant soybean on overall herbicide use

	2015 (Projected)	
With Dicamba-tolerant soybean	**Total Acres Treated (TAT) (000 acres / year)**	**Total lbs a.i. (000 lbs a.i. /year)**
Projected increase in dicamba use	(+) 47,112[a]	(+) 20,546[a]
PRE herbicides replaced by dicamba	(-) 6,816[b]	(-) 3,616[c]
POST herbicides replaced by dicamba	(-) 13,079[d]	(-) 1,596[e]
Net change in herbicide use with introduction of dicamba	**(+) 27,217**	**(+)15,334**
Without Dicamba-tolerant soybean		
Projected total of non-glyphosate herbicides	138,938[f]	33,844[g]
Projected total of glyphosate herbicides	112,800[h]	99,186[i]
Total - non-glyphosate plus glyphosate	**251,738**	**133,030**
Dicamba as % of herbicide use in absence of dicamba	11%	12%

[a] Table A-14
[b] Table A-15
[c] Table A-17
[d] Table A-16
[e] Table A-18
[f] The sum of PRE and POST non-glyphosate herbicide projections from Table A-10 and Table A-11, respectively.
[g] Projected total non-glyphosate herbicides is the sum of 2015 PRE and POST non-glyphosate herbicide projections for total lbs a.i. Projected total lbs a.i. are based on the 2011 unpublished market research data for total lbs a.i. (Monsanto, 2011) and the projected growth rates of 100% and 132% for the PRE and POST segments, respectively.
[h] The sum of PRE and POST glyphosate herbicide projections from Table A-10 and Table A-11, respectively.
[i] Projected total glyphosate herbicides is the sum of 2015 PRE and POST glyphosate herbicide projections for total lbs a.i. Projected total lbs a.i. are based on the 2011 unpublished market research data for total lbs a.i. (Monsanto, 2011) and the projected growth rates of 100% and 132% for the PRE and POST segments, respectively.

A.3.7. Comparative Analysis of Dicamba and Alternative Soybean Herbicides

A.3.7.1. **Introduction**

Dicamba is a selective broadleaf herbicide belonging to the auxin agonist class, the oldest known class of synthetic herbicides, and is a member of the benzoic acids sub-group. Dicamba mimics the action of the plant hormone indole acetic acid and causes rapid uncontrolled cell division, and growth leading to plant death. Dicamba has been registered for agricultural uses in the U.S. since 1967 and has been widely used in agricultural production for over forty years. Dicamba is presently approved for use on asparagus, corn, cotton, grass seed production, pasture and rangeland grasses, small cereals including barley, oats, rye, and wheat, sorghum, soybean, and sugarcane. Dicamba is also used for industrial vegetation management (e.g., forestry and roadsides), professional turf management (e.g., golf courses, sports complexes), and residential turf (U.S. EPA, 2009b).

Monsanto Company has developed a biotechnology-derived DT soybean that is tolerant to dicamba (3,6-dichloro-2-methoxybenzoic acid). DT soybean offers growers expanded use of dicamba in soybean production. The excellent crop tolerance of DT soybean to dicamba facilitates a wider window of application in soybean, allowing a preemergence application up to emergence (cracking) and in-crop postemergence applications through the R1/R2 stage of growth. Dicamba provides effective control of over 95 annual and biennial weed species, and control or suppression of over 100 perennial broadleaf and woody plant species. The most common weeds found in soybean fields are listed in Tables A-14 (Midwest region), A-15 (Southeast region), and A-16 (Eastern Coastal region). Many of those weeds can be controlled effectively by dicamba. DT soybean will be combined with MON 89788 (Roundup Ready 2 Yield soybean) utilizing traditional breeding techniques. The combination of herbicide-tolerance traits allows the use of dicamba and glyphosate herbicides in an integrated weed management program to control a broad spectrum of grass and broadleaf weed species, such that the two herbicides can be used in sequence or tank-mixed. Monsanto has submitted an application to the Environmental Protection Agency (U.S. EPA) to register this new use pattern for dicamba on DT soybean (OPP Decision Number D-432752).

The availability of DT soybean integrated into the Roundup Ready soybean system will result in a simple and effective dual mode-of-action herbicide system that will control hard-to-control broadleaf weeds, assist in the management of resistant broadleaf weeds, including glyphosate-resistant biotypes, and subsequently displace some herbicides currently used in soybeans today (referred to here as alternative herbicides).

The intent of this comparative analysis is to define current herbicide use in U.S. soybean production, and to compare dicamba's efficacy and human health and environmental properties to herbicides currently used by growers for weed control. In order for a pesticide (herbicide) to be registered by EPA the U.S. EPA must conclude that the herbicide, when used according to the label, does not pose an unreasonable risk to humans or the environment, and, in order to establish a tolerance for the use of a herbicide on a food or feed crop, find there is a reasonable certainty of no harm to human health from aggregate non-occupational (food, water and residential/recreational) exposures to the herbicide. Consequently, EPA has determined that all alternative herbicides registered for use in soybean do not pose an unreasonable risk to humans or the environment.

Nonetheless, in some instances dicamba offers a reduction in risk potential in the same risk category compared to some alternative herbicides (e.g., acute human risk, aquatic plant risks). In other instances, dicamba presents a similar risk potential compared to the alternatives. In some instances, dicamba presents a greater risk potential compared to some alternatives.

Overall, the use of dicamba on DT soybean incorporated into the Roundup Ready soybean system will offer a benefit compared to alternative soybean herbicides. For human health, aquatic plants and animals, and for preemergence application flexibility,. dicamba use on DT soybean provides an overall reduction of potential risk (combination of "Yes" and "No" entries in TableA-24) compared to the alternatives, except for flumiclorac-pentyl. Specifically:

- Formulations based on the diglycolamine salt of dicamba, such as Clarity® or M1691 herbicide, have favorable acute toxicity profiles that reduce the risk of acute adverse effects for applicators, agricultural workers and bystanders compared to six alternative herbicide products.
- The active ingredient (a.i.) dicamba has favorable chronic, reproduction, carcinogenicity and developmental toxicity characteristics, which reduce the potential for risks from exposure to applicators, agricultural workers and consumers, compared to exposure from eight alternative herbicide products.
- Dicamba has very low toxicity to fish and aquatic invertebrates, and based on EPA high-end exposure screening level assessment methodology, will not affect listed and non-listed aquatic plants and animals, which reduces the potential risk to aquatic organisms as compared to seven alternative products.
- Dicamba use on DT soybean will strengthen and extend the benefits of glyphosate-based weed control in soybean, which has many well-known and recognized environmental and human health benefits, as acknowledged in previous EPA Office of Pesticide Programs (OPP) decisions to grant reduced risk status to multiple glyphosate-tolerant crop uses, including corn, canola, and sugar beet. Additionally, the use of glyphosate-based weed control in soybean has provided growers with more profit opportunities than conventional soybean by reducing input costs (Gianessi, 2005). By utilizing both active ingredients, which have different herbicidal modes-of- action, the risk to soybean production posed by weeds that are hard-to-control with glyphosate alone, or have developed resistant to glyphosate, is reduced. Hard-to-control weeds generally require a higher rate and/or application at a smaller growth stage in order to consistently achieve commercially acceptable control, and includes copperleaf, hemp sesbania, morningglory, prickly sida, velvetleaf, waterhemp, and a number of other broadleaf and grassy weeds. (Table II.B-3 through Table II.B-5)
- Dicamba use on DT soybean will also provide growers with the option to use an herbicide with a different mode-of-action to manage weed species (e.g., Pigweed) where certain biotypes have demonstrated resistance to herbicide classes other than glyphosate, such as protoporphyrinogen oxidase (PPO) or acetolactate synthase (ALS) inhibitors. Herbicide resistant weeds are those listed on the International Survey of Resistant Weeds website (www.weedscience.org).
- Dicamba use on DT soybean will reduce the risk to soybean production that ensues when growers utilize alternate herbicides that have long rotation restriction periods or pose potential for substantial crop injury and loss of yield.
- Planting glyphosate tolerant soybean, thereby allowing the use of glyphosate to effectively control weeds in no-till fields, has made no-till a viable production system for soybean (Pedersen, 2008). The use of dicamba on DT soybean will reduce the risk of growers reverting back to conventional tillage practices from conservation tillage practices due to

concerns over weed control or resistance, and thereby foster continued adoption of conservation tillage practices, which is an important goal for the agro-ecosystem and the long-term sustainability of U.S. agriculture. The integration of DT soybean into the Roundup Ready soybean system will allow the flexibility to incorporate a second herbicide and mode-of-action in preemergent or postemergent applications and support the continued use of conservation tillage production.

In conclusion, dicamba provides a similar, and in some cases a more benign, comparative risk profile compared to other alternative herbicide products; the use of dicamba on DT soybean will positively impact integrated pest management practices and sustainability of soybean production in the United States by providing a valuable weed management tool for this important agricultural crop. Dicamba imparts greater flexibility and weed control options and will help to mitigate the potential for selection for herbicide-resistant weed biotypes for all herbicide modes-of-action (i.e., ALS, HPPD, PPO, glyphosate) currently registered for use in soybean. DT soybean will continue to support adoption of no-till and conservational tillage practices.

Table A-20. Common Weeds in Soybean Production: Midwest Region

Foxtail spp. (12)[1]	Ragweed, giant (3)	Dandelion (1)
Pigweed spp. (11)	Shattercane (3)	Johnson grass (1)
Velvetleaf (11)	Quackgrass (3)	Milkweed, honeyvine (1)
Lambsquarters (10)	Buckwheat, wild (2)	Nightshade, hairy (1)
Cocklebur (9)	Crabgrass spp. (2)	Oats, wild (1)
Ragweed, common (7)	Kochia (2)	Pokeweed, common (1)
Smartweed spp. (6)	Mustard, wild (2)	Prickly sida (1)
Morningglory spp. (5)	Nightshade, Eastern black (2)	Proso millet, wild (1)
Sunflower, spp. (5)	Palmer pigweed (2)	Sandbur, field (1)
Waterhemp spp. (5)	Canada thistle (1)	Venice mallow (1)
Horseweed (marestail) (3)	Chickweed (1)	Volunteer cereal (1)
Panicum, fall (3)	Cupgrass, woolly (1)	Volunteer corn (1)

[1] Number provided in parenthesis is the number of states out of the thirteen total states in the Midwest region reporting each weed as a common weed.

Sources:

IL: University of Illinois (2002) and Aaron Hager, Extension Weed Specialist, University of Illinois - Personal Communication (2006).

IN: 2003-2005 Statewide Purdue Horseweed Weed Survey, Special database query and personal communication (2006), Bill Johnson, Extension Weed Specialist, Purdue University.

IA, MN, OH, WI: WSSA, 1992.

KS: Dallas Petersen, Extension Weed Specialist, Kansas State - Personal communication (2006).

KY, MO: Webster et al., 2005.

MI: Davis et al., 2005.

NE: Alex Martin, Extension Weed Specialist, University of Nebraska – Personal communication (2006).

ND: Zollinger, 2000.

SD: Michael Moechnig, Extension Weed Specialist, South Dakota State University – Personal communication (2006).

Table A-21. Common Weeds in Soybean Production: Southeast Region

Morningglory spp. (8)[1]	Goosegrass (3)	Cutleaf evening-primrose (1)
Crabgrass spp. (6)	Johnsongrass (3)	Groundcherry (1)
Prickly sida (6)	Ragweed, common (3)	Henbit (1)
Nutsedge spp. (6)	Cocklebur (2)	Lambsquarters (1)
Sicklepod (5)	Florida beggarweed (2)	Ragweed, giant (1)
Signalgrass, broadleaf (5)	Hemp sesbania (2)	Smartweed (1)
Palmer pigweed (4)	Horseweed (marestail) (2)	Spurge, nodding/hyssop (1)
Pigweed spp. (4)	Texas millet (2)	Spurge, Prostrate (1)
Barnyard grass (3)	Browntop millet (1)	Tropic croton (1)
Florida pusely (3)	Copperleaf, hophorn (1)	

[1] Number provided in parenthesis is the number of states out of the eight total states in the Southeast region reporting each weed as a common weed.
Sources:
AL, AR, GA, LA, NC, SC: Webster et al., 2009.
MS, TN: Webster et al., 2005.

Table A-22. Common Weeds in Soybean Production: Eastern Coastal Region

Foxtail spp. (6)[1]	Morningglory spp. (4)	Dandelion (1)
Ragweed, common (6)	Panicum, fall (4)	Goosegrass (1)
Velvetleaf (6)	Crabgrass spp. (3)	Johnson grass (1)
Lambsquarters (5)	Nutsedge spp. (3)	Nightshade, Eastern black (1)
Pigweed spp. (5)	Quackgrass (2)	Prickly sida (1)
Cocklebur (4)	Canada thistle (1)	Shattercane (1)
Jimson weed (4)	Burcucumber (1)	Smartweed spp. (1)

[1] Number provided in parenthesis is the number of states out of the six total states in the Eastern Coastal region reporting each weed as a common weed. Data were not available for DE in soybean.
Sources:
DE, MD, NJ, PA: WSSA, 1992.
NY: Russell Hahn, Extension Weed Specialist, Cornell University – Personal Communication (2006).
VA: Webster et al., 2009.

A.3.7.2. **Properties of Alternative Herbicide Products**

Ninety-seven percent (97%) of soybean treated acres receive an application of glyphosate, and the remaining acres are treated with more than 25 other active ingredients. In some of the soybean acres, these other active ingredients are applied on acres that also receive a glyphosate application. The ten most widely used herbicides are shown in Table A-23. Integration of DT soybean into the Roundup Ready soybean system and the subsequent use of dicamba will result in the displacement of some currently used, or foreseeable future use herbicides, and therefore the properties of these alternative herbicides are summarized in this section to provide a baseline for comparison to dicamba use on DT soybean.

Table A-23. Ten Most Widely Used Alternative Herbicides in U.S. Soybean Production in 2012

Herbicide	Treated acres (millions)[1]	Pounds Applied
2,4-D (acid, salts, and esters,	11.58	6.02
Flumioxazin	8.49	1.56
Imazethapyr	3.86	1.35
cloransulam-methyl	3.09	0.60
chlorimuron-ethyl	8.49	0.52
Fomesafen	6.18	0.22
Clethodim	6.95	0.19
pendimethalin	1.54	0.08
Tribenuron	0.77	0.04
flumiclorac-pentyl	0.77	0.01

[1] USDA-NASS, 2013

Table A-24 summarizes key information from alternate herbicide product labels. Table A-25 lists the eighteen active ingredients that make up the products in Table A-24. 2,4-D, being used primarily as a pre-plant application, is the most widely-used herbicide in this alternate herbicide list, representing about 10% of treated acres; whereas acifluorfen, carfentrazone-ethyl, and flufenacet are the least used among these, representing <0.5% of treated acres. Mesotrione has not been used in soybean production previously; the use on soybean was only recently registered by the EPA (2009d). Table A-25 also lists general regulatory information about each herbicide. Note that only paraquat is classified as a Restricted Use pesticide among this group, on the basis of acute toxicological concern.

Table A-24. Dicamba and Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word[1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Clarity (7969-137)	Dicamba	Caution	4.0 lb a.e./gal	24 hr	1.0 [1]	2.0 [1]	Known to leach; 50-foot buffer to wells; Runoff advisory; Drift advisory; State-specific limitations; Soil type limitations; Maximum crop rotation interval 3 – 6 months.
Aim® (279-3241)	Carfentrazone-ethyl	Caution	2 lb/gal	12 hr	0.008 [5]	0.023	"toxic to fish"; "toxic to algae"; V3 - V10; do not feed foliage; some burn injury
Authority® First DF (279-3246)	Sulfentrazone Cloransulam-methyl	Caution	0.62 lb/lb 0.08 lb/lb	12 hr	0.31 0.04	0.31 0.04	"known to leach"; "toxic to marine / estuarine invertebrates"; 65-day PHI; crop rotation restrictions, up to 30 mts; soil O.M. limits (sands <1% organic matter)
Authority MTZ (279-3340)	Sulfentrazone Metribuzin	Caution	0.18 lb/lb 0.27 lb/lb	12 hr	0.028 0.042	0.046 0.07	"known to leach"; "toxic to marine / estuarine invertebrates"; 120-day PHI (not Over The Top); sensitive varieties, injury possible
Basagran® (7969-45)	Bentazon	Caution	4 lb/gal	48 hr	1	2	"known to leach"; 30-day PHI for feeding treated forage and hay; minor injury
Butoxone® 7500 (71368-49)	2,4-DB	Caution	0.75 lb/lb	48 hr	0.375		soil type limits
Butyrac® 200 (42750-38)	2,4-DB DMA salt	Danger	2 lb/gal	48 hr	0.4	0.4	"toxic to fish"; 60-day PHI; injury may occur, especially with tank mixtures

Table A-24 (continued). Dicamba and Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word[1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Cadet® (279-3338)	Fluthiacet-methyl	Warning	0.91 lb/gal	12 hr	0.0065	0.009	do not feed foliage; minor injury
Callisto® (100-1131)	Mesotrione	Caution	4 lb/gal	12 hr	0.1875	0.1875	"high potential for runoff"; crop rotation restrictions up to 18 mts; "transient bleaching" may occur; pre-emergence use only, no in crop use
Classic® (352-436)	Chlorimuron-ethyl	Caution	0.75 lb/lb	12 hr	0.14	0.14 [6]	60-day PHI; crop rotation restrictions up to 30 mts and complicated description of 3 different intervals specific to US regions and soil pH; do not feed foliage; soil type limits; "temporary leaf yellowing"
Cobra® (59369-34)	Lactofen	Danger	2 lb/gal	12 hr	0.2	0.4 [6]	"toxic to fish"; do not apply past soybean growth stage R6/45-day PHI; minor injury
Extreme ® (241-405)	Imazethapyr	Warning	0.17 lb/gal	48 hr	0.064 [6]	0.064 [6]	"properties & characteristics associated with chemicals detected in ground water"; crop rotation limits
	Glyphosate-IPA		2 lb/gal		0.75	0.75	
FirstRate (62719-275)	Cloransulam-methyl	Caution	0.84 lb/lb	12 hr	0.04	0.055	65-day PHI; crop rotation restrictions up to 30 mts; soil types; 14-day forage and hay feeding restriction

Table A-24 (continued). Dicamba and Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word[1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Flexstar ® (100-1101)	Fomesafen	Warning	1.88 lb/gal	24 hr	0.35	0.375 [6]	"cause tumors"; "known to leach"; 45-day PHI; do not feed foliage; crop rotation limits
Gangster ® Co-pack (59639-131)	Flumioxazin	Caution	51%	12 hr	0.096	0.096	"toxic to aquatic invertebrates"; "Preemergent only"; "properties & characteristics Associated with chemicals detected in ground water"; "toxic to invertebrates."
	Cloransulam-methyl		84%		0.032	0.032	
Gramaoxone Inteon ® (100-1217)	Paraquat dichloride	Danger	2 lb/gal (cation basis)	12 hr	1.5	2.9	"toxic to wildlife"; Restricted Use; no Over-the-Top use
Ignite® (264-829)	Glufosinate-ammonium	Warning	2.34 lb/gal	12 hr	0.66	0.8	"runoff potential"; "toxic to vascular plants"; 70-day PHI; some crop rotation limits up to 180 days; only Over-the-Top to Liberty Link soybean
Liberty® (264-660)	Glufosinate-ammonium	Warning	1.67 lb/gal	12 hr	0.44	0.8	"runoff potential"; "toxic to vascular plants"; 70-day PHI; do not feed foliage; crop rotation limits up to 120 days;
Phoenix® (59639-118)	Lactofen	Caution	2 lb/gal	12 hr	0.3	0.4 [6]	"toxic to fish"; Do not apply past crop growth stage R6 / 45-day PHI; minor injury
Pursuit® (241-310)	Imazethapyr	Caution	2 lb/gal	4 hr	0.063	0.063	"properties & characteristics associated with chemicals detected in ground water"; 85-day PHI; do not feed forage and hay

Table A-24 (continued). Dicamba and Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word [1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Pursuit® Plus (241-331)	Pendimethalin	Caution	2.7 lb/gal	24 hr	0.84	0.84	"properties & characteristics associated with chemicals detected in ground water"; "toxic to fish"; 85-day PHI; crop rotation limits up to 40 months
	Imazethapyr		0.2 lb/gal		0.063	0.063	
Raptor ® (241-379)	Imazamox-ammonium	Caution	1 lb/gal	4 hr	0.04	0.04	"phytotoxic to all plants"; plantback / crop rotation limits up to 26 months, two regions with complicated warnings
Reflex® (100-993)	Fomesafen	Danger	2 lb/gal	24 hr	0.375	0.375 [6]	"known to leach"; 45-day PHI; crop rotation limits up to 18 mts; minor injury, significant geographical restrictions (5 regions each with different rate structure)
Resource® (59639-82)	Flumiclorac-pentyl	Warning	0.86 lb/gal	12 hr	0.081	0.11	"toxic to shrimp"; 60-day PHI; do not feed forage or hay to livestock; temporary spotting or burn to soybean
Scepter ®70 DG (241-306)	Imazaquin	Caution	0.7 lb/lb	12 hr	0.123	0.123 [6]	"properties & characteristics associated with chemicals detected in ground water"; 90-day PHI; do not feed forage or hay to livestock; crop rotation limits up to 40 mts; regional limitations (3 regions)

Table A-24 (continued). Dicamba and Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word [1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Sencor® (DF 75%) (264-738)	Metribuzin	Caution	0.75lb/lb	12 hr	0.66 [6]	1.3 [6]	"can seep or leach"; 70-day grain PHI; 40-day PHI on feeding forage to livestock; no Over-the-Top application, directed spray OK; injury in high pH or low O.M. soils or on certain crop varieties, crop rotation limits up to 18 mts
Synchrony® XP (352-648)	Thifensulfuron	Caution	0.069 lb/lb	12 hr	0.013	0.013	45-day planting restriction applied prior to soybean planting/emergence; 60-day PHI; complicated crop rotation restrictions (3 regions, 4 intervals) with limits up to 30 mts; do not feed forage or hay to livestock; soil types; injury if adjuvants or tank mixed
UltraBlazer (70506-60)	Acifluorfen sodium Chlorimuron-ethyl	Danger	2 lb/gal 0.215 lb/lb	48 hr	0.374 0.04	0.5 0.04	50-day PHI; minor injury
Valor® SX (59639-99)	Flumioxazin	Caution	0.51 lb/lb	12 hr	0.096	0.096	"runoff potential"; "toxic to aquatic invertebrates"; preemergence use only, no in crop use; do not feed forage or hay to livestock; crop rotation limit up to 18 mts. & soil type limits; injury under cool wet conditions or poorly drained soil; restrictions on use with flufenacet, alachlor, metolachlor, or dimenthenamid

Table A-24 (continued). Dicamba and Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word [1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Valor® XLT (59639-117)	Flumioxazin Chlorimuron-ethyl	Caution	0.3 lb/lb 0.103 lb/lb	12 hr	0.094 0.032	0.094 0.032	"toxic to aquatic invertebrates"; preemergence only, no in crop use; do not feed forage or hay to livestock; crop rotation limits up to 30 mts; injury under cool wet conditions or poorly drained soil
Weedone® (650, 638, LV4, LV6) and other 2,4-D brands (71368-3, -6, -10, -11, -14, -19)	2,4-D; 2,4-D salts; 2,4-D esters	Varies	Varies		0.93	0.93	Weedone 650 as an example: "toxic to aquatic invertebrates"; do not use on sandy soils (<1% O. M.); preplant to emerged weeds only, no in crop use; do not feed forage or hay to livestock

1 The EPA-required statement to convey to applicators the overall acute toxicity hazard posed by the product. Caution is more favorable than Warning, which is more favorable than Danger.
2 The period of time following application during which worker reentry into the treated area is restricted, according to EPA's Worker Protection Standard (WPS).
3 The highest single-treatment and seasonal rates that can be applied to soybean according to the product Directions for Use label.
4 Lists specific statements extracted from the product label that represent specific hazards or limitations that may reduce the utility of the product for soybean weed control
5 Higher rates with directed / hooded sprayers.
6 Regional or soil type limitations may lower this rate.
7 Soybean label not yet publically available. Corn label comments are cited
PHI – preharvest interval, O. M. – organic matter, mts - months.

Table A-25. Active Ingredients Contained in Alternative Herbicides

Active Ingredient	First Registered[1]	2006 Treated Soybean Acreage (%)[2]	Registration Review Status[3]	RED Date[4]	Max. Soybean lb/a (single treatment)[5]	Max. Soybean lb/a (season)	Tolerances (40 CFR 180)[6]	Restricted Use[7]
glyphosate salts	3-May-76	97	open 2009	Sep-93	1.5	6	364	No
dicamba-diglycolamine salt	2-Feb-56	<0.5	NA	Jun-09, corrected	1[9]	2[9]	227	No
2,4-D acid, salts, and esters	3-Jun-52	10	2013	Jun-05	0.93	0.93	142	No
Flumioxazin	12-Apr-2001	3	unscheduled	NA	0.096	0.096	568	No
Imazethapyr	30-Jan-87	3	2014	Jun-06	0.064[8]	0.064[8]	447	No
cloransulam-methyl	29-Oct-1997	1	2011	NA	0.04	0.055	514	No
chlorimuron-ethyl	4-Apr-86	4	2011	Sep-04 TRED	0.14	0.14[8]	429	No
Fomesafen	10-Apr-87	2	open 2007	TRED Aug-07	0.375	0.375[8]	433	No
flumiclorac-pentyl	23-Mar-94	1	open 2009	Aug-05 TRED	0.081	0.11	477	No
Sulfentrazone	22-Nov-93	1	open 2009	NA	0.31	0.31	498	No
Thifensulfuron	25-Apr-86	1	2011	NA	0.013	0.013	439	No
Imazaquin	20-Mar-86	1	2014	TRED Dec-05	0.123	0.123[8]	426	No
imazamox-ammonium	17-Apr-95	<0.5	2014	NA	0.04	0.04	1223	No
paraquat dichloride	8-Jan-80	1	2012	Aug-97	1.0	2.9	205	Yes
Lactofen	1-Apr-87	<0.5	open 2007	TRED Sep-03	0.3	0.4	432	No
glufosinate-ammonium	29-May-91	<0.5	open 2008	NA	0.66	0.8	473	No
2,4-DB	30-Jun-66	<0.5	2014	Jan-05	0.4	0.4	331	No
fluthiacet-methyl	14-Apr-99	<0.5	unknown	NA	0.0065	0.009	551	No
acifluorfen sodium	29-May-81	<0.5	unscheduled	Sep-09	0.374	0.5	383	No
Mesotrione	4-Jun-01	0.0	unscheduled	NA	0.1875	0.1875	571	No

TRED denotes Tolerance Reregistration Eligibility Decision

[1] The date the herbicide was first approved for any use (*e.g.*, industrial) by U.S. EPA.

[2] The percentage of the herbicide-treated soybean acres that were treated with each herbicide in AR, IA, IL, IN, KS, KY, LA, MI, MN, MS, MO, NE, NC, ND, OH, SD, TN, VA, and WI in 2006 (USDA-NASS, 2007b) .

[3] The herbicide's progress in the ongoing EPA program named as Registration Review. Year indicates when the official docket was or will be opened. EPA is required by law to re-evaluate pesticides periodically, generally every 10-15 years.

[4] The date when EPA issued a Reregistration Eligibility Decision document. Reregistration was an earlier re-evaluation program designed to ensure that supporting data are up-to-date for a.i.s first registered before 1984. TRED means Tolerance Reassessment Eligibility Decision, which refers to an alternative review path that some post-1984 a.i.s followed.

[5] The maximum amount of the herbicide that can be applied to soybean in a single treatment or during the entire season, according to product labels.

[6] The number of the paragraph in the Code of Federal Regulations where that herbicide's food and feed tolerances are listed.

[7] An EPA pesticide classification that restricts a product, or its uses, to use by a certificated pesticide applicator or under the direct supervision of a certified applicator. See 40 CFR 152.160.

[8] Regional or soil type limitations may lower this rate.

[9] Maximum treatment rates for the proposed dicamba label.

A.3.7.2.1. Human Health Effects of Alternative Herbicide Products

Table A-26 provides information concerning human health parameters for each alternative herbicide compared to dicamba. The listed parameters include:

- Acute Toxicity Categories for the herbicide.
- Cancer Classification of the herbicide.
- FQPA (Food Quality Protection Act) safety factor employed in EPA's risk assessment process for the herbicide.
- Level of Exposure representing the acceptable safe range for acute (acute population adjusted dose, aPAD) and chronic (chronic population adjusted dose, cPAD) exposures.
- Extent to which all presently approved uses exhaust the acceptable safe exposure range (% aPAD and % cPAD utilized for the most highly exposed population subgroups), according to recent Federal Register Rules or other public risk assessment documents.

A variety of chemical-specific public data sources were used to compile this comparison (See Alternative Herbicide-Specific References). Columns 9 to 11 in Table A-26 (to the right of the vertical gray bar) pertain to the use of the herbicide in soybean, specifically:

- The established soybean seed food tolerance in 40 CFR 180 that supports the uses in soybean.
- The Theoretical Maximum Residue Concentration (TMRC) arising from this soybean tolerance using the DEEM dietary exposure software, assuming that residues are at tolerance levels and that 100% of the crop has been treated.
- The percentage of the acceptable chronic exposure (cPAD) that is contributed by the soybean TMRC dietary exposure.

Table A-26. Human Health Risk Parameters for Alternative Herbicides

Active Ingredient	Acute (Oral, Dermal, Inhalation, Eye Irr., Skin Irr., Sens.)[1]	Cancer Classification[2]	cPAD mg/kg/day [3]	% cPAD Utilized[4,5]	aPAD mg/kg/day [6]	% aPAD Utilized [6,5]	FQPA SF[7]	Soy Seed Tol. (ppm) [8,9]	Soybean diet exposure µg/kg/day [5,8,10]	% Soybean diet exposure / cPAD [8,11]
glyphosate acid / potassium salt	IV / IV / NA / II / IV / N; IV / IV / III / III / IV / N	E	1.75	7	NA	NA	1X	20	33.24	1.90%
dicamba acid diglycolamine salt[12]	III / III / IV / II / II / N; III / III / IV / III / III / N	not likely	0.45	6.6	1	11	1X	10	16.62	3.69%
2,4-D acid /salts / esters	III / III / III/ **I** / III-IV / N; III / III / IV / III / IV / N	D	0.005	38	0.067	58	1X	0.02	0.03	0.66%
flumioxazin	IV/III/IV/III/IV/N	not likely	0.02	18	0.03	8	1X	0.02	0.03	0.17%
imazethapyr	IV / III / IV / IV / III / N	not likely	2.5	< 1	NA	NA	1X	0.1	0.17	0.01%
cloransulam-methyl	IV / III / III / III / IV / N	not likely	0.1	<1	NA	NA	1X	0.02	0.03	0.03%
chlorimuron-ethyl	IV / III / IV / III / IV / N	not likely	0.09	0	NA	NA	1X	0.05	0.08	0.09%
fomesafen	III / II /III / **I** / II-III /	not likely	0.0025	31	NA	NA	1X	0.05	0.08	3.32%
flumiclorac-pentyl	IV / III/ IV/ IV/ II/ Y	no evidence	1	< 0.01	NA	NA	1X	0.01	0.02	0.00%
sulfentrazone	III/ III / IV / **I** / IV / Y	not likely	0.14	<1	0.25	1	1X	0.05	0.08	0.06%
thifensulfuron	IV / III / IV / IV / III /	not likely	0.07	<1	1.59	<0.1	1X	0.1	0.17	0.24%
imazaquin	IV / III / III / IV / IV /	no evidence	0.25	<1	NA	NA	1X	0.05	0.08	0.03%
imazamox-ammonium	IV / III / IV / III / IV / N	not likely	NA	NA	NA	NA	1X	ex '03	NA	NA
paraquat dichloride	II / III / **I** /II / IV / N	E	0.00045	26	0.0042	66	1X	0.7	1.16	**258.53%**

Table A-26 (continued). Human Health Risk Parameters for Alternative Herbicides

Active Ingredient	Acute (Oral, Dermal, Inhalation, Eye Irr., Skin Irr., Sens.)[1]	Cancer Classification[2]	cPAD mg/kg/day [3]	% cPAD Utilized[4,5]	aPAD mg/kg/day [6]	% aPAD Utilized [6,5]	FQPA SF[7]		Soy Seed Tol. (ppm) [8,9]	Soybean diet exposure µg/kg/day [5,8,10]	% Soybean diet exposure / cPAD [8,11]
Lactofen	IV / III / IV / III / IV / N	likely/unlikely	0.008	<0.1	0.17	<0.1	**3X (A)**		0.01	0.02	0.21%
glufosinate-ammonium	III / III / III / III / IV / N	no evid. of	0.006	27	0.0063	48	1X		2	3.32	**55.40%**
2,4-DB	III / III / IV / III / IV /	not likely	0.03	2	0.6	<1	1X		0.5	0.83	2.77%
fluthiacet-methyl	IV / III / IV / IV / IV /N	**likely ($7.5x10^{-7}$)**	0.001	<1	NA	NA	1X		0.01	0.02	1.66%
acifluorfen sodium	III / III / IV / **I** / II / N	likely/unlikely	0.013	<1	0.02	<1	**1X/3X /10X**		0.1	0.17	1.28%
Mesotrione	IV / III / IV / III / IV /	not likely	0.007	5.8	NA	NA	**3X**		0.01	0.02	0.23%

Sources of the information summarized in this table are listed in the Alternative Herbicide Specific References Section.
N denotes negative for dermal sensitization
NA stands for not applicable.

[1] EPA categories for the standard six acute toxicity tests of the active ingredient. Categories I and IV denote the least and most favorable findings, respectively. Category I findings are highlighted in **bold** font.

[2] The conclusion reached by the EPA Office of Pesticide Programs Cancer Assessment Review Committee. The system of classification has changed over the years, resulting in a combination of different terminology. Generally, Group E, "not likely" or "no evid." are the most favorable conclusions, Group D indicates some uncertainty, and "likely/not likely" or "likely" indicate that a potential to induce cancer exists. More information can be found at http://www.epa.gov/opp00001/health/cancerfs.htm. "Likely" findings are highlighted in bold font.

[3] The EPA-determined chronic Population Adjusted Dose, against which chronic exposure, primarily from combined food and water residues, are compared for human health risk assessment. This key risk assessment parameter is derived from consideration of all the chronic toxicity studies, and includes all necessary safety factors. Higher values indicate herbicides with less severe chronic toxicity effects.

[4] The percentage of the cPAD that is represented by all presently approved uses of that herbicide for the most highly-exposed population subgroup. It is calculated by summing estimated chronic exposures from dietary and water, and dividing by the level of exposure that is considered safe (*i.e.*, cPAD). Lower percentages indicate that current estimated exposure is a smaller proportion of the safe level, and therefore implies a greater margin of safety. EPA presents this calculation when new risk assessments are conducted, such as when a new food tolerance is petitioned.

[5] Most highly exposed population subgroup.

[6] The acute risk assessment parameters correspond to those described above for chronic exposure. In some cases, EPA's review of the acute toxicity testing does not result in an acute effect of concern, and no aPAD is needed, indicated in the table as NA.

[7] The Safety Factor EPA has utilized according to the requirements of the Food Quality Protection Act. FQPA that requires EPA utilize an additional 10-fold (10x) safety factor to protect infants and children, unless the scientific results indicate that a different level is protective. If the database is complete, and the reproductive and developmental toxicity studies do not indicate that pre- and postnatal exposure results in increased sensitivity, EPA often reduces the FQPA SF to 1x. If there is indication of increased sensitivity, or the necessary data are lacking, SFs of 3X or 10X are sometimes used. These higher safety factors are considered in this analysis to denote higher risk to infants and children, and such cases are highlighted in bold font.
[8] The 3 columns to the right of the gray bar pertain to the use of each herbicide on soybean only, other current uses are excluded from this analysis.
[9] The soybean seed food tolerance established in the relevant numbered paragraph in 40 CFR 180.
[10] The Monsanto-calculated theoretical maximum dietary exposure to the most highly-exposed U.S. population subgroup if 100% of all soybean were treated with that herbicide, and residues were at tolerance levels. This theoretical exposure does not occur in real life, but allows a consistent comparison for all alternate herbicides. The calculation is made using the same DEEM dietary exposure model that EPA routinely uses http://www.durango-software.com/software/deem.html.
[11] The ratio of the prior column divided by the cPAD. It denotes the percentage of the safe exposure level that is attributed to soybean residues, as a soybean risk index. High numbers are less favorable. Any value above 100% requires further risk refinement to be deemed acceptable, such as that for paraquat. Values greater than 10-times that of dicamba are highlighted in bold font.
[12] Dicamba diglycolamine data are for Clarity (U.S. EPA Reg. No. 7969-137) and M1691 formulations (U.S. EPA Reg. No. 524-582).

A.3.7.2.2. Ecological Effects of Alternative Herbicide Products – Non-target Species

Fish and Aquatic Invertebrates

Table A-27 provides information about the hazards, exposures, and risks of dicamba and each of the eighteen alternative herbicides to fish and aquatic invertebrates (considering 2,4-D acid, salts, and esters as one alternative herbicide). The listed parameters include:

- LC_{50} endpoints from acute fish toxicity studies, as reported in EPA's ecotoxicity database[76], published in a RED or in Registration Review risk assessments. The highest and lowest available LC_{50} values for any fish study are listed, regardless of species, including both fresh and marine species together. The purpose is to define a range of concentrations that spans the expected fish toxicity levels.
- EC_{50} endpoints from acute aquatic invertebrate studies, as reported from the same sources cited above. The highest and lowest available EC_{50} values for any invertebrate study are listed, regardless of species, including both fresh and marine species together. The purpose is to define a range of concentrations that spans the expected aquatic invertebrate-toxic levels.
- Estimated environmental exposure concentrations (EECs) in surface water for each of the eighteen alternative herbicides. The third column in Table A-27, identified as "Calculated EEC", provides a simple standard estimate based on the maximum single application rate in soybean, using EPA's standard field-farm pond scenario. This scenario examines a 1-acre pond in a 10-acre field in which (1) 5% of the application drifts into the 6-foot-deep pond and (2) 5% of the application onto the 10 acres runs off into the same pond. The fourth column in Table A-27 lists other model estimates of surface water concentrations as provided by one or more modeling programs, as cited by EPA in public documents, such as Federal Register final tolerance rule drinking water assessments. The purpose is to define a range of concentrations that spans available estimates of potential aquatic exposure levels.
- Calculated Risk Quotients (RQs) for aquatic animals, comprised of fish and aquatic invertebrates combined together. Rather than calculate a single RQ for each species, Monsanto has calculated a range of potential RQs for each herbicide, bracketed by the best- and worst-case values. The "best" RQ is derived from the ratio of the lowest reported EEC concentration divided by the highest LC_{50} or EC_{50} for any aquatic animal. Conversely, the "worst" RQ is derived from the ratio of the highest EEC concentration divided by the lowest LC_{50} or EC_{50} for any aquatic animal. (Note: the RQ figures are rounded to two decimal places, so that entries that appear as "0.00" mean that the specific RQ is less than 0.005.) The purpose is to define a range of RQs that span and describe the risk posed by the alternative herbicide to aquatic animals. The RQs that exceed the EPA's Level of Concern (LOC) of 0.5 are marked in bold font.

Using the worst-case risk quotient, ten of 18 alternative herbicides have risk quotients greater than or equal to 0.01, while the worst-case risk quotient for dicamba and seven other herbicides is <0.01.

[76] National Information System – Regional IPM Centers. OPP Pesticide Ecotoxicity Database. http://www.ipmcenters.org/Ecotox/index.cfm [Accessed May 27, 2010].

Only three of these 10 herbicides have risk quotients greater than 0.05 or 0.1, the levels of concern for threatened or endangered species and acute restricted use, respectively. Two of these 10 herbicides have RQ values greater than 0.5, the highest acceptable level of concern. Monsanto believes that based on risk quotients, dicamba offers a lower potential risk to aquatic animals relative to at least three of the 18 alternative herbicides: 2,4-D esters, flumioxazin, and lactofen. This conclusion is tabulated in Table A-24, which summarizes the comparative analysis of dicamba and alternative herbicides.

In order to approve a new use of a herbicide EPA must conclude that the herbicide, when used according to the label, does not pose an unreasonable adverse effect to humans or the environment. In addition, in order to establish a tolerance for the use of a herbicide on a food or feed crop, EPA must find that there is a reasonable certainty of no harm to human health from non-occupational (food, water and residential/recreational) exposures to the herbicide. Therefore, all alternative herbicides used in soybean production, including those discussed above, can be used safely and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances, such as those mentioned above, dicamba offers a reduction in risk potential (i.e., hazard) compared to some alternative herbicides in the same risk category (e.g., aquatic animal risk). In other instances dicamba presents a similar risk potential compared to some alternatives. In a few cases, dicamba presents a greater risk potential compared to some alternatives. This comparative analysis serves to demonstrate that the use of dicamba on DT soybean is unlikely to result in a significant impact/risk to human health or the environment compared to current herbicide agronomic practices and in some instances its use may impart additional benefits as described above.

Table A-27. Aquatic Toxicity Parameters for Fish and Aquatic Invertebrates for Alternative Herbicides

Active Ingredient	Maximum Soybean lb/acre (single treatment)[1]	Calculated EEC (ppm)[2,3]	FIRST, GENEEC or PRZX/EXAMS Surface Water ppm (RED or Tolerance Rule)[4]	Fish LC_{50} Range (ppm)[5]		Aquatic Invertebrate LC_{50} or EC_{50} Range (ppm)[f]		Risk Quotient for Aquatic Animals Range[6]		Label Warnings[7]
				low	high	low	high	best	worst	
glyphosate salts	1.5	0.050	0.0008 - 0.021	45	>1000	55	780	0.00	0.00	
dicamba /DGA salt	1	0.034	0.01 - 0.036	28	> 270	>100	>270	0.00	0.00	
2,4-D acid + salts	0.93	0.031	0.064 - 0.118	>80	2244	25	820	0.00	0.00	
2,4-D esters	0.93	0.031	0.064 - 0.118	>0.15	14.5	2.2	12	0.00	**< 0.79**	
flumioxazin	0.096	0.003	0.018 - 0.034	2.3	21	0.23	5.5	0.00	0.15	"toxic to invertebrates”
imazethapyr	0.064	0.002	0.006	> 112	423	> 109	> 1000	0.00	0.00	
cloransulam-methyl	0.04	0.001	0.002	> 86	> 154	> 111	> 121	0.00	0.00	"toxic to invertebrates”
chlorimuron-ethyl	0.14	0.005	0.003 - 0.005	> 2	8.4	>10[a]	> 10	0.00	0.00	
fomesafen	0.375	0.013	0.006 - 0.012	126	> 163	25	376	0.00	0.00	
flumiclorac-pentyl	0.081	0.003	0.00024	>0.189	> 24	>0.189	>38	0.00	0.02	"toxic to shrimp"
sulfentrazone	0.31	0.010	0.004 - 0.016	94	> 120	1	60.4	0.00	0.02	"toxic to invertebrates”
thifensulfuron	0.013	0.000	0.0003 - 0.004	>100	> 100	>1000	> 1000	0.00	0.00	

Table A-27 (continued). Aquatic Toxicity Parameters for Fish and Aquatic Invertebrates for Alternative Herbicides

Active Ingredient	Maximum Soybean lb/acre (single treatment)[1]	Calculated EEC (ppm)[2,3]	FIRST, GENEEC or PRZX/EXAMS Surface Water ppm (RED or Tolerance Rule)[4]	Fish LC_{50} Range (ppm)[5]		Aquatic Invertebrate LC_{50} or EC_{50} Range (ppm)[5]		Risk Quotient for Aquatic Animals Range[6]		Label Warnings[7]
				low	high	low	high	best	worst	
imazaquin	0.123	0.004	0.004 - 0.008	280	420	280[a]	280	0.00	0.00	
imazamox-ammonium	0.04	0.001	0.002	> 94.2	> 122	>94.3	> 122	0.00	0.00	
paraquat dichloride	1.0	0.033	0.0015	> 1	156	1.2	1.2	0.00	< 0.05	
lactofen	0.3	0.011	0.000008 - 0.4	0.46	0.46	0.02	4.85	0.00	**20**	"toxic to fish"
glufosinate-ammonium	0.66	0.022	0.043 - 0.094	> 320	> 1000	8	668	0.00	0.01	
2,4-DB	0.4	0.013	0.013 - 0.015	2	18	25[a]	25	0.00	0.01	"toxic to fish"
fluthiacet-methyl	0.0065	0.000	0.0005 - 0.0008	0.043	0.16	0.3	>2.3	0.00	0.02	
acifluorfen sodium	0.374	0.013	0.0024 - 0.010	31	204	28.1	> 1000	0.00	0.00	
mesotrione	0.1875	0.011	0.004 - 0.02	> 114	520	3.3	840	0.00	0.01	

[1]The highest single-treatment rate permitted by the herbicide's product labels. This rate is used to calculate potential acute exposure to aquatic non-target species via spray drift or runoff.
[2]Based on the maximum single treatment rate, with 5% spray drift and 5% runoff from 10 treated acres into a 1-acre 6-foot-deep pond.
[3]The Estimated Environmental Concentration in surface water. It was calculated by Monsanto using the EPA's "standard field-farm pond scenario" http://www.epa.gov/oppefed1/models/water/geneec2_description.htm. In this scenario, it is assumed that the herbicide is applied to a 10 acre farm field containing a 1 acre pond that is six feet deep. The pond experiences 5% of the application rate by spray drift and 5% of the application on the soil enters the pond via runoff. This concentration estimation is a simple, conservative Tier 1 procedure that utilizes only the application rate to estimate aquatic exposures, and allows quick comparison of many different herbicides. Other more increasingly-detailed computer models can be used to obtain more refined EEC estimates, but these require the user to input various physical chemical parameters and weather data for each product to be modeled. Examples of these methods are listed in the next column.
[4]Modeling estimates of potential aquatic exposure levels. When EPA conducts risk assessments, it uses computer models to obtain estimates of potential surface water concentrations. These are published in the RED for each herbicide, or in tolerance rules in the Federal Register. The range of estimates is listed, which can be compared to the single number in the prior column. Sources of these estimates are listed in the "ALTERNATIVE HERBICIDE-SPECIFIC REFERENCES" section.
[5]"Fish LC_{50} Range (ppm)" and "Aquatic Invertebrate LC_{50} or EC_{50} Range (ppm)". These four columns describe the range of hazard data found in public data sources representing the toxicity of each herbicide versus freshwater and marine animals. The LC_{50} or EC_{50} means the water concentration needed to kill or immobilize half of the test species, which is a standard potency descriptor. The highest and lowest values found for any fish species (trout, bluegill, sheepshead, etc.) were tabulated.

Likewise, the highest and lowest values found for any aquatic invertebrate species (Daphnia, shrimp, crab, etc.) were included. Sources of these data are listed in the "ALTERNATIVE HERBICIDE-SPECIFIC REFERENCES" section and in available public databases (National Information System – Regional IPM Centers. OPP Pesticide Ecotoxicity Database. http://www.ipmcenters.org/Ecotox/index.cfm).

[6]EPA's EFED uses a Risk Quotient (RQ) method for ecological risk assessment. The RQ equals the potential exposure level divided by the hazard level. Higher exposures or more potent hazard findings lead to higher RQs. EFED has established Levels of Concern (LOCs) for various non-target species categories. When the RQ exceeds the LOC, further refinement is needed to determine whether risk mitigation might be needed. For non-listed aquatic animals, the LOC for acute risk is 0.5, for acute risk restricted use is 0.1, and for threatened or endangered species it is 0.05. In this analysis, Monsanto calculated best-case RQs by dividing the lowest EEC estimate by the highest hazard (LC_{50} or EC_{50}) value, and calculated the worst-case RQ from the highest EEC and lowest hazard value. The purpose was to bracket a range that typified the aquatic animal risk presented by each herbicide. When neither the worst-case nor the best-case RQs exceed a LOC of 0.05, Monsanto concluded that risk to aquatic animals is minimal. Instances where the LOC threshold of 0.5 is exceeded are highlighted in bold font.

[7]Lists instances where the product label includes warning statements about aquatic animal exposure.

Aquatic Plants

Table A-28 provides information about the hazards, exposures, and risks of dicamba and each of the eighteen (18) alternative herbicides to aquatic plant species, specifically duckweed and aquatic algae species (considering 2,4-D acid, salts, and esters as one alternative herbicide). The data format, sources, and methods of Estimated Environmental Exposure Concentration (EEC) calculation are identical to those described above for the aquatic animals (Table A-27). A Level of Concern (LOC) value of 1.0 has been used for judging RQ exceedances in the case of aquatic plants, consistent with EPA EFED's normal practices.

The assessment and comparison summarized in Table A-28 establishes that dicamba poses little acute risk to aquatic plants at use rates of 0.05 – 1.0 lb dicamba a.e./acre, which is consistent with EFED's assessment published in the RED EFED Chapter. Monsanto was unable to identify aquatic plant hazard data for three of the alternative herbicides (imazaquin, chlorimuron-ethyl, and flumiclorac-pentyl). For nine (9) of the eighteen (18) alternative herbicides, the range of RQs is < 0.005 to 0.75; that is, none of these nine a.i.'s present an aquatic plant risk, which even in the worst-case calculation, reach EFED's Level of Concern (LOC) for aquatic plants. However, for seven of the alternative herbicides, the worst-case RQs did exceed EFED's LOC of 1.0. It is not surprising that some herbicides are quite toxic to aquatic plants, and the worst-case RQs for three of the alternate herbicides (flumioxazin, lactofen, and paraquat dichloride) exceeded the LOC by a factor of more than 50-fold.

Monsanto believes that dicamba offers a lower potential risk to aquatic plants relative to at least seven of the 18 alternative herbicides (2,4-D, flumioxazin, sulfentrazone, thifenslufuron, paraquat dichloride, lactofen, and mesotrione).[77] This conclusion is tabulated in Table A-24, which summarizes the comparative analysis of dicamba and alternative herbicides.

[77] As discussed in section A.3.7.2.2, all alternative herbicides used in soybean production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category.

Table A-28. Aquatic Toxicity Parameters for Aquatic Plants for Alternate Herbicide Active Ingredients

Active Ingredient	Maximum Soybean lb/acre (single treatment)[1]	Calculated EEC (ppm) [2,3]	FIRST, GENEEC or PRZX/EXAMS Surface Water ppm (RED or Tolerance Rule)[4]	Duckweed and Algae EC_{50} Range (ppm)[5]		Risk Quotient for Aquatic Plants Range[6]	
				low	high	best	worst
glyphosate salts	1.5	0.050	0.0008 - 0.021	0.77	38.6	0.00	0.06
dicamba /DGA salt	1	0.034	0.01 - 0.036	0.06	> 3.7	0.00	0.60
2,4-D acid + salts	0.93	0.031	0.064 - 0.118	0.29	156	0.00	0.41
2,4-D esters	0.93	0.031	0.064 - 0.118	0.066	>19.8	0.00	**1.79**
flumioxazin	0.096	0.003	0.018 - 0.034	0.0005	0.019	0.16	**68.00**
imazethapyr	0.064 *	0.002	0.006	0.008	59.2	0.00	0.75
cloransulam-methyl	0.04	0.001	0.002	0.003	135	0.00	0.67
chlorimuron-ethyl	0.14	0.005	0.003 - 0.005	NA	NA	NA	NA
fomesafen	0.375	0.013	0.006 - 0.012	0.09	71	0.00	0.14
flumiclorac-pentyl	0.081	0.003	0.00024	NA	NA	NA	NA
sulfentrazone	0.31	0.010	0.004 - 0.016	0.002	0.033	0.12	**8.0**
thifensulfuron	0.013	0.000	0.0003 - 0.004	0.0016	> 0.026	0.02	**2.50**
imazaquin	0.123	0.004	0.004 - 0.008	NA	NA	NA	NA
imazamox-ammonium	0.04	0.001	0.002	0.011	> 0.038	0.03	0.18
paraquat dichloride	1.0	0.033	0.0015	0.00055	2.84	0.00	**90.9**
lactofen	0.3	0.011	0.000008 - 0.4	0.001	0.001	0.00	**400**
glufosinate-ammonium	0.66	0.022	0.043 - 0.094	1.5	7.8	0.00	0.06
2,4-DB	0.4	0.013	0.013 - 0.015	>0.932	>0.932	<0.01	<0.02
fluthiacet-methyl	0.0065	0.000	0.0005 - 0.0008	0.0022	>0.018	<0.01	0.36
acifluorfen sodium	0.374	0.013	0.0024 - 0.010	> 0.26	0.38	0.01	<0.05
mesotrione	0.1875	0.011	0.004 - 0.02	0.018	132	0.00	**1.11**

The first three columns in this table are identical to- those in Table A-21.

[1]The highest single-treatment rate permitted by the herbicide's product labels. This rate is used to calculate potential acute exposure to aquatic non-target species via spray drift or runoff.

[2]Based on the maximum single treatment rate, with 5% spray drift and 5% runoff from 10 treated acres into a 1-acre 6-foot-deep pond.

[3]The Estimated Environmental Concentration in surface water. It was calculated by Monsanto using the EPA's "standard field-farm pond scenario" http://www.epa.gov/oppefed1/models/water/geneec2_description.htm |Accessed May 28, 2010|. In this scenario, it is assumed that the herbicide is applied to a 10 acre farm field containing a 1 acre pond that is six feet deep. The pond experiences 5% of the application rate by spray drift and 5% of the application on the soil enters the pond via runoff. This concentration estimation is a simple, conservative Tier 1 procedure that utilizes only the application rate to estimate aquatic exposures, and allows quick comparison of many different herbicides. Other more increasingly-detailed computer models can be used to obtain more refined EEC estimates, but these require the user to input various physical chemical parameters and weather data for each product to be modeled. Examples of these methods are listed in the next column.

[4]Modeling estimates of potential aquatic exposure levels. When EPA conducts risk assessments, it uses a computer models to obtain estimates of potential surface water concentrations. These are published in the RED for each herbicide, or in tolerance rules in the Federal Register. The range of estimates is listed, which can be compared to the single number in the prior column. Sources of these estimates are listed in the "ALTERNATIVE HERBICIDE-SPECIFIC REFERENCES" section.

[5]These two columns describe the range of hazard data found in public data sources representing the toxicity of each a.i. versus freshwater and marine plants. The EC_{50} means the water concentration needed to kill or prevent growth of half of the test species, which is a standard potency descriptor. The highest and lowest values found for any aquatic plant species (diatom, duckweed, alga, etc.) were tabulated. Sources of these data are listed in the "ALTERNATIVE HERBICIDE-SPECIFIC REFERENCES" section of this document and in available public databases cited in National Information System – Regional IPM Centers. OPP Pesticide Ecotoxicity Database. http://www.ipmcenters.org/Ecotox/index.cfm

[6]As described above for Table A-27, EPA's EFED uses a Risk Quotient (RQ) method for ecological risk assessment. For non-listed aquatic plants or for threatened or endangered species the LOC is 1.0. In this analysis, Monsanto calculated best-case RQs by dividing the lowest EEC estimate by the highest hazard (EC_{50}) value, and calculated the worst-case RQ from the highest EEC and lowest hazard value. The purpose was to bracket a range that typified the aquatic plant risk presented by each herbicide. When neither the worst-case nor the best-case RQs exceed a LOC of 1.0, Monsanto concluded that risk to aquatic plants is minimal. Instances where the LOC threshold of 1.0 is exceeded are highlighted in bold font.

A.3.7.2.3. Looking Toward the Foreseeable Future

Weeds that are difficult to control with glyphosate and weeds that are glyphosate-resistant, PPO-resistant, or ALS-resistant represent an opportunity for improved weed control in soybean. To address this need, Monsanto is seeking to commercialize DT soybean, which will allow dicamba to be used as a weed control tool in this important U.S. crop. Monsanto is also aware that other companies are developing biotechnology-derived soybean enhanced with other herbicide-tolerant traits.

Biotechnology-derived soybean developed to be tolerant to applications of 2,4-D has been submitted to USDA-APHIS for deregulation.[78] Monsanto believes that the data show that 2,4-D presents more relative risk than dicamba in the area of acute human health and chronic exposure risk, and, for 2,4-DB, relatively more ecological risk for aquatic animals. Applications of 2,4-D will also require management of offsite movement.

In addition, biotechnology-derived soybean enhanced to be tolerant to herbicides that inhibit 4-hydroxyphenylpyruvate dioxygenase (HPPD) has also been submitted to USDA-APHIS for deregulation,[79] and EPA recently approved mesotrione for use on mesotrione-tolerant soybean (U.S. EPA, 2009e). HPPD-tolerance allows use of these broadleaf herbicides in soybean production, which is a good technical fit as highlighted by Table A-29 which shows many of the troublesome soybean weeds are effectively controlled by HPPD herbicide products such as Balance Pro (active ingredient: isoxaflutole), Laudis (active ingredient: tembotrione) or Callisto Herbicide (active ingredient: mesotrione). Since some of these products are not yet registered for soybean use, and the label for Callisto defining application parameters in soybean is not yet commercially available, it is not possible to undertake a rigorous application-rate-based risk comparison with dicamba; however, it is possible to make a hazard comparison, using isoxaflutole and tembotrione as typical examples. (Mesotrione is included above in the discussion of alternate herbicides, since has been approved by EPA).

Inhibition of HPPD in plants results in a disruption of carotenoid biosynthesis, which leaves the plant's chlorophyll pigments unprotected from rapid degradation via photooxidation, and results in a very characteristic white bleached symptomology of plant parts that are normally green. HPPD is also an animal liver enzyme involved in the catabolic breakdown of tyrosine, and its inhibition in laboratory animals results in elevated tyrosine plasma concentrations (tyrosinemia), which can cause adverse ocular, developmental, liver, and kidney effects. Stated simply, the mechanism of herbicidal efficacy based on HPPD inhibition is inherently linked to a potential for negative human health effects.

Publicly available study results show that isoxaflutole and tembotrione both caused ocular and liver effects in test animals, and both caused developmental toxicity at non-maternally toxic levels. Because of the potent toxic effects, EPA has calculated cPADs for isoxaflutole and tembotrione that are lower than that of dicamba by factors of 225 and 1125, respectively. EPA is also considering the

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[78] Dow Agrosciences press release, December 15, 2009. http://www.dowagro.com/newsroom/corporatenews/2009/20091215a.htm.

[79] *See* http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml.

need for a cumulative risk assessment approach for these two chemicals, along with mesotrione and other HPPD-inhibiting herbicides, because they share a common toxic mechanism (U.S. EPA, 2009d,e). In addition, both isoxaflutole and tembotrione had carcinogenic effects in long-term testing summarized by EPA. For tembotrione, carcinogenicity was limited to rats only, but isoxaflutole was found to have carcinogenic effects in two species, and was categorized by EPA as a B2 carcinogen in 1998 when first registered. Isoxaflutole products, such as Balance Pro, are Restricted Use pesticides because of a very high level of concern about damage to non-target plants caused by spray drift, and isoxaflutole labels also bear warning statements about the likelihood of persistence and leaching. There have also been concerns about isoxaflutole use leading to levels of herbicidally-active isoxaflutole metabolites in surface water utilized for irrigation purposes.

A.3.7.2.4. Efficacy and Weed Management Practices of Alternative Herbicide Products

Table A-29 provides weed control effectiveness of formulated products containing dicamba, glyphosate and alternate herbicides. Weed control less than 70% is considered insufficient (white), control between 70 and 85% is considered as marginal effectiveness (black-white), and control of more than 85% is considered commercially acceptable (black). The data presented in Table A-29 are derived by combining state and dealer[80] herbicide guidance for soybean production across major soybean-producing states (Ohio and Indiana[81], Iowa[82], Tennessee[83], North Dakota[84]). Weed control herbicide recommendations provided by University Extension scientists to control specific weeds were converted to a common scale and combined to reflect an average herbicide weed control rating across geographies. Weed control ratings specific to resistant weeds were based mainly on recommendations from Ohio and Indiana. Monsanto weed scientists applied their own expert scientific judgment during the conversion of University Extension recommendations into a common scale. The weeds chosen for inclusion in Table A-29 represent current problem weeds in soybean, either because they exhibit herbicide resistance or because they are generally hard-to-control species. (See Appendix B of this Environmental Report for more information on the most common herbicide-resistant weeds in soybean systems.)

As Table A-29 shows, the alternative herbicides can be used in preemergent applications, postemergent applications, or, like dicamba and glyphosate, as both pre- and postemergent applications. Several herbicides, such as 2,4-D, 2,4-DB, sulfentrazone and paraquat, do not have sufficient soybean safety for application in-crop, so their use is limited to control of existing weeds and preemergent control of later emerging weeds via soil residual activity, if any. Others, such as the protoporphyrinogen oxidase (PPO) inhibitors acifluorofen, lactofen, and fomesafen, are most effective as postemergent treatments, even though they may cause some soybean leaf injury. Acetolactate synthase (ALS) inhibitors like chlorimuron-ethyl and cloransulam-methyl can be used at either timing. Glufosinate, like glyphosate and dicamba, does not have intrinsic soybean selectivity and can only be used as a postemergent application over soybean that is genetically enhanced to provide glufosinate tolerance (*e.g.*, Liberty Link®).

Table A-29 also highlights expected weed efficacy trends. Glyphosate does not provide commercial control of glyphosate-resistant weed biotypes such as common ragweed or horseweed, but does control the wild type plants of these species. Similarly, ALS-inhibiting herbicides provide poor control of ALS-resistant weeds, and PPO inhibitors do not adequately control PPO-resistant weeds. Table A-29 focuses on problem weeds found in soybean and does not include any weeds with auxin resistance, although 2,4-D provides good control of many herbicide-resistant broadleaf weed biotypes in this group. Extreme®, which contains two modes-of-action (glyphosate and

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80 2009 Crop Protection Guide - Information for Dealers http://www.agrisolutionsinfo.com/ *Accessed May 28, 2010*

81 2010 Ohio and Indiana Weed Control Guide (Bulletin 789; Pub. WS16) www.btny.purdue.edu/Pubs/WS/WS-16/ *Accessed May 28, 2010*

82 2009 Herbicide Guide for Corn and Soybean Production - http://www.weeds.iastate.edu [Accessed May 28, 2010]

83 2010 Weed Control Manual for Tennessee http://www.utextension.utk.edu/publications/pbfiles/pb1580.pdf *Accessed may 28, 2010*

84 2010(a) NDSU Weed Control Guide - http://www.ndsu.edu/weeds *Accessed May 28, 2010*

imazethapyr), provides better control of this target weed spectrum than most of the herbicide products having only a single mode-of-action.

Table A-29. Herbicide Efficacy Comparison: Herbicide Resistant Weeds and Hard-to-Control Weeds in Soybean

●	>85% control
◐	70% - 85% control
○	< 70% control

Resistant Weeds[1]

Herbicide	Herbicide Brand	Class	GR Waterhemp	GR Palmer amaranth	GR Horseweed	GR C. ragweed	GR G. ragweed	GR Johnsongrass	ALS C. ragweed	ALS+PPO C. ragweed	ALS+GR C. ragweed	ALS G. ragweed	ALS+GR G. ragweed	ALS+GR Horseweed	ALS Kochia	TRI Lambsquarters
Glyphosate	Roundup	EPSPS	○	○	○	○	○	○	●	●	○	●	○	○	●	◐
Dicamba	Clarity	auxin	●	●	●	●	●	○	●	●	●	●	●	●	●	●
PREEMERGENCE/BURNDOWN[3]																
2,4-D	2,4-D	auxin	●	◐	●	●	●	○	●	●	●	●	●	●	●	●
2,4 DB	Butyrac 200	auxin	○	○	○	○	○	○	○	○	○	○	○	○	○	●
Chlorimuron + Metribuzin	Canopy DF	ALS/PSII	○	◐	●	◐	◐	○	○	○	○	○	○	○	○	●
Chlorimuron + Tribenuron	Canopy EX	ALS	◐		●	●	◐	○	○	○	○	○	○	○	○	●
Imazaquin	Scepter	ALS	○	○	○	◐	◐	○	○	○	○	○	○	○	○	●
Sulfentrazone + Imazethapyr	Authority Assist	PPO/ALS	●	●	◐	○	○	◐	○	○	○	○	○	◐	◐	●
Sulfentrazone + Metribuzin	Authority MTZ	PPO/PSII	●	●	◐	◐	◐	○	○	○	○	○	○	◐	◐	◐
Sulfentrazone + Cloransulam	Authority First / Sonic	PPO/ALS	●	●	◐	●	●	○	○	○	○	○	○	○	◐	●
Flumioxazin	Valor	PPO	◐	●	●	◐	○	○	◐	○	○	○	○	◐	◐	●
Flumioxazin + Chlorimuron	Valor XLT	PPO/ALS	◐	●	●	●	◐	○	◐	○	○	○	○	◐	○	●
Flumioxazin + Cloransulam	Gangster	PPO/ALS	●	●	●	●	●	○	◐	○	○	○	○	◐	○	●
Cloransulam	Firstrate	ALS	○	○	●	●	●	○	◐	○	○	○	○	○	○	●
Paraquat	Gramoxone Inteon	PSI	◐	◐	○	◐	◐	○	◐	◐	◐	◐	◐	○	●	◐
HPPD PREEMERGENCE[4]																
Isoxaflutole	Balance PRO	HPPD	◐	●	●	●	○	◐	●	●	●	○	○	●	◐	●
Mesotrione	Callisto	HPPD	●	●	●	◐	○	○	◐	◐	◐	○	○	●	○	●
HPPD POSTEMERGENCE[5]																
Mesotrione	Callisto	HPPD	●	●	●	◐	◐	○	◐	◐	◐	◐	◐	●	◐	●
Tembotrione	Laudis	HPPD	●	●	◐	●	●	◐	◐	●	●	●	●	◐	●	●
Topramezone	Impact	HPPD	●	◐	●	◐	◐	◐	◐	◐	◐	◐	◐	●	●	●

Hard-to-Control Weeds[2]

Herbicide	Herbicide Brand	Class	A. Morningglory	B. Nightshade	Cocklebur	C. Ragweed	G. Ragweed	Hemp sesbania	Kochia	Lambsquarters	Horseweed	Palmer Amaranth	Prickly Sida	Sicklepod	Velvetleaf	Waterhemp
Glyphosate	Roundup	EPSPS	○	◐	●	●	◐	○	●	◐	●	●	○	●	◐	◐
Dicamba	Clarity	auxin	●	◐	●	●	●		●	●	◐	●	●	●	◐	●
PREEMERGENCE/BURNDOWN[3]																
2,4-D	2,4-D	auxin	●	○	●	●	●		○	●	◐	◐	◐	◐	◐	◐
2,4 DB	Butyrac 200	auxin	◐		◐	○		○				◐	○	○		
Chlorimuron + Metribuzin	Canopy DF	ALS/PSII	○		◐	◐	◐	◐	◐	●	●	◐	◐	○	◐	○
Chlorimuron + Tribenuron	Canopy EX	ALS	◐		◐	●	◐		◐	●	●		◐		◐	
Imazaquin	Scepter	ALS	○	●	●	◐	◐	○	○	●	○	○	◐	◐	○	
Sulfentrazone + Imazethapyr	Authority Assist	PPO/ALS		●	○	○			◐	●	◐	●			◐	●
Sulfentrazone + Metribuzin	Authority MTZ	PPO/PSII	◐	◐	◐	◐			◐	●	◐	●			◐	●
Sulfentrazone + Cloransulam	Authority First / Sonic	PPO/ALS	●	●	◐	●	◐		◐	●	●	●			●	●
Flumioxazin	Valor	PPO	◐	●	○	◐	○	◐	◐	●	◐	●	◐	○	◐	◐
Flumioxazin + Chlorimuron	Valor XLT	PPO/ALS	◐	●	◐	●	◐	●		●	●	●	◐	○	●	◐
Flumioxazin + Cloransulam	Gangster	PPO/ALS	◐	●	○	●	◐	◐	◐	●	●	●	◐	○	◐	●
Cloransulam	Firstrate	ALS	◐	○	◐	●	◐		◐	●	●		◐		◐	
Paraquat	Gramoxone Inteon	PSI				◐	◐			○	○		○			
HPPD PREEMERGENCE[4]																
Isoxaflutole	Balance PRO	HPPD	○	●	○	●	○		◐	●	●	●	◐		●	◐
Mesotrione	Callisto	HPPD	○	●	○	◐	○		○	●	●	●	◐		●	●
HPPD POSTEMERGENCE[5]																
Mesotrione	Callisto	HPPD	◐	●	◐	◐	◐		◐	●	●	●	◐	○	●	●
Tembotrione	Laudis	HPPD	◐	●	◐	◐	◐		◐	●	●	●	◐	◐	●	●
Topramezone	Impact	HPPD	◐	●	◐	◐	◐		◐	●	●	◐	○	○	●	●

Table A-29 (continued). Herbicide Efficacy Comparison: Herbicide Resistant Weeds and Hard-to-Control Weeds in Soybean

●	>85% control
◐	75% - 85% control
○	< 75% control

Resistant Weeds[1]

Herbicide	Herbicide Brand	Class	GR Waterhemp	GR Palmer amaranth	GR Horseweed	GR C. ragweed	GR G. ragweed	GR Johnsongrass	ALS C. ragweed	ALS+PPO C. ragweed	ALS+GR C. ragweed	ALS G. ragweed	ALS+GR G. ragweed	ALS+GR Horseweed	ALS Kochia	TRI Lambsquarters
Glyphosate	Roundup	EPSPS	○	○	○	○	○	○	●	●	○	●	○	○	●	◐
Dicamba	Clarity	auxin	●	●	●	●	●	○	●	●	●	●	●	●	●	●
POSTEMERGENCE[5]																
Imazethapyr + Glyphosate	Extreme	ALS/EPSPS	◐	●	○	●	●	●	●	●	○	●	○	○	●	●
Fomesafen	Flexstar	PPO	●	●	○	●	●	○	●	○	●	●	●	○	○	○
Imazethapyr	Pursuit	ALS	○	○	○	○	○	●	○	○	○	○	○	○	○	○
Cloransulam	Firstrate	ALS	○	○	◐	●	●	○	○	○	○	○	○	○	○	○
Flumiclorac	Resource	PPO	○	○	○	◐	○	○	◐	○	◐	○	○	○	○	○
Chlorimuron	Classic	ALS	○	○	◐	◐	○	○	○	○	○	○	○	○	○	○
Imazamox	Raptor	ALS	○	●	○	○	◐	●	○	○	○	○	○	○	◐	○
Lactofen	Cobra / Phoenix	PPO	●	●	○	●	●	○	●	○	●	●	●	○	○	○
Fomesafen	Reflex	PPO	●	●	○	●	●	○	●	○	●	●	●	○	○	○
Acifluorfen	Ultra Blazer	PPO	●	●	○	●	◐	○	●	○	●	◐	◐	○	○	○
Glufosinate	Ignite	Glu	◐	◐	◐	●	●	○	●	●	●	●	●	◐	●	◐
Chlorimuron + Thifensulfuron	Synchrony XP	ALS	○	●	◐	◐	◐	○	○	○	○	○	◐	○	○	◐
Fluthiacet	Cadet	PPO	◐	○	○	○	○	○	○	○	○	○	○	○	○	◐

Hard-to-Control Weeds[2]

Herbicide	Herbicide Brand	Class	A. Morningglory	B. Nightshade	Cockelbur	C. Ragweed	G. Ragweed	Hemp sesbania	Kochia	Lambsquarters	Horseweed	Palmer Amaranth	Prickly Sida	Sicklepod	Velvetleaf	Waterhemp
Glyphosate	Roundup	EPSPS	○	◐	●	●	◐	○	●	◐	●	●	○	●	◐	◐
Dicamba	Clarity	auxin	●	◐	●	●	●		●	●	◐	●	●	●	◐	●
POSTEMERGENCE[5]																
Imazethapyr + Glyphosate	Extreme	ALS/EPSPS	◐	●	●	●	●		●	●		●	◐		●	◐
Fomesafen	Flexstar	PPO	◐	◐	◐	●	●	◐	○	○		●	○	○	○	●
Imazethapyr	Pursuit	ALS	◐	●	◐	○	○	○	◐	○		○	○	○	◐	○
Cloransulam	Firstrate	ALS	◐	○	●		●	○	○	○		○	○	◐	◐	○
Flumiclorac	Resource	PPO	○	○	○		○	◐	○	○		○	◐	◐	●	○
Chlorimuron	Classic	ALS	◐	○	●		○	●	○	○		○	○	◐	◐	○
Imazamox	Raptor	ALS	◐	●	◐	○	◐		◐	○		●	○	○	●	○
Lactofen	Cobra / Phoenix	PPO	◐	◐	◐	●	●	●	○	○		●	○	○	○	●
Fomesafen	Reflex	PPO	◐	◐	◐	◐	●	●	○	○		●	○	○	○	●
Acifluorfen	Ultra Blazer	PPO	◐	◐	◐	●	◐	●	○	○		●	○	○	○	●
Glufosinate	Ignite	Glu	●	●	●	●	●		●	◐		◐	◐	●	◐	◐
Chlorimuron + Thifensulfuron	Synchrony XP	ALS	◐	○	●	◐	◐		○	◐		●			◐	○
Fluthiacet	Cadet	PPO	◐	◐	○	○			○	◐		○			●	◐

Horseweed is synonymous to marestail.
GR = Glyphosate resistant
ALS = Acetolactate synthase
Tri = Triazine

PPO = protoporphyrinogen oxidase

Note: This table was based primarily on State University Extension weed control recommendations for soybean growing areas, Table A-29 indicates the degree to which each product controls the targeted weeds in soybean. The legend describes the meaning of the symbols.

[1] This section of the table describes control of populations (biotypes) of weeds that are known to have genetic resistance to specific herbicidal modes-of-action

[2] This section describes control of weeds that are difficult to control in soybean with existing herbicide treatments. Generally these are broadleaf weeds whose removal would require herbicide rates that would severely damage the crop.

[3] This section describes weed control by herbicides that are applied prior to soybean emergence. The weeds may or may not be emerged.

[4] This section describes foreseen use of herbicides that are not yet approved for use in soybean that have inhibition of 4-hydroxyphenylpyruvate dioxygenase.

[5] The section describes weed control by herbicides that are applied after the soybean emergence, generally over-the-top of the crop.

A.3.7.3. **Comparison of Dicamba Use in the Dicamba-Tolerant Soybean System to Alternative Herbicides**

The intent of the comparative analysis is to define current herbicide use in U.S. soybean production, and to compare dicamba's human health and environmental properties to herbicides currently used by growers for weed control. In order to approve a new use of a herbicide EPA must conclude that the herbicide, when used according to the label, does not pose an unreasonable adverse effect to humans or the environment. In addition, in order to establish a tolerance for the use of a herbicide on a food or feed crop, EPA must find there is a reasonable certainty of no harm to human health from non-occupational (food, water and residential/recreational) exposures to the herbicide. Consequently all alternative soybean herbicides can be used safely, and do not pose an unreasonable risk to humans or the environment.

Nonetheless, in some instances, dicamba offers a reduction in risk potential (i.e., hazard) compared to some alternative herbicides in the same risk category (e.g., aquatic plant risk). In other instances dicamba presents a similar risk potential compared to some alternatives. In a few cases, dicamba presents a greater risk potential compared to some alternatives. This comparative analysis serves to demonstrate that the use of dicamba on DT soybean is unlikely to result in a significant impact/risk to human health or the environment compared to current herbicide agronomic practices and in some instances, its use may impart additional benefits as described below.

A.3.7.3.1. Comparisons for Human Health Risks

Table A-26 provides information concerning human health parameters for dicamba and the alternative herbicide products. These data allow a comparison of the relative human health safety among the optional weed control products on the basis of:

- Acute toxicity.
- Chronic toxicity.
- Cancer risks and classification.
- Risk to infants and children.
- Magnitude of potential exposure that is considered to be within the acceptable safe range.
- Extent to which all presently approved uses exhaust the acceptable safe acute and chronic dietary exposure ranges for the most highly exposed population subgroups.
- The proportion of present dietary exposure that arises through use on soybean.

A compilation of Monsanto's comparative determinations of the risks posed by the 18 alternate herbicides compared to dicamba in the four basic human health risk categories (acute, cancer, chronic and infants/children) is tabulated in Table A-30. A "Yes" entry indicates a benefit for dicamba compared to that alternative herbicide. Entries not indicated with a "Yes" mean that dicamba is either comparable to or less benign than the alternative herbicide. A "Neutral" entry means that dicamba and the alternative herbicide have similar risks, and a "No" entry denotes alternative herbicides that have a benefit compared to dicamba. Table A-30 is intended as a 1-page scorecard summary of these benefit comparisons. Monsanto has concluded that dicamba use on DT soybean will provide benefits compared to the alternate herbicides used for soybean weed control.

Table A-30. Summary of Comparative Analysis of Dicamba and Alternative Herbicides Used in Soybean

Active Ingredient	Mode-of-Action (WSSA Group[1])	Human Health Risk Measures[2]: Acute Toxicity Risk	Human Health Risk Measures[2]: Cancer Risk	Human Health Risk Measures[2]: Chronic Risk	Human Health Risk Measures[2]: Infants & Children Risk	Aquatic Non-Target Species Risk Measures[3]: Aquatic Animal Risk	Aquatic Non-Target Species Risk Measures[3]: Aquatic Plant Risk	Known Resistant Weed Species[4]	Herbicidal Efficacy[5] (< 50% of dicamba)	Long Rotational Crop Restriction[6]	Serious Crop Injury Potential[7]	Number of "Yes" Entries[8]	Number of "No" Entries[9]
2,4-D acid / esters	Aux (4)	**Yes**	**Yes**	**Yes**	Neutral	**Yes**	**Yes**	28	Neutral	Neutral	Neutral	**6**	**0**
2,4-DB		Neutral	Neutral	Neutral	Neutral	Neutral	Neutral		**Yes**	Neutral	Neutral	**2**	**0**
imazethapyr	ALS (2)	No	Neutral	Neutral	Neutral	Neutral	Neutral	107 (**Yes**)	**Yes**	**Yes**	Neutral	**3**	**1**
cloransulam-methyl	ALS (2)	No	Neutral	Neutral	Neutral	Neutral	Neutral		**Yes**	**Yes**	Neutral	**4**	**1**
chlorimuron-ethyl	ALS (2)	No	Neutral	Neutral	Neutral	Neutral	NA		**Yes**	**Yes**	Neutral	**3**	**1**
thifensulfuron	ALS (2)	No	Neutral	Neutral	Neutral	Neutral	**Yes**		**Yes**	**Yes**	Neutral	**4**	**1**
imazaquin	ALS (2)	No	No	Neutral	Neutral	Neutral	NA		**Yes**	**Yes**	Neutral	**3**	**2**
imazamox-ammonium	ALS (2)	No	Neutral	No	Neutral	Neutral	Neutral		**Yes**	**Yes**	Neutral	**4**	**2**
flumioxazin	PPO (14)	Neutral	Neutral	**Yes**	Neutral	**Yes**	**Yes**	5	**Yes**	**Yes**	Neutral	**5**	**0**
fomesafen	PPO (14)	**Yes**	Neutral	**Yes**	Neutral	Neutral	Neutral		Neutral	**Yes**	**Yes**	**4**	**0**
flumiclorac-pentyl	PPO (14)	No	No	Neutral	Neutral	Neutral	NA		**Yes**	Neutral	Neutral	**1**	**2**
sulfentrazone	PPO (14)	**Yes**	Neutral	Neutral	Neutral	Neutral	**Yes**		**Yes**	Neutral	Neutral	**4**	**0**
lactofen	PPO (14)	No	**Yes**	Neutral	**Yes**	**Yes**	**Yes**		Neutral	Neutral	**Yes**	**5**	**1**
fluthiacet-methyl	PPO (14)	No	**Yes**	Neutral	Neutral	Neutral	Neutral		**Yes**	Neutral	**Yes**	**3**	**1**
acifluorfen sodium	PPO (14)	**Yes**	**Yes**	Neutral	**Yes**	Neutral	Neutral		**Yes**	Neutral	**Yes**	**5**	**0**
paraquat dichloride	BiPyr (22)	**Yes**	No	**Yes**	Neutral	Neutral	**Yes**	24	**Yes**	Neutral	Neutral	**4**	**0**
glufosinate-ammonium	Glu (10)	**Yes**	No	**Yes**	Neutral	Neutral	Neutral	No reports	Neutral	Neutral	Neutral	**3**	**0**
mesotrione	HPPD (28)	**No**	Neutral	**Neutral**	Yes	Neutral	Yes	No reports	Yes	Yes	Neutral	**4**	**1**

Table A-30 is intended to be a 1-page scorecard to track the benefits of dicamba use on DT soybean according to the different listed criteria. Each "Yes" entry signifies that Monsanto has concluded that dicamba represents a benefit versus the relevant alternative herbicide on the basis of the risk factor in that column's heading. The basis for entering a "Yes" under each risk factor is further explained in the relevant portions of this document. "Neutral" entries indicate similar risks exist for dicamba and the alternative herbicide. "No" means the alternative herbicide offers a risk benefit compared to dicamba.

[1] The herbicidal biochemical mechanism of weed-killing activity, according to the Weed Science Society of America. www.plantprotection.org/HRAC/Bindex.cfm?doc=MOA.html

[2] A tally of the benefits dicamba use on DT soybean offers over the alternative herbicide in the four categories of human health risk.

[3] A tally of the benefits dicamba use on DT soybean offers over the alternative herbicides in the two categories of aquatic non-target species risk.

[4] A listing of the worldwide numbers of known resistant weeds for each herbicide based on its mode-of-action group. Dicamba has 5 known resistant spp worldwide. A "Yes" indicates that the number of resistant weeds in this herbicide class is many more than the known five dicamba resistant species biotypes. A comparison of each individual herbicide in the class is not provided. www.weedscience.org/summary/MOASummary.asp

[5] Alternative herbicides that provide commercial control of fewer than 50% of targeted problem weeds in soybean compared to dicamba, according to the data in Table A-23, where commercial control is considered to be >85%, as indicated by a fully-black circle symbol.

[6] Alternative herbicides that require long waiting periods between application and subsequent planting of a crop other than soybean. This constraint is a disadvantage to growers. See Table A-31.

[7] Alternative herbicides that can substantially injure the soybean crop when applied for weed control, potentially reducing soybean yield.

[8] Tabulation of the number of "Yes" entries in each row, indicating a total score for improved risk profile for dicamba use on DT soybean offers versus an alternative herbicide. This summation is not presented as a net value (*i.e.*, subtracting where an alternative herbicide has a benefit over dicamba).

[9] Tabulation of the number of "No" entries in each row, indicating a total score for worse risk profile for dicamba use on DT soybean offers versus an alternative herbicide. This summation is not presented as a net value (*i.e.*, subtracting where an alternative herbicide has a benefit over dicamba).

NA – not available.

Acute Health Risks

Dicamba acid has a Category II classification for eye and skin irritation, but once the acid is neutralized to form the DGA or other salt forms used in herbicide product formulations, all acute Categories are III or IV. These classifications are the most benign acute toxicity categories in EPA's acute hazard paradigm. Several alternative herbicides (acifluorfen, sulfentrazone, and some forms of 2,4-D) have high risk of eye irritation (Category I). Principal formulations of fomesafen, paraquat, lactofen, 2,4-DB (DMA salt), and acifluorfen have a "DANGER!" signal word (Table A-31). The 18 alternate herbicide actives, as a group, also have relatively low acute (oral, dermal or inhalation) toxicity. For eight of the eighteen, EPA determined that an acute dietary risk assessment is not needed because there are no relevant acute toxicological effects. One notable exception is paraquat, which has high risk (Category I) of acute toxicity by the inhalation route; present uses of paraquat occupy 66% of the aPAD (the safe exposure level). 2,4-D and glufosinate have relatively low aPADs compared to their dietary residues, and present uses occupy 58% and 48% of their respective aPADs. Overall, Monsanto concludes that dicamba has a lower acute toxicity risk potential compared to six of the eighteen alternate herbicides and their formulated products (paraquat, 2,4-D, glufosinate, acifluorfen, sulfentrazone, and fomesafen).[85] These six are indicated by a "Yes" in the "Acute Toxicity Risk" column of Table A-30. Flumioxazin and 2,4-DB were judged to have similar acute toxicity risk as dicamba, and are marked as "Neutral" in Table A-30. Ten herbicides, which either did not have relevant acute toxicological effects or which utilized 1% or less of the allowable acute exposure (aPAD), were judged to have less acute toxicity risk than dicamba, and are marked as "No" in Table A-30.

Chronic Risk

Chronic dietary risk can be evaluated by consideration and comparison of the percentage of the safe exposure level (chronic population adjusted dose: cPAD) that is used up by all currently registered uses of an active ingredient. Table A-30 summarizes the % cPAD utilized for each alternative herbicide, according to recently published Federal Register Final Rule information. A number of the alternative herbicides have very low use rates, which results in very low residues in treated food or feed, and accordingly utilize only a small percentage of the cPAD. For dicamba and twelve of the alternate herbicides, the percentage of the cPAD utilized for all approved uses is <10%, so that this group has at least an added 10-fold margin of safety beyond that which EPA has determined is protective of human health. For imazamox, EPA has determined that residues in food or feed are not likely to approach levels of concern, and exempted it from the requirement of food and feed tolerances. The remaining five herbicides (2,4-D, flumioxazin, fomesafen, paraquat, and glufosinate) utilize a somewhat higher portion of the cPAD, ranging from 18% to 38%. Although the 10% cutoff is an arbitrary one, and the increased risk of even the worst-case alternative herbicide for chronic risk is only 6-fold greater than that of dicamba, Monsanto concludes that dicamba offers a lower chronic toxicity risk potential compared to 2,4-D, flumioxazin, fomesafen, paraquat and glufosinate.

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85 As discussed in section A.3.7.2.2, all alternative herbicides used in soybean production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category.

Another way to compare chronic dietary risk would be to focus directly on the soybean seed residues and their contribution to cPAD utilization. In Table A-26, columns 9 to 11 (those to the right of the gray bar) present the established soybean seed tolerance for each herbicide. Using DEEM (a computer dietary exposure model used commonly by EPA) and a theoretical worst-case approach (assume 100% of soybean is treated with a given herbicide that results in residues at the tolerance level), Monsanto calculated the theoretical maximum residue contribution (TMRC, a standard Tier 1 dietary risk method) to dietary exposure of each herbicide via soybean seed in μg/kg/day and as a percentage of the cPAD, as shown in Table A-26. This analysis highlighted paraquat and glufosinate as alternative herbicides with notably higher cPAD utilization by the soybean residue component; both herbicides were considered to present more relative risk than dicamba in the previous comparative method as well. The TMRC soybean calculation for paraquat yields a number that is 2.6-fold higher than the cPAD, because the EPA's risk assessment methodology for paraquat assumes a market penetration in soybean of <5%. If this market share were increased, the risk attributed to soybean residue could become a substantial portion of the cPAD.

Based on this reasoning, Monsanto concluded that dicamba offers lower chronic toxicity risk potential than five alternative herbicides (2,4-D, flumioxazin, fomesafen, paraquat and glufosinate), and these a.i.'s are marked with a "Yes" in the chronic toxicity column of Table A-30.[85] Imazamox-ammonium was considered by EPA to have such low toxicity that no food or feed tolerances were required by EPA, and therefore imazamox-ammonium was judged by Monsanto to have lower chronic toxicity risk potential than dicamba, as indicated by a "No" in Table A-24. The other alternative herbicide a.i.'s under consideration were judged to have similar chronic toxicity risk as dicamba, and are marked "Neutral" in Table A-30.

Cancer Risk

EPA classified dicamba as "not likely" for human carcinogenicity. Fourteen of the alternative herbicides are classified similarly – "not likely", "no evidence", or "Group E (Evidence of Non-Carcinogenicity for Humans)". 2,4-D is classified as "D", meaning that although the studies are acceptable, the evidence is unclear and some uncertainty remains. Two of the alternative herbicides (lactofen and acifluorfen) are classified as "not likely" at low doses but "likely" at high doses, due to liver and other effects. A peroxisome proliferation mechanism is established for acifluorfen. Since acifluorfen is a metabolite of lactofen, the similarity in toxicology and cancer classification is appropriate. One alternative herbicide, fluthiacet-methyl, is categorized as a "likely" human carcinogen, due the occurrence of dose-related tumors in both rats and mice; a Q* of 7.5×10^{-7} has been calculated, which is a measure of carcinogenic potency that EPA utilizes in risk assessment. Overall, Monsanto concludes that dicamba offers a lower cancer risk potential compared to four of the alternative herbicides (2,4-D, lactofen, acifluorfen, and fluthiacet-methyl), and this judgment is indicated by a "Yes" in the Cancer Risk column of Table A-30. Four alternative herbicide a.i.'s (flumiclorac-pentyl, glufosinate, imazaquin, and paraquat) have been categorized by EPA as Group E or "no evidence", and Monsanto judges that these four have lower cancer risk potential than dicamba, and are marked as "No" in Table A-30. The other alternative herbicide a.i.'s that are in the "not likely" category have similar cancer risk potential to dicamba, and are marked as "Neutral" in table A-30.[85]

Risks to Infants and Children

The Food Quality Protection Act (FQPA) requires that EPA take special care in its risk assessments to establish that infants and children do not have increased sensitivity to pesticides and thereby experience greater risks from residues in food than the general U.S. population. EPA's implementation of this requirement is embodied in the additional FQPA safety factor, which is established by the statute at 10-fold, unless there is evidence that another level is protective. When making determinations about the magnitude of the FQPA safety factor, the EPA considers the completeness of the database and specifically the findings from the developmental and reproductive toxicity studies to determine if there is evidence that infants and children are more sensitive than adults. Therefore, the magnitude of the FQPA safety factor (usually 1X, 3X, or 10X) is a comparative parameter that may be used as an indication of the potential risks to infants and children and for overall developmental and reproductive toxicity findings.

Dicamba risk assessments for both acute and chronic effects utilize an FQPA safety factor of 1X. This is also the case for 15 of the 18 alternate herbicides, although in some cases, an acute dietary risk assessment was not necessary due to a lack of acute toxicity effects. For lactofen, acifluorfen, and mesotrione, a 3X or 10X FQPA safety factor was used for the acute and/or chronic assessments, indicating a higher level of risk or uncertainty. Therefore, Monsanto concludes that dicamba offers an improved potential risk profile for infants and children compared to these three alternative herbicides, which are marked with a "Yes" in the Infants & Children Risk column in Table A-30. All other alternative herbicide a.i.'s which have an FQPA safety factor of 1X are judged to have similar potential risk as dicamba, and are marked with "Neutral" in Table A-30.[85]

A.3.7.3.2. Comparisons for Ecological Effects

DT soybean can be treated with preemergence and postemergence in-crop applications of dicamba. Such a weed control treatment regime has the opportunity to reduce risks to aquatic fish and invertebrates by:

- Replacing currently-used or foreseeable future alternative herbicide products that have higher aquatic toxicity risk profiles; and
- Addressing hard-to-control broadleaf weeds or broadleaf weeds that are resistant to glyphosate, PPO inhibitors, or ALS inhibitors, thereby preserving the ability of growers to manage weed problems and maximize soybean yield in the least risky manner, recognizing the ecological benefits offered by the superior hazard and reduced risk profile of glyphosate and the more benign profile of dicamba compared to some of the alternative herbicides.

Aquatic Animals

As mentioned, Table A-27 provides information concerning hazards, potential exposures, and risks to fish and aquatic invertebrates for each alternate herbicide and for dicamba. These data allow a comparison of the relative aquatic animal safety among the optional weed control products on the basis of:

- Potency against the indicator species;
- Estimates of potential exposure to aquatic animals; and

- Calculated RQs for aquatic animals, by combining the hazard and exposure parameters. The RQs that exceed the EPA's LOC for non-listed aquatic animal species of 0.5 are marked in bold font.

The assessment and comparisons summarized in Table A-30 establish that dicamba poses little acute risk to aquatic animals, which is consistent with EFED's assessment published in the RED EFED Chapter. Furthermore, for 16 of the 18 alternate herbicides, aquatic animal RQs range from < 0.005 to 0.05, and do not present a risk to aquatic animals even using a worst-case upper bound exposure estimation. Only 2,4-D (the esters form) and lactofen exceed the LOC of 0.5 using conservative "worst-case" exposure estimates. These are highlighted in bold font. Monsanto notes that EPA considers the LOC for aquatic animals that are listed as endangered or threatened species to be 0.05 and the LOC for acute restricted use to be 0.1. If the 10-fold to 5-fold lower level of concern were applied, flumioxazin would also exceed the LOC based on this "worst-case" exposure estimate.

In addition to the calculated RQs, product labels for five of the alternative herbicides bear EPA-required warning statements for toxicity to fish or invertebrates, based on the hazard values (low LC_{50} or EC_{50}) of those herbicides. These are flumioxazin, cloransulam-methyl, flumiclorac-pentyl, lactofen, and 2,4-DB.

Therefore, Monsanto concludes that dicamba presents a lower risk potential for aquatic animals compared to three of the 18 alternate herbicides: 2,4-D, flumioxazin, and lactofen. This conclusion is tabulated in the Table A-30 scorecard by a "Yes" in the relevant column. The alternative herbicide a.i.'s that have a "worst-case" RQ < 0.05 are similar to dicamba in regards to potential aquatic animal risk, and are marked "Neutral" in Table A-30.[85]

Aquatic Plants

As mentioned, Table A-28 provides information concerning hazards, potential exposures, and risks to aquatic plants for each alternate herbicide and for dicamba. These data allow a comparison of the relative aquatic plant safety among available weed control products on the basis of:

- Potency against the indicator species;
- Estimates of potential exposure to aquatic plants; and
- Calculated RQs for aquatic plants, by combining hazard and exposure parameters. The RQs that exceed the EPA's LOC for non-listed aquatic plant species of 1.0 are marked in bold font.

The data format, sources, and methods are identical to those described above for the aquatic animals (Table A-27). A Level of Concern (LOC) value of 1.0 has been used for judging RQ exceedances in the case of aquatic plants, consistent with EPA EFED's normal practices.

The assessment and comparison summarized in Table A-30 establishes that dicamba poses little acute risk to aquatic plants, which is consistent with EFED's assessment published in the RED EFED Chapter (U.S. EPA, 2005a) and discussed above. Monsanto was unable to locate public aquatic plant hazard data for three of the alternate herbicides (imazaquin, chlorimuron-ethyl, and flumiclorac-pentyl). For 9 of the 18 alternatives, the worst case RQs ranged between < 0.02 and 0.75; and do not present a risk to aquatic plants even using a worst-case upper bound exposure estimation. However, for seven alternative herbicides, the worst-case RQs did exceed EFED's LOC of 1.0. It is not surprising that some herbicides are quite toxic to aquatic plants. The worst-case RQs for three of the alternate herbicides (flumioxazin, paraquat dichloride, and lactofen) exceeded the LOC by a factor of more than 50-fold.

Therefore, Monsanto concludes that dicamba presents a lower risk potential to aquatic plants compared to seven of the 18 alternative herbicides: 2,4-D (ester form), flumioxazin, sulfentrazone, thifensulfuron, paraquat dichloride, lactofen, and mesotrione.[85] This conclusion is tabulated in the Table A-30 scorecard by a "Yes" in the relevant column. The other alternative herbicide a.i.'s, for which RQs are less than EPA's LOC, have similar non-target aquatic plant risk potentials as dicamba, and are marked in Table A-30 with "Neutral". The three herbicides for which no relevant data were available are marked as "NA".

A.3.7.3.3. Comparison for Efficacy and Weed Management, Including Weed Resistance

Comparison of Weed Management Efficacy

As mentioned, Table A-29 compares weed control effectiveness of formulated products containing dicamba and the alternative herbicides. The various products' overall effectiveness can be compared using the simple method of counting the fully-black circle symbols, which identify instances of commercial level weed control. Dicamba provides commercial control for 23 of the listed weeds (primarily broadleaf species), which is the most of any of the herbicides in the table; dicamba offers commercial control for 13 of the herbicide-resistant biotypes and 10 of the hard-to-control species. After dicamba, preemergent treatments with 2,4-D, or postemergent treatments with glufosinate, tembotrione, and imazethapyr plus glyphosate, are the next most effective herbicides against this target group of weeds. The least effective herbicides in this analysis against these targeted weeds and resistant biotypes are 2,4-DB, paraquat, imazethapyr alone, flumiclorac-pentyl, chlorimuron-methyl and fluthiacet. To summarize the comparative herbicidal effectiveness in this analysis, the scorecard in Table A-29 contains a column in which those herbicides that provide commercial control of 50% or fewer weeds compared to the number of weeds controlled by dicamba (i.e., eleven or fewer fully-black circles in Table A-29) are marked with a "Yes", to denote a clear dicamba advantage. Alternative herbicide a.i.'s that provide commercial control of greater than 50% of the number of weeds controlled by dicamba (i.e., 12 or more fully-black circles in Table A-29) are marked in Table A-30 with "Neutral", meaning are judged similar to dicamba. The 50% threshold criterion is Monsanto's arbitrary choice that is intended to identify herbicide options that are expected to provide substantially poorer weed control compared to dicamba.

Comparison for Weed Management Practices

Beyond direct efficacy against the key weeds, other advantages of DT soybean treated with dicamba exist.

Increased Weed Control Flexibility

DT soybean will allow more flexibility for control of weeds just prior to or at planting of the crop, due to elimination of preplant intervals or plant back restrictions on present dicamba labels. These restrictions were in place due to concern over potential soybean injury, which is not a concern for DT soybean. Current common practice is to use 2,4-D for preemergent burndown treatment. When applied too close to soybean planting, 2,4-D can potentially reduce crop stands and cause injury to new seedlings (Thompson et al., 2007). Restrictions have been implemented for most products and are as follows: rates up to 0.5 lb a.i. per acre must be applied at least seven days prior to planting; rates between 0.5 and 1 lb a.i. per acre must be applied at least 30 days prior to planting. Additionally, several sulfonylurea herbicides can also be utilized for preemergent burndown weed control in soybean. For example, Canopy herbicide can be applied prior to planting with the following restrictions: rates of 2.2 oz per acre or less should be applied at least seven days prior to planting; rates of 2.2 to 3.3 oz per acre should be applied at least 14 days before planting.

Current recommendations to control glyphosate-resistant biotypes of waterhemp and Palmer amaranth include the use of a residual herbicide treatment and postemergent applications of PPO-inhibiting herbicides such as Cobra (lactofen), Ultra Blazer (acifluorfen), or Cadet (fluthiacet). It is commonly known that these postemergent herbicides can cause excessive injury to soybean, especially under hot and sunny conditions. Soybean injury, caused by acifluorfen from early (V2 to V3 growth stage) or late postemergence (V5 to V6) applications, was seen as increased chlorosis and stunting that translated into yield reduction (Young et al., 2003). Furthermore, Legleiter et al. (2009) illustrated the effectiveness of preemergent herbicides for the control of resistant waterhemp populations and demonstrated inconsistent control with PPO-inhibiting herbicides or herbicide combinations for the control of waterhemp populations with multiple resistance to glyphosate and PPO-inhibiting herbicides. The introduction of DT soybean will provide an effective management option for herbicide-resistant biotypes of waterhemp and Palmer amaranth that is not expected to cause either crop injury or yield loss.

Residual herbicides containing sulfentrazone, dimethenamid, pendimethalin, metribuzin, or metolachlor have been shown to control waterhemp and Palmer amaranth; however, such products can present other challenges. Limitations include the need of adequate soil moisture for activation, potential crop injury, crop rotation restrictions, and use restrictions based on soil type. As an example, metribuzin should not be used on sands, loamy sands, and sandy loams with less than 1% organic matter[86], and pendimethalin applied after crop-emergence can result in soybean injury.[87]

For some residual herbicides, there are extensive rotational crop restrictions, ranging from four to 40 months after application, to avoid subsequent crop injury to the rotated crop caused by herbicide remaining in the soil. These limitations reduce the choice of crops that can be planted in case the soybean crop is destroyed by weather or even the following growing season. Examples of planting limitations among the alternate herbicides are shown in Table A-31.

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[86] Product label for Metribuzin 75 DF (http://www.cdms.net/LabelsMsds/LMDefault.aspx?pd=7614&t=).

[87] Product label for Pendimax 3.3 (http://aesop.rutgers.edu/~plantbiopath/links/bbcpestweb/GrapeLabels/pendimax33.pdf).

Table A-31. Planting Restrictions (months) for Alternative Herbicide Products

	Herbicide Product (Active Ingredient)			
CROP	Authority MTZ (sulfentrazone + metribuzin)	Pursuit (imazethapyr)	CANOPY EX (chlorimuron + tribenuron)	Raptor (imazamox)
Field corn	4	8.5	8	8.5
Wheat	4	4	4	9
Cotton	12	18	8	9
Peanut	12	0	15	9
Sorghum	12	18	9	3
Onions	18	40	30	9

Dicamba does not have rotational restrictions for such extended time periods and provides a substantial advantage in flexibility. For the majority of crops, no rotational restrictions apply after 120 days following dicamba applications. Specifically, there are no rotational restrictions for planting corn following a dicamba application. For cotton, a rotational restriction of 21 days is recommended. To summarize this advantage, Table A-30 includes a column in which a "Yes" is marked for those alternative herbicides that include substantial rotational or replanting restrictions. Entries for alternative herbicide a.i.'s that do not require long rotation intervals are judged similar to dicamba, and are marked in Table A-30 with a "Neutral" in the relevant column.

Furthermore, in situations where sequential herbicide applications were employed to control common waterhemp populations, reduced soybean yields have been reported. Yield reductions up to 19% compared to a non-treated control were reported when acifluorfen or fomesafen was the postemergent herbicide (Soltani et al., 2009). These reduced yields were associated with crop injury (chlorosis and stunting) following postemergent applications of certain herbicides, especially PPO inhibitors (Baumann et al., 2010; Loux et al., 2009).

Dicamba treatments in DT soybean provide excellent crop safety. Table A-30 includes a column in which the crop injury potential versus dicamba is summarized; a "Yes" entry indicates a substantial potential for visible soybean injury. Entries for alternative herbicide a.i.'s with good soybean crop safety are judged to be similar to dicamba, and are marked with a "Neutral" in the relevant column of Table A-30. In conclusion, the introduction of DT soybean will provide an additional mode-of-action for postemergent weed control with excellent crop safety.

Weed Spectrum Benefits

Dicamba provides control of over 95 annual and biennial weed species, and control or suppression of over 100 perennial broadleaf and woody species. Dicamba provides more effective preemergent weed control than 2,4-D on cutleaf evening primrose, clover, and chickweed (Loux et al., 2009). Furthermore, dicamba provides excellent control compared to 2,4-D on summer annuals, including those with a prostrate growth habit such as knotweed and purslane. With regard to perennial weeds, research conducted at North Dakota State University indicates that dicamba is more effective in controlling Canada thistle compared to 2,4-D and effectively controls field bindweed (Zollinger, 2000; NDSU, 2010b).

Dicamba also provides excellent control of wild buckwheat, while 2,4-D has only limited activity and provides inadequate control (Zollinger et. al, 2006). Other preemergent or postemergent herbicides often provide incomplete control of wild buckwheat, including dinitroanilines or PPO inhibitors. The most effective herbicides for buckwheat are dicamba, and some sulfonylurea products; however, some of the sulfonylurea herbicides may persist and carry over for more than one growing season, especially in high pH soils.

Dicamba has been valued as more efficacious on lambsquarters than fomesafen or acifluorfen based on university weed control guidelines (Moechnig et al., 2010; University of Illinois, 2008; Legleiter et al., 2009; Loux et al., 2009). In addition, dicamba exhibits improved control of sicklepod (Loux et al., 2009), kochia and common ragweed (Legleiter et al., 2009), and waterhemp (Soltani et al., 2009) compared to fomesafen and acifluorfen.

Comparison for Herbicide-Resistant Weeds

The development of weed resistance reduces the effectiveness of all major herbicide classes used in soybean production today, including glyphosate, thereby jeopardizing soybean yields and requiring the introduction of new tools to control populations of resistant weeds. It is widely recognized that utilizing herbicides with different modes-of-action in conjunction with established products is especially effective combating further weed resistance development and to provide control of existing populations (Beckie, 2006). Preplant / preemergent or early-postemergent in-crop applications of dicamba in DT soybean will introduce a new mode-of-action; thus the introduction of dicamba use on DT soybean holds great promise for addressing current and future weed management needs in soybean. The primary basis for this promise is the wide spectrum of activity of dicamba on broadleaf weed species, which are the most common hard-to-control species and resistant weed biotypes in soybean production today.

Dicamba belongs to the auxin agonist class of herbicides, which is the oldest class of known synthetic herbicides. This class includes 2,4-D, 2,4-DB, mecoprop, MCPA, clopyralid, and several other active ingredients, and is WSSA Herbicide Group Number 4.[88] On the basis of their structural and chemical properties, auxinic herbicides have been classified into several sub-groups, *i.e.*, phenoxyalkanoic acids (*e.g.*, 2,4-D, MCPA), benzoic acids (*e.g.*, dicamba, chloramben), pyridines (*e.g.*, picloram, clopyralid), and quinolinecarboxylic acids (*e.g.*, quinclorac, quinmerac). Generally, auxinic herbicides are effective against broadleaf (dicotyledonous) plant species, allowing them to be used in production of narrow leaf (monocotyledonous) crops such as corn and wheat. The relative occurrence of herbicide-resistant weeds differs between the different sub-groups of auxinic herbicides. The largest number of resistant weed biotypes has been found for 2,4-D. Considering that auxinic herbicides have been widely used in agriculture for more than 60 years, the occurrence of weed resistance to this class is relatively low (28 species worldwide, to date) and its development

[88] There are several systems of herbicide mode-of action classification. Among the most widely used are those of the Herbicide Resistance Action Committee (HRAC) and the Weed Science Society of America. The classifications are compared in a chart at http://www.plantprotection.org/HRAC/Bindex.cfm?doc=MOA.html

has been slow, especially when compared to the speed of appearance of resistance to ALS inhibitors (107 species) or triazine-resistant populations (68 species).[89] The relatively low incidence of auxinic herbicide resistance is believed to be attributable to the fact that there are multiple mechanisms of action for these herbicides (Gressel et al., 1982; Morrison and Devine, 1994).

Only five weed species have been reported to date to be resistant to dicamba worldwide: kochia (*Kochia scoparia*)[90], lambsquarters (*Chenopodium album*)[91], prickly lettuce (*Lactuca serriola*), common hempnettle *(Galeopsis tetrahit*) and wild mustard (*Brassica caber*)[92]. Of these five species, resistant populations of lambsquarters have only been reported in New Zealand. Regarding the two species with resistant populations in the U.S. (kochia, prickly lettuce) and Canada (common hempnettle and wild mustard), all were common to cereal production areas in the Western U.S. and Canada. No dicamba-resistant populations have been reported in the main soybean production areas, including the Midwest, the South and the East coast of the U.S. Table A-30 shows the number of U.S. weed species known to have resistance to each of the major herbicide groups (or sub-groups within groups, as appropriate) to which the alternative herbicides belong. It also contains a "Yes" marker for those herbicides that have many more known resistant weed biotypes than the five known for dicamba, indicating a potential lower risk for weed resistance development for dicamba compared to alternative herbicides. Entries not indicated with a "Yes" mean that dicamba is either comparable or less benign than the alternative herbicide. A comparison of each individual herbicide in the class is not provided.

Although dicamba resistance exists, weed populations that are resistant to dicamba in U.S. soybean cropping areas have not been problematic to date, possibly because selection pressure on summer annual weeds has been low. Dicamba has seen very limited use in soybean (1.2% of treated soybean acres as a preplant and pre-harvest applications) and currently has relatively low usage in the crops that are commonly rotated with soybean (10.3% of corn acres as preplant and in-crop applications, 9.6% of cotton acres as a preplant application, and 7.4% of wheat acres, respectively) (Table A-2 of this appendix), although historically dicamba was used more extensively in corn. In addition, there are over 20 commercially-available pre-mixed multiple-herbicide formulations that contain dicamba, so dicamba is often used in combination with other herbicide modes-of-action. It is expected that selection pressure favoring the development of dicamba-resistant weeds will continue to be low even after in-crop use of dicamba on DT soybean is approved. Monsanto believes this is because dicamba will predominantly still be used in combination with other herbicides exhibiting different modes-of-action, principally glyphosate, but also with other soil-active herbicides. The presence of multiple herbicides in the weed management system greatly diminishes the likelihood of weed resistance to dicamba developing to a level of predominance in weed populations. Dicamba is an excellent complement to the weed control spectrum of glyphosate, and it has a relatively low cost

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89 Weed Science Society of America. http://www.weedscience.org/summary/MOASummary.asp [Accessed May 28, 210]

90 "Dicamba Resistance in Kochia". H. J. Cranston, A. J. Kern, J. L. Hackett, E. K. Miller, B. D. Maxwell and W. E. Dyer, Weed Science 49:164-170, 2001.

91 "Chemical Control Options for the Dicamba Resistant Biotype of Fathen (*Chenopodium album*)". A. Rahman, T. K. James, and M. R. Trolove, New Zealand Plant Protection 61: 287-291, 2008.

92 "Inheritance of Dicamba Resistance in Wild Mustard (Brassica Kaber)". M. Jasieniuk, I. N. Morrison and A. L. Brûlé-Babel, Weed Science 43:192-195, 1995.

and low potential for crop injury to DT soybean relative to other broadleaf weed options. Taken together, these factors will help to ensure that more fields receive weed-control treatments using multiple herbicide modes-of-action, in a proactive way, aimed at mitigating the potential for development of resistance. In general, this will serve to further reduce the development of weed resistance to all herbicides, which target broadleaf weeds in soybean production, and in crops rotated with soybean. (See Appendix B of this EIR for more information on herbicide-resistant weeds in soybean systems.)

As part of the projected role of dicamba as a companion herbicide for glyphosate, dicamba will provide growers with a new mode-of-action for use in-crop against summer annual broadleaf weeds. Dicamba will help prevent and/or combat existing weed resistance issues that can limit effectiveness of the PPO- and ALS-inhibiting herbicide classes. Herbicides from these two herbicide classes have historically dominated the non-glyphosate broadleaf weed control tools available in soybean (13 of the 18 alternative herbicides considered here are PPO- or ALS-inhibiting herbicides (Table A-30)), and were the predominant modes-of-action used for weed control in soybean production prior to the introduction of the Roundup Ready soybean system; they remain the primary options recommended for management of glyphosate-resistant or hard-to-control broadleaf weeds in soybean. For example, fomesafen and flumioxazin, both PPO Inhibitors, are the primary herbicides recommended for control of glyphosate-resistant Palmer amaranth (pigweed) in soybean.

Dicamba will foster the adoption of Integrated Pest Management (IPM) practices in soybean by allowing growers to continue to primarily focus on postemergent in-crop weed control, as they have practiced with Roundup Ready soybean, and will make current practices more effective by providing an additional mode-of-action herbicide. This will allow growers to delay some herbicide treatments until field scouting indicates a need for additional weed control, which is consistent with the principles of IPM. Dicamba, as a companion product to glyphosate, will also continue to foster adoption of and maintain the use of conservation tillage practices, because of grower preference to use postemergent products, such as dicamba on DT soybean, compared to reliance on soil-active preemergent products

In summary, the ability to use dicamba as part of a weed management program in U.S. soybean production will provide significant benefits for managing broadleaf weed resistance, not only relative to glyphosate, but also to other herbicides such as those included in PPO- and ALS-inhibitor classes. There is evidence in the scientific literature from data generated in field studies and from model simulations that the application of multiple herbicides, each effective in controlling a weed spectrum, with more than one mode-of-action can significantly mitigate the potential for evolution of resistant populations within a field (Powles et al., 1996; Beckie, 2006). In addition, there is evidence that resistance would be mitigated more effectively by use of herbicide mixtures than by using an herbicide rotation strategy (Diggle et al., 2003; Beckie and Reboud, 2009). Based on this general information on resistance, Monsanto believes that application of dicamba on DT soybean integrated into the Roundup Ready soybean system will reduce the development of herbicide-resistant broadleaf populations to glyphosate and other herbicides. This conclusion is based on the following: 1) the efficacy and broad spectrum of glyphosate and weed control spectrum of dicamba, 2) the low level of dicamba-resistant broadleaf weeds in the major soybean production areas, 3) the low number of species resistant to glyphosate, 4) the expected use of dicamba applied to DT soybean, and 5) the fact that dicamba will be used in combination with glyphosate, and other alternative herbicides as necessary to control problematic weeds. Using available information, Monsanto conservatively estimates that dicamba use on DT soybean could reduce the growth of resistant weed populations on five to ten percent of the expected 77 million U.S. planted soybean acres (Table A-32), which is equal to approximately 3.6 to 7.2 million acres.

Table A-32 Soybean Production in the U.S., 1999 – 2012[1]

Year	Acres Planted (×1000)	Acres Harvested (×1000)	Average Yield (bushels/acre)	Total Production (×1000 bushels)	Value (billions $)
2012	77,198	76,104	39.6	3,014,998	43.19
2011	75,046	73,776	41.9	3,093,524	38.50
2010	77,404	76,610	43.5	3,329,181	37.55
2009	77,451	76,372	44.0	3,359,011	32.15
2008	75,718	74,681	39.7	2,967,007	29.46
2007	64,741	64,146	41.7	2,677,117	26.97
2006	75,522	74,602	42.9	3,196,726	20.47
2005	72,032	71,251	43.1	3,068,342	17.30
2004	75,208	73,958	42.2	3,123,790	17.90
2003	73,404	72,476	33.9	2,453,845	18.02
2002	73,963	72,497	38.0	2,756,147	15.25
2001	74,075	72,975	39.6	2,890,682	12.61
2000	74,266	72,408	38.1	2,757,810	12.47
Ave.	74,310	73,220	40.6	2,976,014	24.76

[1] Source is USDA-NASS (2013a)

Furthermore, Monsanto believes the opportunity for dicamba use on DT soybean will foster continued adoption of conservation tillage practices, an important goal for the agro-ecosystem and the long term sustainability of U.S. agriculture. Presently, 41.5% of an estimated 74 million acres of U.S. soybean acres, or 30.6 million acres, employ no-till or conservation tillage production systems (CTIC, 2007). The introduction of DT soybean into the Roundup Ready soybean system would allow the flexibility to incorporate an additional herbicide mode-of-action in both pre- or postemergent applications, and support the continued use of conservation tillage production systems. The benefits of conservation tillage are well known and demonstrated, including soil and water conservation, improved environmental (*e.g.*, water) quality, and a reduced carbon footprint (Arriaga and Balkcom, 2005; Reicosky, 2008). These conservation tillage acres will represent a significant portion of the 30 million total acres projected for DT soybean planting, in turn representing a significant number of acres where mitigation of the development of glyphosate-resistant biotypes could be expected to occur.

A.4. IMPACT OF DGT COTTON DEREGULATION

A.4.1. Impact of DGT Cotton Deregulation on Dicamba Usage

A.4.1.1. **Overview**

The deregulation and commercialization of DGT cotton will expand dicamba use to in-crop postemergence applications to address hard-to-control and herbicide-resistant broadleaf weeds found in U.S. cotton production. The impact that DGT cotton will have on overall dicamba use will depend on the level of DGT cotton adoption by growers. Therefore, the extent of DGT cotton acreage following the deregulation of DGT cotton is difficult to forecast. Monsanto estimates that dicamba-treated acres could ultimately reach 50% of the total U.S. cotton acres. This estimate is based on a number of factors, including: (1) the percentage of non-glyphosate herbicides currently used in glyphosate-tolerant cotton; (2) the development of glyphosate-resistant weeds; (3) the effectiveness of other non-glyphosate herbicides used in the glyphosate-tolerant cotton weed control systems; (4) the perceived risk of offsite movement onto dicamba-sensitive crops; and (5) the foreseeable future introduction of new competitive GE-derived traits in cotton.

Approximately 53% to 64% of growers used a non-glyphosate herbicide in addition to glyphosate in the glyphosate-tolerant cotton systems in 2005 (Givens et al., 2009b). In 2007, approximately 39% of the growers often or always used herbicides with different modes-of-action in the glyphosate-tolerant cotton systems (Frisvold et al., 2009). Regardless of the availability of DGT cotton, the future use of non-glyphosate herbicides is expected to increase in order to support the management of glyphosate-resistant weeds. Additionally, grower educational programs on weed resistance management conducted by industry and universities encourage the use of non-glyphosate herbicides with alternative modes-of-action in glyphosate-tolerant cropping systems as a proactive measure to minimize the potential for development of glyphosate-resistant weeds (Beckie, 2006; Beckie, 2011; Powles, 2008). These programs will likely drive a further increase in non-glyphosate herbicides applied in cotton production.

A second factor impacting dicamba-treated cotton acreage is the current and future need for control of glyphosate-resistant weeds. Glyphosate-resistant weeds have been identified in multiple states (Heap 2012). When a glyphosate-resistant weed biotype has been confirmed to be present in a geographical area, growers in that area are advised proactively to implement glyphosate-resistant weed management programs to ensure effective control of the resistant weed biotype regardless of whether the weed species has been confirmed to be resistant on a grower's farm. Therefore, the acreage in an area where responsive weed resistance management practices are implemented is potentially greater than the actual acres known to be impacted by glyphosate-resistant weeds. University weed scientists recommend that growers implement best management practices, including a non-glyphosate herbicide with a second mode-of-action, in their cropping systems to minimize the development and potential spread of glyphosate-resistant weeds in the future (Culpepper et al., 2013; Hurley et al., 2009; Norsworthy et al., 2012; Owen et al., 2011; University of Georgia, 2012).

It is anticipated that even in locations where glyphosate-resistant weeds are present, glyphosate will continue to be the base herbicide applied to DGT cotton as a combined trait product with glyphosate-tolerant cotton. Table A-33 provides a summary of the herbicide applications registered for use in cotton in 2011, demonstrating that herbicides are used on essentially all (>99%) cotton acres in the U.S (Brookes, 2012; Monsanto Company, 2012). Approximately 39 million pounds of herbicide active ingredient were applied to cotton in 2011. These alternative herbicides will compete with dicamba and are expected to reduce the potential dicamba use on DGT cotton integrated into the glyphosate-tolerant cotton systems and in future combined trait products containing DGT cotton.

Another factor influencing the number of dicamba-treated cotton acres in the future will be the introduction of competing herbicide-tolerant traits in cotton. Currently, there are numerous herbicide-tolerant cotton products that are under regulatory review or have recently been authorized. This includes several products that have tolerance to multiple herbicides with different modes-of-action. These new GE-derived herbicide-tolerant cotton products are anticipated to be introduced in future years and will compete with Monsanto's DGT cotton and glyphosate-tolerant cotton products, thereby further reducing the potential dicamba use in cotton.

Taking into consideration the above assessment, the potential acreage of DGT cotton treated with dicamba is estimated to be 50% of the U.S. cotton acres, and would result in approximately 5.2 million pounds a.e. of dicamba applied to DGT cotton annually (including preplant, preemergence, and in-crop applications). Currently, 364,000 pounds of dicamba are applied preplant to commercially available cotton (see Table A-2). It is anticipated that dicamba applications will continue for all other currently labeled crops at the current annual level of approximately 3.8 million pounds (see Table A-2). Therefore, the addition of the estimated 5.2 million pounds of dicamba that would be applied to DGT cotton would result in a total U.S. dicamba use of approximately 9 million pounds annually.

Table A-33. Herbicide Applications Registered for Use in Cotton in 2011[1]

Herbicide	Herbicide Family	Mode-of-Action (MOA)	Cotton Acres Treated (%)	Cotton Acres Treated per MOA (%)	Quantity Applied (1000 lbs a.i. [2])	Total Quantity Applied/MOA (1000 lbs a.i.[2])
Glyphosate	Glycine	EPSPS inhibitor	73	73	20,015	20,015
Pendimethalin	Dinitroanaline	Microtubule inhibitor	16	40	1,964	5,043
Trifluralin	Dinitroanaline		24		3,079	
Diuron	Urea	PSII inhibitor	15	34	1,727	3,737
Prometyrn	Triazine		10		1,102	
Fluometuron	Urea		8		870	
Linuron	Urea		<1		38	
Acifluorfen	Diphenylether	PPO inhibitor	<1	38	1	856
Carfentrazone	Triazolinone		<1		<1	
Flumiclorac	N-phenylphthalimide		<1		<1	
Flumioxazin	N-phenylphthalimide		19		192	
Fomesafen	Diphenylether		17		626	
Oxyfluorfen	Diphenylether		1		36	
Pyraflufen	Phenylpyrazole		<1		<1	
2,4-D	Phenoxy	Synthetic Auxin	17	27	1,659	2,023
Dicamba	Benzoic acid		10		364	
Pyrithiobac	Benzoate	ALS inhibitor	14	21	113	120

Table A-33 (continued). Herbicide Applications Registered for Use in Cotton in 2011[1]

Herbicide	Herbicide Family	Mode-of-Action (MOA)	Cotton Acres Treated (%)	Cotton Acres Treated per MOA (%)	Quantity Applied (1000 lbs a.i.[2])	Total Quantity Applied/MOA (1000 lbs a.i.[2])
Thifensulfuron	Sulfonylurea		<1		<1	
Thibenuron	Sulfonylurea		<1		<1	
Trifloxysulfuron	Sulfonylurea		6		6	
Acetochlor	Chloroacetamide	Long-chain fatty acid inhibitor	8	25	1,502	4,587
Metolachlor	Chloroacetamide		17		3,085	
Norflurazon	Pyridazinone	Inhibition of carotenoid	<1	<1	2	2
Paraquat	Bipyridylium	Photosystem-I-electron diverter	10	10	735	735
Glufosinate-ammonium	Phosphinic acid	Glutamine synthesis inhibitor	10	10	800	800
MSMA	Organoarsenical	Cell membrane disruption	6	6	1,066	1,066
Clethodim	Cyclohexanedione	ACCase inhibitor	<1	<1	3	3
Fluazifop	Aryloxphenoxy propionate		<1		<1	
Diflufenzopyr	Semicarbazone	Auxin transport	<1	<1	3	3
Clomazone	Isoxazolidinone	Diterpene synthesis inhibitor	<1	<1	<1	<1
Total				99.4		38,992

[1] Updated version of Table VIII-9 of petition 12-185-01p_a1 with 2011 data (Monsanto, 2012).

[2] a.i.= active ingredient.

A.4.1.2. **Materials and Methods**

This analysis utilizes unpublished grower survey data obtained from an independent, private market research company that provides farm-survey information on agricultural herbicide usage in the U.S. This information reflects the most current data available on U.S. herbicide usage, and presents data on glyphosate-tolerant cotton from 2002 through 2011 to represent herbicide use after widespread adoption of glyphosate-tolerant cotton and after glyphosate-resistant weeds had begun impacting weed control decisions in cotton cultivation. The majority of data are presented in terms of total acres treated (TAT), which is the number of acres treated with an herbicide. The use of TAT provides a way to look at herbicide use that is independent of the various use rates of herbicides. If an herbicide is used more than once on an acre, the TAT will reflect this multiple use, and consequently the TAT may exceed the number of crop acres planted. This method provides a more complete view of herbicide use.

This analysis organizes data in two broad usage sets (Table A-34): preplant/pre-emergence to the crop (PRE) and post-emergence in-crop use (POST). The PRE set are herbicides applied prior to planting the crop through planting of the crop, but before crop emergence regardless of their mode-of-activity. The POST set are herbicides applied after crop emergence regardless of their mode-of-activity. In glyphosate-tolerant cotton, a total of 38 different non-glyphosate herbicides had been used in the PRE timing while 40 non-glyphosate herbicides had been used at the POST timing (Table A-34). The total PRE and POST herbicides used in glyphosate-tolerant cotton acres from 2002-2011 are presented in Table A-35 and Table A-36 below, respectively.

Certain assumptions were made in order to define the level of herbicide use (non-glyphosate and glyphosate) in glyphosate-tolerant cotton at a future time when there is peak use of dicamba in DGT cotton. One of the assumptions is that total planted cotton acres will be less than the 2011 planted acres (*i.e.*, a reduction in planted acres from approximately 14.5 million to approximately 10.5 million). Monsanto estimates an average planted acreage of 10.5 million acres per year for this analysis. Similarly, USDA (2013) predicts a decrease in cotton acreage, with projections for planted cotton acreage of 9.3 to 11.3 million acres for 2013 to 2022, with an average of 10.7 million acres per year. The predicted reduction is based on expected long-term economic conditions relative to the utilization and pricing of cotton. While acreage estimates were used to calculate the predicted herbicide use in glyphosate-tolerant cotton, the comparisons between predicted herbicide use in the presence or absence of DGT cotton are similar regardless of acreage trends because the same predicted acres estimate is used for both analyses.

Table A-34. Non-Glyphosate Herbicides Used in Cotton from 2002-2011

	Preplant/preemergence active ingredients	Postemergence active Ingredients
	2,4-D	2,4-D
	2,4-DB	Acetochlor
	Alachlor	Acifluorfen
	Bromoxynil	Alachlor
	Carfentrazone-Ethyl	Bromoxynil
	Clethodim	Carfentrazone-Ethyl
	Clomazone	Clethodim
	Cyanazine	Cyanazine
	Dicamba	Dicamba
	Diflufenzopyr	Dimethipin
	Diuron	Diuron
	Fluazifop	DSMA
	Flumiclorac	Fenoxaprop
	Flumioxazin	Fluazifop
	Fluometuron	Flumiclorac
	Fomesafen	Flumioxazin
	Glufosinate	Fluometuron
	Lactofen	Fomesafen
	Linuron	Glufosinate
	Metolachlor	Hexazinone
	Metolachlor-S	Lactofen
	MSMA	Linuron
	Norflurazon	Metolachlor
	Oxyfluorfen	Metolachlor-S
	Paraquat	Metsulfuron
	Pendimethalin	MSMA
	Prometryn	Oxyfluorfen
	Pyraflufen Ethyl	Paraquat
	Pyrithiobac-Sodium	Pelargonic Acid
	Quizalofop	Pendimethalin
	Rimsulfuron	Prometryn
	Saflufenacil	Pyraflufen Ethyl
	Sethoxydim	Pyrithiobac-Sodium
	Sulfosate	Quizalofop
	Thifensulfuron	Rimsulfuron
	Tribenuron Methyl	Sethoxydim
	Trifloxysulfuron	Sulfosate
	Trifluralin	Trifloxysulfuron
		Trifluralin
Total	**38**	**40**

Table A-35. Total Treated Cotton Acres for PRE Herbicide Applications[1]

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Projected (2012-2020)
TAT non-glyphosate herbicides	7,608,153	6,973,079	8,022,758	8,278,629	10,422,198	8,619,214	7,645,112	8,720,633	13,079,934	18,532,420	15,752,557
% increase 2002-2009 and 2007-2011								15%		113%	
TAT for glyphosate only	4,794,054	4,481,055	6,085,131	6,605,653	8,160,846	5,959,715	5,020,737	4,362,308	6,133,464	6,653,710	4,790,671
Total TAT (non-glyphosate + glyphosate herbicides)	12,402,207	11,454,134	14,107,889	14,884,282	18,583,044	14,578,929	12,665,849	13,082,941	19,213,398	25,186,130	20,543,228
GT cotton planted acres[2]	10,169,767	9,694,232	10,754,975	11,282,527	11,880,216	9,058,136	7,838,072	7,732,469	9,511,862	13,016,858	
Total Planted Cotton acres	14,380,987	13,626,965	13,869,061	14,024,973	15,113,121	10,731,987	9,308,988	9,042,201	10,801,010	14,533,017	10,500,000

[1] Unpublished grower survey data (Monsanto, 2012).
[2] Estimated.

Table A-36. Total Treated Cotton Acres for POST Herbicide Applications[1]

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Projected (2012-2020)
Total TAT non-glyphosate herbicides	4,666,015	4,119,878	4,864,283	4,625,240	5,513,925	2,941,420	3,303,968	3,734,015	6,341,041	11,018,661	9,365,862
% increase 2002-2007 and 2007-2011								-20%		220%	
TAT for glyphosate only	15,663,805	14,563,604	17,877,154	19,609,494	16,647,267	13,536,614	11,128,357	12,128,747	16,761,716	15,615,631	11,243,254
Total TAT (non-glyphosate + glyphosate herbicides)	20,329,820	18,683,482	22,741,437	24,234,734	22,161,192	16,478,034	14,432,325	15,862,762	23,102,757	26,634,292	20,609,116
GT Cotton planted acres[2]	10,169,767	9,694,232	10,754,975	11,282,527	11,880,216	9,058,136	7,838,072	7,732,469	9,511,862	13,016,858	
Total Planted Cotton acres	14,380,987	13,626,965	13,869,061	14,024,973	15,113,121	10,731,987	9,308,988	9,042,201	10,801,010	14,533,017	10,500,000

[1] Unpublished grower survey data (Monsanto, 2012).

[2] **Estimated.**

A.4.1.3. **Analysis of PRE Cotton Herbicide Use From 2002-2011**

The use of non-glyphosate herbicides included in the PRE set is influenced by use of conservation tillage (*i.e.*, reliance on herbicides to control emerged weeds prior to crop planting) and use of residual herbicides applied preplant and/or preemergent to crop emergence. The use of non-glyphosate PRE herbicides in glyphosate-tolerant cotton was relatively flat from 2002 through 2009 with only a 15% increase in TAT between 2002 and 2009 (Figure A-3 and Table A-37). In 2009, glyphosate-tolerant cotton was grown on 7.7 million acres. In the PRE segment, the primary non-glyphosate herbicides used were those providing postemergence control of broadleaf weeds (*e.g.*, 2,4-D, paraquat), preplant (*e.g.*, trifluralin, fomesafen, flumioxazin) or preemergence (*e.g.*, pendimethalin) control. From 2009 to 2011 there was a 113% increase in the use of non-glyphosate herbicides in the glyphosate-tolerant cotton PRE segment. In 2011, glyphosate-tolerant cotton was grown on approximately 13 million acres, a 68% increase from 2009. This data suggests that the growth in non-glyphosate herbicide use was not driven just by an increase in the total planted acres of glyphosate-tolerant cotton. This increase in use of non-glyphosate herbicides in the 2009-2011 time period is consistent with the increased emphasis by public and private sectors promoting more diversified weed management and also the increase in emergence of glyphosate-resistant weeds during the same time period. Regarding future use of non-glyphosate herbicides, this analysis projects that non-glyphosate herbicide use will decrease 15% (a decrease from 18.5 million TAT to approximately 15.8 million), primarily due to an overall decrease in planted acres, even though use of non-glyphosate herbicides will increase, particularly in the western cotton markets, regardless of the commercialization of DGT cotton. Of the planted glyphosate-tolerant cotton acres in 2011, approximately 65% received a non-glyphosate PRE herbicide application (Table A-38). The number of glyphosate applications per planted acre of glyphosate-tolerant cotton in the PRE segment has remained flat from 2002 through 2011. This figure is not expected to change in the foreseeable future regardless of the commercialization of DGT cotton (Table A-38). However, as indicated above, the total use of glyphosate per year is expected to decrease due to a projected decrease in cotton acres.

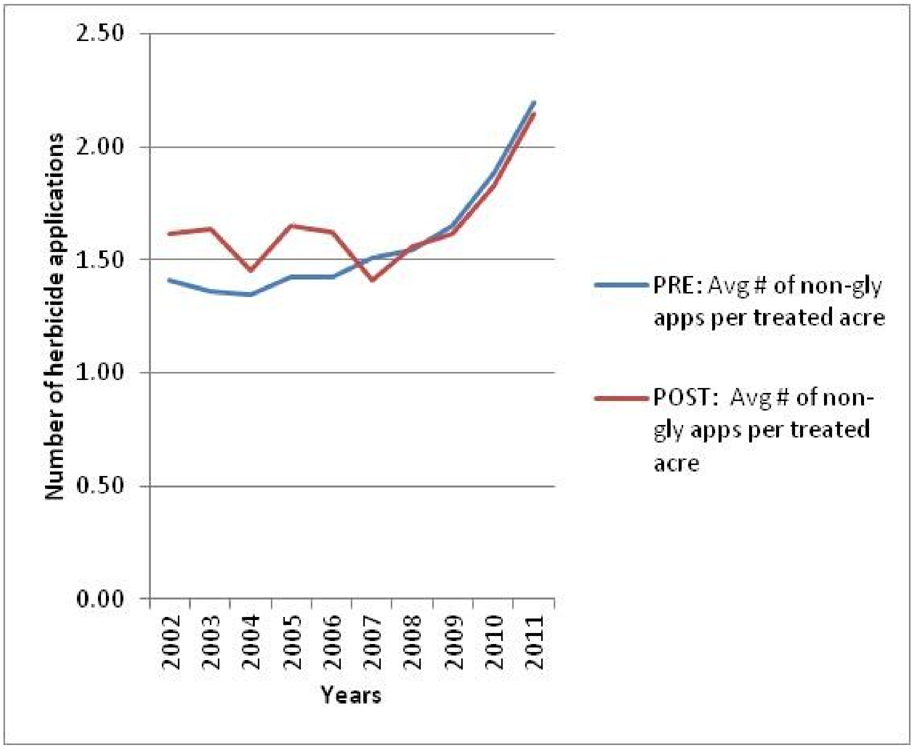

Figure A-3. Average Number of Preplant/Preemergence and Postemergence Non-glyphosate herbicide applications in cotton 2002-2011

Table A-37. Total Treated Cotton Acres for PRE Herbicide Applications[1]

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Projected (2012-2020)
TAT non-glyphosate herbicides	7,608,153	6,973,079	8,022,758	8,278,629	10,422,198	8,619,214	7,645,112	8,720,633	13,079,934	18,532,420	15,752,557
% increase 2002-2009 and 2007-2011								15%		113%	
TAT for glyphosate only	4,794,054	4,481,055	6,085,131	6,605,653	8,160,846	5,959,715	5,020,737	4,362,308	6,133,464	6,653,710	4,790,671
Total TAT (non-glyphosate + glyphosate herbicides)	12,402,207	11,454,134	14,107,889	14,884,282	18,583,044	14,578,929	12,665,849	13,082,941	19,213,398	25,186,130	20,543,228
GT cotton planted acres[2]	10,169,767	9,694,232	10,754,975	11,282,527	11,880,216	9,058,136	7,838,072	7,732,469	9,511,862	13,016,858	
Total Planted Cotton acres	14,380,987	13,626,965	13,869,061	14,024,973	15,113,121	10,731,987	9,308,988	9,042,201	10,801,010	14,533,017	10,500,000

[1] Unpublished grower survey data (Monsanto, 2012).
[2]**Estimated.**

Table A-38. Cotton Base Acres and Average Number of PRE and POST Herbicide Applications in Cotton from 2002-2011[1]

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Preplant/Preemergence Segment										
Base Acres non-gly	5,393,689	5,114,256	5,964,796	5,796,824	7,301,901	5,700,249	4,950,783	5,278,197	6,927,575	8,445,599
% of GT planted acres	53%	53%	55%	51%	61%	63%	63%	68%	73%	65%
Avg # of non-gly apps per treated acre	1.41	1.36	1.35	1.43	1.43	1.51	1.54	1.65	1.89	2.19
Base Acres gly	4,206,852	3,944,302	5,015,080	5,139,869	6,244,992	4,840,283	4,113,912	3,737,966	5,022,647	5,632,286
% of GT planted acres	41%	41%	47%	46%	53%	53%	52%	48%	53%	43%
Avg # of gly apps per treated acre	1.14	1.14	1.21	1.29	1.31	1.23	1.22	1.17	1.22	1.18
Postemergence Segment										
Base Acres non-gly	2,893,224	2,511,625	3,347,572	2,799,905	3,390,985	2,088,573	2,122,123	2,311,575	3,462,215	5,128,952
% of GT planted acres	28%	26%	31%	25%	29%	23%	27%	30%	36%	39%
Avg # of non-gly apps per treated acre	1.61	1.64	1.45	1.65	1.63	1.41	1.56	1.62	1.83	2.15
Base Acres gly	9,648,772	9,172,346	10,429,110	10,838,740	10,620,351	8,743,094	7,348,278	7,269,956	9,282,857	9,428,994
% of GT planted acres[2]	95%	95%	97%	96%	89%	97%	94%	94%	98%	72%
Avg # of gly apps per treated acre	1.62	1.59	1.71	1.81	1.57	1.55	1.51	1.67	1.81	1.66
GT cotton planted acres[2]	10,169,767	9,694,232	10,754,975	11,282,527	11,880,216	9,058,136	7,838,072	7,732,469	9,511,862	13,016,858
Total cotton planted acres	14,380,987	13,626,965	13,869,061	14,024,973	15,113,121	10,731,987	9,308,988	9,042,201	10,801,010	14,533,017

[1] Unpublished grower survey data (Monsanto, 2012).

[2] **Estimated.**

A.4.1.4. **Analysis of POST Cotton Herbicide Use From 2002-2011**

The use of herbicides from 2002 to 2011 was primarily influenced by the need to control weeds after they emerged in the crop or to extend the preemergence residual control of weeds longer into the growing season. As in the case of non-glyphosate PRE herbicides, the use of non-glyphosate POST herbicides applied in glyphosate-tolerant cotton was flat to slightly reduced use from 2002 to 2009 (Figure A-3 and Table A-39). However, from 2009 to 2011 there was a 220% increase in TAT for the use of non-glyphosate POST herbicides in glyphosate-tolerant cotton. In 2009, glyphosate-tolerant cotton was grown on approximately 7.7 million acres, while in 2011 there were approximately 13 million planted acres, a 68% increase. As in the case for the PRE herbicides, these data indicate that the increase in non-glyphosate herbicide use was not solely related to an increase in planted glyphosate-tolerant cotton acres. The increased use of non-glyphosate POST herbicides after 2009 is evidence of increased adoption of diversified weed management practices by farmers. These outcomes are consistent with farmer adoption of recommendations from the public and private sectors on how best to proactively and reactively manage weed resistance. Regarding future use of non-glyphosate herbicides in the POST segment, there will be an expected net 15% decrease, primarily due to a decrease in the planted acres of cotton, even though there will be increased use in certain market segments. In 2011, approximately 39% of glyphosate-tolerant cotton acres received a non-glyphosate POST herbicide application (Table A-38). The number of glyphosate applications per planted acre of glyphosate-tolerant cotton in the POST segment has remained flat from 2002 through 2011. This figure is not expected to change in the foreseeable future regardless of the commercialization of DGT cotton (Table A-38). However, as indicated above, total use of glyphosate per year is expected to decrease due to a projected decrease in cotton acres.

Table A-39. Total Treated Cotton Acres for POST Herbicide Applications[1]

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Projected (2012-2020)
Total TAT non-glyphosate herbicides	4,666,015	4,119,878	4,864,283	4,625,240	5,513,925	2,941,420	3,303,968	3,734,015	6,341,041	11,018,661	9,365,862
% increase 2002-2007 and 2007-2011								-20%		220%	
TAT for glyphosate only	15,663,805	14,563,604	17,877,154	19,609,494	16,647,267	13,536,614	11,128,357	12,128,747	16,761,716	15,615,631	11,243,254
Total TAT (non-glyphosate + glyphosate herbicides)	20,329,820	18,683,482	22,741,437	24,234,734	22,161,192	16,478,034	14,432,325	15,862,762	23,102,757	26,634,292	20,609,116
GT Cotton planted acres[2]	10,169,767	9,694,232	10,754,975	11,282,527	11,880,216	9,058,136	7,838,072	7,732,469	9,511,862	13,016,858	
Total Planted Cotton acres	14,380,987	13,626,965	13,869,061	14,024,973	15,113,121	10,731,987	9,308,988	9,042,201	10,801,010	14,533,017	10,500,000

[1] Unpublished grower survey data (Monsanto, 2012).

[2] Estimated.

A.4.1.5. **Projected Dicamba Use (TAT and Total Pounds) on DGT Cotton**

Based upon anticipated use patterns for dicamba on DGT cotton, projections on the number of dicamba TAT and total pounds of dicamba used on DGT cotton were determined for the combined PRE and POST application timing (Table A-40 and Table A-41). The anticipated use projections represent a high-end estimate of the incremental dicamba use. Projected dicamba use at peak penetration is 10.8 million TAT and 5.2 million pounds active ingredient (Table A-40 and Table A-41).

Table A-40. Estimated Dicamba Total Acres Treated at Peak Dicamba Use on DGT Cotton

Cotton Growing Region	**2011 planted acres (000)[1]**	**% of total planted**	**Planted acres at Peak (*i.e.* 15% reduction)**	**Planted conventional till acres (000) at peak**	**Planted no till acres (000) at peak[2]**	**# dicamba applications conventional**	**# dicamba applications no till**	**TAT assuming 100% acres with DGT Cotton**	**TAT with 50% dicamba use**
SE, Delta, E.TX	6,881	46%	5,849	4,621	1,228	1	2	7,077	3,539
CA	637	4%	541	428	114	1	2	655	328
W.TX, AZ, OK, NM, KS	7,363	49%	6,259	4,944	1,314	2	3	13,831	6,916
Total	14,881								10,782

[1] Acres from USDA-NASS, 2012. Note: Total planted acres for 2011 varies between USDA-NASS and the grower survey data used in previous tables. USDA-NASS was used to calculate dicamba TAT in the different cotton growing areas because only USDA-NASS planted acres is broken out by state.
[2] Based on 21% of cotton acres being no till.

Table A-41. Estimated Dicamba Total lbs a.i. at Peak Dicamba Use on DGT Cotton

Cotton Growing Region	Tillage system	2011 planted acres (000) available for dicamba use[1]	Planted acres at Peak (*i.e.* 15% reduction)	Planted conventional till acres (000) at Peak	Planted no till acres (000) at Peak	Conventional Tillage: # dicamba in-crop applications	Conservation tillage: # dicamba apps in crop[2]	Conservation Tillage: # dicamba application preplant	Conventional Tillage: Dicamba rate in-crop	Conservation tillage: Dicamba Rate Preplant	Total lbs dicamba ai (000)
SE, Delta, E.TX	Conventional			2,310		1			0.5		1,155
	Conservation				614		1	1	0.5	0.375	537
	Total	**3,441**	**2,924**								**1,693**
CA	Conventional			214		1			0.5		107
	Conservation				57		1	1	0.5	0.375	50
	Total	**319**	**271**								**157**
W.TX, AZ, OK, NM, KS	Conventional			2,472		2			0.5		2,472
	Conservation				657		2	1	0.5	0.375	904
	Total	**3,682**	**3,129**								**3,376**
US Total											**5,225**

[1] Acres from USDA-NASS, 2012. Note: Total planted acres for 2011 varies between USDA-NASS and the grower survey data used in previous tables. USDA-NASS was used to calculate dicamba TAT in the different cotton growing areas because only USDA-NASS planted acres is broken out by state.
[2] Based on 21% of cotton acres being no till..

A.4.2. Displacement of Other Non-Glyphosate Herbicides by Dicamba Use Following Deregulation of DGT Cotton

A.4.2.1. **Materials and Methods**

In order to estimate the amount of non-glyphosate herbicides that could be replaced by dicamba, Monsanto weed scientists identified those herbicides most likely to be replaced by dicamba from the list of non-glyphosate herbicides currently being used in glyphosate-tolerant cotton (Table A-34). These herbicides were selected based on criteria such as lower efficacy, carryover concerns, existing resistance, use restrictions, and/or crop safety. This resulted in the selection of 20 and 16 non-glyphosate herbicides in the PRE and POST segments, respectively, that would likely be replaced to some level by dicamba use. The herbicides expected to be replaced by dicamba in the PRE set included, among others, diflufenzopyr, fluometuron, diuron, flumioxazin, pendimethalin, fomesafen, trifluralin, 2,4-D, paraquat, and prometryn (Table A-42). The herbicides in the POST set most likely to be replaced by dicamba included, but were not limited to, paraquat, fomesafen, pyrithiobac, MSMA, fluometuron, diuron, prometryn, flumioxazin, trifloxysulfuron, metolachlor-s, metolachlor and acetochlor (Table A-43). In addition, the percent replacement for each herbicide was estimated based upon a technical understanding of the herbicide products and the marketplace, and then the herbicides were grouped based upon these estimates.

Glyphosate use in glyphosate-tolerant cotton has remained relatively constant over the last decade and is not projected to fluctuate in use per acre in the future, but on a total use basis will decrease due to overall reduction in planted cotton acres (Table A-38). However, there was a noticeable drop in glyphosate use in the POST segment in 2011, as a percent of glyphosate base acres relative to GT planted acres, relative to prior years (Table A-38). It is not known if this is the beginning of a trend towards reduced glyphosate use or a result of causes unique to 2011. In 2011, there were a significant number of acres that were not harvested because of the drought and it is possible that farmers delayed herbicide applications and subsequently never made some POST applications.

To obtain an accurate estimate of the amount of herbicide that dicamba could potentially displace, it was necessary to estimate the number of acres that would be planted to DGT cotton and the number of dicamba-tolerant acres that would be treated with dicamba at peak market penetration. Monsanto estimates that DGT cotton varieties could be planted on up to 50% of the U.S. cotton acres at peak penetration and that dicamba will be used in 100% of these planted acres. This value represents a high-end estimate of incremental dicamba use. It is possible that the actual market penetration and associated dicamba use could be lower.

Additional analyses were conducted for each application timing segment to evaluate trends in glyphosate and non-glyphosate use and to allow for a comparison of the pounds of herbicide applied with and without the commercialization of DGT cotton. These analyses include use of base acres as provided by the market research company (a base acre is defined as one to which at least one glyphosate or non-glyphosate herbicide application has been applied). This contrasts with TAT which accounts for multiple applications on an acre.

Table A-42. Projected Total Acres Treated for PRE Cotton Herbicides Likely to be Displaced by Dicamba

			2011[1]			Peak		
Active Ingredients	**Projected % Replacement**	**Major Reasons for replacement**	**TAT**	**50% of Total TAT[2]**	**TAT replaced**	**TAT without dicamba [3]**	**50% of Total TAT[2]**	**TAT Replaced**
Diflufenzopyr	100%	crop safety	91,117	45,559	45,559	77,449	38,725	38,725
Paraquat Oxyfluorfen Thifensulfuron Tribenuron Methyl Pyraflufen Ethyl Carfentrazone-Ethyl Flumiclorac Rimsulfuron	75%	efficacy grower preference crop safety carryover	1,593,460	796,730	597,548	1,354,441	677,221	507,915
2,4-D Fomesafen Fluometuron Metolachlor-S Prometryn Pyrithiobac-Sodium Metolachlor	50%	crop safety efficacy convenience resistance	7,071,266	3,535,633	1,767,817	6,010,576	3,005,288	1,502,644
Flumioxazin Diuron	25%	crop safety convenience	3,570,338	1,785,169	446,292	3,034,787	1,517,394	379,348
Trifluralin Pendimethalin	10%	convenience	5,068,116	2,534,058	253,406	4,307,899	2,153,949	215,395
Total					3,110,621			2,644,027

[1] Unpublished grower survey data (Monsanto, 2012). TAT is only for those active ingredients within each herbicide grouping.
[2] TAT replaced = TAT x Projected % Replacement x 50%. Monsanto projects dicamba to be conservatively used on 50% of U.S. cotton acres at market penetration.
[3] Peak TAT factors in a reduction of planted acres in 2011 and an increase non-glyphosate use in the west for a net 15% decrease in non-glyphosate herbicide use from 2011 levels.

Table A-43. Projected lbs a.i. for PRE Cotton Herbicides Likely to be Displaced by Dicamba

		2011[1]			Peak			
Active Ingredients	**Major Reasons for replacement**	**Projected % Replacement**	**lbs a.i.**	**50% of Total lbs ai[2]**	**lbs ai replaced**	**lbs ai without dicamba[3]**	**50% of Total lbs ai[2]**	**lbs ai replaced**
Diflufenzopyr	crop safety	100%	3,051	1,526	1,526	2,593	1,297	1,297
Paraquat Oxyfluorfen Thifensulfuron Tribenuron Methyl Pyraflufen Ethyl Carfentrazone-Ethyl Flumiclorac Rimsulfuron	efficacy grower preference crop safety carryover	75%	641,338	320,669	240,502	545,137	272,569	204,426
2,4-D Fomesafen Fluometuron Metolachlor-S Prometryn Pyrithiobac-Sodium Metolachlor	crop safety efficacy convenience resistance	50%	3,971,538	1,985,769	992,885	3,375,807	1,687,904	843,952
Flumioxazin Diuron	crop safety convenience	25%	1,152,496	576,248	144,062	979,622	489,811	122,453
Trifluralin Pendimethalin	convenience	10%	4,289,433	2,144,717	214,472	3,646,018	1,823,009	182,301
Total					1,593,445			1,354,429

[1] Unpublished grower survey data (Monsanto, 2012).

[2] lbs a.i. replaced = lbs a.i. x Projected % Replacement x 50%. Monsanto projects dicamba to be conservatively used on 50% of U.S. cotton acres at market penetration.

[3] Peak lb a.i. factors in a reduction of planted acres in 2011 and an increase non-glyphosate use in the west for a net 15% decrease in non-glyphosate herbicide use from 2011 levels.

A.4.2.2. **Analysis of Displacement of Other Non-Glyphosate Herbicides by Dicamba Use Following Deregulation of DGT Cotton**

The commercialization of a cotton product containing dicamba-tolerance will allow for an increase in the use of dicamba for weed control in cotton due to the elimination of in-crop (POST segment) and preplant (PRE segment) crop safety concerns. While dicamba is presently labeled for preplant uses in cotton, this use is currently limited because the application must be made more than 21 days prior to planting, in order to address crop safety risks. With crop safety no longer a barrier, farmers can incorporate dicamba into their weed management programs because of the advantages it offers versus other herbicides. Those advantages will translate into dicamba replacing certain non-glyphosate herbicides currently used preplant and/or postemergent in cotton. In addition, the ability to use dicamba to manage existing resistant weeds will reduce the need for multiple residual herbicides and/or multiple postemergence herbicides in some situations. This will drive an overall reduction in herbicide use in some situations. For example, Monsanto and academics currently recommend that farmers with glyphosate-resistant weeds apply a residual product, such as flumioxazin, or fomesafen preplant to the crop, followed by fluometuron preemergence, and followed by glyphosate plus acetochlor or metolachlor after planting, and then conclude with hooded applications of paraquat and/or directed applications of MSMA or diruon to control escapes. With the ability of farmers to use dicamba in crop, dicamba would replace the need for several of these products, and others currently being used, thus resulting in a shift and replacement of herbicide use and applications.

Glyphosate is not expected to be replaced by dicamba in either the PRE or the POST segment. Dicamba will primarily be used in combination with glyphosate and this combination will simply displace glyphosate combinations with other non-glyphosate herbicides and/or glyphosate herbicide used alone.

A.4.2.2.1. Projected TAT Estimates for Replacement of Currently Used PRE Herbicides by Dicamba

As stated previously, at peak adoption of DGT cotton, dicamba is projected to be used on approximately 50% of total cotton planted acres. The 18.5 million TAT for all non-glyphosate PRE herbicides used in cotton in 2011 (Table A-37) adjusted for the dicamba use projection of 50% and an estimated 15% reduction in non-glyphosate herbicide use resulting in a theoretical maximum of 7.86 million TAT in the PRE segment that could potentially be displaced by dicamba. The non-glyphosate herbicides most likely to be displacement by dicamba are listed in Table A-42 and include active ingredients that can be used for burndown, residual, or residual and burndown control. These herbicides were selected because of the advantages dicamba would offer relative to each selected herbicide and expected farmer preferences towards dicamba use (see Table A-42 for specific advantages for each group of herbicides). A projected percent replacement by dicamba was then estimated for each herbicide based on criteria such as lower efficacy, carryover concerns, existing resistance, use restrictions, and/or crop safety. Reductions in the use of each herbicide were then estimated and herbicides with the same projected percent replacement were grouped. In the case of the PRE herbicides, the groupings were 100%, 75%, 50%, 25% or 10%. Applying the estimated percent reductions to the TAT for 2011 provided an estimate for the number of treated acres (TAT) that dicamba would replace at peak use of dicamba in DGT cotton. Based on these assumptions, it can be projected that dicamba would replace an estimated 2.6 million non-glyphosate PRE herbicide TAT at peak use of dicamba (Table A-42). Therefore, dicamba could be expected to conservatively replace approximately 34% of the projected TAT for all non-glyphosate herbicides used in PRE application timing at peak dicamba use, based on the 50% of total planted cotton acres where dicamba is projected to be used (7.88 million TAT).

A.4.2.2.2. Projected TAT Estimates for Replacement of Currently Used POST Herbicides by Dicamba

As stated previously, a high-end estimate of dicamba use on cotton is 50% of total cotton acres at peak use in DGT cotton. The projected 11 million TAT for all non-glyphosate POST herbicides used in cotton at peak use of dicamba (Table A-39) adjusted for the dicamba use projection of 50% and an estimated 15% reduction in non-glyphosate herbicide use results in a theoretical maximum of 4.68 million TAT that could potentially be displaced by dicamba. The non-glyphosate herbicides most likely to be displaced by dicamba are listed in Table A-44 and include active ingredients that can be used for burndown, residual, or residual and burndown control. These herbicides were selected because of the advantages dicamba would offer relative to each selected herbicide and expected farmer preferences towards dicamba use (*see* Table A-44 for specific advantages). A projected percent replacement was then estimated for each herbicide based on criteria such as lower efficacy, carryover concerns, existing resistance, use restrictions, and/or crop safety. Reductions in use of each herbicide were then estimated and herbicides with the same projected percent replacement were grouped. In the case of the POST herbicides, the groupings were 75%, 50%, or 10%. Applying the estimated percent reductions to the TAT for 2011 provided an estimate for the number of total acres treated (TAT) that dicamba would replace at peak use of dicamba in DGT cotton. Based on these assumptions, it can be projected that dicamba would replace an estimated 1.75 million non-glyphosate herbicide TAT at peak use of dicamba. Therefore, dicamba could be expected to conservatively replace approximately 37% of the projected TAT for all non-glyphosate herbicides used in POST application timing at peak dicamba use, based upon the above assumption that dicamba will only be used on 50% of total planted cotton acres (4.68 million TAT)

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Table A-44. Projected Total Acres Treated for POST Cotton Herbicides Likely to be Displaced by Dicamba

			2011[1]			Peak		
Active ingredient type	**% Replacement**	**Reasons for replacement**	**2011 TAT**	**50% of Total TAT[2]**	**TAT replaced**	**TAT without dicamba**	**50% of Total TAT[2]**	**TAT Replaced**
Prometryn Flumioxazin, Trifloxysulfuron Paraquat Fomesafen Carfentrazone-Ethyl Pendimethalin Trifluralin	75%	crop safety convenience efficacy	2,962,625	1,481,313	1,110,984	2,518,231	1,259,116	944,337
Pyrithiobac-Sodium MSMA Fluometuron Linuron	50%	crop safety convenience efficacy resistance	2,890,794	1,445,397	722,699	2,457,175	1,228,587	614,294
Metolachlor-S Acetochlor Diruron Metolachlor	10%	crop safety efficacy	4,503,927	2,251,964	225,196	3,828,338	1,914,169	191,417
Total					2,058,879			1,750,047

[1] Unpublished grower survey data (Monsanto, 2012). TAT is only for those active ingredients within each herbicide grouping.
[2] TAT replaced = TAT x Projected % Replacement x 50%. Monsanto projects dicamba to be conservatively used on 50% of U.S. cotton acres at market penetration.
[3] Peak TAT factors in a reduction of planted acres in 2011 and an increase non-glyphosate use in the west for a net 15% decrease in non-glyphosate herbicide use from 2011 levels.

A.4.2.2.3. Projected Total Pound Estimates for Replacement of Currently Used Herbicides by Dicamba

The projected total pounds of herbicides in each application segment (PRE and POST) that would be replaced by dicamba were determined using the same methodology and data source as that used in the TAT analysis described above. Based on this analysis, Monsanto projects that dicamba would replace an estimated 1.35 million pounds of PRE non-glyphosate herbicides and 0.5 million pounds of POST non-glyphosate herbicides at peak market penetration (Table A-43 and Table A-45, respectively).

Table A-45. Projected lbs a.i. for POST Cotton Herbicides Likely to be Displaced by Dicamba

		2011[1]						Peak
Active Ingredients	**Major Reasons for replacement**	**Projected % Replacement**	**lbs a.i.**	**50% of Total lbs ai[2]**	**lbs ai replaced**	**lbs ai without dicamba[3]**	**50% of Total lbs ai[2]**	**lbs ai replaced**
Prometryn Flumioxazin Trifloxysulfuron Paraquat, Fomesafen, Carfentrazone-ethyl, Pendimethalin, Trifluralin	crop safety convenience efficacy	75%	212,487	106,244	79,683	180,614	90,307	67,730
Pyrithiobac-sodium MSMA Fluometuron Linuron	crop safety convenience efficacy resistance	50%	1,232,210	616,105	308,053	1,047,379	523,689	261,845
Metolachlor-s Acetochlor Diruron Metolachlor	crop safety efficacy	10%	4,254,867	2,127,434	212,743	3,616,637	1,808,318	180,832
Total					600,478			510,407

[1] Unpublished grower survey data (Monsanto, 2012).

[2] lbs a.i. replaced = lbs a.i. x Projected % Replacement x 50%. Monsanto projects dicamba to be conservatively used on 50% of U.S. cotton acres at market penetration.

[3] Peak lb a.i. factors in a reduction of planted acres in 2011 and an increase non-glyphosate use in the west for a net 15% decrease in non-glyphosate herbicide use from 2011 levels.

A.4.3. Net Impact of DGT Cotton on Overall Herbicide Use

Estimates of the net impact of DGT cotton on future total acres treated with dicamba and total pounds of active ingredients deployed are presented in Table A-46. At projected peak penetration of DGT cotton, an increase in both total acres treated and total pounds of dicamba herbicide active ingredient applied is projected; however estimated increases are 16% or less of the total herbicide use projections (16% for TAT and 12% of total pounds of active ingredient) if DGT cotton is not commercialized (Table A-46). In addition, this analysis demonstrates the following two key conclusions:

(1) The overall use of non-glyphosate herbicides in cotton production has grown since 2009. While the overall growth in non-glyphosate herbicides is expected to decrease at the time of peak use of dicamba in DGT cotton, due to a reduction in cotton plantings, there will be a growth in non-glyphosate herbicide use, particularly in the western cotton markets. The current and projected growth is due in large part to the adoption of best management practices as recommended by public and private sector weed scientists and the development and spread of weed resistance. This increase in non-glyphosate herbicide use will occur even in the absence of DGT cotton, and

(2) When a DGT cotton system is available, dicamba would displace a significant amount of non-glyphosate herbicides used for weed management. Our analysis conservatively projects that on acres where DGT cotton is planted and dicamba is used, dicamba will replace approximately 34% of the projected PRE non-glyphosate herbicide TAT and 37% of the projected POST non-glyphosate herbicide TAT. Based on expectations by Monsanto and academic weed scientists, farmers will continue to implement diversified weed management programs that utilize multiple herbicide modes-of-action, and dicamba will be an important weed management tool in future cotton production.

The anticipated deregulation and subsequent commercialization of DGT cotton will not alter the number of cultivated cotton acres or the geographical areas where cotton is cultivated in the U.S. Consequently, DGT cotton will be grown on land that is already highly managed for agricultural crop production and where herbicides are widely used today. As described previously, the commercialization of DGT cotton will result in a slight increase in herbicide use (treated acres and pounds of dicamba) on those acres where it is planted and the grower chooses to use dicamba in their weed management program. However, the anticipated increase in dicamba relative to overall herbicide use in cotton production is relatively low, contributing less than 16% to the overall herbicide use in glyphosate-tolerant cotton production.

While an increase in overall herbicide use in cotton growing areas is projected for the commercialization of DGT cotton, assuming growers adopt recommended weed management practices, these practices provide numerous economic and environmental benefits which are detailed in this Environmental Report and Appendices B, C, and F thereto, and summarized below.

- Effective tool for sustainable management of glyphosate-resistant weeds;
- Mitigate the potential for development of weed resistance for all classes of cotton herbicides;

- Improve the consistency of control over hard-to-control weeds, thereby reducing the potential for new resistant biotypes to develop;
- Increase application flexibility;
- Preserve the benefits of the glyphosate-tolerant weed control system; and
- Preserve the many environmental and economic benefits of conservation tillage.

Furthermore, the projected increase in the amount of dicamba used in cotton production is not expected to result in adverse impacts to human health or the environment. The EPA regulates pesticide use and is required under FIFRA to reach a conclusion of no unreasonable adverse effects to human health and the environment before any application of dicamba can be made on DGT cotton (*see* Appendices E and F to this Environmental Report). Monsanto has submitted an application to EPA to approve the use of dicamba on DGT cotton. EPA concluded in the dicamba Reregistration Eligibility Decision (RED) document that all then-registered uses of dicamba can be used without resulting in unreasonable adverse effects when used according to the approved legal label (U.S. EPA, 2009). Because the use pattern for dicamba on DGT cotton is consistent with the use patterns and assumptions on herbicide use intensity evaluated in the RED, any projected increase in dicamba use related to the commercialization of DGT cotton is not expected to result in potential adverse impacts to the human health or the environment, and EPA is expected to reconfirm dicamba's safety as part of its review of the Monsanto application.

Table A-46. Net Impact of DGT Cotton on Overall Herbicide Use

	Projected at Peak planting of DGT Cotton	
With DGT Cotton	**Total Acres Treated (TAT) (000 acres / year)**	**Total lbs a.i. (000 lbs a.i. /year)**
Projected increase in dicamba use	10,782[1]	5,225[2]
PRE herbicides replaced by dicamba	2,644[3]	1,354[4]
POST herbicides replaced by dicamba	1,750[5]	510[6]
Net Change with introduction of DGT Cotton	6,388	3,361
Without DGT Cotton[7]		
Total - non-glyphosate	25,118	14,804
Total - glyphosate	16,034	14,188
Total - non-glyphosate plus glyphosate	41,152	28,992
Dicamba increase with DGT cotton as % of herbicide use in absence of DGT cotton	16%	12%

[1] Table A-40
[2] Table A-41
[3] Table A-42
[4] Table A-43
[5] Table A-44
[6] Table A-45
[7] Totals based upon 15% overall reduction in TAT and lbs ai relative to 2011 levels.

A.4.4. Comparative Analysis of Dicamba and Alternative Cotton Herbicides

A.4.4.1. **Background**

Dicamba use in combination with glyphosate and glufosinate in cotton that is tolerant of all three herbicides offers an attractive opportunity for cotton farmers to preserve the benefits that glyphosate offers while addressing the problem of glyphosate-resistant weeds. Dicamba's risk profile offers key improvements relative to the alternative cotton herbicide a.i.'s. In the following section, a comparative analysis of dicamba to the alternative cotton herbicide a.i.'s is presented.

Table A-47 lists the most-widely used cotton herbicide products. Based on 2011 market data, the a.i.'s listed in Table A-47 account for 46.2 million treated acres or 99.7% of the total herbicide-treated cotton acres. Table A-47 also summarizes key information about the alternative herbicide products that are evaluated in this petition, e.g., signal word, re-entry interval, use rates, and label warnings or special directions. Table A-48 lists further information about the herbicidal a.i.'s used in cotton, such as the registration date, registration review status, RED date, where the tolerance information can be found, whether it is a reduced risk pesticide, and whether it is a restricted use pesticide.

Table A-47. Dicamba and Alternative Registered Cotton Herbicides

Representative Brand (EPA Reg. No.)	Active Ingredient	2011 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Clarity (7969-137)	Dicamba	855 / 1.8	Caution	4.0 lb a.e./gal	24 hr	1.0 [1]	2.0 [1]	Known to leach; 50-foot buffer to wells; Runoff advisory; Drift advisory; State-specific limitations; Soil type limitations; Maximum crop rotation interval 3 – 6 months.
Ignite (264-829)	Glufosinate ammonium	1,297 / 2.8	Warning	2.34 lb/gal	12 hr	0.79	1.59	Toxic to vascular plants; May have runoff potential; Drift advisory; 70-day cotton PHI; Little or no activity in soil; Not in Hawaii or S. Florida.
Roundup WeatherMAX (524-537)	Glyphosate	23,345 / 50.4	Caution	4.5 lb a.e./gal	4 hr	3.71	5.96	Weed resistance advisory; Drift advisory; 7-day cotton PHI.
Treflan HFP (62719-250)	Trifluralin	4,098 / 8.8	Caution	4.0 lb/gal	12 hr	2	2	Extremely toxic to freshwater, estuarine, and marine fish and invertebrates; Some crops have long rotational interval (18 - 20 mos.); 90-day cotton PHI.
Direx 4L (352-678)	Diuron	2,110 / 4.6	Caution	4 lb/gal	12 hr	1.6	2.2	Drift Advisory; Crop rotation intervals of 12 months common; State-specific limitations; Soil type limitations; Do not feed treated foliage to livestock.
Prowl 3.3 EC	Pendimethalin	2,010 / 4.3	Caution	3.3 lb/gal	24 hr	2	2	Toxic to fish; Endangered plant species buffer required; Drift and runoff may be hazardous to aquatic organisms; Long (14 - 24 mos) crop rotation intervals for some crops; 60-day cotton PHI; State-specific limitation; Soil-type limitations; Do not feed treated foliage to livestock.

Representative Brand (EPA Reg. No.)	Active Ingredient	2011 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Valor SX (59639-99)	Flumioxazin	1,835 / 4.0	Caution	0.51 lb/lb	12 hr	0.06	0.13	Toxic to non-target plants & aquatic invertebrates; Runoff advisory; 40-foot aerial buffer to adjacent crops or water bodies; 12-month rotation interval common; Cotton injury possible; Do not feed treated foliage to livestock; 60-day cotton PHI.
Staple (352-576)	Pyrithiobac-sodium	1,689 / 3.6	Warning	0.85 lb/lb	24 hr	0.1	0.13	Highly toxic to non-target plants; Drift warnings; Cotton injury possible; Weed resistance advisory; 60-day cotton PHI; State-specific limitations (Staple LX); 10 – 12 month rotation intervals.
Staple LX (352-613)	Pyrithiobac-sodium		Caution	3.2 lb/gal	4 hr	0.1	0.13	
Dual Magnum (100-816)	S-Metolachlor	1,492 / 3.2	Caution	7.62 lb/gal	24 hr	1.27	2.48	Potential to leach; Potential for runoff; Ground & surface water advisory; State specific limitations; Soil type limitations; Swath adjustment 300 - 400 ft to avoid non-target plant injury; 80- to 100-day cotton PHI; Do not feed treated foliage to livestock.
MSMA 6 Plus (19713-42)	Monosodium Metharsonate	1,451 / 3.1	Caution	6 lb/gal	12 hr	1.88	3.75	50-foot buffer around all permanent water bodies; Drift warning about adjacent crops and sensitive areas; State specific limitations; No preplant cotton treatment; Do not feed treated foliage to livestock.
Barage HF (5905-529)	2,4-D Ethylhexyl Ester (EHE)	1.421 / 3.1	Caution	4.7 lb a.e./gal	12 hr	2.35 [2]	4.7 [2]	Toxic to aquatic invertebrates; Drift may adversely affect non-target plants or invertebrates; Groundwater advisory; Weed resistant biotypes known; Do not spray if wind above 15 mph.
Weedar 64 (71368-1)	2,4-D Dimethylamine Salt (DMA)	[see 2,4-D total above]	Danger	3.8 lb a.e./gal	48 hr	1.9 [2]	3.8 [2]	May be toxic to fish & aquatic invert; May result in groundwater contamination; Drift warning; Do not apply if wind above 15 mph; Apply only when sensitive areas or plants are not with 250 feet downwind.

Representative Brand (EPA Reg. No.)	Active Ingredient	2011 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Reflex (100-993)	Fomesafen-sodium	1,415 / 3.1	Danger	2.0 lb a.e./gal	24hr	0.375	0.375	May leach; Groundwater advisory; Some long rotation intervals (up to 18 mos.); Cotton injury warning; Weed resistance advisory; State-specific limitations; Soil type limitations; 70-day cotton PHI
Gramoxone Inteon (100-1217)	Paraquat	1,078 / 2.3	Danger	2.0 lb cation/gal	12 hr	1	3	Restricted Use Pesticide due to acute toxicity; May be fatal if swallowed or inhaled; Toxic to wildlife; Damage / toxicity to non-target crops / plants; Drift advisory; Cotton injury possible; Do not feed treated foliage to livestock; 3-day cotton PHI.
Cotoran (66622-181)	Fluometuron	786 / 1.8	Caution	4 lb/gal	24 hr	2	3	Known to leach; May result in groundwater contamination; Weed resistance advisory; Avoid drift to sensitive areas; 12-month rotation interval for many crops; State-specific limitations; Soil type limitations; Do not feed treated foliage to livestock; 60-day cotton PHI.
Caparol 4L (100-620)	Prometryn	867 / 1.9	Caution	4 lb/gal	24 hr	2.4	6	Drift and runoff may be hazardous to aquatic organisms; 400 ft upwind swath adjustment for sensitive plants; Weed resistance advisory; Crop injury possible; Soil type limitations; State-specific limitations; Do not feed treated foliage to livestock.
Envoke (100-1132)	Trifloxysulfuron-sodium	423 / 0.9	Caution	0.75 lb / lb	12	0.012	0.019	Toxic to vascular plants; Ground water advisory; Weed resistance advisory; Long rotational intervals (12 -22 mos, some zones); 60-day cotton PHI; 25-foot buffer around treated areas recommended; State specific limitations; Soil type limitations.

Representative Brand (EPA Reg. No.)	Active Ingredient	2011 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Aim EW (279-3242)	carfentrazone ethyl	89/0.16	Caution	1.9 lb/gal	12 hr	0.025	0.124	Carfentrazone-ethyl is very toxic to algae and moderately toxic to fish. Do not allow spray solution to contact cotton foliage, green stem tissue, or blooms.
Resolve DF (352-556)	rimsulfuron	11/0.02	Caution	granule	4 hr	Not labeled for Cotton	0.03	Do not apply preemergence to coarse textured soils (sand, loamy sand, or sandy loam) with less than 1% organic matter. Adequate soil moisture is required for optimum activity. Long rotational restrictions up to 10 months. Crop injury may occur following application if there is prolonged cold weather and/or wet soils.
Treaty (71368-74)	thifensulfuron methyl	81/0.15	Warning	granule	12 hr	0.02	Pre-plant burn down in cotton	Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Do not graze or feed forage or hay from treated areas to livestock. Weed control may be reduced if rainfall or snowfall occurs soon after application.
Victory (71368-75)	tribenuron methyl	70/0.13	Caution	granule	12 hr	0.0125	Pre-plant burn down in cotton	Weed control in areas of thin crop stand or seedling skips may not be satisfactory. Weed control may be reduced if rainfall or snowfall occurs soon after application. Do not apply later than 14 days before planting cotton. Do not graze or feed associated by products for 60 days after application.
ET Herbicide (71711-7	Pyraflufen ethyl	56/0.1	Danger	0.208 lb/gal	12 hr	0.003	0.013	This pesticide is toxic to fish and aquatic invertebrates. Allow a minimum of 30 days between applications for use on cotton. Apply to cotton having less than 3 inches of stem bark using hooded ground equipment only. Avoid contact with desirable vegetation.

Representative Brand (EPA Reg. No.)	Active Ingredient	2011 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Goal 2XL (62719-424)	oxyfluorfen	190/0.34	Warning	2 lb/gal	24 hr	0.5	1	This product is toxic to aquatic invertebrates and wildlife. Do not graze or harvest plants from treated areas for feed or forage. Treated soil must be thoroughly mixed to a depth of 4 inches after harvest prior to planting a rotational crop. Care must be taken to avoid spray contact with cotton leaves. Do not apply to cotton less than 6 inches tall or severe crop injury will result.
Resource (59639-82)	flumiclorac pentyl ester	15/0.03	Warning	0.86 lb/gal	12 hr	0.05	0.094	Causes substantial but temporary eye injury. This product is toxic to shrimp. Keep out of lakes, ponds, and streams. Do not graze animals on green forage or use as feed fewer than 28 days after application.

[1] Dicamba rates cited are those proposed for use on DGT cotton.

[2] 2,4-D products are not labeled for cotton treatments. Preplant treatments, more than 29 days before planting, are used for burndown weed control using the Fallow portion of the label.

[3] Monsanto private market survey data. The data shown are for the cotton acres to which the relevant active ingredient was applied in 2011, and the percentage of total treated acres this constitutes. A treated acre is application of one active ingredient once. Multiple active ingredients or multiple applications results in total treated acres that exceed total planted cotton acres. No entry is shown for products containing more than one active ingredient, since these acres are counted in the single active ingredient rows.

Table A-48. Dicamba Compared to Active Ingredients Contained in Alternative Herbicide Products

Active Ingredient	First Registered	Regis-tration Review Status [1]	RED Date	Max. Cotton lb/a (single application) [2]	Max. Cotton lb/a (season) [2]	Tolerances 40 CFR 180.	EPA Reduced Risk Classification	Restricted Use
dicamba-diglycolamine salt	2-Feb-56	unsched.	2006	1.0[3]	2.0[3]	227	N	N
Glufosinate-ammonium	Glufosinate-ammonium	29-May-91	2008	N/A	0.79	1.59	473	Yes
Glyphosate (salts)	Glyphosate (salts)	7-Sept-88	2009	09/23/2009	3.71	5.96	364	Yes
Herbicide a.i.s Applied Primarily at a PE Timing								
2,4-D EHE (esters)[4]	3-Jun-52	2013	2005	2.0 [5]	4.0 [5]	142	N	N
2,4-D DMA (salts)[4]				2.0 [5]	4.0 [5]			
flumiclorac pentyl	23-Mar-94	2009	N/A	0.05	0.094	477	Yes	No
S-metolachlor	18-May-83	2016	12/01/1994	1.27	2.48	368	Yes	No
oxyfluorfen	17-May-79	2015	10/01/2002	0.5	1	381	No	No
pyraflufen ethyl	27-Sept-02	2014	N/A	0.003	0.013	585	No	No
rimsulfuron	20-Sept-89	2012	N/A	Not labeled for cotton	0.03	478	No	No
thifensulfuron methyl	25-Apr-86	2011	N/A	0.02	N/A	439	No	No
tribenuron methyl	22-May-89	2011	N/A	0.0125	N/A	451	No	No
Herbicide a.i.s Applied at both PE and POE Timings								
carfentrazone ethyl	02-Aug-95	2011	N/A	0.025	0.124	515	Yes	No
fluometuron	28-May-74	Unsched.	09/28/2005			229	No	No
fomesafen sodium	10-Apr-87	2007	N/A	0.375	0.375	433	No	No
paraquat dichloride	08-Jan-80	2011	08/01/1997	1	3	205	No	Yes
Prometryn	19-Aug-74	2013	1996	2.4	5.95	222	N	N
Pyrithiobac-Sodium	29-Jun-95	docket '11	NA	0.1	0.13	487	N	N
Herbicide a.i.s Applied Primarily at a POE Timing								
flumioxazin	01-Aug-96	2011	N/A	0.06	0.13	568	No	No
MSMA	25-Dec-63	2013	2006 corr 2009	1.88	3.75	289	N	N
pendimethalin	20-Mar-75	2012	04/01/1997	2	2	361	No	No
trifloxysulfuron-sodium	29-Jun-03	2013	NA	0.012	0.019	591	N	N

trifluralin	04-Dec-68	2012	09/01/1995	2	2	207	No	No

1 Registration Review Status: year docket is scheduled to open, unless unscheduled. FWP = Final Work Plan stage. If docket is open, "docket XX" = year opened.

2 Rates for dicamba, 2,4-D, fomesafen, and glyphosate are expressed as acid equivalents. All others are on an a.i. basis, as stated, except paraquat is on a cation basis. Regional or soil type limitations may lower this rate.

3 Maximum treatment rates for the proposed dicamba label on DGT cotton.

4 For the 2,4-D ester group, the ethylhexyl ester (EHE) is taken as representative. For the salt group, the dimethylamine (DMA) salt is taken as representative.

5 Rates taken from Master 2,4-D Label (http://www.24d.org/masterlabel/default.aspx) for Fallow application. There are no specific cotton treatment directions. Fallow application must precede planting by 29 days or more.

A.4.4.2. **Alternative Registered Herbicides – Comparative Analysis**

A detailed comparative analysis of the risk profile for glufosinate is not included here because the introduction of DGT cotton will not change the use of glufosinate in cotton. However, the data for glufosinate is included in the comparisons of cotton herbicides.

Dicamba's risk profile offers key improvements relative to the alternative cotton herbicide a.i.'s. In the following section, an analysis comparing dicamba to the alternative cotton herbicide a.i.'s is presented. Tables A-49 through A-54 include an analysis of risks to human health, aquatic organisms, and potential for leaching to groundwater. A variety of chemical-specific public data sources were used to compile this comparison; those sources are listed below in "Chemical-Specific References". Glufosinate and glyphosate were not considered valid comparators, because Monsanto will recommend their use as part of an integrated pest management system. To summarize the findings, a scoring procedure was applied to the data for each a.i. to assign one of three potential risk scores for that risk category:

- A Black Circle represents a relatively higher risk among the alternatives considered for that general risk parameter.
- A Half Circle represents a intermediate risk among the alternatives considered.
- A White Circle represents a reduced risk among the alternatives considered.

In order for a pesticide (herbicide) to be registered by EPA the U.S. EPA must conclude that the herbicide, when used according to the label, does not pose an unreasonable adverse effect to humans or the environment; in order to establish a tolerance for the use of an herbicide on a food or feed crop, EPA must find there is a reasonable certainty of no harm to human health from non-occupational (food, water and residential/recreational) exposures to the herbicide. Consequently, all alternative herbicides used in cotton production, including those discussed below, can be used safely, and do not pose an unreasonable risk to humans or the environment. Therefore, a Black Circle in this evaluation scheme does not mean that the risk parameters are considered to be unacceptable, but rather that in comparison with this set of herbicide active ingredients, the herbicides associated with a Black Circle have a higher relative risk in that particular concern than those with a White Circle or a Half Circle. Conversely, the herbicides with a White Circle indicate a reduced risk in a particular category compared to the other herbicides considered in this analysis.

In some instances, such as those mentioned below, dicamba offers a reduction in risk potential (i.e., hazard) compared to some alternative herbicides in the same risk category (e.g., aquatic animal risk). In other instances dicamba presents a similar risk potential compared to some alternatives. In a few cases, dicamba presents a greater risk potential compared to some alternatives. This comparative analysis serves to demonstrate that the use of dicamba on DGT cotton is unlikely to result in a significant impact/risk to human health or the environment compared to current herbicide agronomic practices and in some instances its use may impart additional benefits as described below.

A.4.4.2.1. Risks to Human Health

Cotton is grown for its lint and only the by-products are used as food and feed. Further, the processed commodities from cotton production, such as oil, do not contain significant herbicide residues (Maher and Foster). Because cotton production does not significantly contribute to human or animal dietary risk, a detailed comparison of dietary exposure was not included in this analysis.

Instead, this analysis is focused on risks to workers, applicators, and potential exposure to pesticides via drinking water.

Table A-49 provides information concerning human health parameters for each alternative a.i. These include:

- Acute Toxicity Categories for the a.i.;[93]
- The acute population adjusted dose, aPAD; and
- An Acute Toxicity Score (described below).

The Acute Toxicity Score was created based on the following criteria: White Circle means no category I findings, not a skin sensitizer, and aPAD ≥ 0.1 mg/kg/day or not needed. Half Circle means one category I acute toxicity finding, a skin sensitizer, or aPAD < 0.1. Black Circle means two or more category I acute toxicity findings, a skin sensitizer, or aPAD < 0.1.

Acute Risk: As shown in Table A-26, dicamba acid has Category II findings for eye and skin irritation, but once the acid is neutralized to form the DGA or other salt forms used in formulations, all acute Categories are III or IV. The acute population adjusted dose (aPAD) is the EPA's maximum acceptable acute exposure level of a substance. The aPAD exposure level is specific for each pesticide and is usually experimentally derived from animal studies. Animals (typically rats) are dosed with varying amounts of the substance in question, and the largest dose at which no effects are observed is identified. This dose level is combined with uncertainty and/or "safety" factors to make up the aPAD. The acute population adjusted dose for dicamba is 1 mg/kg/day. This compares favorably against the fourteen alternative herbicides presented in Table A-49. Seven of the fourteen herbicides (counting 2,4-D dimethylamine (DMA) salt and 2,4-D ethylhexyl ester (EHE) separately) have a greater risk as determined by the Acute Toxicity Score. 2,4-D has a low acute population adjusted dose at 0.067 mg/kg/day and is a severe eye irritant, resulting in Black Circle Acute Toxicity Score. In addition, paraquat dichloride has a low acute population adjusted dose at 0.0042 mg/kg/day and is highly toxic via inhalation, resulting in a Black Circle Acute Toxicity Score. This is especially relevant considering this new use of dicamba will potentially replace the pre-harvest burndown application of paraquat dichloride on cotton and is, therefore, a noteworthy reduction in potential risk from acute exposure.[94]

[93] Toxicity Category I is highly toxic and severely irritating; toxicity Category II is moderately toxic and moderately irritating; toxicity Category III is slightly toxic and slightly irritating; and toxicity Category IV is practically non-toxic and not an irritant.

[94] As discussed in section A.4.4.2, all alternative herbicides used in cotton production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category.

Table A-49. Human Health Risk Parameters for Acute Exposure to Dicamba and Alternate Herbicide Products

Active Ingredient	Acute (Oral, Dermal, Inhalation, Eye Irr., Skin Irr., Sens.) [1]	aPAD mg/kg/day [2]	Acute Toxicity Score [3]
dicamba acid /DGA salt [4]	III / III / IV / II / II / N; III / III / IV / III / III / N	1	○
glufosinate-ammonium	III / III / III / III / IV / N	0.0063	*
glyphosate (salts)	IV / IV / ? / II / IV / N; IV / IV / III / III / IV / N	no need	*
Herbicide A.I.s with Potential Displacement of Preemergent Acres			
2,4-D DMA (salts)	III / III / IV / I / IV / ? [5]	0.067	●
2,4-D EHE (esters)	III / III / IV / III / IV / ? [5]		◐
flumiclorac pentyl	IV / III / IV / II / II / Y	no need	○
S-metolachlor	III / III / IV / III / IV / Y	3	◐
oxyfluorfen	IV / III / IV / IV / IV / N	no need	○
pyraflufen ethyl	IV / III / IV / III / IV / N	no need	○
rimsulfuron	IV / IV / IV / III / IV / IV	no need	○
thifensulfuron methyl	IV / III / IV / III / IV / N	1.59	○
tribenuron methyl	IV / III / III / II / IV / Y	no need	◐
Herbicide A.I.s with Potential Displacement of both Preemergent and Postemergent Acres			
carfentrazone ethyl	IV / III / IV / IV / IV / N	5	○
fluometuron	III / III / III / II / II / N	0.1	○
fomesafen sodium	III / II / III / I / II-III / Y	no need	◐
paraquat dichloride	II / III / I /II / IV / N	0.0042	●
prometryn	III / III / III / III / IV / N	0.12	○
Pyrithiobac-sodium	III / III / IV / II / ? / N	no need	○
Herbicide A.I.s with Potential Displacement of Postemergent Acres			
flumioxazin	IV / III / IV / III / IV / N	0.03	◐
MSMA	III / III / III / III / IV / N	0.1	○
pendimethalin	III / IV / IV / III / IV / N	no need	○
Trifloxysulfuron-sodium	IV / IV / IV / III / III / N	0.5	○
trifluralin	IV / III / III / III / IV / Y	1	◐

1 The standard acute toxicity tests for a pesticide include Oral, Dermal, Inhalation, Eye Irritation, Skin Irritation, and Skin Sensitization. Results are scored using a I to IV scale, where I if worst and IV is best. The skin sensitization test is scored Yes or No. The results of this battery for each a.i. are shown in order. Toxicity Category I is highly toxic and severely irritating; toxicity Category II is moderately toxic and moderately irritating; toxicity Category III is slightly toxic and slightly irritating; and toxicity Category IV is practically non-toxic and not an irritant.

2 The Acute Population Adjusted Dose (aPAD) as determined by EPA risk assessments.

3 White Circle means no category I findings, not a skin sensitizer, and aPAD ≥ 0.1 mg/kg/day or not needed. Half Circle means one category I acute toxicity finding, a skin sensitizer, or aPAD < 0.1. Black Circle means that two or more of the criteria listed for "2" are met.

4 Dicamba diglycolamine salt acute toxicity data for Clarity formulation (EPA Reg. No. 7969-137)
5 2,4-D acid and several salt and ester forms are not skin sensitizers. The data for the DMA salt and EHE were considered "unacceptable" by EPA when the RED was published.
* Glufosinate and glyphosate were not included in the comparison because Monsanto will recommend their use as part of an integrated pest management system.
PE – preemergent
POE – postemergent

Table A-50 provides additional information concerning human health parameters for each alternative a.i.'s. These include:

- Cancer Classification;
- Cancer risk when quantitative risk assessment is required by EPA;
- Cancer Risk Score (described below); and
- Chronic Risk Score (described below).

The scoring method used for the Cancer Risk Score is based on the EPA cancer classification and the quantitative risk where required by EPA. White Circle means favorable cancer classifications, including E, "not likely" or "no evidence of." Half Circle means C or "likely" carcinogens not requiring quantitative risk assessment, or those with quantitative risk estimated below EPA's 1×10^{-6} concern threshold. Black Circle identifies a.i.'s whose cancer risk is above 1×10^{-6}.

The chronic risk score is based on the degree of toxicity represented by the cPAD as follows: A White Circle score is cPAD > 0.1, a Half Circle Score is cPAD between 0.1 and 0.01 (0.1 > cPAD > 0.01), and a Black Circle Score is a cPAD < 0.01.

<u>Cancer Risk:</u> Dicamba is classified as "Not Likely" for human carcinogenicity. Ten of the alternative herbicides also have a White Circle for their Cancer Risk Score. However, nine alternative herbicides have a greater cancer risk—C or higher classifications—than dicamba, and two of them—fluometuron and MSMA— have a significantly higher risk as shown by the Black Circle for Cancer Risk Score, because the required quantitative risk assessment resulted in a finding that was greater than 1×10^{-6}. Overall, Monsanto concludes that dicamba has lower potential cancer risk than eleven of the alternative herbicide a.i.'s used on cotton, as shown in Table A-50.[95]

<u>Chronic Risk</u>. Chronic risk can be evaluated by consideration of the chronic population adjusted dose (cPAD or the "risk cup") for an a.i.. Table A-50 tabulates the cPAD for each alternative a.i., according to recently published Federal Register Final Rule information. For dicamba and three of the alternative herbicides, the cPAD is 0.1 or greater resulting in a White Circle for Chronic Risk Score. Eight alternative a.i.'s, have a cPAD between 0.1 and 0.01 resulting in a Half Circle Chronic Risk Score. And five of the alternative a.i.'s (2,4-D, tribenuron methyl, fluometuron, fomesafen sodium, and paraquat dichloride) have a cPAD of less than 0.01, resulting in a Black Circle Chronic

95 As discussed in section A.4.4.2, all alternative herbicides used in cotton production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category.

Risk Score. Therefore, dicamba represents a lower potential risk for chronic risk compared to thirteen of the alternative a.i.'s.[95]

Table A-50. Human Health Risk Parameters for Chronic Exposure to Dicamba and Alternative Herbicides

Active Ingredient	Cancer Classification [1]	Cancer Risk [2]	Cancer Risk Score [3]	cPAD mg/kg/day [4]	Chronic Risk Score [5]
dicamba acid /DGA salt [4]	not likely	NA	○	0.45	○
glufosinate-ammonium	no evid. of	NA	*	0.006	*
glyphosate (salts)	E	NA	*	1.75	*
Herbicide A.I.s with Potential Displacement of Preemergent Acres					
2,4-D DMA (salts)	D (not classifiable)	NA	○	0.005	●
2,4-D EHE (esters)					
flumiclorac pentyl	No evidence	NA	○	1	○
S-metolachlor	C (no Q1*)	NA	◐	0.1	○
oxyfluorfen	C (7.32×10^{-2})	3.8×10^{-7}	◐	0.03	◐
pyraflufen ethyl	C (3.32×10^{-2})	**2.6×10-6**	◐	0.2	○
rimsulfuron	not likely	NA	○	0.118	○
thifensulfuron methyl	No evidence	NA	○	0.043	◐
tribenuron methyl	C (no Q1*)	NA	◐	0.008	●
Herbicide A.I.s with Potential Displacement of both Preemergent and Postemergent Acres					
carfentrazone ethyl	not likely	NA	○	0.03	◐
fluometuron	C (1.8×10^{-2})	**1.2×10^{-5}**	●	0.0055	●
fomesafen sodium	not likely	NA	○	0.0025	●
paraquat dichloride	E	NA	○	0.0045	●
prometryn	E	NA	○	0.04	◐
Pyrithiobac-sodium	C (1×10^{-3})	2×10^{-7}	◐	0.58	○
Herbicide A.I.s with Potential Displacement of Postemergent Acres					
flumioxazin	not likely	NA	○	0.02	◐
MSMA	carcinogenic metab. [6]	**1×10^{-4} to 4×10^{-4}**	●	0.03	◐
pendimethalin	C (no Q1*)	NA	◐	0.03	◐
Trifloxysulfuron-sodium	not likely	NA	○	0.237	○
trifluralin	C (5.8×10^{-3})	1.6×10^{-7}	◐	0.024	◐

[1] Cancer Classification, followed by Q1* value, when required

[2] Cancer risk is calculated by EPA when quantitative risk assessment is warranted.. It is based on estimated exposure, using the potency factor Q1*, as listed in the column to the left. Risk below 1 x 10-6 is considered an acceptable risk threshold. Risk above this level is highlighted in red.

[3] Cancer Risk Score. White Circle means favorable cancer classifications, including E, “not likely”, or “no evidence of”, Half Circle means C or “Likely” carcinogens not requiring quantitative risk assessment, or those with risk below the 1 x 10-6 threshold. Black Circle identifies a.i.s whose cancer risk is above 1 x 10 -6.

[4] The chronic population adjusted dose (cPAD) as determined by EPA risk assessments.

[5] The chronic risk score is based on cPAD, a white circle score is cPAD > 0.1, a Half Circle Score is cPAD between 0.1 and 0.01 (0.1 > cPAD > 0.01), and a Black Circle Score is a cPAD < 0.01

[6] Inorganic arsenic is a degradate of MSMA and is considered a human carcinogen.

*Glufosinate and glyphosate were not included in the comparison because Monsanto will recommend their use as part of an integrated pest management system.

A.4.4.2.2. Risk to Fish and Aquatic Invertebrates

Table A-51 provides information about the hazards, exposures, and risks of dicamba DGA salt and each of the twenty-two alternative a.i.'s used in cotton to fish and aquatic invertebrates. For this analysis, 2,4-D DMA salt and 2,4-D EHE are considered separately, since they have substantially different water solubility. The criteria in this category include:

- Estimated environmental concentrations (EECs) of each of the seventeen (17) a.i.'s in surface water using the 4-day EEC as described by the Generic Estimated Environmental Concentration (GENEEC)[96] model. This model is used by EPA to estimate a pesticide's environmental exposure to aquatic ecosystems based on parameters including application rate, degradation rate, soil-binding properties, etc.
- LC_{50} endpoints from acute fish toxicity studies or EC_{50} hazard values from the National Site for the USDA Regional IPM Centers Information System. The highest and lowest LC_{50} values for any reported fish study are listed for each a.i., regardless of species, including both fresh and marine species together. The purpose is to define a range of concentrations that encompass expected fish-toxic levels. In some cases, study results based on testing end-use formulations were generally omitted unless data on the active ingredient was not available, or it was likely that formulation components did not influence the study results.
- EC_{50} or LC_{50} endpoints from acute aquatic invertebrate studies, as reported from the National Site for the USDA Regional IPM Centers Information System. The highest and lowest EC_{50} or LC_{50} values for any invertebrate study are listed, regardless of species, including both fresh water and marine species together. The purpose is to define a range of concentrations that encompass expected aquatic invertebrate-toxic levels. Studies on end-use formulations were considered as described above. Results attributable to formulation ingredients, such as solvents or surfactants, were sometimes omitted.
- Calculated Risk Quotients (RQs) for aquatic animals, comprised of fish and aquatic invertebrates combined together. Rather than calculate a single RQ for each species, Monsanto has calculated a range of potential RQs for each a.i., bracketed by the best- and worst-case values. The "best" RQ is derived from the ratio of the lowest reported EEC concentration divided by the highest LC_{50} or EC_{50} for any aquatic animal. Conversely, the "worst" RQ is derived from the ratio of the highest EEC concentration divided by the lowest LC_{50} or EC_{50} for any aquatic animal. The purpose is to define a range of RQs that span and describe the risk posed by the alternative herbicide to aquatic animals. The RQs that exceed the EPA's Level of Concern (LOC) of 0.5 are marked in bold red font.
- The Aquatic Fish and Invertebrate Score is a means of summarizing the risk data for aquatic animals that is based entirely on the calculated risk quotient. A White Circle means that the worst-case RQ estimate < 0.05, which is EPA's LOC for acute aquatic risk for endangered aquatic animals. A Half Circle means that the worst case risk quotient is greater than 0.05 and less than 0.5 (0.5 > RQ > 0.05). 0.5 is EPA's LOC for acute aquatic risk for non-endangered

[96] US EPA provides access to GENEEC via a downloadable executable program and users manual at http://www.epa.gov/oppefed1/models/water/#geneec2.

animals. A Black Circle means that the worst-case RQ is greater than 0.5, indicating an acute risk for aquatic animals above EPA's Level of Concern (LOC).

The assessment and comparison summarized in Table A-51 establishes that dicamba poses little acute risk to aquatic animals, which is consistent with EFED's assessment published in the EFED chapter in the RED (EPA 2006). The entries that exceed this LOC are those "worst case" values for 2,4-D (acid / salt and esters considered separately), flumiclorac pentyl, oxyluorfen, pyraflufen ethyl, pendimethalin, and trifluralin. These a.i.'s received a Black Circle for their Aquatic Fish and Invertebrate Score, and their RQ's are highlighted in red bold font.

Five alternative a.i.'s (S-metolachlor, carfentrazone ethyl, fluometuron, prometryn, and flumioxazin) have worst case RQs above 0.05 but less than 0.5 and received a Half Circle for their Aquatic Fish and Invertebrate Scores. EPA considers the LOC for aquatic animals that are endangered species to be 0.05. The labels for herbicide products that received a Black Circle Aquatic Fish and Invertebrate Score and the labels for some of the herbicide products that received a Half-Circle Aquatic Fish and Invertebrate Score also bear warning statements for toxicity to fish or invertebrates based on the hazard values of those a.i.'s. Therefore, Monsanto concludes that dicamba presents a lower risk potential to aquatic animals than twelve of the twenty-two alternative herbicidal a.i.'s used on cotton as presented in Table A-51.[97]

[97] As discussed in section A.4.2.2, all alternative herbicides used in cotton production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category.

Table A-51. Aquatic Toxicity for Fish and Aquatic Invertebrates from Acute Exposure

Active Ingredient	GENEEC[2] 4-day EEC	Fish LC_{50} Range [3] (ppm)		Aquatic Invertebrate LC_{50} or EC_{50} [3] Range (ppm)		Risk Quotient for Aquatic Animals Range [4] Exposure/Hazard		Aquatic Fish and Invertebrate Score [5]
	(ppm)	low	high	low	high	best	worst	
dicamba acid /DGA salt[6]	0.049	> 270	-	> 270	-	-	0	○
glufosinate-ammonium	0.022	13.1	> 1000	7.5	668	0	0.003	*
glyphosate (salts)	0.0597	45	> 1000	> 10	934	0	0.001	*
Herbicide A.I.s with Potential Displacement of Preemergent Acres								
2,4-D DMA (salts)	0.087	> 100	524	0.15	103	0.001813	**0.580**	●
2,4-D EHE (esters)	0.09	18	180	0.054	> 5	0.0005	**1.67**	●
flumiclorac pentyl	0.95	1.1	17.4	0.56	38	0.025	**1.70**	●
S-metolachlor	0.054	3.2	17	1.4	26	0.002077	0.039	◑
oxyfluorfen	2.55	0.074	0.17	0.069	1000	0.00255	**37**	●
pyraflufen ethyl	74.14	0.056	99	0.043	121	0.612727	**1724**	●
rimsulfuron	2.33	110	1000	110	390	0.00233	0.021	○
thifensulfuron methyl	2.29	100	100	NA	NA	0	0.023	○
tribenuron methyl	2.87	1000	1000	720	720	0.00287	0.004	○
Herbicide A.I.s with Potential Displacement of both Preemergent and Postemergent Acres								
carfentrazone ethyl	279.89	1.14	2	1.16	9.8	0.00551	0.05	◑
fluometuron	0.107	0.64	65	> 1	22	0	0.167	◑
fomesafen sodium	0.021	> 163	6030	22.1	397	0	0.001	○
paraquat dichloride	0.0026	> 1	156	> 1	11	0	0.0026	○
prometryn	0.09	> 1	10	1.7	21	0	0.052941	◑
Pyrithiobac-sodium	0.0057	> 145	> 1000	> 140	> 910	0	0	○
Herbicide A.I.s with Potential Displacement of Postemergent Acres								
flumioxazin	0.0016	2.3	> 21	0.23	5.5	0	0.007	◑
MSMA	0.0498	12	323	77.5	173	0	0.00415	○
pendimethalin	0.013	0.0098	90.4	0.017	11	0.0001	**1.33**	●
Trifloxysulfuron-sodium	0.00068	> 97	> 104	60.1	> 119	0	0	○
trifluralin	18.69	0.0084	0.21	0.037	2.2	8.495	**89**	●

[1] Dicamba, 2,4-D salts and esters, fomesafen, and glyphosate are expressed on acid equivalent basis. Paraquat is on a cation basis. All others are on an a.i. basis as stated.

[2] GENEEC is a surface water model to Estimate Environmental Concentration (EEC) used by US EPA. Further information can be found at
http://www.epa.gov/pesticides/science/models_pg.htm#aquatic.

[3] LC50 or EC50 hazard values from http://www.ipmcenters.org/ecotox/index.cfm. Entries are the highest and lowest values provided for the a.i. for fish and invertebrates, separately. [10-Apr-2013 download].

[4] Risk Quotient is defined as exposure / hazard, both expressed as ppm (mg/L). “Best” means lowest exposure / hazard endpoint. “Worst” means highest exposure / hazard endpoint. Entries of 0 mean that the RQ is less than 0.0005 or the data was not available.

[5] Aquatic Fish and Invertebrate Score: White Circle means that the worst-case RQ estimate < 0.05. Half Circle means that for the worst-case RQ, 0.05 < RQ < 0.5. Black Circle means that the worst-case RQ is greater than 0.5, indicating acute risk for aquatic animals.

[6] Data for dicamba diglycolamine salt from EFED Chapter for the Dicamba RED.

Note: As much as possible, LC50 or EC50 hazard values were chosen from tests with the technical a.i. to avoid using hazard endpoints that are caused by solvents, surfactants, or other formulation ingredients.

*Glufosinate and glyphosate were not included in the comparison because Monsanto will recommend their use as part of an integrated pest management system. Dicamba, 2,4-D salts and esters, fomesafen, and glyphosate are expressed on acid equivalent basis. Paraquat is on a cation basis. All others are on an a.i. basis as stated.

A.4.4.2.3. Risk to Aquatic Plants

Table A-52 provides information about the hazards, exposures, and risks related to aquatic plants for dicamba and each of the twenty-two alternative herbicide a.i.'s used on cotton. The data format, sources, and methods of Estimated Environmental Concentration (EEC) calculation for aquatic plants are identical to those described for aquatic animals (Table A-51). A Level of Concern (LOC) value of 1.0 has been used for judging RQ exceedances in the case of aquatic plants, consistent with EPA EFED's normal practices.

- Aquatic Plant Toxicity is based on the hazard values from the National Site for the USDA Regional IPM Centers Information System. Table A-52 lists the LC_{50} and no observed effect concentration (NOEC) for each named species. Entries are for the named genus with the lowest EC50, and the corresponding NOEC level. .
- The Risk Quotient for Aquatic Plants is defined as EEC / hazard, both expressed as ppm (mg/L). RQ Range is determined from the EC50 and the NOEC concentration. A Level of Concern (LOC) value of 1.0 has been used for judging RQ exceedance in the case of aquatic plants, consistent with EPA EFED's normal practices. It should be noted that there are currently no threatened or endangered non-vascular aquatic plants, and therefore exceedances based on non-vascular plants would have no impact for listed species.
- The Aquatic Plant Score is based entirely on the Risk Quotient for Aquatic Plants. A White Circle means that only the high range limit for endangered (listed) aquatic plant species exceeds EPA's LOC of at most 1.0. A Half Circle means that both the RQ range limits for endangered (listed) plant species exceed EPA's LOC of 1.0 for aquatic plant risk. A Black Circle means that both the RQ range limits for endangered (listed) plant species exceed EPA's LOC by more than 100.
- The assessment and comparison summarized in Table A-52 establishes that dicamba poses little acute risk to aquatic plants, which is consistent with EFED's assessment published in the EFED chapter of the RED. Dicamba and two of the alternative herbicide a.i.'s used in cotton have RQs with the high range limit for aquatic plant species higher than EPA's LOC of 1.0, while another two do not exceed the LOC of 1.0 even at the high range limit. Seven of the alternative herbicides have both the RQ range limits for aquatic plant species higher than EPA's LOC of 1.0. Seven alternative herbicides have both the RQ range limits for aquatic species higher than EPA's LOC by more than 100. Dicamba has a lower risk for aquatic plant toxicity when compared to fourteen of the alternative herbicides used in cotton. Therefore, Monsanto concludes that dicamba offers a lower risk potenail for use on cotton with regard to aquatic plant risk.[98]

[98] As discussed in section A.4.2.2, all alternative herbicides used in cotton production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category.

Table A-52. Aquatic Toxicity Parameters for Aquatic Plants for Dicamba and Alternate Herbicide Active Ingredients

Active Ingredient[1]	GENEEC[2] 4-day EEC	Aquatic Plants Toxicity [3] (Most Sensitive Species Tested)	LC50	NOEC[3]	Risk Quotient for Aquatic Plants [4]	Aquatic Plant Score[6]
	(ppm)	Species	(ppm)	(ppm)	RQ Range	
dicamba acid /DGA salt	0.049	anabena[5]	0.06	0.005	0.82-9.8	○
glufosinate-ammonium	0.022	lemna	1.47	0.8	0.015-0.0275	*
glyphosate (salts)	0.0597	skeletonema	0.34	0.057	0.175-1.05	*
Herbicide A.I.s with Potential Displacement of Preemergent Acres						
2,4-D DMA (salts)	0.087	skeletonema	0.58	0.27	0.15-0.32	○
2,4-D EHE (esters)	0.09	skeletonema	0.23	0.094	0.39-0.96	○
flumiclorac pentyl	0.95	lemna	> 0.035	NA	>2.7	○
S-metolachlor	0.054	selenastrum	0.008	0.0015	6.75-36	◑
oxyfluorfen	2.55	selenastrum	0.00029	0.0001	8793-25500	●
pyraflufen ethyl	74.14	navicula	0.0015	0.00052	49426-142577	●
rimsulfuron	2.33	lemna	0.0116	0.00009	201-25888	●
thifensulfuron methyl	2.29	lemna	0.00159	0.00051	1440-4490	●
tribenuron methyl	2.87	lemna	0.003	0.001	957-2870	●
Herbicide A.I.s with Potential Displacement of both Preemergent and Postemergent Acres						
carfentrazone ethyl	279.89	lemma	0.006	0.002	46648-139945	●
fluometuron	0.107	anabena	0.13	0.07	0.82-1.53	○
fomesafen sodium	0.021	selenastrum	0.092	0.0095	0.23-2.21	○
paraquat dichloride	0.0026	navicula	0.00055	0.00022	4.73-11.82	◑
prometryn	0.09	navicula	0.001	0.0003	90-300	◑
Pyrithiobac-sodium	0.0057	lemna	0.0009	0.00027	6.33-21.11	◑
Herbicide A.I.s with Potential Displacement of Postemergent Acres						
flumioxazin	0.0016	lemna	0.00049	0.00022	3.26-7.27	◑
MSMA	0.0498	selenastrum	5.63	< 0.3	0.009-0.17	○
pendimethalin	0.013	skeletonema	0.0052	0.0007	2.5-18.57	◑
Trifloxysulfuron-sodium	0.00068	lemna	2.50E-05	2.00E-07	27.2-3400	◑
trifluralin	18.69	navicula	0.0153	0.0046	1221-4063	●

1 Dicamba, 2,4-D salts and esters, fomesafen, and glyphosate application rates are expressed on acid equivalent basis. Paraquat is on a cation basis. All others are on an a.i. basis as stated.

2 GENEEC is a surface water model to Estimate Environmental Concentration (EEC) used by US EPA. Further information can be found at http://www.epa.gov/pesticides/science/models_pg.htm#aquatic

3 NOEC means No Effect Concentration. Entries are for the named genus with the lowest LC50 or EC50, and the corresponding NOEC level. LC50 or EC50 and NOEC hazard values from http://www.ipmcenters.org/ecotox/index.cfm . [10-Apr-2013 download]

4 Risk Quotient is defined as EEC / hazard, both expressed as ppm (mg/L). RQ Range is determined from the EC50 or LC50 and the NOEC concentration.

5 Data are for dicamba acid from EFED Chapter for the Dicamba RED. No data are available for testing of dicamba DGA salt against aquatic plants.

6 Aquatic Plant Score: A White Circle means that only the high range limit is exceeds EPA's LOC of 1.0. A Half Circle means both the RQ range limits exceed EPA's LOC of 1.0. A Black Circle means both of the RQ range limits exceed EPA's LOC by more than 100.

Note: As much as possible, LC50 or EC50 hazard values were chosen from tests with the technical a.i. to avoid using hazard endpoints that are caused by solvents, surfactants, or other formulation ingredients.

* Glufosinate and glyphosate were not included in the comparison because Monsanto will recommend their use as part of an integrated pest management system.

A.4.4.2.4. Groundwater and Leaching

Table A-53 provides information about the soil leaching potential of dicamba and the twenty-two alternative herbicide a.i.'s used in cotton. The two aspects of this evaluation are: (1) the properties of each substance indicating that it may likely move downward through the soil layers and reach groundwater; and (2) estimated groundwater concentrations.

Herbicide physico-chemical properties that are associated with downward soil mobility have been widely investigated. Persistence in soil (slow degradation) and weak soil binding are common predictors of leachability risk. The Groundwater Ubiquity Score (GUS) is an empirical index that mathematically combines these two parameters to sort chemicals into categories ranging from "extremely low" likelihood of leaching to "very high" likelihood (Gustafson 1989).[99] Table A-53 lists information about:

- Soil degradation rate (soil half-life), which quantifies the time for 50% of the initial amount to dissipate. The typical values were obtained from the IUPAC Footprint database.[100]
- Soil mobility constant with regard to organic carbon (K_{oc}), which is the equilibrium concentration ratio between soil and pore water, normalized for the organic carbon content of the soil. Typical values were obtained from the IUPAC Footprint database.[101]
- The GUS index, calculated by the published mathematical formula, using the typical soil half-life and typical K_{oc} values, along with the interpretive category.
- The maximum single application rate in both pounds per acre and in kilograms per hectare for dicamba and each alternative herbicide a.i. Potential groundwater concentrations are directly related to application rate.
- The IUPAC Footprint database provides a standard estimate of groundwater concentration using EPA's SCI-GROW model and assumes a consistent 1.0 kilogram per hectare application. Because these estimates have been calculated in the same way for dicamba and the alternative herbicide a.i.'s, they serve as a basis for comparison of leachability.
- The IUPAC Footprint SCI-GROW estimates were adjusted to reflect the proposed labeled maximum application rate in cotton by multiplication of the application rate in kilograms per hectare.
- In a dietary risk assessment, EPA assumes that a 10 kilogram child consumes 1 liter of water per day. Using this standard, the SCI-GROW-estimated groundwater concentrations due to the maximum cotton application rate were converted to the potential exposure to a child arising from drinking such groundwater, in milligrams of a.i. per kilogram of body weight per day. This calculation provides a way to compare potential groundwater concentration to toxicity thresholds. The child's water consumption was chosen over that of an adult because

[99] GUS is calculated as GUS = LOG_{10}(soil half-life)*(4-LOG_{10}(K_{oc})). The interpretation of GUS as a measure of the likelihood of leaching is as follows: < 0.1 = Extremely Low (EL); 0.1 – 1.0 = Very Low (VL); 1.1 – 2.0 = Low (L); 2.1 – 3.0 = Moderate (M); 3.1 – 4.0 = High (H); > 4.0 = Very High (VH).

[100] The Footprint database, as presented by IUPAC at http://sitem.herts.ac.uk/aeru/iupac/index.htm

[101] Values from the Footprint database were not confirmed by comparison to values in U.S. registration documents such as REDs.

children's waterborne exposure is greater than that of an adult on a body weight basis, so it represents a worst-case assessment.

- The chronic Population Adjusted Dose from Table A-50 is shown for comparison.
- The child's potential exposure to dicamba and each alternative herbicide a.i. via drinking groundwater expressed as a percentage of the cPAD.

Dicamba's SCI-GROW-estimated groundwater concentration (0.033 μg/L) is very small, particularly in relationship to dicamba's chronic toxicity reference point (cPAD). Table A-53 shows that a child's potential drinking water exposure to dicamba is calculated to be 0.0008% of the cPAD, where the cPAD is considered to be the highest safe chronic exposure level. Dicamba's estimated child exposure level is the 6^{th} lowest among the twenty-two potential alternative a.i.'s for which such a value could be calculated in this analysis; data were not available for MSMA (see below). For some alternative herbicide a.i.'s, the child's potential drinking water exposure as a percentage of the respective cPAD was calculated to be 100- to 1000-fold higher than that of dicamba.

Two criteria were evaluated to determine a Groundwater Risk Score as shown in Table A-53. The first criterion was the GUS groundwater vulnerability index, indicating whether the a.i.'s physico-chemical properties predict downward soil mobility. GUS values above 3.0 are rated as high or very high leachability potential, which was chosen as one trigger for groundwater risk. A second criterion was the percentage of the cPAD potentially experienced by a child consuming the SCI-GROW-estimated groundwater concentration of each a.i. The % exposure above 0.1% of the cPAD was chosen as a second trigger for groundwater risk. A.i.'s that met both triggers, i.e., a high or very high GUS index and exposures > 0.1% of cPAD, were scored with a Black Circle. An a.i. that met just one of these two triggers was scored with a Half Circle. Those a.i.'s that met neither trigger are indicated in Table A-53 with a White Circle.

Monsanto believes that for groundwater risk, dicamba offers a lower risk potential compared to thirteen of the alternative herbicide a.i.'s which were shown to have Black Circle or Half Circle scores.[102] The dietary exposure and groundwater contamination risk could be considered relatively greater for MSMA and fluometuron as compared to dicamba, therefore justifying their categorization as higher groundwater risk with Black Circle Groundwater Risk scores. Seven alternative herbicide a.i.'s have low Groundwater Risk Scores and are marked with White Circles.

102 As discussed in section A.4.2.2, all alternative herbicides used in soybean production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category.

Table A-53. Groundwater and Leaching Parameters for Dicamba and Alternate Active Ingredients

Active Ingredient	Typical Soil Half-life[1]	Soil Mobility Koc[1]	GUS Leaching Index3 (Interpretation) [2]	Maximum Cotton lb/acre (single treatment) [3]	Maximum Cotton kg/ha (single treatment) [3]	SCI-GROW Conc. Est. @ 1 kg/ha [1]	SCI-GROW Conc. Est. @ cotton Max Rate [4]	Child (10 kg) consumption (1L/day) [5]	cPAD mg/kg/day [6]	Child's water exposure as % cPAD [7]	Groundwater and Leaching Score [8]
	days	(calc)		lb/acre	kg/ha	µg/L	µg/L	mg/kg			
dicamba acid /DGA salt	8	13.4	2.6 (M)	1	1.1	0.0326	0.03586	3.59E-06	0.45	0.0008	○
glufosinate-ammonium	7.4	600	1.1 (L)	0.79	0.89	0.00982	0.00874	8.74E-07	0.006	0.01457	*
glyphosate (salts)	10	1435	0.9 (VL)	2	4.2	0.00535	0.02247	2.25E-06	1.75	0.00013	*
Herbicide A.I.s with Potential Displacement of Preemergent Acres											
2,4-D DMA (salts)	2.5	88.4	2.1 (M)	2	2.24	0.0248	0.05555	5.56E-06	0.005	0.1111	◑
2,4-D EHE (esters)	64		1.62			0.0248	0.05555	5.56E-06	0.005	0.1111	◑
flumiclorac pentyl	86	30	1 (EL)	0.054	0.06048	0.0025	0.00015	1.51E-08	1	1.5E-06	○
S-metolachlor	90	120	1.9 (L)	1.31	1.4672	0.051	0.07483	7.48E-06	0.1	0.00748	◑
oxyfluorfen	4	100,000	0.19 (EL)	0.5	0.56	0.00658	0.00368	3.68E-07	0.03	0.00123	◑
pyraflufen ethyl	4	1949	0.43 (EL)	0.0053	0.005936	0.0023	1.3E-05	1.35E-09	0.2	6.7E-07	○
rimsulfuron	14	50.3	3.23 (H)	0.03	0.0336	0.317	0.01065	1.07E-06	0.118	0.0009	○
thifensulfuron methyl	4	28.3	1.53 (L)	0.047	0.05264	0.00351	0.00018	1.85E-08	0.043	4.3E-05	○
tribenuron methyl	0.5	35	2.88 (M)	0.047	0.05264	0.135	0.00711	7.11E-07	0.008	0.00888	◑
Herbicide A.I.s with Potential Displacement of both Preemergent and Postemergent Acres											
carfentrazone ethyl	15	866	0.32 (EL)	0.031	0.03472	5.9E-05	2.1E-06	2.06E-10	0.03	6.9E-07	○
fluometuron	35	175	**3.9 (H)**	2	2.24	1.04	2.3296	2.33E-04	0.006	4.23564	●
fomesafen sodium	1067	50	**4.4 (VH)**	0.38	0.4256	0.408	0.17364	1.74E-05	0.003	0.69458	●
paraquat dichloride	24.3	100000	-0.6 (EL)	1	1.12	0.00535	0.00599	5.99E-07	0.005	0.01332	◑
prometryn	49	400	2.3 (M)	2.4	2.688	0.0113	0.03037	3.04E-06	0.04	0.00759	◑
Pyrithiobac-sodium	181	9	**5.4 (VH)**	0.1	0.112	5.49	0.61488	6.15E-05	0.58	0.0106	●
Herbicide A.I.s with Potential Displacement of Postemergent Acres											
flumioxazin	200	889	1.4 (L)	0.06	0.0672	0.029	0.00195	1.95E-07	0.02	0.00097	○
MSMA	41	-	2.3 (M)	1.88	2.1056	-	-	-	0.03	-	●
pendimethalin	60	17581	-0.5 (EL)	1.98	2.2176	0.00535	0.01186	1.19E-06	0.03	0.00395	◑
Trifloxysulfuron-sodium	63.5	306	**5.6 (VH)**	0.012	0.01344	0.216	0.0029	2.90E-07	0.237	0.00012	○
trifluralin	181	15800	-0.4 (EL)	2	2.24	0.00613	0.01373	1.37E-06	0.024	0.00572	◑

[1] Parameters obtained from the Footprint database, as presented by IUPAC http://sitem.herts.ac.uk/aeru/iupac/index.htm or http://pmep.cce.cornell.edu/profiles/extoxnet/index.html

[2] Gustafson DI (1989): Groundwater ubiquity score: A simple method for assessing pesticide leachability. Environ Toxicol. Chem. 8, 339–357. GUS is calculated as GUS = LOG10(soil half-life)*(4-LOG10(Koc)). The interpretation of GUS as a measure of the likelihood of leaching is as follows: < 0.1 = Extremely Low (EL); 0.1 – 1.0 = Very Low (VL); 1.1 – 2.0 = Low (L); 2.1 – 3.0 = Moderate (M); 3.1 – 4.0 = High (H); > 4.0 = Very High (VH).

[3] Maximum labeled single application rate to cotton. This rate was converted to kg/hectare (ha) units using: 1 lb = 0.454 kg and 1 acre = 0.405 ha.

[4] The Footprint database, as presented by IUPAC http://sitem.herts.ac.uk/aeru/iupac/index.htm, provides a SCI-GROW concentration estimate for groundwater based on the a.i.s chemical properties using a consistent set of assumptions, including a 1 kg/ha application. This was converted to a concentration estimate by multiplying by the maximum single cotton application rate in kg/ha.

[5] Using standard EPA assumptions for a child's water consumption and weight (1 liter per day, 10 kg body weight), the groundwater concentration estimate was converted to a daily exposure estimate.

[6] The chronic population adjusted dose (cPAD) as determined by EPA risk assessments.

[7] The child's daily exposure estimate was compared to the chronic population adjusted dose (cPAD) as determined for the a.i. by EPA, and expressed as a percentage.

[8] The Groundwater and Leaching score is determined by combining two criteria listed in Table 53. A GUS groundwater vulnerability index that is rated high (H) or very high (VH) constitutes one criterion. When the Child's water exposure is greater than 0.001 that constitutes a second criterion. When both criteria are exceeded, the a.i. is marked with a Black Circle. When only one is exceeded, the a.i. is marked with a half Circle. Exceedance of neither criterion earns a White Circle.

* Glufosinate and glyphosate were not included in the comparison because Monsanto will recommend their use as part of an integrated pest management system.

A.4.4.2.5. Summary of Human Health and Environmental Risk

Table A-54 provides a one-page summary scorecard of the specific risk reduction opportunities versus each of the alternative active ingredients. Each of the columns in Table A-54 repeats the risk scores presented in Tables A-42 through A-46. The last column in Table A-54 is a summary where the number of Half and Black circles for each a.i. is added across to determine an overall Human Health and Environmental Summary Score. In each individual risk category and in the overall human health and environmental risk, dicamba has a favorable risk comparison.

Table A-54. Summary of Comparative Analysis of Dicamba and Alternative Herbicides Used in Cotton

Active Ingredient	Human Health Risk Measures			Environmental Risk Measures			Summary
	Acute Toxicity Risk [1]	Cancer Risk [2]	Chronic Risk [2]	Aquatic Animal Risk [3]	Aquatic Plant Risk [4]	Ground Water / Leaching Risk [5]	Number of Half and Black Circles
dicamba acid /DGA salt [4]	○	○	○	○	○	○	0
glufosinate-ammonium	*	*	*	*	*	*	*
glyphosate (salts)	*	*	*	*	*	*	*
Herbicide A.I.s with Potential Displacement of Preemergent Acres							
2,4-D DMA (salts)	●	○	●	●	○	◐	4
2,4-D EHE (esters)	◐			●	○	◐	4
flumiclorac pentyl	○	○	○	●		○	2
S-metolachlor	◐	◐	○	◐	◐	○	5
oxyfluorfen	○	◐	◐	●	●	◐	6
pyraflufen ethyl	○	◐	○	●	●	○	4
rimsulfuron	○	○	○	○	●	◐	2
thifensulfuron methyl	○	○	◐	○	●	○	2
tribenuron methyl	◐	◐	●	○	●	◐	5
Herbicide A.I.s with Potential Displacement of both Preemergent and Postemergent Acres							
carfentrazone ethyl	○	○	◐	◐	●	○	4
fluometuron	○	●	●	◐	○	●	5
fomesafen sodium	◐	○	●	○	○	●	4
paraquat dichloride	●	○	●	○	◐	◐	5
prometryn	○	○	◐	◐	◐	○	4
Pyrithiobac-sodium	○	◐	○	○	◐	●	3
Herbicide A.I.s with Potential Displacement of Postemergent Acres							
flumioxazin	◐	○	◐	◐	◐	◐	6
MSMA	○	●	◐	○	○	●	3
pendimethalin	○	◐	◐	●	◐	○	5
Trifloxysulfuron-sodium	○	○	○	○	◐	◐	3
trifluralin	◐	◐	◐	●	●	○	6

[1] See Table A-49 for details.

[2] See Table A-50 for details.

[3] See Table A-51 for details.

[4] See Table A-52 for details.

[5] See Table A-53 for details.

Note: Glufosinate and glyphosate were not included in the comparison because Monsanto will recommend their use as part of an integrated pest management system.

A.4.4.2.6. Comparative Herbicide Effectiveness in Cotton

Monsanto scientists have projected that the new use of dicamba in DGT cotton will displace the use of certain currently used herbicides in cotton. This section describes some of the advantages and disadvantages of dicamba and alternate herbicides used in cotton cultivation. This analysis shows the reasons farmers would be expected to adopt the use of dicamba in their cotton cultivation practice.

To summarize the comparative herbicidal effectiveness in this analysis, Table A-55 contains a column titled "Herbicidal Efficacy" in which a White Circle means that the a.i. provides commercial level control (>85%) of at least 50% of the hard-to-control or resistant weeds. A Half Circle means that the a.i. provides commercial level control of at least 30% of the hard-to-control or resistant weeds. And a Black Circle means that the a.i. provides commercial level control on less than 30% of the hard-to-control or resistant weeds.

Table A-55 also contains a column titled "Palmer amaranth resistance to the class" in which the various herbicides are compared relative to the presence or absence of recorded resistance to Palmer amaranth and/or other Amaranthus spp. Palmer amaranth and Amaranthus spp. were selected for this comparison because of the importance of controlling glyphosate-resistant biotypes of these species in cotton from an agronomic standpoint. A White Circle indicates no resistance to any Amaranthus species in the U.S. A Half Circle indicates no resistance to Palmer amaranth but resistance to other Amaranthus species. A Black Circle indicates resistance to Palmer amaranth in the U.S.

Another important measure of herbicidal efficacy is the number of herbicide-resistant weeds to the class. Table A-55 includes a column titled "Number of resistant weeds to the class," in which a White circle indicates resistance to 10 or fewer weed species. A Half Circle indicates resistance to between 10 and 50 weed species. A Black Circle indicates resistance to greater than 50 weed species.

In addition, Table A-55 includes a column titled "Long Rotational Restrictions," in which information from label use restrictions is summarized. A White Circle indicates a waiting period of 6 months or less. A Half circle indicates a waiting period of 6 to 12 months. And A Black Circle indicates a waiting period of greater than 12 months.

Because DGT cotton is tolerant to dicamba, the use of dicamba in DGT cotton provides good crop safety. Table A-55 includes a column in which the crop injury potential is summarized. A White Circle means the a.i. does not cause significant cotton injury. A Half Circle means that the a.i. does not cause significant crop injury when applied prior to cotton emergence or with a hooded sprayer. A Black Circle means that the a.i. will cause significant cotton injury regardless of application timing. Therefore, the use of dicamba in DGT cotton will provide an additional mode-of-action for postemergent weed control with good crop safety to DGT cotton.

Table A-55 includes a "Summary" column where the number of Half and Black Circles are added across the rows to provide an overall Agronomic Risk Summary Score. A lower number of Half or Black Circles indicates a relatively lower potential agronomic risk.

Table A-55. Alternative Herbicide Agronomic Risk Measures

Active Ingredient		Agronomic Risk Measures					Summary
	Chemical Family or Class[1]	Herbicidal Efficacy [2]	Palmer amaranth resistance to the class[3]	Number of resistant weeds to the class[4]	Long Rotational Restrictions [5]	Serious Crop Injury Potential [6]	Number of Half and Black Circle Entries
dicamba acid /DGA salt[4]	Benzoic Acid	○	○	○	○	○	0
glufosinate-ammonium	Glutamine Synthetase	○	○	○	○	○	*
glyphosate (salts)	EPSP	◑	●	◑	○	○	*
Herbicide A.I.s with Potential Displacement of Preemergent Acres							
2,4-D DMA (salts)	Phenoxy	◑	◑	◑	○	●	4
2,4-D EHE (esters)	Phenoxy	◑	◑	◑	○	●	4
flumiclorac pentyl	Dicarboximide	◑	◑	○	○	○	2
S-metolachlor	Chloracetamide	◑	○	○	●	○	2
oxyfluorfen	Diphenyl-ether	◑	◑	○	◑	◑	4
pyraflufen ethyl	Phenyl pyrazole	●	◑	○	○	●	3
rimsulfuron	Sulfonyl Urea	◑	●	●	◑	●	5
thifensulfuron methyl	Sulfonyl Urea	◑	●	●	○	●	4
tribenuron methyl	Sulfonyl Urea	◑	●	●	○	●	4
Herbicide A.I.s with Potential Displacement of both Preemergent and Postemergent Acres							
carfentrazone ethyl	Triaolinone	◑	◑	○	○	◑	3
fluometuron	Urea	◑	●	●	◑	◑	5
Fomesafen sodium	Diphenyl-ether	○	◑	○	●	◑	3
paraquat dichloride	Bipyridylium	○	○	◑	○	◑	2
prometryn	Triazines	◑	●	●	●	◑	5
Pyrithiobac-sodium	Pyrimidinyl benzoates	●	●	●	◑	○	4
Herbicide A.I.s with Potential Displacement of Postemergent Acres							
flumioxazin	Phenylphthalimide	●	◑	○	○	◑	3
MSMA	Organo Arsenicals	●	○	○	○	◑	2
pendimethalin	Dinitroaniline	●	●	◑	●	○	4
Trifloxysulfuron-sodium	Sulfonylurea	●	●	●	●	○	4
trifluralin	Dinitroaniline	○	●	◑	●	○	3

1 Information from the Herbicide Resistance Action Committee (HRAC). http://www.hracglobal.com/Publications/ClassificationofHerbicideSiteofAction/tabid/222/Default.aspx

2 A White Circle means that the a.i. provides commercial level control (>85%) of at least 50% of the hard-to-control or resistant weeds, Half Circle means that the A.I provides commercial level control of at least 30% of the hard-to-control or resistant weeds, and Black Circle means the a.i. provides commercial level control on less than 30% of the hard-to-control or resistant weeds.

3 Information from http://www.weedscience.org/summary/MOASummary.asp [accessed 16-Apr-2013]. A White Circle indicates no resistance to any Amaranthus species in the US. A Half Circle indicates no resistance to *Palmer amaranth* but resistance to other Amaranthus species. A Black Circle indicates resistance to *Palmer amaranth* in US.

4 Information from http://www.weedscience.org/summary/MOASummary.asp [accessed 16-Apt-2013]. A White Circle indicates resistance to 10 or less weed species. A Half Circle indicates resistance to between 10 and 50 weed species. A Black Circle indicates resistance to greater than 50 weed species.

5 Alternate herbicides that require long waiting periods between application and subsequent planting of a crop other than cotton, information from label use restrictions. This constraint is a disadvantage to farmers. A White circle indicates a waiting period of 6 months or less, a Half circle indicates a waiting period of 6 to 12 months, and a Black circle indicates a waiting period of greater than 12 months.

6 Herbicides with potential for serious injury to cotton. White Circle means that the a.i. does not cause significant crop injury. Half Circle means that when applied prior to crop emergence or used under a hooded sprayer the a.i. does not cause significant crop Injury. Black Circle means that a.i. may cause significant crop injury regardless of application timing.

* Not evaluated

In addition to the items summarized in table A-55, the new use of dicamba in DGT cotton offers additional benefits to the cotton farmer. Dicamba provides control of over 95 annual and biennial weed species and control or suppression of over 100 perennial broadleaf and woody species. Dicamba provides more effective preemergent weed control than 2,4-D on cutleaf evening primrose, clover, and chickweed (Loux et al., 2009). Furthermore, dicamba provides excellent control compared to 2,4-D on summer annuals including those with a prostrate growth habit such as knotweed and purslane. With regard to winter annual weeds, University of Arkansas data indicated that dicamba is more effective in controlling marestail compared to 2,4-D (Arkansas, 2011).

Dicamba also provides excellent control of wild buckwheat, while 2,4-D has only limited activity and provides inadequate control (Zollinger at al.). Other preemergent or postemergent herbicides often provide incomplete control of wild buckwheat including dinitroanilines or PPO inhibitors. The most effective herbicides for buckwheat are dicamba and some sulfonylurea products. However, some of the sulfonylurea herbicides may persist and carry over for more than one growing season, especially in high pH soils.

Dicamba has been valued as more efficacious on lambsquarters than fomesafen, based on university weed control guidelines (Moeching, et al., 2010; Illinois, 2008). In addition, dicamba exhibits improved control of sicklepod, kochia, and common ragweed, and waterhemp compared to fomesafen.

Dicamba use on DGT cotton will reduce the number of applications of soil residual herbicides needed for season long control of Palmer amaranth (fomesafen, pyrithiobac, fluometuron) (Steckel, 2012; Culpepper, 2012). Multiple applications of residual herbicides are needed today because of the lack of effective postemergent options.

Dicamba use in DGT cotton will continue to support the adoption of IPM (integrated pest management) practices in cotton by allowing farmers to continue to focus primarily on postemergent, in-crop weed control, as they have practiced with glyphosate- and glufosinate-tolerant cotton, and by making current practices more effective by providing an additional mode-of-action option. This will allow farmers to delay some herbicide treatments until field scouting indicates a need for additional weed control, consistent with the principles of IPM. Dicamba, as a companion product to glyphosate and glufosinate, will also continue to foster adoption of and maintain the use of conservation tillage practices, because farmers prefer to use postemergent products, such as dicamba in DGT cotton, rather than rely on preemergent applications of soil-residual herbicides.

A.4.4.2.7. Summary of Dicamba Reduced Risk Opportunity in Cotton Production

Monsanto has requested reduced risk status for the new use of dicamba in DGT cotton based on the introduction of this trait and dicamba use pattern to the cotton weed management system that will:

- Reduce risks to human health;
- Reduce risks to non-target organisms;
- Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources; and
- Improve the management of herbicide-resistant weeds, thus overall weed management in cotton, which is critical for the long term sustainability of cotton in the U.S.

In addition, dicamba use on DGT cotton provides a favorable comparative risk profile, the reduced need to use certain higher relative risk herbicides, and improved management of herbicide-resistant weeds, and thus overall weed management and sustainability of cotton production in the United States. Dicamba will provide a valuable weed management tool for this important U.S. agricultural crop; provide additional flexibility and weed control options to cotton farmers; help to mitigate the potential for the development of resistant herbicide genotypes for all herbicide modes-of-action that are currently registered for use in cotton; and support adoption of no-till and conservational tillage practices.

Table A-56 provides a one-page summary scorecard of the specific risk reduction opportunities and the acres projected to be displaced of the alternate active ingredients. Each of the columns in Table A-49 repeat the risk scores presented in Tables A-42 to A-47, plus the agronomic risk measures shown in table A-48. The right-most column of Table A-49 presents a sum of the number of Half and Black Circle entries for each a.i. across the columns. This sum represents the overall risk score that each herbicidal a.i. achieved based on this analysis. A lower number denotes a lower potential (more favorable) risk profile. Dicamba's risk profile was more favorable than all of the alternate herbicides used in cotton.

Table A-56. Summary of Dicamba Reduced Risk Opportunities vs. Alternative Herbicides

	Human Health Risk Measures[1]			Environmental Risk Measures[1]				Agronomic Risk Measures[2]							Summary
	Acute Toxicity Risk	Cancer Risk	Chronic Risk	Aquatic Animal Risk	Aquatic Plant Risk	Ground Water / Leaching Risk	Volatility Risk	Herbicidal Efficacy	Palmer amaranth resistance to the class	Number of resistant weeds to the class	Long Rotational Restrictions	Serious Crop Injury Potential	Acres Displaced at Peak[3]	Number of Half and Black Circle Entries
dicamba acid /DGA salt	○	○	○	○	○	○	○	○	○	○	○	○	*	0
Herbicide A.I.s with Potential Displacement of Preemergent Acres														
2,4-D DMA (salts)	●	○	●	●	○	◐	○	◐	◐	◐	○	●	608,000	8
2,4-D EHE (esters)	◐			●	○	◐		◐	◐	◐	○	●		8
flumiclorac pentyl	○	○	○	●		○	●	◐	◐	○	○	○	6,000	4
S-metolachlor	◐	◐	○	◐	◐	○	◐	◐	○	○	●	○	152,000	7
oxyfluorfen	○	◐	◐	●	●	◐	●	◐	◐	○	◐	◐	31,000	10
pyraflufen ethyl	○	◐	○	●	●	○	◐	●	◐	○	○	●	18,000	7
rimsulfuron	○	○	○	○	●	◐	○	◐	●	●	◐	●	4,000	7
thifensulfuron methyl	○	○	◐	○	●	○	○	◐	●	●	○	●	31,000	6
tribenuron methyl	◐	◐	●	○	●	◐	○	◐	●	●	○	●	27,000	9
Herbicide A.I.s with Potential Displacement of both Preemergent and Postemergent Acres														
carfentrazone ethyl	○	○	◐	◐	●	○	◐	◐	◐	○	○	◐	27,000	7
fluometuron	○	●	●	◐	○	●	◐	◐	●	●	◐	◐	248,000	10
fomesafen sodium	◐	○	●	○	○	●	○	○	◐	○	●	◐	639,000	7
paraquat dichloride	●	○	●	○	◐	◐	○	○	○	◐	○	◐	534,000	7
prometryn	○	○	◐	◐	◐	○	●	◐	●	●	●	◐	449,000	9
Pyrithiobac-sodium	○	◐	○	○	◐	●	○	●	●	●	◐	○	536,000	7
Herbicide A.I.s with Potential Displacement of Postemergent Acres														
flumioxazin	◐	○	◐	◐	◐	◐	●	●	◐	○	○	◐	324,000	9
MSMA	○	●	◐	○	○	●	○	●	○	○	○	◐	213,000	5
pendimethalin	○	◐	◐	●	◐	○	◐	●	●	◐	●	○	11,000	9
Trifloxysulfuron-sodium	○	○	○	○	◐	◐	◐	●	●	●	●	○	303,000	7
trifluralin	◐	◐	◐	●	●	○	●	○	●	◐	●	○	6,000	9

[1] See Table A-54 for details.

[2] See Table A-55 for details

Note: Glufosinate and glyphosate were not included in the comparison because Monsanto will recommend their use as part of an integrated pest management system.

A Black Circle represents a relatively higher risk among the alternates considered for that general risk parameter. A Half Circle represents an intermediate risk among the alternates considered. A White Circle represents a reduced risk among the alternates considered.

A.5. SUMMARY AND CONCLUSION

Dicamba's use is expected to grow with the deregulation of DT soybean and DGT cotton. As the foregoing analysis of grower survey data shows, dicamba use will likely increase for both preplant/pre-emergence (PRE) and post-emergence (POST) in-crop applications, as measured in total acres treated and pounds of dicamba. With or without the introduction of DT soybean and DGT cotton, non-glyphosate herbicide usage is expected to increase to support the management of glyphosate-resistant weeds. If DT soybean and DGT cotton are approved for use, it is expected that glyphosate will continue to be the base herbicide applied in combination with other herbicides, including dicamba, as the central component of weed management systems. This competitive environment will combine with the introduction of other herbicide-tolerant traits in soybean and cotton crops to limit the expected increase in dicamba use.

Observable qualities of certain non-glyphosate herbicides—lower efficacy, carryover concerns, existing resistance, use restrictions, and/or crop safety—suggest a number of PRE and POST herbicides that dicamba will displace if DT soybean and DGT cotton are deregulated. Overall herbicide usage is expected to grow under any scenario; however, the growth in dicamba usage accounts for a relatively small percentage of the overall projected growth in herbicide usage in glyphosate-tolerant soybean and cotton production.

The foregoing comparative analysis of dicamba and alternative soybean and cotton herbicides reflects dicamba's favorable health and ecological risk profile relative to a some of non-glyphosate herbicides currently approved and on the market. The analysis accounted for acute health risks, chronic risks, cancer risk, risk to infants and children, and risks to aquatic animals and plants. Further, dicamba was found to be more efficacious and better at weed management than a number of currently-available herbicides.

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APPENDIX B: HERBICIDE RESISTANCE

Table of Contents

Tables and Figures

Table B-20. Dicamba Compared to Active Ingredients Contained in Alternative Herbicide Products. 582

B.1. Introduction and Background on Herbicide Resistance

B.1.1. Overview of Herbicide Resistance

Herbicide resistance is "the inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type" (WSSA 1998). In the mid-1950s, Harper (1957) theorized that annual, repeated use of any herbicide could lead to shifts in weed species composition within a crop-weed community. Similarly, Bandeen et al. (1982) suggested that a normal variability in response to herbicides exists among plant species and tolerance can increase with repeated use of a herbicide. To simplify, herbicide resistance in weeds is a result of natural selection. Plants of a given species are not all identical, but are made up of "biotypes" with various genetic traits. The use of any herbicide results in the potential for the selection of weed biotypes resistant to that herbicide, particularly when the herbicide is not used as part of a diversified weed management program. Within a weed species, individuals may possess an inherent ability to withstand the effects of a particular herbicide. Repeated use of that herbicide will expose the weed population to a "selection pressure," which may lead to an increase in the number of surviving resistant individuals in the population (HRAC 2011). Where such repeated use of a herbicide over time occurs with no other appropriate herbicide or weed management practices, the resistant biotypes have the potential to become the dominant biotype in that weed community.

As of April 2013, 400 herbicide-resistant weed biotypes have been reported to be resistant to 21 different herbicide modes-of-action worldwide (Heap 2013b). Glyphosate-resistant weeds, which occur in certain areas of the U.S., account for approximately 6% of the herbicide-resistant biotypes while weeds resistant to herbicides that inhibit acetolactate synthase (ALS) account for 32% of the herbicide-resistant biotypes. Dicamba-resistant and glufosinate-resistant weeds account for <1% and 0.5% of resistant biotypes respectively (Heap 2012d; b; 2013b).

For as long as herbicide resistance has been a known phenomenon, public-sector weed scientists, private-sector weed scientists, and growers have been identifying methods to address the problem. For instance, when a farmer uses multiple weed control tools, resistant biotypes generally will not become the dominant biotype within a population (Gunsolus 2008). By contrast, weed resistance is more likely to occur in areas where there is a sole reliance on a single herbicide used repeatedly over multiple crop generations for the management of a specific weed spectrum and where appropriate management practices are not utilized.

On agricultural land which contains a weed biotype that is resistant to a particular herbicide, the grower may use an alternate method of weed control. Management practices that can be used to retard the development of resistance include herbicide mixtures, herbicide rotation, and crop rotation. The Weed Science Society of America (WSSA) reports: "Weed scientists know that the best defense against weed resistance is to proactively use a combination of agronomic practices, including the judicious use of herbicides with alternative modes-of-action either concurrently or sequentially" (WSSA 2010). Studies have demonstrated that using the same combination of herbicides with multiple modes of action and overlapping effectiveness over multiple seasons is an effective way to proactively manage resistance (Beckie and Reboud 2009).

Due to the broad spectrum activity of glyphosate, it has been possible for growers to rely predominately on glyphosate for weed management and not utilize diversified weed management practices such as crop rotation, cultivation, or use of multiple herbicide modes of action; these practices have resulted in the selection of certain glyphosate-resistant weed biotypes.

Monsanto considers product stewardship to be a fundamental component of customer service and business practices. Stewardship of the dicamba and glyphosate herbicides to preserve their usefulness for growers is an important aspect of Monsanto's stewardship commitment. Although herbicide resistance may eventually occur in weed species when an herbicide is widely used, resistance can be postponed, contained and managed through research, education and good management practices. These are the key elements of Monsanto's approach to providing stewardship of dicamba used on DT soybean and DGT cotton integrated into the glyphosate-tolerant soybean and cotton systems. Monsanto will invest in research, and grower/retailer education and training programs to provide information on best practices to manage dicamba weed resistance in soybean and cotton production. This appendix provides an overview of Monsanto's approach to the development of best management practices to mitigate weed resistance. Monsanto works closely with weed scientists in academia and with other companies to research and develop best management practices and to uniformly communicate such practices to growers. Evidence of this cooperative effort is the recent development and posting of herbicide resistant training modules on the WSSA website (www.wssa.net) and the publication of guidelines by the Herbicide Resistance Action Committee (HRAC) on their website (www.hracglobal.com).

B.1.2. The Herbicide Dicamba

Dicamba (3,6-dichloro-2-methoxybenzoic acid) is classified as a benzoic acid herbicide belonging to the synthetic auxin group of herbicides (HRAC, 2010). The herbicides in this group act as growth regulators similar to endogenous indole acetic acid (IAA), but are structurally diverse. The synthetic auxin group includes five chemical families (benzoic acid, pyridine-carboxylic acid, quinoline carboxylic acid, phenoxy-carboxylic acid and a separate class which includes one herbicide, benazolin ethyl). In addition to dicamba, specific herbicides in this group include 2,4-D, 2,4-DB, mecoprop, MCPA, clopyralid, picloram, quinclorac and several other active ingredients. Dicamba and other synthetic auxin herbicides are classified in Herbicide Group 4 by the WSSA (HRAC, 2009). Most herbicides in this group are active on broadleaf weeds only, but a few have significant activity on grasses, *e.g.*, quinclorac. The specific site of action among the different chemistry families may be different. Dicamba provides preemergence and postemergence control of over 95 annual and biennial broadleaf weed species and control or suppression of over 100 perennial broadleaf and woody species[103]. Dicamba is not active on grass weeds and is often used in combination with other herbicides to provide broad spectrum weed control.

Dicamba was commercialized in the U.S. for agricultural use in 1967 and is currently labeled for preemergence and/or postemergence weed control in corn, soybean, cotton, sorghum, small grains (wheat, barley and oats), millet, pasture, rangeland, asparagus, sugarcane, turf, grass grown for seed, conservation reserve program land, and fallow cropland (U.S. EPA, 2009). Dicamba is sold as a standalone formulation which can be tank mixed with one or more active ingredients depending upon the crop and the weed spectrum. Dicamba is also sold as a premix formulation with other herbicides.

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[103] Clarity product label http://www.cdms.net/LDat/ld797002.pdf

Dicamba kills plants by mimicking naturally-occurring plant growth hormones called auxins, thereby destroying tissue through uncontrolled cell division and growth (Ahrens, 1994). Ahrens (1994) further states that dicamba in some cases has been found to affect cell wall integrity and nucleic acid metabolism, whereas in other cases it has been found to increase cell wall permeability, leading to cell enlargement. At low concentrations, dicamba has been found to increase synthesis of DNA, RNA, and proteins, resulting in altered cell division and growth. At high concentrations, inhibition of cell division and growth occur. In general, dicamba and other synthetic auxin herbicides have been found to affect multiple plant physiological systems. The molecular mechanism of auxin action is still not known in detail nor completely understood (Devine et al., 1993, Jugulam et al. 2011). However, Grossmann (2010), in a review of auxin herbicides, outlined a proposed mechanism and mode-of-action for auxin herbicides and IAA at supraoptimal endogenous concentrations in dicot plant species. The proposal was based upon recent identification of receptors for auxins and hormone interaction in signaling between auxin, ethylene and the upregulations of abscisic acid biosynthesis, which would account for a large part of the various auxin-herbicide-mediated responses that are seen in sensitive dicots. In addition, research has indicated that there is a high level of redundancy in auxin receptors, which may account for the lack of development of widespread resistance to this herbicide group (Walsh et al., 2006).

Dicamba is taken up by plants through the roots, stems, and foliage (Ahrens, 1994; NPIC, 2002). Dicamba translocates to all plant tissues but accumulates in growing tissues. Translocation of dicamba is typically slower in tolerant plants such as grasses as compared to broadleaf plants. Dicamba has a relatively low soil-binding coefficient.

B.1.3. The Herbicide Glufosinate

Glufosinate [2-Amino-4-(hydroxymethylphosphinyl) butanoic acid] is classified as a phosphinic acid herbicide belonging to the glutamine synthetase inhibitor group of herbicides (HRAC, 2010). Bialaphos is the only other active ingredient belonging to the phosphinic acid chemical family. Glufosinate and bialaphos are classified in Herbicide Group 10 by the WSSA (HRAC, 2010). Glufosinate provides postemergence control of over 90 annual grass and broadleaf weed species and 25 biennial and perennial grass and broadleaf weed species.

Glufosinate was first approved for use in the U.S. in 1994 (U.S. EPA, 2008) and is currently labeled for non-crop uses, preplant burndown to glufosinate-tolerant and nontolerant crops and/or in-crop postemergence weed control in glufosinate-tolerant canola, corn, cotton, and soybean, (Bayer CropScience, 2011). Glufosinate is sold as standalone formulation which can be tank mixed with one or more active ingredients depending upon the crop and the weed spectrum.

Glufosinate acts in plants by inhibiting the enzyme glutamine synthase, causing a toxic buildup of ammonia within the treated plant (Bayer, 2010). Glufosinate is a nonselective herbicide and has no residual activity. This herbicide has a different mode-of-action than the other major herbicides used in cotton.

B.1.4. Herbicide-Resistant Weeds and Resistance Management Strategies

The development of herbicide-resistant weeds is not a new phenomena and resistance is not limited to certain select herbicides. In 1957, the first U.S. herbicide-resistant weed, a spreading dayflower biotype resistant to 2,4-D, was identified in Hawaii (Heap, 2010). Currently, there are 73 individual weed species that have known herbicide-resistant biotypes to one or more herbicides in the U.S.

For example, there are 42 weed species resistant to ALS herbicides, 15 to ACCase inhibitors, 24 to photosystem II inhibitors, and 10 to glycine herbicides (Heap, 2010). Growers have been managing herbicide-resistant weeds for decades with the use of alternative herbicides and/or cultural methods such as tillage or crop rotation.

The occurrence of an herbicide-resistant weed biotype does not end the useful lifespan or preclude the effective use of the herbicide in question as part of an overall diversified weed management system. The three herbicide classes with the highest number of resistant species, ALS, ACCase and triazine herbicides, are still effectively used by growers today.

It is important to distinguish herbicide resistance from herbicide tolerance. A herbicide-resistant weed is one in which there is an inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type (WSSA, 2012). A herbicide-tolerant weed species is one that is naturally tolerant to a herbicide; for example, a grass species is not killed by the application of a broadleaf herbicide (WSSA, 2012). Furthermore, certain weed species, while neither resistant nor tolerant, are inherently difficult to control with a particular herbicide, requiring more careful herbicide use and weed management practices.

Since the first confirmed cases of herbicide resistance, research has been directed at determining which practices are best for managing existing resistance situations and how best to reduce the development of herbicide resistance. Resistant management practices most often recommended by university/Cooperative Extension Service (CES) and industry are: 1) use of multiple herbicide modes-of-action in mixture, sequence, or in rotation, 2) crop rotation, 3) use of cultural control measures such as tillage and time of planting, and 4) use of the labeled herbicide rate at the recommended timing of application (Gressel and Segel, 1990; Beckie, 2006). Recent research by Beckie and Reboud (2009) indicates that in some cases herbicide mixtures offer a better management option than rotating herbicides. Simultaneously using two herbicides with different modes-of-action significantly reduce the probability of weeds developing resistance to either or both herbicides (Beckie and Reboud, 2009). Crop rotation can also be an effective method for resistance management due to the fact that it fosters the use of additional herbicide modes-of-action and, potentially, use of additional cultural practices to manage weeds over time. The use of multiple methods of weed control in a single location is the technical basis for developing management programs to mitigate the potential for development of resistance. This general concept has been referred to as applying “diversity” within a crop or across a crop rotation (Beckie, 2006; Powles, 2008).

It is generally accepted that conservation tillage practices (minimum-till and no-till) create environments where herbicide resistance is more likely to develop (Beckie, 2006). This is probably due to selection pressure put on weeds by herbicides in these environments and the absence of tillage as a cultural weed management practice to supplement herbicide use. However, this is not always the case. Legere et al. (2000) found that an increase in the use of ACCase inhibitors in a conservation tillage system (*e.g.* aryloxyphenosy propionates and phenylpyrazolines herbicide families) did not result in an increased incidence of wild oat populations resistant to ACCase inhibitors. Thus, conservation tillage practices should not be considered a primary contributing factor to the development of resistance in all cases

B.1.5. Characteristics of Herbicides and Herbicide Use Influencing Resistance

While the incidence of weed resistance is often associated with repeated applications of an herbicide, the actual probability for the development of resistant populations is related, in part, to the specific herbicide active ingredient, chemical family and the herbicide group. Some herbicides are more prone to the development of resistance than others (Heap, 2010). The graph in Figure A-1 illustrates the global instances of weed resistance to various herbicide groups. The different slopes of observed resistance are largely due to the factors described above, which relate to the specific herbicide active ingredient as well as to the group and herbicide family and its function.

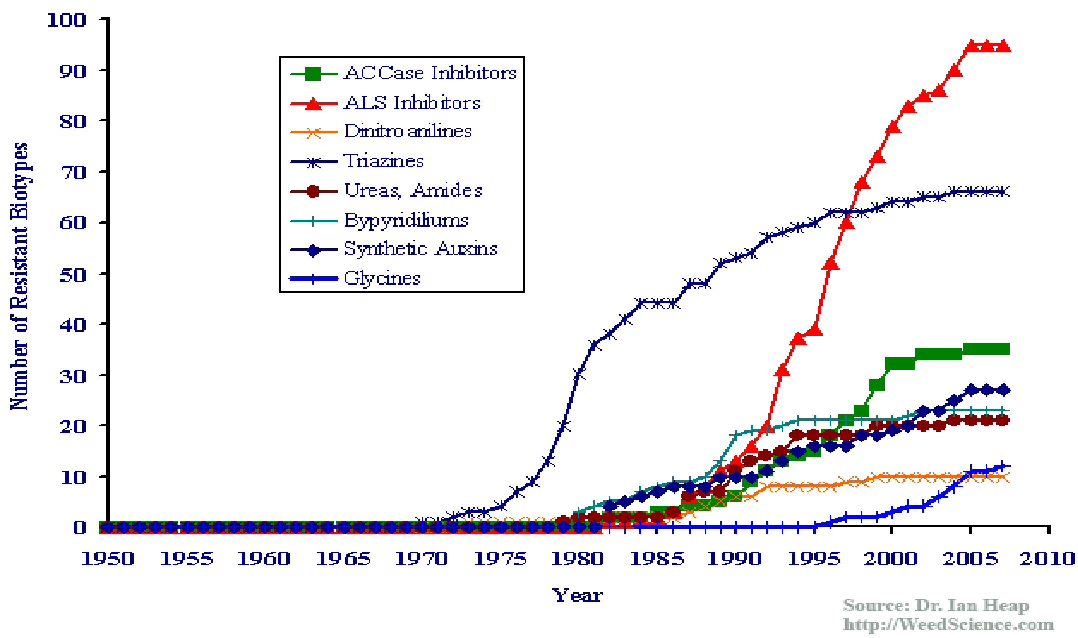

Figure B-1. Weed Resistance to Various Herbicide Families[1]

As can be seen in Figure A-1, weed resistance to the synthetic auxin group of herbicides has been slower to develop than for other herbicide groups even though these were the first synthetic herbicides discovered and used commercially. Possible reasons for this are discussed below.

[1]Global number of resistant biotypes

B.1.6. Mechanisms of Resistance and Inheritance of Resistance

To date, the three known basic mechanisms by which weed species develop resistance to a herbicide have been identified: 1) target site alteration (target site), 2) enhanced metabolism of the herbicides (metabolism), and 3) reduced absorption and/or translocation of the herbicide such that the herbicide does not get to the site of action within the plant cell (exclusion) (Sammons et al., 2007).

Herbicide resistance via target site alteration is the most common resistance mechanism among the various herbicide groups and chemical families. It has been found that a target site mechanism is the most common mechanism for ALS inhibitors, ACCase inhibitors, and triazines, but is less common for other herbicide groups, such as glycines (Powles and Yu, 2010). The most common type of target site alteration is one where amino acid substitution(s) in the protein that is the target of the herbicide occurs such that the alteration prevents the binding of the herbicide to the protein and as a result the activity of the targeted protein is not altered and the plant grows normally.

In the case of synthetic auxin herbicides, resistance has been speculated to be due to mutation(s) in genes encoding an auxin-binding protein causing reduced herbicide binding (Zheng and Hall, 2001; Goss and Dyer, 2003). In several studies, differential herbicide absorption, translocation, and metabolism were ruled out as possible mechanisms of resistance in kochia (Cranston et al., 2001) and in wild mustard (Zheng and Hall, 2001). However, current research has not presented convincing evidence for a single mechanism of resistance and this inability to elucidate the mechanism of resistance may be due to a lack of thorough understanding of auxin mechanism of activity (Jasieniuk et al., 1996). Walsh et al. (2006) identified seven alleles at two distinct genetic loci that conferred significant resistance to picolinate auxins (picloram) in *Arabidopsis*, yet had minimal cross-resistance to 2,4 D and IAA.

Multiple mechanisms for inheritance of dicamba resistance have been reported in the literature. Jasieniuk et al. (1995) reported results indicating that inheritance of dicamba resistance in wild mustard is determined by a single, completely dominant nuclear allele. However, Cranston et al. (2001) reported results indicating that dicamba resistance in kochia is determined by a quantitative trait (two or more genes).

In summary, the slow development of weed resistance to synthetic auxin herbicides may in part be due to their proposed multiple sites of physiological action in plants (Jasieniuk et al., 1996) and to the possibility that inheritance, at least in some species, is determined by a quantitative trait (Cranston et al., 2001).

B.1.7. Weeds Resistant to Dicamba and Glufosinate

To date, there are four species with known resistant biotypes to dicamba in the U.S./Canada after over 40 years of use: common hempnettle, kochia, prickly lettuce, and wild mustard (Heap, 2012a). Additionally, a population of common lambsquarters has been confirmed to be resistant in New Zealand, for a total of five species worldwide with confirmed resistant biotypes to dicamba. For the synthetic auxin group of herbicides, there exist a total of 29 species globally with biotypes having confirmed resistance to at least one member of this group, but only nine species in the U.S. and four species in Canada (Heap, 2012a). Except for two (wild carrot in OH and MI, and waterhemp in NE), all of these populations are found in western states or western Canadian provinces. In some weed species, cross-resistance between different herbicides within the auxin group has been confirmed (plant cross-resistance to another herbicide as a result of exposure to a similarly acting herbicide). Therefore, consideration has to be given to the possibility that dicamba resistance could extend to some of the other broadleaf species listed as resistant to other synthetic auxin herbicides (Cranston et al., 2001; Jasieniuk et al., 1995; Miller et al., 2001). However, because of differences in sites of action among the chemistry families within this group (i.e., benzoic acids compared to pyridine-carboxylic acids) cross-resistance between the herbicide groups is not a certainty, and it can be mitigated with diversified weed management practices (Monaco et al., 2002).

With the introduction of DT soybean and DGT cotton into glyphosate-tolerant soybean and cotton systems, where dicamba will be applied in combination with glyphosate (and glufosinate in the case of cotton), it is important to note that kochia is the only broadleaf species with resistant biotypes to either synthetic auxins or glyphosate. However, there are no known kochia biotypes resistant to both of these herbicides or resistant to glufosinate. In addition, the evolution of a dicamba-glyphosate-resistant biotype is unlikely because dicamba, glyphosate, and/or glufosinate (for DGT cotton only), each with a distinct mode-of-action, will likely be applied in the same season to DT soybean or DGT cotton in the glyphosate-tolerant soybean and cotton systems. If populations with resistance to both glyphosate and dicamba herbicides were to occur, there are other herbicide options for managing the weed in soybean and cotton (*e.g.*, glufosinate, clomazone and flumioxazin) and in its rotational crops (*e.g.*, atrazine and isoxaflutole in corn) (See Table B-10). The glyphosate-resistant kochia biotype is also found in western soybean growing areas, but it is isolated to small areas where soybean is grown in limited acreage. The glyphosate-resistant kochia biotype may be found in western cotton growing areas of Texas and Oklahoma.

To date, there are two weed species with confirmed resistance to glufosinate: goosegrass in Malaysia and Italian ryegress in Oregon, U.S. (Heap, 2012d). In the case of goosegrass, the resistant populations evolved due to use of glufosinate in a rubber plantation (Seng et al, 2010). In the case of Italian ryegrass, the resistance was actually discovered in populations exposed to glyphosate that evolved resistance to glyphosate and which had not been exposed to glufosinate, exemplifying a case of cross-resistance (Avila-Garcia and Mallory-Smith, 2011). No resistance in a broadleaf species has been found to date.

Italian ryegrass may require special consideration when designing appropriate management programs because of the potential for cross-resistance between glyphosate and glufosinate to exist. Avila-Garcia and Mallory-Smith (2011) demonstrated the only case of glufosinate cross-resistance, which developed when the populations evolved resistance to glyphosate. It is not known if the reverse is true. Where there are known glyphosate resistant ryegrass populations Monsanto will recommend not using glufosinate to control these populations. Likewise, dicamba will not be an option, since it does not control grasses such as ryegrass. Other herbicides such as those in the ACCase or ALS classes will be recommended. It is important to note that ryegrass is generally a weed target in preplant burndown applications and not in the cotton crop itself because of the biology of the species.

B.2. DT Soybean

B.2.1. Introduction

This section addresses weeds and weed management in soybean production, followed by a discussion of herbicide-resistant weeds and the benefits of DT soybean production.

B.2.2. Weeds in Soybeans

Annual weeds are perceived to be the greatest pest problem in soybean production, followed by perennial weeds (Aref and Pike 1998). Weed control in soybean is essential to optimizing yields because weeds compete with soybean for light, nutrients, and soil moisture. Weeds can also harbor insects and diseases, and can interfere with harvest, causing extra wear on harvest equipment (Pedersen 2008b).

Foxtail spp. (*Setaria spp.*), pigweed (*Amaranthus spp.*), velvetleaf (*Abutilon theophrasti*), lambsquarters (*Chenopodium album*), and cocklebur (*Xanthium strumarium*) are common weeds in Midwest corn and soybean fields. However, growers in Indiana consider giant ragweed (*Ambrosia artemisiifolia*), lambsquarters, Canada thistle (*Cirsium arvense*), cocklebur, and velvetleaf to be the top five most problematic weeds in corn and soybean because of the difficulty controlling these weeds (Nice and

Johnson, 2005). Giant and/or common ragweed are also common and problematic in Minnesota, Missouri, Arkansas, Wisconsin and Illinois (Iowa State University 2003; Boerboom 2006; Anderson 2012). In a 2005-2006 survey of 1,200 growers of glyphosate-tolerant crops (soybean, corn and cotton) in six Midwestern and southern states, growers in Illinois and Iowa, the two leading soybean-producing states, most frequently named common waterhemp (*Amaranthus tuberculatus*) as most problematic (Kruger et al., 2009). Waterhemp is also a common problem weed in Minnesota, Indiana, Nebraska, Wisconsin and Missouri (Kruger et al., 2009; ISU, 2003; Boerboom, 2006; Boerboom and Owen, 2006; Legleiter et al., 2009; Anderson, 2012). Horseweed (Conyza canadensis, also called marestail) is problematic in Ohio, Arkansas, Tennessee, Kansas, Wisconsin and Illinois (Peterson and Shoup, 2012; Boerboom, 2006; Mueller et al., 2005).

Tables B-1 through B-3 summarize the most common weeds for each of the three major soybean growing regions (Midwest, Southeast and Eastern Coastal).

Table B-1. Common Weeds in Soybean Production: Midwest Region

Foxtail spp. (12)[1]	Ragweed, giant (3)	Dandelion (1)
Pigweed spp. (11)	Shattercane (3)	Johnson grass (1)
Velvetleaf (11)	Quackgrass (3)	Milkweed, honeyvine (1)
Lambsquarters (10)	Buckwheat, wild (2)	Nightshade, hairy (1)
Cocklebur (9)	Crabgrass spp. (2)	Oats, wild (1)
Ragweed, common (7)	Kochia (2)	Pokeweed, common (1)
Smartweed spp. (6)	Mustard, wild (2)	Prickly sida (1)
Morningglory spp. (5)	Nightshade, Eastern black (2)	Proso millet, wild (1)
Sunflower, spp. (5)	Palmer pigweed (2)	Sandbur, field (1)
Waterhemp spp. (5)	Canada thistle (1)	Venice mallow (1)
Horseweed (marestail) (3)	Chickweed (1)	Volunteer cereal (1)
Panicum, fall (3)	Cupgrass, woolly (1)	Volunteer corn (1)

[1] Number provided in parenthesis is the number of states out of the thirteen total states in the Midwest region reporting each weed as a common weed.

Sources:

IL: University of Illinois (2002) and Aaron Hager, Extension Weed Specialist, University of Illinois - Personal Communication (2006).
IN: 2003-2005 Statewide Purdue Horseweed Weed Survey, Special database query and personal communication (2006), Bill Johnson, Extension Weed Specialist, Purdue University.
IA, MN, OH, WI: WSSA, 1992.
KS: Dallas Petersen, Extension Weed Specialist, Kansas State - Personal communication (2006).
KY, MO: Webster et al., 2005.
MI: Davis et al., 2005.
NE: Alex Martin, Extension Weed Specialist, University of Nebraska – Personal communication (2006).
ND: Zollinger, 2000.
SD: Michael Moechnig, Extension Weed Specialist, South Dakota State University – Personal communication (2006).

Table B-2. Common Weeds in Soybean Production: Southeast Region

Morningglory spp. (8)[1]	Goosegrass (3)	Cutleaf evening-primrose (1)
Crabgrass spp. (6)	Johnsongrass (3)	Groundcherry (1)
Prickly sida (6)	Ragweed, common (3)	Henbit (1)
Nutsedge spp. (6)	Cocklebur (2)	Lambsquarters (1)
Sicklepod (5)	Florida beggarweed (2)	Ragweed, giant (1)
Signalgrass, broadleaf (5)	Hemp sesbania (2)	Smartweed (1)
Palmer pigweed (4)	Horseweed (marestail) (2)	Spurge, nodding/hyssop (1)
Pigweed spp. (4)	Texas millet (2)	Spurge, Prostrate (1)
Barnyard grass (3)	Browntop millet (1)	Tropic croton (1)
Florida pusely (3)	Copperleaf, hophorn (1)	

[1] Number provided in parenthesis is the number of states out of the eight total states in the Southeast region reporting each weed as a common weed.
Sources:
AL, AR, GA, LA, NC, SC: Webster et al., 2009.
MS, TN: Webster et al., 2005.

Table B-3. Common Weeds in Soybean Production: Eastern Coastal Region

Foxtail spp. (6)[1]	Morningglory spp. (4)	Dandelion (1)
Ragweed, common (6)	Panicum, fall (4)	Goosegrass (1)
Velvetleaf (6)	Crabgrass spp. (3)	Johnson grass (1)
Lambsquarters (5)	Nutsedge spp. (3)	Nightshade, Eastern black (1)
Pigweed spp. (5)	Quackgrass (2)	Prickly sida (1)
Cocklebur (4)	Canada thistle (1)	Shattercane (1)
Jimson weed (4)	Burcucumber (1)	Smartweed spp. (1)

[1] Number provided in parenthesis is the number of states out of the six total states in the Eastern Coastal region reporting each weed as a common weed. Data were not available for DE in soybean.
Sources:
DE, MD, NJ, PA: WSSA, 1992.
NY: Russell Hahn, Extension Weed Specialist, Cornell University – Personal Communication (2006).
VA: Webster et al., 2009.

B.2.3. Weed Management in Soybean

The factors that affect a potential yield loss in soybean from weed competition are the weed species, weed density, and the duration of the competition. When weeds are left to compete with soybean for the entire growing season, yield losses can exceed 75% (Dalley et al. 2001). Generally, the competition between crops and weeds increases with increasing weed density. The time period that weeds compete with the soybean crop influences the level of yield loss. In general, the later the weeds emerge, the less impact the weeds will have on yield. Soybean plants withstand early-season weed competition longer than corn, and the canopy generally closes earlier in soybean than corn (i.e., plants in adjacent rows grow to a sufficient size such that their foliage touches between the rows blocking the sunlight from reaching the ground). In addition, canopy closure is much sooner when soybean is planted in narrow rows.

The most effective weed management programs in soybean use a combination of cultural, mechanical, and/or herbicide control practices, hereafter called diversified weed management practices, instead of relying on one particular method of weed control (Beckie et al. 2011; University of California 2009; Vargas et al. 1996). Herbicide application practices that are compatible with diversified weed management practices include the use of several herbicides with different modes of action, either within or across seasons, applying herbicides at the labeled rate at the correct timing, and proper application of the herbicide. Cultural and mechanical practices can also be important components of an effective diversified weed management program (Ashigh et al. 2012). Cultural practices such as crop rotation, narrow row spacing and planting date are a few of the crop management practices that are implemented to provide the crop with a competitive edge over weeds. Mechanical methods of weed control, including tillage, have been used for centuries to control weeds in crop production. Spring or fall preplant tillage and in-crop shallow cultivation can effectively reduce the competitive ability of weeds by burying the plants, disturbing or weakening their root systems, or causing sufficient physical injury to kill the plants. A consequence of in-crop cultivation for weed control is that it can injure crop roots and cause moisture loss. The planting of winter cover crops is another cultural practice that can also be utilized. The planting of cover crops, such as grasses, legumes or small grains, can protect and improve soil quality, help reduce erosion, and can serve as surface mulch in no-till cropping practices (Mannering et al, 2007). However the planting of a cover crop incurs additional costs to the grower and therefore cover crops are typically not a major weed management practice in major soybean growing areas (Singer, 2006).

The use of herbicides has become an important part of managing weeds in soybean. Approximately 98 percent of the soybean acreage received an herbicide application in 2012 (USDA-NASS, 2013a). The availability of herbicide-tolerant soybean products is an important aspect of weed management in U.S. soybean production. Herbicide-tolerant soybean was introduced to provide growers with additional options by improving crop safety (no herbicide damage to the crop) and improving weed control. In 2013, 93% of the U.S. soybean crop was herbicide-tolerant (USDA-NASS 2013e); almost all is glyphosate-tolerant. As a result, glyphosate is the most widely used herbicide, being applied on 98 percent of the soybean acreage in 2012, including for preplant burndown and postemergence in crop applications (USDA-NASS 2013a).

Over 35 different herbicide active ingredients are registered and available for use by soybean growers to control weeds. The ten most widely used alternative herbicides in soybean are listed in Table B-4. Alternative soybean herbicides use has almost doubled between 2009 and 2012. Integration of DT soybean into the glyphosate-tolerant soybean system and the subsequent use of dicamba will result in the displacement of some currently used, or foreseeable future use herbicides (see Appendix A for more details), and therefore the properties of these alternative herbicides are summarized in this section to provide a baseline for comparison to dicamba use on DT soybean.

Herbicide weed control programs in conventional soybean consist of preemergence herbicides used alone or in mixtures. Mixtures of two preemergence herbicides are used to broaden the spectrum of control to both grasses and broadleaf weed species. Preemergence herbicides are followed by postemergence applications to control weeds that emerge later in the crop. Total postemergence weed control programs were seldom used in conventional soybean prior to 1995. Prior to glyphosate-tolerant soybean, soybean planted in a no-till system would receive a preplant burndown herbicide application for broad-spectrum control of existing weeds at time of planting, followed by different soil residual herbicides at planting and possibly still other herbicides applied postemergence to the crop and the weeds. In conventional soybeans, the typical herbicide program consisted of multiple soil residual herbicides applied preemergence to the crop and weeds and, possibly, other herbicides applied postemergence to the crop and weeds. Therefore, multiple herbicides and/or multiple applications were generally used in conventional and no-till non-glyphosate-tolerant soybean. The average number of herbicide applications per acre in soybean rose from 1.5 in 1990 to 1.7 applications in 1995, reflecting the use of at-plant and postemergence applications or two postemergence applications (Gianessi et al., 2002).

Table B-4. Ten Most Widely Used Alternative Herbicides in U.S. Soybean Production in 2012

Herbicide	Treated Acres (millions)[1]	Pounds Applied
2,4-D (acid, salts, and esters,	11.58	6.02
Flumioxazin	8.49	1.56
Imazethapyr	3.86	1.35
cloransulam-methyl	3.09	0.60
chlorimuron-ethyl	8.49	0.52
Fomesafen	6.18	0.22
Clethodim	6.95	0.19
pendimethalin	1.54	0.08
Tribenuron	0.77	0.04
flumiclorac-pentyl	0.77	0.01

[1] USDA-NASS, 2013

Selective herbicides are designed to kill specific types of plants, usually grasses or broadleaf weeds, and have proven effective to reduce in-crop tillage or cultivation to control weeds in soybean production. The development of selective herbicides has progressed since the introduction of the first herbicide (2,4-D) for weed control in corn in early 1940s. Although the primary purpose of tillage is for seedbed preparation, tillage still is used to supplement weed control with selective herbicides in soybean production.

Table B-5 lists the most-widely used soybean herbicide products that contain active ingredients (a.i.s). Table B-5 also summarizes some key information about the alternative herbicide products that are evaluated in this Environmental Report, such as signal word, re-entry interval, use rates, and label warnings or special directions.

Table B-6 lists the eighteen active ingredients that make up the products in Table B-5. 2,4-D, being used primarily as a pre-plant application, is the most widely-used herbicide in this alternate herbicide list, representing about 10% of treated acres; whereas acifluorfen, carfentrazone-ethyl, and flufenacet are the least used among these, representing <0.5% of treated acres. Mesotrione has not been used in soybean production previously; the use on soybean was only recently registered by the EPA (2009d). Table B-6 also lists general regulatory information about each herbicide. Note that only paraquat is classified as a Restricted Use pesticide among this group, on the basis of acute toxicological concern.

Table B-5. Dicamba and Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word[1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Clarity (7969-137)	Dicamba	Caution	4.0 lb a.e./gal	24 hr	1.0 [1]	2.0 [1]	Known to leach; 50-foot buffer to wells; Runoff advisory; Drift advisory; State-specific limitations; Soil type limitations; Maximum crop rotation interval 3 – 6 months.
Aim® (279-3241)	Carfentrazone-ethyl	Caution	2 lb/gal	12 hr	0.008 [5]	0.023	"toxic to fish";"toxic to algae"; V3 - V10; do not feed foliage; some burn injury
Authority® First DF (279-3246)	Sulfentrazone	Caution	0.62 lb/lb	12 hr	0.31	0.31	"known to leach"; "toxic to marine / estuarine invertebrates";65-day PHI; crop rotation restrictions, up to 30 mts; soil O.M. limits (sands <1% organic matter)
	Cloransulam-methyl		0.08 lb/lb		0.04	0.04	
Authority MTZ (279-3340)	Sulfentrazone	Caution	0.18 lb/lb	12 hr	0.028	0.046	"known to leach"; "toxic to marine / estuarine invertebrates"; 120-day PHI (not Over The Top); sensitive varieties, injury possible
	Metribuzin		0.27 lb/lb		0.042	0.07	
Basagran® (7969-45)	Bentazon	Caution	4 lb/gal	48 hr	1	2	"known to leach";30-day PHI for feeding treated forage and hay; minor injury
Butoxone® 7500 (71368-49)	2,4-DB	Caution	0.75 lb/lb	48 hr	0.375		soil type limits
Butyrac® 200 (42750-38)	2,4-DB DMA salt	Danger	2 lb/gal	48 hr	0.4	0.4	"toxic to fish";60-day PHI; injury may occur, especially with tank mixtures
Cadet® (279-3338)	Fluthiacet-methyl	Warning	0.91 lb/gal	12 hr	0.0065	0.009	do not feed foliage; minor injury
Callisto® (100-1131)	Mesotrione	Caution	4 lb/gal	12 hr	0.1875	0.1875	"high potential for runoff"; crop rotation restrictions up to 18 mts; "transient bleaching" may occur; pre-emergence use only, no in crop use

Table B-5 (continued). Dicamba and Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word[1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Classic® (352-436)	Chlorimuron-ethyl	Caution	0.75 lb/lb	12 hr	0.14	0.14 [6]	60-day PHI; crop rotation restrictions up to 30 mts and complicated description of 3 different intervals specific to US regions and soil pH; do not feed foliage; soil type limits; "temporary leaf yellowing"
Cobra® (59369-34)	Lactofen	Danger	2 lb/gal	12 hr	0.2	0.4 [6]	"toxic to fish"; do not apply past soybean growth stage R6/45-day PHI; minor injury
Extreme ® (241-405)	Imazethapyr	Warning	0.17 lb/gal	48 hr	0.064 [6]	0.064 [6]	"properties & characteristics associated with chemicals detected in ground water"; crop rotation limits
	Glyphosate-IPA		2 lb/gal		0.75	0.75	
FirstRate (62719-275)	Cloransulam-methyl	Caution	0.84 lb/lb	12 hr	0.04	0.055	65-day PHI; crop rotation restrictions up to 30 mts; soil types; 14-day forage and hay feeding restriction
Flexstar ® (100-1101)	Fomesafen	Warning	1.88 lb/gal	24 hr	0.35	0.375 [6]	"cause tumors"; "known to leach"; 45-day PHI; do not feed foliage; crop rotation limits
Gangster ® Co-pack (59639-131)	Flumioxazin	Caution	51%	12 hr	0.096	0.096	"toxic to aquatic invertebrates"; "Preemergent only"; "properties & characteristics Associated with chemicals detected in ground water"; "toxic to invertebrates."
	Cloransulam-methyl		84%		0.032	0.032	
Gramaoxone Inteon ® (100-1217)	Paraquat dichloride	Danger	2 lb/gal (cation basis)	12 hr	1.5	2.9	"toxic to wildlife"; Restricted Use; no Over-the-Top use

Table B-5 (continued). Dicamba and Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word[1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Ignite® (264-829)	Glufosinate-ammonium	Warning	2.34 lb/gal	12 hr	0.66	0.8	"runoff potential"; "toxic to vascular plants"; 70-day PHI; some crop rotation limits up to 180 days; only Over-the-Top to Liberty Link soybean
Liberty® (264-660)	Glufosinate-ammonium	Warning	1.67 lb/gal	12 hr	0.44	0.8	"runoff potential"; "toxic to vascular plants"; 70-day PHI; do not feed foliage; crop rotation limits up to 120 days;
Phoenix® (59639-118)	Lactofen	Caution	2 lb/gal	12 hr	0.3	0.4 [6]	"toxic to fish"; Do not apply past crop growth stage R6 / 45-day PHI; minor injury
Pursuit® (241-310)	Imazethapyr	Caution	2 lb/gal	4 hr	0.063	0.063	"properties & characteristics associated with chemicals detected in ground water"; 85-day PHI; do not feed forage and hay
Pursuit® Plus (241-331)	Pendimethalin Imazethapyr	Caution	2.7 lb/gal 0.2 lb/gal	24 hr	0.84 0.063	0.84 0.063	"properties & characteristics associated with chemicals detected in ground water"; "toxic to fish"; 85-day PHI; crop rotation limits up to 40 months
Raptor ® (241-379)	Imazamox-ammonium	Caution	1 lb/gal	4 hr	0.04	0.04	"phytotoxic to all plants"; plantback / crop rotation limits up to 26 months, two regions with complicated warnings

Table B-5 (continued). Dicamba and Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word [1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Reflex® (100-993)	Fomesafen	Danger	2 lb/gal	24 hr	0.375	0.375 [6]	"known to leach"; 45-day PHI; crop rotation limits up to 18 mts; minor injury, significant geographical restrictions (5 regions each with different rate structure)
Resource® (59639-82)	Flumiclorac-pentyl	Warning	0.86 lb/gal	12 hr	0.081	0.11	"toxic to shrimp"; 60-day PHI; do not feed forage or hay to livestock; temporary spotting or burn to soybean
Scepter ®70 DG (241-306)	Imazaquin	Caution	0.7 lb/lb	12 hr	0.123	0.123 [6]	"properties & characteristics associated with chemicals detected in ground water"; 90-day PHI; do not feed forage or hay to livestock; crop rotation limits up to 40 mts; regional limitations (3 regions)
Sencor® (DF 75%) (264-738)	Metribuzin	Caution	0.75lb/lb	12 hr	0.66 [6]	1.3 [6]	"can seep or leach"; 70-day grain PHI; 40-day PHI on feeding forage to livestock; no Over-the-Top application, directed spray OK; injury in high pH or low O.M. soils or on certain crop varieties, crop rotation limits up to 18 mts
Synchrony® XP (352-648)	Thifensulfuron	Caution	0.069 lb/lb	12 hr	0.013	0.013	45-day planting restriction applied prior to soybean planting/emergence; 60-day PHI; complicated crop rotation restrictions (3 regions, 4 intervals) with limits up to 30 mts; do not feed forage or hay to livestock; soil types; injury if adjuvants or tank mixed
UltraBlazer (70506-60)	Acifluorfen sodium Chlorimuron-ethyl	Danger	2 lb/gal 0.215 lb/lb	48 hr	0.374 0.04	0.5 0.04	50-day PHI; minor injury

Table B-5 (continued). Dicamba and Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word [1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Valor® SX (59639-99)	Flumioxazin	Caution	0.51 lb/lb	12 hr	0.096	0.096	"runoff potential"; "toxic to aquatic invertebrates"; preemergence use only, no in crop use; do not feed forage or hay to livestock; crop rotation limit up to 18 mts. & soil type limits; injury under cool wet conditions or poorly drained soil; restrictions on use with flufenacet, alachlor, metolachlor, or dimenthenamid
Valor® XLT (59639-117)	Flumioxazin	Caution	0.3 lb/lb	12 hr	0.094	0.094	"toxic to aquatic invertebrates"; preemergence only, no in crop use; do not feed forage or hay to livestock; crop rotation limits up to 30 mts; injury under cool wet conditions or poorly drained soil
	Chlorimuron-ethyl		0.103 lb/lb		0.032	0.032	
Weedone® (650, 638, LV4, LV6) and other 2,4-D brands (71368-3, -6, -10, -11, -14, -19)	2,4-D; 2,4-D salts; 2,4-D esters	Varies	Varies		0.93	0.93	Weedone 650 as an example: "toxic to aquatic invertebrates"; do not use on sandy soils (<1% O. M.); preplant to emerged weeds only, no in crop use; do not feed forage or hay to livestock

1 The EPA-required statement to convey to applicators the overall acute toxicity hazard posed by the product. Caution is more favorable than Warning, which is more favorable than Danger.
2 The period of time following application during which worker reentry into the treated area is restricted, according to EPA's Worker Protection Standard (WPS).
3 The highest single-treatment and seasonal rates that can be applied to soybean according to the product Directions for Use label.
4 Lists specific statements extracted from the product label that represent specific hazards or limitations that may reduce the utility of the product for soybean weed control
5 Higher rates with directed / hooded sprayers.
6 Regional or soil type limitations may lower this rate.
7 Soybean label not yet publically available. Corn label comments are cited
PHI – preharvest interval, O. M. – organic matter, mts - months.

Table B-6. Dicamba Compared to Active Ingredients Contained in Alternative Herbicide Products

Active Ingredient	First Registered[1]	2006 Treated Soybean Acreage (%)[2]	Registration Review Status[3]	RED Date[4]	Max. Soybean lb/a (single treatment)[5]	Max. Soybean lb/a (season)	Tolerances (40 CFR 180)[6]	Restricted Use[7]
glyphosate salts	3-May-76	97	open 2009	Sep-93	1.5	6	364	No
dicamba-diglycolamine salt	2-Feb-56	<0.5	NA	Jun-09, corrected	1[9]	2[9]	227	No
2,4-D acid, salts, and esters	3-Jun-52	10	2013	Jun-05	0.93	0.93	142	No
flumioxazin	12-Apr-2001	3	unscheduled	NA	0.096	0.096	568	No
imazethapyr	30-Jan-87	3	2014	Jun-06	0.064[8]	0.064[8]	447	No
cloransulam-methyl	29-Oct-1997	1	2011	NA	0.04	0.055	514	No
chlorimuron-ethyl	4-Apr-86	4	2011	Sep-04 TRED	0.14	0.14[8]	429	No
fomesafen	10-Apr-87	2	open 2007	TRED Aug-07	0.375	0.375[8]	433	No
flumiclorac-pentyl	23-Mar-94	1	open 2009	Aug-05 TRED	0.081	0.11	477	No
sulfentrazone	22-Nov-93	1	open 2009	NA	0.31	0.31	498	No
thifensulfuron	25-Apr-86	1	2011	NA	0.013	0.013	439	No
imazaquin	20-Mar-86	1	2014	TRED Dec-05	0.123	0.123[8]	426	No
imazamox-ammonium	17-Apr-95	<0.5	2014	NA	0.04	0.04	1223	No
paraquat dichloride	8-Jan-80	1	2012	Aug-97	1.0	2.9	205	**Yes**
lactofen	1-Apr-87	<0.5	open 2007	TRED Sep-03	0.3	0.4	432	No
glufosinate-ammonium	29-May-91	<0.5	open 2008	NA	0.66	0.8	473	No
2,4-DB	30-Jun-66	<0.5	2014	Jan-05	0.4	0.4	331	No
fluthiacet-methyl	14-Apr-99	<0.5	unknown	NA	0.0065	0.009	551	No
acifluorfen sodium	29-May-81	<0.5	unscheduled	Sep-09	0.374	0.5	383	No
Mesotrione	4-Jun-01	0.0	unscheduled	NA	0.1875	0.1875	571	No

TRED denotes Tolerance Reregistration Eligibility Decision

1. The date the herbicide was first approved for any use (*e.g.*, industrial) by U.S. EPA.
2. The percentage of the herbicide-treated soybean acres that were treated with each herbicide in AR, IA, IL, IN, KS, KY, LA, MI, MN, MS, MO, NE, NC, ND, OH, SD, TN, VA, and WI in 2006 (USDA-NASS, 2007b) .
3. The herbicide's progress in the ongoing EPA program named as Registration Review. Year indicates when the official docket was or will be opened. EPA is required by law to re-evaluate pesticides periodically, generally every 10-15 years.
4. The date when EPA issued a Reregistration Eligibility Decision document. Reregistration was an earlier re-evaluation program designed to ensure that supporting data are up-to-date for a.i.s first registered before 1984. TRED means Tolerance Reassessment Eligibility Decision, which refers to an alternative review path that some post-1984 a.i.s followed.
5. The maximum amount of the herbicide that can be applied to soybean in a single treatment or during the entire season, according to product labels.
6. The number of the paragraph in the Code of Federal Regulations where that herbicide's food and feed tolerances are listed.
7. An EPA pesticide classification that restricts a product, or its uses, to use by a certificated pesticide applicator or under the direct supervision of a certified applicator. See 40 CFR 152.160.
8. Regional or soil type limitations may lower this rate.
9. Maximum treatment rates for the proposed dicamba label.

B.2.4. Herbicide-resistant Weeds in Soybean Production

The emergence and growth of herbicide-resistant weeds (including glyphosate-resistant weed biotypes) in certain areas of the U.S. over the past decade has required growers to adapt and implement improved weed management strategies. Glyphosate-resistant weed biotypes that can be found in soybean fields include Palmer pigweed (*Amaranthus palmeri*), spiny pigweed (*Amaranthus spinosus*), tall waterhemp (*Amaranthus tuberculatus*), common ragweed (*Ambrosia artemisiifolia*), giant ragweed (*Ambrosia trifida*), horseweed (*Conyza canadensis*), kochia (*Kochia scoparia*), goosegrass (*Eleusine indica*), Italian ryegrass (*Lolium multifloru*), and Johnsongrass (*Sorghum halepe*) (Heap, 2011, 2013).

Tables B-7 and B-8 summarize known resistance among the major weed species present in certain soybean-growing regions of the U.S. within each of the key soybean herbicide groups and herbicide classes active on broadleaf weeds (Heap, 2011). In certain areas of the U.S., resistance to the ALS group of herbicides is present in most of the major broadleaf weed species commonly found in soybeans. For common ragweed and waterhemp, there is known resistance to at least one member for several of the major soybean herbicide chemistry classes. While there are effective options for managing common ragweed, waterhemp, Palmer pigweed and other key broadleaf weeds, the availability of additional herbicide modes-of-action will help combat future resistance in soybeans and manage existing herbicide-resistant weed populations in areas of the U.S. where such populations exist. Similarly, there has been an increase in the detection of weed populations with multiple resistance (i.e., resistance to multiple herbicide modes-of-action) in some weed species, for example, *Amaranthus* spp. (Tranel et al 2010). The emergence of these resistant biotypes in certain areas of the U.S. and continued need to utilize diversified weed management practices supports the need for additional herbicide modes-of-action in major crops such as soybean.

The relative occurrence of herbicide-resistant weeds varies between the different sub-groups of auxinic (phenoxy in B-7 and B-8) herbicides. Considering that auxin herbicides have been widely used in agriculture for more than 60 years, weed resistance to this class is relatively low (29 species, to date, worldwide) and its development has been slow, especially when compared to the speed of appearance of resistance to ALS inhibitors (107 species) or triazine-resistant populations (68 species) (Heap 2012b). The relatively low incidence of auxinic herbicide resistance is believed to be attributable to the fact that there are multiple target sites for these herbicides (Gressel and Segel 1982; Morrison and Devine 1993).

Monsanto scientists and academics recommend the use of multiple herbicide modes-of-action in the glyphosate-tolerant soybean system regardless of whether glyphosate-resistant or hard-to-control broadleaf weeds are present. Monsanto specifically recommends the use of a soil residual as part of the weed management system. Growers may also choose to switch to other weed management systems in their soybean fields. APHIS has approved other herbicide-tolerant soybean including phosphinothricin-tolerant, ALS-tolerant, and HPPD-tolerant soybean events (Table B-9). For growers who choose to use the glyphosate-tolerant soybean system, Monsanto and university extension agents provide recommended control options for glyphosate-resistant weeds. These options include the use of residual and postemergent herbicides such as synthetic auxins (2,4-D), ACCase inhibitors (clethodim, sethoxydim), PPO inhibitors (lactofen, fomesafen), and ALS inhibitors (cloransulam). These herbicides alone or combinations of these herbicides as well as traditional tillage methods are and will continue to be used to control glyphosate-resistant or hard-to-control broadleaf weeds.

Table B-7. Known Weed Resistance in the Southern U.S.[1]

Most Common Broadleaf Weeds (# states where listed as a top weed)	Resistance Group [2]	ALS (Group 2)			PPO (Group 14)		PS II (Group 5)	Glycine (Group 9)	Phenoxy (Group 4)	
	Chemistry Class [2]	Sulfonyl Urea	Imidazolinones	Triazoles	Diphenyl ether	N-phenyl thalimide	Triazinones	-	Phenoxy	Benzoic acid
	Example	chlorimuron	imazapyr	chloransulam	lactofen fomesafen	flumioxazin	metribuzin	glyphosate	2,4 D	dicamba
Morning glory (5)										
Sida (prickly sida (5)			X							
Sicklepod (4)										
Hemp sesbania (3)										
Pigweed spp.[3] (3)		X	X	X	X		X	X	X	
Palmer pigweed (2)		X	X	X				X		
Cocklebur (1)		X	X	X						
Horseweed (marestail) (1)		X		X				X		

1 Source: www.weedscience.org
2 Cross resistance is possible within a resistance group and/or chemistry class, but cross resistance can be mitigated with diversified weed management practices.
3 Includes redroot pigweed, common waterhemp, spiny amaranth, and smooth pigweed

Table B-8. Known Weed Resistance in the Midwest U.S. [1]

Most Common Broadleaf Weeds (# states where listed as a top weed)	Resistance Group [2]	ALS (Group 2)			PPO (Group 14)		PS II (Group 5)	Glycine (Group 9)		Phenoxy (Group 4)
	Chemistry Class [2]	Sulfonyl Urea	Imidazolinones	Triazoles	Diphenyl ether	N-phenyl thalimide	Triazinones	-	Phenoxy	Benzoic acid
	Example	chlorimuron	imazapyr	chloransulam	lactofen fomesafen	flumioxazin	metribuzin	glyphosate	2,4 D	dicamba
Pigweed spp. [3] (12)		X	X	X	X		X			
Velvetleaf (11)										
Lambsquarters (10)		X	X				X			
Cocklebur (9)		X	X	X						
Common ragweed (7)		X	X	X	X	X		X		
Smartweed spp. (6)										
Morning glory (5)										
Waterhemp (5)		X	X	X	X			X	X	
Horesweed (marestail) (3)		X		X				X		
Giant ragweed (3)		X	X	X				X		
Kochia (2)		X	X					X		X

1 Source: www.weedscience.org
2 Cross resistance is possible within a resistance group and/or chemistry class, but cross resistance can be mitigated with diversified weed management practices.
3 Includes redroot pigweed and smooth pigweed

Table B-9. Deregulated Biotechnology-derived Soybean Products[1]

Phenotype	Event	Institution	Date Deregulated
Herbicide-tolerant (Glyphosate/Isoxaflutole)	FG72	Bayer Crop Sciences	August, 2013
Omega 3 Fatty Acid	MON 87769	Monsanto	July, 2013
High Oleic Acid, Low Saturated Fat	MON 87705	Monsanto	December, 2011
Lepidopteran Resistant	MON 87701	Monsanto	June, 2011
High Oleic Acid	DP-3Ø5423-1	Pioneer	June, 2010
Glyphosate- and ALS-	DP-356043-5	Pioneer	July, 2008
Glyphosate-tolerant	MON 89788	Monsanto	February, 2007
Phosphinothricin-tolerant	GU262	AgrEvo	October, 1998
Phosphinothricin-tolerant	A5547-127	AgrEvo	May, 1998
Altered Oil Profile	G94-1, G94-19, G-168	DuPont	May, 1997
Phosphinothricin-tolerant	W62, W98, A2704-12, A2704-21, A5547-35	AgrEvo	August, 1996
Glyphosate-tolerant	40-3-2	Monsanto	May, 1994

[1] USDA-APHIS 2013

B.2.4.1. Sustainable Use of Dicamba as a Weed Management Option in Soybean

Dicamba is a broadleaf herbicide that does not provide control of grass weeds. For that reason, DT soybean will be sold only in soybean varieties that also contain other herbicide-tolerant traits, such as with the glyphosate-tolerant soybean system (*e.g.*, MON 89788). Soybean varieties containing both DT soybean and MON 89788 will enable dicamba to be applied with glyphosate or other soybean herbicides in an diversified weed management program, ideally as a mixture, to control a broad spectrum of grass and broadleaf weed species. Dicamba applications on DT soybean will provide effective control of glyphosate-resistant broadleaf weeds and improve the control of annual and perennial broadleaf weed species, some of which are difficult to control with glyphosate. Dicamba will also help mitigate the potential for development of and/or combat existing weed resistance issues that can limit the use of the PPO- and ALS-inhibiting herbicide groups by providing an additional mode-of-action for management of certain broadleaf species that are known to be prone to resistance to many of the current options for weed management (i.e. *Amaranthus* spp.). DT soybean will foster the adoption of Integrated Pest Management (IPM) practices in soybeans by allowing growers to continue to focus primarily on postemergence in-crop weed control, as they have practiced with the glyphosate-tolerant soybean system. This will allow growers to delay some herbicide treatments until field scouting indicates a need for additional postemergence weed control, which is consistent with the principles of IPM. Increasing postemergence herbicide options in soybeans is important, especially in conservation tillage situations, where consistency of postemergence herbicides has generally been greater than that of soil active residual products and thus a driving factor in the adoption of conservation tillage systems in the U.S.

Upon the inclusion and integration of DT soybean into the glyphosate-tolerant soybean system and approval of the use of dicamba on DT soybean[104], preplant/preemergence applications of dicamba can be made up to 1.0 lb a.e./A up through crop emergence (cracking) followed by two in-crop postemergence applications up to 0.5 lb a.e./A through the R1/R2 growth stage in soybean. However, the majority of weed control scenarios in DT soybean will not require the use of the proposed maximum labeled rate, and the anticipated commercial pre-plant/preemergence and in-crop use rates are between 0.25 to 0.38 lb a.e./A (based on established weed control rates for soybean weeds), with an average application rate of 0.38 lb a.e./A as described in Section VIII.H of the DT soybean Petition for Deregulation). Residual herbicides also will be recommended for use, in addition to glyphosate and dicamba, to provide early season weed control and to supplement dicamba activity on certain hard-to-control and glyphosate-resistant weed biotypes, such as glyphosate-resistant Palmer Amaranth, where weed populations can be very substantial.

Dicamba, as a complementary herbicide to glyphosate, will provide new weed control options in soybean that strengthen the utility and sustainability of glyphosate as a weed control tool in the glyphosate-tolerant soybean system. Likewise, glyphosate, as a complementary herbicide to dicamba, would strengthen the utility and sustainability of dicamba as a weed control tool for DT soybean to be integrated into the glyphosate-tolerant soybean system.

In the event that there is known or suspected presence of a dicamba-resistant weed, it will be possible to provide the affected grower(s) with options for managing the dicamba-resistant biotype. There are multiple preemergence (including soil residuals) and postemergent herbicide options for managing broadleaf weed populations that are resistant or may potentially develop resistance to dicamba in soybean, as well as for crops grown in rotation with soybean. These options are noted in Table B-10.

[104] Monsanto has submitted to EPA an application to amend Registration Number 524-582 to register a new use pattern for dicamba on DT soybean.

Table B-10. Management Recommendations for Control of Dicamba- and Other Synthetic Auxin-Resistant Weeds

		Rotational Crops / Other Uses			
Weed Species	Primary Crop Soybean	Corn	Wheat	Pastures/Roadsides	Rice
Kochia (***Kochia scoparia***)	Saflufenacil[a] Clomazone[a] Flumioxazin[a] Glyphosate[a] Paraquat[a]	Atrazine[a] Saflufenacil[a] Isoxaflutole[a] Mesotrione[a] Glyphosate[a]	Saflufenacil[a] Glyphosate[a] Bromoxynil/MCPA[a]		
Prickly Lettuce (***Lactuca serriola***)	Saflufenacil[a] Chlorimuron/metribuzin[a] Glyphosate + imazethapyr[a]	Saflufenacil[a] Atrazine[a] Carfentrazone + atrazine[a] Isoxaflutole + atrazine[a]	Saflufenacil[a] Triasulfuron[a] Metsulfuron + thifensulfuron[a]		
Wild Carrot (***Daucus carota***)	Glyphosate[c] Chlorimuron[c] Chlorimuron/metribuzin[c]	Glyphosate[c] Atrazine[c] Primisulfuron[c] Nicosulfuron[d] Halosulfuron[d]			
Field Bindweed (***Convolvulus arvensis***)	Glyphosate[a]	Glyphosate[a] Glyphosate + imazethapyr[a] Glyphosate + Imazamox[a]	Glyphosate[a]		

Table B-10 (continued). Management Recommendations for Control of Dicamba- and Other Synthetic Auxin- Resistant Weeds

Weed	Primary Crop Soybean	Rotational Crops / Other Uses Corn	Wheat	Pastures/Roadsides	Rice
Yellow Starthistle (*Centaurea solstitialis*)				Chlorsulfuron Aminopyralid[e]	
Spreading Dayflower (*Commelina diffusa*)					Bentazon halosulfuron penoxsulam bispyribac[f]
Lambsquarters (*Chenopodium album*)[g]	Metribuzin[b] Cloransulam[b] Saflufenacil[a] Imazamox[b] Glyphosate[b]	Isoxaflutole[a] Atrazine[a] Saflufenacil[a] Mesotrione[a] Bromoxynil[b]	Bromoxynil[a] Chlorsulfuron/Metsulfuron[a] Glyphosate[a] Saflufenacil[a]		
Waterhemp (*Amaranthus tuberculatus*)[h]	Saflufenacil[i] Flumioxazin[i] Sulfentrazone[i] Fomesafen[i] Metolachlor[i]	Metolachlor[i] Atrazine[i] Saflufenacil[i] Mesotrione[i] Carfentrazone[i]	Mesulfuron[j] Triasulfuron[j] Prosulfuron[j] Fluroxypry/bromoxynil[j]		

[a]Bernards et al., 2010.
[b]Loux et al., 2010.
[c]Michigan State University Extension, 2010.
[d]Kells and Stachler, 1997.
[e]PNWE, 2010.
[f]University of Arkansas CES, 2010.
[g]Resistance to lambsquarters has only been confirmed in New Zealand.
[h]Bernards et al., 2012
[i]Loux et al., 2013
[j]University of Nebraska, 2013

B.2.4.2. Stewardship of Dicamba Use on DT soybean

In order to steward the use of agricultural herbicides and herbicide-tolerant cropping systems such as DT soybean integrated into the glyphosate-tolerant soybean, Monsanto has conducted investigations and worked extensively with academics and other herbicide manufacturers to understand and recommend best practices to manage herbicide resistance. These investigations have demonstrated that one of the major factors contributing to the development of resistant weed biotypes in certain areas of the U.S. has been inadequate weed control management practices. The lack of adequate management includes: 1) application of herbicides at rates below those indicated on the product label for the weed species, and 2) sole reliance on a particular herbicide for weed control without the use of other herbicides or cultural control methods (Beckie, 2006; Peterson et al., 2007).

B.2.4.3. Weed Control Recommendations

The proposed label for dicamba use on DT soybean – which is currently pending before EPA - is based on the maximum allowable use rates and patterns. Prior to launch of DT soybean in the glyphosate-tolerant soybean system, Monsanto, in cooperation with academics, will conduct trials to confirm the optimum rate and timing for dicamba alone and in combination with glyphosate and other herbicides for particular weed species. Recommendations to growers will be developed from this information and will be provided in herbicide product labels, Monsanto's Technology Use Guide (TUG), and in other education and training materials to be broadly distributed. Specifically, current research conducted by Monsanto to define the optimum weed management systems indicate the following: 1) in the absence of glyphosate-resistant populations, the recommendation will be to apply a soil active residual herbicide followed by a postemergence application of glyphosate plus dicamba to control weed escapes, and 2) in the presence of glyphosate-resistant populations, the same system will be recommended with a potential second application of glyphosate plus dicamba if needed. In this latter case, the preemergence herbicide to be recommended will be one with activity against the targeted glyphosate-resistant species. This will ensure more than one mechanism of action against the targeted species, which is a fundamental component of a good weed resistance management program. These management systems will reduce the potential for further resistance development to glyphosate, or to dicamba or other critical soybean herbicides. In conservation tillage systems, a preplant application of glyphosate plus dicamba may be recommended in some situations in addition to the in-crop applications described above. This is not expected to increase selection pressure on either product since the preplant weed spectrum is generally different from the in-crop spectrum.

B.2.4.4. Dispersal of Technical and Stewardship Information

To support the introduction of varieties containing DT soybean, Monsanto will use multiple methods to distribute technical and stewardship information to growers, academics and grower advisors regarding the use of the product as part of a diversified weed management system. Growers who purchase Monsanto varieties containing DT soybean sign a limited use license known as the Monsanto Technology Stewardship Agreement (MTSA). The MTSA obligates growers to comply with certain requirements, including the Monsanto Technology Use Guide (TUG). The TUG will set forth the requirements and best practices for the cultivation of DT soybean including recommendations on weed resistance management practices.

The weed resistance management practices that will be articulated in the TUG will also be broadly communicated to growers and retailers in order to minimize the potential for the development of resistant weeds. These practices will be communicated through a variety of means, including direct mailings to each grower purchasing a soybean variety containing DT soybean, a public website[105], and reports in farm media publications. The overall weed resistance management program will be reinforced through collaborations with U.S. academics who will provide their recommendations for appropriate stewardship of dicamba in soybean production, as well as by collaboration with crop commodity groups who have launched web-based weed resistance educational modules. Finally, Monsanto will urge growers to report any incidence of repeated non-performance of dicamba on weeds in fields planted with DT soybean, and Monsanto will investigate cases of unsatisfactory weed control to determine the cause as discussed below in Section B.2.4.6.

The EPA is the U.S. federal regulatory agency that administers the federal law governing pesticide sale and use under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). EPA regulates under FIFRA the pesticides (including herbicides) that are used with crops, including GE herbicide-tolerant crops like DT soybean and DGT cotton. FIFRA requires all pesticides to be registered before distribution or sale, unless they are exempted. Under FIFRA, EPA must approve each distinct pesticide product, each distinct use pattern, and each distinct use site. Each crop for example, consititues a unique use site and no registered pesticide may be applied to any crop unless EPA has approved that specific pesticide/crop use.

In addition each pesticide must be labeled with enforceable directions for use on a crop by crop basis. It is a violation of FIFRA to use any registered pesticide in a manner inconsistent with its labeling, subject to criminal and civil penalty. [1] For that reason, an approved herbicide cannot be lawfully used on a corresponding herbicide-tolerant crop, unless EPA approves a label amendment for such use.

EPA encourages pesticide manufacturers to provide growers with information regarding an herbicide's mode-of-action to aid growers in planning herbicide use practices and to foster the adoption of effective weed resistance management practices as specified by EPA in Pesticide Registration (PR) Notice 2001-5 (U.S. EPA, 2001). In that document EPA states that "this approach to resistance management is sound and would be highly beneficial to pesticide manufacturers and pesticide users." EPA approves all pesticide label use instructions based on its evaluation of supporting data supplied by the pesticide registrant or manufacturer. By approving a label, EPA has concluded that the product will not cause unreasonable adverse effects to the environment when used in accordance with the label's directions. After EPA approves a pesticide label, it is a violation of federal law to use the pesticide for a use or in a manner not in accordance with the label directions. Monsanto incorporates EPA's guidelines for pesticide resistance management labeling on its agricultural herbicide labels, and will continue to do so in the future. Monsanto will adopt a similar approach to pesticide resistance management guidance on its dicamba product labels.

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[105] http://www.monsanto.com/weedmanagement/Pages/default.aspx

In summary, Monsanto will require weed resistance management practices through the MTSA and TUG for its biotechnology-derived herbicide-tolerant products, such as DT soybean integrated into the glyphosate-tolerant soybean system, and to promote these practices through product labeling and educational outreach efforts as an effective means to manage weed resistance development for both dicamba and glyphosate.

B.2.4.5. Weed Resistance Management Practices

Monsanto will provide information to growers and grower advisors on best management practices to mitigate the potential for development of resistance to dicamba. The weed resistance management recommendations for the use of dicamba in conjunction with soybean varieties containing DT soybean will be consistent with the Herbicide Resistance Action Committee's guidelines for prevention and management of herbicide resistance (HRAC, 2010)[106]. These guidelines recommend a diversified approach to weed resistance management including crop management (*i.e.*, row spacing, etc), cultivation techniques, and the use of multiple herbicide modes-of-action to manage a weed population.

In cases where resistance is confirmed for dicamba in soybean producing areas, Monsanto and university/Cooperative Extension Service (CES) personnel will provide recommendations for alternative herbicide control methods to growers. These recommendations would be made available through Monsanto supplemental labels, Monsanto and university publications, and internet sites to growers, consultants, retailers and distributors. For all existing cases of dicamba-resistant weeds in the U.S. and globally today, alternative herbicides and cultural methods are available to growers to effectively control these biotypes. Examples of recommended alternative herbicides from university/CES personnel that are applicable to weed species known to be resistant to dicamba and other synthetic auxin herbicides are found in Table B-10. It is important to note that there are many alternative options in each situation.

B.2.4.6. Monsanto Weed Performance Evaluation and Weed Resistance Management Plan

An important part of a weed resistance management plan is the timely acquisition of information regarding product performance. Monsanto has an extensive technical, sales and marketing presence in the soybean markets where DT soybean will be grown. Through our relationships with farm advisors, key university/CES personnel, and growers using our seeds and traits products, Monsanto will acquire important and timely information regarding product performance. This will allow the timely recognition of performance issues that could arise related to weed resistance or other means. Field employees and hired consultants are trained and provided processes for responding to product performance inquiries. Individual performance issues that could be related to potential resistance are promptly handled. In addition, performance inquiries are periodically reviewed by Monsanto for trends that could indicate the need for follow up action on a broad scale.

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[106] The Herbicide Resistance Action Committee (HRAC) is an international body founded by the agrochemical industry for the purpose of supporting a cooperative approach to the management of herbicide resistance and the establishment of a worldwide herbicide resistance database.

If resistance is confirmed, the scientific and grower communities will be notified and a weed resistance mitigation plan will be implemented by Monsanto in cooperation with the university/CES. The mitigation plan will be designed to manage the resistant biotype through effective and economical weed management recommendations implemented by the grower. The scope and level of intensity of the mitigation plan may vary depending on a combination of the following factors: 1) biology and field characteristics of the weed (seed shed, seed dormancy, etc.), 2) importance of the weed in the agricultural system, 3) resistance status of the weed to other herbicides with alternate modes-of-action, and 4) availability of alternative control options. These factors are analyzed by Monsanto and university/CES personnel in combination with economic and practical management considerations to develop a tailored mitigation strategy. The plan considers what is technically appropriate for the particular weed and incorporates practical management strategies that can be implemented by the grower.

After a mitigation plan is developed, Monsanto communicates the plan to the grower community through the use of supplemental labeling (labeling which includes newly approved use directions, or other instructions), informational fact sheets, retailer training programs, agriculture media and/or other means, as appropriate.

In addition to the grower inquiry initiated process, Monsanto, alone and/or in cooperation with university/CES, will conduct field studies to understand the potential for weed resistance and weed shifts as the result of various weed management programs implemented for DT soybean integrated into the glyphosate-tolerant soybean system. These studies will allow researchers to better track specific factors that can influence the development of resistance to specific weeds.

B.2.5. Benefits of DT Soybean Production

B.2.5.1. Overview

As discussed previously, Dicamba-tolerant soybean will provide an additional weed management tool for effective and sustainable weed management in soybean production. Dicamba-tolerant soybean will be combined with glyphosate-tolerant soybean, e.g., Roundup Ready 2 Yield® (MON 89788), utilizing traditional breeding techniques to produce a stacked trait product of dicamba-glyphosate-tolerant soybean. This combination of herbicide-tolerance traits will allow growers to use dicamba and glyphosate herbicides in a diversified weed management program to control a broad spectrum of grass and broadleaf weed species in soybean. Dicamba-tolerant soybean will contribute additional benefits and value to the well-established and effective glyphosate-tolerant weed control system. Glyphosate provides excellent control of many annual and perennial grass and broadleaf weed species, whereas dicamba provides effective control of many annual and perennial broadleaf weed species.

Dicamba-tolerant soybean will enable early preplant applications, preemergence applications up to the day of crop emergence (cracking), and postemergence in-crop applications through the R1 growth stage of soybean. Dicamba will be complementary to glyphosate for weed management in soybeans due to the efficacy of dicamba on glyphosate-resistant broadleaf weeds and other hard-to-control broadleaf weed species and the application flexibility facilitated with dicamba-tolerant soybean, and it will help to preserve the glyphosate-tolerant weed control system and other mode-of-action herbicides in the major row crop production practices in soybean, corn and cotton.

Beginning in 2007, numerous field experiments have been conducted by university weed control specialists and Monsanto researchers in the major soybean production regions of the U.S. to evaluate the control of glyphosate-resistant and hard-to-control weeds using various rates and timing of dicamba and glyphosate plus dicamba tank mixtures in dicamba-glyphosate-tolerant soybean. These experiments provide valuable data for determining the best recommendations and weed management systems for optimum control of problematic weed species in various climate conditions and soybean production systems across the U.S. Although additional studies are on going to further refine these product and system recommendations, Table B-11 provides a concise summary of the general weed management system recommendations proposed for dicamba-glyphosate-tolerant soybean for both conventional and conservation tillage practices.

These weed management system recommendations represent a high-end proposal for dicamba use associated with dicamba-glyphosate-tolerant soybean. The actual number of applications and timing of applications of dicamba or glyphosate that the grower will make will vary depending on the specific weed spectrum, weed infestation levels, and the agronomic situation of the individual soybean field. Applying a residual herbicide preemergence in sequence with glyphosate plus dicamba postemergence, or tank mixing a residual herbicide with glyphosate plus dicamba postemergence could be considered as an alternative to two postemergence applications of glyphosate plus dicamba for season-long weed control.

These proposed recommendations recognize the differences in growth habits and competitiveness of certain glyphosate-resistant weed species. Option 1 would be recommended for more aggressive glyphosate-resistant weed species, such as Palmer amaranth (*Amaranthus palmeri*) and waterhemp (*Amaranthus tuberculatus*). These weed species are very fast growing, highly competitive with crops, high seed producers, very densely populated, and germinate and emerge throughout the growing season (Nordby et al., 2007; Sprague, 2012; Keely et al., 1987; Fast et al., 2009). Two sequential postemergence applications will generally be required to control late-season emergence of these weed species. However, low rainfall conditions and/or early crop canopy closure that can be associated with narrow row spacing of soybean can reduce late-season weed emergence and potentially reduce the number of dicamba postemergence applications. Option 2 would be used for less aggressive glyphosate-resistant weed species, such as horseweed (*Conyza canadensis*), common ragweed (*Ambrosia artemisiifolia*) and giant ragweed (*Ambrosia trifida*).

Table B-11. Anticipated Weed Management Recommendations for DT Soybean Combined with Glyphosate-Tolerant Soybean[1]

Application Timing	Conventional Tillage[2]			Conservation Tillage [2] (No-till or reduced till)		
	No GR Weeds	GR Weeds or Suspected GR Weeds		No GR Weeds	GR Weeds or Suspected GR Weeds	
		Option 1[3]	Option 2[4]		Option 1[3]	Option 2[4]
Preemergence (burndown, at planting) [5]	Residual	Residual	Residual	Residual + Glyphosate + Dicamba	Residual + Glyphosate + Dicamba	Residual + Glyphosate + Dicamba
Postemergence 1 (V1-V3)	Glyphosate + Dicamba	Glyphosate + Dicamba	Glyphosate + Dicamba	Glyphosate + Dicamba	Glyphosate + Dicamba	Glyphosate + Dicamba
Postemergence 2 (V4-R2)	---	Glyphosate + Dicamba	---	---	Glyphosate + Dicamba	---

[1] The anticipated use patterns represent a high-end estimate for predicating dicamba use associated with DT soybean integrated with the glyphosate-tolerant soybean system. Actual weed control practices by growers will vary depending on the specific weed spectrum and agronomic situation of the individual soybean field, specifically dicamba use could be lower especially for the preemergence and second postemergence applications.

[2] Average rate for dicamba is 0.38 pound a.e. per acre except for fields with glyphosate resistant (GR) species where a 0.5 pound a.e. per acre postemergence application rate will be recommended. In some situations, the second postemergence application may not be needed.

[3] Option 1 would be used for more aggressive glyphosate resistant weed species, such as *Ambrosia* or *Amaranthus* species.

[4] Option 2 would be used for less aggressive glyphosate resistant weed species, such as marestail.

[5] Monsanto and academics recommend the use of soil residuals as part of a comprehensive weed resistance management program to ensure that two effective herbicide modes-of-action are used in soybean and to provide protections against additional resistance development to existing soybean herbicides.

Monsanto and university weed control specialists continue to recommend and encourage preemergence applications of soil residuals as part of a comprehensive weed resistance management program to ensure the use of two or more effective herbicide modes-of-action for weed control and to minimize the risk of additional weed species developing resistance to existing soybean herbicides. Preemergence soil residuals also provide early season weed control to reduce early weed competition to protect yield potential and provide greater flexibility in timing of postemergence applications. In addition, preemergence residuals will assist in the control of grasses and certain hard-to-control broadleaf weed species. The addition of residual preemergence herbicides with glyphosate and dicamba will be an effective program for optimum weed control and long-term sustainability of the dicamba-tolerant technology.

B.2.5.2. Benefits of the Weed Management System of Dicamba-Glyphosate-Tolerant Soybean

Extensive research by both university weed control specialists and Monsanto researchers from 2007 through 2011 demonstrates that growers will realize several benefits from utilizing the proposed weed management systems of dicamba-glyphosate-tolerant soybean. These benefits include:

- Effective and sustainable management of glyphosate-resistant weed species;
- Improved and more consistent control of hard-to-control broadleaf weed species;
- Excellent crop safety to dicamba and glyphosate herbicides to maximize soybean yield potential;
- Application flexibility in the event of challenging weather conditions especially in the spring;
- Proactive program for weed resistance management; and
- Preservation of conservation tillage benefits.

Each benefit attribute is described and discussed below to substantiate the benefit in greater detail.

B.2.5.2.1. Effective and Sustainable Management of Glyphosate-Resistant Weed Species

Glyphosate has been used extensively in agricultural production systems since being commercially introduced in 1974. Roundup Ready soybean was commercially introduced in 1996, further expanding the use of glyphosate in soybean. Currently, glyphosate-tolerant soybean represent 93% of all soybean acres planted in the U.S. (USDA-NASS, 2012), up from 89% in 2006 (USDA-NASS, 2007). Due to the broad-spectrum activity of glyphosate, it has been possible for growers to rely predominately on glyphosate for weed management and not utilize diversified weed management practices such as crop rotation, mechanical cultivation or use of multiple herbicide modes-of-action. Reliance on glyphosate-only herbicide programs in glyphosate-tolerant crops for total weed management in the absence of other herbicides and weed control practices has contributed to the evolution of weed species that are resistant to glyphosate in certain areas of the U.S. Currently, there are 13 weed species (6 grasses and 7 broadleaf species) that are resistant to glyphosate in the U.S (Heap, 2012). Populations of the following six broadleaf weed species are resistant to glyphosate and are agronomically important weeds in soybean: Palmer amaranth (*Amaranthus palmeri*), common waterhemp (*Amaranthus tuberculatus*), giant ragweed (*Ambrosia trifida*), horseweed (*Conyza Canadensis*), common ragweed (*Ambrosia artemisiifolia*), and kochia (*Kochia scoparia*) (Johnson et al., 2010). University weed control specialists and Monsanto researchers have extensively evaluated the effectiveness of dicamba and glyphosate to control several of these glyphosate-resistant weeds. Many of the early studies (2007-2009) were focused on determining the efficacy of dicamba and dicamba plus glyphosate applied preplant, preemergence, and postemergence in soybean compared to glyphosate applied alone. Later studies (2010-2011) were focused on evaluating the efficacy of various weed management systems utilizing dicamba and glyphosate with and without residual herbicides for control of glyphosate-resistant weed species. In these studies glyphosate was applied at labeled rates of 0.75 to 1.0 lbs. a.e./acre.

B.2.5.2.1.1. Glyphosate-Resistant Palmer Amaranth

Palmer amaranth is a summer annual broadleaf that is a problematic weed in the mid-south and southeastern U.S. (Sprague, 2012). It is considered to be one of the most competitive and aggressive of the pigweed species because of its rapid growth and prolific seed production. Palmer amaranth is also dioecious (the male and female flowers occur on separate plants, which leads to greater genetic diversity in the plant population and increases the potential for spreading herbicide resistance). Studies conducted on glyphosate-resistant Palmer amaranth support the importance of making dicamba applications early in the season to small weeds (4 inches or less in height) and applying dicamba at a minimum rate of 0.5 lbs. a.e./acre for effective control. Although dicamba rates of 0.25 lbs. a.e./acre were effective in the early studies, later studies showed more consistent control with a dicamba rate of 0.5 lbs. a.e./acre. Diversified weed management programs consisting of a residual preemergence herbicide followed by one or two sequential postemergence applications of glyphosate plus dicamba or a total post program consisting of two sequential postemergence applications of glyphosate plus dicamba provide excellent control of glyphosate-resistant Palmer amaranth.

- Field efficacy studies conducted by university researchers in Georgia and North Carolina from 2007 to 2009 indicate that the inclusion of dicamba in the postemergence treatment with glyphosate significantly improved the control of natural populations of glyphosate-resistant Palmer amaranth versus glyphosate alone (Johnson et al., 2010). Palmer amaranth control increased from 60 to 100% with the addition of dicamba (0.25 lbs. a.e./acre) to glyphosate as a postemergence treatment.

- Results from field studies conducted in 2011 across seven locations in the southeast and mid-south states on mixed populations of glyphosate-resistant and glyphosate-susceptible palmer amaranth emphasize the importance of early application timing for effective control of this weed (Eubank et al., 2012). When applied to 3-inch plants, two sequential in-crop postemergence applications of dicamba (0.5 lbs a.e./acre) and glyphosate plus dicamba (0.5 lbs. a.e./acre) provided 90 to 92% control. When applied to 9-inch plants, the control following the two sequential applications of dicamba plus glyphosate dropped to 81-85%.

- Studies conducted in the mid-south also demonstrate the importance of rate plus timing of dicamba applications on the control of glyphosate-resistant Palmer amaranth (Edwards et al., 2012). Dicamba at 0.25 lbs. a.e./acre tank mixed with glyphosate and applied on 2-, 4-, and 6-inch plants provided 94, 74, and 62% control at 28 days after treatment, respectively. Increasing the rate of dicamba to 0.5 lbs. a.e./acre in the tank mixture resulted in 97, 86, and 77% control. This study indicates that 0.5 lbs. a.e./acre of dicamba is required in tank mixture with glyphosate to achieve satisfactory control of Palmer amaranth plants up to 4 inches in height and will be a key component of Monsanto's weed management recommendations for dicamba. Greenhouse studies conducted on various populations of Palmer amaranth indicate there is a 2.2 fold difference in dicamba dose required to provide 80% control between most and least susceptible Palmer amaranth plants which further supports the need for the 0.5 lbs. a.e./acre rate to provide consistent control (Crespo et al., 2011; Crespo et al., 2012). Furthermore, since control with dicamba was only 86% with a single application of glyphosate plus dicamba (0.5 lbs. a.e./acre) at 28 days after treatment, these results suggest that two sequential applications of glyphosate plus dicamba will likely be required for effective full season control.

- Results from studies conducted in North Carolina in 2010 show the value and effectiveness of the diversified weed management approach to control a mixed population of glyphosate-susceptible and -resistant Palmer amaranth (York et al., 2012). Two in-crop postemergence applications of glyphosate alone to 3- to 4-inch Palmer amaranth provided 61% control 26 days after treatment. This result demonstrates that glyphosate still provides control in natural field mixed populations, in addition to providing control of other weed species present in the soybean field. Postemergence applications of glyphosate plus dicamba (0.5 lbs. a.e./acre) followed by glyphosate alone provided 90% control. When flumioxazin was applied preemergence to these postemergence applications, control increased to 96%. Results reported by these same researchers in 2011 showed that a weed control system of flumioxazin preemergence followed by two sequential postemergence applications of glyphosate plus dicamba (0.5 lbs. a.e./acre) provided 99-100% control of Palmer amaranth at 70 days after treatment (York et al., 2012). Palmer amaranth control was similar when dicamba (0.5 lbs. a.e./acre) replaced flumioxazin as the preemergence application in this same system. The addition of acetochlor to the initial postemergence application in either system slightly improved the early season control (12-15%). These data indicate the importance of a preemergence residual herbicide for controlling weed species such as Palmer amaranth that can germinate over an extended period of time.

- Field studies conducted in the mid-south (AR, MO, MS, TN) in 2011 showed that a weed control system of flumioxazin preemergence followed by dicamba (0.5 lbs. a.e./acre) plus glyphosate applied to 4-inch plants provided 97% control of Palmer amaranth (Steckel et al., 2012).

B.2.5.2.1.2. Glyphosate-Resistant Waterhemp

Waterhemp is a summer annual broadleaf that is common in the Midwest, but is also found in other areas as well (Nordby et al., 2007). Like Palmer amaranth, waterhemp is dioecious and produces significant amounts of seed which can germinate and compete with the crop throughout the growing season. Studies conducted on glyphosate-resistant waterhemp show that optimum control is achieved when dicamba is applied to small weeds (3-4 inches or less in height) at a rate of 0.5 lbs. a.e./acre. Weed management systems consisting of a preemergence residual herbicide followed by one or two sequential postemergence applications of glyphosate plus dicamba or a total post program consisting of two sequential postemergence applications of glyphosate plus dicamba provide excellent control of glyphosate-resistant waterhemp. These conclusions are consistent with the conclusions for Palmer amaranth.

- Results from a field experiment conducted by the University of Missouri on natural populations of glyphosate-resistant waterhemp indicate that application rate, weed height, and the addition of glyphosate significantly impact the level of glyphosate-resistant waterhemp control achieved with dicamba (Spaunhorst et al., 2011). The highest level of control (~70%) at 21 days after treatment was achieved with glyphosate plus dicamba when applied to 3-inch plants at the highest dicamba rate of 0.5 lbs. a.e./acre. Control was reduced significantly when dicamba at the same rate was applied to taller plants 6-inch (~30%) and 12-inch (~20%). A postemergence application of a glyphosate plus dicamba tank mixture provided higher levels of control than either glyphosate or dicamba alone. Similar results were reported on another application timing study (Spaunhorst et al., 2012). When applied to 3-inch plants, two sequential postemergence applications of glyphosate plus dicamba (0.5 followed by 0.5 lbs. a.e./acre) provided 86 to 92% control of glyphosate-resistant waterhemp, while control dropped to approximately 40% when applied to 9-inch plants. Populations of glyphosate-resistant waterhemp do vary in their response to dicamba, indicating that the minimum rate of dicamba should be 0.5 lbs. a.e./acre to provide more consistent control (Crespo et al., 2012).

- Field efficacy studies conducted by university researchers in Missouri and Illinois from 2007 to 2009 indicate that the addition of dicamba to in-crop postemergence applications of glyphosate significantly improved the control of glyphosate-resistant waterhemp versus glyphosate applied alone (Johnson et al., 2010). Waterhemp control increased from 30 to 95% with the inclusion of dicamba (0.25 lbs a.e./acre) with glyphosate as a postemergence application. In addition to improving the control of glyphosate-resistant waterhemp, adding dicamba to glyphosate also improved the control of waterhemp populations that were susceptible to glyphosate.

- A preemergence-postemergence weed control system consisting of flumioxazin plus chlorimuron preemergence followed by glyphosate plus dicamba (0.5 lbs a.e./acre) postemergence provided 99% late-season control of glyphosate-resistant waterhemp in a study conducted by the University of Missouri in 2011 (Bradley et al., 2012). A total post program including two sequential applications of glyphosate plus dicamba (0.5 lbs. a.e./acre) also provided 99% late-season control. Control was the same (99%) whether the initial post application was to 4-inch or 7.5-inch waterhemp. Two sequential postemergence applications of glyphosate alone provided 72% control.

B.2.5.2.1.3. Glyphosate-Resistant Horseweed

Horseweed (also referred to as marestail) is a broadleaf weed that can follow a winter or summer annual life cycle and can germinate in the fall or spring, but plants can also germinate in midsummer

(Loux et al., 2006). It is predominantly a problem in no-till systems, as tillage helps to control this weed. Dicamba is currently recommended and rated very effective as an early preplant burndown application with glyphosate for control of glyphosate-resistant horseweed in soybean (MSU, 2012; Steckel et al., 2012). However, a minimum of one inch of rainfall/irrigation and up to a 28-day waiting period (dependent on the rate of dicamba) after rainfall/irrigation is required before planting soybean to avoid crop injury (Steckel et al., 2012). Dicamba-glyphosate-tolerant soybean enables early preplant, preemergence, and in-crop postemergence applications of dicamba and the dicamba-glyphosate weed management system can provide effective full season control of glyphosate-resistant horseweed. A very effective system consists of a preplant burndown application of glyphosate plus dicamba (0.5 lbs. a.e./acre) plus residual herbicide followed by an in-crop postemergence application of glyphosate plus dicamba (0.5 lbs. a.e./acre). Preplant burndown plus in-crop postemergence applications of glyphosate plus dicamba also provided excellent control of glyphosate-resistant horseweed. However, researchers recommend the addition of a preemergence residual in the preplant burndown application to reduce the selection pressure for dicamba-resistant plants in the population (Stebbing et al., 2011).

- Field efficacy studies conducted by university researchers in Illinois, Nebraska and Tennessee in 2008 and 2009 indicate that inclusion of dicamba in the postemergence treatment with glyphosate significantly improved control of glyphosate-resistant horseweed versus glyphosate alone (Johnson et al., 2010). Horseweed control increased from 85 to 98% with the addition of dicamba. Horseweed control was higher and less variable in treatments including a preemergence treatment of dicamba, flumioxazin, sulfentrazone, chlorimuron or cloransulam compared to treatments which included only postemergence glyphosate or glyphosate plus dicamba.

- Studies conducted in Tennessee over two years showed that glyphosate plus dicamba (0.5 lbs. a.e./acre) applied preplant followed by the same treatment postemergence on 6-inch weeds provided the highest control of horseweed (>96%) in no-till soybean (Steckel and Montgomery, 2008). Excluding dicamba from the preplant application resulted in consistently poor horseweed control (60-80%). A preplant application of glyphosate alone provided 50% control.

- Field studies conducted in 2010 at the University of Nebraska in no-till soybean indicate that glyphosate-resistant horseweed control exceeded 96% when both the preplant burndown application and in-crop postemergence application included dicamba (Stebbing et al., 2011). Follow up studies in 2011 showed that weed control systems that included a preemergence residual herbicide plus glyphosate plus dicamba followed by glyphosate plus dicamba postemergence provided 99% control of glyphosate-resistant horseweed (Stebbing et al., 2011). Glyphosate-resistant horseweed control was unacceptable with preplant burndown plus postemergence applications of glyphosate alone (< 30%).

- Researchers at Kansas State University achieved complete control (100%) of glyphosate-resistant horseweed in no-till soybean in 2011 utilizing a weed control system including a preplant burndown application of glyphosate plus dicamba (0.5 lbs. a.e./acre) plus flumioxazin/chlorimuron (sold as a package mixture) followed by a postemergence application of glyphosate plus dicamba (0.5 lbs. a.e./acre) (Peterson et al., 2011). When sulfentrazone/chlorimuron was used as the residual herbicide in the preplant application in place of flumioxazin/chlorimuron, control was also excellent (98%).

B.2.5.2.1.4. Glyphosate-Resistant Giant Ragweed

Giant ragweed is a summer annual broadleaf weed found in the Midwest and East, but tends to be most problematic in the eastern Corn Belt (Johnson et al., 2007). The early emergence, rapid growth rate, and large leaf area gives giant ragweed an initial competitive advantage over many other weeds and soybean. Dicamba at rates of 0.25 to 0.5 lbs. a.e./acre provides excellent control of glyphosate-resistant giant ragweed when applied to plants 3 to 6 inch in height. Control is reduced and inconsistent when applications are made to taller plants. Single postemergence applications of glyphosate plus dicamba to small plants (3-6 inches in height) have provided excellent control of glyphosate-resistant giant ragweed in conventional tillage systems. In no-till systems, preplant burndown applications of glyphosate plus dicamba plus a preemergence residual herbicide followed by an in-crop postemergence application of glyphosate plus dicamba has provided excellent control.

- Results reported by the University of Missouri indicate the importance of application height and dicamba rate on control of glyphosate-resistant giant ragweed (Spaunhorst et al., 2011; Spaunhorst et al., 2012). Studies conducted in 2011 indicate that dicamba rates of 0.25, 0.375 and 0.5 lbs. a.e./acre resulted in excellent control of glyphosate-resistant giant ragweed (90-95%) plants that were 3-inch and 6-inch in height at the time of application (Spaunhorst et al., 2011). Dicamba at 0.5 lbs. a.e./acre provided the highest level of control. These same rates of dicamba provided significantly lower levels of control (50-65%) when applied to plants that were 12 inches in height. A separate field study conducted in 2011 showed that two sequential applications of dicamba (0.25 followed by 0.5 lbs. a.e./acre) to 3-inch plants provided 100% control at 21 days after treatment, regardless of whether or not glyphosate was included in the treatment (Spaunhorst et al., 2012). Giant ragweed control was reduced slightly when the initial postemergence application was made to 9-inch plants. Single applications of dicamba (0.5 lbs. a.e./acre) alone provided 96% control of 3-inch plants and only 84% control of 9-inch plants. Although a single application of dicamba at a lower rate of 0.25 lbs. a.e./acre alone to 3-inch plants provided excellent control (95%), this rate was ineffective (62%) on 9-inch giant ragweed. This study also showed that giant ragweed is much more sensitive to dicamba than waterhemp.

- The control of glyphosate-resistant giant ragweed improved with the addition of dicamba to postemergence applications of glyphosate compared to glyphosate alone in field studies conducted in Ohio in 2008 and 2009 (Johnson et al., 2010). Sequential applications of dicamba (0.25 lbs. a.e./acre) alone provided complete control of glyphosate-resistant giant ragweed compared to only 70% control with sequential applications of glyphosate alone.

- Three field trials conducted by the University of Guelph in 2010 and 2011 indicate that the use of dicamba in dicamba-glyphosate-tolerant soybean will provide effective control of glyphosate-resistant giant ragweed (Vink et al., 2012). Glyphosate plus dicamba (0.25 and 0.5 lbs. a.e./acre) applied preplant followed by glyphosate plus dicamba (0.25 and 0.5 lbs. a.e./acre) postemergence consistently provided 100% control of glyphosate-resistant giant ragweed at 7 weeks after treatment. In comparison, glyphosate alone applied preplant, postemergence, or sequentially provided 15 to 68%, 40 to 46%, and 54 to 98% control at 7 weeks after treatment, respectively. Glyphosate plus dicamba (0.5 lbs. a.e./acre) applied preplant and postemergence provided 93 to 100% and 95 to 100% control at 7 weeks after treatment, respectively.

- The University of Missouri conducted field experiments evaluating various pre-post systems containing dicamba for control of glyphosate-resistant giant ragweed in a no-till system (Bradley et al., 2012). Systems containing a preplant application of glyphosate plus dicamba (0.5 lbs. a.e./acre) plus a preemergence residual herbicide followed by glyphosate plus dicamba (0.5 lbs. a.e./acre) provided 100% late season control. The residual herbicides were flumioxazin, flumioxazin/chlorimuron, and sulfentrazone/chlorimuron. Complete control was achieved whether the application was made to 4-inch or 8-inch plants.

B.2.5.2.1.5. Glyphosate-Resistant Common Ragweed and Kochia

At this time, results have not been published for field studies evaluating the control of glyphosate-resistant common ragweed and kochia. Dicamba-glyphosate weed control systems are expected to provide excellent control of glyphosate-resistant common ragweed because dicamba has a 90 to 100% control rating on common ragweed (see Table VIII-17 in the Dicamba-Tolerant Soybean MON 87708 petition #10-188-01p). Kochia is not a common or problematic weed species in most of the soybean producing states. However, kochia is a problematic weed in western sections of Kansas and Nebraska where some soybean is produced. Dicamba has a control rating of 8 out of a possible 10 on kochia as a postemergence application in corn (University of Nebraska, 2012).

B.2.5.2.2. Improved Control of Hard-to-Control Broadleaf Weed Species

Dicamba use on dicamba-tolerant soybean offers a new management tool for improved control of hard-to-control weed species in soybean (Maxwell et al., 2011; Moechnig et al., 2010; Peterson et al., 2011). Certain problematic broadleaf weed species in certain areas of the U.S. that are naturally relatively less sensitive to glyphosate, namely morningglory spp., hemp sesbania, prickly sida, and wild buckwheat are generally hard to control with postemergence applications of glyphosate alone. Alternative broadleaf postemergence soybean herbicides (ALS and PPO) provide inconsistent or less than acceptable control of these problematic broadleaf species in soybean. (Tables A-12 and A-13). Populations of common lambsquarters, prickly sida, and black nightshade are resistant to ALS herbicides, and common waterhemp and common ragweed have populations resistant to PPO herbicides (Heap, 2012). Postemergence applications of the glyphosate plus dicamba tank mixture will improve the control of these hard-to-control broadleaf weed species compared to glyphosate alone. Also, the control with the glyphosate plus dicamba mixture will often exceed the control of glyphosate mixtures with other commercial standards on certain of these weed species.

- Field studies conducted from 2007 and 2008 indicate that glyphosate plus dicamba (0.25 lbs. a.e./acre) provided 98-99% control of morningglory species compared to glyphosate alone at 90-93% control (Johnson et al., 2010). The researchers noted that dicamba improved the consistency of control of morningglory. Results from additional field studies conducted by the University of Illinois in 2011 show that a tank mixture of glyphosate plus dicamba (0.5 lbs. a.e./acre) applied postemergence provided improved late season control of tall morningglory (98%) compared to the control with glyphosate alone at 63% (Maxwell et al., 2011).

- Studies conducted at Kansas State University have demonstrated similar improvements in control of ivyleaf morningglory in weed control systems that incorporate dicamba (Peterson et al., 2011). A weed control system of glyphosate preplant followed by two in-crop postemergence applications of glyphosate plus dicamba (0.25 lbs. a.e./acre) provided 94% control of ivyleaf morningglory while the weed control system without dicamba provided 78% control. The addition of dicamba to glyphosate also resulted in improved control of ivyleaf morningglory in a Texas experiment compared to glyphosate alone (Cogdill and Chandler, 2012).

- Studies conducted in Louisiana show that dicamba will improve control of hemp sesbania and prickly sida, two common broadleaf weeds in the South (Bauerle et al., 2012). Dicamba preemergence followed by glyphosate plus dicamba postemergence provided 98-100% control of pigweed, hemp sesbania, and prickly sida. Hemp sesbania control was improved when dicamba (0.5 lbs. a.e./acre) was added to preemergence applications of residual herbicides: metolachlor/fomesafen (33 to 73%), metolachlor (50 to 90%), acetochlor (23 to 85%), flumioxazin/metribuzin (43 to 93%), pyroxasulfone (15 to 72%), and chlorimuron/metribuzin (52 to 92%).

- Wild buckwheat is a hard-to-control broadleaf weed species in soybeans in the Plains region of the U.S. Dicamba (0.25 lbs. a.e./acre) plus glyphosate applied as a no-till burndown application provided 98% and 82% control of wild buckwheat at 30-35 days after treatment in South Dakota State University trials in 2008 and 2009, respectively (Moechnig et al., 2010). In comparison, a burndown application of sulfentrazone/cloransulam plus glyphosate provided 90 and 95% control in 2008 and 2009, respectively. All two-pass in-crop postemergence systems of glyphosate alone or glyphosate plus dicamba resulted in nearly complete control of wild buckwheat.

Table B-12. Common Broadleaf Weed Responses to Preplant Burndown Herbicides

	Common Broadleaf Weeds[1,2]														
Herbicide/Application	LQ	CR	GR	SW	CC	M, SP	CT	RC	AL	HV	MT	PL	DN, HB	DL	CG
Spring Preplant Application															
2,4-D (0.5 lb/1.0 lb)	-	-	-	-	-	9	-/6	6/8	-/7	6/8	8/9	8/9	-/8	6/7	9/9
Dicamba	9	9	9	9	6	7	-	9	8	8	7	9	-	7	-
Dicamba + 2,4-D	9	9	9	9	6	9	6	9	8	9	9	9	-	8	9
Glyphosate	8	9	8	7	7	8	6	7	6	6	6	8	-	7	7
Glyphosate + 2,4-D	9	9	9	8	7	9	6	8	8	8	8+	9	6	8	9
Glyphosate + Canopy	8	9	9	9	7	8	6	7	6	6	8	8+	9	8+	9
Glyphosate + Canopy + 2,4-D	9	9	9	9	7	9	6	8	8	8	9	9	9	8+	9
Glyphosate + Gangster + 2,4-D	9	9	9	9	7	9	6	8	8	8	9	9	8	8	9
Glyphosate + Python + 2,4-D	9	9	9	8	7	9	6	8	8	8	9	9	6	8	9
Glyphosate + Scepter + 2,4-D	9	9	9	8	7	9	6	8	8	8	8+	9	6	8	9
Gly + Sonic/Authority First + 2,4-D	9	9	9	9	7	9	6	8	8	8	9	9	8	8	9
Glyphosate + Valor + 2,4-D	9	9	9	8	7	9	6	8	8	8	8+	9	8	7	9

[1]All weed control ratings are from the 2009 Weed Control Guide for Ohio and Indiana – Weed Responses to Burndown Herbicides, Ohio State University and Purdue University (Loux et al., 2009). Weed control ratings for weeds are: 9 = 90% to 100%, 8 = 80% to 90%, 7 = 70% to 80%, 6 = 60% to 70%, and - = less than 60% control, not recommended. Ratings assume the herbicides are applied in the manner suggested in the guidelines and according to the label under optimum growing conditions.

[2]Weed species: LQ = lambsquarters, CR = common ragweed, GR = giant ragweed, SW = annual smartweed, CC = common chickweed, M & SP = mustard and shephard's purse, CT = Canada thistle, RC = red clover, AL = alfalfa, HV = hairy vetch, MT = marestail, PL = prickly sida, DN & HB = deadnettle & henbit, DL = dandelion, and CG = crested groundsel

Table B-13. Common Broadleaf Weed Responses to Dicamba Compared to Labeled Postemergence Herbicides in Soybean Production

	Common Broadleaf Weeds[1,2]													
Herbicide/Application	BN	CB	CR	GR	HS	LQ	MG	PA	PW	PS	SP	SW	VL	WH
Postemergence														
Bentazon	-	9	7	6	4	7	2-9	4	-	8	0	9	8+	-
Chlorimuron	-	9	8	7+	8	-	8-9	6	9	2	7	8	8	-
Cloransulam	-	9	9	9	3	-	8-9	2	-	2	7	8	9	-
Chlorimuron/thifensulfuron	-	9	8	7+	NA	8	NA	NA	9	NA	NA	9	9	-
Dicamba[3]	8	9	9	9	9	8	9	9	8	8	8	8	7+	8
Flumiclorac	-	7	7	-	NA	7	NA	NA	7	NA	NA	-	9	7
Fomesafen	8	7	8+	8	9	-	8-9	8	9	2	3	7	6	9
Glyphosate	8	9	8+	8	7	8	7-9	9	9	7	8	8	8	8
Glyphosate/imazethapyr	9	9	8+	8+	NA	8+	NA	NA	9	NA	NA	9	9	8
Imazamox	9	8	7	8	NA	8	NA	NA	9	NA	NA	8	9	-
Imazethapyr	9	9	6	7	0	6	7-9	6	9	6	0	9	9	-
Lactofen	8+	8	9	8	9	-	8-9	8	9	8	5	6	7	9
Thifensulfuron	-	6	-	-	NA	8	NA	NA	9	NA	NA	8	9	-

[1]All weed control ratings except for HS, MG, PA, PS, and SP are from the 2009 Weed Control Guide for Ohio and Indiana – Ohio State University and Purdue University (Loux et al., 2009). Ratings for HS, MG, PA, PS, and SP are from the 2009 Weed Control Guidelines for Mississippi, Mississippi State University (MSU, 2010), except for dicamba ratings for PA are from the 2010 Weed Control Manual for Tennessee (University of Tennessee, 2010). Weed control ratings for weeds, except HS, MG, PA, PS, and SP, are: 9 = 90% to 100%, 8 = 80% to 90%, 7 = 70% to 80%, 6 = 60% to 70%, and - = less than 60% control, not recommended. Weed control ratings for HS, MG, PA, PS, and SP are: 9-10 = excellent, 7-8 = good, 4-6 = fair, 0-3 = none to slight. Ratings assume the herbicides are applied in the manner suggested in the guidelines and according to the label under optimum growing conditions. NA denotes not available.

[2]Weed species: BN = black nightshade, CB = cocklebur, CR = common ragweed, GR = giant ragweed, LQ = lambsquarters, MG = morningglory spp., HS = hemp sesbania, PA = palmer and spiny pigweed, PW = pigweed, PS= prickly sida, SP = sicklepod, SW = smartweed, VL = velvetleaf, and WH = waterhemp

[3]Weed control ratings for dicamba are from postemergence applications in corn

B.2.5.2.3. Crop Tolerance

Weed management systems utilizing dicamba-glyphosate-tolerant soybean have proven very effective in controlling important problematic weed species in soybean. Weed control systems must display excellent crop tolerance to the herbicide to allow soybean to reach their full yield potential. Dicamba-glyphosate-tolerant soybean provides excellent crop tolerance to dicamba and glyphosate applied preemergence and in-crop postemergence. Dicamba displayed excellent tolerance in weed control systems that include sequential preemergence and in-crop postemergence applications of dicamba or in systems including two sequential in-crop postemergence applications of dicamba. Many of the commercial herbicide standards for postemergence broadleaf weed control in soybeans exhibit fair to poor crop tolerance ratings, namely acifluorfen, chlorimuron, fluthiacet, fomesafen, and lactofen (see Table VIII-9 in the Dicamba-Tolerant Soybean MON 87708 Petition #10-188-01p).

A total of 35 separate field experiments were conducted on dicamba-glyphosate-tolerant soybean in the Midwest, Midsouth, and Southeastern soybean growing regions of the U.S. in 2010 and 2011 that included visual evaluations of crop tolerance to dicamba applications. No visual symptoms of crop injury such as epinasty, leaf malformation, leaf cupping, stunting, or chlorosis to soybean were reported in any of these studies from applications of dicamba or dicamba tank mixtures with glyphosate.

Dicamba-glyphosate-tolerant soybeans demonstrated excellent crop tolerance to preemergence applications of dicamba at 0.5 to 1.0 lbs. a.e./acre in 11 experiments conducted in the Midsouth and Southeastern states (Bauerle, et al., 2012; Bernards et al., 2011; Steckel et al., 2012; York et al., 2012). No crop injury was reported with any dicamba applications in these experiments. Excellent crop tolerance was displayed to single in-crop postemergence applications of dicamba at rates up to two to three times the proposed use rate (1.0 to 1.5 lbs. a.e./acre) in experiments conducted in Kansas and Mississippi in 2010 and 2011 (Peterson et al., 2011; Edwards et al., 2012).

As presented in Table B-11, the proposed weed control system recommendations for dicamba-glyphosate-tolerant soybean in conservation tillage recommend preemergence followed by in-crop postemergence applications of dicamba, or sequential in-crop postemergence applications of dicamba in conventional tillage practices. Dicamba-glyphosate-tolerant soybean provides excellent crop tolerance in these systems. No crop injury was reported in studies evaluating preemergence applications of dicamba (0.5 to 1.0 lbs. a.e./acre) followed by postemergence applications of dicamba (0.5 lbs. a.e./acre) (Bauerle et al., 2012; Stebbing et al., 2011; Steckel and Montgomery, 2008; Steckel et al., 2012 York et al., 2012). No crop injury was reported when flumioxazin or glyphosate was added to the preemergence application or glyphosate was added to the postemergence application. Numerous studies were conducted to evaluate the efficacy of two sequential in-crop postemergence applications of dicamba on dicamba-glyphosate-tolerant soybean (Maxwell et al., 2011; Spaunhorst et al., 2011 and 2012; Bradley et al., 2012; Steckel et al., 2012; Eubank et al., 2012). No crop injury was reported from sequential in-crop postemergence applications of dicamba up to 0.5 lbs. a.e./acre with any of these experiments regardless of the absence or presence of glyphosate in the treatment.

B.2.5.2.4. Application Flexibility With Dicamba in Dicamba-Glyphosate-Tolerant Soybean

Dicamba-glyphosate-tolerant soybean will facilitate a wider window of application for dicamba in soybean and application flexibility for both preemergence and postemergence applications in soybean. Current labeled uses of dicamba in soybean are limited to early preplant and late postemergence (preharvest) applications. To avoid soybean injury, significant planting restrictions exist currently in soybean for preplant applications of dicamba. The waiting interval prior to planting soybeans is 28 days following application of a maximum dicamba rate of 0.5 lbs. a.e. per acre and a minimum accumulation of one inch of rainfall or overhead irrigation (Clarity Herbicide label; CDMS, 2012). University weed control specialists indicate that the dicamba-tolerant soybean technology will be important because it will enable preplant and preemergence applications of dicamba without a preplant interval for control of existing weeds in no-till cropping systems (Peterson et al., 2011, Steckel et al., 2012).

To support the introduction of dicamba-glyphosate-tolerant soybean, Monsanto has submitted an application to U.S. EPA to amend Registration Number 524-582, a DGA salt formulation, to remove all preemergence planting restrictions (intervals and rainfall) and to allow in-crop postemergence applications of dicamba to dicamba-tolerant soybean up to and including the R1/R2 growth stage of soybean. Once approved, growers would be authorized to apply dicamba alone or tank mixed with glyphosate for preplant or postemergence in-crop applications on dicamba-glyphosate tolerant soybean. Dicamba would also be authorized to be applied preemergence up to day of crop emergence at up to 1.0 lb. a.e. per acre and postemergence with two sequential applications at up to 0.5 lb a.e. per acre up to and including the R1/R2 growth stage of soybean. Dicamba will have the added flexibility to be applied using water or sprayable fertilizer as a carrier. It can also be tank mixed and applied with insecticides or other herbicides as needed due to its excellent compatibility with these products.

B.2.5.2.5. Proactive program for weed resistance management

With the potential, in certain areas of the U.S., for continued selection pressure for new glyphosate-resistant weed species and the spread of current glyphosate-resistant weed species, additional weed management tools are needed to slow the development and spread of these resistant weed species. University weed control specialists involved with the evaluation of dicamba-glyphosate-tolerant soybean indicate that this new technology would provide an additional management tool and mode-of-action to control glyphosate-resistant weeds (Johnson et al., 2010; Edwards et al., 2012; Maxwell et al., 2011; Peterson et al., 2011; York et al., 2012). In addition, this new dicamba technology will reduce the dependence on PPO-inhibiting herbicides, thereby reducing the selection pressure to glyphosate and to PPO-inhibiting herbicides such as fomesafen, acifluorfen, and lactofen (York et al., 2012). As recommended by weed scientists, the proposed weed management recommendations include the use of a preemergence residual herbicide to further reduce selection pressure and improve the sustainability of the dicamba-tolerant soybean technology (Table B-11). University weed control specialist stress the importance of using other herbicides with different modes of action and the use of residual preemergence herbicides to maximize the long-term sustainability and utility of the dicamba-tolerant technology (Stebbing et al., 2011).

B.2.5.2.6. Preserves conservation tillage benefits

The benefits of conservation tillage are well known, namely reduced labor, savings of time and fuel, improved soil health, reduced soil erosion, and improved water quality – as well as air quality benefits from reduced use of farm machinery (CTIC, 2012a; Price et al., 2011). Conservation tillage systems are well established in soybean production, with 62% and 76% of the full season and double crop soybean acres, respectively, utilizing some form of conservation tillage (CTIC, 2012b). No-tillage systems are used on 39% and 72 % of full season and double crop soybean, respectively. Glyphosate-tolerant soybean has been a primary enabler for continued adoption of conservation tillage systems and for the success of USDA Natural Resource Soil Conservation (NRCD) programs (CAST, 2012). Weed resistance to glyphosate in certain areas of the U.S. is a threat to soil conservation gains in some situations (CAST, 2012; Price et al., 2011). In particular, Palmer amaranth and horseweed are very difficult to manage in no-tillage systems with currently available herbicide systems (Price et al., 2011; (Steckel and Montgomery, 2008)). The postemergence options for effective control of Palmer amaranth and horseweed are limited in soybean (Steckel and Montgomery, 2008; Steckel et al., 2012). Dicamba-glyphosate-tolerant soybean will assist in preserving the use of conservation tillage and the benefits growers and the environment realize from utilizing these systems by enabling effective management of glyphosate-resistant weed species and other hard-to-control weeds in the areas of the U.S. where they occur.

Dicamba applications in dicamba-glyphosate-tolerant soybean provide excellent control of glyphosate-resistant weeds and other problematic weeds in no-tillage soybean (Bernards et al., 2011; Stebbing et al., 2011; Bradley et al., 2012; Steckel et al., 2012; York et al., 2012). This, combined with the application flexibility of the dicamba-glyphosate-tolerant soybean system, will benefit no-tillage and other conservations tillage systems for soybean, and enable growers to return to conservation tillage systems that may have abandoned these systems because of inadequate control of glyphosate-resistant weeds in certain areas of the U.S.

B.2.5.3. Conclusion

Dicamba-glyphosate-tolerant soybean will enable an additional weed management tool for effective and sustainable weed management in soybean production. Dicamba-glyphosate-tolerant soybean will allow growers to use dicamba and glyphosate herbicides in a diversified weed management program to control a broad spectrum of grass and broadleaf weed species. Dicamba tolerance will facilitate a wider window of application for dicamba in soybean and application flexibility for both preemergence and postemergence applications in soybean compared to current labeled uses of dicamba in soybean. A significant number of field studies conducted by university weed control specialist in the major soybean production regions from 2007 to 2011 have lead to the development of weed management system recommendations for dicamba-glyphosate-tolerant soybean. These systems recommendations will provide for effective and sustainable management of glyphosate-resistant weed species including Palmer amaranth, waterhemp, giant ragweed, and horseweed. In addition, weed control systems in dicamba-glyphosate-tolerant soybean will improve control of certain hard-to-control broadleaf weed species which are known to be problematic in soybean production such as morningglory, hemp sesbania, prickly sida, and wild buckwheat, compared to glyphosate alone. Dicamba-glyphosate-tolerant soybean weed management systems provide excellent crop tolerance as evidenced by no reports of visual crop injury symptoms in 35 field experiments evaluating dicamba applications at and above the maximum proposed use rates of dicamba for both preemergence and postemergence applications.

Dicamba-glyphosate-tolerant soybean provides a new technology with an additional mode-of-action to control glyphosate-resistant weed species and provide an easy means to incorporate an additional herbicide mode-of-action in soybean production practices. In addition, this technology has the potential to reduce the dependence on PPO-inhibiting herbicides, thereby reducing the selection pressure and mitigating the potential for the development of weed resistance to PPO-inhibiting herbicides. Weed resistance to glyphosate in certain areas of the U.S. is a threat to soil conservation gains in recent years. Dicamba-glyphosate-tolerant soybean provides excellent control of glyphosate-resistant weeds and other problematic weeds in no-tillage soybean. This performance in no-tillage systems and the application flexibility facilitated by dicamba-glyphosate-tolerant soybean will help preserve conservation tillage usage and its well documented environmental and economic benefits in soybean.

All of these benefits strongly support the need for dicamba-tolerant soybean as a new and beneficial tool for soybean growers in the U.S.

B.3. DGT Cotton

B.3.1. Introduction

This section addresses weeds and weed management in cotton production, followed by a discussion of herbicide-resistant weeds and the benefits of DGT cotton production.

B.3.2. Weeds in Cotton

Across the Cotton Belt many annual and perennial weeds occur, resulting in economic damage to cotton yield, fiber quality, and economic returns. Barnyardgrass, crabgrass, pigweed spp. (including Palmer amaranth), morningglory spp., common cocklebur, and common lambsquarters are common annual weed species in almost all cotton-growing regions. Johnsongrass, bermudagrass, and nutsedge are common perennial weed species. Nightshade spp. and groundcherry are more common in the Southwest and West regions. Palmer amaranth, morningglory spp., and nutsedge spp. are often reported as the most problematic weed species in cotton (Webster et al. 2009). Tables B- 14 through B-17 summarize the most common weeds for each of the four major cotton growing regions (Southeast, Midsouth, Southwest and West).

Table B-14. Common weeds in Cotton Production in the Southeast Region of the U.S.[1,2]

Crabgrass spp. (6)	Pigweed spp (3)	Crowfootgrass (1)
Morningglory spp (6)	Common cocklebur (2)	Horseweed (marestail) (1)
Prickly sida (5)	Common lambsquarters (2)	Jimsonweed (1)
Florida pusley (4)	Common ragweed (2)	Johnsongrass (1)
Nutsedge spp. (4)	Florida beggarweed (2)	Smartweed spp. (1)
Sicklepod (4)	Palmer amaranth (2)	Spurge spp (1)
Broadleaf signalgrass (3)	Texas millet (2)	Volunteer peanut (1)
Goosegrass (3)	Bermudagrass (1)	

1 Source: (Webster et al. 2009).
2 Number provided in parenthesis is the number of states out of the six total states (AL, FL, GA, NC, SC, & VA) in the Southeast Region reporting each weed as one of the ten most common weeds.

Table B-15. Common weeds in Cotton Production in the Midsouth Region of the U.S.1,2

Morningglory spp (5)	Velvetleaf (3)	Common cockleburr (1)
Broadleaf signalgrass (4)	Barnyardgrass (2)	Cutleaf evening-primrose (1)
Crabgrass spp (4)	Horseweed (marestail) (2)	Goosegrass (1)
Nutsedge spp (4)	Johnsongrass (2)	Hemp sesbania (1)
Prickly sida (4)	Palmer amaranth (2)	Henbit (1)
Spurge spp (4)	Bermudagrass (1)	Spurred anoda (1)
Pigweed spp (3)	Browntop millet (1)	

1 Source: (Webster et al. 2005; Webster et al 2009) Webster et al., 2005 (MS & TN); Webster et al., 2009 (AR, LA, & MO).

2 Number provided in parenthesis is the number of states out of the five total states (AR, LA, MS, MO, & TN) in the Midsouth Region reporting each weed as one of the ten most common weeds.

Table B-16. Common weeds in Cotton Production in the Southwest Region of the U.S.[1,2]

Johnsongrass (4)	Pigweed spp (2)	Smartweed (1)
Nutsedge spp (4)	Russian thistle (2)	Smellmelon (1)
Common cockleburr (3)	Barnyardgrass (1)	Spurred anoda (1)
Palmer amaranth (3)	Bermudagrass (1)	Red Sprangletop (1)
Silverleaf Nightshade (3)	Bindweed, field (1)	Sunflower (1)
Common lambsquarters (2)	Foxtail spp (1)	Texas blueweed (1)
Large Crabgrass (2)	Groundcherry spp (1)	Texas millet (2)
Devil's claw (2)	Kochia (1)	Velvetleaf (1)
Morningglory spp (2)	Horseweed (marestail) (1)	Woolyleaf bursage (1)
Mustard spp (2)	Shepardspurse (1)	

1 Source: OK - Webster et al., 2009; KS – Dr. Stewart Duncan, Kansas State University – Personal Communication 11/4/2010; NM – Dr. Jamshid Ashigh, New Mexico State University – Personal Communications 11/12/2010; TX – Dr. Wayne Keeling and Dr. Gaylon Morgan, Texas A&M University - Personal communications 11/4/2010.

2 Number provided in parenthesis is the number of states out of the four total states (KS, OK, TX, & NM) in the Southwest Region reporting each weed as one of the ten most common weeds.

Table B-17. Common weeds in Cotton Production in the West Region of the U.S.[1,2]

Barnyardgrass (2)	Common lambsquarters (1)	Silverleaf Nightshade (1)
Morningglory spp (2)	Johnsongrass (1)	Palmer amaranth (1)
Sprangletop (2)	Junglerice (1)	Common Purslane (1)
Bermudagrass (1)	Nutsedge spp (1)	Horse Purslane (1)
Field Bindweed (1)	Pigweed spp (1)	Volunteer corn (1)
Cupgrass, southwestern (1)	Black Nightshade (1)	
Groundcherry spp (1)	Hairy Nightshade (1)	

1 Source: AZ – Bill McCloskey, University of Arizona – Personal Communication 11/5/2010; CA – Steven Wright, University of California - Personal Communication 11/16/2010.

2 Number provided in parenthesis is the number of states out of the two total states (AZ & CA) in the West Region reporting each weed as one of the ten most common weeds.

B.3.3. Weed Management in Cotton

Weed control in cotton is essential to maximize both yield and quality of cotton fiber. The slow early growth of cotton does not permit the crop to aggressively compete against weed species that often grow more rapidly and utilize the available water, nutrients, light, and other resources for growth (Smith and Cothren 1999). Cotton yields can be reduced substantially if weeds are uncontrolled. Palmer amaranth can cause yield losses as high as 54% (Morgan, et al. 2001) and johnsongrass and barnyardgrass can reduce yields by 90% and 98%, respectively (Vargas, et al. 1996). Based on 2005 data, not using herbicides in cotton would result in an increased production cost of approximately $2.3 billion annually and an estimated yield loss of 27% (Gianessi and Reigner 2006).

Weed-crop competition studies have demonstrated that the control of weeds during the first four to eight weeks after cotton planting is critical as weeds compete against the crop for water, nutrients, light and other resources necessary for growth (Smith and Cothren 1999). The primary weed competition factors affecting yield loss potential are the weed species, weed density, and the timing/duration of weed competition. Cotton emergence and above ground growth is relatively slow during the first few weeks after planting, and does not permit the crop to aggressively compete against often more rapidly developing weed species (Smith and Cothren 1999). In addition, cotton is primarily planted using wide row spacing which delays crop canopy closure until layby stage of cotton and extends the window of weed-crop competition.

While late-season infestations may not impact yield, they reduce harvesting efficiency, contribute to the weed seed bank and lower the lint grade (McWhorter and Bryson 1992; Vargas et al. 1996). Weeds can also increase cotton disease and insect management issues because certain weed species can be a host for pathogens, such as *Rhizoctonia* and *Verticillium*, and harbor insects such as lygus bugs.

The most effective weed management programs in cotton use diversified weed management, a combination of cultural, mechanical, and/or herbicide control practices, instead of relying on one particular method of weed control (Beckie, et al. 2011; University of California 2009; Vargas et al. 1996). Herbicide application practices that are compatible with diversified weed management include the use of several herbicides with different modes-of-action, either within or across seasons, applying herbicides at the labeled rate and at the correct timing, and proper application of the herbicide. Cultural and mechanical practices can also be important components of an effective diversified weed management program (Ashigh et al. 2012). Cultural practices such as crop rotation, use of optimal planting dates, and the use of cover crops, when implemented, can increase the crop's ability to compete with weeds. Crop rotation (limiting continuous cotton planting), in conjunction with other weed control methods, can play a role in the overall weed spectrum and can drastically reduce the overall weed population observed (Smith and Cothren 1999). Approximately 38% of the total cotton acres are post-plant cultivated for weed control and in conventional tillage systems, and over 50% of cotton acres are cultivated for weed control with as many as five tillage operations occurring after emergence to harvest (USDA-ERS 2012c. Spring preplant or fall postplant tillage and in-crop shallow cultivation can effectively reduce the competitive ability of weeds. A consequence of in-crop cultivation for weed control is that tillage equipment can damage crop roots or apical meristem, causing soil moisture loss. More recently, cotton growers in certain areas of the U.S. have begun utilizing more hand-weeding to control glyphosate-resistant Palmer amaranth in fields. For example, Georgia cotton growers have increased hand-weeding from 17% of the state cotton acreage in 2000-2005 to 52% of the acreage in 2006-2010. Hand-weeding has a current cost of $23 per acre (Sosnoskie and Culpepper 2012). A survey of Georgia cotton growers conducted in 2010 found that 92% of growers spent $16 million on hand-weeding 53% of the total Georgia cotton crop; similarly, at least 20% of the cotton acres in Tennessee were hand-weeded at cost of more than $3 million (Culpepper, et al. 2011).

The planting of winter cover crops can be utilized as part of a diversified weed management strategy. The planting of cover crops, such as grasses, legumes, or small grains can protect and improve soil quality, help reduce erosion, serve as surface mulch in no-till cropping practices, and provide habitat for beneficial insects (Guerena and Sullivan 2003; Hitt and Roos 2007; Mannering, et al. 2007). Small grain crops such as rye are commonly used as a cover crop; incorporating rye or oats as a cover crop have been shown to suppress Palmer amaranth germination and growth (Price, et al. 2011). However, the planting of cover crops in general incurs additional costs to the grower and therefore cover crops are not typically a major weed management practice utilized in cotton production systems (Singer 2006).

Herbicides are used on essentially all (>99%) cotton acres, and in 2011 approximately 39 million pounds of herbicides were applied pre- or postemergence in cotton production (Brookes and Barfoot 2012; Monsanto 2012). According to 2010 market data[107], there were approximately 46.3

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[107] Monsanto Company. 2011. Farmer Survey Data. St. Louis, MO.

million herbicide-treated cotton acres. Herbicides were applied to 21.8 million acres prior to the planting or emergence of cotton (preemergent) and to 24.5 million acres after the emergence of cotton (postemergent). For clarification, the market survey data counts one treated acre as the application of one active ingredient (a.i.) one time to an acre. If the same a.i. is applied a second time to that same acre or if two a.i.s are applied, it counts as two treated acres. USDA reports that 11.0 million acres of cotton were planted in 2010,[108] so that the 46.3 million herbicide-treated cotton acres means that on average each planted acre received at least 4 herbicide treatments. Cotton acres also received on average four treatments with herbicides during the 2011 growing season (USDA-ERS 2012).

Of these treatments, 50% (23.3 million acres) were made with glyphosate herbicides, and the remaining 50% of treatments were made with more than 25 other active ingredients. The number of glyphosate applications on an average cotton acre was between 2 and 3 applications per year at an average rate of 2.0 pounds acid equivalent (a.e.) of glyphosate active ingredient per acre per crop year.

Herbicide-tolerant cotton is planted on the majority of U.S. cotton acres (73% in 2011), which allows for the postemergence in-crop use of glyphosate for control a broad spectrum of weeds. Glyphosate is the most widely-used herbicide in cotton, applied on 91% of cotton acres with an average of 2.4 applications per growing season (Monsanto 2012). In 2010, between 49 and 76% of the growers who plant glyphosate-tolerant (GT) cotton applied non-glyphosate herbicides prior to planting, at planting, or postemergence. Percentages varied among cropping systems, with 76% of GT cotton in a rotation system with GT soybean receiving non-glyphosate herbicide applications, whereas non-glyphosate herbicides were only applied 49% of the time in continuous cotton cropping systems (Prince, et al. 2011a). Non-glyphosate herbicides with different modes-of-action are also frequently used to provide residual weed control, improve control on certain weed species, and extend weed control or control resistant weed species (Prince et al. 2011a). The non-glyphosate herbicides applied on cotton in 2011, included ALS inhibitors (trifloxysulfuron, pyrithiobac), longchain fatty acid inhibitors (acetochlor, metolachlor), microtubule inhibitors (pendimethalin, trifluralin), PSII inhibitors (prometryn, fluometuron, diuron), PPO inhibitors (flumioxazin, fomesafen), synthetic auxins (2,4-D, dicamba), glufosinate, MSMA and paraquat (Monsanto 2012).

In 2010, dicamba-treated acres in cotton accounted for only 0.85 million acres, or 3.9% of the total preemergent treated acres.[109] This is primarily because dicamba is phytotoxic to current cotton varieties and is currently only labeled for application at timings that avoid contact with the growing plant, such as preplant treatments prior to planting, depending on rate and rainfall.

Over 30 different herbicide active ingredients are registered and available for use by cotton growers to control weeds. The ten most widely used alternative herbicides in cotton in 2010 are listed in Table B-18, compared to 2007 use. Integration of DGT cotton into the glyphosate-toleran cotton

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108 USDA Statistics for crops and geographic regions are available at http://www.nass.usda.gov/index.asp.

109 Monsanto Company. 2011. Farmer Survey Data. St. Louis, MO.

system and the subsequent use of dicamba will result in the displacement of some currently used, or foreseeable future use herbicides, and therefore the properties of these alternative herbicides are summarized in this section to provide a baseline for comparison to dicamba use on DGT cotton.

Table B-18. Ten Most Widely Used Alternative Herbicides in U.S. Cotton Production

Herbicide	2007 Applications (million lbs)[1]	2010 Applications (million lbs)[1]
Trifluralin	2.8	3.1
Diuron	1.3	1.3
Pendimenthalin	1.3	1.2
S-metolachlor	0.6	1.1
Prometryn	0.6	0.4
2,4D, dimethylamine salt	0.3	0.4
Fluormeturon	0.3	0.4
MSMA	0.4	0.3
Fomesafen	0.05	0.2
2,4-D, ethylhexyl ester	0.1	0.1

1 USDA-NASS, 2013

Table B-19 lists the most-widely used cotton herbicide products. Based on 2010 market data, the a.i.s listed in Table B-19 account for 46.2 million treated acres or 99.7% of the total herbicide-treated cotton acres. Table B-19 also summarizes some key information about the alternative herbicide products that are evaluated in this Environmental Report, such as signal word, re-entry interval, use rates, and label warnings or special directions.

Table B-19 lists further information about the herbicidal a.i.s used in cotton, such as the registration date, registration review status, U.S. EPA Registration Eligibility Decision (RED) date, where the tolerance information can be found, whether it is a reduced risk pesticide, and whether it is a restricted use pesticide.

Table B-19. Dicamba and Alternative Registered Cotton Herbicides.

Representative Brand (EPA Reg. No.)	Active Ingredient	2010 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Clarity (7969-137)	Dicamba	855 / 1.8	Caution	4.0 lb a.e./gal	24 hr	1.0 [1]	2.0 [1]	Known to leach; 50-foot buffer to wells; Runoff advisory; Drift advisory; State-specific limitations; Soil type limitations; Maximum crop rotation interval 3 – 6 months.
Ignite (264-829)	Glufosinate ammonium	1,297 / 2.8	Warning	2.34 lb/gal	12 hr	0.79	1.59	Toxic to vascular plants; May have runoff potential; Drift advisory; 70-day cotton PHI; Little or no activity in soil; Not in Hawaii or S. Florida.
Roundup WeatherMAX (524-537)	Glyphosate	23,345 / 50.4	Caution	4.5 lb a.e./gal	4 hr	3.71	5.96	Weed resistance advisory; Drift advisory; 7-day cotton PHI.
Treflan HFP (62719-250)	Trifluralin	4,098 / 8.8	Caution	4.0 lb/gal	12 hr	2	2	Extremely toxic to freshwater, estuarine, and marine fish and invertebrates; Some crops have long rotational interval (18 - 20 mos.); 90-day cotton PHI.
Direx 4L (352-678)	Diuron	2,110 / 4.6	Caution	4 lb/gal	12 hr	1.6	2.2	Drift Advisory; Crop rotation intervals of 12 months common; State-specific limitations; Soil type limitations; Do not feed treated foliage to livestock.
Prowl 3.3 EC	Pendimethalin	2,010 / 4.3	Caution	3.3 lb/gal	24 hr	2	2	Toxic to fish; Endangered plant species buffer required; Drift and runoff may be hazardous to aquatic organisms; Long (14 - 24 mos) crop rotation intervals for some crops; 60-day cotton PHI; State-specific limitation; Soil-type limitations; Do not feed treated foliage to livestock.

Representative Brand (EPA Reg. No.)	Active Ingredient	2010 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Valor SX (59639-99)	Flumioxazin	1,835 / 4.0	Caution	0.51 lb/lb	12 hr	0.06	0.13	Toxic to non-target plants & aquatic invertebrates; Runoff advisory; 40-foot aerial buffer to adjacent crops or water bodies; 12-month rotation interval common; Cotton injury possible; Do not feed treated foliage to livestock; 60-day cotton PHI.
Staple (352-576)	Pyrithiobac-sodium	1,689 / 3.6	Warning	0.85 lb/lb	24 hr	0.1	0.13	Highly toxic to non-target plants; Drift warnings; Cotton injury possible; Weed resistance advisory; 60-day cotton PHI; State-specific limitations (Staple LX); 10 – 12 month rotation intervals.
Staple LX (352-613)	Pyrithiobac-sodium		Caution	3.2 lb/gal	4 hr	0.1	0.13	
Dual Magnum (100-816)	S-Metolachlor	1,492 / 3.2	Caution	7.62 lb/gal	24 hr	1.27	2.48	Potential to leach; Potential for runoff; Ground & surface water advisory; State specific limitations; Soil type limitations; Swath adjustment 300 - 400 ft to avoid non-target plant injury; 80- to 100-day cotton PHI; Do not feed treated foliage to livestock.
MSMA 6 Plus (19713-42)	Monosodium Metharsonate	1,451 / 3.1	Caution	6 lb/gal	12 hr	1.88	3.75	50-foot buffer around all permanent water bodies; Drift warning about adjacent crops and sensitive areas; State specific limitations; No preplant cotton treatment; Do not feed treated foliage to livestock.
Barage HF (5905-529)	2,4-D Ethylhexyl Ester (EHE)	1.421 / 3.1	Caution	4.7 lb a.e./gal	12 hr	2.35 [2]	4.7 [2]	Toxic to aquatic invertebrates; Drift may adversely affect non-target plants or invertebrates; Groundwater advisory; Weed resistant biotypes known; Do not spray if wind above 15 mph.

Representative Brand (EPA Reg. No.)	Active Ingredient	2010 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Weedar 64 (71368-1)	2,4-D Dimethylamine Salt (DMA)	[see 2,4-D total above]	Danger	3.8 lb a.e./gal	48 hr	1.9 [2]	3.8 [2]	May be toxic to fish & aquatic invert; May result in groundwater contamination; Drift warning; Do not apply if wind above 15 mph; Apply only when sensitive areas or plants are not with 250 feet downwind.
Reflex (100-993)	Fomesafen-sodium	1,415 / 3.1	Danger	2.0 lb a.e./gal	24hr	0.375	0.375	May leach; Groundwater advisory; Some long rotation intervals (up to 18 mos.); Cotton injury warning; Weed resistance advisory; State-specific limitations; Soil type limitations; 70-day cotton PHI
Gramoxone Inteon (100-1217)	Paraquat	1,078 / 2.3	Danger	2.0 lb cation/gal	12 hr	1	3	Restricted Use Pesticide due to acute toxicity; May be fatal if swallowed or inhaled; Toxic to wildlife; Damage / toxicity to non-target crops / plants; Drift advisory; Cotton injury possible; Do not feed treated foliage to livestock; 3-day cotton PHI.
Cotoran (66622-181)	Fluometuron	786 / 1.8	Caution	4 lb/gal	24 hr	2	3	Known to leach; May result in groundwater contamination; Weed resistance advisory; Avoid drift to sensitive areas; 12-month rotation interval for many crops; State-specific limitations; Soil type limitations; Do not feed treated foliage to livestock; 60-day cotton PHI.

Representative Brand (EPA Reg. No.)	Active Ingredient	2010 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Caparol 4L (100-620)	Prometryn	867 / 1.9	Caution	4 lb/gal	24 hr	2.4	6	Drift and runoff may be hazardous to aquatic organisms; 400 ft upwind swath adjustment for sensitive plants; Weed resistance advisory; Crop injury possible; Soil type limitations; State-specific limitations; Do not feed treated foliage to livestock.
Envoke (100-1132)	Trifloxysulfuron-sodium	423 / 0.9	Caution	0.75 lb / lb	12	0.012	0.019	Toxic to vascular plants; Ground water advisory; Weed resistance advisory; Long rotational intervals (12 -22 mos, some zones); 60-day cotton PHI; 25-foot buffer around treated areas recommended; State specific limitations; Soil type limitations.
Aim EW (279-3242)	carfentrazone ethyl	89/0.16	Caution	1.9 lb/gal	12 hr	0.025	0.124	Carfentrazone-ethyl is very toxic to algae and moderately toxic to fish. Do not allow spray solution to contact cotton foliage, green stem tissue, or blooms.
Resolve DF (352-556)	rimsulfuron	11/0.02	Caution	granule	4 hr	Not labeled for Cotton	0.03	Do not apply preemergence to coarse textured soils (sand, loamy sand, or sandy loam) with less than 1% organic matter. Adequate soil moisture is required for optimum activity. Long rotational restrictions up to 10 months. Crop injury may occur following application if there is prolonged cold weather and/or wet soils.

Representative Brand (EPA Reg. No.)	Active Ingredient	2010 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Treaty (71368-74)	thifensulfuron methyl	81/0.15	Warning	granule	12 hr	0.02	Pre-plant burn down in cotton	Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Do not graze or feed forage or hay from treated areas to livestock. Weed control may be reduced if rainfall or snowfall occurs soon after application.
Victory (71368-75)	tribenuron methyl	70/0.13	Caution	granule	12 hr	0.0125	Pre-plant burn down in cotton	Weed control in areas of thin crop stand or seedling skips may not be satisfactory. Weed control may be reduced if rainfall or snowfall occurs soon after application. Do not apply later than 14 days before planting cotton. Do not graze or feed associated by products for 60 days after application.
ET Herbicide (71711-7	Pyraflufen ethyl	56/0.1	Danger	0.208 lb/gal	12 hr	0.003	0.013	This pesticide is toxic to fish and aquatic invertebrates. Allow a minimum of 30 days between applications for use on cotton. Apply to cotton having less than 3 inches of stem bark using hooded ground equipment only. Avoid contact with desirable vegetation.
Goal 2XL (62719-424)	oxyfluorfen	190/0.34	Warning	2 lb/gal	24 hr	0.5	1	This product is toxic to aquatic invertebrates and wildlife. Do not graze or harvest plants from treated areas for feed or forage. Treated soil must be thoroughly mixed to a depth of 4 inches after harvest prior to planting a rotational crop. Care must be taken to avoid spray contact with cotton leaves. Do not apply to cotton less than 6 inches tall or severe crop injury will result.

Representative Brand (EPA Reg. No.)	Active Ingredient	2010 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Resource (59639-82)	flumiclorac pentyl ester	15/0.03	Warning	0.86 lb/gal	12 hr	0.05	0.094	Causes substantial but temporary eye injury. This product is toxic to shrimp. Keep out of lakes, ponds, and streams. Do not graze animals on green forage or use as feed fewer than 28 days after application.

[1] Dicamba rates cited are those proposed for use on DGT cotton.

[2] 2,4-D products are not labeled for cotton treatments. Preplant treatments, more than 29 days before planting, are used for burndown weed control using the Fallow portion of the label.

[3] Monsanto private market survey data. The data shown are for the cotton acres to which the relevant active ingredient was applied in 2010, and the percentage of total treated acres this constitutes. A treated acre is application of one active ingredient once. Multiple active ingredients or multiple applications results in total treated acres that exceed total planted cotton acres. No entry is shown for products containing more than one active ingredient, since these acres are counted in the single active ingredient rows.

Table B-20. Dicamba Compared to Active Ingredients Contained in Alternative Herbicide Products.

Active Ingredient	First Registered	Regis-tration Review Status [1]	RED Date	Max. Cotton lb/a (single application) [2]	Max. Cotton lb/a (season) [2]	Tolerances 40 CFR 180.	Reduced Risk	Restricted Use
dicamba-diglycolamine salt	2-Feb-56	unsched.	2006	1.0[3]	2.0[3]	227	N	N
Glufosinate-ammonium	Glufosinate-ammonium	29-May-91	2008	N/A	0.79	1.59	473	Yes
Glyphosate (salts)	Glyphosate (salts)	7-Sept-88	2009	09/23/2009	3.71	5.96	364	Yes
Herbicide a.i.s Applied Primarily at a PE Timing								
2,4-D EHE (esters)[4]	3-Jun-52	2013	2005	2.0 [5]	4.0 [5]	142	N	N
2,4-D DMA (salts)[4]				2.0 [5]	4.0 [5]			
flumiclorac pentyl	23-Mar-94	2009	N/A	0.05	0.094	477	Yes	No
S-metolachlor	18-May-83	2016	12/01/1994	1.27	2.48	368	Yes	No
oxyfluorfen	17-May-79	2015	10/01/2002	0.5	1	381	No	No
pyraflufen ethyl	27-Sept-02	2014	N/A	0.003	0.013	585	No	No
rimsulfuron	20-Sept-89	2012	N/A	Not labeled for cotton	0.03	478	No	No
thifensulfuron methyl	25-Apr-86	2011	N/A	0.02	N/A	439	No	No
tribenuron methyl	22-May-89	2011	N/A	0.0125	N/A	451	No	No
Herbicide a.i.s Applied at both PE and POE Timings								
carfentrazone ethyl	02-Aug-95	2011	N/A	0.025	0.124	515	Yes	No
fluometuron	28-May-74	Unsched.	09/28/2005			229	No	No
fomesafen sodium	10-Apr-87	2007	N/A	0.375	0.375	433	No	No
paraquat dichloride	08-Jan-80	2011	08/01/1997	1	3	205	No	Yes
Prometryn	19-Aug-74	2013	1996	2.4	5.95	222	N	N
Pyrithiobac-Sodium	29-Jun-95	docket '11	NA	0.1	0.13	487	N	N
Herbicide a.i.s Applied Primarily at a POE Timing								
flumioxazin	01-Aug-96	2011	N/A	0.06	0.13	568	No	No

MSMA	25-Dec-63	2013	2006 corr 2009	1.88	3.75	289	N	N
pendimethalin	20-Mar-75	2012	04/01/1997	2	2	361	No	No
trifloxysulfuron-sodium	29-Jun-03	2013	NA	0.012	0.019	591	N	N
trifluralin	04-Dec-68	2012	09/01/1995	2	2	207	No	No

1 Registration Review Status: year docket is scheduled to open, unless unscheduled. FWP = Final Work Plan stage. If docket is open, “docket XX” = year opened.

2 Rates for dicamba, 2,4-D, fomesafen, and glyphosate are expressed as acid equivalents. All others are on an a.i. basis, as stated, except paraquat is on a cation basis. Regional or soil type limitations may lower this rate.

3 Maximum treatment rates for the proposed dicamba label on DGT cotton.

4 For the 2,4-D ester group, the ethylhexyl ester (EHE) is taken as representative. For the salt group, the dimethylamine (DMA) salt is taken as representative.

5 Rates taken from Master 2,4-D Label (http://www.24d.org/masterlabel/default.aspx) for Fallow application. There are no specific cotton treatment directions. Fallow application must precede planting by 29 days or more.

Soil residual herbicides play an important role in cotton weed management by providing control of a number of weeds species that continuously germinate in cotton prior to canopy closure (Wilcut et al. 2003). Soil residual herbicides, such as pendimethalin, trifluralin, diuron, fluometuron, acetochlor, and metolachlor, are applied to more than 40% of the current cotton acres (Monsanto 2012). In addition, many of the soil residual herbicides are limited by application restrictions, plant-back restrictions, the need for adequate soil moisture for activation, and the need to apply prior to planting or with hooded sprayers in-crop to minimize crop injury. Approximately 20% of growers applied a fall residual herbicide to control weeds prior to planting the following spring, and 60% (continuous cotton system) to 75% (GR cotton/GR soybean rotation) applied a mixture of glyphosate and a synthetic auxin herbicide (2,4-D or dicamba) as a spring burndown application (Prince et al. 2011a). Post emergent residual herbicides, such as metolachlor and acetochlor, were applied on over 25% of cotton acres in 2010 (Monsanto 2012).

Further details on the use of non-glyphosate herbicides in cotton producing states can be found in Prince et al. (2011a; 2011b), where it is reported that approximately 50% of surveyed growers who did not have glyphosate-resistant weeds on their farm used a non-glyphosate residual and/or postemergence herbicide in the 2009 growing season. For growers who have on-farm herbicide-resistant weed populations, the percentage of growers was higher, with 72% to 75% reporting the use of non-glyphosate herbicides. Older studies report that approximately 40 to 50% of the growers utilizing glyphosate-tolerant crops indicate that applying herbicides with different modes-of-action in sequence, rotating herbicides with different modes-of-action across the season, or tank mixing glyphosate with other herbicide modes-of-action are effective management practices to minimize the evolution and/or development of glyphosate resistance (Beckie 2006; Beckie and Reboud 2009; Diggle et al. 2003; Powles et al. 1996). The use of non-glyphosate herbicides in cotton production is expected to continue to increase as more growers adopt more diversified weed management strategies.

B.3.4. Herbicide-resistant Weeds in Cotton Production

Glyphosate-resistant weed biotypes found in cotton fields in certain areas of the U.S. may include broadleaf biotypes of Palmer amaranth, waterhemp, common ragweed, giant ragweed, marestail, spiny amaranth (*Amaranthus spinosus*), and grass biotypes of ryegress, Johnsongrass (*Sorghum halapense*) and goosegrass (*Elusine indica*) (Heap 2012). The emergence and growth of herbicide-resistant weeds (including glyphosate-resistant weed biotypes) in certain areas of the U.S. over the past decade, has required growers to adapt and implement improved weed management strategies.

The occurrence of weed-resistant biotypes varies across the cotton-growing regions, with more resistance issues observed in certain areas of the Southeast and Midsouth cotton-growing regions. Table B-21 summarizes known resistance among the major weed species present in the southern U.S. for each of the key herbicide groups and herbicide classes that are efficacious on broadleaf weeds (Heap 2013a). *Amaranthus* spp., in particular Palmer amaranth, are problematic weeds in the mid-south and southeastern U.S. Palmer amaranth is considered to be one of the most competitive and aggressive of the *Amaranthus* spp. because of its rapid growth and prolific seed production. In addition, it has developed resistance to multiple herbicide classes (glycines, ALS, and dinitroanilines) (Culpepper et al 2011; Heap 2013b). Managing herbicide-resistant Palmer amaranth has proven to be challenging due to the biology of this particular weed, including its dioecious nature (the male and female flowers occur on separate plants), which leads to greater genetic diversity in the plant population and increases the potential for spreading herbicide resistance (Sosnoskie et al. 2011).

Resistance to the ALS group of herbicides is present in most of the major broadleaf weed species commonly found in cotton. For *Amaranthus* spp. and *Ambrosia* spp., there is known resistance to at least one member for several of the major herbicide chemistry classes. In an effort to manage glyphosate-resistant Palmer amaranth in certain areas of the U.S., certain non-glyphosate cotton herbicides are being used in conditions and practices that can result in increased selection of resistant biotypes to those herbicides, and as a result some key agricultural herbicides in some major herbicide classes, such as glufosinate and PPO inhibitors, are at further risk (Nichols et al. 2010; Prostko 2011a; b) (Dr. Larry Steckel and Dr. Stanley Culpepper, personal communications, August 2012). While there are effective options for managing *Ambrosia* spp., and *Amaranthus* spp., including Palmer amaranth and other key broadleaf weeds, the availability of additional herbicide modes-of-action will help combat potential future resistance of the key herbicides needed for weed management in cotton. In addition, there has been an increase in the detection of weed populations with multiple resistances (*i.e.*, resistance to multiple herbicide modes-of-action) in some weed species, for example, *Amaranthus* spp. (Tranel et al. 2010). The emergence of these resistant biotypes in certain areas of the U.S. highlights the continuing need to utilize diversified weed management practices and the ongoing need for additional herbicide modes-of-action that are effective in major crops.

The relative occurrence of herbicide-resistant weeds varies between the different sub-groups of auxinic (phenoxy in Table B-21) herbicides. Considering that auxin herbicides have been widely used in agriculture for more than 60 years, weed resistance to this class is relatively low (29 species, to date, worldwide) and its development has been slow especially when compared to the speed of appearance of resistance to ALS inhibitors (107 species) or triazine-resistant populations (68 species) (Heap 2012b). The relatively low incidence of auxinic herbicide resistance is believed to be attributable to the fact that there are multiple target sites for these herbicides (Gressel and Segel 1982; Morrison and Devine 1993).

Specific weed management recommendations by area or farm are made by local experts versed in the best methods for both proactive and reactive resistance management. Since more than 53.4% of cotton is repeatedly grown on the same land with only limited utilization of conservation tillage practices, the use of multiple herbicide modes-of-action with overlapping effectiveness on the targeted weed spectrum is the primary method recommended and employed for weed resistance management. Studies have shown that using the same combination of herbicides with multiple modes-of-action and overlapping effectiveness over multiple seasons can effectively manage resistance (Beckie and Reboud 2009). Monsanto and the weed scientist community recommend the use of multiple herbicide modes-of-action in herbicide-tolerant cotton systems regardless of whether glyphosate-resistant or hard-to-control broadleaf weeds are present (University of Georgia 2012; University of Tennessee 2012). APHIS has deregulated multiple herbicide-tolerant cotton traits (Table B-22), and the use of diversified weed management systems with these traits helps ensure sustained profitable cotton production across the Cotton Belt. For growers using the herbicide-tolerant cotton systems, Monsanto and university extension weed scientists provide recommended control options for herbicide-resistant weeds[110] (Bond et al. 2011; Culpepper et al. 2013; Ferrell et

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110 https://www.roundupreadyplus.com

al. 2012; Jordan et al 2011; Monsanto Company 2012; Norsworthy et al. 2012; Price et al 2011; Prostko 2011b; University of Tennessee 2012). These options include the use of residual and postemergence herbicides such as microtubule inhibitors (pendimethalin, trifluralin), PSII inhibitors (diuron, fluometuron, prometryn), PPO inhibitors (flumioxazin, fomesafen), long-chain fatty acid inhibitors (acetochlor, metolachlor), synthetic auxins (2,4-D, dicamba), and ALS inhibitors (pyrithiobac).[111] These herbicides alone or in combinations, as well as traditional tillage methods, are and will continue to be used to control herbicide-resistant or hard-to-control broadleaf weeds.

111 Monsanto Technology Use Guide; www.weedresistancemanagement.com.

Table B-21. Known Weed Resistance in the Southern U.S. in 2012[1]

Resistance (Group) [2]	**ALS (Group 2)**	**PPO (Group 14)**		**PSI (Group 22)**	**PS II (Group 5)**	**PS II (Group 7)**	**Organo-arsenicals (Group 25)**	**Microtubule Assembly Inhibitors (Group 3)**	**Glycine (Group 9)**	**Phenoxy (Group 4)**	
Chemistry Class [2]	sulfonylurea	diphenyl ether	N-phenyl thalimide	bipyridiliums	triazine	ureas	organo-arsenicals	dinitroaniline	glycine	phenoxy	benzoic acid
Cotton Herbicide Examples	Trifloxy-sulfuron	Fomesafen	Flumioxazin	Paraquat	Prometryn	Diuron Fluometuron	MSMA	Trifluralin	Glyphosate	2,4 D	Dicamba
Most Common Broadleaf Weeds in Southeast / Midsouth (# of states listing as a top weed)											
morningglory (11) *Ipomoea spp.*											
prickly sida (9) *Sida spinosa*											
pigweed spp. (6) *Amaranthus* spp.[3]	X	X			X	X			X		
Palmer amaranth (4) *Amaranthus palmeri*	X				X			X	X		
Florida Pusley (4) *Richardia scabra*											
sicklepod (4) *Senna obtusifolia*											
cocklebur (3) *Xanthium strumarium*	X						X				
horseweed (marestail) (3) *Conyza canadensis*	X			X	X	X			X		
Ragweed spp. (2) *Ambrosia* spp.	X	X	X						X		
Florida Beggarweed (2) *Desmodium tortuosum*											

[1] Source: (Heap 2012), www.weedscience.org

[2] Cross resistance is possible within a resistance group and/or chemistry class.

[3] Includes redroot pigweed, smooth pigweed and common waterhemp.

Note: Blank boxes indicate no resistant biotypes for weed species/ herbicide combination in Southern U.S.

Table B-22. Deregulated Biotechnology-derived Cotton Products[1]

Phenotype	Event	Institution	Deregulation Effective Date
Glufosinate tolerant, Lepidopteran resistant	T303-3XGHB119	Bayer CropScience	August, 2012
Glufosinate tolerant, Lepidopteran resistant	T304-40XGHB119	Bayer CropScience	October, 2011
Lepidopteran resistant	COT 67B	Syngenta	September, 2011
Glyphosate tolerant	GHB614	Bayer CropScience	May, 2009
Glyphosate tolerant	MON 88913	Monsanto	December, 2004
Lepidopteran resistant	COT 102	Syngenta	July, 2005
Lepidopteran resistant	281-24-236	Mycogen/Dow	July, 2004
Lepidopteran resistant	3006-210-23	Mycogen/Dow	July, 2004
Phosphinothricin tolerant[2]	LLCotton25	Aventis	March, 2003
Lepidopteran resistant	Cotton 15985	Monsanto	November, 2002
Bromoxynil tolerant and lepidopteran resistant	31807 and 31808	Calgene	April, 1997
Sulfonylurea tolerant	19-51a	DuPont	January, 1996
Glyphosate tolerant	1445, 1698	Monsanto	July, 1995
Lepidopteran resistant	531, 757, 1076	Monsanto	June, 1995
Bromoxynil tolerant	BXN	Calgene	February, 1994

[1] USDA-APHIS 2013.
[2] Glufosinate tolerant.

B.3.4.1. Sustainable Use of Dicamba as a Weed Management Option in Cotton

DGT cotton will be sold only in cotton varieties that also contain other herbicide-tolerant traits, including glyphosate-tolerance. Cotton varieties containing both DGT cotton and a glyphosate-tolerant system will enable dicamba and glufosinate to be applied with glyphosate and/or other cotton herbicides in an diversified weed management program. Dicamba primarily will be used in mixtures with either glyphosate or glufosinate or in sequence with glyphosate or glufosinate to control a broad spectrum of grass and broadleaf weed species. Glyphosate and glufosinate will not be used in mixtures due to antagonism (i.e., glufosinate damages the leaf tissue before glyphosate gets into the plant and/or can be translocated to growing parts of the plant) that reduces the efficacy of glyphosate on susceptible weed species. Dicamba and glufosinate applications on DGT cotton will provide effective control of glyphosate-resistant broadleaf weeds and improve the control of annual and perennial broadleaf weed species, some of which are difficult to control with glyphosate. Dicamba and glufosinate will also help mitigate the potential for the evolution and development of and/or combat existing weed resistance issues that can limit the use of the PPO- and ALS-inhibiting herbicide groups by providing additional modes-of-action for management of certain broadleaf species known to be prone to resistance to many of the current herbicide options for weed management (i.e., A*marathus* spp.). Likewise, dicamba will help to mediate potential evolution of resistance to glufosinate in broadleaf species and glufosinate will do the same for the potential evolution of resistant broadleaf species to dicamba. Cultivation of a combined DGT cotton and glyphosate-tolerance trait product will foster the adoption of Integrated Pest Management (IPM) practices in cotton by allowing growers to continue to primarily focus on postemergence in-crop weed control, as they have practiced with the glyphosate-tolerant cotton systems. This will allow growers to delay some herbicide treatments until field scouting indicates a need for additional postemergence weed control which is consistent with the principles of IPM, and also herbicide resistance management practices. Increasing postemergence herbicide options in cotton is important, especially in conservation tillage situations, where consistency of postemergence herbicides has generally been greater than that of soil active residual products, which have greater degree of inconsistent weed control, and thus has been a factor in the adoption of conservation tillage systems in the U.S.

Upon the integration of DGT cotton into the glyphosate-tolerant cotton systems and proposed approval of the use of dicamba on DGT cotton by the U.S. EPA, preplant/preemergence applications of dicamba can be made up to 1.0 lb a.e./acre up through crop emergence (cracking) and in-crop postemergence applications up to 0.5 lb a.e./acre could be applied through 7 days preharvest, with the combined total not to exceed 2.0 lbs a.e. dicamba per year for all applications. Residual herbicides also will be recommended for use, to provide early season weed control and to supplement dicamba and glufosinate activity on certain hard-to-control and glyphosate-resistant weed biotypes, such as glyphosate-resistant Palmer amaranth where weed populations can be very substantial.

Dicamba and glufosinate, as complementary herbicides to glyphosate, will provide new weed control options in cotton that strengthen the utility and sustainability of glyphosate as a weed control tool for the combined DGT cotton glyphosate-tolerance trait product.

In the event that there is known or suspected presence of a dicamba-resistant or glufosinate-resistant weed biotype, other options for managing the resistant biotypes are available to the grower. There are multiple preemergence (including soil residuals) and postemergent herbicide options for managing weed populations that are resistant or may potentially develop resistance to dicamba or glufosinate in cotton, as well for crops grown in rotation with cotton. These options are noted in Table B-23.

Table B-23. Management Recommendations for Control of Dicamba-, Glufosinate- and Other Selected Synthetic Auxin-Resistant Weeds

				Rotational Crops		
Weed Species [1]	**Herbicide Resistant Biotypes**	**Primary Crop Cotton**	**Corn**	**Sorghum**	**Soybeans**	**Wheat**
Kochia	dicamba, fluroxpyr (populations also resistant to glyphosate)	Clomazone[a] Flumioxazin[i] Glyphosate[i] Paraquat[i]	Atrazine[a] Saflufenacil[a] Isoxaflutole[a] Mesotrione[a] Glyphosate[a]	Atrazine[a] Saflufenacil[a] Isoxaflutole[a] Mesotrione[a] Glyphosate[a]	Saflufenacil[a] Clomazone[a] Flumioxazin[a] Glyphosate[a] Paraquat[a]	Saflufenacil[a] Glyphosate[a] Bromoxynil/MCPA[a]
Prickly Lettuce	Dicamba, 2,4 D, MCPA	Glyphosate[i] Paraquat[i] Flumioxazin[i]	Saflufenacil[a] Atrazine[a] Carfentrazone + atrazine[a] Isoxaflutole + atrazine[a]	Saflufenacil[a] Atrazine[a] Carfentrazone + atrazine[a] Isoxaflutole + atrazine[a]	Saflufenacil[a] Chlorimuron/ metribuzin[c] Glyphosate + imazethapyr[a]	Saflufenacil[a] Triasulfuron[a] Metsulfuron + thifensulfuron[a]a
Wild mustard	Dicamba , 2,4 D,MCPA, picloram, dichlorprop, mecoprop	Glyphosate[i] Paraquat[i]	Glyphosatei[c] Atrazine[c] Primisulfuron[c] Nicosulfuron[d] Halosulfuron[d]	Glyphosatei[c] Atrazine[c] Primisulfuron[c] Nicosulfuron[d] Halosulfuron[d]	Glyphosate[c] Chlorimuron[c] Chlorimuron/ metribuzin[c]	
Field Bindweed	2,4 D	Glyphosate[i] Paraquat[i] Flumioxazin[i]	Glyphosate[a] Glyphosate + imazethapyr[a] Glyphosate + Imazamox[a]	Glyphosate[a] Glyphosate + imazethapyr[a] Glyphosate + Imazamox[a]	Glyphosate[c]	Glyphosate[a]
Yellow Starthistle[e]	Picloram					

Table B-23 (continued). Management Recommendations for Control of Dicamba-, Glufosinate- and Other Selected Synthetic Auxin- Resistant Weeds

			Rotational Crops			
Weed Species[1]	**Herbicide Resitant Biotypes**	**Primary Crop Cotton**	**Corn**	**Sorghum**	**Soybeans**	**Wheat**
Spreading Dayflower	2,4 D					Bentazon halosulfuron penoxsulam bispyribac[f]
Lambsquarters[g]	Dicamba	Paraquat[i] Flumioxazin[i] Glyphosate[b]		Isoxaflutole[a] Atrazine[a] Saflufenacil[a] Mesotrione[a] Bromoxynil[b]	Metribuzin[b] Cloransulam[b] Saflufenacil[a] Imazamox[b] Glyphosate[b]	Bromoxynil[a] Chlorsulfuron / Metsulfuron[a] Glyphosate[h] Saflufenacil[a]
Goosegrass	Glufosinate	Clethodim[h] Glyphosate[h] pendimethalin[h] trifluralin[h]	Glyphosate[h] pendimethalin[h]	Glyphosate[h]	Clethodim[h] Glyphosate[h] pendimethalin[h] trifluralin	Glyphosate[h]
Italian ryegrass	Glufosinate (populations also resistant to glyphosate)	Metolachlor (fall applied)[h] Clethodim[h] Glyphosate[h] Paraquat[i]	Metolachlor (fall applied)[h] Glyphosate[h]	Metolachlor (fall applied)[h] Glyphosate[h]	Metolachlor (fall applied)[h] Clethodim[h] Glyphosate[h]	Glyphosate[h]
Waterhemp	2,4 D[j]	Fomesafen[k] Fluometuron[k] Metolachlor[k] Diuron[k] Flumioxazin[k]	Metolachlor[l] Atrazine[l] Saflufenacil[l] Mesotrione[l] Carfentrazone[l]	Metolachlor[m] Fluroxypyr[m] Atrazine[m] Saflufenacil[m] Carfentrazone[m]	Metolachlor[l] Flumioxazin[l] Sulfentrazone + metribuzin[l] Fomesafen[l] Acifluorfen[l]	Metsulfuron[n] Triasulfuron[n] Prosulfuron[n] Fluroxypry+ bromoxynil[n]

[1]Scientific names for each weed species can be found in Table VIII-4 of the DGT coybean Petition for Deregulation.
[a]Bernards et al., 2010.
[b]Loux et al., 2010.
[c]MSU, 2010.
[d]Kells and Stachler, 1997.
[e]PNWE, 2010.
[f]University of Arkansas CES, 2010.
[g]Resistance to lambsquarters has only been confirmed in New Zealand.
[h]Steckel et al., 2011
[i]Smith et al., 2012
[j]Bernards et al., 2012.
[k]Mississippi State University, 2013
[l]Loux et al., 2013
[m]University of Missouri,2013
[n]University of Nebraska, 2013

B.3.4.2. Stewardship of Dicamba Use on DGT Cotton

In order to steward the use of agricultural herbicides and herbicide-tolerant cropping systems such as the combined trait DGT cotton and glyphosate-tolerant cotton product, Monsanto has conducted investigations and worked extensively with academics and other herbicide manufacturers to understand and recommend best practices to manage herbicide resistance. These investigations have demonstrated that one of the major factors contributing to the development of resistant weed biotypes in certain areas of the U.S. has been inadequate weed control management practices. The primary reasons for lack of adequate management includes: 1) application of herbicides at rates below those indicated on the product label for the weed species, and 2) sole reliance on a particular herbicide for weed control without the use of other herbicides or cultural control methods (Beckie, 2006; Peterson et al., 2007).

B.3.4.3. Weed Control Recommendations

The proposed label for dicamba use on DGT cotton – which is currently pending before EPA - is based on the maximum allowable use rates and patterns. Prior to launch of DGT cotton in glyphosate-tolerant cotton systems, Monsanto, in cooperation with academics, will conduct trials to confirm the optimum rate and timing for dicamba, glufosinate and glyphosate, alone and in combination, and other herbicides. Recommendations to growers will be developed from this information and will be provided in herbicide product labels, Monsanto's Technology Use Guide (TUG), and in other education and training materials to be broadly distributed. Specifically, current research conducted by Monsanto to define the optimum weed management systems support use recommendations that include the application of dicamba and glyphosate for preemergence on conservation tillage acres and early postemergence in-crop applications. In some situations, a second in-crop application of either dicamba tank-mixed with glyphosate or glufosinate, with or without a soil residual will be recommended (see Section VIII.G.4 for additional details)

These recommendations will ensure more than one mechanism of action against the targeted species, which is a fundamental component of a good weed resistance management program. These management systems, which include the use of multiple effective herbicide modes-of-action, will reduce the potential for further resistance development to glyphosate, dicamba, and glufosinate, as well as other critical cotton herbicides. Furthermore, the preplant weed spectrum is generally different from the in crop weed spectrum; therefore, multiple applications of glyphosate and dicamba are not expected to increase selection pressure on either herbicide.

B.3.4.4. Dispersal of Technical and Stewardship Information

To support the introduction of varieties containing DGT cotton, Monsanto will use multiple methods to distribute technical and stewardship information to growers, academics and grower advisors regarding the use of the product as part of a diversified weed management system. Growers who purchase Monsanto varieties containing DGT cotton sign a limited use license known as the Monsanto Technology Stewardship Agreement (MTSA). The MTSA obligates growers to comply with certain requirements, including the Monsanto

Technology Use Guide (TUG). The TUG will set forth the requirements and best practices for the cultivation of DGT cotton including recommendations on weed resistance management practices.

The weed resistance management practices that will be articulated in the TUG will also be broadly communicated to growers and retailers in order to minimize the potential for the development of resistant weeds. These practices will be communicated through a variety of means, including direct mailings to each grower purchasing a cotton variety containing DGT cotton, a public website, and reports in farm media publications. The overall weed resistance management program will be reinforced through collaborations with U.S. academics, who will provide their recommendations for appropriate stewardship of dicamba and glufosinate in cotton production, as well as by collaboration with crop commodity groups who have launched web-based weed resistance educational modules. Finally, Monsanto will urge growers to report any incidence of repeated nonperformance of dicamba or glufosinate on weeds in fields planted with DGT cotton, and Monsanto will investigate cases of unsatisfactory weed control to determine the cause as discussed below in Section B.4.4.6.

EPA regulates under FIFRA the pesticides (including herbicides) that are used with crops, including GE herbicide-tolerant crops like DT soybean and DGT cotton. FIFRA requires all pesticides to be registered before distribution or sale, unless they are exempted. Under FIFRA, EPA must approve each distinct pesticide product, each distinct use pattern, and each distinct use site. Each crop for example, consititues a unique use site and no registered pesticide may be applied to any crop unless EPA has approved that specific pesticide/crop use.

EPA encourages pesticide manufacturers to provide growers with information regarding an herbicide's mode-of-action to aid growers in planning herbicide use practices and to foster the adoption of effective weed resistance management practices as specified by EPA in Pesticide Registration (PR) Notice 2001-5 (U.S. EPA, 2001). In that document, EPA states that "this approach to resistance management is sound and would be highly beneficial to pesticide manufacturers and pesticide users." It is a violation of FIFRA to use any registered pesticide in a manner inconsistent with its labeling, subject to criminal and civil penalty. [112] For that reason, an approved herbicide cannot be lawfully used on a corresponding herbicide-tolerant crop, unless EPA approves a label amendment for such use.

In summary, Monsanto will require weed resistance management practices through the MTSA and TUG for its biotechnology-derived herbicide-tolerant products, such as DGT cotton integrated into the glyphosate-tolerant cotton systems, and to promote these practices through product labeling and educational outreach efforts as an effective means to mitigate the potential for weed resistance development for dicamba, glufosinate, and glyphosate.

[112] FIFRA §12(a)(2)(G) and §14

B.3.4.5. Weed Resistance Management Practices

Monsanto will provide information to growers and grower advisors on best management practices to mitigate the potential for evolution and development of resistance to dicamba and glufosinate. The weed resistance management recommendations for the use of dicamba and glufosinate in conjunction with cotton varieties containing DGT cotton will be consistent with the Herbicide Resistance Action Committee's guidelines for prevention and management of herbicide resistance (HRAC, 2010). These guidelines recommend an diversified approach to weed resistance management, including crop management (i.e., cover crops, crop rotation, etc.), cultivation techniques, and the use of multiple herbicide modes-of-action to manage a weed population.

In cases where resistance is confirmed for dicamba or glufosinate in cotton producing areas, Monsanto and university/Cooperative Extension Service (CES) personnel will provide recommendations for alternative herbicide control methods to growers. These recommendations would be made available through Monsanto supplemental labels, Monsanto and university publications, and internet sites to growers, consultants, retailers and distributors. For all existing cases of dicamba-resistant and glufosinate-resistant weeds in the U.S. and globally today, alternative herbicides and cultural methods are available to growers to effectively control these biotypes. Examples of recommended alternative herbicides from university/CES personnel that are applicable to weed species known to be resistant to glufosinate, dicamba and other synthetic auxin herbicides are found in Table B-23. However, these examples in Table B-24 are only a subset of product combinations of available cotton herbicides.

B.3.4.6. Monsanto Weed Performance Evaluation and Weed Resistance Management Plan

An important part of a weed resistance management plan is the timely acquisition of information regarding product performance. Monsanto has an extensive technical, sales and marketing presence in the cotton markets where DGT cotton will be grown. Through our relationships with farm advisors, key university/CES personnel, and growers using our seeds and traits products, Monsanto will acquire important and timely information regarding product performance. This will allow the timely recognition of performance issues that could arise related to weed resistance or other means. Field employees and hired consultants are trained and provided processes for responding to product performance inquiries. Individual performance issues that could be related to potential resistance are promptly handled. In addition, performance inquiries are periodically reviewed by Monsanto for trends that could indicate the need for follow up action on a broad scale.

If dicamba or glufosinate resistance is confirmed, the scientific and grower communities will be notified and a weed resistance mitigation plan will be implemented by Monsanto in cooperation with the university/CES and/or the appropriate herbicide producer . The mitigation plan will be designed to manage the resistant biotype through effective and economical weed management recommendations implemented by the grower. The scope and level of intensity of the mitigation plan may vary depending on a combination of the following factors: 1) biology and field characteristics of the weed (seed shed, seed dormancy, etc.), 2) importance of the weed in the agricultural system, 3) resistance status of the weed to other herbicides with alternate modes-of-action, and 4) availability of alternative control options. These factors are analyzed by Monsanto and university/CES personnel in combination with economic and practical management considerations to develop a tailored mitigation strategy. The plan considers what is technically appropriate for the particular weed and incorporates practical management strategies that can be implemented by the grower.

After a mitigation plan is developed, Monsanto communicates the plan to the grower community through the use of supplemental herbicide labeling (labeling which includes newly approved use directions, or other instructions), informational fact sheets, retailer training programs, agriculture media and/or other means, as appropriate.

In addition to the grower inquiry-initiated process, Monsanto, alone and/or in cooperation with university/CES, will conduct field studies to understand the potential for weed resistance and weed shifts as the result of various weed management programs implemented for DGT cotton integrated into glyphosate-tolerant cotton systems. These studies will allow researchers to better track specific factors that can influence the development of resistance to specific weeds.

B.3.5. Benefits of DGT Cotton Production

B.3.5.1. Overview

DGT cotton will provide additional weed management options for effective and sustainable weed management in cotton production. DGT cotton will be combined with glyphosate-tolerant cotton utilizing traditional breeding techniques. This combination of herbicide-tolerance traits will allow growers to use dicamba, glufosinate and glyphosate herbicides in a diversified weed management program to control a broad spectrum of grass and broadleaf weed species. DGT cotton will contribute additional benefits and value to the well-established and effective glyphosate-tolerant weed control systems in cotton. Glyphosate provides excellent control of many annual and perennial grass and broadleaf weed species. Dicamba provides effective control of many summer and winter annual broadleaf weed species and will be very complementary to glyphosate by offering improved control of hard-to-control broadleaf weed species in cotton, including Florida pusley, hemp sesbania, lambsquarters, morningglory species, prickly sida, purslane, and Pennsylvania smartweed. Glufosinate will offer improved control of certain broadleaf weeds, including lambsquarters and morning glory species as compared to glyphosate. Dicamba and glufosinate will also offer effective control options for glyphosate-resistant broadleaf weed biotypes in certain areas of the U.S., including glyphosate-resistant biotypes of Palmer amaranth, horseweed, and common ragweed. Additionally, dicamba and glufosinate will offer an effective control option for broadleaf species resistant to other herbicide classes (*e.g.*, ALS and PPO chemistries). DGT cotton will provide growers expanded use of dicamba in cotton production by enabling preemergence applications of dicamba at rates up to 1.0 lb a.e. per acre up to the day of crop emergence and postemergence in-crop applications up to 0.5 lbs. a.e. per acre per application up through seven days prior to harvest. Additionally, like commercially available glufosinate-tolerant cotton, DGT cotton enables application of up to 0.53 lb a.i. per acre per application of glufosinate from emergence through early bloom growth stage.

Beginning in 2010, numerous field experiments have been conducted by university weed control specialists and Monsanto researchers in the Southeastern and Midsouth regions of the U.S. and Texas to evaluate the efficacy of weed control programs in dicamba, glufosinate, and glyphosate-tolerant cotton. These studies evaluated the control of glyphosate-resistant and hard-to-control weeds with the primary focus on the control of glyphosate-resistant Palmer amaranth. Dicamba, glufosinate, and tank mixtures of dicamba plus glyphosate or glufosinate were evaluated in weed control programs involving preemergence residual herbicides on the stacked trait cotton product. These experiments provided valuable data for determining the best recommendations and weed management systems for optimum control of weeds in various climatic conditions and cotton production systems across the various cotton regions of the U.S.

The expected use patterns for dicamba and glufosinate on DGT cotton will vary across U.S. cotton growing regions. This variability is dictated by the environment, weed spectrum and tillage options. In general cotton acres are expected to receive one or two in-crop application of dicamba regardless of tillage. Conservation tillage or no-tillage acres are expected to receive an additional preplant application of dicamba. One application of glufosinate is recommended in the MidSouth and Southeast where glyphosate-resistant weeds are present, regardless of tillage. In addition, glyphosate and soil residuals will be included in the recommended weed management programs for DGT cotton.

Monsanto and university weed control specialists recommend and encourage the use of preemergence and/or postemergence applications of soil residuals, along with postemergent products, as part of a comprehensive weed resistance management program. This ensures that two or more effective herbicide modes-of-action are used to provide protection against additional resistance development to existing cotton herbicides (Bullington et al., 2011; Culpepper et al., 2011; Steckel et al., 2012). Preemergence soil residuals also provide early-season weed control to reduce early weed competition to protect yield potential and provide greater flexibility in timing of postemergence applications. In addition, preemergence residuals will assist in the control of grasses and certain hard-to-control weed species. The addition of soil residual herbicides is an effective component of a program for optimum weed control and long-term sustainability of cotton weed control products.

Table B-24. Anticipated Weed Management Recommendations for DGT Cotton Combined with Glyphosate-Tolerant Cotton Systems for MO, AR, TN, AL, FL, GA, NC, SC, VA, LA, MS, eastern TX and CA.[1,2]

Application Timing	Conventional Tillage	Conservation Tillage (No-till or reduced till)
Preplant burndown and/or Preemergence	Residual	Dicamba + Glyphosate + Residual
Postemergence 1	Dicamba + Glyphosate + Residual[3]	Dicamba + Glyphosate + Residual
Postemergence 2	Glyphosate OR Glufosinate[4,5]	Glyphosate OR Glufosinate + Residual[5,6]

[1] Recommendations modified from those presented in Petition 12-185-01p_a1.

[2] Monsanto and academics recommend the use of soil residuals as part of a comprehensive weed resistance management program to ensure that two effective herbicide modes-of-action are used in cotton and to provide protections against additional resistance development to existing cotton herbicides.

[3] Residual recommended if GR weeds present.

[4] Glyphosate recommended if no GR weeds present, glufosinate recommended in the presence of GR weeds.

[5]Tank mixes of glyphosate and glufosinate will not be recommended, because reduced weed control has been observed with the glyphosate and glufosinate tank mix as compared to each individual herbicide (Dotray et al. 2011; Reed et al. 2011; Reed et al. 2012).

[6] Glyphosate only if no GR weeds present, glufosinate and residual recommended in the presence of GR weeds.

Table B-25. Anticipated Weed Management Recommendations for DGT Cotton Combined with Glyphosate-Tolerant Cotton Systems for western TX, NM, KS, OK, and AZ [1,2]

Application Timing	Conventional Tillage	Conservation Tillage (No-till or reduced till)
Preplant burndown and/or Preemergence	Dicamba + Glyphosate + Residual	Dicamba + Glyphosate + Residual
Postemergence 1	Dicamba + Glyphosate	Dicamba + Glyphosate
Postemergence 2	Glyphosate ± Dicamba[3]	Glyphosate ± Dicamba[3]

[1] Recommendations modified from those presented in Petition 12-185-01p_a1.

[2] Monsanto and academics recommend the use of soil residuals as part of a comprehensive weed resistance management program to ensure that two effective herbicide modes-of-action are used in cotton and to provide protections against additional resistance development to existing cotton herbicides.

[3] Dicamba recommended when GR weeds present.

B.3.5.2. Benefits of the Weed Management System of Dicamba, Glufosinate, and Glyphosate-Tolerant Cotton

Extensive research by both university weed control specialists and Monsanto researchers in 2010 and 2011 demonstrates that growers will realize several benefits from utilizing the proposed weed management systems of dicamba, glufosinate, and glyphosate-tolerant cotton. These benefits include:

- Effective and sustainable management of glyphosate-resistant weed species;
- Improved and more consistent control of hard-to-control broadleaf weed species;
- Crop safety to dicamba, glufosinate, and glyphosate herbicides to maximize cotton lint yield potential;
- Application flexibility in the event of challenging weather conditions especially in the spring;
- Proactive program for weed resistance management; and
- Preservation of conservation tillage benefits.

Each benefit attribute is described and discussed below to substantiate the benefit in greater detail.

B.3.5.2.1. Effective and Sustainable Management of Glyphosate Resistant Weed Species

Glyphosate has been used extensively in agricultural production systems since being commercially introduced in 1974. Roundup Ready cotton was commercially introduced in 1997, further expanding the use of glyphosate in cotton. In 2006, a second generation glyphosate-tolerant product (Roundup Ready Flex cotton) was introduced that provided increased tolerance to glyphosate in the reproductive stages of cotton and allowed for an expanded window for over-the-top applications of glyphosate in cotton. In 2012, glyphosate-tolerant cotton represented 80% of all upland cotton acres planted in the U.S., up from 73% in 2011 (USDA-NASS, 2012). Due to the broad-spectrum activity of glyphosate, it has been possible for growers to rely predominately on glyphosate for weed management and not utilize diversified weed management practices such as crop rotation, mechanical cultivation or the use of multiple herbicide modes-of-action. Reliance on glyphosate in glyphosate-tolerant crops for total weed management in the absence of other herbicides and weed control management practices has contributed to the selection of weed populations that are resistant to this herbicide in certain areas of the U.S. Currently, there are 13 weed species (6 grasses and 7 broadleaf species) that are resistant to glyphosate in the U.S (Heap, 2012). Populations of the following four broadleaf weed species are resistant to glyphosate and are agronomically important weeds in cotton: Palmer amaranth, common waterhemp, horseweed, and common ragweed. Glyphosate-resistant Palmer amaranth may occur in up to 50% of the U.S. upland cotton acres according to some estimates (Sosnoskie and Culpepper, 2012).

University weed control specialists and Monsanto researchers have extensively evaluated the effectiveness of dicamba and glufosinate for control of several of these glyphosate-resistant weeds. Studies conducted in dicamba, glufosinate, and glyphosate-tolerant cotton were beneficial in determining the efficacy of dicamba and glufosinate applied preemergence and postemergence for glyphosate-resistant Palmer amaranth control. Studies with dicamba, glufosinate, and glyphosate-tolerant cotton were initiated in 2011 and were focused almost entirely on evaluating the efficacy of various weed management systems utilizing dicamba, glufosinate, and glyphosate with and without residual herbicides for control of glyphosate-resistant Palmer amaranth.

B.3.5.2.1.1. Glyphosate-Resistant Palmer Amaranth

Palmer amaranth is a summer annual broadleaf that is a problematic weed in the mid-south and southeastern U.S. (Morichetti et al., 2012). It is considered to be one of the most competitive and aggressive of the pigweed species because of its rapid growth and prolific seed production. Palmer amaranth is also dioecious (the male and female flowers occur on separate plants) which leads to greater genetic diversity in the plant population and increases the potential for spreading herbicide resistance. Since the development of glyphosate-resistant Palmer amaranth in the southeast, herbicide use patterns have changed, increasing the herbicide costs to $60 to $70 per acre in heavily infested areas (Sosnoskie and Culpepper, 2012). In addition, growers have increased the use of hand-weeding and in-crop cultivation to manage the high populations of glyphosate-resistant Palmer amaranth. Georgia growers indicate that up to 50 to 60% of their cotton acres are currently hand-weeded at a cost of $23 per acre (Sosnoskie and Culpepper, 2012). Prior to the development of glyphosate-resistant Palmer amaranth (2005), 17% or less of Georgia cotton acres were hand-weeded. According to Georgia growers, 44% of the cotton acres are subjected to in-crop mechanical cultivation in 2010/2011 (Sosnoskie and Culpepper, 2012).

Studies conducted on glyphosate-resistant Palmer amaranth support the importance of making dicamba applications early in the season to small weeds (4 inches or less in height) and applying dicamba at a rate of 0.5 lbs. a.e./acre for effective control. Studies showed the most consistent control with a dicamba rate of 0.5 lbs. a.e./acre. Diversified weed management programs consisting of a residual preemergence herbicide followed by one or two sequential postemergence applications of glyphosate plus dicamba or a total post program consisting of two sequential postemergence applications of glyphosate plus dicamba provide excellent control of glyphosate-resistant Palmer amaranth.

- Field trials conducted across the cotton belt in 2010 and 2011 on glyphosate-susceptible and resistant Palmer amaranth showed that both dicamba and glufosinate are effective on Palmer amaranth when applications are made to weeds less than four inches in height (Voth et al., 2012). However, efficacy is reduced as the weeds increase in size, especially when greater than 6-8 inches in height. The tank mixtures of dicamba plus glufosinate provided better control than either product applied alone.

- Field trials were conducted at five locations in 2011 to compare the efficacy of dicamba and glufosinate applied alone, as tank mixtures, or in sequence for control of tall (8 and 16 inches) glyphosate-resistant Palmer amaranth plants (Bollman et al., 2012). The general recommended timing for best control of Palmer amaranth for these products is to apply to plants less than 4 inches. Palmer control was greater with dicamba and glufosinate when applications were made to 8-inch plants compared to 16-inch plants regardless of whether applied alone, tank mixed or applied in sequence. Tank mixtures and sequential applications of dicamba and glufosinate improved control over either product used alone in these studies.

- Studies conducted by Mississippi State University show that glyphosate-resistant Palmer amaranth control is improved with single applications of dicamba when the rates are increased from 0.25 to 0.5 lbs. a.e./acre (50 - 63% vs. 66 – 68%) (Samples et al., 2012). Single applications of glufosinate at 0.53 lbs. a.i./acre provided similar control at 56 - 74%. Sequential applications of dicamba (0.5 lbs. a.e./acre) and glufosinate (0.53 lbs. a.i./acre) are required for adequate control of Palmer amaranth. Where sequential applications of these herbicides are utilized, the best results were obtained when dicamba was applied first followed by glufosinate.

- Field trials were conducted at three locations in 2011 to evaluate the efficacy of several weed control programs in dicamba, glufosinate, and glyphosate-tolerant cotton on control of glyphosate-resistant Palmer amaranth (Bollman et al., 2012). These programs included various preemergence (PRE) herbicide treatments followed by various early post (EPOST) treatments. All programs received one late post (LPOST) application of glufosinate plus acetochlor. Including a PRE treatment of fomesafen, dicamba (0.5 lbs a.e./acre) or a tank mixture of fomesafen plus dicamba (0.5 lbs a.e./acre) significantly improved Palmer control (>92% control) compared to programs with no PRE treatment regardless of the EPOST treatment (15-85% control). Programs with fomesafen plus dicamba applied PRE provided the most consistent Palmer control (>95%). Glyphosate plus dicamba (0.5 lbs a.e./acre), glyphosate plus dicamba (0.5 lbs a.e./acre) plus acetochlor, and glufosinate (0.53 lbs a.i./acre) plus dicamba (0.5 lbs a.e./acre) were effective EPOST treatments with the inclusion of a PRE herbicide treatment in the program. The addition of acetochlor EPOST to the tank mixture of glyphosate plus dicamba improved control slightly. Glufosinate plus acetochlor EPOST provided unsatisfactory control when following dicamba PRE.

- Field studies were conducted in five Midsouth and Southeastern states in 2011 on glyphosate-resistant Palmer amaranth (Dodd et al., 2012). Control of glyphosate-resistant Palmer amaranth from EPOST applications to 2- to 4-inch plants was less than 55% with glyphosate alone while EPOST applications of dicamba (0.5 lbs. a.e./acre) alone provided 86% control. Fourteen weed management programs were evaluated that included glyphosate, glufosinate and dicamba applied at various application timings. All the program treatments also received a LAYBY application of diuron plus MSMA. The total POST programs that provided greater than 97% control were glyphosate or glufosinate tank mixed with dicamba (0.5 lbs. a.e./acre) EPOST to 2- to 4-inch plants followed by glufosinate (0.53 lbs. a.i./acre) MIDPOST to 10- to 18-inch plants. The PRE/POST programs that provide >97% control were dicamba (0.5 lbs. a.e./acre) PRE followed by EPOST application of glufosinate (0.53 lbs. a.i./acre) alone, glufosinate (0.53 lbs. a.i./acre) or glyphosate plus dicamba (0.5 lbs. a.e./acre) followed by MIDPOST application of glufosinate (0.53 lbs. a.i./acre) or glyphosate plus dicamba (0.5 lbs. a.e./acre). Programs with lesser post applications such as dicamba PRE followed by EPOST application of glufosinate alone or glufosinate or glyphosate tank mixed with dicamba provided 83 – 93% control. The researchers concluded that season-long control (greater than 90%) was achieved with various PRE/POST programs utilizing dicamba, glyphosate, and glufosinate when applied in timely manner (weeds less than 4 inches in height). However, residual herbicides should continue to be an integral part of a total weed management program.

- Trials were conducted in NC and GA in 2010 and 2011 on a site infested entirely with glyphosate-resistant Palmer amaranth and a site with both glyphosate-resistant and –susceptible Palmer amaranth to evaluate several weed management programs utilizing residual herbicides and the addition of dicamba and glufosinate (York et al., 2012). The glyphosate only program failed to provide adequate control of glyphosate-resistant Palmer amaranth. Excellent control was achieved with dicamba (0.5 lbs. a.e./acre) PRE followed by glyphosate plus dicamba EPOST and MPOST. Glufosinate (0.5 lbs. a.i./acre) EPOST or LPOST followed by diuron +MSMA lay-by provided 80 to 97% control of glyphosate-resistant Palmer amaranth depending on the location and year. The addition of dicamba (0.5 lbs. a.e./acre) either as a PRE or POST application to a glufosinate program improved control of glyphosate-resistant Palmer amaranth, with one and two applications of dicamba being equally effective. Late-season control of glyphosate-resistant Palmer amaranth was 93 to 100% with glufosinate systems including one or more dicamba applications. The researcher suggested grass control could be improved in fields with heavy grass pressure by replacing one application of glufosinate plus dicamba with glyphosate plus dicamba in sequential programs. Cotton yields were generally greater with treatments including dicamba PRE suggesting reduced early season weed completion with dicamba PRE.

- Field trials were conducted at seven locations in southeastern and Midsouth states in 2011 to determine the effects of the timing of sequential dicamba applications on the control of mixed populations of glyphosate-resistant and –susceptible Palmer amaranth (Weirich et al., 2012). When applied to 3-inch plants, all sequential applications of dicamba (0.5 lbs. a.e./acre) provided 90 to 92% control, regardless of the absence or presence of glyphosate as a tank mix partner. Control was reduced when the initial dicamba applications were made to 9-inch plants. When applied to 9-inch plants, sequential applications of dicamba plus glyphosate provided from 81 to 85% control. No significant differences in control were observed between sequential applications (tested intervals were 4, 7, or 14 days).

- Clemson University conducted a study in 2011 to determine the effectiveness of dicamba-based weed management programs for Palmer amaranth control (Marshall, 2012). Various PRE/POST and POST only programs were evaluated. Dicamba (0.5 lbs. a.e./acre), fomesafen, and dicamba (0.5 lbs. a.e./acre) plus fomesafen applied PRE provided excellent early season control of Palmer amaranth. When these PRE treatments were followed with EPOST and LPOST applications of glyphosate plus dicamba (0.5 lbs. a.e./acre) or glufosinate plus dicamba (0.5 lbs. a.e./acre), all these programs provided 100% control of Palmer amaranth at 35 days after the LPOST application. These POST treatments also provided 100% control when no PRE treatments were used.

B.3.5.2.2. Improved Control of Hard-to-Control Broadleaf Weed Species

Dicamba use on DGT cotton offers a new management tool for improved control of hard-to-control weed species in cotton (Keeling et al., 2012; Marshall 2012). Certain problematic broadleaf weed species in certain areas of the U.S. are naturally less sensitive to glyphosate, namely morningglory spp., hemp sesbania, prickly sida, and purslane are generally hard to control with postemergence applications of glyphosate alone. Alternative broadleaf postemergence cotton herbicides (fluometuron, pyrithiobac, and thifloxsulfuron) provide inconsistent or less than acceptable control of these problematic broadleaf species in cotton. (See Table B-23 of this appendix; see also Appendix A). Postemergence applications of a glyphosate plus dicamba tank mixture or glufosinate plus dicamba will improve the control of these hard-to-control broadleaf weed species compared to glyphosate alone. Also, the control with the glyphosate plus dicamba mixture will often exceed the control of glyphosate mixtures with other commercial standards on certain of these weed species. With the research emphasis on glyphosate-resistant Palmer amaranth, limited data is currently available on other broadleaf weed species.

An experiment was conducted in Texas in 2011 on two hard-to-control broadleaf weeds – glyphosate-susceptible smellmelon (*Cucumis melo*) and ivyleaf morningglory (*Ipomoea hederacea*) (Cogdill and Chandler, 2012). Preemergence applications of dicamba alone provided 40 to 50% reduction in broadleaf weed emergence. Dicamba tank mixed with glyphosate or glufosinate applied postemergence improved broadleaf weed control to over 90% compared to glyphosate or glufosinate alone with less than 80% control.

Studies conducted by Clemson University in 2011 demonstrated that glyphosate or glufosinate plus dicamba provided 93 to 100% control of pitted morningglory, regardless of the preemergence herbicide treatment (Marshall, 2012). The control of pitted morningglory was greater than 94% with these tank mixtures when no preemergence treatment was applied.

Monsanto studies conducted in 2010 and 2011 showed that dicamba and glufosinate applied alone were effective in controlling morningglory species (Bollman et al., 2012; Voth et al., 2012). Results also showed that a number of dicamba, glufosinate, and glyphosate herbicide combinations provided excellent broad-spectrum weed control throughout the season and the most consistent results were achieved when a preemergence residual herbicide was included in the weed management program. In locations where annual grasses were present, treatments containing glyphosate were significantly better than those that did not contain glyphosate. Based on the above studies, in-crop applications of dicamba herbicide would be a beneficial addition to the weed managements systems in cotton.

B.3.5.2.3. Crop Tolerance

Weed management systems utilizing dicamba, glufosinate, and glyphosate-tolerant cotton have proven to be very effective in controlling a broad spectrum of weeds including glyphosate-resistant Palmer amaranth and other hard-to-control broadleaf weed species in cotton. Weed control systems must also display good crop tolerance to the herbicides to allow cotton to reach full yield potential. Dicamba, glufosinate, and glyphosate-tolerant cotton provides good crop tolerance to dicamba applied preemergence and in-crop postemergence. In addition, good tolerance is displayed when dicamba is applied in various weed management systems when tank mixed with glyphosate or glufosinate applied early post and mid-post.

Twenty-four university field experiments and approximately 27 Monsanto field experiments were conducted on dicamba, glufosinate, and glyphosate-tolerant cotton in the Midsouth and Southeastern cotton growing regions of the U.S. in 2010 and 2011. Dicamba, glufosinate, and glyphosate-tolerant cotton demonstrated good crop tolerance to dicamba, glufosinate, and glyphosate when used in a weed management system.

Low levels of cotton visual symptoms have been observed in DGT cotton. York et al. (2012) reported that glufosinate applied mid-post alone and in a tank mix with dicamba caused minor foliar necrosis at one of four study locations. There was no evidence this affected yield. No crop response was noted with dicamba PRE or with dicamba plus glufosinate or dicamba plus glyphosate applied early post. Dodds et al. (2012) reported that early post applications of dicamba (0.5 lbs a.e./acre) plus glufosinate or glyphosate with or without preemergence applications of dicamba (0.5 lbs a.e./acre) resulted in 3.5 – 4% visual cotton injury in five study locations. Cotton visual symptoms were greatest (~11%) with the following treatments: dicamba (0.5 lbs a.e./acre) preemergence followed by dicamba (0.5 lbs a.e./acre) early post followed by glufosinate mid-post or dicamba preemergence followed by glufosinate early post followed by dicamba (0.5 lbs a.e./acre) mid-post. Cotton visual symptoms were less than 1% with many other early post and mid-post treatments of dicamba tank mixtures following dicamba preemergence. No detrimental affects on seed cotton yields were reported. The researchers concluded that dicamba, glufosinate, and glyphosate-tolerant cotton demonstrated good tolerance to dicamba, glufosinate, and glyphosate herbicides applied alone or when tank mixed (Dodds et al., 2012).

Dicamba, glufosinate, and glyphosate-tolerant cotton demonstrated good crop tolerance to dicamba, glufosinate, and glyphosate when used in a weed management system. Low levels of foliar visual symptoms are occasionally observed as a result of glufosinate, or dicamba tank mix applications with glyphosate or glufosinate. No yield effects have been associated with the foliar visual symptoms.

B.3.5.2.4. Application Flexibility with Dicamba in Dicamba, Glufosinate, and Glyphosate-Tolerant Cotton

Dicamba, glufosinate, and glyphosate-tolerant cotton will facilitate a wider window of application for dicamba in cotton and application flexibility for both preemergence and postemergence herbicide applications in cotton. Current labeled uses of dicamba in cotton are limited to early preplant applications and the current maximum rate of dicamba is 0.25 lbs. a.e./acre. To avoid cotton injury, significant planting restrictions exist currently for preplant applications of dicamba in cotton. The waiting interval between application and planting cotton is a minimum of 21 days and a minimum accumulation of one inch of rainfall or overhead irrigation must occur prior to planting (BASF Corporation 2008; CDMS, 2012).

To support the introduction of dicamba, glufosinate, and glyphosate-tolerant cotton, Monsanto has submitted an application to U.S. EPA to amend Registration Number 524-582, a DGA salt formulation of dicamba, to allow preemergence and in-crop postemergence applications in DGT cotton. If approved, growers will be authorized to apply dicamba alone or in mixtures with glyphosate, glufosinate, or other labeled herbicides in these applications. Dicamba would be authorized to be applied up to 1.0 lbs. a.e./acre prior to planting, up to the emergence of cotton, and in-crop postemergence up through seven days prior to harvest at up to 0.5 lbs. a.e./acre.

The use pattern and rate of glufosinate on DGT cotton will follow the existing glufosinate-tolerant cotton uses outlined on the glufosinate herbicide label (Bayer Crop Science 2007). Consequently, Monsanto will not pursue any changes in the glufosinate label or the established tolerances for its use on DGT cotton.

B.3.5.2.5. Proactive Program for Weed Resistance Management

With the potential for continued selection pressure on glyphosate and other frequently used cotton herbicides (*e.g.*, SU and PPO herbicides), additional modes-of-actions are needed to mitigate the potential for the development and spread of these resistant weed species. University weed control specialists conducting the evaluation of dicamba, glufosinate, and glyphosate-tolerant cotton indicate that this new technology would provide an additional tool and mode-of-action to control herbicide-resistant weeds and manage selection for additional resistance in weed species (York et al., 2012). The proposed weed management recommendations include the use of a preemergence residual herbicide (Tables A-24 and A-25). University weed control specialists stress the importance of using several herbicides with different modes-of-action, including the use of residual preemergence herbicides, to maximize the long-term sustainability and utility of the currently available cotton herbicides (Culpepper et al., 2011; Dodds et al., 2012).

B.3.5.2.6. Preserves conservation tillage benefits

The benefits of conservation tillage are well known, namely reduced labor, savings of time and fuel, improved soil health, reduced soil erosion, and improved water quality – as well as air quality benefits from reduced use of farm machinery (CTIC, 2012a; Price et al., 2011).

Conservation tillage systems are well established in cotton production, with 34% of the cotton acres utilizing some form of conservation tillage (Monsanto, 2012). Glyphosate-tolerant cotton has been a primary enabler for continued adoption of conservation tillage systems and for the success of USDA Natural Resource Soil Conservation (NRCD) programs (CAST, 2011). Weed resistance to glyphosate in certain areas is a threat to soil conservation gains in some situations (CAST, 2011; Price et al., 2011). In particular, glyphosate-resistant Palmer amaranth is difficult to manage in no-tillage systems with currently available herbicide systems. Controlling glyphosate-resistant Palmer amaranth solely with herbicides is no longer an effective management approach in some cotton producing areas (Culpepper et al., 2012). Dicamba, glufosinate, and glyphosate-tolerant cotton will assist in preserving the use of conservation tillage and the benefits growers and the environment realize from utilizing these systems by enabling effective management of glyphosate-resistant weed species and other hard-to-control weeds in areas of the U.S. where they occur.

The use of dicamba and glufosinate applications in a diversified weed management in dicamba, glufosinate, and glyphosate-tolerant cotton provides excellent control of glyphosate-resistant Palmer amaranth in cotton. This combined with the herbicide application flexibility of the dicamba, glufosinate, and glyphosate-tolerant cotton system will benefit no-tillage and other conservations tillage systems for cotton, and enable growers to return to conservation tillage systems that they may have abandoned because of inadequate control of glyphosate-resistant weeds in certain areas of the U.S.

B.3.5.3. Conclusion

Dicamba, glufosinate, and glyphosate-tolerant cotton will enable an additional weed management tool for effective and sustainable weed management in cotton production. Dicamba, glufosinate, and glyphosate-tolerant cotton will allow growers to use dicamba, glufosinate, and glyphosate herbicides in a diversified weed management program to control a broad spectrum of grass and broadleaf weed species. Dicamba tolerance facilitates a wider window of application, as well as application flexibility for both preemergence and postemergence applications in cotton compared to current labeled uses of dicamba in cotton. A significant number of field studies conducted by university weed control specialist in the major cotton production regions in 2010 and 2011 have led to the development of weed management system recommendations for dicamba, glufosinate, and glyphosate tolerant cotton. These system recommendations will provide for effective and sustainable management of weeds in cotton, including glyphosate-resistant Palmer amaranth. In addition, weed control systems in dicamba, glufosinate, and glyphosate-tolerant cotton will improve management of certain hard-to-control broadleaf weed species which are known to be problematic in cotton production, such as horseweed, morningglory spp., hemp sesbania, prickly sida, and purslane. Dicamba, glufosinate, and glyphosate-tolerant cotton has demonstrated good crop tolerance to dicamba and glufosinate in numerous university and Monsanto field experiments when evaluated in the various proposed weed management systems and in stand-alone tolerance trials.

Dicamba, glufosinate, and glyphosate-tolerant cotton provides three modes-of-action for improved weed control and weed resistance management. Use of dicamba, glufosinate, and glyphosate in-crop will help preserve the value of glyphosate and other existing pre- and postemergent herbicides, including glufosinate, by reducing the development of herbicide-resistant weeds. Weed resistance to glyphosate in certain areas of the U.S. is a growing threat to gains made in soil conservation practices after the introduction of glyphosate-tolerant cotton. Diversified weed management practices enabled by dicamba, glufosinate, and glyphosate-tolerant cotton provide excellent control of glyphosate-resistant and other problematic weeds and will help preserve conservation tillage usage and its well documented environmental and economic benefits in cotton.

All of these benefits strongly support the need for DGT cotton as a new and beneficial tool for cotton growers in the U.S.

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APPENDIX C: EFFECTS OF CHANGES IN FARMING PRACTICES ON WATER, SOIL AND AIR DUE TO USE OF DT SOYBEANS AND DGT COTTON

Table of Contents

Tables and Figures

C.1. Introduction

Dicamba is a selective broadleaf herbicide belonging to the auxin agonist class, the oldest known class of synthetic herbicides, and is a member of the benzoic acids sub-group. Dicamba mimics the action of the plant hormone indole acetic acid and causes rapid uncontrolled cell division, and growth leading to plant death. Dicamba has been registered for agricultural uses in the U.S. since 1967 and has been widely used in agricultural production for over forty years. Dicamba is presently approved for use on asparagus, corn, cotton, grass seed production, pasture and rangeland grasses, small cereals including barley, oats, rye, and wheat, sorghum, soybean, and sugarcane. Dicamba is also used for industrial vegetation management (e.g., forestry and roadsides), professional turf management (e.g., golf courses, sports complexes), and residential turf (U.S. EPA, 2009b). Dicamba provides effective control of over 95 annual and biennial weed species, and control or suppression of over 100 perennial broadleaf and woody plant species.

C.1.1. DT Soybean and DGT Cotton

Monsanto Company has developed biotechnology-derived soybean that is tolerant to dicamba (3,6-dichloro-2-methoxybenzoic acid) herbicide (DT soybean) and biotechnology-derived cotton that is tolerant to dicamba and glufosinate (DGT cotton).

DT soybean offers growers expanded use of dicamba in soybean production. The crop tolerance of DT soybean to dicamba facilitates a wider window of application in soybean, allowing preemergence application any time up to soybean emergence (cracking), and two in-crop postemergence applications up to 0.5 lb a.e. per acre per application through the early reproductive R1 stage of growth. DGT cotton offers growers expanded use of dicamba in cotton production. The crop tolerance of DGT cotton to dicamba also enables a wider window of application; dicamba would be authorized to be applied up to 1.0 lb a.e. per acre any time prior to cotton emergence, and postemergence in-crop application up to 0.5 lbs a.e. per acre per application up through seven days prior to harvest.

Using traditional breeding techniques, DT soybean will be combined with glyphosate-tolerant soybean and DGT cotton will be combined with glyphosate-tolerant cotton. The combination of herbicide-tolerance traits allows the use of dicamba and glyphosate (and, in the case of DGT cotton, glufosinate) herbicides in an integrated weed management program to control a broad spectrum of grass and broadleaf weed species. For DT soy, the two herbicides can be used in sequence or tank-mixed. For DGT cotton, the herbicides can be used in sequence, or dicamba can be tank-mixed with either glyphosate or glufosinate. Monsanto has submitted to U.S. EPA applications to amend Registration Number 524-582 to register new use patterns for dicamba on DT soybean and DGT cotton to expand the existing window of application as described above. The use pattern and rate of glufosinate on DGT cotton will follow the existing glufosinate-tolerant cotton uses outlined on the glufosinate herbicide label.

The availability of DT soybean and DGT cotton integrated into the glyphosate-tolerant soybean and cotton systems will result in a simple and effective dual or triple mode-of-action herbicide system that will control hard-to-control broadleaf weeds, assist in the management of resistant broadleaf weeds, including glyphosate-resistant weeds, and subsequently displace some soybean and cotton herbicides currently in use today (also referred to as alternative herbicides).

C.1.1.1. Comparative Analysis

The intent of this comparative analysis is to define current herbicide use in U.S. soybean and cotton production, and to compare dicamba's potential impacts on water, soil and air to herbicides currently used by growers for weed control. In order for a pesticide (e.g, dicamba herbicide) to be registered by U.S. EPA it must meet the FIFRA and FFDCA standards for safety to human health and the environment. The U.S. EPA must conclude that the herbicide when used according to the label does not pose an unreasonable risk to humans or the environment. Therefore, all alternative herbicides used in soybean and cotton production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba offers a reduction in risk potential (i.e., hazard) compared to some alternative herbicides in the same risk category (e.g., aquatic plant risk). In other instances dicamba presents a similar risk potential compared to the some alternatives, and in some instances, dicamba presents a greater risk potential compared to some alternatives. This comparative assessment serves to demonstrate that the use of dicamba on DT soybeans is unlikely to result in a significant impact/risk to human health or the environment compared to current herbicide agronomic practices, and in some instances its use may impart additional benefits as described in this Environmental Report.

C.2. Background Dicamba

C.2.1. Dicamba Chemical Name and Structure

Dicamba (3,6-dichloro-2-methoxybenzoic acid) is a carboxylic acid that can form salts in aqueous solution. The chemical structure is provided in Figure C.1. Dicamba products registered for agricultural uses are formulated with various dicamba salts. The formulated products Clarity and M1691 contain the diglycolamine (DGA) salt of dicamba at a nominal level of 56.8% by weight, which is equivalent to 38.5% by weight dicamba acid (also referred to acid equivalents or a.e.).

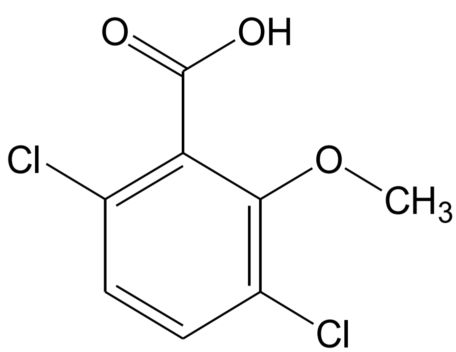

Figure C-1. Structure of Dicamba

C.2.2. Dicamba Herbicide Class and Herbicidal Mode-of-Action

Dicamba belongs to the "benzoic acid class" of herbicides. The Weed Science Society of America (WSSA) places dicamba in herbicide group number 4.[113] It is an auxin agonist; it is a plant hormone (indole acetic acid, IAA) mimic that causes rapid uncontrolled cell division and growth, leading to plant death. Dicamba is mainly used to control broadleaf weeds and woody plants.

C.2.3. Dicamba - Current U.S. Uses

Dicamba is a selective herbicide labeled for control of certain broadleaf weeds and woody plants. It was first registered for agricultural use in the U.S. in 1967 and is widely used today in agricultural, industrial, and residential settings. Dicamba salts have approved uses on asparagus, corn, cotton, grass seed production, pasture and rangeland grasses, small cereals including barley, oats, rye, and wheat, sorghum, soybean, and sugarcane. Dicamba is also used for industrial vegetation management (*e.g.*, forestry and roadside right-of-ways), professional turf management (*e.g.*, golf courses, sports complexes), and residential turf (U.S. EPA, 2009b; Durkin and Bosch, 2004).

C.2.4. Proposed Use Pattern for Dicamba on DT Soybean and DGT Cotton

Monsanto has submitted two applications to U.S. EPA to amend Registration No. 524-582, a low-volatility DGA salt formulation for new use patterns, one for DT soybean and one for DGT cotton.

DT Soybean. The proposed new use pattern allows for sequential applications of dicamba, formulated as the DGA salt, to DT soybean:

- Preplant / preemergent applications, totaling up to 1.0 pound per acre of dicamba a.e.
- One or two postemergent in-crop applications (up to 0.5 pounds a.e. per acre each), timed between soybean emergence (cracking) and early flowering (R1 growth stage) of the soybean.
- Maximum annual application rate of 2.0 pounds dicamba a.e. per acre.

The proposed use pattern for dicamba on DT soybean is within the maximum single and annual application rates that have previously been assessed by EPA.

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113 There are several systems of herbicide mode-of-action classification. Among the most widely used are those of the Herbicide Resistance Action Committee (HRAC) and the WSSA. The classifications are compared in a chart at: http://www.plantprotection.org/HRAC/Bindex.cfm?doc=MOA.html. Accessed May 27, 2010

DGT Cotton. The proposed new use pattern allows for sequential applications of dicamba, formulated as the DGA salt, to DGT cotton:

- Preplant / preemergent applications, totaling up to 1.0 pound per acre of dicamba a.e.
- Postemergent in-crop applications (up to 0.5 pounds a.e. per acre each), up to 7 days prior to harvest.
- Maximum annual application rate of 2.0 pounds dicamba a.e. per acre.

The proposed application rates associated with both DT soybean and DGT cotton would be less than or equivalent to rates for dicamba established for other uses in the dicamba RED including the 2.0 lbs a.e. dicamba per year for all applications (U.S. EPA 2009a). Once approved by U.S. EPA, these labels will become legally-binding constraints on the use of dicamba on DT soybean and DGT cotton.

C.3. Herbicides – Environmental Properties

The environmental fate and transport of a herbicide depends on its persistence (measured by half-life) and its mobility. Herbicides may be degraded by microorganisms, by reaction with other chemicals (including water, oxygen or others), or by sunlight. After application, an herbicide may absorb to soil or vegetation particles, dissolve in water, or volatilize. Soil particles may stay in place, or may erode by wind or water. Water containing dissolved herbicides may be taken up by plants, run off into surface water, or infiltrate into the subsurface or groundwater. The potential for an herbicide to persist in the soil and potentially runoff or move to groundwater are based on its soil degradation and affinity to bind with soil. EPA will use the herbicide's environmental fate and physical/chemical properties to determine the risk potential to aquatic and terrestrial species.

C.3.1. Environmental Properties of Dicamba

Table C-1 summarizes the physical and chemical properties of dicamba that can influence its mobility and persistence in the environment. These measures are the result of conventional laboratory testing, as required for U.S. EPA registration. Results are presented using standard environmental fate indices, such as the time required for 50% degradation (half-life) of the initial concentration.

Table C-1. Environmental Fate and Physical/Chemical Properties of Dicamba Acid

Environmental Physical Properties	Results
Dicamba acid vapor pressure	3.4 x 10^{-5} torr (25° C)
Dicamba acid acidity (pKa)	1.87
Dicamba acid water solubility	6100 mg/L
Dicamba acid octanol / water partition coefficient	0.1
Dicamba acid K_{oc} (Freundlich soil-binding constant)	3.5 – 21.1 mL/g
Dicamba acid field dissipation half-life (conducted with salt formulations)	3 – 19.8 days
Dicamba acid aerobic soil half-life, Laboratory	6 days
Dicamba acid anaerobic soil half-life, Laboratory	141 days
Dicamba acid aerobic aquatic half-life, Laboratory	20.2 – 24.3 days
Dicamba acid aqueous photolysis half-life	38.1 days
Dicamba acid soil photolysis degradation rate	~20% after 30 days
Hydrolysis half-life	Stable

Dicamba (dicamba acid/DGA salt) has a Groundwater Ubiquitous Score (GUS), a groundwater leaching index, of 2.6 indicating moderate leachability. (Gustafson, 1989 as cited in Monsanto, 2013. See Appendix A, Section IV.D.2).

C.3.2. Ecological Properties of Dicamba

The following tables summarize the hazard potency of dicamba to non-target species. These data were taken from the Environmental Fate and Effects Division (EFED) Chapter of the dicamba RED (U.S. EPA, 2005a). These measures are the result of conventional laboratory testing against standard indicator species of fish, birds, mammals, and plants as required for EPA registration. Results are presented using standard toxicity indices, such as the concentration or dose required for 50% lethality (LC_{50} or LD_{50}) or the concentration required for a 25 or 50% reduction in growth or biomass (EC_{25} or EC_{50}). In some cases the "No Observable Effect Concentration" (NOEC) or "No Observable Adverse Effect Level" (NOAEL) is also listed. A summary of the findings of the ecotoxicity studies conducted on dicamba acid is provided in Tables C-2 through C-4. Ecotoxicity studies have also been conducted on the diglycolamine (DGA) salt of dicamba and are summarized in Table C-5.

Table C-2. Dicamba Acid Ecotoxicity Findings on Mammals, Birds and Fish (U.S. EPA. 2005a)

Study	Toxicity Endpoint
Mammals	
Dicamba acid acute oral (rat) LD_{50}	2740 mg/kg body wt
Multigeneration reproduction (rat) NOAEL/LOAEL	45 /136mg/kg/day
Birds	
Dicamba acid acute oral (quail) LD_{50}	188 mg/kg body wt
Dicamba acid acute oral (duck) LD_{50}	1373 mg/kg body wt
Dicamba acid sub-acute oral (quail) LC_{50}	>10,000 mg/kg diet
Dicamba acid sub-acute oral (duck) LC_{50}	2009 mg/kg diet
Dicamba acid sub-acute oral (duck) LC_{50}	>10,000 mg/kg diet
Dicamba acid reproduction (quail) NOEC/LOEC	1390 (HDT[1]) mg/kg diet
Dicamba acid reproduction (duck) NOEC/LOEC	695/1390mg/kg diet
Fish	
Dicamba acid (trout) LC_{50}	28 mg/L
Dicamba acid (trout) LC_{50}	135 mg/L
Dicamba acid (trout) LC_{50}	153 mg/L
Dicamba acid (Bluegill) LC_{50}	135 mg/L
Dicamba acid (Bluegill) LC_{50}	>50 mg/L
Dicamba acid (Sheepshead) LC_{50}	>180 mg/L
Dicamba acid fish early life stage	NA
Dicamba acid fish life cycle	NA

NA denotes Not Applicable.
NOEC stands for No Observable Effect Concentration.
LOEC stands for Lowest Observable Effect Concentration.
[1]HDT stands for the Highest Dose Tested.

Table C-3. Dicamba Acid Ecotoxicity Findings on Aquatic and Terrestrial Invertebrates (U.S. EPA. 2005a)

Study	Toxicity Endpoint	Comment
Aquatic Invertebrates		
Dicamba acid (Daphnia) LC_{50}	111 mg/L	
Dicamba acid (Daphnia) LC_{50}	>100 mg/L	Replicate
Dicamba acid (Sowbug) LC_{50}	>100 mg/L	
Dicamba acid (Scud) LC_{50}	>100 mg/L	
Dicamba acid (Grass Shrimp) LC_{50}	>132 mg/L	
Dicamba acid (Fiddler Crab) LC_{50}	>173 mg/L	
Dicamba acid (Oyster) LC_{50}	>1 mg/L	
Dicamba acid (Glass Shrimp) LC_{50}	>56 mg/L	
Invertebrate life cycle	NA	
Terrestrial Invertebrates		
Honeybee LD_{50}	>90.6 µg/bee	

NA denotes Not Applicable.

Table C-4. Dicamba Acid Ecotoxicity Results on Aquatic and Terrestrial Plants (U.S. EPA. 2005a)

Study	Toxicity Endpoint	Comment
Aquatic Plants		
Dicamba acid duckweed EC_{50} / NOEC	>3.25 / 0.2 mg/L	
Dicamba acid green alga EC_{50} / NOEC	>3.7 / 3.7 mg/L	
Dicamba acid marine diatom EC_{50} / NOEC	0.49 / 0.011 mg/L	
Dicamba acid blue-green alga EC_{50} / NOEC	0.061 / 0.005 mg/L	
Dicamba acid freshwater diatom EC_{50} / NOEC	2.3 / 0.5 mg/L	
Terrestrial Plants		
Dicamba acid seedling emergence monocot EC_{25} / NOEC	0.004 / <0.032 lb/a	Onion
Dicamba acid seedling emergence dicot EC_{25} / NOEC	0.0027 / < 0.0022 lb/a	Soybean
Dicamba acid vegetative vigor monocot EC_{25} / NOEC	0.15/ 0.13 lb/a	Onion
Dicamba acid vegetative vigor dicot EC_{25} / NOEC	0.0068 / <0.004 lb/a	Soybean

Table C-5. Dicamba, Diglycolamine (DGA) Salt Ecotoxicity Findings (U.S. EPA. 2005a)

Study	Toxicity Endpoint	Comment
Birds		
Dicamba DGA salt acute oral (quail) LD_{50}	262 mg a.e./kg body weight	
Dicamba DGA salt sub-acute oral (quail) LC_{50}	>1522 mg a.e./kg diet	
Dicamba DGA salt sub-acute oral (duck) LC_{50}	>1522 mg a.e./kg diet	
Fish		
Dicamba DGA salt (trout) LC_{50}	>270mg a.e./L	
Dicamba DGA salt (bluegill) LC_{50}	>270mg a.e./L	
Aquatic Invertebrates		
Dicamba DGA salt (Daphnia) LC_{50}	>270 mg a.e./L	

C.4. Alternative Herbicides

C.4.1. Alternative Herbicides for Soybean

If DT soybean is not integrated into the glyphosate-tolerant soybean system, the potential for glyphosate-resistant weed populations to evolve and develop in soybean producing areas may increase. In addition, the potential for resistance to evolve and develop for other herbicides used in soybean production could also increase in these areas where growers do not use multiple modes-of-action. The increased use of other non-glyphosate alternative herbicides would also be expected. The DT soybean combined with the glyphosate-tolerant soybean system will result in a simple and effective dual mode-of-action herbicide system that will control hard-to-control broadleaf weeds, assist in the management of resistant broadleaf weeds, including glyphosate-resistant biotypes, and has the potential to eliminate the need for some soybean herbicides currently in use today. As a result, DT soybean combined with the glyphosate-tolerant soybean system will provide benefits to the soybean grower that current weed control options do not have, such as:

- Effective tool for sustainable management of glyphosate resistant weeds;
- Mitigate the potential for the evolution development of weed resistance for all classes of soybean herbicides;
- Improve the consistency of control over hard-to-control weeds, thereby reducing the potential for new resistant biotypes to develop;
- Increase application flexibility;
- Preserve the benefits of the Roundup Ready weed control system; and
- Preserve the many environmental and economic benefits of conservation tillage

As discussed in Appendix A.3.7.2 of this Environmental Report, ninety-seven percent (97%) of soybean treated acres receive an application of glyphosate; the remaining acres are treated with more than 25 other active ingredients. In some of the soybean acres, these other active ingredients are applied on acres that also receive a glyphosate application. Integration of DT soybean into the glyphosate-tolerant soybean system and the subsequent use of dicamba will result in the displacement of some currently used, or foreseeable future use herbicides, and therefore the properties of these alternative herbicides are summarized in this section to provide a baseline for comparison to dicamba use on DT soybean.

Table C-6 summarizes key information from alternate herbicide product labels. Table C-7 lists the eighteen active ingredients that make up the products in Table C-6. Tables C-6 and C-7 are the same as Tables A-24 and Table A-25 in Appendix A. 2,4-D, being used primarily as a pre-plant application, is the most widely-used herbicide in this alternate herbicide list, representing about 10% of treated acres; whereas acifluorfen, carfentrazone-ethyl, and flufenacet are the least used among these, representing <0.5% of treated acres. Mesotrione has not been used in soybean production previously; the use on soybean was only recently registered by the EPA (2009d). Table C-7 also lists general regulatory information about each herbicide. Note that only paraquat is classified as a Restricted Use pesticide among this group, on the basis of acute toxicological concern.

Table C-6. Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word[1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Aim® (279-3241)	Carfentrazone-ethyl	Caution	2 lb/gal	12 hr	0.008 [5]	0.023	"toxic to fish";"toxic to algae"; V3 - V10; do not feed foliage; some burn injury
Authority® First DF (279-3246)	Sulfentrazone	Caution	0.62 lb/lb	12 hr	0.31	0.31	"known to leach"; "toxic to marine / estuarine invertebrates.";65-day PHI; crop rotation restrictions, up to 30 mts; soil O.M. limits (sands <1% organic matter)
	Cloransulam-methyl		0.08 lb/lb		0.04	0.04	
Authority MTZ (279-3340)	Sulfentrazone	Caution	0.18 lb/lb	12 hr	0.028	0.046	"known to leach"; "toxic to marine / estuarine invertebrates. 120-day PHI (not Over The Top); sensitive varieties, injury possible
	Metribuzin		0.27 lb/lb		0.042	0.07	
Basagran® (7969-45)	Bentazon	Caution	4 lb/gal	48 hr	1	2	"known to leach";30-day PHI for feeding treated forage and hay; minor injury
Butoxone® 7500 (71368-49)	2,4-DB	Caution	0.75 lb/lb	48 hr	0.375		soil type limits
Butyrac® 200 (42750-38)	2,4-DB DMA salt	Danger	2 lb/gal	48 hr	0.4	0.4	"toxic to fish";60-day PHI; injury may occur, especially with tank mixtures
Cadet® (279-3338)	Fluthiacet-methyl	Warning	0.91 lb/gal	12 hr	0.0065	0.009	do not feed foliage; minor injury
Callisto® (100-1131)	Mesotrione	Caution	4 lb/gal	12 hr	0.1875	0.1875	"high potential for runoff"; crop rotation restrictions up to 18 mts; "transient bleaching" may occur; pre-emergence use only, no in crop use

Table C-6 (continued). Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word[1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Classic® (352-436)	Chlorimuron-ethyl	Caution	0.75 lb/lb	12 hr	0.14	0.14 [6]	60-day PHI; crop rotation restrictions up to 30 mts and complicated description of 3 different intervals specific to US regions and soil pH; do not feed foliage; soil type limits; "temporary leaf yellowing"
Cobra® (59369-34)	Lactofen	Danger	2 lb/gal	12 hr	0.2	0.4 [6]	"toxic to fish"; Do not apply past soybean growth stage R6 / 45-day PHI; minor injury
Extreme ® (241-405)	Imazethapyr Glyphosate-IPA	Warning	0.17 lb/gal 2 lb/gal	48 hr	0.064 [6] 0.75	0.064 [6] 0.75	"properties & characteristics associated with chemicals detected in ground water"; crop rotation limits
FirstRate (62719-275)	Cloransulam-methyl	Caution	0.84 lb/lb	12 hr	0.04	0.055	65-day PHI; crop rotation restrictions up to 30 mts; soil types; 14-day forage and hay feeding restriction
Flexstar ® (100-1101)	Fomesafen	Warning	1.88 lb/gal	24 hr	0.35	0.375 [6]	"cause tumors"; "known to leach"; 45-day PHI; do not feed foliage; crop rotation limits
Gangster ® Co-pack (59639-131)	Flumioxazin Cloransulam-methyl	Caution	51% 84%	12 hr	0.096 0.032	0.096 0.032	"toxic to aquatic invertebrates."; "Preemergent only. "properties & characteristics Associated with chemicals detected in ground water"; "toxic to invertebrates."
Gramaoxone Inteon ® (100-1217)	Paraquat dichloride	Danger	2 lb/gal (cation basis)	12 hr	1.5	2.9	"toxic to wildlife"; Restricted Use; no Over-the-Top use

Table C-6 (continued). Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word[1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Ignite® (264-829)	Glufosinate-ammonium	Warning	2.34 lb/gal	12 hr	0.66	0.8	"runoff potential"; "toxic to vascular plants"; 70-day PHI; some crop rotation limits up to 180 days; only Over-the-Top to Liberty Link soybean
Liberty® (264-660)	Glufosinate-ammonium	Warning	1.67 lb/gal	12 hr	0.44	0.8	"runoff potential"; "toxic to vascular plants"; 70-day PHI; do not feed foliage; crop rotation limits up to 120 days;
Phoenix® (59639-118)	Lactofen	Caution	2 lb/gal	12 hr	0.3	0.4 [6]	"toxic to fish"; Do not apply past crop growth stage R6 / 45-day PHI; minor injury
Pursuit® (241-310)	Imazethapyr	Caution	2 lb/gal	4 hr	0.063	0.063	"properties & characteristics associated with chemicals detected in ground water"; 85-day PHI; do not feed forage and hay
Pursuit® Plus (241-331)	Pendimethalin Imazethapyr	Caution	2.7 lb/gal 0.2 lb/gal	24 hr	0.84 0.063	0.84 0.063	"properties & characteristics associated with chemicals detected in ground water"; "toxic to fish"; 85-day PHI; crop rotation limits up to 40 months
Raptor ® (241-379)	Imazamox-ammonium	Caution	1 lb/gal	4 hr	0.04	0.04	"phytotoxic to all plants"; plantback / crop rotation limits up to 26 months, two regions with complicated warnings

Table C-6 (continued). Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word [1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Reflex® (100-993)	Fomesafen	Danger	2 lb/gal	24 hr	0.375	0.375 [6]	"known to leach"; 45-day PHI; crop rotation limits up to 18 mts; minor injury, significant geographical restrictions (5 regions each with different rate structure)
Resource® (59639-82)	Flumiclorac-pentyl	Warning	0.86 lb/gal	12 hr	0.081	0.11	"toxic to shrimp"; 60-day PHI; do not feed forage or hay to livestock; temporary spotting or burn to soybean
Scepter ®70 DG (241-306)	Imazaquin	Caution	0.7 lb/lb	12 hr	0.123	0.123 [6]	"properties & characteristics associated with chemicals detected in ground water"; 90-day PHI; do not feed forage or hay to livestock; crop rotation limits up to 40 mts; regional limitations (3 regions)
Sencor® (DF 75%) (264-738)	Metribuzin	Caution	0.75lb/lb	12 hr	0.66 [6]	1.3 [6]	"can seep or leach"; 70-day grain PHI; 40-day PHI on feeding forage to livestock; no Over-the-Top application, directed spray OK; injury in high pH or low O.M. soils or on certain crop varieties, crop rotation limits up to 18 mts
Synchrony® XP (352-648)	Thifensulfuron	Caution	0.069 lb/lb	12 hr	0.013	0.013	45-day planting restriction applied prior to soybean planting / emergence; 60-day PHI; complicated crop rotation restrictions (3 regions, 4 intervals) with limits up to 30 mts; do not feed forage or hay to livestock; soil types; injury if adjuvants or tank mixed
UltraBlazer (70506-60)	Acifluorfen sodium Chlorimuron-ethyl	Danger	2 lb/gal 0.215 lb/lb	48 hr	0.374 0.04	0.5 0.04	50-day PHI; minor injury

Table C-6 (continued). Alternative Registered Soybean Herbicides

Brand (U.S. EPA Reg. No.)	Active Ingredient	Signal Word [1]	Active Ingredient Content	Re-entry Interval (REI)[2]	Max. Soybean lb/a (single treatment)[3]	Max. Soybean lb/a (season)	Label Warnings or Special Directions[4]
Valor® SX (59639-99)	Flumioxazin	Caution	0.51 lb/lb	12 hr	0.096	0.096	"runoff potential"; "toxic to aquatic invertebrates."; preemergence use only, no in crop use; do not feed forage or hay to livestock; crop rotation limit up to 18 mts. & soil type limits; injury under cool wet conditions or poorly drained soil; restrictions on use with flufenacet, alachlor, metolachlor, or dimenthenamid
Valor® XLT (59639-117)	Flumioxazin Chlorimuron-ethyl	Caution	0.3 lb/lb 0.103 lb/lb	12 hr	0.094 0.032	0.094 0.032	"toxic to aquatic invertebrates."; preemergence only, no in crop use; do not feed forage or hay to livestock; crop rotation limits up to 30 mts; injury under cool wet conditions or poorly drained soil
Weedone® (650, 638, LV4, LV6) and other 2,4-D brands (71368-3, -6, -10, -11, -14, -19)	2,4-D; 2,4-D salts; 2,4-D esters	Varies	Varies		0.93	0.93	Weedone 650 as an example: "toxic to aquatic invertebrates."; do not use on sandy soils (<1% O. M.); preplant to emerged weeds only , no in crop use; do not feed forage or hay to livestock.

[1]The EPA-required statement to convey to applicators the overall acute toxicity hazard posed by the product. Caution is more favorable than Warning, which is more favorable than Danger.

[2]The period of time following application during which worker reentry into the treated area is restricted, according to EPA's Worker Protection Standard (WPS).

[3]The highest single-treatment and seasonal rates that can be applied to soybean according to the product Directions for Use label.

[4]Lists specific statements extracted from the product label that represent specific hazards or limitations that may reduce the utility of the product for soybean weed control

[5]Higher rates with directed / hooded sprayers.

[6]Regional or soil type limitations may lower this rate.

[7]Soybean label not yet publically available. Corn label comments are cited

PHI – preharvest interval, O. M. – organic matter, mts - months.

Table C-7. Active Ingredients Contained in Alternative Herbicides

Active Ingredient	First Registered[1]	2006 Treated Soybean Acreage (%)[2]	Registration Review Status[3]	RED Date[4]	Max. Soybean lb/a (single treatment)[5]	Max. Soybean lb/a (season)	Tolerances (40 CFR 180)[6]	Restricted Use[7]
glyphosate salts	3-May-76	97	open 2009	Sep-93	1.5	6	364	No
dicamba-diglycolamine salt	2-Feb-56	<0.5	NA	Jun-09, corrected	1[9]	2[9]	227	No
2,4-D acid, salts, and esters	3-Jun-52	10	2013	Jun-05	0.93	0.93	142	No
flumioxazin	12-Apr-2001	3	unscheduled	NA	0.096	0.096	568	No
imazethapyr	30-Jan-87	3	2014	Jun-06	0.064[8]	0.064[8]	447	No
cloransulam-methyl	29-Oct-1997	1	2011	NA	0.04	0.055	514	No
chlorimuron-ethyl	4-Apr-86	4	2011	Sep-04 TRED	0.14	0.14[8]	429	No
fomesafen	10-Apr-87	2	open 2007	TRED Aug-07	0.375	0.375[8]	433	No
flumiclorac-pentyl	23-Mar-94	1	open 2009	Aug-05 TRED	0.081	0.11	477	No
sulfentrazone	22-Nov-93	1	open 2009	NA	0.31	0.31	498	No
thifensulfuron	25-Apr-86	1	2011	NA	0.013	0.013	439	No
imazaquin	20-Mar-86	1	2014	TRED Dec-05	0.123	0.123[8]	426	No
imazamox-ammonium	17-Apr-95	<0.5	2014	NA	0.04	0.04	1223	No
paraquat dichloride	8-Jan-80	1	2012	Aug-97	1.0	2.9	205	**Yes**
lactofen	1-Apr-87	<0.5	open 2007	TRED Sep-03	0.3	0.4	432	No
glufosinate-ammonium	29-May-91	<0.5	open 2008	NA	0.66	0.8	473	No
2,4-DB	30-Jun-66	<0.5	2014	Jan-05	0.4	0.4	331	No
fluthiacet-methyl	14-Apr-99	<0.5	unknown	NA	0.0065	0.009	551	No
acifluorfen sodium	29-May-81	<0.5	unscheduled	Sep-09	0.374	0.5	383	No
Mesotrione	4-Jun-01	0.0	unscheduled	NA	0.1875	0.1875	571	No

TRED denotes Tolerance Reregistration Eligibility Decision

[1]The date the herbicide was first approved for any use (*e.g.*, industrial) by U.S. EPA.

[2]The percentage of the herbicide-treated soybean acres that were treated with each herbicide in AR, IA, IL, IN, KS, KY, LA, MI, MN, MS, MO, NE, NC, ND, OH, SD, TN, VA, and WI in 2006 (USDA-NASS, 2007b) .

[3]The herbicide's progress in the ongoing EPA program named as Registration Review. Year indicates when the official docket was or will be opened. EPA is required by law to re-evaluate pesticides periodically, generally every 10-15 years.

[4]The date when EPA issued a Reregistration Eligibility Decision document. Reregistration was an earlier re-evaluation program designed to ensure that supporting data are up-to-date for a.i.s first registered before 1984. TRED means Tolerance Reassessment Eligibility Decision, which refers to an alternative review path that some post-1984 a.i.s followed.

[5]The maximum amount of the herbicide that can be applied to soybean in a single treatment or during the entire season, according to product labels.

[6]The number of the paragraph in the Code of Federal Regulations where that herbicide's food and feed tolerances are listed.

[7]An EPA pesticide classification that restricts a product, or its uses, to use by a certificated pesticide applicator or under the direct supervision of a certified applicator. See 40 CFR 152.160.

[8]Regional or soil type limitations may lower this rate.

[9]Maximum treatment rates for the proposed dicamba label.

C.4.2. Alternative Herbicides for Cotton

If DGT cotton is not integrated into the glyphosate-tolerant cotton system, the potential for glyphosate-resistant weed populations to evolve and spread in cotton producing areas may increase. In addition, the potential for resistance to evolve and spread for other cotton herbicides could also increase in these areas where growers do not use multiple modes-of-action. The increased use of other non-glyphosate alternative herbicides would also be expected.

The DGT cotton system will be an effective alternative to the current Monsanto and academic recommended practice for weed control in cotton cultivation and will eliminate the need for the application of multiple residual herbicides and reduce the overall number of herbicide applications.

The new use of dicamba in cotton will displace some of the currently used alternate herbicides because the DGT cotton system will provide benefits to the cotton farmer that current weed control options do not have, such as:

- Providing improved postemergent weed control and added residual efficacy relative to other commercially available herbicides to control tough broadleaf weeds and weeds that are resistant to glyphosate and other herbicides used in cotton[114]
- Increased convenience and flexibility
- An effective weed management system to control and reduce the spread of herbicide-resistant weeds
- Increased crop safety relative to other herbicide options
- Remove concerns about plant-back and crop rotation due to long residuals
- Eliminate the need for complex application techniques such as soil incorporation
- Eliminate the need for escape management using directed sprays with a hooded applicator
- Reduced handling restrictions
- A more favorable toxicity profile and lower risk potential to applicators, consumers, and the environment compared to alternate herbicides

Dicamba use in combination with glyphosate and glufosinate in cotton that is tolerant of all three herbicides offers an attractive opportunity for cotton farmers to preserve the risk benefits that glyphosate offers while addressing the problem of glyphosate-resistant weeds. Dicamba's risk profile offers key improvements relative to the alternative cotton herbicide a.i.'s. In the following section, a comparative analysis of dicamba to the alternative cotton herbicide a.i.'s is presented.

Table C-8 lists the most-widely used cotton herbicide products. Table C-9 lists further information about the herbicidal a.i.'s used in cotton, such as the registration date, registration review status, RED date, where the tolerance information can be found, whether it is a reduced

[114] Johnson, B., B. Young, J. Matthews, P. Marquardt, C. Slack, K. Bradley, A. York, S. Culpepper, A. Hager, K. Al-Khatib, L. Steckel, M. Moechnig, M. Loux, M. Bernards and R. Smeda. 2010. Weed control in dicamba-resistant cottons. Plant Management Network, St. Paul, Minnesota. http://www.plantmanagementnetwork.org/sub/cm/research/2010/dicamba/

risk pesticide, and whether it is a restricted use pesticide. Tables C-8 and C-9 are the same as Tables A-47 and A-48 in Appendix A.

Table C-8. Dicamba and Alternative Registered Cotton Herbicides

Representative Brand (EPA Reg. No.)	Active Ingredient	2010 use area [3] For a.i. (K acres / %)	Signal Word	Content	Re-entry Interval (REI)	Max. Cotton lb/a (single application)	Max. Cotton lb/a (season)	Label Warnings or Special Directions
Clarity (7969-137)	Dicamba	855 / 1.8	Caution	4.0 lb a.e./gal	24 hr	1.0 [1]	2.0 [1]	Known to leach; 50-foot buffer to wells; Runoff advisory; Drift advisory; State-specific limitations; Soil type limitations; Maximum crop rotation interval 3 – 6 months.
Ignite (264-829)	Glufosinate ammonium	1,297 / 2.8	Warning	2.34 lb/gal	12 hr	0.79	1.59	Toxic to vascular plants; May have runoff potential; Drift advisory; 70-day cotton PHI; Little or no activity in soil; Not in Hawaii or S. Florida.
Roundup WeatherMAX (524-537)	Glyphosate	23,345 / 50.4	Caution	4.5 lb a.e./gal	4 hr	3.71	5.96	Weed resistance advisory; Drift advisory; 7-day cotton PHI.
Treflan HFP (62719-250)	Trifluralin	4,098 / 8.8	Caution	4.0 lb/gal	12 hr	2	2	Extremely toxic to freshwater, estuarine, and marine fish and invertebrates; Some crops have long rotational interval (18 - 20 mos.); 90-day cotton PHI.
Direx 4L (352-678)	Diuron	2,110 / 4.6	Caution	4 lb/gal	12 hr	1.6	2.2	Drift Advisory; Crop rotation intervals of 12 months common; State-specific limitations; Soil type limitations; Do not feed treated foliage to livestock.

Table C-8 (continued). Dicamba and Alternative Registered Cotton Herbicides

Prowl 3.3 EC	Pendimethalin	2,010 / 4.3	Caution	3.3 lb/gal	24 hr	2	2	Toxic to fish; Endangered plant species buffer required; Drift and runoff may be hazardous to aquatic organisms; Long (14 - 24 mos) crop rotation intervals for some crops; 60-day cotton PHI; State-specific limitation; Soil-type limitations; Do not feed treated foliage to livestock.
Valor SX (59639-99)	Flumioxazin	1,835 / 4.0	Caution	0.51 lb/lb	12 hr	0.06	0.13	Toxic to non-target plants & aquatic invertebrates; Runoff advisory; 40-foot aerial buffer to adjacent crops or water bodies; 12-month rotation interval common; Cotton injury possible; Do not feed treated foliage to livestock; 60-day cotton PHI.
Staple (352-576)	Pyrithiobac-sodium	1,689 / 3.6	Warning	0.85 lb/lb	24 hr	0.1	0.13	Highly toxic to non-target plants; Drift warnings; Cotton injury possible; Weed resistance advisory; 60-day cotton PHI; State-specific limitations (Staple LX); 10 – 12 month rotation intervals.
Staple LX (352-613)	Pyrithiobac-sodium		Caution	3.2 lb/gal	4 hr	0.1	0.13	
Dual Magnum (100-816)	S-Metolachlor	1,492 / 3.2	Caution	7.62 lb/gal	24 hr	1.27	2.48	Potential to leach; Potential for runoff; Ground & surface water advisory; State specific limitations; Soil type limitations; Swath adjustment 300 - 400 ft to avoid non-target plant injury; 80- to 100-day cotton PHI; Do not feed treated foliage to livestock.
MSMA 6 Plus (19713-42)	Monosodium Metharsonate	1,451 / 3.1	Caution	6 lb/gal	12 hr	1.88	3.75	50-foot buffer around all permanent water bodies; Drift warning about adjacent crops and sensitive areas; State specific limitations; No preplant cotton treatment; Do not feed treated foliage to livestock.

Table C-8 (continued). Dicamba and Alternative Registered Cotton Herbicides

Barage HF (5905-529)	2,4-D Ethylhexyl Ester (EHE)	1.421 / 3.1	Caution	4.7 lb a.e./gal	12 hr	2.35 [2]	4.7 [2]	Toxic to aquatic invertebrates; Drift may adversely affect non-target plants or invertebrates; Groundwater advisory; Weed resistant biotypes known; Do not spray if wind above 15 mph.
Weedar 64 (71368-1)	2,4-D Dimethylamine Salt (DMA)	[see 2,4-D total above]	Danger	3.8 lb a.e./gal	48 hr	1.9 [2]	3.8 [2]	May be toxic to fish & aquatic invert; May result in groundwater contamination; Drift warning; Do not apply if wind above 15 mph; Apply only when sensitive areas or plants are not with 250 feet downwind.
Reflex (100-993)	Fomesafen-sodium	1,415 / 3.1	Danger	2.0 lb a.e./gal	24hr	0.375	0.375	May leach; Groundwater advisory; Some long rotation intervals (up to 18 mos.); Cotton injury warning; Weed resistance advisory; State-specific limitations; Soil type limitations; 70-day cotton PHI
Gramoxone Inteon (100-1217)	Paraquat	1,078 / 2.3	Danger	2.0 lb cation/gal	12 hr	1	3	Restricted Use Pesticide due to acute toxicity; May be fatal if swallowed or inhaled; Toxic to wildlife; Damage / toxicity to non-target crops / plants; Drift advisory; Cotton injury possible; Do not feed treated foliage to livestock; 3-day cotton PHI.
Cotoran (66622-181)	Fluometuron	786 / 1.8	Caution	4 lb/gal	24 hr	2	3	Known to leach; May result in groundwater contamination; Weed resistance advisory; Avoid drift to sensitive areas; 12-month rotation interval for many crops; State-specific limitations; Soil type limitations; Do not feed treated foliage to livestock; 60-day cotton PHI.

Table C-8 (continued). Dicamba and Alternative Registered Cotton Herbicides

Caparol 4L (100-620)	Prometryn	867 / 1.9	Caution	4 lb/gal	24 hr	2.4	6	Drift and runoff may be hazardous to aquatic organisms; 400 ft upwind swath adjustment for sensitive plants; Weed resistance advisory; Crop injury possible; Soil type limitations; State-specific limitations; Do not feed treated foliage to livestock.
Envoke (100-1132)	Trifloxysulfuron-sodium	423 / 0.9	Caution	0.75 lb / lb	12	0.012	0.019	Toxic to vascular plants; Ground water advisory; Weed resistance advisory; Long rotational intervals (12 -22 mos, some zones); 60-day cotton PHI; 25-foot buffer around treated areas recommended; State specific limitations; Soil type limitations.
Aim EW (279-3242)	carfentrazone ethyl	89/0.16	Caution	1.9 lb/gal	12 hr	0.025	0.124	Carfentrazone-ethyl is very toxic to algae and moderately toxic to fish. Do not allow spray solution to contact cotton foliage, green stem tissue, or blooms.
Resolve DF (352-556)	rimsulfuron	11/0.02	Caution	granule	4 hr	Not labeled for Cotton	0.03	Do not apply preemergence to coarse textured soils (sand, loamy sand, or sandy loam) with less than 1% organic matter. Adequate soil moisture is required for optimum activity. Long rotational restrictions up to 10 months. Crop injury may occur following application if there is prolonged cold weather and/or wet soils.
Treaty (71368-74)	thifensulfuron methyl	81/0.15	Warning	granule	12 hr	0.02	Pre-plant burn down in cotton	Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Do not graze or feed forage or hay from treated areas to livestock. Weed control may be reduced if rainfall or snowfall occurs soon after application.

Table C-8 (continued). Dicamba and Alternative Registered Cotton Herbicides

Victory (71368-75)	tribenuron methyl	70/0.13	Caution	granule	12 hr	0.0125	Pre-plant burn down in cotton	Weed control in areas of thin crop stand or seedling skips may not be satisfactory. Weed control may be reduced if rainfall or snowfall occurs soon after application. Do not apply later than 14 days before planting cotton. Do not graze or feed associated by products for 60 days after application.
ET Herbicide (71711-7	Pyraflufen ethyl	56/0.1	Danger	0.208 lb/gal	12 hr	0.003	0.013	This pesticide is toxic to fish and aquatic invertebrates. Allow a minimum of 30 days between applications for use on cotton. Apply to cotton having less than 3 inches of stem bark using hooded ground equipment only. Avoid contact with desirable vegetation.
Goal 2XL (62719-424)	oxyfluorfen	190/0.34	Warning	2 lb/gal	24 hr	0.5	1	This product is toxic to aquatic invertebrates and wildlife. Do not graze or harvest plants from treated areas for feed or forage. Treated soil must be thoroughly mixed to a depth of 4 inches after harvest prior to planting a rotational crop. Care must be taken to avoid spray contact with cotton leaves. Do not apply to cotton less than 6 inches tall or severe crop injury will result.
Resource (59639-82)	flumiclorac pentyl ester	15/0.03	Warning	0.86 lb/gal	12 hr	0.05	0.094	Causes substantial but temporary eye injury. This product is toxic to shrimp. Keep out of lakes, ponds, and streams. Do not graze animals on green forage or use as feed fewer than 28 days after application.

Table C-8 (continued). Dicamba and Alternative Registered Cotton Herbicides

[1] Dicamba rates cited are those proposed for use on DGT cotton.

[2] 2,4-D products are not labeled for cotton treatments. Preplant treatments, more than 29 days before planting, are used for burndown weed control using the Fallow portion of the label.

[3] Monsanto private market survey data. The data shown are for the cotton acres to which the relevant active ingredient was applied in 2010, and the percentage of total treated acres this constitutes. A treated acre is application of one active ingredient once. Multiple active ingredients or multiple applications results in total treated acres that exceed total planted cotton acres. No entry is shown for products containing more than one active ingredient, since these acres are counted in the single active ingredient rows.

Table C-9. Dicamba Compared to Active Ingredients Contained in Alternative Herbicide Products

Active Ingredient	First Registered	Registration Review Status [1]	RED Date	Max. Cotton lb/a (single application) [2]	Max. Cotton lb/a (season) [2]	Tolerances 40 CFR 180.	EPA Reduced Risk Classification	Restricted Use
dicamba-diglycolamine salt	2-Feb-56	unsched.	2006	1.0[3]	2.0[3]	227	N	N
Glufosinate-ammonium	Glufosinate-ammonium	29-May-91	2008	N/A	0.79	1.59	473	Yes
Glyphosate (salts)	Glyphosate (salts)	7-Sept-88	2009	09/23/2009	3.71	5.96	364	Yes
Herbicide a.i.s Applied Primarily at a PE Timing								
2,4-D EHE (esters)[4]	3-Jun-52	2013	2005	2.0 [5]	4.0 [5]	142	N	N
2,4-D DMA (salts)[4]				2.0 [5]	4.0 [5]			
flumiclorac pentyl	23-Mar-94	2009	N/A	0.05	0.094	477	Yes	No
S-metolachlor	18-May-83	2016	12/01/19	1.27	2.48	368	Yes	No
oxyfluorfen	17-May-79	2015	10/01/20	0.5	1	381	No	No
pyraflufen ethyl	27-Sept-02	2014	N/A	0.003	0.013	585	No	No
rimsulfuron	20-Sept-89	2012	N/A	Not labeled for cotton	0.03	478	No	No
thifensulfuron methyl	25-Apr-86	2011	N/A	0.02	N/A	439	No	No
tribenuron methyl	22-May-89	2011	N/A	0.0125	N/A	451	No	No
Herbicide a.i.s Applied at both PE and POE Timings								
carfentrazone ethyl	02-Aug-95	2011	N/A	0.025	0.124	515	Yes	No
fluometuron	28-May-74	Unsched.	09/28/20			229	No	No
fomesafen sodium	10-Apr-87	2007	N/A	0.375	0.375	433	No	No
paraquat dichloride	08-Jan-80	2011	08/01/19	1	3	205	No	Yes
Prometryn	19-Aug-74	2013	1996	2.4	5.95	222	N	N
Pyrithiobac-Sodium	29-Jun-95	docket '11	NA	0.1	0.13	487	N	N

Table C-9 (continued). Dicamba Compared to Active Ingredients Contained in Alternative Herbicide Products

Herbicide a.i.s Applied Primarily at a POE Timing								
flumioxazin	01-Aug-96	2011	N/A	0.06	0.13	568	No	No
MSMA	25-Dec-63	2013	2006 corr	1.88	3.75	289	N	N
pendimethalin	20-Mar-75	2012	04/01/19	2	2	361	No	No
trifloxysulfuron-sodium	29-Jun-03	2013	NA	0.012	0.019	591	N	N
trifluralin	04-Dec-68	2012	09/01/19	2	2	207	No	No

- 1 Registration Review Status: year docket is scheduled to open, unless unscheduled. FWP = Final Work Plan stage. If docket is open, "docket XX" = year opened.
- 2 Rates for dicamba, 2,4-D, fomesafen, and glyphosate are expressed as acid equivalents. All others are on an a.i. basis, as stated, except paraquat is on a cation basis. Regional or soil type limitations may lower this rate.
- 3 Maximum treatment rates for the proposed dicamba label on DGT cotton.
- 4 For the 2,4-D ester group, the ethylhexyl ester (EHE) is taken as representative. For the salt group, the dimethylamine (DMA) salt is taken as representative.
- 5 Rates taken from Master 2,4-D Label (http://www.24d.org/masterlabel/default.aspx) for Fallow application. There are no specific cotton treatment directions. Fallow application must precede planting by 29 days or more.

C.5. Comparative Analysis for Water Impacts

The intent of this comparative analysis is to define current herbicide use in U.S. soybean and cotton production, and to compare dicamba's potential impacts on water, soil and air to herbicides currently used by growers for weed control. In order for a pesticide (e.g., dicamba herbicide) to be registered by U.S. EPA it must meet the FIFRA and FFDCA standards for safety to human health and the environment. The U.S. EPA must conclude that the herbicide when used according to the label does not pose an unreasonable risk to humans or the environment. Therefore, all alternative herbicides used in soybean and cotton production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba offers a reduction in risk potential (i.e., hazard) compared to some alternative herbicides in the same risk category (e.g., aquatic plant risk). In other instances dicamba presents a similar risk potential compared to some alternatives, and in some instances, dicamba presents a greater risk potential compared to some alternatives. This serves to demonstrate that with respect to potential impacts/risk to human health and the environment dicamba does not pose any appreciable difference to the human environment.

C.5.1. Soybean Analysis

C.5.1.1. Groundwater Comparison

Table C-10 provides information about the soil leaching potential of dicamba and the twenty-two alternative herbicide a.i.'s used in cotton. The two aspects of this evaluation are: (1) the properties of each substance indicating that it may likely move downward through the soil layers and contaminate groundwater; and (2) estimated groundwater concentrations at a level that could potentially represent a toxicity concern.

Herbicide physico-chemical properties that are associated with downward soil mobility have been widely investigated. Persistence in soil (slow degradation) and weak soil binding are common predictors of leachability risk. The Groundwater Ubiquity Score (GUS) is an empirical index that mathematically combines these two parameters to sort chemicals into categories ranging from "extremely low" likelihood of leaching to "very high" likelihood (Gustafson 1989).[115] Table C-10 lists information about:

[115] GUS is calculated as GUS = LOG_{10}(soil half-life)*(4-LOG_{10}(K_{oc})). The interpretation of GUS as a measure of the likelihood of leaching is as follows: < 0.1 = Extremely Low (EL); 0.1 – 1.0 = Very Low (VL); 1.1 – 2.0 = Low (L); 2.1 – 3.0 = Moderate (M); 3.1 – 4.0 = High (H); > 4.0 = Very High (VH).

- Soil degradation rate (soil half-life), which quantifies the time for 50% of the initial amount to dissipate. The typical values were obtained from the IUPAC Footprint database.[116]
- Soil mobility constant with regard to organic carbon (K_{oc}), which is the equilibrium concentration ratio between soil and pore water, normalized for the organic carbon content of the soil. Typical values were obtained from the IUPAC Footprint database.[117]
- The GUS index, calculated by the published mathematical formula, using the typical soil half-life and typical K_{oc} values, along with the interpretive category.
- The maximum single application rate in both pounds per acre and in kilograms per hectare for dicamba and each alternative herbicide a.i. Potential groundwater concentrations are directly related to application rate.
- The IUPAC Footprint database provides a standard estimate of groundwater concentration using EPA's SCI-GROW model and assumes a consistent 1.0 kilogram per hectare application. Because these estimates have been calculated in the same way for dicamba and the alternative herbicide a.i.'s, they serve as a basis for comparison of leachability.
- The IUPAC Footprint SCI-GROW estimates were adjusted to reflect the labeled maximum application rate in cotton by multiplication of the application rate in kilograms per hectare.
- In a dietary risk assessment, EPA assumes that a 10 kilogram child consumes 1 liter of water per day. Using this standard, the SCI-GROW-estimated groundwater concentrations due to the maximum cotton application rate were converted to the potential exposure to a child arising from drinking such groundwater, in milligrams of a.i. per kilogram of body weight per day. This calculation provides a way to compare potential groundwater concentration to toxicity thresholds. The child's water consumption was chosen over that of an adult because children's waterborne exposure is greater than that of an adult on a body weight basis, so it represents a worst-case assessment.
- The chronic Population Adjusted Dose from EPA is shown for comparison.
- The child's potential exposure to dicamba and each alternative herbicide a.i. via drinking groundwater expressed as a percentage of the cPAD.

Dicamba's SCI-GROW-estimated groundwater concentration (0.033 μg/L) is very small, particularly in relationship to dicamba's chronic toxicity reference point (cPAD). Table C-10 shows that a child's potential drinking water exposure to dicamba is calculated to be 0.0008% of the cPAD, where the cPAD is considered to be the highest safe chronic exposure level. Dicamba's estimated child exposure level is the 6th lowest among the twenty-two potential alternative a.i.'s for which such a value could be calculated in this analysis; data were not available for MSMA (see below). For some alternative herbicide a.i.'s, the child's potential drinking water exposure as a percentage of the respective cPAD was calculated to be 100- to 1000-fold higher than that of dicamba.

Two criteria were evaluated to determine a Groundwater Risk Score as shown in Table C-10. The first criterion was the GUS groundwater vulnerability index, indicating whether the a.i.'s physico-

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[116] The Footprint database, as presented by IUPAC at http://sitem.herts.ac.uk/aeru/iupac/index.htm

[117] Values from the Footprint database were not confirmed by comparison to values in U.S. registration documents such as REDs.

chemical properties predict downward soil mobility. GUS values above 3.0 are rated as high or very high leachability potential, which was chosen as one trigger for groundwater risk. A second criterion was the percentage of the cPAD potentially experienced by a child consuming the SCI-GROW-estimated groundwater concentration of each a.i. The % exposure above 0.1% of the cPAD was chosen as a second trigger for groundwater risk. A.i.'s that met both triggers, i.e., a high or very high GUS index and exposures > 0.1% of cPAD, were scored with a Black Circle. An a.i. that met just one of these two triggers was scored with a Half Circle. Those a.i.'s that met neither trigger are indicated in Table C-10 with a White Circle.

Monsanto believes that for groundwater risk, dicamba offers lower potential risk compared to thirteen of the alternative herbicide a.i.'s which were shown to have Black Circle or Half Circle scores.[118] The dietary exposure and groundwater contamination risk could be considered relatively greater for MSMA and fluometuron as compared to dicamba, therefore justifying their categorization as higher groundwater risk with Black Circle Groundwater Risk scores. Seven alternative herbicide a.i.'s have low Groundwater Risk Scores and are marked with White Circles.

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118 As discussed in section A.3.7.2.2, all alternative herbicides used in soybean production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category.

Table C-10. Groundwater and Leaching Parameters for Dicamba and Alternate Active Ingredients

Active Ingredient	Typical Soil Half-life[1]	Soil Mobility Koc[1]	GUS Leaching Index3 (Interpretation) [2]	Maximum Cotton lb/acre (single treatment) [3]	Maximum Cotton kg/ha (single treatment) [3]	SCI-GROW Conc. Est. @ 1 kg/ha [1]	SCI-GROW Conc. Est. @ cotton Max Rate [4]	Child (10 kg) consumption (1L/day) [5]	cPAD mg/kg/day [6]	Child's water exposure as % cPAD [7]	Groundwater and Leaching Score [8]
	days	(calc)		lb/acre	kg/ha	µg/L	µg/L	mg/kg			
dicamba acid /DGA salt	8	13.4	2.6 (M)	1	1.1	0.0326	0.03586	3.59E-06	0.45	0.0008	○
glufosinate-ammonium	7.4	600	1.1 (L)	0.79	0.89	0.00982	0.00874	8.74E-07	0.006	0.01457	*
glyphosate (salts)	10	1435	0.9 (VL)	2	4.2	0.00535	0.02247	2.25E-06	1.75	0.00013	*
Herbicide A.I.s with Potential Displacement of Preemergent Acres											
2,4-D DMA (salts)	2.5	88.4	2.1 (M)	2	2.24	0.0248	0.05555	5.56E-06	0.005	0.1111	◑
2,4-D EHE (esters)	64		1.62			0.0248	0.05555	5.56E-06	0.005	0.1111	◑
flumiclorac pentyl	86	30	1 (EL)	0.054	0.06048	0.0025	0.00015	1.51E-08	1	1.5E-06	○
S-metolachlor	90	120	1.9 (L)	1.31	1.4672	0.051	0.07483	7.48E-06	0.1	0.00748	◑
oxyfluorfen	4	100,000	0.19 (EL)	0.5	0.56	0.00658	0.00368	3.68E-07	0.03	0.00123	◑
pyraflufen ethyl	4	1949	0.43 (EL)	0.0053	0.005936	0.0023	1.3E-05	1.35E-09	0.2	6.7E-07	○
rimsulfuron	14	50.3	3.23 (H)	0.03	0.0336	0.317	0.01065	1.07E-06	0.118	0.0009	○
thifensulfuron methyl	4	28.3	1.53 (L)	0.047	0.05264	0.00351	0.00018	1.85E-08	0.043	4.3E-05	○
tribenuron methyl	0.5	35	2.88 (M)	0.047	0.05264	0.135	0.00711	7.11E-07	0.008	0.00888	◑
Herbicide A.I.s with Potential Displacement of both Preemergent and Postemergent Acres											
carfentrazone ethyl	15	866	0.32 (EL)	0.031	0.03472	5.9E-05	2.1E-06	2.06E-10	0.03	6.9E-07	○
fluometuron	35	175	**3.9 (H)**	2	2.24	1.04	2.3296	2.33E-04	0.006	4.23564	●
fomesafen sodium	1067	50	**4.4 (VH)**	0.38	0.4256	0.408	0.17364	1.74E-05	0.003	0.69458	●
paraquat dichloride	24.3	100000	-0.6 (EL)	1	1.12	0.00535	0.00599	5.99E-07	0.005	0.01332	◑
prometryn	49	400	2.3 (M)	2.4	2.688	0.0113	0.03037	3.04E-06	0.04	0.00759	◑
Pyrithiobac-sodium	181	9	**5.4 (VH)**	0.1	0.112	5.49	0.61488	6.15E-05	0.58	0.0106	●
Herbicide A.I.s with Potential Displacement of Postemergent Acres											
flumioxazin	200	889	1.4 (L)	0.06	0.0672	0.029	0.00195	1.95E-07	0.02	0.00097	○
MSMA	41	-	2.3 (M)	1.88	2.1056	-	-	-	0.03	-	●
pendimethalin	60	17581	-0.5 (EL)	1.98	2.2176	0.00535	0.01186	1.19E-06	0.03	0.00395	◑
Trifloxysulfuron-sodium	63.5	306	**5.6 (VH)**	0.012	0.01344	0.216	0.0029	2.90E-07	0.237	0.00012	○
trifluralin	181	15800	-0.4 (EL)	2	2.24	0.00613	0.01373	1.37E-06	0.024	0.00572	◑

[1] Parameters obtained from the Footprint database, as presented by IUPAC http://sitem.herts.ac.uk/aeru/iupac/index.htm or http://pmep.cce.cornell.edu/profiles/extoxnet/index.html

[2] Gustafson DI (1989): Groundwater ubiquity score: A simple method for assessing pesticide leachability. Environ Toxicol. Chem. 8, 339–357. GUS is calculated as GUS = LOG10(soil half-life)*(4-LOG10(Koc)). The interpretation of GUS as a measure of the likelihood of leaching is as follows: < 0.1 = Extremely Low (EL); 0.1 – 1.0 = Very Low (VL); 1.1 – 2.0 = Low (L); 2.1 – 3.0 = Moderate (M); 3.1 – 4.0 = High (H); > 4.0 = Very High (VH).

[3] Maximum labeled single application rate to cotton. This rate was converted to kg/hectare (ha) units using: 1 lb = 0.454 kg and 1 acre = 0.405 ha.

[4] The Footprint database, as presented by IUPAC http://sitem.herts.ac.uk/aeru/iupac/index.htm, provides a SCI-GROW concentration estimate for groundwater based on the a.i.s chemical properties using a consistent set of assumptions, including a 1 kg/ha application. This was converted to a concentration estimate by multiplying by the maximum single cotton application rate in kg/ha.

[5] Using standard EPA assumptions for a child's water consumption and weight (1 liter per day, 10 kg body weight), the groundwater concentration estimate was converted to a daily exposure estimate.

[6] The chronic population adjusted dose (cPAD) as determined by EPA risk assessments.

[7] The child's daily exposure estimate was compared to the chronic population adjusted dose (cPAD) as determined for the a.i. by EPA, and expressed as a percentage.

[8] The Groundwater and Leaching score is determined by combining two criteria listed in Table C-10. A GUS groundwater vulnerability index that is rated high (H) or very high (VH) constitutes one criterion. When the Child's water exposure is greater than 0.001 that constitutes a second criterion. When both criteria are exceeded, the a.i. is marked with a Black Circle. When only one is exceeded, the a.i. is marked with a half Circle. Exceedance of neither criterion earns a White Circle.

* Glufosinate and glyphosate were not included in the comparison because Monsanto will recommend their use as part of an integrated pest management system.

C.5.1.2. Surface water and ecological effects on aquatic organisms

C.5.1.2.1. Fish and Aquatic Invertebrates

Table C-11 provides information about the hazards, exposures, and risks of dicamba and each of the eighteen alternative herbicides to fish and aquatic invertebrates (considering 2,4-D acid, salts, and esters as one alternative herbicide). The listed parameters include:

- LC_{50} endpoints from acute fish toxicity studies, as reported in EPA's ecotoxicity database[119], published in a RED or in Registration Review risk assessments. The highest and lowest available LC_{50} values for any fish study are listed, regardless of species, including both fresh and marine species together. The purpose is to define a range of concentrations that spans the expected fish toxicity levels.
- EC_{50} endpoints from acute aquatic invertebrate studies, as reported from the same sources cited above. The highest and lowest available EC_{50} values for any invertebrate study are listed, regardless of species, including both fresh and marine species together. The purpose is to define a range of concentrations that spans the expected aquatic invertebrate-toxic levels.
- Estimated environmental exposure concentrations (EECs) in surface water for each of the eighteen alternative herbicides. The third column in Table C-11, identified as "Calculated EEC", provides a simple standard estimate based on the maximum single application rate in soybean, using EPA's standard field-farm pond scenario. This scenario examines a 1-acre pond in a 10-acre field in which (1) 5% of the application drifts into the 6-foot-deep pond and (2) 5% of the application onto the 10 acres runs off into the same pond. The fourth column in Table C-11 lists other model estimates of surface water concentrations as provided by one or more modeling programs, as cited by EPA in public documents, such as Federal Register final tolerance rule drinking water assessments. The purpose is to define a range of concentrations that spans available estimates of potential aquatic exposure levels.
- Calculated Risk Quotients (RQs) for aquatic animals, comprised of fish and aquatic invertebrates combined together. Rather than calculate a single RQ for each species, Monsanto has calculated a range of potential RQs for each herbicide, bracketed by the best- and worst-case values. The "best" RQ is derived from the ratio of the lowest reported EEC concentration divided by the highest LC_{50} or EC_{50} for any aquatic animal. Conversely, the "worst" RQ is derived from the ratio of the highest EEC concentration divided by the lowest LC_{50} or EC_{50} for any aquatic animal. (Note: the RQ figures are rounded to two decimal places, so that entries that appear as "0.00" mean that the specific RQ is less than 0.005.) The purpose is to define a range of RQs that span and describe the risk posed by the alternative herbicide to aquatic animals. The RQs that exceed the EPA's Level of Concern (LOC) of 0.5 are marked in bold font.

Using the worst-case risk quotient, ten of 18 alternative herbicides have risk quotients greater than or equal to 0.01, while the worst-case risk quotient for dicamba and seven other herbicides is <0.01.

[119] National Information System – Regional IPM Centers. OPP Pesticide Ecotoxicity Database. http://www.ipmcenters.org/Ecotox/index.cfm [Accessed May 27, 2010].

Only three of these 10 herbicides have risk quotients greater than 0.05 or 0.1, the levels of concern for threatened or endangered species and acute restricted use, respectively. Two of these 10 herbicides have RQ values greater than 0.5, the highest acceptable level of concern. Monsanto believes that based on risk quotients, dicamba offers a lower risk to aquatic animals relative to at least three of the 18 alternative herbicides: 2,4-D esters, flumioxazin, and lactofen. This conclusion is tabulated in Table C-6, which summarizes the comparative analysis of dicamba and alternative herbicides.

Table C-11. Aquatic Toxicity Parameters for Fish and Aquatic Invertebrates for Alternative Herbicides

Active Ingredient	Maximum Soybean lb/acre (single treatment)[1]	Calculated EEC (ppm) [2,3]	FIRST, GENEEC or PRZX/EXAMS Surface Water ppm (RED or Tolerance Rule)[4]	Fish LC_{50} Range (ppm)[5]		Aquatic Invertebrate LC_{50} or EC_{50} Range (ppm)[f]		Risk Quotient for Aquatic Animals Range[6]		Label Warnings[7]
				low	high	low	high	best	worst	
glyphosate salts	1.5	0.050	0.0008 - 0.021	45	>1000	55	780	0.00	0.00	
dicamba /DGA salt	1	0.034	0.01 - 0.036	28	> 270	>100	>270	0.00	0.00	
2,4-D acid + salts	0.93	0.031	0.064 - 0.118	>80	2244	25	820	0.00	0.00	
2,4-D esters	0.93	0.031	0.064 - 0.118	>0.15	14.5	2.2	12	0.00	**< 0.79**	
flumioxazin	0.096	0.003	0.018 - 0.034	2.3	21	0.23	5.5	0.00	0.15	"toxic to invertebrates"
imazethapyr	0.064	0.002	0.006	> 112	423	> 109	> 1000	0.00	0.00	
cloransulam-methyl	0.04	0.001	0.002	> 86	> 154	> 111	> 121	0.00	0.00	"toxic to invertebrates"
chlorimuron-ethyl	0.14	0.005	0.003 - 0.005	> 2	8.4	>10[a]	> 10	0.00	0.00	
fomesafen	0.375	0.013	0.006 - 0.012	126	> 163	25	376	0.00	0.00	
flumiclorac-pentyl	0.081	0.003	0.00024	>0.189	> 24	>0.189	>38	0.00	0.02	"toxic to shrimp"
sulfentrazone	0.31	0.010	0.004 - 0.016	94	> 120	1	60.4	0.00	0.02	"toxic to invertebrates"
thifensulfuron	0.013	0.000	0.0003 - 0.004	>100	> 100	>1000	> 1000	0.00	0.00	

Table C-11 (continued). Aquatic Toxicity Parameters for Fish and Aquatic Invertebrates for Alternative Herbicides

Active Ingredient	Maximum Soybean lb/acre (single treatment)[1]	Calculated EEC (ppm) [2,3]	FIRST, GENEEC or PRZX/EXAMS Surface Water ppm (RED or Tolerance Rule)[4]		Fish LC_{50} Range (ppm)[5]		Aquatic Invertebrate LC_{50} or EC_{50} Range (ppm)[5]		Risk Quotient for Aquatic Animals Range[6]			Label Warnings[7]
					low	high	low	high	best	worst		
imazaquin	0.123	0.004	0.004 - 0.008		280	420	280[a]	280	0.00	0.00		
imazamox-ammonium	0.04	0.001	0.002		> 94.2	> 122	>94.3	> 122	0.00	0.00		
paraquat dichloride	1.0	0.033	0.0015		> 1	156	1.2	1.2	0.00	< 0.05		
lactofen	0.3	0.011	0.000008 - 0.4		0.46	0.46	0.02	4.85	0.00	**20**		"toxic to fish"
glufosinate-ammonium	0.66	0.022	0.043 - 0.094		> 320	> 1000	8	668	0.00	0.01		
2,4-DB	0.4	0.013	0.013 - 0.015		2	18	25[a]	25	0.00	0.01		"toxic to fish"
fluthiacet-methyl	0.0065	0.000	0.0005 - 0.0008		0.043	0.16	0.3	>2.3	0.00	0.02		
acifluorfen sodium	0.374	0.013	0.0024 - 0.010		31	204	28.1	> 1000	0.00	0.00		
mesotrione	0.1875	0.011	0.004 - 0.02		> 114	520	3.3	840	0.00	0.01		

[1]The highest single-treatment rate permitted by the herbicide's product labels. This rate is used to calculate potential acute exposure to aquatic non-target species via spray drift or runoff.

[2]Based on the maximum single treatment rate, with 5% spray drift and 5% runoff from 10 treated acres into a 1-acre 6-foot-deep pond.

[3]The Estimated Environmental Concentration in surface water. It was calculated by Monsanto using the EPA's "standard field-farm pond scenario" http://www.epa.gov/oppefed1/models/water/geneec2_description.htm. In this scenario, it is assumed that the herbicide is applied to a 10 acre farm field containing a 1 acre pond that is six feet deep. The pond experiences 5% of the application rate by spray drift and 5% of the application on the soil enters the pond via runoff. This concentration estimation is a simple, conservative Tier 1 procedure that utilizes only the application rate to estimate aquatic exposures, and allows quick comparison of many different herbicides. Other more increasingly-detailed computer models can be used to obtain more refined EEC estimates, but these require the user to input various physical chemical parameters and weather data for each product to be modeled. Examples of these methods are listed in the next column.

[4]Modeling estimates of potential aquatic exposure levels. When EPA conducts risk assessments, it uses computer models to obtain estimates of potential surface water concentrations. These are published in the RED for each herbicide, or in tolerance rules in the Federal Register. The range of estimates is listed, which can be

compared to the single number in the prior column. Sources of these estimates are listed in the "ALTERNATIVE HERBICIDE-SPECIFIC REFERENCES" section.

[5]"Fish LC_{50} Range (ppm)" and "Aquatic Invertebrate LC_{50} or EC_{50} Range (ppm)". These four columns describe the range of hazard data found in public data sources representing the toxicity of each herbicide versus freshwater and marine animals. The LC_{50} or EC_{50} means the water concentration needed to kill or immobilize half of the test species, which is a standard potency descriptor. The highest and lowest values found for any fish species (trout, bluegill, sheepshead, etc.) were tabulated. Likewise, the highest and lowest values found for any aquatic invertebrate species (Daphnia, shrimp, crab, etc.) were included. Sources of these data are listed in the "ALTERNATIVE HERBICIDE-SPECIFIC REFERENCES" section and in available public databases (National Information System – Regional IPM Centers. OPP Pesticide Ecotoxicity Database. http://www.ipmcenters.org/Ecotox/index.cfm).

[6]EPA's EFED uses a Risk Quotient (RQ) method for ecological risk assessment. The RQ equals the potential exposure level divided by the hazard level. Higher exposures or more potent hazard findings lead to higher RQs. EFED has established Levels of Concern (LOCs) for various non-target species categories. When the RQ exceeds the LOC, further refinement is needed to determine whether risk mitigation might be needed. For non-listed aquatic animals, the LOC for acute risk is 0.5, for acute risk restricted use is 0.1, and for threatened or endangered species it is 0.05. In this analysis, Monsanto calculated best-case RQs by dividing the lowest EEC estimate by the highest hazard (LC_{50} or EC_{50}) value, and calculated the worst-case RQ from the highest EEC and lowest hazard value. The purpose was to bracket a range that typified the aquatic animal risk presented by each herbicide. When neither the worst-case nor the best-case RQs exceed a LOC of 0.05, Monsanto concluded that risk to aquatic animals is minimal. Instances where the LOC threshold of 0.5 is exceeded are highlighted in bold font.

[7]Lists instances where the product label includes warning statements about aquatic animal exposure.

C.5.1.2.2. Aquatic Plants

Table C-12 provides information about the hazards, exposures, and risks of dicamba and each of the eighteen (18) alternative herbicides to aquatic plant species, specifically duckweed and aquatic algae species (considering 2,4-D acid, salts, and esters as one alternative herbicide). The data format, sources, and methods of Estimated Environmental Exposure Concentration (EEC) calculation are identical to those described above for the aquatic animals (Table C-11). A Level of Concern (LOC) value of 1.0 has been used for judging RQ exceedances in the case of aquatic plants, consistent with EPA EFED's normal practices.

The assessment and comparison summarized in Table C-12 establishes that dicamba poses little acute risk to aquatic plants at use rates of 0.05 – 1.0 lb dicamba a.e./acre, which is consistent with EFED's assessment published in the RED EFED Chapter. Monsanto was unable to identify aquatic plant hazard data for three of the alternative herbicides (imazaquin, chlorimuron-ethyl, and flumiclorac-pentyl). For nine (9) of the eighteen (18) alternative herbicides, the range of RQs is < 0.005 to 0.75; that is, none of these nine a.i.'s present an aquatic plant risk, which even in the worst-case calculation, reach EFED's Level of Concern (LOC) for aquatic plants. However, for seven of the alternative herbicides, the worst-case RQs did exceed EFED's LOC of 1.0. It is not surprising that some herbicides are quite toxic to aquatic plants, and the worst-case RQs for three of the alternate herbicides (flumioxazin, lactofen, and paraquat dichloride) exceeded the LOC by a factor of more than 50-fold.

Monsanto believes that dicamba offers a lower risk to aquatic plants relative to at least seven of the 18 alternative herbicides (2,4-D, flumioxazin, sulfentrazone, thifenslufuron, paraquat dichloride, lactofen, and mesotrione). This conclusion is tabulated in Table C-6, which summarizes the comparative analysis of dicamba and alternative herbicides.

Table C-12. Aquatic Toxicity Parameters for Aquatic Plants for Alternative Herbicides

Active Ingredient	Maximum Soybean lb/acre (single treatment)[1]	Calculated EEC (ppm) [2,3]	FIRST, GENEEC or PRZX/EXAMS Surface Water ppm (RED or Tolerance Rule)[4]	Duckweed and Algae EC_{50} Range (ppm)[5]		Risk Quotient for Aquatic Plants Range[6]	
				low	high	best	worst
glyphosate salts	1.5	0.050	0.0008 - 0.021	0.77	38.6	0.00	0.06
dicamba /DGA salt	1	0.034	0.01 - 0.036	0.06	> 3.7	0.00	0.60
2,4-D acid + salts	0.93	0.031	0.064 - 0.118	0.29	156	0.00	0.41
2,4-D esters	0.93	0.031	0.064 - 0.118	0.066	>19.8	0.00	**1.79**
flumioxazin	0.096	0.003	0.018 - 0.034	0.0005	0.019	0.16	**68.00**
imazethapyr	0.064 *	0.002	0.006	0.008	59.2	0.00	0.75
cloransulam-methyl	0.04	0.001	0.002	0.003	135	0.00	0.67
chlorimuron-ethyl	0.14	0.005	0.003 - 0.005	NA	NA	NA	NA
fomesafen	0.375	0.013	0.006 - 0.012	0.09	71	0.00	0.14
flumiclorac-pentyl	0.081	0.003	0.00024	NA	NA	NA	NA
sulfentrazone	0.31	0.010	0.004 - 0.016	0.002	0.033	0.12	**8.0**
thifensulfuron	0.013	0.000	0.0003 - 0.004	0.0016	> 0.026	0.02	**2.50**
imazaquin	0.123	0.004	0.004 - 0.008	NA	NA	NA	NA
imazamox-ammonium	0.04	0.001	0.002	0.011	> 0.038	0.03	0.18
paraquat dichloride	1.0	0.033	0.0015	0.00055	2.84	0.00	**90.9**
lactofen	0.3	0.011	0.000008 - 0.4	0.001	0.001	0.00	**400**
glufosinate-ammonium	0.66	0.022	0.043 - 0.094	1.5	7.8	0.00	0.06
2,4-DB	0.4	0.013	0.013 - 0.015	>0.932	>0.932	<0.01	<0.02
fluthiacet-methyl	0.0065	0.000	0.0005 - 0.0008	0.0022	>0.018	<0.01	0.36
acifluorfen sodium	0.374	0.013	0.0024 - 0.010	> 0.26	0.38	0.01	<0.05
mesotrione	0.1875	0.011	0.004 - 0.02	0.018	132	0.00	**1.11**

The first three columns in this table are identical to- those in Table C-11.

[1]The highest single-treatment rate permitted by the herbicide's product labels. This rate is used to calculate potential acute exposure to aquatic non-target species via spray drift or runoff.

[2]Based on the maximum single treatment rate, with 5% spray drift and 5% runoff from 10 treated acres into a 1-acre 6-foot-deep pond.

[3]The Estimated Environmental Concentration in surface water. It was calculated by Monsanto using the EPA's "standard field-farm pond scenario" http://www.epa.gov/oppefed1/models/water/geneec2_description.htm |Accessed May 28, 2010|. In this scenario, it is assumed that the herbicide is applied to a 10 acre farm field containing a 1 acre pond that is six feet deep. The pond experiences 5% of the application rate by spray drift and 5% of the application on the soil enters the pond via runoff. This concentration estimation is a simple, conservative Tier 1 procedure that utilizes only the application rate to estimate aquatic exposures, and allows quick comparison of many different herbicides. Other more increasingly-detailed computer models can be used to obtain more refined EEC estimates, but these require the user to

input various physical chemical parameters and weather data for each product to be modeled. Examples of these methods are listed in the next column.

[4]Modeling estimates of potential aquatic exposure levels. When EPA conducts risk assessments, it uses a computer models to obtain estimates of potential surface water concentrations. These are published in the RED for each herbicide, or in tolerance rules in the Federal Register. The range of estimates is listed, which can be compared to the single number in the prior column. Sources of these estimates are listed in the "ALTERNATIVE HERBICIDE-SPECIFIC REFERENCES" section.

[5]These two columns describe the range of hazard data found in public data sources representing the toxicity of each a.i. versus freshwater and marine plants. The EC_{50} means the water concentration needed to kill or prevent growth of half of the test species, which is a standard potency descriptor. The highest and lowest values found for any aquatic plant species (diatom, duckweed, alga, etc.) were tabulated. Sources of these data are listed in the "ALTERNATIVE HERBICIDE-SPECIFIC REFERENCES" section of this document and in available public databases cited in National Information System – Regional IPM Centers. OPP Pesticide Ecotoxicity Database. http://www.ipmcenters.org/Ecotox/index.cfm

[6]As described above for Table C-11, EPA's EFED uses a Risk Quotient (RQ) method for ecological risk assessment. For non-listed aquatic plants or for threatened or endangered species the LOC is 1.0. In this analysis, Monsanto calculated best-case RQs by dividing the lowest EEC estimate by the highest hazard (EC_{50}) value, and calculated the worst-case RQ from the highest EEC and lowest hazard value. The purpose was to bracket a range that typified the aquatic plant risk presented by each herbicide. When neither the worst-case nor the best-case RQs exceed a LOC of 1.0, Monsanto concluded that risk to aquatic plants is minimal. Instances where the LOC threshold of 1.0 is exceeded are highlighted in bold font.

C.5.2. Cotton Analysis

C.5.2.1. Groundwater Comparison

Table C-10 provides information about the soil leaching potential of dicamba and the twenty-two alternative herbicide a.i.'s used in cotton. The two aspects of this evaluation are: (1) the properties of each substance indicating that it may likely move downward through the soil layers and contaminate groundwater; and (2) estimated groundwater concentrations at a level that could potentially represent a toxicity concern.

Herbicide physico-chemical properties that are associated with downward soil mobility have been widely investigated. Persistence in soil (slow degradation) and weak soil binding are common predictors of leachability risk. The Groundwater Ubiquity Score (GUS) is an empirical index that mathematically combines these two parameters to sort chemicals into categories ranging from "extremely low" likelihood of leaching to "very high" likelihood (Gustafson 1989).[120] Table C-11 lists information about:

[120] GUS is calculated as GUS = LOG_{10}(soil half-life)*(4-$LOG_{10}(K_{oc})$). The interpretation of GUS as a measure of the likelihood of leaching is as follows: < 0.1 = Extremely Low (EL); 0.1 – 1.0 = Very Low (VL); 1.1 – 2.0 = Low (L); 2.1 – 3.0 = Moderate (M); 3.1 – 4.0 = High (H); > 4.0 = Very High (VH).

- Soil degradation rate (soil half-life), which quantifies the time for 50% of the initial amount to dissipate. The typical values were obtained from the IUPAC Footprint database.[121]
- Soil mobility constant with regard to organic carbon (K_{oc}), which is the equilibrium concentration ratio between soil and pore water, normalized for the organic carbon content of the soil. Typical values were obtained from the IUPAC Footprint database.[122]
- The GUS index, calculated by the published mathematical formula, using the typical soil half-life and typical K_{oc} values, along with the interpretive category.
- The maximum single application rate in both pounds per acre and in kilograms per hectare for dicamba and each alternative herbicide a.i. Potential groundwater concentrations are directly related to application rate.
- The IUPAC Footprint database provides a standard estimate of groundwater concentration using EPA's SCI-GROW model and assumes a consistent 1.0 kilogram per hectare application. Because these estimates have been calculated in the same way for dicamba and the alternative herbicide a.i.'s, they serve as a basis for comparison of leachability.
- The IUPAC Footprint SCI-GROW estimates were adjusted to reflect the labeled maximum application rate in cotton by multiplication of the application rate in kilograms per hectare.
- In a dietary risk assessment, EPA assumes that a 10 kilogram child consumes 1 liter of water per day. Using this standard, the SCI-GROW-estimated groundwater concentrations due to the maximum cotton application rate were converted to the potential exposure to a child arising from drinking such groundwater, in milligrams of a.i. per kilogram of body weight per day. This calculation provides a way to compare potential groundwater concentration to toxicity thresholds. The child's water consumption was chosen over that of an adult because children's waterborne exposure is greater than that of an adult on a body weight basis, so it represents a worst-case assessment.
- The chronic Population Adjusted Dose from EPA is shown for comparison.
- The child's potential exposure to dicamba and each alternative herbicide a.i. via drinking groundwater expressed as a percentage of the cPAD.

Dicamba's SCI-GROW-estimated groundwater concentration (0.033 μg/L) is very small, particularly in relationship to dicamba's chronic toxicity reference point (cPAD). Table C-10 shows that a child's potential drinking water exposure to dicamba is calculated to be 0.0008% of the cPAD, where the cPAD is considered to be the highest safe chronic exposure level. Dicamba's estimated child exposure level is the 6th lowest among the twenty-two potential alternative a.i.'s for which such a value could be calculated in this analysis; data were not available for MSMA (see below). For some alternative herbicide a.i.'s, the child's potential drinking water exposure as a percentage of the respective cPAD was calculated to be 100- to 1000-fold higher than that of dicamba.

Two criteria were evaluated to determine a Groundwater Risk Score as shown in Table C-10. The first criterion was the GUS groundwater vulnerability index, indicating whether the a.i.'s physico-

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121 The Footprint database, as presented by IUPAC at http://sitem.herts.ac.uk/aeru/iupac/index.htm

122 Values from the Footprint database were not confirmed by comparison to values in U.S. registration documents such as REDs.

chemical properties predict downward soil mobility. GUS values above 3.0 are rated as high or very high leachability potential, which was chosen as one trigger for groundwater risk. A second criterion was the percentage of the cPAD potentially experienced by a child consuming the SCI-GROW-estimated groundwater concentration of each a.i. The % exposure above 0.1% of the cPAD was chosen as a second trigger for groundwater risk. A.i.'s that met both triggers, i.e., a high or very high GUS index and exposures > 0.1% of cPAD, were scored with a Black Circle. An a.i. that met just one of these two triggers was scored with a Half Circle. Those a.i.'s that met neither trigger are indicated in Table C-10 with a White Circle.

Monsanto believes that for groundwater risk, dicamba offers reduced risk compared to thirteen of the alternative herbicide a.i.'s which were shown to have Black Circle or Half Circle scores.[123] The dietary exposure and groundwater contamination risk could be considered relatively greater for MSMA and fluometuron as compared to dicamba, therefore justifying their categorization as higher groundwater risk with Black Circle Groundwater Risk scores. Seven alternative herbicide a.i.'s have low Groundwater Risk Scores and are marked with White Circles.

C.5.2.2. Surface Water and Ecological Effects on Aquatic Organisms

C.5.2.2.1. Fish and Aquatic Invertebrates

Table C-13 provides information about the hazards, exposures, and risks of dicamba DGA salt and each of the twenty-two alternative a.i.'s used in cotton to fish and aquatic invertebrates. For this analysis, 2,4-D DMA salt and 2,4-D EHE are considered separately, since they have substantially different water solubility. The criteria in this category include:

- Estimated environmental concentrations (EECs) of each of the seventeen (17) a.i.'s in surface water using the 4-day EEC as described by the Generic Estimated Environmental Concentration (GENEEC)[124] model. This model is used by EPA to estimate a pesticide's environmental exposure to aquatic ecosystems based on parameters including application rate, degradation rate, soil-binding properties, etc.
- LC_{50} endpoints from acute fish toxicity studies or EC_{50} hazard values from the National Site for the USDA Regional IPM Centers Information System. The highest and lowest LC_{50} values for any reported fish study are listed for each a.i., regardless of species, including both fresh and marine species together. The purpose is to define a range of concentrations that encompass expected fish-toxic levels. In some cases, study results based on testing end-use formulations

123 As discussed in section A.4.2.2, all alternative herbicides used in soybean production can be used safely, and do not pose an unreasonable risk to humans or the environment. Nonetheless, in some instances dicamba has a more benign human health or environmental profile compared to some alternative herbicides in the same risk category.

124 US EPA provides access to GENEEC via a downloadable executable program and users manual at http://www.epa.gov/oppefed1/models/water/#geneec2.

were generally omitted unless data on the active ingredient was not available, or it was likely that formulation components did not influence the study results.

- EC_{50} or LC_{50} endpoints from acute aquatic invertebrate studies, as reported from the National Site for the USDA Regional IPM Centers Information System. The highest and lowest EC_{50} or LC_{50} values for any invertebrate study are listed, regardless of species, including both fresh water and marine species together. The purpose is to define a range of concentrations that encompass expected aquatic invertebrate-toxic levels. Studies on end-use formulations were considered as described above. Results attributable to formulation ingredients, such as solvents or surfactants, were sometimes omitted.
- Calculated Risk Quotients (RQs) for aquatic animals, comprised of fish and aquatic invertebrates combined together. Rather than calculate a single RQ for each species, Monsanto has calculated a range of potential RQs for each a.i., bracketed by the best- and worst-case values. The "best" RQ is derived from the ratio of the lowest reported EEC concentration divided by the highest LC_{50} or EC_{50} for any aquatic animal. Conversely, the "worst" RQ is derived from the ratio of the highest EEC concentration divided by the lowest LC_{50} or EC_{50} for any aquatic animal. The purpose is to define a range of RQs that span and describe the risk posed by the alternative herbicide to aquatic animals. The RQs that exceed the EPA's Level of Concern (LOC) of 0.5 are marked in bold red font.
- The Aquatic Fish and Invertebrate Score is a means of summarizing the risk data for aquatic animals that is based entirely on the calculated risk quotient. A White Circle means that the worst-case RQ estimate < 0.05, which is EPA's LOC for acute aquatic risk for endangered aquatic animals. A Half Circle means that the worst case risk quotient is greater than 0.05 and less than 0.5 ($0.5 > RQ > 0.05$). 0.5 is EPA's LOC for acute aquatic risk for non-endangered animals. A Black Circle means that the worst-case RQ is greater than 0.5, indicating an acute risk for aquatic animals above EPA's Level of Concern (LOC).
- The assessment and comparison summarized in Table C-13 establishes that dicamba poses little acute risk to aquatic animals, which is consistent with EFED's assessment published in the EFED chapter in the RED (EPA 2006). The entries that exceed this LOC are those "worst case" values for 2,4-D (acid / salt and esters considered separately), flumiclorac pentyl, oxyluorfen, pyraflufen ethyl, pendimethalin, and trifluralin. These a.i.'s received a Black Circle for their Aquatic Fish and Invertebrate Score, and their RQ's are highlighted in red bold font.
- Five alternative a.i.'s (S-metolachlor, carfentrazone ethyl, fluometuron, prometryn, and flumioxazin) have worst case RQs above 0.05 but less than 0.5 and received a Half Circle for their Aquatic Fish and Invertebrate Scores. EPA considers the LOC for aquatic animals that are endangered species to be 0.05. The labels for herbicide products that received a Black Circle Aquatic Fish and Invertebrate Score and the labels for some of the herbicide products that received a Half-Circle Aquatic Fish and Invertebrate Score also bear warning statements for toxicity to fish or invertebrates based on the hazard values of those a.i.'s. Therefore, Monsanto concludes that dicamba presents less risk to aquatic animals than twelve of the twenty-two alternative herbicidal a.i.'s used on cotton as presented in Table C-13.

Table C-13. Aquatic Toxicity for Fish and Aquatic Invertebrates from Acute Exposure

Active Ingredient	GENEEC[2] 4-day EEC	Fish LC_{50} Range [3] (ppm)		Aquatic Invertebrate LC_{50} or EC_{50} [3] Range (ppm)		Risk Quotient for Aquatic Animals Range [4] Exposure/Hazard		Aquatic Fish and Invertebrate Score [5]
	(ppm)	low	high	low	high	best	worst	
dicamba acid /DGA salt[6]	0.049	> 270	-	> 270	-	-	0	○
glufosinate-ammonium	0.022	13.1	> 1000	7.5	668	0	0.003	*
glyphosate (salts)	0.0597	45	> 1000	> 10	934	0	0.001	*
Herbicide A.I.s with Potential Displacement of Preemergent Acres								
2,4-D DMA (salts)	0.087	> 100	524	0.15	103	0.001813	**0.580**	●
2,4-D EHE (esters)	0.09	18	180	0.054	> 5	0.0005	**1.67**	●
flumiclorac pentyl	0.95	1.1	17.4	0.56	38	0.025	**1.70**	●
S-metolachlor	0.054	3.2	17	1.4	26	0.002077	0.039	◑
oxyfluorfen	2.55	0.074	0.17	0.069	1000	0.00255	**37**	●
pyraflufen ethyl	74.14	0.056	99	0.043	121	0.612727	**1724**	●
rimsulfuron	2.33	110	1000	110	390	0.00233	0.021	○
thifensulfuron methyl	2.29	100	100	NA	NA	0	0.023	○
tribenuron methyl	2.87	1000	1000	720	720	0.00287	0.004	○
Herbicide A.I.s with Potential Displacement of both Preemergent and Postemergent Acres								
carfentrazone ethyl	279.89	1.14	2	1.16	9.8	0.00551	0.05	◑
fluometuron	0.107	0.64	65	> 1	22	0	0.167	◑
fomesafen sodium	0.021	> 163	6030	22.1	397	0	0.001	○
paraquat dichloride	0.0026	> 1	156	> 1	11	0	0.0026	○
prometryn	0.09	> 1	10	1.7	21	0	0.052941	◑
Pyrithiobac-sodium	0.0057	> 145	> 1000	> 140	> 910	0	0	○
Herbicide A.I.s with Potential Displacement of Postemergent Acres								
flumioxazin	0.0016	2.3	> 21	0.23	5.5	0	0.007	◑
MSMA	0.0498	12	323	77.5	173	0	0.00415	○
pendimethalin	0.013	0.0098	90.4	0.017	11	0.0001	**1.33**	●
Trifloxysulfuron-sodium	0.00068	> 97	> 104	60.1	> 119	0	0	○
trifluralin	18.69	0.0084	0.21	0.037	2.2	8.495	**89**	●

[1] Dicamba, 2,4-D salts and esters, fomesafen, and glyphosate are expressed on acid equivalent basis. Paraquat is on a cation basis. All others are on an a.i. basis as stated.

[2] GENEEC is a surface water model to Estimate Environmental Concentration (EEC) used by US EPA. Further information can be found at
http://www.epa.gov/pesticides/science/models_pg.htm#aquatic.

[3] LC50 or EC50 hazard values from http://www.ipmcenters.org/ecotox/index.cfm. Entries are the highest and lowest values provided for the a.i. for fish and invertebrates, separately. [10-Apr-2013 download].

[4] Risk Quotient is defined as exposure / hazard, both expressed as ppm (mg/L). "Best" means lowest exposure / hazard endpoint. "Worst" means highest exposure / hazard endpoint. Entries of 0 mean that the RQ is less than 0.0005 or the data was not available.

[5] Aquatic Fish and Invertebrate Score: White Circle means that the worst-case RQ estimate < 0.05. Half Circle means that for the worst-case RQ, 0.05 < RQ < 0.5. Black Circle means that the worst-case RQ is greater than 0.5, indicating acute risk for aquatic animals.

[6] Data for dicamba diglycolamine salt from EFED Chapter for the Dicamba RED.

Note: As much as possible, LC50 or EC50 hazard values were chosen from tests with the technical a.i. to avoid using hazard endpoints that are caused by solvents, surfactants, or other formulation ingredients.

*Glufosinate and glyphosate were not included in the comparison because Monsanto will recommend their use as part of an integrated pest management system. Dicamba, 2,4-D salts and esters, fomesafen, and glyphosate are expressed on acid equivalent basis. Paraquat is on a cation basis. All others are on an a.i. basis as stated.

C.5.2.2.2. Aquatic Plants

Table A-52 provides information about the hazards, exposures, and risks related to aquatic plants for dicamba and each of the twenty-two alternative herbicide a.i.'s used on cotton. The data format, sources, and methods of Estimated Environmental Concentration (EEC) calculation for aquatic plants are identical to those described for aquatic animals (Table C-13). A Level of Concern (LOC) value of 1.0 has been used for judging RQ exceedances in the case of aquatic plants, consistent with EPA EFED's normal practices.

- Aquatic Plant Toxicity is based on the hazard values from the National Site for the USDA Regional IPM Centers Information System. Table C-14 lists the LC_{50} and no observed effect concentration (NOEC) for each named species. Entries are for the named genus with the lowest EC50, and the corresponding NOEC level. .
- The Risk Quotient for Aquatic Plants is defined as EEC / hazard, both expressed as ppm (mg/L). RQ Range is determined from the EC50 and the NOEC concentration. A Level of Concern (LOC) value of 1.0 has been used for judging RQ exceedance in the case of aquatic plants, consistent with EPA EFED's normal practices. It should be noted that there are currently no threatened or endangered non-vascular aquatic plants, and therefore exceedances based on non-vascular plants would have no impact for listed species.
- The Aquatic Plant Score is based entirely on the Risk Quotient for Aquatic Plants. A White Circle means that only the high range limit for endangered (listed) aquatic plant species exceeds EPA's LOC of at most 1.0. A Half Circle means that both the RQ range limits for endangered (listed) plant species exceed EPA's LOC of 1.0 for aquatic plant risk. A Black Circle means that both the RQ range limits for endangered (listed) plant species exceed EPA's LOC by more than 100.
- The assessment and comparison summarized in Table C-14 establishes that dicamba poses little acute risk to aquatic plants, which is consistent with EFED's assessment published in the EFED chapter of the RED. Dicamba and two of the alternative herbicide a.i.'s used in cotton have RQs with the high range limit for aquatic plant species higher than EPA's LOC of 1.0, while another two do not exceed the LOC of 1.0 even at the high range limit. Seven of the alternative herbicides have both the RQ range limits for aquatic plant species higher than EPA's LOC of 1.0. Seven alternative herbicides have both the RQ range limits for aquatic species higher than EPA's LOC by more than 100. Dicamba has a lower risk for aquatic plant toxicity when compared to fourteen of the alternative herbicides used in cotton. Therefore, Monsanto concludes that dicamba offers a reduced risk opportunity for use on cotton with regard to aquatic plant risk.

Table C-14. Aquatic Toxicity Parameters for Aquatic Plants for Dicamba and Alternate Herbicide Active Ingredients

Active Ingredient[1]	GENEEC[2] 4-day EEC	Aquatic Plants Toxicity [3] (Most Sensitive Species Tested)	LC50	NOEC[3]	Risk Quotient for Aquatic Plants [4]	Aquatic Plant Score[6]
	(ppm)	Species	(ppm)	(ppm)	RQ Range	
dicamba acid /DGA salt	0.049	anabena[5]	0.06	0.005	0.82-9.8	○
glufosinate-ammonium	0.022	lemna	1.47	0.8	0.015-0.0275	*
glyphosate (salts)	0.0597	skeletonema	0.34	0.057	0.175-1.05	*
Herbicide A.I.s with Potential Displacement of Preemergent Acres						
2,4-D DMA (salts)	0.087	skeletonema	0.58	0.27	0.15-0.32	○
2,4-D EHE (esters)	0.09	skeletonema	0.23	0.094	0.39-0.96	○
flumiclorac pentyl	0.95	lemna	> 0.035	NA	>2.7	○
S-metolachlor	0.054	selenastrum	0.008	0.0015	6.75-36	◑
oxyfluorfen	2.55	selenastrum	0.00029	0.0001	8793-25500	●
pyraflufen ethyl	74.14	navicula	0.0015	0.00052	49426-142577	●
rimsulfuron	2.33	lemna	0.0116	0.00009	201-25888	●
thifensulfuron methyl	2.29	lemna	0.00159	0.00051	1440-4490	●
tribenuron methyl	2.87	lemna	0.003	0.001	957-2870	●
Herbicide A.I.s with Potential Displacement of both Preemergent and Postemergent Acres						
carfentrazone ethyl	279.89	lemma	0.006	0.002	46648-139945	●
fluometuron	0.107	anabena	0.13	0.07	0.82-1.53	○
fomesafen sodium	0.021	selenastrum	0.092	0.0095	0.23-2.21	○
paraquat dichloride	0.0026	navicula	0.00055	0.00022	4.73-11.82	◑
prometryn	0.09	navicula	0.001	0.0003	90-300	◑
Pyrithiobac-sodium	0.0057	lemna	0.0009	0.00027	6.33-21.11	◑
Herbicide A.I.s with Potential Displacement of Postemergent Acres						
flumioxazin	0.0016	lemna	0.00049	0.00022	3.26-7.27	◑
MSMA	0.0498	selenastrum	5.63	< 0.3	0.009-0.17	○
pendimethalin	0.013	skeletonema	0.0052	0.0007	2.5-18.57	◑
Trifloxysulfuron-sodium	0.00068	lemna	2.50E-05	2.00E-07	27.2-3400	◑
trifluralin	18.69	navicula	0.0153	0.0046	1221-4063	●

[1] Dicamba, 2,4-D salts and esters, fomesafen, and glyphosate application rates are expressed on acid equivalent basis. Paraquat is on a cation basis. All others are on an a.i. basis as stated.

[2] GENEEC is a surface water model to Estimate Environmental Concentration (EEC) used by US EPA. Further information can be found at http://www.epa.gov/pesticides/science/models_pg.htm#aquatic

[3] NOEC means No Effect Concentration. Entries are for the named genus with the lowest LC50 or EC50, and the corresponding NOEC level. LC50 or EC50 and NOEC hazard values from http://www.ipmcenters.org/ecotox/index.cfm . [10-Apr-2013 download]

[4] Risk Quotient is defined as EEC / hazard, both expressed as ppm (mg/L). RQ Range is determined from the EC50 or LC50 and the NOEC concentration.

[5] Data are for dicamba acid from EFED Chapter for the Dicamba RED. No data are available for testing of dicamba DGA salt against aquatic plants.

[6] Aquatic Plant Score: A White Circle means that only the high range limit is exceeds EPA's LOC of 1.0. A Half Circle means both the RQ range limits exceed EPA's LOC of 1.0. A Black Circle means both of the RQ range limits exceed EPA's LOC by more than 100.

Note: As much as possible, LC50 or EC50 hazard values were chosen from tests with the technical a.i. to avoid using hazard endpoints that are caused by solvents, surfactants, or other formulation ingredients.

*Glufosinate and glyphosate were not included in the comparison because Monsanto will recommend their use as part of an integrated pest management system.

C.5.3. Comparative Analysis of Potential Effects on Soil, Water and Air: Dicamba and Alternative Herbicides

This section describes potential effects of dicamba as used on DT soybean and DGT cotton, and compare potential effects with the alternative herbicides evaluated above. Note that this assessment does not include all the herbicides used on soybean or cotton, only those most widely used and/or with use likely to be reduced by the introduction of DT soybean and/or DGT cotton.

C.5.3.1. Effects on Soil

Multiple herbicides are already used in soybean and cotton production. In the U.S., 98% of soybean acreage was treated with an herbicide in 2006 (USDA-NASS, 2007b). Herbicides are used on nearly all (>99%) the cotton acres in the U.S., and over 30 herbicides, including dicamba and glufosinate, are registered for use on cotton. The U.S. EPA evaluated the environmental safety of dicamba and its metabolites as part of the RED (U.S. EPA, 2005a), and concluded that dicamba may accumulate with frequent and intensive use (2.0 and 2.8 lb per acre a.e. single application and 7.7 lb per acre a.e. annually). The U.S. EPA mandated reductions in dicamba use rates as part of dicamba's continued registration to effect these and other potential impacts (U.S. EPA, 2009b). Based on the reduced application rates (1.0 lb per acre a.e. with a maximum annual rate of 2.0 lb a.e. per acre), dicamba is unlikely accumulate or persist in the environment. In addition, results of standardized tests with dicamba and dicamba formulations indicate no long-term effects on functional processes of soil microorganisms (carbon respiration and nitrogen transformation) at rates proposed for dicamba on DT soybean (European Commission, 2007a).

Glufosinate use on DGT cotton is equivalent to currently deregulated glufosinate-tolerant cotton and is considered baseline. No changes in potential impacts of glufosinate on soil quality are anticipated.

Based on soil mobility and half live, some of the alternative herbicides for soybean and/or cotton are more persistent, e.g., pendimethalin, paraquat and in the case of cotton S-metolachlor. However, in terms of potential for long-term buildup in soil, the herbicide MSMA, which is used in cotton production, appears to be of much more concern than any of the herbicides. It is relatively immobile, and contains arsenic as a herbicidal ingredient. The arsenic does not degrade and may build up in the soil with repeated use of MSMA. Thus, in terms of potential impacts to soil, dicamba is definitely more positive than MSMA and may also be preferable to some of the more persistent alternative herbicides.

C.5.3.2. Effects on Surface Water and Groundwater

This section describes potential effects of dicamba as used on DT soybean and DGT cotton, and compare potential effects with the alternative herbicides evaluated above. Note that this assessment does not include all the herbicides used on soybean or cotton, only those most widely used and/or with use likely to be reduced by the introduction of DT soybean and/or DGT cotton.

It is important to recognize that, while some herbicides have greater potential to impact surface water or groundwater, the U.S. EPA controls these impacts through label restrictions such that there will be no unreasonable adverse impacts to human health or the environment when the herbicides are used in accordance with the legally-mandated label. While some of the herbicides used in soybean and/or cotton have been detected in surface water or groundwater, the mere detection does not necessarily indicate a risk concern.

The US-EPA reports that the major causes of surface water impairment (by number of impairments) in the U.S., are, in order of decreasing numbers: pathogens, metals (other than mercury), nutrients, organic enrichment/oxygen depletion, sediment, PCBs, mercury, pH, impaired biota, temperature and turbidity, which together account for 86% of all impairments (US-EPA, 2013a). Of these, crop farming may contribute to impairment from pathogens (15% of impairments), metals (10% of impairments), nutrients (9.5% of impairments), sediment (8.5% of impairments) and turbidity (4.1% of impairments). Pathogen impairment may result from runoff of manure fertilizer. A few pesticides contain metals, notably arsenic, and some limited impairment may result from runoff of metals from these pesticides. Nutrient impairments may result from runoff of fertilizers (synthetic and manure) and sediment and turbidity may result from cropland erosion and runoff. Crop farming can also contribute to impairments from pesticides, which account for 2.6% of impairments (US-EPA, 2013a). However, the majority of the pesticides causing impairments are chlorinated chemicals such as DDT, chlordane and DDE, which are no longer registered for use in the U.S.

Dicamba has been widely used in agriculture over the last four decades with dicamba's peak use occurring in 1994. In the dicamba Reregistration Eligibility Decision (RED) document, EPA considered potential risks associated with dicamba use, and its degradate 3,6-dichlorosalicylic acid (DCSA) when appropriate, in surface or ground water using screening level (high-end exposure) models to estimate environmental concentrations (U.S. EPA 2009b). The EPA then compared these exposure estimates to appropriate endpoints from mammalian, aquatic animal and plant ecotoxicity studies to determine potential impacts on human health and the environment. The EPA used the models PRZM/EXAMS (Pesticide Root Zone Model/Exposure Analysis Modeling System) and SCI-GROW (Screening Concentration in Groundwater) to estimate levels of dicamba in surface and ground water, respectively, using the physical, chemical, and environmental fate properties, and approved high-end use patterns of dicamba.

For drinking water resources, estimated surface water concentrations were calculated by U.S. EPA using a simulated sugarcane crop scenario and a simulated soybean crop scenario for ground and aerial applications of 2.8 and 2.0 lbs a.e./acre for sugarcane and soybean, respectively. EPA's modeled scenarios assumed 100% of crop acres within the watershed were treated with dicamba. The highest predicted concentration was 36.1 μg/L dicamba a.e., which is significantly less than the lifetime Health Advisory Level (HAL) of 4000 ug/L for dicamba (U.S. EPA 2005). Furthermore, the U.S. Geological Survey National Water Quality Assessment (NAWQA) monitoring program also analyzed surface water in a 1993-2003 survey of surface waters of the United States, which included geographical areas where dicamba use has historically been most intense. Dicamba had a low incidence of detections (approximately 3% of samples) and the highest levels detected were approximately 2 μg/L, which is significantly less than the lifetime Health Advisory Level (HAL) of 4000 ug/L for dicamba. (U.S. EPA 2005). Both the modeling predictions and the NAWQA monitoring results show that dicamba concentrations that might occur in drinking water are very low and confirm that the potential risk of dicamba leaching into groundwater or running off into surface water does not threaten human health or acceptable water quality.

Some of the alternative herbicides for soybean and/or cotton are more soluble and/or more persistent in water and have higher potential for impacts to surface water, e.g., imazethapyr, cloransulam-methyl, fomesafen, and acetochlor. In addition, paraquat is persistent and adheres strongly to soil particles, and could potentially be found in surface water systems associated with soil particles carried by erosion, and MSMA has the potential to impact surface water with arsenic. Some of the alternative herbicides for soybean and/or cotton have higher potential for leaching and therefore impacting groundwater, e.g. imazethapyr, cloransulam-methyl, fomesafen, fluometuron, and the degradation products of flumioxazin. Thus, in terms of potential impacts to surface water and groundwater, dicamba is more positive than several of the alternative herbicides.

Surface water and associated aquatic organisms have the potential to be impacted from soybean and cotton production by runoff from soybean and cotton fields that may carry soil particles and herbicides or other pesticides to streams, rivers, lakes, wetlands and other water bodies. Tables A-27 and A-51 provide comparative information concerning hazards, potential exposures, and risks to fish and aquatic invertebrates for alternative herbicides and for dicamba. Similar comparative tables aquatic plants are shown in Tables A-28 and Tables A-29. The non-target species assessments for aquatic animals and plants in Appendix F demonstrate that risk from exposure to dicamba following use on DT soybean or DGT cotton can be excluded from concern and, therefore, aquatic animals and plants would not be affected. Additional details can be found in Appendices A and F.

C.5.3.3. Potential Air Impacts

Dicamba is a low-volatility herbicide, and would be expected to have minimal air impacts. Dicamba does not include any fluorine atoms, which are characteristic of ozone depletion risk. Based on the vapor pressure presented in Table C-1, dicamba is not sufficiently volatile to be present in the stratosphere at ozone-threatening levels.

Alternative herbicides with relatively high volatility, such as pendimethalin (used on both soybean and cotton), could have localized and temporary air impacts, but none would be expected to affect any regulatory air quality standards.

C.6. Conservation Tillage: Potential Benefit of DT Soybean and DGT Cotton to Soil, Water and Air

The positive impacts of conservation tillage or no-till systems to soil, water and air are well documented and include reduced soil erosion (from water and wind), improved soil tilth (including structure improvement and reduction in compaction), increased organic matter, improved water quality, increased carbon storage through enhanced soil sequestration, and conservation of soil moisture (CTIC 2011; U.S. EPA, 2010).

As a result of weed shifts and the spread of weeds resistant to glyphosate and other herbicides used on soybean and cotton, there is a growing challenge to soil conservation gains resulting from conservation tillage, because of the need to manage such weeds through additional means, including tillage. For example, mechanical methods (machine tillage or hand-weeding) have been found to be one of the few consistent control options for Palmer amaranth, which has become a frequent hard-to-control weed in southeastern cotton production (CAST 2012). The use of DT soybean and DGT cotton may help preserve the benefits of conservation tillage.

Growth of conservation tillage in the U.S. was greatly accelerated with the introduction of glyphosate-tolerant crops in large part because of the broad spectrum postemergence control offered by glyphosate (Price et al. 2011). By 2008 conservation tillage was employed on approximately 42% of the crop acres, compared to 35% in 1994 prior to the introduction of herbicide-tolerant crops (CTIC 2008). In 2007, approximately 27.5 million acres (39.6%) of soybean were planted in a no-till system (CTIC, 2007). As of 2008, conservation tillage systems are used on approximately 21% of the U.S. cotton acres (CTIC 2008).

Tillage causes widespread soil disturbance. Vegetative residues protect the soil surface from the impact of raindrops and slow the movement of water, reducing its load-carrying potential. Slower moving water leads to water absorption and less run off. Runoff may carry soil particles, nutrients and pesticides away from fields to water bodies. Even as little as 30% residue cover typically reduces soil erosion rates by >50 % compared to bare ground (University of Missouri 1993). Typical soil loss from a field with a 93% residue cover may be only 2% of the loss from a field with 0% residue cover (Hill and Mannering 1995). Thus, erosion of topsoil, nutrient loss, and the resulting sedimentation, turbidity, and transport of nutrients to streams are likely to increase with increased tillage.

Based on miles of impact in streams and rivers, sediments and nutrients, primarily from agricultural crops, are the second and third leading causes of impairment in U.S. streams and rivers (pathogens are the leading cause), accounting for 21% and 20% of the miles of impaired streams and rivers, respectively. By comparison, pesticides account for 3% of miles of impaired streams and rivers, and these are primarily persistent pesticides such as DDT, chlordane, and DDE, which are no longer used in the U.S. (U.S. EPA 2012; 2013a). EPA has projected conservation tillage to be "the major soil protection method and candidate best management practice for improving surface water quality" (U.S. EPA 2002). EPA identifies conservation tillage as the first of its CORE4 agricultural management practices for water quality protection (U.S. EPA 2013b).

EPA reports conservation tillage as an agricultural practice that "increases carbon storage through enhanced soil sequestration" and that "may reduce energy-related CO2 emissions from farm equipment" (U.S. EPA, 2010). When carbon is stored, it is not available to be emitted in the form of carbon dioxide (CO2), a greenhouse gas.

C.7. Potential Impacts of Genetic Modifications to Soil, Water and Air

C.7.1. Potential Impacts from DT Soybean

Other than changes associated with herbicide use, DT soybean will not alter the agronomic practices typically utilized in the cultivation of soybean. DT soybean has been found to be compositionally, agronomically and phenotypically equivalent to conventional soybean. The phenotypic, agronomic, and environmental interaction assessment of DT soybean included a near isogenic conventional soybean control and the commercial reference varieties. Characteristics assessed included: seed dormancy and germination, pollen morphology, and symbiont interactions conducted in the laboratory and greenhouse; and plant phenotypic and agronomic evaluations and environmental interaction observations conducted in the field. The commercial soybean reference varieties grown concurrently were used to establish a range of natural variability for each assessed characteristic in soybean. The phenotypic, agronomic, and environmental interaction assessment demonstrated that DT soybean is equivalent to the conventional control. Therefore, microbial populations and associated biochemical processes in soil are not expected to change with the introduction of DT soybean. For symbiont interactions, there were no statistically significant differences (5% level of significance) observed between DT soybean and the conventional control for any of the parameters measured, including pollen viability and diameter, nodule number and dry weight, shoot total nitrogen, and shoot and root dry weight. Based on these data, the cultivation of DT soybean is not expected to impact microbial populations and associated biochemical processes.

Because the genetic modification itself will not affect agronomic practices, and DT soybean has been found to be compositionally, agronomically and phenotypically equivalent to conventional soybean, DT soybean will not affect water or air differently than commercially available soybean. Potential impacts from changes in herbicide use are discussed in Sections C.4 and C.5.

C.7.2. Potential Impacts from DGT Cotton

Other than changes associated with herbicide use, DGT cotton will not alter the agronomic practices typically utilized in the cultivation of cotton. DGT cotton has been found to be compositionally, agronomically and phenotypically equivalent to conventional cotton. The phenotypic, agronomic, and environmental interaction assessment of DGT cotton included the parental conventional control and a range of commercial reference varieties as comparators. Characteristics assessed included: seed dormancy and germination, pollen morphology, plant phenotypic observations, plant mapping, and environmental interaction evaluations conducted in the field. The phenotypic, agronomic, and environmental interaction assessment demonstrated that DGT cotton is comparable to conventional cotton. In an individual site assessment of abiotic stress response and disease damage, no differences were observed between DGT cotton and the conventional control for any of the 296 comparisons for the assessed abiotic stressors or for any of the 299 comparisons for the assessed diseases among all observations at the 26 replicated field sites across the U.S. cotton producing region. In an assessment of arthropod-related damage, no differences were detected between DGT cotton and the conventional control for any of the 288 comparisons for the assessed arthropods. The lack of significant biological differences in plant responses to abiotic stress, disease damage, and arthropod-related damage for DGT cotton support the conclusion that the introduction of the dicamba and glufosinate tolerance traits are unlikely to result in increased plant pest potential or an altered environmental impact from DGT cotton compared to commercially cultivated cotton. Therefore, microbial populations and associated biochemical processes in soil are not expected to change with the introduction of DGT cotton. Based on these data, the cultivation of DGT cotton is not expected to impact microbial populations and associated biochemical processes.

Because the genetic modification itself will not affect agronomic practices, and DGT cotton has been found to be compositionally, agronomically and phenotypically equivalent to conventional cotton, DGT cotton will not affect water or air differently than commercially available cotton. Potential impacts from changes in herbicide use are discussed in Sections C.4 and C.5.

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APPENDIX D: POTENTIAL FOR SPRAY DRIFT AND VOLATILIZATION TO AFFECT ADJACENT CROP & NON-CROP AREAS, AND MITIGATION MEASURES

Table of Contents

Tables and Figures

D.1 Introduction

Offsite movement of dicamba from spray drift or volatilization is a concern due to the potential for effects to off-target vegetation, including sensitive crops and threatened or endangered species, and effects on air quality. An herbicide could undergo offsite movement via air transport from the intended application site either by particle drift during spray application or by post-application volatilization from treated surfaces. Drift is "the movement of pesticide droplets or particles through the air at the time of pesticide application or soon thereafter from the target site to any non- or off-target site. Spray drift shall not include movement of pesticides to non- or off-target sites caused by erosion, migration, volatility, or windblown soil particles that occurs after application " (US-EPA, 2001). Volatilization of herbicides occurs when the substance vaporizes at atmospheric pressure and moves offsite. A variety of factors impact a given herbicide's potential for drift or volatilization. Monsanto is proposing a multi-faceted approach to address any potential for off-site movement of dicamba used on DT soybean or DGT cotton, described herein.

D.2 Pesticide Regulation & Registration

Although APHIS has traditionally conducted a range of analyses under the National Environmental Policy Act (NEPA) in connection with petitions for deregulation, APHIS does not have any statutory authority to regulate herbicide uses in agriculture. Instead the use of a pesticide is regulated by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).[125]

EPA regulates under FIFRA the herbicides that are applied to GE herbicide-tolerant crops like DT soybean and DGT cotton. Each pesticide (including herbicides) must be labeled with enforceable directions for use on a crop by crop basis. It is a violation of FIFRA to use any registered pesticide in a manner inconsistent with its labeling, subject to criminal and civil penalty. For that reason, an approved herbicide cannot be lawfully used on a corresponding herbicide-tolerant crop, unless EPA approves a label amendment for such use.

EPA's use restrictions are included in the FIFRA label for any given pesticide. EPA's labels describe, among other things, how a pesticide can be applied to a given crop and any restrictions on the use of the pesticide. Use of any pesticide not in compliance with the label is unlawful under FIFRA. For that reason, before a pesticide can be used on an herbicide-tolerant crop, the pesticide manufacturer must seek approval – which, in the case of DT soybean and DGT cotton, is a label amendment – for that pesticide.

Before EPA can approve any registration or label, EPA must find that the use/registration "will not cause unreasonable adverse effects on humans and the environment." In addition, if EPA finds that an approved herbicide use presents "unreasonable hazard to … species

[125] 7 U.S.C. §136 et seq.

declared endangered or threatened by the [Endangered Species Act]," EPA may immediately suspend the pesticide's registration. 7 U.S.C. §§136(l), 136d(c).

In addition to EPA's FIFRA authority, EPA also regulates potential human-health impacts from pesticides under the FFDCA. EPA does so by establishing "tolerance levels" (i.e., "the amount of pesticide that may remain on food products") under the FFDCA. The FFDCA "defines pesticide tolerances as 'safe' when there is 'a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.'

EPA considers possible effects from offsite movement as part of the pesticide registration process required under FIFRA. Additionally, pesticide registrants must report drift incidents to EPA as an adverse effect in order to ensure the pesticide continues to meet FIFRA requirements for registration. 40 C.F.R. § 159.195(a)(2). Before any registered herbicide can be applied to any new use site (including any deregulated GE-derived crop), EPA must approve a label amendment setting out the use pattern and specific application requirements for that new use site. Specifically, in order to approve a new use of a pesticide , EPA must conclude that no unreasonable adverse effects will result from the new use when applied according to label directions, which includes potential offsite movement. Offsite impacts are diminished when herbicides are applied in accordance with label instructions. Registered herbicides, including dicamba and glufosinate, are assessed by EPA for potential risks to non-target plants. A detailed discussion of the use of dicamba herbicide in the U.S. can be found in Appendix A.

D.3 Use of Dicamba on DT soybean and DGT Cotton

Dicamba (3,6-dichloro-2-methoxybenzoic acid) is a broad-spectrum, selective, post-emergence systemic herbicide with activity on a wide range of annual and perennial broadleaf plants. It was first registered in the United States in 1967 and is widely used in agricultural, industrial and residential settings. Dicamba controls annual, biennial and perennial broadleaf weeds in monocotyledonous crops and grasslands, and it is used to control brush and bracken in pastures. Because of the sensitivity of broadleaf plants to dicamba, the uses of dicamba in broadleaf crops until now have been limited to early pre-emergence and pre-harvest applications. DT soybean and DGT cotton have been developed to exhibit tolerance to dicamba herbicide applications by the insertion of a demethylase gene from *Stenotrophomonas maltophilia*. As a result DT soybean and DGT cotton express the dicamba mono-oxygenase (DMO) protein that rapidly demethylates dicamba to form the herbicidally inactive metabolite DCSA.

The use of dicamba is projected to increase if DT soybean and DGT cotton are deregulated. Please see Appendix A to this Environmental Report for a detailed discussion of the projections for increased use of dicamba in this scenario.

Offsite movement of herbicide to sensitive crops and plants during application is a concern during the growing season (Jordan et al. 2009). The potential for effects to off-target crops from offsite movement due to spray drift is generally greatest with a postemergence application because the treatment is made directly to the crop and requires the spray equipment to be higher above the ground, which results in more spray drift potential. In addition, postemergence herbicides typically have foliar activity, thereby increasing the potential of foliar effects or visual symptoms on desirable plants. The presence of dicamba can cause visible morphological effects to trees and certain sensitive crops, particularly beans (e.g., dry and snap beans), cotton, flowers, fruit trees, grapes, ornamentals, peas, potatoes, soybean, sunflower, tobacco, tomatoes, and other broadleaf plants when contacting their roots, stems or foliage (BASF Corporation 2008; Jordan et al. 2009). These plants are most sensitive to dicamba during their development or growing stage (BASF Corporation 2008).

Please see Appendix F of this Environmental Report for a detailed discussion of the potential impacts on wildlife, plants and ecosystems, including threatened and endangered species.

D.4 Spray Drift

Spray drift of herbicides is a familiar and well-studied phenomenon, notably by the Spray Drift Task Force, of which Monsanto is a member. EPA defines drift as "the movement of pesticide through air at the time of application or soon thereafter, to any site other than that intended for application" (US-EPA, 2000). Factors affecting the occurrence of spray drift include application equipment and method, weather conditions, topography, and the type of crop being sprayed (US-EPA, 2000). Aerial application is associated with an increased drift potential compared to ground spray application because the herbicide is released at a greater distance above the crop canopy. In addition to the method of application, spray drift potential is also impacted by equipment type (e.g., nozzle types and ratings), settings (e.g., spray pressure, application speed, and application volume), equipment maintenance, environmental conditions (wind speed, temperature inversion), applicator behavior and distance from the edge of the application area (SDTF, 1997; Felsot et al., 2010).

D.4.1 Prevention of Spray Drift

Growers and commercial herbicide applicators have been applying dicamba to agricultural row crops for over 40 years. This experience has provided valuable knowledge and learning on the proper application of dicamba for effective weed control and also for minimizing offsite movement to sensitive crops. Spray drift can be reduced during application by using industry standard procedures for minimizing spray drift. Depending upon the herbicide being used, factors for managing the potential for spray drift include the selectivity and sensitivity of the herbicide, local weather conditions at the time of application (wind, temperature, humidity, inversion potential), droplet size distribution, application volume, boom height (height of the application equipment above the crop canopy), sprayer speed, and distance from the edge of the application area (SDTF, 1997; Felsot et al., 2010). The minimization of droplets less than 150 microns is important in reducing any potential for spray drift. Droplet size can be increased by requiring the use of certain nozzle types, reducing spray pressure, increasing volume per minute spray rates, and by specifying an application volume per acre rate of at least 10 gallons. (SDTF, 1997; Teejet Technologies, 2011). Arvidsson et al. (2011) investigated meteorological and technical factors affecting total spray drift and determined that boom height and wind speed were the primary factors affecting the potential for spray drift among those tested, followed by air temperature, driving speed and vapor pressure deficit. Arvidsson et al. (2011) demonstrated that drift increased with driving speed. This increase was attributed to either air flows associated with the forward movement of the sprayer or to increased vertical boom movement.

EPA's Office of Pesticide Programs (OPP), which regulates the use of pesticides in the U.S., encourages pesticide applicators to use all feasible means available to them to minimize off-target drift. The Agency has introduced several initiatives to help address and prevent issues associated with drift. Currently, EPA is evaluating new regulations for pesticide drift labeling and the identification of best management practices to control such drift (US-EPA, 2009a), as well as identifying scientific issues surrounding field volatility of conventional pesticides (US-EPA, 2010). Additionally, OPP and EPA's Office of Research and Development are developing a new voluntary program, the Drift Reduction Technology (DRT) Program, which encourages the development, marketing and use of application technologies verified to significantly reduce spray drift (US EPA, 2009a).

When herbicides are applied according to the FIFRA label application instructions, offsite impacts can be avoided. EPA concluded in the dicamba RED (U.S. EPA, 2009b) that existing label language to mitigate offsite movement was sufficient to reduce the potential risk of damage to adjacent vegetation. Because the proposed application rates for dicamba on DT soybean and DGT cotton are less than or equivalent to rates for dicamba established for other uses in the dicamba RED, and because these uses were evaluated by EPA as part of the RED and the proposed label contains the offsite movement mitigation language, it is reasonable to conclude that the use of dicamba on DT soybean and DGT cotton also meets the FIFRA no unreasonable effects standard for drift and offsite movement (U.S. EPA, 2009b).

Growers and commercial applicators follow label directions and restrictions, and are educated by university specialists and industry representatives on the proper application equipment, equipment setup, and climatic conditions to maximize herbicide performance and minimize offsite movement of herbicides. For example, with the introduction of glyphosate-tolerant crops and the subsequent increase in glyphosate use, university specialists conducted extensive education programs on proper application procedures and precautions (Dr. W. Johnson – Purdue University, 2010 personal communication). Equipment manufacturers have developed spray nozzles that provide uniform coverage for effective weed control while applying larger spray droplets to reduce the potential for particle drift.

D.4.2 Monsanto's Proposed Label Instructions

Monsanto is proposing a multi-faceted approach to address potential for off-site movement of dicamba used on DT soybean and DGT cotton. Monsanto has proposed a range of application restrictions on its dicamba label that would be legally-binding on the grower/applicator. Collectively, these restrictions (which are currently pending before EPA) would go far beyond any other currently applicable limitations on dicamba application—indeed go beyond any label restrictions ever imposed on dicamba in the nearly half century that dicamba has been on the market.[126] Monsanto proposes to EPA that the supplemental

[126] For example, Monsanto's proposed limits are far more restrictive than those for Dicamba Max 4, which allows aerial applications and does not require the use of drift-reducing additives. *See* Dicamba Max 4 Label,

labels for M1691 Herbicide use on DT soybean and DGT cotton contain application requirements that would minimize dicamba offsite movement, summarized as follows:

- No aerial application of M1691 Herbicide.
- Use only spray nozzles that produce extremely coarse to ultra-coarse spray droplets and minimal amounts of fine spray droplets as defined by the American Society of Agricultural and Biological Engineers (ASABE S-572.1) and follow nozzle manufacturer's recommendations to deliver desired droplet size.
- Apply using a minimum of 10 gallons of spray solution per acre.
- Select a ground speed under 15 mph that will deliver the desired spray volume while maintaining the desired spray pressure.
- Spray at the appropriate boom height based on nozzle selection and nozzle spacing (not more than 24 inches above target pest or crop canopy). Set boom to lowest effective height over the target pest or crop canopy based on equipment manufacturer's directions.
- When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation.
- Do not apply during a temperature inversion.
- Survey the application site for neighboring sensitive areas prior to application. A potential way of locating sensitive areas is through the use of sensitive crop registries.[127]
- Do not apply when the wind is blowing in the direction of a sensitive area at a wind speed greater than 10 mph. Sensitive areas include known habitat for threatened or endangered species, non-target sensitive crops, residential areas, and greenhouses.
- Implement a spray buffer (to be determined by EPA) between the last treated row and the closest downwind edge of any sensitive area when the wind is blowing in the direction of a sensitive area at a speed of 10 mph or less.
- Do not apply if wind speed is greater than 15 mph.

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http://www.kellysolutions.com/erenewals/documentsubmit/KellyData/ND/pesticide/Product%20Label/83222/83222-14/83222-14_DICAMBA_MAX_4_3_10_2009_6_06_42_PM.pdf.

[127] For example, www.driftwatch.org

- Do not use crop oil concentrate or methylated seed oil as adjuvants when applied with glyphosate-based agricultural products. Do not add acidifying buffering agents.

- Clean equipment immediately after using this product using the procedures outlined in the label.

These proposed label instructions and/ or any measures imposed by EPA will limit the offsite movement of dicamba via spray drift and inadvertent spray application for the reasons described in more detail in the following paragraphs.

D.4.2.1 Reduction of Small Droplets

Monsanto has taken a variety of important measures to reduce offsite spray drift, including proposing label requirements to minimize the factors that result in small droplet generation, suspension, and movement into non-target areas. The factors that affect spray drift and associated impacts to adjacent areas can be divided into three main categories: a) droplet size and number, b) droplet transport, and c) the physical location of the spray. Droplet size and number is controlled by the nozzle type, application volume, spray pressure, and additives in the tank. Droplet transport is affected by wind speed, boom height, air temperature, vapor pressure deficit[128], and application speed. The third factor includes the proximity to sensitive non-target species which can be controlled through a mandate that applicators be aware of sensitive areas - including areas where threatened or endangered species may be present - that could be impacted from a dicamba application and implement a no-spray buffer as specified on the label.

D.4.2.1.1 Droplet Size and Number

The minimization of droplets less than 150 microns is important in reducing any potential for spray drift. Nozzles used for application of agricultural products do not produce droplets of one uniform size, but rather produce a spectrum of droplet sizes (TeeJet Technologies, 2011). Nozzles are generally classified as very fine, fine, medium, coarse, very coarse, extremely coarse, or ultra-coarse by comparison of a nozzle's droplet size distribution when spraying water to that of a set of standard nozzles. ASABE has established a nozzle classification system in its published standard, ASABE S-572.1 (Wilson, 2011a; ASABE, 2009), which is the U.S. industry standard for agricultural spray drop size classification. Nozzles classified as Extremely Coarse to Ultra Coarse have a small percentage of the spray volume in droplets with diameters less than 150 microns.

Nozzle orifice size and operating pressure also affect the droplet size spectrum for a given nozzle type (SDTF, 1997). The relationship between orifice size, operating pressure, spray volume delivered, and droplet size classification can be found in the nozzle manufacturers'

[128] Vapor pressure deficit is the difference between the amount of water vapor in the air and the amount of water vapor in the air at saturation. Evaporation reduces droplet size, and the greater the vapor pressure deficit the more rapid the evaporation and the greater the potential for drift.

catalogs. The use of a larger orifice size allows the application to be made at a higher volume per minute rate without increasing the operating pressure, and consequently reducing the droplet size classification (TeeJet Technologies, 2011). Additionally, a higher volume per minute rate allows the spray volume per acre to be higher at a given operating speed. Specifying an application volume per acre of at least 10 gallons may result in the use of larger orifice nozzles for some equipment to reduce the percentage of small droplets with the higher potential to drift.

The proposed label instructions direct the applicator to employ all of the relevant practices – including nozzle type, operating pressure, and application volume – to ensure that the droplet size distribution can be classified as extremely coarse to ultra-coarse – which limits the percentage of spray droplets in the size category that has the potential to move offsite.

D.4.2.1.2 Reduction of the Transport of Small Droplets

Arvidsson et al. (2011) investigated meteorological and technical factors affecting total spray drift and determined that boom height and wind speed were the primary factors affecting the potential for spray drift among those tested, followed by air temperature, driving speed and vapor pressure deficit. Establishing a maximum wind speed (15 mph, or 10 mph if sensitive areas are downwind) limits the distance that fine droplets will travel before settling. A temperature inversion[129] can result when wind speeds are less than 3 mph, and can cause the suspension of the small spray droplets for extended periods of time. Prohibiting application during inversion conditions avoids the potential for suspension and farther transport of fine spray droplets (Wilson, 2011b).

Boom height is also restricted in the proposed application use instructions for dicamba to the minimum height required to get a uniform spray pattern in order to minimize the amount of time that spray droplets are suspended before settling to the ground (Wilson, 2011c). As shown in the Spray Drift Task Force information booklet on Ground Applications (SDTF, 1997), a difference in boom height between 20 and 50 inches can impact the extent to which spray volume may move offsite by allowing additional time for the droplets to be blown offsite before settling. Prohibiting aerial application and limiting the boom height for ground applications to 24 inches above the target pest or crop canopy will minimize the amount of time that spray droplets are suspended and available to move offsite.

Arvidsson et al. (2011) demonstrated that drift increased with driving speed. This increase was attributed to either air flows associated with the forward movement of the sprayer or to increased vertical boom movement. Limiting driving speed to 15 mph or less will minimize this potential contributing factor.

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[129] A temperature inversion occurs when the air at the soil surface is cooler than the air above. Since cool air sinks, the surface air layer does not mix with upper layers of air. Under this condition, spray droplets are trapped near the surface and may stay suspended for increased periods of time.

D.4.2.1.3 Physical Location of the Spray and Use of Wind Buffers

Awareness of the presence of sensitive areas and whether the wind direction at the time of application may move any suspended spray droplets toward a sensitive area are important considerations at the time of application. Since the implementation of the DriftWatch™ [130]program in Indiana, drift incidents onto sensitive crops have been significantly reduced (Hahn, 2011). This program has now been expanded to several states across the major Midwest soybean growing area and to some Great Plains states as well (IL, IN, MI, MN, MO, WI, CO, MT, and NE). Under some circumstances, a buffer may be needed to provide further protection to a sensitive area. This method is highly effective when used.

For these reasons, the proposed FIFRA product labels state that applicators should consult with available sensitive crop registries prior to making dicamba applications to DT soybean or DGT cotton. Many state lead agriculture agencies (IA, IL, IN, KS, MI, MN, MO, NE, OK, WI) have developed tools and resources to assist the applicator in the location of sensitive areas, such as vegetable or organic production fields, in an effort to minimize commercial impacts associated with pesticide offsite movement. Furthermore, prior to commercialization of DT soybeans and DGT cotton, Monsanto will implement an endangered species mitigation system for dicamba. The implemented system will either be an EPA-specific system and/or a web-based system, similar to that currently available for glyphosate at PreServe.org. This will facilitate applicator and grower implementation of use restrictions for protection of threatened and endangered non-monocotyledonous terrestrial plant species.

D.4.2.2 Determination of Proper Buffer Distances

Monsanto has submitted information to the EPA that summarizes studies conducted at eight field locations to assess the buffer distance required to be protective of survival, growth, and reproduction of plant species that are very sensitive to dicamba (Orr et al., 2012). These studies utilized nozzles that fit the droplet size classification requirements, the minimum application volume and the maximum boom height requirements specified above.

Justification for use of soybean plant height as the endpoint for risk assessment

Soybean was selected as the test species since it has been shown to be a highly sensitive indicator species for post-emergence dicamba effects. In the vegetative vigor study conducted in a greenhouse with the DGA salt of dicamba, soybean had the lowest endpoint of the ten species tested (Porch et al., 2009). Comparable sensitivity for soybean to that observed in the greenhouse has also been displayed in field studies (Al-Khatib and Peterson,

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[130] Driftwatch is a voluntary program that allows growers to reports locations of fields in which sensitive crops are being grown (and also identified other types of sensitive areas such as organic fields). The sensitive crop information is presented on a website in a map format which can then be utilized by pesticide applicators prior to application.

1999; Auch and Arnold, 1978; Kelley et al., 2005; Wax et al., 1969; and Weidenhamer et al., 1989). See Table D-1 for a summary of endpoints from these studies.

Higher Dicamba rates are needed to cause effects on soybean yield than are needed to cause effects on soybean plant height at early growth stages

Effects of dicamba on plant growth have been evaluated by considering effects on plant height at very sensitive early growth stages. Effects of dicamba on plant reproduction can be evaluated by assessing the effect of dicamba on plant species seed or fruit yields. A number of the field studies (Al-Khatib and Peterson, 1999; Auch and Arnold, 1978; Kelley et al., 2005; Wax et al., 1969; Weidenhamer et al., 1989; and Wright, 2012) indicate that soybean yield is no more sensitive, and is generally less sensitive, to dicamba treatment than is soybean plant height at the early growth stages at which studies to estimate buffer distances have been conducted. Additionally, results of these studies demonstrate that significant morphological effects in soybeans such as plant height reduction do not always result in yield reduction, but yield reduction in soybeans occurs at rates greater than that affecting soybean plant height at the early vegetative stages which were used in studies for buffer distance estimation. See Table D-2 for a summary of the results of these studies.

Dicamba effects on yields of other crops occur at rates greater than or equal to rates affecting soybean plant height

The effects of dicamba on crop yield have been reported by a number of investigators in at least eleven other crops besides soybean. Monsanto has submitted field data on soybean to EPA and conducted an extensive review of relevant literature for use by EPA in establishing an appropriate buffer distance from potentially sensitive plant communities. The field data was generated across multiple growing seasons with diverse geographic and climatic conditions. The literature review included results from studies testing 12 possible sensitive crops, with many crops tested across multiple growing seasons and/or geographies and/or growth stages. The potential sensitive crops included in these studies were soybean, tomato, cantaloupe, cotton, pea, peanut, pepper, potato, sugarbeet, sunflower, tobacco, and watermelon.

These studies also indicate that the dicamba no effect rate for soybean plant height at vegetative growth stages is a lower value (approximately 0.3 g a.e./ha) than the dicamba no effect rates for plant yield in these other species that have been tested. See Table D-3 for a summary of endpoints from these studies.

Because soybean plant height measured at vegetative growth stages is a more sensitive endpoint for dicamba effects than soybean yield or yield of eleven other plant species in five additional plant families, the use of the soybean plant height endpoint is appropriate to assess potential dicamba effects on survival, growth, and reproduction of sensitive species.

Monsanto's application management practices, including buffer distances that have been determined to not result in soybean plant height reduction after dicamba applications, can therefore be considered effective measures for mitigation of potential effects of dicamba on non-target plants.

Table D-1. Soybean Field Studies with Dicamba

Growth Stage & Other Treatment Information	Dicamba Salt [a]	Time of Measurement	Plant Height No Effect Rate (g a.e./ha)[b]	Reference
2-3 trifoliate 1997	Not Specified	60 DAT	<5.6	Al-Khatib and Peterson, 1999
2-3 trifoliate 1998	Not Specified	60 DAT	5.6	Al-Khatib and Peterson, 1999
1-2 trifoliate - 1974	DMA	At maturity	56	Auch and Arnold 1978
3-4 trifoliate - 1974	DMA	At maturity	1	Auch and Arnold, 1978
6-7 trifoliate - 1974	DMA	At maturity	1	Auch and Arnold, 1978
V3	DMA	At maturity	< 1.1	Wax et al., 1969
Williams - prebloom 1980 (41 DAP)	DMA	At maturity	0.32[c]	Weidenhamer et al., 1989
Elf - prebloom 1980 (41 DAP)	DMA	At maturity	1.3[c]	Weidenhamer et al., 1989
V3	DGA	Full height before leaf senescence	< 0.56	Kelley et al., 2005
V7	DGA	Full height before leaf senescence	< 0.56	Kelley et al., 2005

[a] DMA – dimethylamine; DGA – diglycolamine

[b] For conversion of g a.e./ha to lb a.e./A divide the g a.e./ha value by 1120. Application rates expressed as oz/A were assumed to be of a 4 lb a.e./gal formulation and were converted to g a.e./ha

[c] Highest rate at which less than 10% effect on height was observed based on Table 2 of the publication

Table D-2. Comparison of No Effect Rates for Plant Height and Yield from Dicamba Application to Soybeans

Growth Stage & Other Treatment Information	No Effect Rate (g a.e./ha)[a]		Reference
	Plant Height	Yield	
Williams - prebloom 1980	0.32[b,c]	20[b]	Weidenhamer et al., 1989
Elf - prebloom 1980	1.3[b,c]	10[b]	Weidenhamer et al., 1989
8-12 inches, 3 WAE[d], RM1 2009	--	11	Johnson et al., 2012
8-12 inches, 3 WAE, RM2 2009	--	41	Johnson et al., 2012
8-12 inches, 3 WAE, RM1 2010	--	3	Johnson et al., 2012
8-12 inches, 3 WAE, RM2 2010	--	3	Johnson et al., 2012
2-3 trifoliate 1997	5.6[e]	17	Al-Khatib and Peterson, 1999
2-3 trifoliate 1998	<5.6[e]	17	Al-Khatib and Peterson, 1999
V3[f] - SE Farm	--	< 5.6	Andersen et al., 2004
V3 - Brookings Farm	--	< 5.6	Andersen et al., 2004
V3	< 1[c]	1	Wax et al., 1969
V3	< 0.56[c]	< 0.56[g]	Kelley et al., 2005
1-2 trifoliate - 1974	56[c]	56	Auch and Arnold 1978
3-4 trifoliate - 1974	1[c]	56	Auch and Arnold, 1978
6-7 trifoliate - 1974	1[c]	56	Auch and Arnold, 1978
V7[h]	< 0.56[c]	0.56	Kelley et al., 2005
Early bloom - 1974	1[c]	11	Auch and Arnold, 1978
Early bloom - 1975	1[c,i]	1	Auch and Arnold, 1978
Early bloom - 1976	< 11[c]	< 11	Auch and Arnold, 1978
R2[j]	NA[k]	< 1	Wax et al., 1969
R2	NA	0.56	Kelley et al., 2005
Elf - midbloom 1980	NA	40[b]	Weidenhamer et al., 1989
Mid-bloom - 1976	NA	28	Auch and Arnold, 1978
Williams - midbloom 1980	NA	10[b]	Weidenhamer et al., 1989
Williams - midbloom 1981	NA	7.4[b]	Weidenhamer et al., 1989
Early-pod - 1975	NA	11	Auch and Arnold, 1978
Early pod - 1976	NA	11	Auch and Arnold, 1978
Late pod - 1976	NA	28	Auch and Arnold, 1978

[a] For conversion of g a.e./ha to lb a.e./A divide the g a.e./ha value by 1120. Application rates expressed as oz/A were assumed to be of a 4 lb a.e./gal formulation and were converted to g a.e./ha

[b] Highest rate at which less than 10% and 20% effect on height and yield, respectively, were observed based on Table 2 & Table 3 of the publication

[c] Height at maturity

[d] WAE – weeks after emergence

[e] Assessed at 60 days after treatment

[f] At V3 growth stage the third trifoliate leaf is unfolded (http://extension.agron.iastate.edu/soybean/production_growthstages.html)

[g] Yield reduction was statistically significant but not considered biologically significant at rates of 0.56 and 5.6 g a.e./ha because a ten-fold increase in rate did not cause an increase in the yield reduction, and the percent reduction is small compared to the untreated control (i.e., less than 10% yield reduction).

[h] At V7 growth stage the seventh trifoliate leaf is unfolded.

[i] A height reduction of 18% was observed at rates above 1 g a.e./ha, but this reduction was not statistically significant

[j] R2 growth stage is when there is an open flower at one of the two uppermost nodes (http://extension.agron.iastate.edu/soybean/production_growthstages.html)

[k] Rates at which no effect on plant height are provided in the literature references, but are not provided here since yield values are being compared to rates causing plant height effects at earlier time points.

Table D-3. Effect of dicamba on yield in plant species other than soybean

Crop	Growth Stage & Other Treatment Information	Effect	No Effect Rate (g a.e./ha)[a]	Reference
Soybean	pre-bloom	Plant Height	0.32[b]	Weidenhamer et al, 1989
Cantaloupe	3 Weeks after transplanting	Total Harvest	560	Hynes and Weller, 2010
Cantaloupe	3 Weeks after transplanting	Total Harvest	11.2	Hynes et al., 2011
Cotton	Cot – 2 Leaf	Lint Yield	140	Everitt and Keeling, 2009
Cotton	4-5 Leaf Pinhead Square First Bloom	Lint Yield	14	Everitt and Keeling, 2009
Cotton	20-30 cm tall RM 2009 LW 2009 LW 2010	Yield	140	Johnson et al., 2012
Cotton	20-30 cm tall RM 2010	Yield	11	Johnson et al., 2012
Cotton	6-8 Leaf	Lint Yield	2.8	Marple et al., 2007
Cotton	3-4 Leaf 8-node 14-node 18-node	Lint Yield	2.8	Marple et al., 2008
Pea	Flower buds formed	Yield	6.25 [c]	Al-Khatib and Tamhane, 1999
Pea	Vegetative & Flowering	Seed dry weight	5.63	Olszyk et al., 2009
Peanut	15-20 cm width RM 2010	Yield	140	Johnson et al., 2012
Peanut	15-20 cm width RM 2009 LW 2010	Yield	41	Johnson et al., 2012
Peanut	15-20 cm width LW 2009	Yield	11	Johnson et al., 2012
Pepper	3 Weeks after transplanting	Total harvest	11.2	Hynes and Weller, 2010
Pepper	3 Weeks after transplanting	Total harvest	560	Hynes and Weller, 2010
Pepper	3 Weeks after transplanting	Total harvest	560	Hynes et al., 2011
Potato	11-15 Days after emergence	Tuber fresh weight	5.58	Olszyk et al., 2010
Potato	15% flowering	Tuber Yield	11.2	Leino and Haderlie, 1985
Sugarbeet	10-15 leaf	Extractable sucrose	70	Schroeder et al., 1983
Sugarbeet	10-15 leaf	Root yield	>140	Schroeder et al., 1983

Crop	Growth Stage & Other Treatment Information	Effect	No Effect Rate (g a.e./ha)[a]	Reference
Sunflower	2-4 leaf	Yield	1.6	Derksen, 1989
Tomato	Full bloom - 1972	Total Yield	1	Jordan and Romanowski, 1974
Tomato	Green fruit stage 1971	Total Yield	20	Jordan and Romanowski, 1974
Tomato	Green fruit stage 1972	Total Yield	100	Jordan and Romanowski, 1974
Tomato	3 Weeks after transplanting	Total Yield Fruit weight	11.2 5.6	Hynes and Weller, 2010
Tomato	3 Weeks after transplanting	Total Yield	560	Hynes et al., 2011
Tomato	15 cm tall Early vegetative	Marketable Fruit	0.9[d]	Kruger et al., 2012
Tomato	25 cm tall Early bloom	Marketable Fruit	0.5[d]	Kruger et al., 2012
Watermelon	3 Weeks after transplanting	Total Harvest	11.2	Hynes and Weller, 2010
Watermelon	3 Weeks after transplanting	Total Harvest	560	Hynes et al., 2011

[a] For conversion of g a.e./ha to lb a.e./A divide the g a.e./ha value by 1120. Application rates expressed as oz/A were assumed to be of a 4 lb a.e./gal formulation and were converted to g a.e./ha

[b] Lowest rate from

[c] Next rate below rate with greater than a 25% effect on yield (lowest such rate of 5 sites). 25% effect on yield was chosen due to high variability.

[d] Value from dose response curve estimated to result in 1% fruit loss

D.4.2.3 Applicator Education and Awareness

As mentioned above, growers and commercial applicators are aware of the sensitivity of certain crops to dicamba and the extra precautions that should be taken in making dicamba applications when these crops are nearby. In addition, growers and commercial applicators follow label directions and restrictions, and growers are educated by university specialists and industry representatives on the proper application equipment, equipment setup, and climatic conditions to maximize herbicide performance and minimize offsite movement of herbicides. To provide growers with specific information for dicamba applications to dicamba-tolerant crops, Monsanto is implementing a robust stewardship program that will include a strong emphasis on grower and applicator training. In addition, U.S. EPA and state agencies have enforcement authority over the use of any registered pesticide in a manner inconsistent with its labeling.

For example, following the introduction of glyphosate-tolerant crops and the subsequent increase in use of the non-selective herbicide glyphosate, university specialists conducted extensive education programs on proper application procedures and precautions (Dr. W. Johnson – Purdue University, 2010 personal communication). Equipment manufacturers developed spray nozzles that provide uniform coverage for effective weed control while applying larger spray droplets to reduce the potential for particle drift. Similarly, offsite movement of dicamba has been managed with the knowledge of the proper spray equipment and equipment setup, climatic conditions for accurate, on-target applications, and based on the requirements for applying dicamba at an appropriate distance from sensitive crops and plants (Jordan et al. 2009).

D.5 Volatilization

Volatilization of fertilizers and pesticides from soil and plant surfaces also introduces certain chemicals to the air and can cause offsite movement. A substance is volatile if it is likely to vaporize at atmospheric pressure. The USDA Agricultural Research Service (ARS) is conducting a long-term study to identify factors that affect pesticide levels in the Chesapeake Bay region airshed (USDA-ARS, 2011). This study has determined that volatilization is highly dependent upon exposure of disturbed unconsolidated soils, and that variability in measured compound levels is correlated with temperature and wind conditions. Another ARS study of volatilization of certain herbicides after application to fields has found moisture in dew and soils in higher temperature regimes significantly increases volatilization rates (USDA-ARS, 2011).

Physicochemical characteristics of the individual chemical have been shown to have little impact on spray drift. However, unlike spray drift, the potential for post-application volatilization is primarily a function of the physicochemical properties of the chemical, (e.g., vapor pressure, Henry's Law constant, etc.), method of application (e.g., soil-incorporated or not), and the local environmental conditions (e.g., temperature, humidity, wind speed). Due to this complexity, the potential for post-application vapor loss is often measured experimentally.

In EFED's Chapter in the Dicamba RED, laboratory volatility data have been summarized for potassium and dimethylamine (DMA) salts of dicamba from a moist soil. Monsanto has also submitted information to the EPA that summarizes a field study that was conducted to measure the volatilization rate of a dicamba DGA salt formulation from foliage.

D.5.1 DGA Salts Reduce Volatilization

Monsanto seeks to minimize volatile loss from treated soybean and cotton fields by labeling optimal formulations and salt forms of dicamba. The DGA salt formulation of dicamba, which is proposed for use on DT soybean and DGT cotton, has low volatility. Side-by-side field experiments have indicated that a formulation of the diglycolamine (DGA) salt of dicamba dramatically reduced volatilization of dicamba compared to a similar formulation of the DMA salt form and that volatility is not a significant component of offsite movement for the DGA salt of dicamba (Egan, 2012). The use of formulations of, or similar to, the DGA salt of dicamba will help to limit non-target plant risk due to post-application vapor loss. In the publication, the authors state, "Our data demonstrate that the diglycolamine formulation has a dramatic effect on reducing dicamba vapor drift. Estimates of total g acid equivalent vapor drift outside of the treated area were reduced 94% relative to the dimethylamine formulation, and the dose-distance curves indicate that predicted mean exposures drop close to zero only short distances away from the treated area." Additionally, measured air concentrations when using the DGA salt were at least 70-fold lower than those in the potassium and DMA salt laboratory studies EFED evaluated, even though the application rate was twice that of DMA (Mueller et al., 2013).

Monsanto has requested the use of dicamba on DT soybean and DGT cotton only for low-volatility salts, including the DGA salt formulation (U.S. EPA Reg. No. 524-582). Specific application requirements on the proposed FIFRA product label (currently pending before EPA), and/or any other measures imposed, by EPA will minimize dicamba offsite movement. Monsanto plans to continue to invest in research and development of new dicamba formulations for use with DT soybean and DGT cotton. Monsanto and BASF have submitted separate applications to EPA seeking the approval of novel dicamba formulations (EPA File Symbols 7969-GUL, 524-ANO and 524-ARN). EPA will review relevant data and information as a part of its registration process and confirm that the product when used according to the approved label directions meets the FIFRA standard before granting a registration including the use on DT soybean or DGT cotton. Furthermore, Monsanto will not allow growers to use dimethylamine salt (DMA) of dicamba and/or dicamba acid on DT soybean or DGT cotton.

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APPENDIX E: HEALTH AND SAFETY RISKS OF DICAMBA TO THE GENERAL POPULATION & WORKERS

Table of Contents

Tables and Figures

E.1 Introduction

This appendix describes the health and safety risks to U.S. consumers and to workers involved in soybean and cotton farming operations. Cotton and soybean are broad acre, highly managed crops where herbicides are used on essentially all (> 98%) commercially cultivated crop acres. Potential risks to consumers from the production of cotton and soybean may occur from herbicide use which can result in residues in food or by from exposure to novel proteins present in the GE plant.

The following assessment considers potential risks from the use of dicamba on DT soybean and DGT cotton, in addition to potential risks from herbicide use in practice today. The assessment of potential risks to consumers from exposure to food derived from DT soybean and DGT cotton, and food derived from animals fed DT soybean or DGT cotton is discussed in Appendix H.

Dicamba use is regulated at the federal level by EPA, not APHIS. APHIS's authority under the Plant Protection Act does not allow it to specify conditions for the use of pesticides, including herbicides. Instead, EPA specifically approves labeling for any pesticide use, including uses on agricultural crops. EPA regulates under FIFRA the pesticides that are used with crops, including GE herbicide-tolerant crops like DT soybean and DGT cotton. FIFRA requires all pesticides to be registered before distribution or sale, unless they are exempted. Under FIFRA, EPA must approve each distinct pesticide product, each distinct use pattern, and each distinct use site. Each crop for example, constitutes a unique use site and no registered pesticide may be applied to any crop unless EPA has approved that specific pesticide/crop use.

Each pesticide must be labeled with enforceable directions for use on a crop by crop basis. It is a violation of FIFRA to use any registered pesticide in a manner inconsistent with its labelling, subject to criminal and civil penalty.[131] For that reason, an approved herbicide cannot be lawfully used on a corresponding herbicide-tolerant crop, unless EPA approves a label amendment for such use.

E.2 Pesticide Registration, Reregistration and Tolerance Setting

FIFRA requires that before the sale or distribution of a new pesticide or a new use of a registered pesticide, a company must obtain a registration, or license, from EPA. The EPA must ensure that the pesticide, when used according to its label directions, will not cause unreasonable adverse effects on human health and the environment. In order to address this standard, EPA evaluates potential risks to humans and the environment, and may require applicants to submit more than 100 different scientific studies conducted according to EPA guidelines. According to EPA, more than 1000 active ingredients are currently registered as pesticides in the U.S., which are, in turn, formulated into many thousands of pesticide products that are available in the marketplace (U.S. EPA, 2010).

Pesticide registration is a scientific, legal, and administrative procedure through which EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, method and timing of application, and other conditions of its use; and storage and disposal practices. In evaluating a pesticide registration application, EPA assesses a wide variety

[131] FIFRA §12(a)(2)(G) and §14

of data indicating the potential human health and environmental effects associated with use of the pesticide product. The data required by EPA are used to evaluate a wide array of potential impacts, including whether a pesticide has the potential to cause adverse effects on humans, wildlife, fish, and plants (including endangered species and other non-target organisms, *i.e.*, organisms that the pesticide is not intended to act against). The registration applicant must also supply data on the pesticide's potential impact on surface water and ground water, should leaching or runoff occur. The potential human health and safety risks assessed range from short-term toxicity to long-term effects such as cancer and reproductive system disorders.

Pesticide label directions are considered as part of EPA's evaluation. All pesticides must meet the FIFRA standard ensuring that they do not pose unreasonable adverse effects to humans or the environment before they can be registered., In addition, each pesticide must be labeled with enforceable directions for use on a crop by crop basis. It is a violation of FIFRA to use any registered pesticide in a manner inconsistent with its labelling, subject to criminal and civil penalty.[132] For that reason, an approved herbicide cannot be lawfully used on a corresponding herbicide-tolerant crop, unless EPA approves a label amendment for such use.

The registration of a new pesticide is not EPA's only opportunity to evaluate the product's safety. EPA has recently completed a program to review older pesticides (those initially registered before November 1984) under FIFRA to ensure that they meet current scientific and regulatory standards. Reregistration, like the initial registration process, considers the human health and ecological effects of pesticides and results in actions to reduce risks that are of concern.

Where pesticides may be used on food or feed crops, EPA also sets pesticide tolerances, i.e., maximum pesticide residue levels that can legally remain in or on foods. EPA undertakes this analysis under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). Under the FFDCA, EPA must find that such tolerances will be safe, meaning that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide residue. This finding must be made and the appropriate tolerance established before a pesticide can be registered for use on the particular food or feed crop in question. EPA must consider several factors before a tolerance can be established, including:

- the aggregate, non-occupational exposure from the pesticide (exposure through diet, from using pesticides in and around the home, and from drinking water);

- the cumulative effects from exposure to different pesticides that produce similar effects in the human body;

- evidence of increased susceptibility to infants and children, or other sensitive subpopulations, from exposure to the pesticide; and

- evidence that the pesticide produces an effect in humans similar to an effect produced by a naturally occurring estrogen or produces other endocrine-disruption effects.

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[132] FIFRA §12(a)(2)(G) and §14

E.2.1 Pesticide Human Risk Assessment

The process EPA uses for evaluating the health impacts of a pesticide, under either FIFRA or FFDCA, is called risk assessment. EPA uses the National Research Council's four-step process to assess potential human health risks. This process involves hazard identification, dose-response assessment, exposure assessment and risk characterization. Each of these steps is discussed below.

The first step in the risk assessment process is hazard identification to identify potential health effects, or hazards, which may occur from different types of pesticide exposure. EPA considers the full spectrum of a pesticide's potential health effects. Hazards are identified through a battery of studies that examine the potential toxicity of the pesticide in various tests including, where appropriate, tests with laboratory animals.

To assess human health risk of the pesticide, pesticide companies conduct many toxicity studies based on EPA guidelines and the Good Laboratory Practice (GLP) standards. Results are evaluated for acceptability by EPA scientists. EPA evaluates pesticides for a wide range of effects, from eye and skin irritation to cancer and birth defects. EPA may also consult the public literature or other sources of information on any aspect of the chemical.

The next step of the risk assessment is dose-response assessment which considers the levels at which the pesticide produces adverse effects. Dose levels at which adverse effects were observed in test animals are then translated into equivalent doses for humans.

Step three of the process involves an exposure assessment. People can be exposed to pesticides in three ways:

1. Inhaling pesticides (inhalation exposure),

2. Absorbing pesticides through the skin (dermal exposure), and

3. Ingesting pesticides (oral exposure).

Depending on the situation, pesticides could enter the body by any one or all of these routes. Typical sources of pesticide exposure include food (following agricultural uses); home and personal use pesticides; pesticides applied to lands that make their way into the drinking water; or occupational exposure for agricultural workers or pesticide applicators.

Risk characterization is the final step in assessing human health risks from pesticides. It is the process of combining the hazard, dose-response and exposure assessments to describe the overall risk from the use of a pesticide. It explains the assumptions used in assessing exposure as well as the uncertainties that are built into the dose-response assessment. The strength of the overall database is considered, and broad conclusions are made. EPA's role is to evaluate both toxicity and exposure and to determine the risk associated with use of the pesticide.

The risk to human health from pesticide exposure depends on both the toxicity of the pesticide and the likelihood of people coming into contact with it, *i.e.*, the probability of exposure. At least some exposure and some toxicity are required to result in a risk. For example, if the pesticide is found to have a high level of toxicity, but people are not exposed to the pesticide, there is no risk. Likewise, if there is ample exposure but the pesticide is nontoxic, there is no risk. Typically, however, there is some toxicity and exposure, which results in a potential risk.

EPA recognizes that effects vary between animals of different species and from person to person. To account for this variability, a 100-fold uncertainty factor is built into the risk assessment with a 10X factor to account for differences between test species and humans, and a 10X factor to account for differences between people. This uncertainty factor creates an additional margin of safety for protecting people who may be exposed to the pesticides. The Food Quality Protection Act (FQPA) requires EPA to use an additional, up to a 10-fold safety factor, if necessary, to protect special subpopulations if they show potential increased susceptibility to effects of the pesticide, typically infants, children or women of child-bearing age.

Once EPA completes the risk assessment process for a pesticide, the Agency uses this information to determine if there is a reasonable certainty of no harm to human health as a result of the use of the pesticide according to label directions as required by FIFRA. Using the conclusions of a risk assessment, EPA can then make an informed decision regarding whether to approve a pesticide chemical or use, as proposed by the product label, or whether additional protective measures are necessary to limit exposure to a pesticide. For example, EPA may prohibit pesticide use on certain crops because consuming the treated commodity may result in an unacceptable risk to consumers. Another example of protective measures is requiring workers to wear personal protective equipment (PPE) such as a respirator or chemical resistant gloves, or not allowing workers to enter treated crop fields until a specific period of time has elapsed (Restricted Reentry Interval or REI). If, after considering all appropriate risk reduction measures, the pesticide still does not meet EPA's safety standard, the Agency will not allow the proposed chemical or use. Regardless of the specific measures enforced, EPA's primary goal is to ensure that legal uses of the pesticide are protective of human health, especially the health of children, and the environment.

E.3 Dicamba Regulatory Status in U.S.

E.3.1 Dicamba – Registration History

Dicamba is a selective broadleaf herbicide belonging to the auxin agonist class, the oldest known class of synthetic herbicides, and is a member of the benzoic acids sub-group. Dicamba mimics the action of the plant hormone indole acetic acid, and causes rapid uncontrolled cell division and growth, leading to plant death. Dicamba has been registered in the U.S. for use on food crops since 1967 (U.S. EPA, 2009) and has been widely used in agricultural production for over forty years. Dicamba is presently approved for use on asparagus, corn, cotton, grass seed production, pastures and rangelands, small cereals (including wheat), sorghum, soybean, and sugarcane. Dicamba is also used for industrial vegetation management (*e.g.*, forestry and roadsides), professional turf management (*e.g.*, golf courses, sports complexes), and residential turf (U.S. EPA, 2009; Durkin and Bosch, 2004).

Dicamba has a complete and comprehensive regulatory database (toxicity, environmental fate, and ecological toxicity) that has been evaluated by the United States Environmental Protection Agency (U.S. EPA). A Reregistration Eligibility Decision (RED) for dicamba was completed by EPA in 2006 and subsequently amended in 2008 and 2009 (U.S. EPA, 2009), as required for continued registration of all pesticides originally registered prior to 1984. EPA concluded the available data submitted for dicamba are complete and adequate to support the continued registration of dicamba products. EPA has evaluated the available toxicity data and concluded that a high level of confidence exists in the quality of the dicamba data base and in the reliability of the dicamba toxicity endpoints for risk assessment. EPA also considered toxicity data and available information concerning the variability of sensitive subpopulations, including infants and children. The EPA concluded there is reasonable certainty that no harm will result to the general population, or to infants and children, as a result of aggregate (all) exposure to dicamba residues. Thus, all current dicamba uses were eligible for reregistration (U.S. EPA, 2008a; U.S. EPA, 2008b; U.S. EPA, 2008c). In 2008, dicamba also successfully completed reevaluation by the Pest Management Regulatory Agency of Health Canada (PMRA, 2008) and the European Commission Health and Consumer Protection Directorate-General (European Commission, 2008). Dicamba has been approved by the EPA for a number of food and feed uses, including the major agricultural crops of corn, soybean and small grains (*e.g.*, wheat or barley). Dicamba presently has 68 food and feed pesticide tolerances (40 CFR §180.227) established in support of these uses.

In soybean, dicamba is presently registered for preemergence (early pre-plant) applications up to 0.5 pound acid equivalence per acre (lb a.e./A) and late postemergence (pre-harvest) applications at rates up to 1.0 lb a.e./A, and a pesticide tolerance is established for residues of dicamba on soybean seed (10 ppm) in support of these uses.

In cotton, dicamba is presently registered for preemergence (early pre-plant) applications up to 0.25 pound acid equivalence per acre (lb a.e./A), and a pesticide tolerance is established for residues of dicamba on cotton seed, undelinted (0.2 ppm) in support of these uses.

E.4 Overview of Dicamba Herbicide

Dicamba (3,6-dichloro-2-methoxybenzoic acid) is a carboxylic acid that can form salts in aqueous solution. The chemical structure is provided in Figure E-1. Dicamba products registered for agricultural uses are formulated with various dicamba salts. The formulated products Clarity and M1691 contain the diglycolamine salt of dicamba at a nominal level of 56.8% by weight, which is equivalent to 38.5% by weight dicamba acid (also referred to acid equivalents or a.e.).

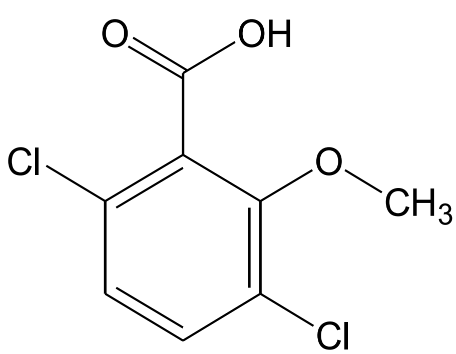

Figure E-1. Structure of Dicamba

E.4.1 Properties of Dicamba Herbicide

Both dicamba, as the Clarity or the M1691 formulation, and glyphosate, as various Roundup-branded formulations, have “CAUTION!” signal words (CAUTION is the most favorable of three possible label signal words that can be required by EPA) and favorable chronic toxicity profiles. In a comparative analysis with other alternative soybean weed control products, dicamba products offer better, or at least equivalent, human health safety profiles, as discussed below.

In 2006, EPA issued the Reregistration Eligibility Decision (RED) document for dicamba and its associated salts (U.S. EPA, 2009). The RED document, and the related Health Effects Division (HED) chapter (U.S. EPA, 2005b), presented an overview of the toxicological properties of dicamba, which is summarized below.

The measurement of human health is the result of conventional laboratory testing against standard indicator species (generally rats, mice, and dogs) and is required for the registration of a pesticide by the EPA. Results are presented using standard toxicity indices, such as the concentration or dose required for 50% lethality (LC_{50} or LD_{50}), the highest dosing level that produced No Observable Adverse Effects (NOAEL), or the lowest dosing level that produced an Observable Adverse Effect (LOAEL). The results of the acute (single exposure) toxicity studies for dicamba are presented in Table E-1. Results for developmental, reproduction, mutagenic and neurotoxicological studies are presented in Table E-2. Subchronic, chronic and carcinogenicity study results are presented in Table E-3.

Table E-1. Dicamba Acid Acute Toxicity Study Findings

Study	Endpoint	EPA Category[1]
Acute oral (rat) LD_{50}	2740 mg/kg	III
Acute dermal (rat) LD_{50}	2000 mg/kg	III
Acute inhalation (rat) LC_{50}	5.3 mg/L	IV
Primary eye irritation (rabbit)	Irritant	II
Primary dermal irritation (rabbit)	Irritant	II
Dermal sensitization (guinea pig)[2]	Negative	NA

[1]EPA acute toxicity categories range from I (worst) to IV (best).

[2]Determination of the potential to cause or elicit skin sensitization reactions (allergic contact dermatitis) is an important element in evaluating a substance’s toxicity.

Table E-2. Dicamba Acid Reproductive, Developmental, Mutagenic, and Neurotoxicologic Findings

Study	Systemic Toxicity Endpoint (mg/kg body wt/day)	Offspring Toxicity Endpoint (if any) (mg/kg body wt/day)
Developmental (rat)	Maternal NOAEL 160; LOAEL 400. Clinical signs: decreased food consumption and weight gain, increased mortality.	Developmental NOAEL 400 (HDT[1]).
Developmental (rabbit)	Maternal NOAEL 62.5; LOAEL 150. Clinical signs: decreased motor activity, ataxia, increased abortion.	Developmental NOAEL 62.5; LOAEL 150. Clinical signs: Increased abortion.
Developmental Neurotoxicity	Not Required	
Reproduction, multigeneration (rat)	Parental NOAEL 122/136 (M/F[2]); LOAEL 419/450 (M/F). Clinical signs: reduced righting reflex. Reproductive NOAEL 122; LOAEL 419. Delayed F1 male maturation.	Offspring NOAEL 45; LOAEL 136. Clinical signs: Decreased pup weights, all generations.
Acute Neurotoxicity (rat)	NOAEL not established; LOAEL 300. Clinical signs: Impaired gaits and righting reflex, impaired respiration, rigidity.	
Subchronic Neurotoxicity (rat)	NOAEL 401/472 (M/F); LOAEL 768/1029 (M/F). Clinical signs: Rigidity, slightly impaired gait and righting reflex.	
Gene Mutation – Salmonella	Not mutagenic.	
Chromosome aberration (CHO[3])	Aberrations not induced at any tested concentration with or without S9 activation.	
Unscheduled DNA Synthesis (UDS)	No Evidence of UDS up to 3000 μg/mL	

[1]HDT stands for the highest dose tested.

[2]M/F stands for males/females.

[3]Chinese hamster ovaries.

Table E-3. Dicamba Acid Subchronic, Chronic and Cancer Findings

Study	Toxicity Endpoints (mg/kg body weight/day)
Subchronic Oral (rat)	NOAEL 479/536 (M/F[1]); LOAEL 1000/1065 (M/F). Clinical signs: decreased weight gains, liver effects.
28-day dermal (rat)	NOAEL 1000 (HDT[2]).
Chronic / Carcinogenicity (rat)	NOAEL 107/127 (M/F; HDT). Not carcinogenic.
Chronic (dog)	NOAEL 52 (HDT).
Carcinogenicity (mouse)	NOAEL 358/354 (M/F); (HDT). Not carcinogenic.

[1]M/F stands for males/females.
[2]HDT stands for the highest dose tested.

The EPA has classified dicamba as "Not Likely to Cause Cancer in Humans" (the most favorable among EPA's cancer categories), and concluded that dicamba is not mutagenic and is not a developmental toxin. There was no evidence of behavioral or neurological effects on offspring and, therefore, a developmental neurotoxicity study was not required by the EPA.

In the human health risk assessments for dicamba, the EPA employed a chronic Population Adjusted Dose (cPAD) of 0.45 mg/kg/day, based on a 100-fold safety factor applied to the offspring NOAEL in the multigeneration rat study. For evaluating acute exposures to dicamba, the EPA employed an acute Population Adjusted Dose (aPAD) of 1 mg/kg, based on a 300-fold safety factor (for use of the LOAEL rather than the NOAEL) applied to the LOAEL in the rat acute neurotoxicity study (U.S. EPA 2008a).

Using a dietary exposure model to estimate combined exposures from all presently approved uses, including both food and water exposure routes, and assuming that 100% of all labeled crops are treated with dicamba and that the resulting foods have tolerance-level residues, total dietary exposure reached only 4.4% of the aPAD level and 2.7% of the cPAD level for the general U.S. population; and 11% of the aPAD and 6.8% of the cPAD for the most highly exposed subpopulations of children 1-2 years old (U.S. EPA 2008a).

The proposed dicamba use on DT soybean does not require an increase in the soybean seed food tolerance. However, Monsanto has requested new tolerances for soybean forage and hay; to support the potential feeding of soybean forage and hay to livestock. Monsanto has also requested an increase in the cotton seed tolerance to 3 ppm and establishment of a cotton gin by-product tolerance of 70 ppm. Since cotton production does not contribute significantly to human dietary exposure and the proposed changes to existing dicamba crop tolerances as outlined do not increase the livestock dietary burden utilized in the RED assessment, all dietary exposures from the proposed dicamba use on DT soybean and DGT cotton are already accounted for in these assessments.

E.4.2 Toxicology of Dicamba Plant and Animal Metabolites

DT soybean and DGT cotton have been genetically enhanced to express a dicamba metabolizing enzyme (dicamba mono-oxygenase). The enzyme catalyzes a mono-oxygenation reaction resulting in an oxidative demethylation of dicamba, forming 3,6-dichloro-2-hydroxybenzoic acid, also known as 3,6-dichlorosalicylic acid (DCSA). In the dicamba-treated DT soybean and DGT cotton, glucoside conjugates of DCSA were the major plant metabolites.

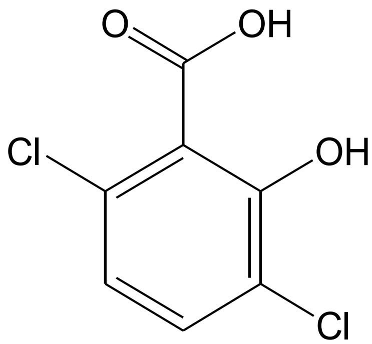

Figure E-2. Structure of DCSA

DCSA is a known metabolite of dicamba in soil, plants, and livestock. It is presently included in the residue expression specified in the food and feed tolerance for dicamba in 40 CFR 180.227(a)(3). Therefore, the existing food tolerance for soybean seed includes DCSA residues.

In the RED, EPA considered that DCSA has structural similarity to dicamba, and concluded that it would have similar toxicity to the parent dicamba. Monsanto has conducted and submitted additional toxicity studies involving direct dosing with DCSA (U.S. EPA OPP Decision Number D432752) to further substantiate the conclusion reached by the EPA in the RED. The results of these studies, summarized in Table E-4, can be compared to those of dicamba (Tables E-1 through E-3). Monsanto has submitted these studies to the EPA in support of our application to register the use of dicamba on DT soybean and DGT cotton.

Table E-4. Summary of Toxicological Findings from Testing of DCSA

Study	Systemic Toxicity Endpoint (mg/kg body wt/day)	Offspring Toxicity Endpoint (if any) (mg/kg body wt/day)
Acute oral (rat) LD_{50}	2641 (Category III)	NA
Developmental (rat)	Maternal NOAEL 100	Developmental NOAEL 100
Developmental (rabbit)	Maternal NOAEL 25	Developmental NOAEL 65 (HDT)
Reproduction, multigeneration (rat)	Parental NOAEL 42 (M/F[1] combined)	Offspring NOAEL 42
Gene mutation – *S. typhimurium* & *E. coli*	Not mutagenic	NA
In vitro chromosome aberration (CHO)	Aberrations not induced	NA
Micronucleus (mouse)	Negative	NA
Subchronic (90-day) oral (Rat)	NOAEL 362/222 (M/F)	NA
Chronic (12-month)(rat)	NOAEL 171/206 (M/F).	NA
Subchronic (90-day) (dog)	NOAEL 50	NA
In Vitro cytogentics (human lymphocytes)	Weakly positive with S9 activation	NA
In Vivo cytogenetics (rat)	Negative	NA
Carcinogenicity	Ongoing	NA

NA denotes Not Applicable.
[1]M/F stands for males/females.

Smaller amounts of a glucoside of another known metabolite, 5-dichloro-3,6-dihydroxybenzoic acid (3,6-dichlorogentisic acid, DCGA) were also identified in the soybean and cotton metabolism studies. Levels of the DCGA glucoside were less than 10% of total DT soybean- and DGT cotton-contained radioactivity. Monsanto conducted a limited set of toxicity studies on DCGA; and has provided these studies to EPA to support our application to register dicamba on DT soybean.

The results of the DCSA and DCGA toxicity studies substantiate the EPA conclusion that dicamba metabolites will have similar toxicity to parent dicamba.

E.5 Potential Impact of Dicamba on Human Health

E.5.1 Dicamba Safety Evaluations for Consumers

On the basis of the risk assessments summarized below, EPA has concluded that there is a reasonable certainty that the existing uses of dicamba will not pose a risk to consumers, including infants and children.

Dicamba presently has 68 established food and feed pesticide tolerances in the U.S. (40 CFR § 180.227). Each time EPA reviews an application to add a new food or feed use to the dicamba label, the EPA is required by FFDCA to conduct an aggregate risk assessment. This assessment considers potential exposure from the proposed new use with all other existing exposures, including non-occupational sources of exposure to the pesticide, and must conclude that aggregate exposure to the pesticide will be safe as defined by the statute and regulations. Risks associated with potential occupational exposure for each new use are considered under the FIFRA standard of no unreasonable adverse effects to the environment, which includes humans and workers (hereafter referred to as FIFRA unreasonable risk standard). Over the course of numerous reviews, the toxicology of dicamba has been extensively studied. Dicamba does not pose any unusual toxicological concerns (U.S. EPA, 2009; Durkin and Bosch, 2004; European Commission, 2007a) and is classified by EPA as "Not likely to be Carcinogenic to Humans" (U.S. EPA, 2009). PMRA and the European Commission have also classified dicamba as non-carcinogenic (PMRA, 2007, 2008; European Commission, 2007a).

Dietary exposure, as previously stated, is included in the aggregate exposure assessment, and considers pesticide residues that may remain on food from crops on which the pesticide is applied (pre- or postemergence), as well as any residue in drinking water as a result of pesticide use. Non-dietary exposure is also included in this assessment, and includes exposure to the pesticide through residential use, such as on lawns, as well as exposure in a recreational context, such as from a golf course or sports field. Based on these data, EPA must be able to make a determination of reasonable certainty of no harm to human health as required by the FFDCA. At the time that dicamba was undergoing reregistration, occupational exposure was not considered as part of the aggregate exposure and was evaluated separately under the FIFRA unreasonable risk standard.

In making a determination of whether a reasonable certainty of no harm to human health exists, dietary risk assessments are performed that consider both the potential exposure and toxicity of a given pesticide. The dietary risk is then described as a percentage of a level of concern. The level of concern, which is also referred to as the population adjusted dose (PAD), is the dose (level of exposure) predicted to result in no adverse health effects to any human population subgroup, including sensitive subgroups, such as infants and children. The PAD may be expressed based on acute (aPAD, one day or less) or chronic exposures (cPAD, lifetime exposure). The PAD is the reference dose (RfD) for the compound but with any additional safety/uncertainty factors to protect sensitive subpopulations, or to address the completeness, quality or reliability of the toxicity data. The PAD is an estimate of the amount of daily pesticide exposure to the human population that can occur acutely (less than one day) or over a lifetime with a reasonable certainty of no harm to human health.[133] An estimated exposure less than 100% of the PAD is below the level of concern for the EPA.

The EPA evaluated the potential risks to human health associated with all then-registered dicamba uses as part of the reregistration of dicamba, and published the results and conclusion in the dicamba RED (U.S. EPA, 2009). Since reregistration, the EPA has approved an additional use on sweet corn, and as part of the approval included this new use in an updated dietary risk assessment. Since the sweet corn use pattern was within that reviewed during reregistration, EPA determined that the ecological and environmental fate assessments did not need to be updated and utilized the drinking water concentration from the RED in the updated sweet corn dietary risk assessment. The sweet corn use did not result in any noticeable increase in dietary exposure compared to the assessment from the RED; therefore, the risk assessment conduced for the dicamba RED is representative of all current registered uses of dicamba. EPA has conducted acute and chronic dietary (food and water) risk assessments for dicamba based on a theoretical worst case exposure estimate. For food, this estimate assumes that dicamba is used on 100 percent of all the crops on which the pesticide is currently approved for use. It further assumes that the resulting pesticide residues found on all harvested food crops and derived animal food commodities (*e.g.*, meat and milk) are at the level of the legally established tolerance (*i.e.*, the maximum allowable pesticide residue level). Residues of dicamba are defined as dicamba and its metabolites 5-hydroxy dicamba and 3,6-dichlorosalicylic acid (DCSA) in soybean commodities, and as dicamba and DCSA in animal food commodities, as currently regulated in 40 CFR § 180.227 (U.S. EPA, 2005a; U.S. EPA, 2005b). For water, EPA assumed that dicamba could potentially move offsite to adjacent surface water bodies as a result of drift or runoff. EPA also assumed dicamba could move through soil to groundwater; however, estimated concentrations in groundwater were significantly lower and therefore surface water estimates were used in the worse case dietary assessments. Surface water estimates were generated with the conservative screening level models SCIGROW and PRZM/EXAM using an exaggerated application rate that is 2.8 times higher than the current 1.0 lb a.e./A maximum single application rate established in the dicamba RED (U.S. EPA, 2009, U.S. EPA, 2005b), and the maximum single application rate proposed for DT soybean and DGT cotton. EPA mandated reductions in dicamba use rates as part of the dicamba RED (1 lb a.e./A and 2 lb a.e./A for a single application and for annual application, respectively).

The acute PAD for dicamba is 1 mg per kg body weight per day (mg/kg/day), based on an acute neurotoxicity study in rats (U.S. EPA, 2009). Based on the worst-case assumptions outlined above, the result of the dietary assessment gave a conservative, high-end (95th percentile) estimate of risk, which was well below the Agency's level of concern for both the U.S. population in general and for all population subgroups. As shown in Table E-5, when both food and water are combined, infants were the most highly exposed subgroup with 11% of the aPAD, or acute level of concern, consumed. Because even this most highly exposed subgroup consumes a small percentage of the acute level of concern for dicamba, EPA concluded there is a reasonable certainty that acute dietary exposure to dicamba will not pose a risk to human health, including that of infants and children (U.S. EPA, 2009).

[133] RfD is the current terminology used by EPA; however, earlier EPA risk assessment terminology used the term Acceptable Daily Intake (ADI). RfD and ADI are synonymous.

The chronic PAD for dicamba is 0.45 mg/kg/day, based on a two-generation reproduction study in rats (U.S. EPA, 2009). Based on worst-case assumptions outlined above, EPA developed exposure estimates for the general U.S. population and the 8 other subpopulations of consumers evaluated by EPA; the major subpopulations are summarized in Table E-5. EPA determined that the most highly exposed subgroup for chronic dietary exposure (including both food and water) was children aged 1-2 years old, which consumed 6.6% of the cPAD, or chronic level of concern. Since even the most highly exposed subgroup consumes a small percentage of the chronic level of concern, EPA concluded there is a reasonable certainty that chronic dietary exposure to dicamba will not pose a risk to human health, including that of infants and children (U.S. EPA, 2009).

Table E-5. Summary of Dietary Exposure and Risk for Dicamba: Food and Water

	Acute dietary (95th percentile)		Chronic dietary	
Population subgroup	Dietary exposure (mg/kg/day)	% aPAD	Dietary exposure (mg/kg/day)	% cPAD
General U.S. population	0.0435	4.4	0.0118	2.6
All infants (<1 year old)	0.108	11	0.0199	4.4
Children 1-2 years old	0.0756	7.6	0.0297	6.6

Source: EPA 2005b.

The EPA also conducted an aggregate risk assessment which included dietary exposure (food and water) as well as other non-occupational exposures (*e.g.*, from residential uses such as lawns and recreational uses such as golf courses or sports fields). For acute and chronic aggregate risk assessment, the aggregate exposure is the same as the dietary exposure. EPA does not typically aggregate acute dietary exposures with acute non-occupational exposures because it is unlikely that high end dietary exposure will occur on the same day as maximum non-occupational exposures (U.S. EPA, 2005b). Current residential uses of dicamba do not result in long term residential exposure scenarios, so chronic aggregate exposure/risk is equal to chronic dietary exposure/risk. Therefore, the acute and chronic dietary exposure and risk summarized in Table E-5 also represents the acute and chronic aggregate exposure and risk.

For short-term aggregate risk assessment of dicamba, EPA considered exposures from food, water, and residential handling and post-application. As shown in Table E-6, the highest exposed individuals in this assessment were adult males mixing, loading and applying dicamba using a hose-end sprayer, resulting in an aggregate exposure of 5.1% of the cPAD, and toddlers playing on treated turf which results in an aggregate exposure of 9.7% of cPAD. This short-term risk aggregate risk assessment was also considered to be protective of intermediate and long term exposures to dicamba. A large margin of safety exists for exposure to dicamba, even considering all the approved food, feed and non-crop uses of dicamba.

Table E-6. Aggregate (Short-term) Exposure Assessment for Dicamba

Population	Food + Water Exposure mg/kg/day	Incidental Oral Exposure, mg/day	Dermal Dose, mg/kg/day	Combined Exposure, mg/kg/day	%PAD
Adult Male - Handler	0.0128	0	0.0102	0.023	5.1
Adult Male – Post Application	0.0128	0	0.0037	0.0165	3.7
Child – 1-2 years	0.0297	0.0078	0.0062	0.0437	9.7

Source: EPA, 2005b.

In summary, based on the EPA risk assessments discussed above, there is a reasonable certainty that the existing uses of dicamba will not pose a risk to consumers, including infants and children.

E.5.2 Dicamba – Proposed New Use on DT Soybean and DGT Cotton – General Population Including Infants and Children

Applications have been submitted to the EPA to amend Registration Number 524-582 (a diglycolamine (DGA) salt formulation) to register a new use pattern for dicamba on DT soybean and DGT cotton. A new product based on BAPMA salt of dicamba has also been submitted to EPA for use on DT soybean. In support of the new uses of dicamba on DT soybean and DGT cotton, mammalian toxicity data on the dicamba metabolites DCSA (3,6-dichlorosalicylic acid) and DCGA (3,6-dichlorogentisic acid), and crop metabolism and residue data on dicamba-treated DT soybean and DGT cotton have been generated. These data confirm that existing dicamba food tolerances are sufficient to address any incremental exposure to dicamba resulting from its use on DT soybean or DGT cotton. Furthermore, the proposed use patterns for dicamba on DT soybean and DGT cotton maintain the presently established maximum single and annual application rates.

Monsanto has submitted to EPA applications to register the use of dicamba on DT soybean and DGT cotton (U.S. EPA OPP Decision Numbers D-432752 and D-467997). The proposed use of dicamba on DT soybean and DGT cotton will not result in measurable increases in the exposure to dicamba or significant changes in the human health risk assessment. Plant metabolism studies have shown that the majority of the dicamba residue found in DT soybean and DGT cotton is DCSA, with lesser amounts of 3,6-dichlorogentisic acid (DCGA), 5-hydroxydicamba (5-OH dicamba) and parent dicamba (Tables E-7-8). Toxicology studies submitted to EPA have demonstrated that the toxicology profiles for both DCSA and DCGA are comparable to that of parent dicamba, and that the existing hazard endpoints (RfDs and PADs) for dicamba are adequate to assess the potential human health risks from the metabolites as well.

Studies have shown that the total dicamba residues in soybean seed following application of dicamba to DT soybean will be well below the current 10 ppm soybean seed tolerance, an exposure level which has been determined as acceptable by EPA. In addition, Monsanto is proposing to establish new feed tolerances for soybean forage (45 ppm) and hay (70 ppm), which will allow the feeding of forage and hay to livestock. This practice is not presently allowed because the preharvest application occurs after the stage where the crop would be useful as forage and hay. Note that the maximum residue for forage at 51.2 ppm is above the proposed MRL of 45 ppm. This is due to the way the data are distributed and the use of the NAFTA MRL calculator, which is the standard method used by EPA to calculate pesticide tolerance levels (U.S. EPA, 2011a). The EPA will perform its own calculations based on the data summarized in the table below to establish an appropriate feed tolerance for dicamba on soybean forage and hay.

Table E-8. Residues of Dicamba, DCSA, 5-Hydroxydicamba and DCGA in DT Soybean Forage, Hay and Seed

Commodity	PPM (Expressed as Each Analyte per se)				PPM (Dicamba Acid Equivalents)
	Dicamba	DCSA	5-OH dicamba	DCGA	Total as current definition of residue (dicamba + DCSA + 5-OH dicamba)
Forage					
Mean	0.342	15.8	<0.006	2.04	17.3
Median	0.068	14.0	<0.005	1.95	15.2
Minimum	<0.021	8.34	<0.005	0.359	10.0
Maximum	2.62	47.9	0.010	5.95	51.2
Hay					
Mean	0.130	30.1	<0.014	2.68	32.3
Median	0.051	29.8	<0.014	2.02	31.9
Minimum	<0.014	11.4	<0.014	0.169	12.2
Maximum	1.16	57.1	<0.014	7.33	61.1
Seed					
Mean	<0.013	0.055	<0.021	0.032	<0.091
Median	<0.013	0.031	<0.021	0.017	<0.065
Minimum	<0.013	0.009	<0.021	<0.011	<0.041
Maximum	<0.013	0.411	<0.021	0.136	0.471

Human dietary exposure will not increase beyond what has already been evaluated and determined acceptable by the EPA because established tolerances for animal food commodities (*e.g.*, meat or milk) are sufficient to address livestock consumption of soybean forage or hay. This is because the proposed soybean forage and hay tolerances (residues) are lower than existing livestock dietary constituents that could potentially be replaced with soybean forage or hay in the livestock diet (*e.g.*, grass forage at 125 ppm could be replaced with soybean forage at 45 ppm). Soybean forage and hay are also not common livestock dietary constituents, as concluded by the EPA in its policy to permit label restrictions for livestock feeding of soybean forage and hay (U.S. EPA, 1996).

Studies have been conducted to determine the residues in cottonseed and gin by-products following dicamba applications (Table E-9). Based on this data Monsanto has requested a registration from U.S. EPA for the expanded use of dicamba on DT soybean, an increase in the dicamba residue tolerance from 0.2 ppm to 3 ppm for cottonseed, the establishment of a tolerance of 70 ppm for cotton gin by-products, and the inclusion of DCSA in the residue definitions for cottonseed and gin by-products. No other revisions to dicamba pesticide residue tolerances are needed including animal products such as meat, eggs, or milk.

The existing 0.2 ppm pesticide residue tolerance for cottonseed supporting the current registered uses of dicamba on cotton (40 CFR § 180.227) is for the combined residues of parent dicamba and its metabolite 5-hydroxy dicamba. Cotton gin by-products, a ruminant feed supplement, have no established dicamba tolerance. Studies have shown that the proposed use of dicamba on DGT cotton results in total residue concentrations of parent dicamba and its metabolites, including DCSA and 5-hydroxy dicamba, are less than 3 ppm for cottonseed and less than 70 ppm for gin by-products. The EPA will perform its own calculations based on the data summarized in the table below to establish an appropriate feed tolerance for dicamba on cotton seed and gin by-products.

Table E-9. Residues of Dicamba, DCSA, 5-Hydroxydicamba and DCGA in DGT Cotton Seed and Gin By-products

Commodity	PPM (Expressed as Each Analyte per se)				PPM (Dicamba Acid Equivalents)
	Dicamba	DCSA	5-OH dicamba	DCGA	Total (dicamba + DCSA + 5-OH dicamba)
Seed					
Mean	0.61	0.08	<0.02	0.05	0.71
Median	0.47	0.06	<0.02	0.03	0.54
Minimum	0.12	0.02	<0.02	0.02	0.17
Maximum	1.42	0.27	0.002	0.14	1.72
Gin By-Products					
Median	14.9	4.50	<0.04	2.41	19.7
Minimum	3.13	1.78	<0.04	0.45	5.06
Maximum	23.0	6.17	<0.04	4.14	29.6

Furthermore, since existing dicamba food tolerances (soybean seed and animal by-products) are inclusive of dicamba exposures arising from its use on DT soybean, the most recent EPA dietary and aggregate risk assessments for dicamba also address exposure from the proposed use in DT soybean. As discussed in the DGT Cotton Petition and Appendices H and I to this Environmental Report, the only human food currently produced from cottonseed is refined, bleached, and deodorized (RBD) oil, and to a smaller extent, linters so there is no direct consumption of cottonseed or gin by-products. Therefore, these risk assessments demonstrate that there is a reasonable certainty that the use of dicamba on DT soybean or DGT cotton, together with all other approved uses of dicamba, will not pose a risk to human health, including that of infants and children. While the use of dicamba is expected to increase as a result of the availability of DT Soybean and DGT cotton integrated into the glyphosate-tolerant systems, the risks associated with the new uses have been adequately assessed by EPA through the risk assessment conducted as part of the dicamba RED. Lastly, EPA will review and confirm the acceptability of dietary exposure of dicamba residues on DT soybean and DGT cotton as part of the review of our pending applications.

E.5.3 Dicamba Safety Evaluation for Applicator

Other potential impacts considered by EPA in its human health assessment are occupational exposure of the pesticide handler/applicator, and post-application exposure resulting from re-entry to treated fields or areas. The occupational exposure scenarios evaluated by the EPA as a part of the dicamba RED are also applicable to the proposed use of dicamba on DT soybean and DGT cotton (U.S. EPA, 2005b; U.S. EPA, 2005c).

Using exposure data from the Pesticide Handler Exposure Database (PHED), Outdoor Residential Exposure Task Force (ORETF), and California Department of Pesticide Regulations, the EPA assessed short-term and intermediate-term occupational handler and post-application exposures. Handler exposure scenarios included mixer-loader, applicator and flagger activities. When exposure assumptions included the wearing of chemical resistant gloves during mixer/loader operations involving liquids required by dicamba product labeling, all occupational handler and post-application re-entry scenarios exhibited margins of exposure greater than 100 and did not exceed the EPA level of concern (U.S. EPA, 2009). The use of dicamba on DT soybean and DGT cotton does not pose any new exposure considerations for workers beyond those which have been previously evaluated by EPA as part of the dicamba RED. Therefore the use of dicamba on DT soybean and DGT cotton will not pose a risk to agricultural workers.

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APPENDIX F: POTENTIAL IMPACTS ON WILDLIFE, PLANTS, ECOSYSTEMS, AND THREATENED OR ENDANGERED SPECIES FROM DICAMBA USAGE

Table of Contents

Tables and Figures

F.1. Introduction

This Appendix evaluates the potential for exposure and effects of low-volatility dicamba formulations, including diglycolamine salt formulations, to wildlife, plants, ecosystems and threatened and endangered species from the increased use of dicamba on dicamba-tolerant soybean (DT soybean) and dicamba and glufosinate-tolerant cotton (DGT cotton). The analysis below follows in large measure EPA's Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. EPA: Endangered and Threatened Species Effects Determinations (U.S. EPA 2004) and EPA's Environmental Fate and Ecological Risk Assessment for dicamba (U.S. EPA 2005), from which the majority of the environmental fate input parameters and toxicity endpoints were taken to determine Risk Quotient (RQ) values for this analysis. Available toxicity data for the dicamba diglycolamine (DGA) salt were also considered, where available.

F.2. Dicamba Product Use and General Approach to Risk Assessment

F.2.1. Background – Dicamba

Dicamba (Figure F-1) is a broad-spectrum, systemic herbicide with activity on a wide range of annual and perennial plants. It was first registered in the United States in 1967 and is widely used in agricultural, industrial and residential settings. Dicamba controls annual, biennial and perennial broadleaf weeds in crops and grasslands, and it is used to control brush and bracken in pastures. In combination with a phenoxyalkanoic acid or other herbicide(s), dicamba is used in pastures, rangeland, and non-crop areas, such as fence-rows and roadways, to control weeds. Dicamba is a benzoic acid herbicide similar in structure and mode of action to phenoxy herbicides. Typical terrestrial application methods consist of ground and aerial spray, however application to soybean and cotton containing the dicamba tolerance trait will be limited to ground application under the proposed FIFRA label, which is currently pending before EPA. Additional requirements on the proposed FIFRA label (e.g. nozzle selection, wind speed, ground speed, and boom height) and/or any other measures imposed by EPA will minimize off-field exposure to nontarget organisms from the use of dicamba on soybean and cotton with the DT trait (see Appendix D for additional details).

Dicamba is formulated primarily as a salt in an aqueous solution, although the acid form may be used in some cases. Dicamba salts that are or have been used in commercial herbicide formulations include dicamba dimethylamine salt (DMA), dicamba sodium salt (Na+), dicamba diglycolamine salt (DGA), dicamba isopropylamine salt (IPA), and dicamba potassium salt (K+). Table F-1 gives conversion factors to convert the various salt forms of dicamba into an equivalent amount of the acid form (expressed as acid equivalents, or a.e.) of dicamba. Monsanto has requested the use of dicamba with DT soybean and DGT cotton only for low volatility salt formulations of dicamba.

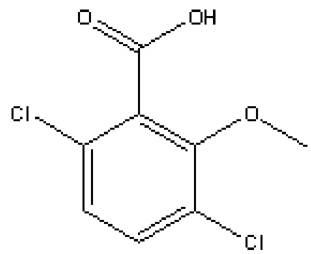

Figure F-1. 3,6-dichloro-2-methoxybenzoic acid (Dicamba) (CAS No. 1918-00-9)

Unless stated otherwise, the information and calculations presented in this document are based on the amount of active ingredient as acid equivalents (a.e.) rather than as the salt form.

Table F-1. Conversion Factors for Dicamba Acid and Dicamba Salts

Form	Molecular Weight	Acid Equivalent Conversion Factor[a]
dicamba acid	221	----
dimethylamine salt of dicamba	266	0.831
sodium salt of dicamba	243	0.909
potassium salt of dicamba	259.1	0.853
diglycolamine salt of dicamba	326.18	0.678

[a] To get the equivalent amount of the acid (a.e., acid equivalent), multiply the amount of the dicamba salt by this factor.

F.2.2. Dicamba Application Rate and Timing

The dicamba tolerance trait allows for application of dicamba to occur from any time before soybean emergence up to R1/R2 (first reproductive flowering stages) growth stage. The dicamba tolerance trait allows for application of dicamba to cotton with the DT trait to occur preplant with no planting interval, pre-emergence or post-emergence up to 7 days before harvest. Application rates considered in this analysis (which are the maximum rates permissible under the proposed FIFRA label) are set forth in Tables F-2 and F-3:

Table F-2. Dicamba Application Rates for DT-Soybean

	Maximum Application Rates
Combined total per year for all applications	2.0 lb dicamba a.e. per acre
Total of all Preplant, At-Planting, and Pre-emergence applications	1.0 lb a.e. per acre
Total of all In-crop applications from emergence up to first reproductive flowering stages (R1/R2 stage soybeans) [a]	1.0 lb a.e. per acre
Maximum In-crop, single application	0.5 lb a.e. per acre

[a] In-crop applications are only permitted from emergence to R1/R2 growth stage.

Table F-3. Dicamba Application Rates for Cotton Containing the Dicamba Tolerance Trait

	Maximum Application Rates (lb dicamba a.e./A)
Combined total per year for all applications	2.0
Total of all Preplant, At-Planting, and Pre-emergence applications	1.0
Total of all In-crop applications from emergence up to 7 days pre-harvest [a]	
If no application prior to emergence:	2.0
With application prior to emergence:	2.0 minus Prior to Emergence amount
Maximum In-crop, single application	0.5

[a] In-crop applications are permitted from emergence to seven days before harvest.

For DT soybeans, applications can occur at any or all of these plant growth stages combined. For in-crop applications the proposed label recommends one application between emergence and V3 growth stage when weeds are small and actively growing, and, if needed, a second application up to the R1/R2 growth stage to control new flushes of weeds. This analysis considers only ground applications of dicamba, which are required under the proposed FIFRA label, to DT-soybeans, and considers that interval between applications will be at least 6 days.

For DGT cotton, applications can occur at any or at several of these plant growth stages. In-crop applications can be made from emergence up to 7 days prior to harvest when weeds are small and actively growing. Sequential applications with at least a 7 day interval between applications may be necessary to control new flushes of weeds. This analysis considers only ground applications of dicamba to cotton with the DT trait since aerial applications will not be permitted, and considers that the interval between applications will be at least 6 days which is more conservative than the 7-day interval currently required on the proposed label.

Figures F-2 and F-3, respectively, give a graphical illustration of the soybean and cotton growth stages and the application window that is proposed.

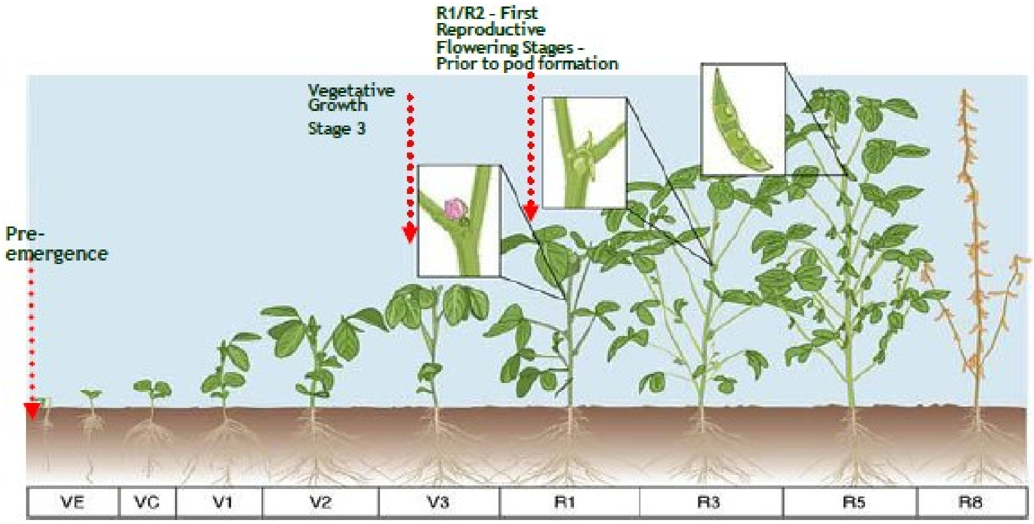

Figure F-2. Soybean Growth Stages and Dicamba Window of Application

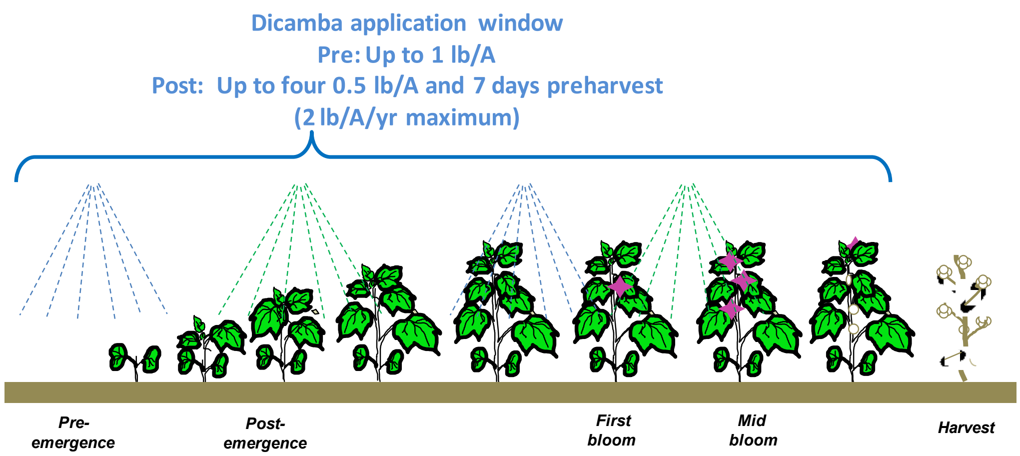

Figure F-3. Cotton Growth Stages and Dicamba Window of Application

F.2.3. Physical and Chemical Properties of Dicamba

A summary of the chemical and physical properties of dicamba used in this analysis is given in Table F-4. These values were taken from the EPA *Environmental Fate and Effects Division Environmental Fate and Ecological Risk Assessment for the Reregistration of Dicamba and Dicamba Sodium, Potassium, Diglycoamine, Dimethylamine and Isopropylamine Salts* (U.S. EPA 2005). These properties were used to calculate environmental exposures via the water, soil, or foliage as appropriate.

Table F-4. Environmental Fate and Physical Properties of Dicamba

CAS Name	3,6-dichloro-2-methoxybenzoic acid
IUPAC Name	3,6-dichloro-o-anisic acid
CAS No (Chemical Abstracts Service Registry Number)	1918-00-9
Empirical Formula	$C_8H_6Cl_2O_3$
Molecular Weight	221.04
Common Name	Dicamba
Chemical Family	Benzoic acid
Color/Form	Colorless crystals
Odor	Odorless
Melting Point	114 – 116°C
Flash Point	199°C
Relative Density	1.57 g/ml at 25°C
Water Solubility	6100 mg/L
Vapor Pressure	3.41×10^{-05} torr (25°C)
Henry's Law Constant	1.79×10^{-8}
pKa	1.87
Kd(Freundlich) mL/g	0.07 (sandy loam), 0.1 (clay loam), 0.16 (loam), 0.21 (loam), 0.53 (silt loam)
Koc (mL/g)	3.45 (clay loam), 7.27 (loam), 17.5 (loam and sandy loam), 21.1 (silt loam)
Soil volatilization	2.91×10^{-4} to 4.97×10^{-4} ug/cm^2/hr at 0.5 lb a.i./A
Field dissipation half-life (DGA salt)	3.0 days (LA silt loam), 3.29 (NC loam sand), 12.9 (IN loam)
(DMA salt)	4.4 – 19.8 days
Anaerobic soil half-life	141 days
Aerobic soil half-life	6 days
Soil photolysis	Approx 20% at 30 days, 25° C (continuous irradiation)
Aqueous hydrolysis	Stable
Aqueous photolysis half-life	38.1 days (continuous irradiation)
Anaerobic aquatic half-life	141 days
Aerobic aquatic half-life (days)	20.2 days (flooded loam), 24.3 (non-linear fit)

F.2.4. Risk Presumptions and Exposure Analysis

Table F-5 summarizes the risk presumptions as established by the U.S. EPA for endangered species assessments. Both acute risk and chronic risk are assessed for birds, wild mammals, and aquatic animals. For plants (aquatic, terrestrial, and semi-aquatic) and for terrestrial invertebrates, EPA only assesses acute risk. Consistent with the approach described in the *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency, Endangered and Threatened Species Effects Determinations* (USEPA, 2004) (Overview Document), the potential for effects on a group of species from exposure is assessed by comparing a risk quotient (RQ) to EPA's Level of Concern (LOC). The RQ is calculated by dividing the estimated environmental concentration (EEC) by the appropriate toxicity value as indicated in Table F-5. The LOC is a fractional value that defines how much lower the exposure value (EEC) must be, compared to the toxicity value, for the species group to be eliminated from concern at the screening level. That is, if the RQ value is less than the LOC, it can be concluded that risk to the species group from exposure can be excluded from concern because of the conservative nature of the screening-level assessment assumptions, and, therefore, a conclusion of no effect on the group of species can be reached.[134] If the RQ value exceeds the LOC, then additional refinements may be performed in order to assess whether risk to the taxa can be excluded from concern and, therefore, whether there would be any effect on the taxa.

Table F-5. Summary of EPA Risk Presumptions for Ecological Effects Assessments

Wildlife Category	**Acute Risk**		**Chronic Risk**	
	Risk Quotient Formula	**Level of Concern (LOC)**	**Risk Quotient Formula**	**Level of Concern (LOC)**
Direct Effects to Non-Endangered Species				
Aquatic Animals	EEC/EC_{50}	0.5	EEC/NOEC	1.0
Terrestrial Animals	EEC/LD_{50}	0.5	EEC/NOEC	1.0
Terrestrial Invertebrates	EEC/LD_{50}	0.5	--	Not assessed
Aquatic Plants (vascular and non-vascular)	EEC/EC_{50}	1.0	--	Not assessed
Terrestrial Plants	EEC/EC_{25}	1.0	--	Not assessed

EEC: Estimated environmental concentration.
LC_{50}/EC_{50}: Exposure concentration resulting in death or immobilization of 50% of the test animals or 50% inhibition of a growth parameter for test plants.
LD_{50}: Dose resulting in death of 50% of the test organisms.
NOEC: no-observed-effect concentration.

F.2.5. Exposure Models and Methods

The potential exposure of each taxon evaluated in this analysis for dicamba was determined using the standard EPA models (current versions at the time of preparation) or methods as described in Table F-6.

[134] Throughout the rest of the document, this conclusion will be stated more simply as "there would be no effect" or "these species would not be affected".

Table F-6. Summary of Models or Methods Used to Estimate Exposure of Each Taxon to Dicamba

Wildlife Category	Model or Method to Determine Estimated Environmental Concentration (EEC)
Birds	T-REX version 1.5.2[a]
Wild Mammals	T-REX version 1.5.2 [a]
Amphibians and Reptiles – Aquatic	Assessed as for aquatic animals
Amphibians and Reptiles – Terrestrial	Assessed as for birds T-HERPS version 1.1 as a refinement
Terrestrial Invertebrates	T-REX version 1.5.2 [a] (arthropod residues)
Aquatic Animals	Tier I: GENEEC2 Drift from ground applications was estimated to be 1%
Aquatic Plants (algae, duckweed)	Tier I: GENEEC2, Drift from ground applications was estimated to be 1%
Terrestrial and Semi-Aquatic Plants	Tier I: TerrPlant; Higher Tier: (semi-aquatic plants) Water monitoring analysis

[a] T-REX Version 1.5.2 was used to calculate DGT cotton RQ values. Version 1.5.1 was used to calculate DT soybean RQ values. Most current T-REX versions were used at the time of preparation. For a given diet type/body weight combination, the RQ values obtained were the same for both versions of T-REX.

F.2.6. Literature Review

The toxicity endpoints discussed herein were typically obtained from EPA's Environmental Fate and Ecological Risk Assessment for dicamba (U.S. EPA 2005) and were comprised primarily of registrant-submitted data; however, published literature sources were also considered. Consistent with EPA's Overview Document (U.S. EPA 2004), an open literature review was conducted to identify publically available literature that could be used in screening level risk assessments. Studies were evaluated that provide data, supplemental to registrant-submitted data, which included information on additional taxa, toxicity endpoints, routes of exposure or test materials.

The literature review was conducted in two steps. The first step included an evaluation of endpoints included in the U.S. EPA ECOTOX (ECOTOXicology) database.[135] The most recent publication relevant for this analysis included in the ECOTOX database was published in 2006. The second step was to conduct a literature search for more recent studies published between 2005 and 2013. The open literature search was conducted using ISI Web of Knowledge and Chemical Abstracts Service. In total, a search using the criteria "dicamba or 1918-00-9" yielded 1,023 unique results. Of these results, 27 were identified as being potentially relevant for use in ecological risk assessment.

[135] U.S. EPA ECOTOX Database (v 4.0); URL: http://cfpub.epa.gov/ecotox/

A further review of the abstracts from these 27 results identified 9 journal articles that warranted further review. Each of these articles was obtained and reviewed in detail. Of these, 4 articles presented relevant ecotoxicological endpoints that were not previously considered in U.S. EPA risk assessments for dicamba.

Three of the four studies that were identified as relevant to ecological risk assessment presented terrestrial plant toxicity endpoints; however, all endpoints were greater than the registrant-submitted vegetative vigor endpoints used in this assessment (i.e. showed less phytotoxicity) and were therefore not considered in the quantitative portion of this assessment. The three relevant studies are discussed in more detail below.

- Olszyk et al. (2009) conducted greenhouse studies with pea (*Pisum sativum*) in 2004. Dicamba test rates were 0, 0.0005, 0.001, 0.005, and 0.05 lb a.e./A. Plant height, leaf injury and seed yield were study endpoints. Dicamba caused characteristic auxin leaf malformation at 0.05 lb/A dicamba but effects were absent at lower rates. Dicamba affected seed formation but had no effect on overall stem height or biomass production. Across all treatments no effect on seed weight (yield) was observed at 0.005 lb/A, and a 25% reduction seed weight (yield) at 0.035 lb/A dicamba. Both endpoints are higher than the endpoints presented in registrant-submitted studies.

- Greenhouse studies were conducted with potato (*Solanum tuberosum*) in 2004–2005 (Olszyk et al. 2010). Dicamba test rates were 0, 0.0005, 0.001, 0.005, and 0.05 lb a.e./A. Plants were harvested at two time points: 28 DAT and 42 DAT on average. Plant height, shoot dry weight, injury and tuber weight were measured. Fresh tuber weight was unaffected at the 0.005 lb/A dicamba treatment level, but significantly reduced at 0.05 lb a.e./A allowing the calculation of an EC25 of 0.035 lb/A Shoot dry weight was the most sensitive endpoint with no effects on shoot dry weight at rates up to 0.001 lb/A. NOEC and EC25 values for plant height and tuber weight occurred at similar treatment rates. All endpoints are higher than endpoints presented in registrant-submitted studies.

- A study was conducted in 2008 to evaluate peanuts response to postemergence applications of dicamba (Prostko et al. 2011). Dicamba test rates were 0, 0.036, 0.063, 0.125, 0.250, 0.500 lb a.e./A. Applications were made at 30, 60, and 90 days after peanut planting. Significant peanut yield losses were observed at rates as low as 0.036 lb a.e./A and losses at this rate range from 2–29% yield reduction relative to controls. The endpoint for yield reduction is higher than endpoints presented in registrant-submitted studies.

- A study conducted by Bohnenblust et al. (2013) evaluated direct and indirect effects of dicamba on two Lepidopteran species and is potentially relevant for use in ecological risk assessment. The results from this study indicate that dicamba is not directly toxic to Lepidopteran species at rates up to 0.5 lb a.e./A, the highest rate tested. Since there was no direct toxicity observed at the highest rate tested, the study was not utilized in the evaluation of potential direct effects. Although indirect effects on one of the species were reported at 0.05 lb a.e./A, which is equivalent to 10% spray drift of a 0.5 lb a.e./A application or 5% of a 1.0 lb a.e./A application, these effects were not observed when the experiment was repeated with larger plants. These drift rates are well above the 1% default spray drift rate assumed in the screening level assessment (Overview Document, US EPA, 2004); and furthermore, with the mandatory label requirements (e.g. nozzle selection, wind speed, ground speed, and boom height) to limit the off-site movement of dicamba even further, dicamba exposure off-site will not reach the level at which these indirect effects were observed.

The U.S. EPA ECOTOX database did not include any terrestrial endpoints that were lower (more sensitive) than endpoints from registrant-submitted studies. Some aquatic endpoints were available in ECOTOX that were lower than endpoints available from registrant-submitted studies; however, the associated studies did not meet quality standards set forth in U.S. EPA (2011). Specifically, those studies that reported lower aquatic endpoints did not appropriately identify the test material[136] or were not a primary source of the data[137], which invalidates these studies from further analysis as specified in U.S. EPA (2011).

Previous risk assessments, including an assessment prepared for the U.S. Forest Service (Durkin and Bosch 2004) were also reviewed. Durkin and Bosch (2004) provided a detailed review of relevant routes of exposure and toxicity endpoints and did not present any additional information that is inconsistent with U.S. EPA (2005) or this assessment.

F.2.7. Estimates of Foliar Residues and Residue Decline

F.2.7.1. Default Residues

Equations from the U.S. EPA Environmental Fate and Effects Division's T-REX model (U.S. EPA 2012, 2013) were used to generate maximum and mean estimated environmental concentrations (EECs) resulting from an application of 1 lb dicamba a.e./A followed at 6-day intervals by two 0.5 lb a.e./A applications based on the proposed dicamba use pattern for soybean and cotton with the DT trait.[138] The exposure estimates were calculated in multiple steps or levels of refinement. In the first step, the default assumptions for residue values on foliage and insects were used. This step utilized residues in food items as reported in the U.S. EPA's RED assessment for dicamba (U.S. EPA 2005). Dicamba concentrations on food items based on data from Hoerger and Kenaga (1972), as modified by Fletcher et al. (1994), were estimated using a first-order residue decline method assuming the default half-life of 35 days.

In the absence of product-specific information, the EPA uses the product application rate coupled with the information first presented by Hoerger and Kenaga (1972) to estimate chemical residues on foliage, and uses modified values for arthropods as reflected in T-REX Versions 1.5.1 and 1.5.2. Using this method, historical residue data gathered from available literature sources are used to give

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[136] General Invalidation Guideline 5 from U.S. EPA (2011) states that "if the study does not provide proper identification of the test material in terms of the percentage of active ingredient, trade name, and/or TGAI, the study is invalid."

[137] From Section 2.1, page 12 of U.S. EPA (2011)

[138] This use pattern results in higher residues than the use-pattern in which four post-emergence applications are made with a minimum interval of at least 7 days, so this is the use pattern evaluated using T-REX and T-HERPS. As noted previously, this use pattern is also more conservative than the proposed label-mandated use pattern for cotton with a 7-day interval between pre- and post-emergence applications and the two post-emergence applications.

a generic estimate of residues. The residue estimates are divided into residues on short grass; tall grass; broadleaf plants; fruits/pods; arthropods; and seeds. When available, product-specific residue information may be used in place of the generic values, and this product-specific information can also be used to calculate the rate of dissipation of residues for use in chronic exposure assessments (U.S. EPA 2004). Also useful in estimating the exposures to animals in the environment are the residue values used to establish food tolerances on animal feed, forage, hay, and fodder. Based on the Residue Chemistry Guidelines, a minimum number of field sites are needed to propose an animal feed tolerance for pasture, forage and hay (Test Guideline OPPTS 860.1500, U.S. EPA 1995). For grass forage, fodder, and hay, Bermuda grass, bluegrass, and brome grass or fescue from a total of at least 12 trials (4 for each variety) is needed from field sites that represent the different geographic regions of the US. The feed tolerance established from these trials was 125 ppm for dicamba applications at 1 lb a.e./A.

F.2.7.2. Grass Forage Residues

For dicamba, grass (pasture forage) Day 0 residue values are available from 59 different treatments using dicamba salt formulations at application rates of 0.5, 1.0, or 2.0 lb a.e./A. These data from each site and rate were normalized to residue values assuming a 1 lb a.e./A application rate, in a manner similar to the treatment of the residue data used by Hoerger and Kenaga (1972). This normalization of the measured residues assumes *a priori* that a linear relationship holds across the application rate range tested. These values were then plotted as a cumulative distribution and the maximum measured value (179 ppm a.e./lb applied) was selected as the worst-case value to use in the T-REX calculations based on the large compound-specific dataset available. The calculated maximum value of 179 ppm was used as the short grass residue value for a 1 lb a.e./A application. The residue value for short grass (179 ppm) was used to derive the tall grass value (82.0 ppm) by assuming the same ratio of tall grass to short grass residues (110 ppm ÷ 240 ppm). as reported in Hoerger and Kenaga (1972).

The grass residue studies previously cited also had a residue decline component for each site and rate. A summary of the foliar half-life times (in days) calculated from these field trials on pasture forage is given in Table F-7. The half-life estimate is the time for half of the dicamba residues to be lost from the plant tissue; i.e., the number of days needed for the day 0 measured dicamba residues to be half of the amount measured on the day of application. The estimated foliar half-life across all pasture forage trials was 5.06 days (arithmetic mean) with an upper 90 percentile confidence limit (single sided) of 5.63 days. For the wheat forage trials, the half-life was 2.82 days (arithmetic mean) with an upper 90th percentile confidence limit (single sided) of 3.00 days. The upper 90th percentile, one tailed, confidence interval for pasture grasses was used to calculate a refined EEC, based upon EPA guidance (U.S. EPA 2009a).

Table F-7. Summary of Dicamba Residue Half-Life in Pasture Grasses and Wheat

Item	Dicamba Half-Life (days) in Foliage					
	Number of Values	Arithmetic Mean	Std Dev	Max	Min	Upper 90% CL on the mean
Pasture grasses (all salts)	58	5.06	3.36	19.3	1.95	**5.63** [a]
Wheat forage (all salts)	41	2.82	0.87	4.87	1.35	**3.00**

[a] Half-life value used for refined T-REX analysis.

All EEC estimates derived using refined residue half-life values employed the half-life value for pasture grasses (5.63 days) as opposed to using the value from the wheat forage studies, as it was the more conservative estimate (i.e. allows for a slower rate of decline) for dicamba residue decline.

F.2.7.3. Broadleaf Plant Forage Residue Refinements

A residue decline study was conducted for DT-soybeans at two application rates (0.5 and 1.0 lb a.e./A) at three field locations (in Arkansas, Illinois, and Nebraska; Mueth and Foster 2010). This study provides dicamba-specific information on residues and residue decline on a surrogate broadleaf plant (soybean). As for the grass forage, Day 0 residue values from all sites and rates were normalized to residue values for a 1.0 lb a.e./A application rate. This normalization of the measured residues assumes *a priori* that a linear relationship holds across the application rate range tested. From these normalized values, the maximum residue value per pound applied was determined as 103.9 mg/kg[139]. This illustrates the conservativeness of the broadleaf plant residues used in the T-REX model.

A foliar decline DT_{50} was also calculated for dicamba-derived residues from this study. The upper 90th percentile confidence interval on the mean value of the six DT_{50} values (4.2 days) was shorter than the DT_{50} derived from the grass forage residue decline study, so the latter value (5.63 days) was used in refined T-REX calculations.

F.2.7.4. Estimates of Dicamba Residues in Wildlife Food Items

As noted above, the T-REX model uses residues in wildlife food items based on data from Hoerger and Kenaga (1972), as modified by Fletcher et al. (1994), and a default half-life of 35 days. For a single application of 1.0 lb/A, the T-REX default residue values are summarized in Table F-8.

Table F-8. T-REX Default Residue Values for Wildlife Food Items

Food Item	Kenaga Residue Value (ppm) (for a 1 lb/A application)	
	Upper Bound	Mean
Short grass	240	85
Tall grass	110	36
Broadleaf plants	135	45
Fruits/pods/seeds	15	7.0
Arthropods	94	65

[139] For the soybean forage residue study, the Day 0 residue values and DT_{50} calculations considered residues as the sum of dicamba plus the metabolites DCSA, DGSA, and 5-hydroxydicamba.

The exposure scenario considered in this analysis is referred to as the 6-day interval maximum use pattern (6diMUP) for soybean and cotton with the DT trait, which is an application of 1.0 lb a.e./A, followed at 6-day intervals with two sequential applications of 0.5 lb a.e./A each. This 6diMUP was modeled using T-REX (U.S. EPA 2012).

In the following situations, the approaches considered in this analysis to define the maximum dicamba residues for the 6-day interval maximum use pattern for soybean and cotton with the DT trait are summarized below and presented in Table F-9:

(1) Maximum residues estimated using the T-REX default residues and default half-life value (35 days). For example, the highest residue on short grass estimated using default residue values and a half-life of 35 days was 415.8 ppm, immediately after the 3rd sequential application (Day 12).

(2) Maximum residues estimated using the T-REX default residues and a compound-specific half-life value (5.63 days). For example, the highest residue on short grass estimated using default residue values and a refined half-life of 5.63 days was 240 ppm, immediately following the initial application of 1 lb a.e./A (Day 0).

(3) Maximum residues estimated using measured foliar residues for short and tall grasses (maximum and mean measured Day 0 compound-specific residues for the upper bound and mean residues, respectively) and a compound-specific refined half-life value (5.63 days). For example, the highest residue on short grass estimated using measured residue values and a half-life of 5.63 days was 179 ppm, immediately following the initial application of 1 lb a.e./A (Day 0).

(4) Maximum residues estimated using measured foliar residues for short and tall grasses (90th percentile value for the upper bound residues in short and tall grasses) and a compound-specific half-life value (5.63 days). For example, the highest residue (90th centile value) on short grass estimated using measured residue values and a half-life of 5.63 days was 131 ppm, immediately following the initial application of 1 lb a.e./A (Day 0).

Table F-9. Dicamba Residue Values for Wildlife Food Items Considered in the Risk Quotient Calculations for Birds and Mammal

Food Item	Highest Residue estimated for the 6-day interval maximum-use pattern for soybeans and cotton with the DT trait (3 sequential applications with a 6-day interval) (ppm a.e.)			
	Using Kenaga Default Residues & T-REX Default Half-Life [a]		Using Maximum Measured Residues & Refined Half-Life [b,c]	
	Upper Bound	Mean	Upper Bound	Mean
Short grass	415.8	147.3	179	77.9
Tall grass	190.6	62.4	82.0	33.0
Broadleaf plants	233.9	78.0	135	45
Fruits/pods/seed	26.0	12.1	15.0	7.0

s				
Arthropods	162.9	112.6	94	65

[a] Using the default residue values and the default half-life of 35 days.

[b] Using compound-specific refined residue values for short and tall grass, and a compound-specific refined half-life of 5.63 days. Note that residues do not build up with sequential applications because of the short half-life. The highest residue occurs immediately after the 1.0 lb a.e./A application at Day 0.

[c] Tall grass upper bound and mean values were calculated using the refined short grass value and the ratio of Kenaga tall grass to short grass values for the upper bound and mean values, respectively.

In situation (1), the 6-day application interval is less than the default half-life; approximately 89% of the dicamba from a prior application is present when the next application is made. This results in the maximum estimated residues occurring immediately after the third application of the 6-day interval maximum use pattern for soybean and cotton with the DT trait. For other situations, the 6-day application interval is longer than the compound-specific refined half-life value (5.63 days). Thus, approximately 48% of the dicamba from a prior application is present when the next application is made. Use of the compound-specific half-life value results in the maximum estimated residues on food items occurring immediately after the first application (the 1-lb application).

The versions of the T-REX model used for these analyses allow for modeling residues in the various diet types following application of a pesticide at differing applications rates and spray intervals; however, it is not designed to allow modification of the dietary food item residues. Thus, the maximum refined residues for grasses, based on measured dicamba residues, reported in Table F-9 were considered in the risk quotient calculations by applying a correction factor to the estimated environmental concentrations (EEC) values computed using the standard T-REX model for a single 1-lb/A application.

Correction factors for the conservative 6-day interval maximum use pattern for soybean and cotton with the DT trait assuming **refined residue values and refined half-life of 5.63 days** were derived as follows for short grass and tall grass. The following equations indicate how correction factors were derived for upper bound residues:

Correction factor (refined short grass) $= \dfrac{\text{179 ppm (max residue in pasture forage for 1 lb/A)}}{\text{240 ppm (Kenaga upper bound residue for 1 lb/A)}} = 0.746$

Correction factor (refined tall grass) = same correction factor as for short grass = 0.746

The following equations indicate how correction factors were derived for mean residues:

Correction factor (refined short grass) $= \dfrac{\text{77.9 ppm (mean residue in pasture forage for 1 lb/A)}}{\text{85 ppm (Kenaga mean residue for 1 lb/A)}} = 0.916$

Correction factor (refined tall grass) = same correction factor as for short grass = 0.916

Example showing correction of EECs to computed EECs for the 6-day interval maximum use pattern for soybean and cotton with the DT trait with refined residues and half-life[140]:

Avian EEC (short grass) for Cotton with DT Trait 6diMUP (20-g size class)	=	273.3 ppm (TREX EEC for 1 lb/A)	x	0.746	=	203.9 ppm
Mammalian EEC (short grass) for Cotton with DT Trait 6diMUP (15-g size class)	=	228.8 ppm (TREX EEC for 1 lb/A)	x	0.746	=	170.7 ppm

F.2.8. Estimates of Pond Water Concentrations

The dicamba concentration in a pond immediately adjacent to a treated field was estimated using GENEEC Version 2.0, a program to calculate estimated environmental concentration (EEC) values considering a standard farm pond scenario.

F.2.8.1. DT Soybean

For the use of dicamba on DT soybean, pond water concentrations were estimated for two application scenarios: (1) a single application of dicamba at 1.0 lb a.e./A; and (2) two sequential applications of 0.5 lb a.e./A separated by 6 days using the relevant environmental fate parameters from Table F-3. The GENEEC EEC values are reported in Table F-10. For the single application at 1.0 lb a.e/A, the peak water concentration estimated by GENEEC was 44.33 µg a.e./L. The maximum 4 day average concentration was 42.3 ppb and the maximum 90 day average was 14.81 µg a.e./L. The peak water concentration following two applications at 0.5 lb a.e/A was 33.35 µg a.e./L. The maximum 4 day average concentration was 31.82 µg a.e./L and the maximum 90 day average was 11.14 µg a.e./L.

Table F-10. Summary of Dicamba Concentrations in Pond Water Estimated by GENEEC

Estimate	GENEEC EEC (µg a.e./L)	
	1.0 lb/A	**0.5 + 0.5 lb/A**
Peak	44.33	33.35
4-day avg (max)	42.30	31.82
21-day avg (max)	32.84	24.71
60-day avg (max)	20.08	15.10
90-day avg (max)	14.81	11.14

[140] Values in example may differ slightly from tables due to rounding.

The combined PRZM and EXAMS programs were used as a higher tier approach to estimate exposure concentrations in pond water. In the ecological exposure assessment, PRZM/EXAMS simulates a 10 hectare (ha) field immediately adjacent to a 1 ha pond, 2 meters deep with no outlet. PRZM/EXAMS were used to simulate the same application scenarios as GENEEC as well as to simulate three sequential applications at the maximum use pattern. GENEEC is unable to analyze application rates of differing amounts. In practice, PE5 was used as an interface to run the combined PRZM/EXAMS programs with varying dates of dicamba application and application rates. The PE5 program takes the user inputs, runs PRZM and hands off the edge of field values to EXAMS which then estimates the pond water concentrations. Using the multi-run feature within PE5, individual dicamba applications were allowed with the first application between March 1 and June 15. These dates were chosen to represent a very broad estimate of the time span when soybeans would be planted and potentially treated with dicamba in soybean production areas in the southern U.S. The soybean application scenario used was the standard EPA Mississippi soybean scenario (MSsoybeanSTD.txt) and the Memphis weather data. Combined, this scenario is widely recognized as providing a very conservative estimate of runoff from treated fields. The three sets of analyses were conducted assuming either a single application rate of 1 lb a.e./A; two applications of 0.5 lb a.e./A separated by 6 days; or three sequential applications of 1.0 + 0.5 + 0.5 lb a.e./A each separated by 6 days.

A comparison of the results from the GENEEC and PRZM/EXAMS modeling is provided in Table F-11:

Table F-11. Dicamba Concentrations in Pond Water Estimated by GENEEC and PRZM/EXAMS

Applications[a]	Estimated Water Concentration (µg a.e./L)			
	GENEEC		PRZM/EXAMS [b]	
	Peak (max)	4 Day (max)	Peak	4 Day
1.0	44.33	42.30	32.35	30.45
0.5 + 0.5	33.35	40.02	21.22	19.92
1.0 + 0.5 + 0.5	-- [c]	-- [c]	41.64	38.22

[a] Individual or sequential applications in lb a.e./A; 6-day application intervals.

[b] 1-in-10-year values.

[c] The GENEEC model was only used for use patterns with a single rate because it does not have the capability to model multiple applications at different rates.

F.2.8.2. DGT Cotton

For the use of dicamba on DGT cotton, pond water concentrations were estimated for two application scenarios: (1) a single application of dicamba at 1.0 lb a.e./A; and (2) four sequential applications of 0.5 lb a.e./A separated by 6 days using the relevant environmental fate parameters from Table F-3. The GENEEC EEC values are reported in Table F-12. For the single application at 1.0 lb a.e/A, the peak water concentration estimated by GENEEC was 44.33 µg a.e./L. The maximum 4 day average concentration was 42.3 µg a.e./L and the maximum 90 day average was 14.81 µg a.e./L. The peak water concentration following four applications at 0.5 lb a.e/A was 41.93

μg a.e./L. The maximum 4 day average concentration was 40.02 μg a.e./L and the maximum 90 day average was 14.01 μg a.e./L.

Table F-12. Summary of Dicamba Concentrations in Pond Water Estimated by GENEEC

Estimate	GENEEC EEC (μg a.e./L)	
	1.0 lb/A	0.5 + 0.5 + 0.5 + 0.5 lb/A
Peak	44.33	41.93
4-day avg (max)	42.30	40.02
21-day avg (max)	32.84	31.08
60-day avg (max)	20.08	19.00
90-day avg (max)	14.81	14.01

GENEEC 2.0 does not have the capability to model multiple applications at different rates. The combined PRZM and EXAMS programs were used as a higher tier approach to estimate exposure concentrations in pond water assuming a 6-day interval maximum use pattern for dicamba (application of 1 lb dicamba a.e./A preemergence followed by two applications of 0.5 lb a.e./A postemergence). In the ecological exposure assessment, PRZM/EXAMS simulates a 10 hectare (ha) field immediately adjacent to a 1 ha pond, 2 meters deep with no outlet. In practice, PE5 was used as an interface to run the combined PRZM/EXAMS programs with varying dates of dicamba application and application rates. The PE5 program takes the user inputs, runs PRZM and hands off the edge of field values to EXAMS which then estimates the pond water concentrations. Using the multi-run feature within PE5, the date of the preemergence application was varied to be any date within two weeks prior to the cotton emergence date designated in the selected EPA scenario. The second application was fixed to be 5 days after emergence, and the third application date was set to be 6 days after the second application. The cotton application scenarios used were the two southeastern U.S. standard EPA cotton scenarios--Mississippi (MScottonSTD.txt) and North Carolina (NCcottonSTD). These scenarios are widely recognized as providing very conservative estimates of runoff from treated fields.

The results from the GENEEC and PRZM/EXAMS modeling is provided in Table F-13.

Table F-13. Dicamba Concentrations in Pond Water Estimated by GENEEC and PRZM/EXAMS

Applications [a]	Estimated Water Concentration (μg a.e./L)			
	GENEEC		PRZM/EXAMS [b]	
	Peak (max)	4 Day (max)	Peak	4 Day
1.0	44.33	42.30	--[c]	--[c]
0.5 + 0.5+ 0.5+ 0.5	41.93	40.02	--[c]	--[c]
1.0 + 0.5 + 0.5	--[c]	--[c]	41.64	38.22

[a] Individual or sequential applications in lb a.e./A; 6-day application intervals for GENEEC and as described above for PRZM/EXAMS.

[b] 1-in-10-year value based on the highest peak value from the two Southeastern U.S. scenarios (in this case the North Carolina scenario with an application date of May 28).

[c] The indicated water model was not utilized to determine water concentrations for the defined use pattern on DGT cotton. The GENEEC model was only used for use patterns with a single rate. PRZM/EXAMS was run for a use pattern with more than one use rate.

F.3. Assessment of Non-Target Species

The following sections assess impacts from dicamba on non-target species. The analysis addresses avian species, wild mammals, terrestrial invertebrates, aquatic animals, aquatic plants, and terrestrial and semi-aquatic plants.

F.3.1. Avian Analysis

F.3.1.1. Avian Toxicity Summary

Table F-14 summarizes the avian toxicity endpoints for dicamba used in this analysis. Where available, endpoints with dicamba DGA salt were selected over those for dicamba acid.

Table F-14. EPA Levels of Concern and Toxicity Endpoints for Birds Used in the Analysis

Organism	Acute/Chronic		LOC	Criteria	Dicamba Endpoint	Units
Birds	acute	non-listed	0.5	EEC/ LD_{50}	262 [a]	mg a.e./kg bw
	acute	listed	0.1	EEC/LD_{50}	262 [a]	mg a.e./kg bw
	chronic	all	1	EEC/NOAEC	695 [b]	mg a.e./kg diet

[a] Dicamba DGA salt, Bobwhite quail oral LD_{50} study

[b] Dicamba acid, reproduction study, Mallard duck.

For acute toxicity endpoint values, the T-REX model uses the LD_{50} value from the surrogate species (in this case Bobwhite quail) and the Mineau factor, and calculates adjusted LD_{50} values based on avian body weight. These adjusted values are presented in Table F-15 and are used in the T-REX model to calculate risk quotient values.

Table F-15. Adjusted LD_{50} values based on body weight

Avian Body Weight (g)	Adjusted LD_{50} (mg/kg-bw)
20	188.75
100	240.29
1000	339.42

Table F-16 summarizes the avian acute oral toxicity data for dicamba as reported in the dicamba EFED assessment (U.S. EPA 2005) and also includes data from one recent study. Table F-17 summarizes the avian subacute dietary study[141] endpoints, and Table F-18 summarizes the avian reproduction study endpoints as reported in the dicamba EFED assessment.

Dicamba acid is categorized as moderately toxic to avian species with a 14-day oral LD_{50} for bobwhite quail of 188 mg a.e./kg (NOEL = 13.6 mg a.e./kg bw) (U.S. EPA 2005). However, since the product being considered for use on DGT cotton and DT soybean is the diglycolamine salt of dicamba, the LD_{50} for that salt (262 mg a.e./kg bw) was used for the risk quotient calculations.

Table F-16. Avian Acute Oral Toxicity for Dicamba Acid and Dicamba Salts

Species	% ai	LD_{50} (mg a.i./kg bw)	LD_{50} (mg a.e./kg bw)	Toxicity Category
Dicamba acid				
Northern bobwhite quail *(Colinus virginianus)*	86.9	188	188	Moderately toxic
Mallard duck *(Anas platyrhynchos)*	86.9	1373	1373	Slightly toxic
Zebra finch[a] *(Taeniopygia guttata)*	93.9	213	213	Moderately toxic
Dimethylamine salt				
Mallard duck *(Anas platyrhynchos)*	48.2	>2510	>2452	Practically non-toxic
Mallard duck *(Anas platyrhynchos)*	11.5	>2510	>2452	Practically non-toxic
Potassium salt				
Northern bobwhite quail *(Colinus virginianus)*	38	724	618	Moderately toxic
Diglycolamine salt				
Northern bobwhite quail *(Colinus virginianus)*	40	387	262	Moderately toxic

[a] Results of a recent study; others as cited in U.S. EPA (2005).

[141] The EPA Overview Document (U.S. EPA, 2004) also refers to this study as an acute dietary study and identifies this study as a part of the acute avian assessment.

Table F-17. Avian Subacute Dietary Studies for Dicamba Acid and Dicamba Salts

Species	% ai	LC_{50} (mg a.i./kg-feed) (ppm)	LC_{50} (mg a.e./kg-feed) (ppm)	EPA Toxicity Category
Dicamba acid				
Northern bobwhite quail *(Colinus virginianus)*	86.6	>10,000	>10,000	Practically non-toxic
Northern bobwhite quail *(Colinus virginianus)*	10	>10,000	>10,000	Practically non-toxic
Mallard duck (*Anas platyrhynchos)*	86.6	>10,000	>10,000	Practically non-toxic
Mallard duck (*Anas platyrhynchos)*	86.6	2009	2009	Practically non-toxic
Mallard duck (*Anas platyrhynchos)*	10	>10,000	>10,000	Practically non-toxic
Dimethylamine salt of dicamba				
Northern bobwhite quail *(Colinus virginianus)*	48.2	>4640	>4533	Practically non-toxic
Northern bobwhite quail *(Colinus virginianus)*	11.5	>5620	>5490	Practically non-toxic
Mallard duck (*Anas platyrhynchos)*	48.2	>4640	>4533	Practically non-toxic
Mallard duck (*Anas platyrhynchos)*	11.5	>5620	>5490	Practically non-toxic
Sodium salt of dicamba				
Northern bobwhite quail *(Colinus virginianus)*	26.5	>10,000	>9090	Practically non-toxic
Northern bobwhite quail *(Colinus virginianus)*	22	>10,000	>9090	Practically non-toxic
Mallard duck (*Anas platyrhynchos)*	22	>10,000	>9090	Practically non-toxic
Potassium salt of dicamba				
Northern bobwhite quail *(Colinus virginianus)*	38	>5620	>4794	Practically non-toxic
Mallard duck (*Anas platyrhynchos)*	38	>5620	>4794	Practically non-toxic
Diglycolamine salt of dicamba				
Northern bobwhite quail *(Colinus virginianus)*	40	>2248	>1522	No more than slightly toxic
Mallard duck (*Anas platyrhynchos)*	40	>2248	>1522	No more than slightly toxic

As cited in U.S. EPA (2005).

Table F-18. Avian Reproduction Toxicity Endpoints for Dicamba Acid

Species	Dicamba acid purity (%)	NOEC/LOEC (mg tech/kg feed)	NOEC/LOEC (mg a.e./kg feed) [a]	LOEC Endpoints
Northern bobwhite quail *(Colinus virginianus)*	86.9	1600/--	1390/--	No treatment-related toxicity
Mallard duck *(Anas platyrhynchos)*	86.9	800/1600	695/1390	Reduction in hatchability

[a] Corrected for percent purity of the test material (technical grade dicamba in the acid form).

As cited in U.S. EPA (2005).

F.3.1.2. Avian Exposure Estimates

Dicamba concentrations on food items based on data from Hoerger and Kenaga (1972), as modified by Fletcher et al. (1994), were calculated in the manner described above.

The estimated environmental concentrations (EECs) derived assuming a 6-day interval maximum use pattern for cotton with the DT trait using the default residue values and a half life of 35 days, are provided in Table F-19. The refined dose-based and dietary-based EECs for birds are provided in Table F-20, Table F-21, and Table F-22.

Table F-19. Avian: Estimated Environmental Concentrations Using Kenaga Residues and Foliar Half-Life of 35 Days (assuming a 6-day interval maximum use pattern for DGT cotton or DT soybean)

Diet	Dose-based EECs (mg/kg bw)					
	Upper Bound			Mean		
	20 g	100 g	1000 g	20 g	100 g	1000 g
Short grass	473.5	270.0	120.9	167.7	95.6	42.8
Tall grass	217.0	123.8	55.4	71.0	40.5	18.1
Broadleaf plants	266.4	151.9	68.0	88.8	50.6	22.7
Fruits/pods	29.6	16.9	7.6	13.8	7.9	3.5
Arthropods	185.5	105.8	47.4	128.2	73.1	32.7
Seeds	6.6	3.8	1.7	3.1	1.8	0.78

Diet	Dietary-based EECs (mg/kg feed)			
	Upper Bound		Mean	
	Subacute	Chronic	Subacute	Chronic
Short grass	415.8	415.8	147.3	147.3
Tall grass	190.6	190.6	62.4	62.4
Broadleaf plants	233.9	233.9	78.0	78.0
Fruits/pods/seeds	26.0	26.0	12.1	12.1
Arthropods	162.9	162.9	112.6	112.6

Table F-20. Avian: Estimated Environmental Concentrations Using Kenaga Residues and Refined Foliar Half-Life of 5.63 Days (assuming a 6-day interval maximum-use pattern for DGT cotton or DT soybean)

Diet	Dose-based EECs (mg/kg bw)					
	Upper Bound			Mean		
	20 g	100 g	1000 g	20 g	100 g	1000 g
Short grass [a]	273.3	155.9	69.8	96.8	55.2	24.7
Tall grass [a]	125.3	71.4	32.0	41.0	23.4	10.5
Broadleaf plants	153.8	87.7	39.3	51.2	29.2	13.1
Fruits/pods	17.1	9.7	4.4	8.0	4.6	2.0
Arthropods	107.1	61.0	27.3	74.0	42.2	18.9
Seeds	3.8	2.2	1.0	1.8	1.0	0.45

Diet	Dietary-based EECs (mg/kg feed)			
	Upper Bound		Mean	
	Subacute	Chronic	Subacute	Chronic
Short grass [a]	240.0	240.0	85.0	85.0
Tall grass [a]	110.0	110.0	36.0	36.0
Broadleaf plants	135.0	135.0	45.0	45.0
Fruits/pods/seeds	15.0	15.0	7.0	7.0
Arthropods	94.0	94.0	65.0	65.0

[a] Residues refined as described in Section F.2.7.4.

Table F-21. Avian: Estimated Environmental Concentrations Using Maximum Measured Residue Estimates (short and tall grass) and Refined Foliar Half-Life of 5.63 Days (assuming a 6-day interval maximum use pattern for DGT cotton or DT soybean)

Diet	Dose-based EECs (mg/kg bw)					
	Upper Bound			Mean		
	20 g	100 g	1000 g	20 g	100 g	1000 g
Short grass [a]	203.9	116.3	52.0	88.7	50.6	22.7
Tall grass [a]	93.4	53.3	23.8	37.6	21.4	9.6
Broadleaf plants	153.8	87.7	39.3	51.3	29.2	13.1
Fruits/pods	17.1	9.7	4.4	8.0	4.5	2.0
Arthropods	107.1	61.0	27.3	74.0	42.2	18.9
Seeds	3.8	2.2	0.97	1.8	1.0	0.45

Diet	Dietary-based EECs (mg/kg feed)			
	Upper Bound		Mean	
	Subacute	Chronic	Subacute	Chronic
Short grass [a]	179.0	179.0	77.9	77.9
Tall grass [a]	82.0	82.0	33.0	33.0
Broadleaf plants	135.0	135.0	45.0	45.0
Fruits/pods/seeds	15.0	15.0	7.0	7.0
Arthropods	94.0	94.0	65.0	65.0

[a] Residues refined as described in Section F.2.7.4.

Table F-22. Avian: Estimated Environmental Concentrations Using Refined Maximum Measured Residue Estimates (90th centile value for short and tall grass) and Refined Foliar Half-Life of 5.63 Days (assuming a 6-day interval maximum use pattern for DGT cotton or DT soybean)

Diet	Dose-based EECs (mg/kg bw)					
	Upper Bound			Mean		
	20 g	100 g	1000 g	20 g	100 g	1000 g
Short grass [a]	149.2	85.1	38.1	88.7	50.6	22.7
Tall grass [a]	68.4	39.0	17.5	37.6	21.4	9.6
Broadleaf plants	153.8	87.7	39.3	51.3	29.2	13.1
Fruits/pods	17.1	9.7	4.4	8.0	4.5	2.0
Arthropods	107.1	61.0	27.3	74.0	42.2	18.9
Seeds	3.8	2.2	0.97	1.8	1.0	0.45

Diet	Dietary-based EECs (mg/kg feed)			
	Upper Bound		Mean	
	Subacute	Chronic	Subacute	Chronic
Short grass [a]	131.0	131.0	77.9	77.9
Tall grass [a]	60.0	60.0	33.0	33.0
Broadleaf plants	135	135	45	45
Fruits/pods/seeds	15.0	15.0	7.0	7.0
Arthropods	94	94	65	65

[a] Residues refined as described in Section F.2.7.4.

F.3.1.3. Avian Risk Quotient Calculations

As an initial screening-level analysis, the estimated exposure concentrations from the T-REX model along with the appropriate toxicity endpoints (Table F-14), adjusted to avian body weight by T-REX as indicated in Table F-15 were used to calculate chronic and acute risk quotients using default Kenaga residue and half-life values (see Table F-23). The EECs used to derive these risk quotients are summarized in Table F-19.

In addition to the default exposure values, refined exposure estimates were developed utilizing default Kenaga residue values and the dicamba-specific refined foliar half-life of 5.63 days, and also utilizing maximum measured dicamba residues on grasses and the dicamba-specific refined foliar half-life value of 5.63 days. Risk quotients considering default Kenaga residue values and the refined foliar half-life value were calculated using the EECs summarized in Table F-20. The refined risk quotients are provided in Table F-24. Risk quotients considering the refined residues in short and tall grasses, and a foliar half-life of 5.63 days were also calculated using the residues summarized in Table F-21. The refined risk quotients are provided in Table F-25. All risk quotients presented in Table F-23 – Table F-25 assume a 6-day interval maximum use pattern for DGT cotton or DT soybean.

Table F-23. Avian: Risk Quotients Using Kenaga Residues and Foliar Half-Life of 35 Days (assuming a 6-day interval maximum use pattern for DGT cotton or DT soybean)

Diet	Acute RQs: (Dose-based EEC/adjusted LD50)		
	Upper Bound Residues		
	20 g	100 g	1000 g
Short grass	**2.51**	**1.12**	0.36
Tall grass	**1.15**	**0.52**	0.16
Broadleaf plants	**1.41**	**0.63**	0.20
Fruits/pods	0.16	0.07	0.02
Arthropods	**0.98**	0.44	0.14
Seeds	0.03	0.02	< 0.01

Diet	Dietary-based RQs: (Dietary-based EEC/LC50 or NOAEC)			
	Upper Bound Residues		Mean Residues	
	Subacute	Chronic	Subacute	Chronic
Short grass	<0.28	0.60	<0.10	0.21
Tall grass	<0.13	0.27	<0.04	0.09
Broadleaf plants	<0.16	0.34	<0.05	0.11
Fruits/pods/seeds	<0.02	0.04	<0.01	0.02
Arthropods	<0.11	0.23	<0.07	0.16

Values in bold font indicate where the risk quotient exceeds the level of concern (0.5 for acute; 1.0 for chronic).

Table F-24. Avian: Risk Quotients Using Kenaga Residues and Refined Foliar Half-Life of 5.63 Days (assuming a 6-day interval maximum-use pattern for DGT cotton or DT soybean)

Diet	Acute RQs: (Dose-based EEC/adjusted LD50)		
	Upper Bound Residues		
	20 g	100 g	1000 g
Short grass [a]	**1.45**	**0.65**	0.21
Tall grass [a]	**0.66**	0.30	0.09
Broadleaf plants	**0.81**	0.36	0.12
Fruits/pods	0.09	0.04	0.01
Arthropods	**0.57**	0.25	0.08
Seeds	0.02	0.01	<0.01

Diet	Dietary-based RQs (Dietary-based EEC/LC50 or NOAEC)			
	Upper Bound Residues		Mean Residues	
	Subacute	Chronic	Subacute	Chronic
Short grass [a]	<0.16	0.35	<0.06	0.12
Tall grass [a]	<0.08	0.16	<0.02	0.05
Broadleaf plants	<0.09	0.19	<0.03	0.06
Fruits/pods/seeds	<0.01	0.02	<0.01	0.01
Arthropods	<0.07	0.14	<0.04	0.09

Values in bold font indicate where the risk quotient exceeds the level of concern (0.5 for acute; 1.0 for chronic).

[a] Residues refined as described in Section F.2.7.4.

Table F-25. Avian: Risk Quotients Using Maximum Measured Residues for Vegetation (short and tall grass) and Refined Foliar Half-Life of 5.63 Days (assuming a 6-day interval maximum use pattern for DGT cotton or DT soybean)

Diet	Acute RQs: (Dose-based EEC/adjusted LD50)		
	Upper Bound Residues		
	20 g	100 g	1000 g
Short grass [a]	**1.08**	0.48	0.15
Tall grass [a]	0.49	0.22	0.07
Broadleaf plants	**0.81**	0.36	0.12
Fruits/pods	0.09	0.04	0.01
Arthropods	**0.57**	0.25	0.08
Seeds	0.02	0.01	<0.01

Diet	Dietary-based RQs (Dietary-based EEC/LC50 or NOAEC)			
	Upper Bound Residues		Mean Residues	
	Subacute	Chronic	Subacute	Chronic
Short grass [a]	<0.12	0.26	<0.06	0.11
Tall grass [a]	<0.06	0.12	<0.03	0.05
Broadleaf plants	<0.09	0.19	<0.03	0.07
Fruits/pods/seeds	<0.01	0.02	<0.01	0.01
Arthropods	<0.07	0.14	<0.05	0.09

Values in bold font indicate where the risk quotient exceeds the level of concern (0.1 for acute; 1.0 for chronic).

[a] Residues refined as described in Section F.2.7.4.

F.3.1.4. Avian Discussion and Conclusions

The risk quotients shown in Section F.3.1.3 above, even those calculated with refined residues, are based on very conservative assumptions which likely overestimate the potential for adverse effects. These assumptions are:

- The organism consumes 100% of its diet from a dicamba-treated area.
- For RQs calculated with upper bound EECs, 100% of the organism's diet, 100% of the time, contains residues at the upper bound.
- The organism consumes 100% of its diet as one food type (e.g. short grass, tall grass, broadleaf forage, arthropods, or fruits, seeds and pods) which for certain food types (e.g. short grass) may have very high EECs.

This potential for overestimation should be taken into consideration as results are considered.

Importantly, LOCs are not exceeded even using default residue assumptions when the most relevant route of exposure—dietary-based—is considered. Although EPA's default approach to assessing acute risk is based on a single oral gavage dose (i.e., the entire dose is delivered to the animal at one time, typically after being dissolved in corn oil), in reality, any pesticide exposure will not occur in this manner – but rather through dietary consumption of dicamba-exposed prey or food items. As a result, the gavage route of administration overestimates the exposure expected to occur in nature, and methods resulting in a dose-delivery over time (e.g., dietary exposure) are more environmentally relevant. Therefore, the use of the acute oral toxicity test (i.e., oral gavage) to predict risk of dicamba to birds in this case should be considered to be a screening-level approach that is expected to overestimate actual risk.

Even with gavage dosing, the LOC is exceeded only for the smallest birds consuming 100% short grass, broadleaf plants, or arthropods at the maximum residue value. Given the layers of conservative assumptions incorporated within that assessment (including that birds this size are not strictly herbivores) and the only slight exceedances of the LOC, it is reasonable to conclude that dicamba use on DT soybean or DGT cotton will not harm avian species. A similar conclusion can be reached for terrestrial-phase amphibians and reptiles, for which avian species are a surrogate.

F.3.2. Wild Mammal Analysis

F.3.2.1. Wild Mammal Toxicity Summary

Table F-26 summarizes the mammalian toxicity endpoints for dicamba used in this analysis.

Table F-26. Mammals: EPA Levels of Concern and Toxicity Endpoints Used in the Analysis

Organism	Acute/Chronic		LOC	Criteria	Dicamba Endpoint	Units
Mammals	Acute	non-listed	0.5	EEC/LD50	2,740 [a]	mg a.e./kg-bw
	Acute	listed	0.1	EEC/LD50	2,740 [a]	mg a.e./kg bw
	chronic	all	1	EEC/NOAEC	500 [b]	mg a.e./kg diet
	chronic	all	1	EEC/NOAEL	45 [b]	mg a.e./kg bw

[a] Dicamba acid, rat oral LD50 study. As cited in U.S. EPA (2005).

[b] Dicamba acid, rat reproduction study. As cited in U.S. EPA (2005).

The acute and chronic toxicity values adjusted for body weight as calculated by T-REX are shown TableF-27. These values are used by T-REX to calculate risk quotient values.

Table F-27. Adjusted toxicity values based on body weight

Mammalian Class	Body Weight	Adjusted LD50 (mg/kg bw)	Adjusted NOAEL
Herbivores/ insectivores	15	6022.06	98.90
	35	4872.49	80.02
	1000	2107.50	34.61
Granivores	15	6022.06	98.90
	35	4872.49	80.02
	1000	2107.50	34.61

Table F-28 provides a summary of the acute toxicity endpoints and Table F-29 summarizes the mammalian sub-chronic and reproductive toxicity values for dicamba. Dicamba acid is classified as "practically nontoxic" to laboratory mammals in acute oral toxicity studies.

Table F-28. Mammalian Acute Toxicity for Dicamba Acid

Species	% Purity	Test Type	Toxicity Value (mg a.e./kg -bw) [a]	Affected Endpoints
Rat (*Rattus norvegicus*)	Tech	Acute oral	LD50 = 2,740	Mortality

[a] Study: MRID 00078444, as cited in U.S. EPA (2005).

Table F-29. Mammalian Subchronic and Developmental/Reproductive Toxicity for Dicamba Acid

Species	Purity	Test Type	Endpoint	Toxicity Value (mg a.e./kg-bw/day)	Affected Endpoints
Rat (Charles River CD)	86.8 %	Subchronic feeding 13 weeks	NOAEL / LOAEL	500 / 1000	body weight changes; liver effects
Rat (Charles River CD)	85.8 %	Developmental	NOAEL / LOAEL	160 / 400 >400/--	Maternal tox [a] Developmental
Rabbit (New Zealand White)	90.5 %	Developmental	NOAEL / LOAEL	62.5 / 150 150 / 300	Maternal tox [b] Developmental [c]
Rat (Sprague-Dawley)	86.5 %	Reproduction	NOAEL / LOAEL	122 / 419 (males) 136 / 450 (females) 45 / 136 [d]	Systemic tox Offspring tox Reproductive

[a] Maternal toxicity – Mortality, clinical signs of neurotoxicity, decreased body weight gain and food consumption

Developmental toxicity - No treatment related fetal gross, skeletal, or visceral anomalies

[b] Maternal toxicity – Abortion, clinical signs of toxicity (ataxia, rales, decreased motor activity), decreased body weight gain and food consumption

[c] Developmental toxicity – Irregular ossification of internasal bones

[d] These dose-based values are equivalent to 500 and 1500 mg/kg diet, respectively.

Source: U.S. EPA (2005).

F.3.2.2. Wild Mammal Exposure Estimates

Dicamba concentrations on food items based on data from Hoerger and Kenaga (1972), as modified by Fletcher et al. (1994), were calculated in the manner described above.

The estimated environmental concentrations (EECs) derived for a 6-day interval maximum use pattern for DGT cotton or DT soybean using the default residue values and a default half-life of 35 days, are provided in Table F-30. The refined dose-based and dietary-based EECs for wild mammals are provided in Table F-31 through Table F-33.

Table F-30. Mammals: Estimated Environmental Concentrations Using Kenaga Residues & Foliar Half-Life of 35 Days (assuming a 6-day interval maximum use pattern for DGT cotton or DT soybean)

Diet	Dose-based EECs (acute and chronic) (mg/kg bw)					
	Upper Bound			Mean		
	15 g	35 g	1000 g	15 g	35 g	1000 g
Short grass	396.4	274.0	63.5	140.4	97.0	22.5
Tall grass	181.7	125.6	29.1	59.5	41.1	9.5
Broadleaf plants	223.0	154.1	35.7	74.3	51.4	11.9
Fruits/pods	24.8	17.1	4.0	11.6	8.0	1.9
Arthropods	155.3	107.3	24.9	107.4	74.2	17.2
Seeds	5.5	3.8	0.88	2.6	1.8	0.4

Diet	Dietary-based EECs (chronic) (mg/kg feed)	
	Upper Bound	Mean
Short grass	415.8	147.3
Tall grass	190.6	62.4
Broadleaf plants	233.9	78.0
Fruits/pods/seeds	26.0	12.1
Arthropods	162.9	112.6

Table F-31. Mammals: Estimated Environmental Concentrations Using Kenaga Residues and Refined Foliar Half-life of 5.63 Days (assuming a 6-day interval maximum-use pattern for DGT cotton or DT soybean)

Diet	Dose-based EECs (acute and chronic) (ppm)					
	Upper Bound			Mean		
	15 g	35 g	1000 g	15 g	35 g	1000 g
Short grass [a]	228.8	158.2	36.7	81.0	56.0	13.0
Tall grass [a]	104.9	72.5	16.8	34.3	23.7	5.50
Broadleaf plants	128.7	89.0	20.6	42.9	29.7	6.88
Fruits/pods	14.3	9.88	2.29	6.67	4.61	1.07
Arthropods	89.6	61.9	14.4	62.0	42.8	9.93
Seeds	3.18	2.20	0.51	1.48	1.03	0.24

Diet	Dietary-based EECs (chronic) (ppm)	
	Upper Bound	Mean
Short grass [a]	240	85
Tall grass [a]	110	36
Broadleaf plants	135	45
Fruits/pods/seeds	15.0	7.0
Arthropods	94	65

[a] Residues refined as described in Section F.2.7.4.

Table F-32. Mammals: Estimated Environmental Concentrations Using Maximum Measured Residues (short and tall grass) and Refined Foliar Half-life of 5.63 Days (assuming a 6-day interval maximum-use pattern for DGT cotton or DT soybean)

Diet	**Dose-based EECs (acute and chronic) (ppm)**					
	Upper Bound			**Mean**		
	15 g	**35 g**	**1000 g**	**15 g**	**35 g**	**1000 g**
Short grass [a]	170.6	117.9	27.3	74.3	51.3	11.9
Tall grass [a]	78.2	54.1	12.5	31.5	21.7	5.04
Broadleaf plants	128.7	89.0	20.6	42.9	29.7	6.88
Fruits/pods	14.3	9.88	2.29	6.67	4.61	1.07
Arthropods	89.6	61.9	14.4	62.0	42.8	9.93
Seeds	3.18	2.20	0.51	1.48	1.03	0.24

Diet	**Dietary-based EECs (chronic) (ppm)**	
	Upper Bound	Mean
Short grass [a]	179	77.9
Tall grass [a]	82	33
Broadleaf plants	135	45
Fruits/pods/seeds	15.0	7.0
Arthropods	94	65

[a] Residues refined as described in Section F.2.7.4.

Table F-33. Mammals: Estimated Environmental Concentrations Using Refined Maximum Measured Residues (90th centile value for short and tall grass) and Refined Foliar Half-life of 5.63 Days (assuming a 6-day interval maximum-use pattern for DGT cotton or DT soybean)

Diet	Dose-based EECs (acute and chronic) (mg/kg bw)					
	Upper Bound			Mean		
	15 g	35 g	1000 g	15 g	35 g	1000 g
Short grass [a]	124.9	86.3	20.0	74.3	51.3	11.9
Tall grass [a]	57.2	39.6	9.2	31.5	21.7	5.04
Broadleaf plants	128.7	89.0	20.6	42.9	29.7	6.88
Fruits/pods	14.3	9.88	2.29	6.67	4.61	1.07
Arthropods	89.6	61.9	14.4	62.0	42.8	9.93
Seeds	3.18	2.20	0.51	1.48	1.03	0.24

Diet	Dietary-based EECs (chronic) (mg/kg feed)	
	Upper Bound	Mean
Short grass [a]	131.0	77.9
Tall grass [a]	60.0	33.0
Broadleaf plants	135	45
Fruits/pods/seeds	15.0	7.0
Arthropods	94.0	65.0

[a] Residues refined as described in Section F.2.7.4.

F.3.2.3. Wild Mammal Risk Quotient Calculations

The T-REX model and the appropriate toxicity endpoints (Table F-26) modified by T-REX as indicated in Table F-27 were used to calculate acute and chronic risk quotients for wild mammals. At the screening-level, the default Kenaga residue and default half-life value of 35 days were considered (Table F-34). The EECs used to derive these risk quotients are summarized in Table F-30.

Refined exposure estimates were developed utilizing default Kenaga residue values and the dicamba-specific refined foliar half-life of 5.63 days, and also utilizing maximum and 90th percentile measured dicamba residues on grasses and the dicamba-specific refined foliar half-life value of 5.63 days. Chronic risk quotients considering default Kenaga residue values and the refined foliar half-life value were calculated using the residues summarized in Table F-31. The refined risk quotients are provided in Table F-35. Risk quotients for chronic exposure, considering refined residues in grasses, and a refined foliar half-life of 5.63 days, were calculated using the EEC values presented in Table F-32 and Table F-33. The refined risk quotients are provided in Table F-36 and Table F-37. All risk quotients are for a 6-day interval maximum use pattern for DGT cotton or DT soybean.

Table F-34. Mammals: Risk Quotients Using Kenaga Residues and Foliar Half-Life of 35 Days (assuming a 6-day interval maximum use pattern for DGT cotton or DT soybean)

Diet	Acute RQs: (Dose-based EEC/adjusted LD50)		
	Upper Bound		
	15 g	**35 g**	**1000 g**
Short grass	0.066	0.056	0.030
Tall grass	0.030	0.026	0.014
Broadleaf plants	0.037	0.032	0.017
Fruits/pods	0.004	0.004	0.002
Arthropods	0.026	0.022	0.012
Seeds	< 0.001	< 0.001	< 0.001

Diet	Chronic RQs: (Dose-based EEC/adjusted NOAEL)					
	Upper Bound			Mean		
	15 g	**35 g**	**1000 g**	**15 g**	**35 g**	**1000 g**
Short grass	**4.01**	**3.42**	**1.84**	**1.42**	**1.21**	0.65
Tall grass	**1.84**	**1.57**	0.84	0.60	0.51	0.28
Broadleaf plants	**2.25**	**1.93**	**1.03**	0.75	0.64	0.34
Fruits/pods	0.25	0.21	0.11	0.12	0.10	0.05
Arthropods	**1.57**	**1.34**	0.72	**1.09**	0.93	0.50
Seeds	0.06	0.05	0.03	0.03	0.02	0.01

Diet	Chronic RQs: (Dietary-based EEC/NOAEC)	
	Upper Bound	Mean
Short grass	0.83	0.29
Tall grass	0.38	0.12
Broadleaf plants	0.47	0.16
Fruits/pods/seeds	0.05	0.02
Arthropods	0.33	0.23

Values in bold font indicate where the risk quotient exceeds the level of concern (0.5 for acute; 1.0 for chronic).

Table F-35. Mammals: Chronic Risk Quotients Using Kenaga Residues and Refined Foliar Half-Life of 5.63 Days (assuming a 6-day interval maximum-use pattern for DGT cotton or DT soybean)

Diet	Chronic RQs: (Dose-based EEC/adjusted NOAEL)					
	Upper Bound			Mean		
	15 g	35 g	1000 g	15 g	35 g	10000 g
Short grass[a]	**2.31**	**1.97**	**1.06**	0.82	0.70	0.38
Tall grass[a]	**1.06**	0.91	0.49	0.35	0.30	0.16
Broadleaf plants	**1.30**	**1.11**	0.60	0.43	0.37	0.20
Fruits/pods	0.14	0.12	0.07	0.07	0.06	0.03
Arthropods	0.91	0.77	0.41	0.63	0.54	0.29
Seeds	0.032	0.027	0.015	0.015	0.013	0.007

Values in bold font indicate where the risk quotient exceeds the level of concern (1.0 for chronic).

[a] Residues refined as described in Section F.2.7.4.

Table F-36. Mammals: Chronic Risk Quotients Using Maximum Measured Residues (short and tall grass) and Refined Foliar Half-life of 5.63 Days (assuming a 6-day interval maximum-use pattern for DGT cotton or DT soybean)

Diet	Chronic RQs: (Dose-based EEC/adjusted NOAEL)					
	Upper Bound			Mean		
	15 g	35 g	1000 g	15 g	35 g	10000 g
Short grass [a]	**1.72**	**1.47**	**0.79**	0.75	0.64	0.34
Tall grass [a]	0.79	0.68	0.36	0.32	0.27	0.15
Broadleaf plants	**1.30**	**1.11**	0.60	0.43	0.37	0.0
Fruits/pods	0.14	0.12	0.07	0.07	0.06	0.03
Arthropods	0.91	0.77	0.41	0.63	0.54	0.29
Seeds	0.032	0.027	0.015	0.015	0.013	0.007

Values in bold font indicate where the risk quotient exceeds the level of concern (1.0 for chronic).

[a] Residues refined as described in Section F.2.7.4.

Table F-37. Mammals: Chronic Risk Quotients Using Refined Maximum Measured Residues (90th centile value for short and tall grass) and Refined Foliar Half-life of 5.63 Days (assuming a 6-day interval maximum-use pattern for DGT cotton or DT soybean)

Diet	Chronic RQs: (Dose-based EEC/adjusted NOAEL)					
	Upper Bound			Mean		
	15 g	35 g	1000 g	15 g	35 g	10000 g
Short grass [a]	**1.26**	**1.08**	**0.58**	0.75	0.64	0.34
Tall grass [a]	0.57	0.49	0.26	0.32	0.27	0.15
Broadleaf plants	**1.30**	**1.11**	0.60	0.43	0.37	0.20
Fruits/pods	0.14	0.12	0.07	0.07	0.06	0.03
Arthropods	0.91	0.77	0.41	0.63	0.54	0.29
Seeds	0.032	0.027	0.015	0.015	0.013	0.007

Values in bold font indicate where the risk quotient exceeds the level of concern (1.0 for chronic).

[a] Residues refined as described in Section F.2.7.4.

F.3.2.4. Wild Mammal Discussion and Conclusions

The risk quotients shown in Section F.3.2.3 above, even those calculated with refined residues, are based on very conservative assumptions which likely overestimate the potential for adverse effects. These assumptions are:

- The organism consumes 100% of its diet from a dicamba-treated area
- For RQs calculated with upper bound EECs, 100% of the organism's diet 100% of the time contains residues at the upper bound
- The organism consumes 100% of its diet as one food type (e.g. short grass, tall grass, broadleaf forage, arthropods, or fruits, seeds and pods) which for certain food types (e.g. short grass) may have very high EECs.

This potential for overestimation should be taken into consideration as results are considered.

For wild mammals, the acute risk quotients are much less than the LOC of 0.5. Therefore, it can be concluded that risk from acute exposure to dicamba used on DGT cotton or DT soybean can be excluded from concern and, therefore, wild mammals would not be affected by dicamba use on DT soybean or DGT cotton.

For chronic risk, the risk quotients derived using Kenaga residue and the default half-life values exceed the LOC of 1.0 for several dietary types (Table F-34).

When upper bound maximum measured residue estimates for grasses and a refined half-life value are considered (Table F-32), small and medium-sized wild mammals consuming short grass and broadleaf plants have risk quotients that only slightly exceed the LOC. Importantly, however, even when assessing risks to threatened and endangered species, EPA specifies that mean residues can be considered for chronic exposures (rather than using maximum residues) (Overview Document, p. 40). Considering the rapid decline of foliar residues of dicamba, exposure over days or weeks will not occur continuously at the maximum Day 0 residue value. Use of the mean Day 0 residue value is still a conservative assumption. When mean residues are considered (with the refinements mentioned above), none of the chronic risk quotients for wild mammals exceed the LOC, indicating that risk of adverse effects from chronic exposure to dicamba used on DGT cotton or DT soybean can be excluded from concern and, therefore, wild mammals would not be affected.

F.3.3. Terrestrial Invertebrate Analysis

F.3.3.1. Honeybee Toxicity Summary

The potential for adverse effects to threatened or endangered terrestrial invertebrate species was assessed using the honeybee as a surrogate. Table F-38 summarizes the honeybee toxicity data for dicamba acid, as reported in the dicamba European Union and EFED assessments (EFSA 2011; U.S. EPA 2005).

Table F-38. Non-Target Invertebrates - Acute Contact Toxicity to Dicamba

Species	Test Material	LD_{50} (µg a.e./bee)	Toxicity Category	Source
Honeybee (*Apis mellifera*)	Technical	>100	Practically non-toxic	EFSA 2011
	Technical	>90.65	Practically non-toxic	U.S. EPA 2005

The toxicity endpoint used to assess the potential for adverse effects to terrestrial invertebrates is calculated by converting the acute contact LD_{50} value of >100 µg a.e./bee to a dose-based estimate by assuming an adult honeybee weighs approximately 0.128 g (i.e., 100 µg a.e./bee ÷ 0.128 g = 781 µg a.e./g bee) (US EPA 2008a).

F.3.3.2. Honeybee Exposure Estimates

The EECs to honey bees were estimated from upper bound residues on arthropods (T-REX v1.5.2) assuming a 6-day interval maximum use pattern using refined compound-specific half-life values described in Section F.2.7.4.

F.3.3.3. Honeybee Risk Quotient Calculations

The RQ values were estimated by dividing the EECs for arthropods by the dose-based LD50 value (µg a.e./g bee). The RQ values are presented in Table F-39.

Table F-39. Risk Quotients for Non-target Invertebrates (assuming a 6-day interval ve maximum use pattern for DGT cotton or DT soybean)

Organism	EEC [a] (µg a.e./g) Arthropods	LD50 [b] (µg a.e./g)	RQ Arthropods
Honeybee (*Apis mellifera)*	94	>781	<0.12

[a] See Table F-9.

[b] LD_{50} (µg/g) = LD_{50} (µg/bee) / 0.128 g

F.3.3.4. Honeybee Discussion and Conclusions

The RQ value for arthropods (<0.12) is less than the LOC (0.5) for terrestrial invertebrates, indicating that risk to pollinators from dicamba use on DGT cotton or DT soybean can be excluded from concern.

When non-listed terrestrial invertebrates are considered, the RQ value is below the LOC (0.5), indicating that there would be no indirect effects on wildlife categories relying on terrestrial invertebrates as a food source.

F.3.4. Aquatic Animal Analysis

F.3.4.1. Aquatic Animal Toxicity Summary

Table F-40 summarizes the acute toxicity of dicamba DGA salt to aquatic animals (fish, invertebrates, and aquatic- phase amphibians) as cited in the U.S. EPA EFED assessment (U.S. EPA 2005) as well as more recent chronic tests conducted with dicamba acid. Freshwater fish are used as a surrogate for aquatic-phase amphibians (EFED Registration Chapter, U.S. EPA 2005, page 24). As shown in Table F-40, dicamba DGA salt and dicamba acid have very little biological activity with respect to aquatic animals.

Table F-40. Toxicity of Dicamba and Dicamba DGA salt to Aquatic Animals

Species	% a.i.	Exposure Duration (d)	LC_{50} / EC_{50} / NOEC (mg a.i./L)	LC_{50} / EC_{50} / NOEC (mg a.e./L)	EPA Toxicity Category
Acute					
Rainbow trout *(Oncorhynchus mykiss)*	40.15 [a]	4	>400	>270.8	Practically non-toxic
Bluegill sunfish *(Lepomis macrochirus*	40.15 [a]	4	>400	>270.8	Practically non-toxic
Waterflea (*Daphnia magna*)	40.15 [a]	2	>400	>270.8	Practically non-toxic
Chronic					
Fathead minnow ELS *(Pimephales promelas)*	92.9 [b]	32		≥10	Practically non-toxic
Sheepshead minnow ELS *(Cyprinodon variegatus)*	93.9 [b]	32		11	Practically non-toxic
Mysid Lifecycle *(Americamysis bahia*)	93.9 [b]	28		5.8	Practically non-toxic

[a] Studies conducted with the dicamba DGA salt.

[b] Studies conducted with TGAI.

F.3.4.2. Aquatic Animal Exposure Estimates

Exposure estimates for aquatic animals potentially exposed to dicamba are derived from GENEEC and PRZM/EXAMS modeling estimates as reported in Section F.2.8.

F.3.4.3. Aquatic Risk Quotient Calculations

For aquatic animal species, the risk quotients are calculated as follows:

$$\text{Aquatic Animal } RQ_{acute} = \frac{\text{Maximum initial EEC (mg a.e./L)}}{EC_{50} \text{ or } LC_{50} \text{ (mg a.e./L)}}$$

$$\text{Aquatic Animal } RQ_{chronic} = \frac{\text{Maximum initial EEC (mg a.e./L)}}{\text{NOEC (mg a.e./L)}}$$

Table F-41 and Tables F-42 to F-43 summarize the acute and chronic risk quotients for endangered aquatic animals determined from the most sensitive endpoints for each taxa listed in Table F-40.

Table F-41. Tier I Risk Quotients for Aquatic Animals based on GENEEC Exposure Estimates for DGT Cotton and DT Soybeans.

Taxonomic Group	Peak		Peak		Peak	
	1 lb/A		2 x 0.5 lb/A		4 × 0.5 lb/A	
	EEC (ppm)	RQ[a]	EEC (ppm)	RQ[a]	EEC (ppm)	RQ[a]
Acute						
Fish	0.0443	<0.0002	0.0334	<0.0002	0.0419	<0.0002
Invertebrate	0.0443	<0.0002	0.0334	<0.0002	0.0419	<0.0002
Amphibian (aquatic-phase)[b]	0.0443	<0.0002	0.0334	<0.0002	0.0419	<0.0002
Chronic						
Fish	0.0443	≤0.0044	0.0334	≤0.0033	0.0419	≤0.0042
Invertebrate	0.0443	0.0076	0.0334	0.0058	0.0419	0.0072
Amphibian (aquatic-phase) [b]	0.0443	≤0.0044	0.0334	≤0.0033	0.0419	≤0.0042

a GENEEC is unable to model a 6-day interval maximum use pattern for dicamba use on soybeans or cotton with the DT trait due to sequential applications at different application rates.

b Risk quotient calculated based on effects endpoint for fish.

Table F-42. Tier II Risk Quotients for Aquatic Animals based on PRZM/EXAMS Exposure Estimates using a 6-day interval maximum use pattern for DGT coton (1.0 lb/A + 0.5 lb/A + 0.5 lb/A)

Taxonomic Group	Peak (1-in-10 yr)		96 Hour (1-in-10 yr)	
	EEC (ppm)	RQ	EEC (ppm)	RQ
Acute				
Fish	0.0416	<0.0002	0.0382	<0.0002
Invertebrate	0.0416	<0.0002	0.0382	<0.0002
Amphibian (aquatic phase) [b]	0.0416	<0.0002	0.0382	<0.0002
Chronic				
Fish	0.0416	≤0.0042	0.0382	≤0.0038
Invertebrate	0.0416	0.0072	0.0382	0.0066
Amphibian (aquatic phase) [b]	0.0416	≤0.0042	0.0382	≤0.0038

[b]Risk quotient calculated based on effects endpoint for fish.

Table F-43. Tier II Risk Quotients for Aquatic Animals based on PRZM/EXAMS Exposure Estimates using the maximum use pattern for DT soybean (1.0 lb/A + 0.5 lb/A + 0.5 lb/A)

Taxonomic Group	Peak		96 Hour	
	EEC (ppm)	RQ	EEC (ppm)	RQ
Acute				
Fish	0.0327	<0.00013	0.0308	<0.00012
Invertebrate	0.0327	<0.00013	0.0308	<0.00012
Amphibian (aquatic phase)	0.0327	<0.00013	0.0308	<0.00012
Chronic				
Fish	0.0327	0.0033	0.0308	0.0031
Invertebrate	0.0327	0.0056	0.0308	0.0053
Amphibian (aquatic phase)	0.0327	0.0033	0.0308	0.0031

F.3.4.4. Aquatic Animal Analysis Summary and Conclusions

The acute and chronic RQ values for endangered and non-endangered aquatic animals exposed to dicamba as estimated by GENEEC and PRZM/EXAMS are all less than the LOC values. Therefore, it can be concluded that risk from exposure to dicamba following use on DGT cotton or DT soybean can be excluded from concern and, therefore, aquatic animals would not be affected.

F.3.5. Aquatic Plant Analysis

F.3.5.1. Aquatic Plant Toxicity Summary

Table F-44 summarizes the toxicity of dicamba to aquatic plants (algal species and duckweed) derived from the U.S. EPA EFED assessment (U.S. EPA 2005).

Table F-44. Non-Target Aquatic Plant Toxicity of Dicamba Acid

Species	% a.e.	EC_{50}/NOEC (mg a.e./L)	Endpoints Affected
Duckweed (*Lemna gibba*)	89.5	>3.25 / 0.20	Frond production
Green Algae (*Selenastrum capricornutum*)	89.5	>3.7 / 3.7	Cell density
Blue-green Algae (*Anabaena flos-aquae*)	89.5	0.061 / 0.005	Cell density
Diatom (*Navicula pelliculosa*)	89.5	2.3 / 0.50	Cell density
Diatom (*Skeletonema costatum*)	89.5	0.493 / 0.011	Cell density

Source: U.S. EPA (2005)

F.3.5.2. Aquatic Plant Exposure Estimates

Exposure estimates for aquatic plants potentially exposed to dicamba are derived from GENEEC and PRZM/EXAMS modeling.

F.3.5.3. Aquatic Plant Risk Quotient Calculations

For aquatic plant species, the acute risk quotient is calculated as follows:

$$\text{Aquatic Plant } RQ_{acute} = \frac{\text{Peak EEC (mg a.e./L)}}{EC_{50} \text{ (mg a.e./L)}}$$

EPA currently does not assess chronic risk to aquatic plants.

The lowest EC50 value from Table F-44 was used for the risk quotient calculation for aquatic plants. Table F-45summarizes the Tier I risk quotients for endangered aquatic plants exposed to dicamba derived using exposure estimates from GENEEC; Table F-46 summarizes the Tier II risk quotients derived using PRZM/EXAMS for the 6-day interval maximum use pattern.

Table F-45. Tier I Risk Quotients for Aquatic Plants based on GENEEC Exposure Estimates for DGT Cotton and DT Soybean.

		Toxicity Endpoint (mg a.e./L)	**Peak**		**Peak**		**Peak**	
			1 lb/A		**2 x 0.5 lb /A**		**4 × 0.5 lb/A**	
			EEC (ppm)	**RQ**	**EEC (ppm)**	**RQ**	**EEC (ppm)**	**RQ**
Aquatic Plants (non-vascular)	non-listed	EC_{50}: 0.061	0.0443	0.73	0.0334	0.548	0.0419	0.687
Aquatic Plants (vascular)	non-listed	EC_{50}: > 3.25	0.0443	< 0.014	0.0334	<0.0103	0.0419	< 0.0129

Table F-46. Tier II Risk Quotients for Aquatic Plants Based on PRZM/EXAMS Exposure Estimates using a 6-day interval maximum use pattern for DT Soybean and DGT Cotton (1.0 lb/A + 0.5 lb/A + 0.5 lb/A)

Application Scenario		Toxicity Endpoint (mg a.e./L)	Peak (1-in-10-yr)		96 Hour (1-in-10-yr)	
			EEC (ppm)	RQ	EEC (ppm)	RQ
1.0 lb a.e./A + 0.5 lb a.e./A + 0.5 lb a.e./A – DT Soybean						
Aquatic Plants (non-vascular)	non-listed	EC_{50}: 0.061	0.0327	0.54	0.0308	0.50
Aquatic Plants (vascular)	non-listed	EC_{50}: > 3.25	0.0327	<0.011	0.0308	<0.01
1.0 lb a.e./A + 0.5 lb a.e./A + 0.5 lb a.e./A – DGT Cotton						
Aquatic Plants (non-vascular)	non-listed	EC_{50}: 0.061	0.0416	0.68	0.0382	0.63
Aquatic Plants (vascular)	non-listed	EC_{50}: > 3.25	0.0416	<0.013	0.0382	<0.012

F.3.5.4. Aquatic Plant Analysis Summary and Conclusions

The risk quotients for non-endangered aquatic vascular and non-vascular plants are below the LOC for all use patterns indicating that risk from exposure to dicamba following application to DGT cotton or DT soybean can be excluded from concern and, therefore, aquatic vascular and non-vascular plants would not be affected.

F.3.6. Terrestrial and Semi-Aquatic Plant Analysis

F.3.6.1. Terrestrial and Semi-Aquatic Plant Toxicity Summary

To assess the potential risk to terrestrial and semi-aquatic plants, the U.S. EPA uses plant toxicity data generated according to existing test guidelines. There are two kinds of studies used, a test designed to evaluate the potential injury to a plant before and just after emergence from the soil (i.e., seedling emergence, pre-emergence) and a test designed to evaluate the potential injury when applied directly to the plant foliage (i.e., vegetative vigor, post emergence). EPA guidelines give the option of using data from plants grown in the field or grown in the greenhouse.

For dicamba, two sets of non-target plant studies have been submitted to the U.S. EPA; the first studies were completed in 1993 (Hoberg, 1993) using the Subdivision J guidance, and the second set of studies was completed in 2009 using the updated Series 850 and OECD guidelines (Porch et al., 2009a, 2009b). See Table F-47 for a comparison of the methodology employed using the different guidelines. For the 2009 studies, the experiments were conducted in a greenhouse, and the test substance was the dicamba DGA salt formulation, Clarity (a BASF product), with the addition of 0.125% of a non-ionic surfactant and 14 g/L of di-ammonium sulfate. The 1993 studies were conducted in a growth chamber, and the test substance for these studies was dicamba acid.

Table F-47. Comparison of non-target plant testing methodology

Subdivision J guideline Dicamba Test I (Hoberg, 1993)	Current Series 850 Guideline Dicamba Test II (Porch, 2009a, 2009b)
Silica sand	Natural or artificial soil
OM = 0.11 – 0.17%	Up to 1.5% OC (approx 3% OM)
Growth chamber	Growth chamber, glasshouse, semi-field
¼ strength AAP nutrient solution	Fertility as needed based on controls
200 ml solution "added" to sand	Surface application
Seeds planted 1 cm deep	Seeding depth appropriate for seeds
Onion seedling survival in control = 83%	Survival of at least 90% needed
30 ml test solution sprayed (1026 gal/A)	Typical application volumes (10-100 gal/A) "not to exceed runoff"
NOEC not determined for all	1 dose below EC25, 1 dose above EC50, determine NOEC (or calculate EC_{05} if necessary)

The latter studies (Porch et al., 2009a, 2009b) were initiated at the request of the EPA following a review of the 1993 studies that occurred during the product reregistration process. In their review, EPA concluded that the initial non-target terrestrial plant studies were not adequate because a NOEC was not determined for the most sensitive endpoints in either study (U.S. EPA, 2005). In addition, the study reports from the initial studies (Hoberg, 1993) document numerous observations that cast doubt on the validity and interpretation of the test results. For example, the study reports note visual injury symptoms of brown leaf tips, necrosis, and chlorosis. However, it has been shown that these plant responses are different than typical sublethal plant symptoms associated with exposure to dicamba such as leaf curling, epinasty, thickened internodes, and shortened plants (Auch and Arnold, 1978; Weidenhamer et al.,1989).

It is likely that the observed plant responses in the 1993 studies were the result of unfavorable test conditions rather than the test material itself. The tip browning and necrosis observed in the studies were likely caused by excess salt accumulation in the leaf tips and leaf margins. The excess salt accumulation, in turn, was likely the result of growing the plants in silica sand, a medium with little or no buffering capacity, coupled with the use of a nutrient solution that was one-quarter strength AAP nutrient solution and applied daily without regard to nutritional requirements for the plants.[142] This continued application of nutrient solution likely resulted in the accumulation of excess salt in the leaf tips and leaf margins and in the desiccation and browning of the tissue.[143] Another key test

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142 The 1993 study did not follow the most current guidance which requires that nutrient and fertilizer needs should be based on observations of the control plants.

143 The fact that tip browning noted in the 1993 study was reported as occurring on corn, a plant that is not normally sensitive to dicamba effects, is a further demonstration that the effects observed were not dicamba-specific effects.

condition was the use of KNO3 in the media in place of NH4NO3. The use of KNO3 commonly leads to alkalization over time and plant chlorosis due to iron and magnesium deficiencies.

The AAP medium was designed for use in hydroponic systems and in algal studies where the solution is replaced at regular intervals rather than allowed to accumulate in a closed container.

There are also differences between the guidelines used in the 1993 study as compared to the current guidelines, thus calling into question the quality of the 1993 study: the previous use of growth chambers to grow plants versus the current use of greenhouses or field-grown plants; the previous planting of seeds from all species at the same depth (1 cm) versus the current guidance to plant seeds at a depth appropriate to the seed size; and the previous germination of seeds first in paper "rag dolls", followed by transfer to pots, versus the current guidance to allow germination to occur in soil.

Finally, it is notable that the test material used in 1993 was technical grade dicamba and not a typical end use product, i.e., a formulated product, as is currently required.

In light of the discussion above, the results of the 2009 seedling emergence study are considered to be more indicative of the effects of dicamba when applied to plants pre-emergence (at the seedling and early growth stage) and to have been performed according to current test guidance. The 2009 vegetative vigor study also reflects the current use of dicamba. As a result, the current analysis uses the data from these studies to assess potential effects of dicamba on non-target terrestrial plants.

Table F-48 summarizes the seedling emergence data (Porch, 2009b; MRID 47815101) and Table F-49 summarizes the vegetative vigor data (Porch, 2009a; MRID 47815102) used in this analysis.

Table F-48. 21-Day Seedling Emergence Endpoints for Dicamba DGA Salt

Species	Taxon	NOER (oz/A)	NOER (lb a.e./A)	ER_{25} [a] (oz/A)	ER_{25} [b](lb a.e./A)	Measured Endpoint
Corn	Monocot	64.0	2.00	> 64	> 2	NA
Onion	Monocot	21.3	**0.666**	37.4	**1.17**	Height, dry weight
Ryegrass	Monocot	21.3	0.666	63.8	2.0	Height, dry weight
Wheat	Monocot	64.0	2.00	> 64	> 2	NA
Cabbage	Dicot	21.3	0.666	59.9	1.87	Height, dry weight
Carrot	Dicot	7.11	0.222	16.0	0.50	Height, survival
Lettuce	Dicot	2.37	0.074	8.66	0.271	Dry weight
Oilseed rape	Dicot	2.37	0.074	18.1	0.566	Dry weight
Soybean	Dicot	2.37	0.074	4.53	0.142	Height, dry weight
Tomato	Dicot	2.37	**0.074**	4.42	**0.138**	Dry weight

NOER = No Effect Rate, the highest application rate at which no measurable effects occurred

ER_{25} = Effective Rate that caused a 25% effect such as a 25% reduction in plant height

NA = not applicable, no injury evident

[a] Ounces per acre of the formulated product containing 4 lb acid equivalent of active ingredient per gallon

[b] Values used for risk quotient calculation are indicated in bold type.

Table F-49. 21-Day Vegetative Vigor Endpoints for Dicamba DGA Salt

Species	Taxon	NOER (oz/A)	NOER [b] (lb a.e./A)	ER_{25} [a] (oz/A)	ER_{25} [b] (lb a.e./A)	Measured Endpoint
Corn	Monocot	64	2.000	> 64	> 2	NA
Onion	Monocot	8	**0.250**	12.7	**0.40**	Dry weight
Ryegrass	Monocot	64	2.000	> 64	> 2	Dry weight
Wheat	Monocot	8	0.250	16.4	0.51	NA
Cabbage	Dicot	0.79	0.025	2.61	0.08	Dry weight
Carrot	Dicot	0.79	0.025	22.5	0.70	Dry weight
Lettuce	Dicot	0.074	0.00231	0.614	0.02	Dry weight
Oilseed rape	Dicot	2.4	0.07500	15.7	0.49	Dry weight
Soybean	Dicot	0.0082	**0.000256**	0.0194	**0.00061**	Height
Tomato	Dicot	0.0082	0.000256	0.0286	0.00089	Dry weight

NOER = No Effect Rate, the highest application rate at which no measurable effects occurred

ER_{25} = Effective Rate that caused a 25% effect such as a 25% reduction in plant height or dry weight

NA = not applicable, no injury evident at the highest rate tested

[a] Ounces per acre of the formulated product containing 4 lb acid equivalent of active ingredient per gallon

[b] Values used for risk quotient calculation is indicated in bold type.

F.3.6.2. Terrestrial and Semi-Aquatic Plant Exposure Estimates

EPA uses the TerrPlant model (U.S. EPA 2009b) as a Tier I model to determine EECs for terrestrial and semi-aquatic plants from runoff and drift. Consistent with guidance provided by the TerrPlant User Manual, application scenarios were considered separately without regard to application intervals. Two scenarios were considered, a single application of 1.0 lb a.e./A and a single application at 0.5 lb a.e./A of dicamba. The single application rate of 1.0 lb a.e./A is the proposed maximum rate for application prior to emergence of the crop. Such an application may be used to help prepare the seedbed for planting and to control initial weed infestations. This initial application prior to emergence may be followed by two subsequent applications of 0.5 lb a.e./A, at least six days apart (seven for DGT cotton, per the requirement on the proposed label) between emergence and seven days prior to harvest for DGT cotton and between emergence and the first reproductive flowering stages (R1) for DT soybean. The evaluation of risk associated with single applications is considered appropriate as a Tier I screening approach because such an approach assumes that the dicamba applied to the target field will move off-site to adjacent areas on the day of application with no degradation and no interaction with the soil and plant foliage.

The EECs for terrestrial and semi-aquatic plants were calculated as described below, based on guidance regarding runoff values based on active ingredient solubility. The resulting EEC values are summarized in Table F-50.

Unincorporated ground application:

Drift = maximum application rate x 0.01

Runoff (dry areas) = maximum application rate x 0.05

Runoff (semi-aquatic areas) = maximum application rate x 0.05 X 10

Total = Drift + Runoff

Table F-50. Dicamba: TerrPlant EECs for Terrestrial and Semi-Aquatic Plants

Application Rate (lb a.e./A)	EEC (lb a.e./A)				
	Runoff		Spray Drift	Total	
	Dry Areas	Semi-Aquatic		Dry Areas	Semi-Aquatic
1.0	0.05	0.5	0.01	0.06	0.51
0.5	0.025	0.25	0.005	0.03	0.255

F.3.6.3. Terrestrial and Semi-Aquatic Plant Risk Quotient Calculations

For terrestrial plant species, the acute risk quotient is calculated as follows:

$$\text{Terrestrial and Semi-Aquatic Plant } RQ_{acute} = \frac{\text{EEC (lb/A)}}{\text{NOER (lb/A; endangered plants) or } ER_{25} \text{ (lb/A; non-endangered plants)}}$$

EPA currently does not assess chronic risk to terrestrial plants.

Table F-51 and Table F-52 summarize the resulting risk quotients for terrestrial and semi-aquatic plant species potentially exposed to drift and sheet runoff (Dry), drift and channelized runoff (Semi-aquatic), or drift only from terrestrial applications of dicamba at 1.0 lb a.e./A and 0.5 lb a.e./A, respectively. Risk quotients for runoff exposure utilize effects data from the seedling emergence study (Table F-48), while risk quotients for spray-drift-only exposure utilize effects data from the vegetative vigor study (Table F-49).

Table F-51. Tier I Risk Quotients for Terrestrial and Semi-aquatic Plants for a 1 lb a.e./A Application

Plant Type	Listed Status	Risk Quotient [a]		
		Dry [b]	Semi-Aquatic [b]	Spray Drift [c]
Monocot	non-listed	<0.1	0.44	<0.1
Dicot	non-listed	0.43	**3.70**	**16.39**

Bold numbers indicate that the LOC (1.0) is exceeded.

[a] RQ = EEC Table F-50)/or ER_{25} (for non-listed species).

[b] Considering the lowest monocot and dicot ER_{25} values from the seedling emergence study (Table).

[c] Considering the lowest monocot and dicot ER_{25} values from the vegetative vigor study (Table F-49 Table).

Table F-52. Tier I Risk Quotients for Terrestrial and Semi-aquatic Plants at the 0.5 lb a.e./A Application

Plant Type	Listed Status	Risk Quotient [a]		
		Dry [b]	Semi-Aquatic [b]	Spray Drift [c]
Monocot	non-listed	<0.1	0.22	<0.1
Dicot	non-listed	0.22	**1.85**	**8.20**

Bold numbers indicate that the LOC (1.0) is exceeded.

[a] RQ = EEC (Table F-50)/or EC_{25} (for non-listed species).

[b] Considering the lowest monocot and dicot ER_{25} values from the seedling emergence study (Table F-48).

[c] Considering the lowest monocot and dicot ER_{25} values from the vegetative vigor study (Table F-49).

F.3.6.4. Terrestrial and Semi-Aquatic Plant Summary and Conclusions

F.3.6.4.1. Conclusions based on TerrPlant

The RQ values calculated for terrestrial and semi-aquatic monocot plant species resulting from estimated exposure to run-off and spray drift are below the LOC of 1 for all use patterns, indicating that risk from exposure to dicamba used on soybean or cotton with the DT trait can be excluded from concern, and therefore, terrestrial and semi-aquatic monocot plant species would not be affected. For terrestrial dicot plant species subject to sheet runoff, the LOC is also not exceeded at the 1.0 lb a.e./A and 0.5 lb a.e./A application rates, indicating that risk resulting from dicamba exposure from sheet runoff at the indicated rates can be excluded from concern, and therefore, non-listed dicot plant species would not be affected.

For terrestrial and semi-aquatic dicot plants exposed only to spray drift and for semi-aquatic dicot plants subject to channelized runoff (and drift), the LOC is exceeded at the 1.0 lb a.e./A and 0.5 lb a.e./A application rates. However, as discussed later in this Appendix, Monsanto plans to implement a web-based tool, Pre-Serve, in conjunction with application requirements on the label, to address potential sensitive areas that may be downwind of the application site. In any event, before approving the proposed labels for dicamba use on DGT cotton and DT soybean, EPA must ensure that there will be no unreasonable adverse effects on the environment.

F.3.6.4.2. Conclusions from a more refined exposure assessment of semi-aquatic dicot plants

Because dicamba has been registered for use as a herbicide since 1967, there are extensive surface water monitoring data available. Water monitoring data for dicamba in surface water were compiled from publicly available information sources; there were of 21,626 surface water monitoring records identified between 1990 and 2010.[144] Sources of surface water monitoring data include:

- USDA Pesticide Data Program (PDP)
  Website: http://www.ams.usda.gov/AMSv1.0/PesticideDataProgram
- USEPA STORET (Storage and Retrieval)
  Website: http://www.epa.gov/storet/
- USGS National Water Quality Assessment (NAWQA)
  Website: http://water.usgs.gov/nawqa/
- USGS National Water Information System (NWIS)
  Website: http://waterdata.usgs.gov/nwis

[144] Additionally, the USGS National Water Quality Assessment (NAWQA) database was also queried for surface water monitoring results for dicamba in 2011 and 2012. A total of 162 samples were analyzed for dicamba during this period and all results were non-detect with levels of quantitation ranges from 0.04 – 0.06 μg a.s./L.

- Various State water quality monitoring programs

Of the available 21,626 records for dicamba, 3,431 (15.9%) were reported as detected concentrations (having a dicamba concentration above the analytical detection limit). Summary statistics for the 3,431 reported detection records are provided in Table F-53. The 90th percentile of detected dicamba concentrations in the water quality monitoring database is 0.34 μg a.e./L (Table F-53).[145]

Table F-53. Summary Statistics for Detected Dicamba Concentrations Reported in Water Quality Monitoring Databases.

	Surface Water Concentration (μg a.e./L)
n	21,626
Detects	3,431
10th Percentile	0.020
25th Percentile	0.060
Median	0.077
75th Percentile	0.15
90th Percentile	0.34
Detects: First Sample Date	Feb 1, 1990
Detects: Last Sample Date	June 8, 2010

Overall, dicamba was not detected in more than 89% of the samples. For samples with detected dicamba levels, the minimum, median, 90th percentile and maximum concentrations are provided in Table F-54. When the water monitoring data were evaluated to assess historical dicamba concentrations in major corn production states during periods when dicamba would typically have been applied for agricultural uses, and for which maximum concentrations of dicamba in surface water would be expected, the 90th percentile of dicamba detections during 1994–1998, corresponding to the peak dicamba usage period, and across the entire monitoring period (1990 – 2010) was 0.74 and 0.88 μg/L (Table F-54), respectively. The maximum level of dicamba detected in surface water between 1990 and 2010 was 17 μg/L.[146]

Table F-54. Summary Statistics for Detected Dicamba Concentrations (μg a.e./L) in Surface Water in Major Corn Growing States (April – July sampling dates)

	1990-1993	**1994-1998**	**1999-2004**	**2005-2010**	**1990-2010**
n	588	1,362	2,443	1,033	5,426

[145] When all data between 1990 and 2010 were considered (n = 21,626), the 90th percentile value is 0.062 μg a.s./L (details not presented).

[146] For the analysis for major corn production states, when all data between 1990 and 2010 were considered (n = 5,426), the 90th percentile value is 0.040 μg a.e./L (details not presented).

Number of Detects		146	206	222	14	588
For Detects only	Minimum	0.010	0.0080	0.010	0.030	0.0080
	Median	0.20	0.25	0.29	0.29	0.25
	90^{th} Percentile	1.4	0.74	0.94	0.050	0.88
	Maximum	17	9.4	3.3	0.94	17

These 90th percentile water concentrations were then compared to the lowest NOER for the 2009 seedling emergence study by assuming that NOER in lb a.e./A is the result of water in the EPA standard pond drying down and being deposited on a soil surface with the same area as the pond without further dicamba degradation.[147] The dicamba concentration in the pond water is then calculated using these assumptions. The aquatic EEC that corresponds to an RQ of 1 for the lowest NOER was determined to be 4.16 µg a.e./L. When all surface water monitoring data available for the period 1990 – 2010 are considered, 4.16 µg a.e./L corresponds to a percentile of 99.9%. When only detected concentrations are considered, 4.16 µg a.e./L corresponds to a percentile of 99.7%. Similarly, using the EC_{25} of the most sensitive dicot in the seedling emergence study, the aquatic EEC that would result in an RQ of 1 is 7.75 µg a.e./L.[148] A concentration of 7.75 µg a.e./L corresponds to a percentile of 99.9% when all data available for the period 1990 – 2010 are considered. When only detected concentrations are considered, 7.75 µg a.e./L corresponds to a percentile of 99.8%. The surface water monitoring data indicate that dicamba concentrations are very rarely present in surface water at concentrations that may pose a risk to semi-aquatic plants.

F.4. Threatened and Endangered Species Analysis for Dicamba, DT Soybean and DGT Cotton

Congress passed the Endangered Species Act (ESA) of 1973, as amended, to prevent extinctions facing many species of fish, wildlife, and plants. The purpose of the Endangered Species Act (ESA) is to provide a means for conserving the ecosystems upon which endangered and threatened species depend and a program for the conservation of such species.[149] To implement the ESA, the U.S. Fish and Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS); other Federal, State, and local agencies; Tribes; non-governmental organizations; and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal list of threatened and endangered wildlife and plants.

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[147]The NOEC value for the most sensitive broadleaf plant species in the dicamba DGA salt seedling emergence study (Porch et al., 2009b) is 0.074 lb a.e./A for tomato. To calculate the concentration in the EPA standard pond that would result in this rate being deposited on soil upon drying of the pond without degradation of the dicamba present, the NOEC value is converted from lb a.e./Ato kg a.e./ha and then divided by 20 x 10^6, the volume of the pond in liters

[148] The EC_{25} value for the most sensitive broadleaf plant species in the dicamba DGA salt seedling emergence study (Porch et al., 2009b) is 0.138 lb a.e./A for tomato.

[149] Endangered Species Act of 1973 (as amended through Public Law 107-136), Section 2(b).

A species is added to the list when the USFWS and/or NMFS determined it to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; and
- The natural or manmade factors affecting its survival.

In accordance with the ESA, once an animal or plant is added to the list, protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or critical habitat. To facilitate APHIS' ESA consultation process, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS' regulatory authority and effects analysis for petitions for nonregulated status, and developed a process for conducting an effects determination consistent with the Plant Protection Act of 2000 (Title IV of Public Law 106-224). This process is described in a decision tree document, which has been included in recent Environmental Assessments and the Final Environmental Impact Statement for glyphosate-tolerant H7-1 sugar beet (USDA-APHIS, 2011a; 2012b). APHIS has used this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for GE regulatory actions.

F.4.1. Monsanto's Technical Analysis Follows EPA's Guidance, and Relies on the "Best Information Available" Regarding Threatened and Endangered Species

This portion of Appendix F provides a summary of the final steps in a multi-step approach that has been utilized to evaluate the potential effects on federally-listed threatened or endangered ("listed") plant and animal species from the use of the herbicide dicamba on DT soybean and DGT cotton. This analysis follows the procedures described in the Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency, Endangered and Threatened Species Effects Determinations (US EPA, 2004), as well as methods utilized in more recent threatened and endangered species effects determinations conducted by the U.S. Environmental Protection Agency ("USEPA") for a number of active ingredients in assessing their potential effects on the California red-legged frog.[150] The project involved an analysis of the potential proximity of relevant land use to sub-county locations of listed species that had been

[150] Effects determinations are available at http://www.epa.gov/oppfead1/endanger/litstatus/effects/redleg- frog/index.html

identified as "requiring further analysis" in a county-level analysis (Frank and Kemman, 2012, 2013a, b, c).

For both threatened or endangered ("TES") animals and plants, Monsanto first conducted the type of screening-level analyses set forth in OPP's *Overview Document*. Using the maximum use pattern set out in the proposed label at issue, Monsanto estimated exposure of designated animal and plant taxa using current EPA environmental exposure models. Monsanto then utilized these conservative exposure estimates, in conjunction with effects values for species of designated taxa derived from toxicity tests meeting EPA quality standards, to calculate risk quotients ("RQs"). If the RQ value, calculated by dividing the estimated exposure by the appropriate toxicity value, was less than the Level of Concern ("LOC") for TES in the designated taxa, Monsanto concluded that risks to a taxonomic category could be excluded from concern because of the conservative nature of the screening-level assessment assumptions and, therefore, that there would be no effect on the relevant threatened or endangered species.[151] Monsanto undertook a similar analysis at the screening level to evaluate potential indirect effects on threatened and endangered species and potential effects on critical habitat, thereby enabling Monsanto to exclude from concern such effects on certain species.

Again, following EPA's Overview Document, Monsanto next conducted a more detailed, county-level analysis for the animal taxonomic groups (and associated listed species) that could not be excluded from concern at the screening level, and for all listed plant species. This analysis identified: (i) all counties indicated as having soybean or cotton farms in the last three Ag. Census (1997, 2002, and 2007) as having "potential" for soy or cotton production, and (ii) all threatened or endangered species with reported presence within those counties (or in adjacent counties) in the taxonomic groups evaluated. A "no effect" determination could then be made for species "co-occurrences" based on a number of exclusions (*e.g.*, habitat, not of concern, proximity, diet, and feeding).

For animals, this analysis expressly recognized and took into account the fact that the animals at issue may move from location to location. Specifically, the feeding and diet exclusions for animals are based on inherent characteristics of the individual endangered species and are not in any way impacted by where the species is physically present. For both animals and plants, the "not of concern" designation is provided *only* where the species has not been reported in the county in the past 35 years, or where FWS does not include the county on the list of counties where the species is known or believed to occur in the county (and no other source indicates species presence), or where the species has been delisted. The habitat exclusion applies only where the individual endangered species' habitat is not suitable for agricultural production[152] and reported locations of the species are

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151 "If assumptions associated with the screening level action area result in RQs that are below the listed species LOCs, a 'no effect' determination conclusion is made with respect to listed species in that taxa, and no further refinement of the action area is necessary." EFED Reregistration Chapter for Dicamba/Dicamba Salts, p. 72.

152 For example, the silver rice rat (located in Monroe County, Florida) typically use three zones that are delineated by their salinity and topography: (1) low intertidal areas, (2) salt marsh flooded by spring or storm tides, and (3) buttonwood transitional areas that are slightly more elevated and only flooded by storm tides. In general, rice rats use mangrove habitats primarily for foraging, while higher-elevation salt marshes are used for nesting and foraging. Crop agriculture is not practiced near these shoreline/marshy areas.

not near land suitable for agricultural production.[153] The proximity exclusion (for animal species) only applies when land relevant for soybean or cotton production is not within a relevant species' "home range" – *i.e.*, the area within which the species lives and travels, based on information from FWS and other sources.[154] Finally, for listed plants that are monocots, a product-property determination applies based on the results of the screening-level analysis described above.

For listed plant species co-occurrences not excluded from concern based on the county-level analysis, a refined sub-county analysis was undertaken to assess the proximity of reported species observations to relevant land use for soybean or cotton production. In addition, mitigation measures were proposed, where necessary, to prevent effects on such plant species. The pertinent proximity distance evaluated for each species observation to relevant land use for soybean and soybean production, or cotton and cotton production, was initially and conservatively set at 450 feet.[155] For species observations within 450 feet of relevant land use, guidance both from NatureServe and State endangered species programs, and in some cases from the U.S. Fish & Wildlife Service, was used to define the boundaries of what we call "Use Limitation Areas (ULAs)."[156]

A number of specific points are important to understand how ULAs function. The boundaries of the ULAs are based on data gathered from a variety of sources, including NatureServe, the U.S. Fish & Wildlife Service, and the States. The NatureServe Multijurisdictional Database ("MJD")[157] includes threatened and endangered species location data at the sub-county level. It may also include additional information, including date of last observation and observation notes. Monsanto supplemented the NatureServe MJD with State-specific information from sources such as the California Natural Diversity Database, published by the California Department of Fish and Game. Data was also obtained from New Jersey and, North Carolina. Frequent environmental litigants have demanded that EPA use these species-location data. *See* Center for Food Safety, *Comments on EPA Reregistration of Atrazine*, August 22, 2013 ("NatureServe provides detailed life history

153 Suitability for agricultural production was based on the National Land Cover Database 2001 and 2006, Class 81 (Pasture/Hay) and Class 82 (Cultivated Crops).

154 For example, the proximity exclusion for the Arroyo toad includes the following rationale: based on sub-county location information, reported locations of the Arroyo toad in certain counties were not within 28 miles of land relevant for cotton production. This species, however, only has a home range of approximately 1.2 miles, with a travel distance of just 0.3 to 1.2 miles. Moreover, every species with a "proximity" exclusion also had at least one other applicable exclusion.

155 The distance of 450 feet is a conservative distance that is greater than the distance from the edge of the dicamba application area to a point at which an effect on soybean plant height is no longer observed, when the proposed FIFRA label application requirements for the dicamba diglycolamine salt are employed. Utilizing the EPA screening assessment approach as described in the *Overview Document*, soybeans have been demonstrated to be the most sensitive species to the effects of dicamba, and plant height was the most sensitive endpoint in the vegetative vigor study. Effects on soybean plant height have, therefore, been used to determine a distance beyond which dicamba would not impact TE plants.

156 Monsanto also adhered to the *Overview Document* in its assessment of plant-dependent and plant-obligate species, as well as lands identified as critical habitat. Where necessary to protect listed species that rely upon a specific plant and or critical habitat, Monsanto will include relevant use instructions for applicators / growers on Pre-Serve.

157 The NatureServe MJD is available to Monsanto under a licensing agreement with the FIFRA Endangered Species Task Force of which Monsanto is a member.

information, including spatial distribution, for native species across the United States. In addition, many State governments collect detailed information on non-game species through their State Wildlife Action Plans."). This is exactly what Monsanto has done—it has utilized and relied upon these data to devise appropriate measures to avoid impacts to threatened and endangered species. It has also utilized a wide range of land use data to conservatively ascertain land relevant to soybean and/or cotton production. Likewise, it relied upon extensive toxicity testing, exposure data, state-of-the art modeling, and other relevant scientific and commercial data in conducting its assessment.

Furthermore, the NatureServe, State, and other species and location data relied on by Monsanto form the basis for ULAs contained within Pre-Serve, the convenient and simple web and hotline-based tool that guides growers/applicators through a checklist to determine whether their fields fall within ULAs. Where fields do fall within ULAs and appropriate habitat is present, the web and hotline-based system will reiterate to the growers the mandatory steps (as specified on the proposed label, which is currently pending before EPA) that must be taken to avoid effects on pertinent species.

F.4.2. Reports Submitted

In lengthy and detailed submissions to EPA over the past two years, Monsanto has established the scientific predicate for its conclusions that specific measures will preclude the dicamba applications at issue from having any effect on threatened or endangered species. Specifically, Monsanto has submitted the following reports on DT soybean:

- Honegger JL. 2012a. Information to Support an Endangered Species Assessment for Dicamba Use in Dicamba-Tolerant Soybeans: Overview for Plant Taxa. Monsanto Technical Report MSL-23721. MRID 48900401;

- Frank AR, Kemman R. 2012. Information to Support an Endangered Species Assessment for Dicamba Use in Dicamba-Tolerant Soybeans: A County-Level Analysis for Plant Taxa. Monsanto Technical Report MSL-23442. MRID 48900402;

- Carr KH, Leopold VA. (2012a) Information to Support an Endangered Species Assessment for Dicamba Use in Dicamba-Tolerant Soybeans. Sub-County Proximity Analysis for Listed Plants: Western U.S. States and Hawaii. Monsanto Technical Report MSL-22548. MRID 48900403;

- Carr KH, Leopold VA. (2012b) Information to Support an Endangered Species Assessment for Dicamba Use in Dicamba-Tolerant Soybeans. Sub-County Proximity Analysis for Listed Plants: Eastern U.S. States. Monsanto Technical Report MSL-22549. MRID 48900404.

- Carr KH, Leopold VA. 2013. Information to Support an Endangered Species Assessment for Dicamba Use in Dicamba-Tolerant Soybeans. Sub-County Proximity Analysis for Listed Plants: Iowa Monsanto Technical Report MSL-24694. MRID 49093201.

- Wright JP, Schuler LJ, Carr KH, Orr TB, Honegger JL. 2013. Information to Support an Endangered Species Assessment Dicamba Use in Dicamba-Tolerant Soybeans: An

Evaluation of Potential Exposure and Biological Effects. Monsanto Technical Report MSL-24665. MRID 49022301

- Honegger JL. (2013) Information to Support an Endangered Species Assessment for Dicamba Use in Dicamba-Tolerant Soybeans: Overview of an Evaluation of Potential Exposure and Biological Effects. Monsanto Technical Report MSL-24667. MRID 49022401.

- Schuler LJ, Leopold VA, Fredricks TB, and Carr KH. 2013a. Information to Support an Endangered Species Assessment for Dicamba Use in Dicamba-Tolerant Soybeans: Refined Analysis for Terrestrial Animals. Monsanto Technical Report MSL-24666. MRID 49022402.

- Frank AT, Kemman R. 2013). Information to Support an Endangered Species Assessment for Dicamba Use in Dicamba-Tolerant Soybeans: A County-Level Analysis for Animal Taxa (2013 Update). , Monsanto Technical Report MSL-24678. MRID 49022403.

- Schuler LJ, Fredricks TB, Levine SL and Carr KH. 2013b. Information to Support an Endangered Species Assessment for Dicamba Use in Dicamba-Tolerant Soybeans: Indirect Effects Analysis. Monsanto Technical Report MSL-24677. MRID 49093202;

- Honegger JL. (2012b) Overview of Proposed Approach to Address the Potential for Off-site Movement from Use of Dicamba on Dicamba-Tolerant Soybeans. Monsanto Technical Report MSL0024401. MRID 48892302;

- Orr, TB, Wright, JP, Honegger, JL. (2012) Summary of Investigations of the Potential for Off-Site Movement through the Air of the Herbicide MON 54140 Following Ground Applications. Monsanto Study Number RPN-2012-0201. Monsanto Technical Report MSL0024124. MRID 48876001;

- Wright JP, Schuler LJ, Carr KH, Orr TB, Honegger JL. 2013. Information to Support an Endangered Species Assessment Dicamba Use in Dicamba-Tolerant Soybeans: An Evaluation of Potential Exposure and Biological Effects. Monsanto Technical Report MSL-24665. MRID 49022301;

- Orr, TB, Wright, JP, Honegger, JL. (2012) Summary of Investigations of the Potential for Off-Site Movement through the Air of the Herbicide MON 54140 Following Ground Applications. Monsanto Study Number RPN-2012-0201. Monsanto Technical Report MSL0024124. MRID 48876001;

- Sall, et. al., Measurement of the Volatile Flux of Dicamba under Field Conditions using the Theoretical Profile Shape Method, Mar. 25, 2013.

Monsanto also has submitted the following reports on DGT cotton:[158]

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[158] Monsanto anticipates completing two additional reports on DGT cotton in December 2013.

- Honegger JL, Schuler LJ, Wright JP, Fredricks TB, Carr KH, Orr TB. 2013. Information to Support an Endangered Species Assessment for Dicamba Use in Cotton Containing the Dicamba Tolerance Trait: An Evaluation of Potential Exposure and Biological Effects. Monsanto Technical Report MSL0025079. MRID 49221301;

- Frank AR, Kemman R. (2013) Information to Support an Endangered Species Assessment for Dicamba Use in Cotton Containing the Dicamba Tolerance Trait: A County-Level Analysis for Plant Taxa. Monsanto Technical Report MSL0025083. MRID 49221306;

- Carr KH, Orr TB. 2013. Information to Support an Endangered Species Assessment for Dicamba Use in Cotton Containing the Dicamba Tolerance Trait. Potential Exposure and Effects for Listed Plants (Screening Level through Proximity Analysis). Monsanto Technical Report MSL0025084. MRID 49221307;

- Honegger JL. 2013. Information to Support an Endangered Species Assessment for Dicamba Use in Cotton Containing the Dicamba Tolerance Trait: Overview of an Evaluation of Potential Exposure and Biological Effects for Animals. Monsanto Technical Report MSL0025078. MRID 49221302;

- Frank AR, Kemman R. 2013. Information to Support an Endangered Species Assessment for Dicamba Use in Cotton Containing the Dicamba Tolerance Trait: A County-Level Analysis for Animal Taxa. Monsanto Report No. MSL0025081. MRID 49221303;

- Schuler LJ, Fredricks TB, Tompsett-Higley AR, Carr KH. 2013c. Information to Support an Endangered Species Assessment for Dicamba Use in Cotton Containing the Dicamba Tolerance Trait: Refined Analysis for Terrestrial Animals. Monsanto Technical Report MSL0025080. MRID 49221304;

- Schuler LJ, Fredricks TB, Tompsett-Higley AR, Carr KH. 2013d. Information to Support an Endangered Species Assessment for Dicamba Use in Cotton Containing the Dicamba Tolerance Trait : Indirect Effects Analysis for Terrestrial Animals. Monsanto Technical Report MSL0025082. MRID 49221305.

F.4.3. Effects on Threatened or Endangered Plant Species From Dicamba Use on DT Soybean

F.4.3.1. Endangered Species Exposure and Effects Analysis

F.4.3.1.1. Screening-Level Analysis

An initial analysis of the potential for exposure and effects to all taxa (including plants) from dicamba use in DT soybean based on the use pattern pending at EPA was conducted (Wright et al.,

2013) using the EPA deterministic risk quotient approach (USEPA, 2004).[159] The use pattern for dicamba utilized in this analysis was a pre-emergence application at a rate of 1.0 lb dicamba acid equivalents per acre (a.e/A) followed by two post-emergence applications each at a rate of 0.5 lb a.e./A with a 6-day interval between the pre-emergence application and the first post-emergence application, and a 6-day interval between the two post-emergence applications, with all applications being made using ground application equipment.[160] The 6-day application intervals utilized in this analysis are anticipated to be shorter than the intervals actually used in practice, since a grower is anticipated to wait at least 7 days before deciding to make a subsequent application in order to allow evidence of dicamba efficacy to develop.

For aquatic plants, initial exposure estimates using the above described use pattern were based on the standard EPA exposure models GENEEC 2.0 and PRZM (3.12.2)/EXAMS (2.98.04.6) and toxicity effects endpoints taken from the EPA Environmental Fate and Effects Division (EFED) Science Chapter for the Reregistration Eligibility Decision for dicamba (USEPA, 2005).

For terrestrial plants, initial exposure estimates using the above described use pattern were based on the standard EPA exposure model TerrPlant 1.2.2 and default assumptions; toxicity effects endpoints were taken from EPA guideline studies conducted by BASF under an EPA data call-in (Porch et al., 2009a and 2009b[161]).

The conclusion from this initial analysis (Wright et al., 2013), based on risk quotients (RQs) being less than the EPA Levels of Concern (LOCs), is that dicamba use on DT soybean would not affect threatened and endangered plant species in the following taxa:[162]

- Aquatic vascular plants
- Monocotyledonous terrestrial plant species (monocots)[163,164]

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159 This approach calculates a risk quotient (RQ) by dividing the Estimated Environmental Concentration (EEC) by the appropriate toxicity endpoint, and then compares that value with the appropriate Level of Concern LOC). The LOC is established by EPA policy as the criteria used by EPA in comparison to the calculated risk quotient (RQ) to assess the potential for a pesticide use to cause adverse effects to non-target organisms.

160 The proposed dicamba label for DT soybeans will not permit aerial application.

161 New studies were required by EPA because previous studies did not meet current regulations requiring the use of formulated product for these studies. This new testing resulted in a more conservative endpoint for the vegetative vigor study and confirmed field observations of relative sensitivity for the seedling emergence study.

162 "If assumptions associated with the screening level action area result in RQs that are below the listed species LOCs, a "no effect" determination conclusion is made with respect to listed species in that taxa, and no further refinement of the action area is necessary." EFED Reregistration Chapter for Dicamba/Dicamba Salts, p. 72.

163 According to EPA methodology (USEPA 2004), risk to non-target plants is assessed only outside the application area.

164 There is no distinction between acute and chronic exposure durations for plants in the EPA assessment process for endangered species.

Although the RQ for listed aquatic non-vascular plants exceeded the LOC, additional analysis was not conducted because there are no federally listed non-vascular aquatic plants. The RQ for non-listed aquatic non-vascular plants was less than the LOC, indicating that other taxa of threatened and endangered species would not incur indirect effects as a result of effects on non-listed non-vascular aquatic plants.

These conclusions for aquatic plants are consistent with the risk conclusions presented in the EFED science chapter for dicamba reregistration (USEPA, 2005 and 2009).

The conclusion for monocots is supported by more recent nontarget plant studies with a typical dicamba end use product containing the diglycolamine salt of dicamba.[165] These studies were required by EPA during the reregistration process to assess the phytotoxicity of an end-use product containing the diglycolamine salt. Only endpoints for dicamba acid were available for consideration in the EFED science chapter (USEPA, 2005 and 2009), for which it was concluded that the RQ exceeded the LOC. Toxicity endpoints for the diglycolamine salt were not available at that time to calculate an RQ for comparison with the LOC (Porch et al., 2009a and 2009b).[166] Using the no-observed-effect endpoints from these 2009 studies and the EPA model TerrPlant to calculate exposure and risk quotients, the RQs for monocots were below the LOC (Wright et al., 2013), and thus result in a conclusion that monocots would not be affected by use of the diglycolamine salt of dicamba on DT soybean. The levels of concern considered by EPA for threatened and endangered (listed) species risk assessments are given in Table F-55.

Table F-55. EPA Levels of Concern for Threatened and Endangered Plant Species (USEPA, 2004)

Risk Presumption	Calculation for Risk Quotient	Level of Concern
Terrestrial and Semi-Aquatic Plants		
Acute Risk	EEC/EC_{05} or NOAEC	1.0
Aquatic Plants		
Acute Risk	EEC/EC_{05} or NOAEC	1.0

For threatened and endangered terrestrial plant species in classes other than monocotyledons, further analysis is required.

F.4.3.1.2. Refined Analysis for Listed Plants Considering County-Level Information

Consistent with EPA guidance found in the Overview Document (USEPA, 2004), if screening-level assessments do not result in a "no effect" determination, EPA does not then conclude that an

165 M1691, the formulation for which the new use on DT soybeans is under review, contains dicamba in the form of the diglycolamine salt.

166 The new study was conducted under the OPPTS 850.4225 draft guideline, which is very similar to the current OECD nontarget plant guideline. The results are considered to be more representative of effects that would be anticpated in the field than previous studies because of an improved study design.

herbicide "may affect" threatened and endangered species; rather, more refined assessments must be conducted to ascertain if any effects are expected to occur. Based on this guidance, a more detailed evaluation of the locations of threatened and endangered plant species relative to potential areas of soybean production, and, therefore, potential dicamba use was undertaken.[167]

First, the co-occurrence of threatened and endangered plant species and the production of soybeans was evaluated at the county level. Listing status[168], species habitat, species observation history in the county, and proximity data to soybean production at the county level were evaluated to determine: (1) which species in which counties can be excluded from further evaluation; and (2) which require further evaluation. This process is referred to as the "county-level analysis" (Frank and Kemman 2012) and is discussed in more detail in Section IV.C.F.4.3.2.

F.4.3.2. County-Level Analysis: Co-occurrence of Listed Plant Species in Crop Production Areas

The procedures used in the county-level analysis to identify counties containing threatened or endangered species that require further evaluation are described in detail in Frank and Kemman (2012). The U.S. counties where soybean production was reported were identified using available data from the U.S. Census of Agriculture.[169] Census data from 1997, 2002, and 2007 were utilized to identify these counties. This information was supplemented with soybean production data available from the California Department of Pesticide Regulation. Counties without soybean production, but adjacent to counties with soybean production were also identified. In total, there were 2,728 counties considered in this analysis (2,198 soybean counties, 530 adjacent counties).

In the identified counties, available county-level presence information for threatened or endangered plant species was evaluated, using county-level location information compiled by the FIFRA Endangered Species Task Force (FESTF) in the FESTF Information Management System (IMS).[170] Of the 2,728 counties initially considered, there were 1,274 counties in 48 states with soybean production (or adjacent to soybean production) and reported presence of listed plants species.

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167 Overview Document (USEPA, 2004), p. 69.

168 Listing status refers to whether the species is classified as threatened, endangered, no longer considered threatened or endangered (delisted), etc.

169 Although this analysis considered counties where soybean production was reported, a review of the available data demonstrates that almost every county in the eastern two thirds of the U.S. is included. Thus, it is very unlikely that any counties with soybean production were missed using this approach.

170 The FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) Endangered Species Task Force (FESTF) Information Management System 2.7 (IMS) (referred to as the "FESTF IMS") was developed in order to meet the legal obligations of its member companies to submit data required by EPA/OPP under FIFRA (as described in Pesticide Registration Notice 2000-2) in support of the members' registration and re-registration actions. The purpose of the IMS is to meet the data requirements in a manner that significantly improves the consistency, quality, availability and use of existing information on threatened and endangered species and pesticide use. http://www.festf.org/visitors/default.asp. Sources of information for the county-level species information in the IMS include: a dataset provided to the FESTF by the U.S. EPA in June 2003, county-level plant species location data from NatureServe's Multi-Jurisdictional Database (MJD) licensed to the FESTF, and the United States Fish & Wildlife Service (USFWS) endangered species by county lists.

These counties represented 477 listed plant species. There were 2,658 species-county co-occurrence records considered across all plant taxa.

In these counties, each species was evaluated with respect to the current listing status, county-level locations, species habitat requirements, and plant classification in order to determine whether exposure to dicamba from use on DT-soybean could potentially result in effects to the species. Some listed species could be removed from concern for effects based on exclusions that currently exist and are documented. Exclusions that have been employed include change in species listing status, not present due to extirpation[171], historic observations (no observations since 1977 or earlier), habitat not in proximity to agriculture, product properties related to plant taxa selectivity[172], or species not in proximity to agriculture for other reasons. Table F-56, taken from Frank and Kemman (2012), provides a summary of the results of the county-level analysis after exclusions have been considered. Species assigned a Not of Concern determination have information from a U.S. Fish & Wildlife Service (USFWS) or NatureServe source, or a state or local expert to indicate that the species is not present in the county or is not in proximity to soybean production.

Table F-56. Summary of Species Determinations for this Analysis

Determination Type	Number of States	Number of Counties	Number of Species	Number of Co-Occurrences
Not of Concern	41	517	115	721[a]
Product-Property	38	486	54	554
Habitat[b]	35	269	237	532
Species Management Practice[c]	8	13	7	13
Requires Further Analysis	38	545	183	838
Total				**2,658**
Total distinct[d]	**48**	**1,274**	**477**	

[a] Of the 721 co-occurrences with a Not of Concern determination, 705 of the determinations were supported by information from the U.S. Fish & Wildlife Service county list or a regional office expert; 16 determinations were supported by information from NatureServe or a state or local species expert.

[b] For species assigned a Habitat determination, supporting information regarding proximity of species' locations to agricultural land relevant for soybean production is provided in Carr and Leopold (2012a, 2012b).

[c] Species is present on public or private land protected by conservation plans or agreements.

[d] More than one determination type may be assigned to different county-level co-occurrences of the same species. Therefore, the total number of species (or counties) for all determination types is more than the total number of distinct species (or counties).

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171 An extirpated species is defined as "a species no longer surviving in regions that were once part of its range" (http://www.fws.gov/midwest/endangered/glossary/index.html).

172 A product property exclusion is based on results of screening level risk analysis indicating that the risk quotient for monocotyledonous plants is below the Level of Concern and, therefore, monocots would not be affected by dicamba use on DT soybean.

After considering co-occurrences for which exclusions apply, county-species co-occurrences remain in 38 states, in a total of 545 counties, and for 183 species, which require further analysis. As described in the EPA Overview Document (USEPA, 2004), the next step in the analysis is to consider these co-occurrences at the sub-county level evaluating the proximity of the species observation and the land areas that have the potential to be used for soybean production.[173]

F.4.3.3. Sub-County Plant Species Observations versus Land Use Proximity Analysis

The analysis of proximity of relevant land use to sub-county locations of threatened or endangered plant species that have been identified as "requiring further analysis" in the county-level analysis (Frank and Kemman, 2012) is described in detail in Carr and Leopold (2012a and 2012b). A summary of the spatial information used and the proximity analysis is provided in the sections that follow.

F.4.3.3.1. Land Use Information

For the contiguous U.S. and Hawaii, land cover data considered in this analysis were obtained from the National Land Cover Dataset (NLCD 2001) (minimum mapping unit: 30-meters). Data for the 2001 NLCD were collected from 1994-1998 and represent the best comprehensive collection of national land use and land cover information for the U.S. The spatial data (resolution [minimum mapping unit]: 30 meters) was converted from raster format to vector format for Class 81 (pasture/hay) and Class 82 (cultivated crops). These two classes were considered "relevant land use" for this analysis, since land designated as cultivated crops could potentially be used for DT-soybean production, and some pasture/hay fields could be converted to cultivated cropland.

In some situations, available satellite imagery was used to verify the proximity of species observations to agricultural lands (a verification of the NLCD 2001 land use classification). The source of satellite imagery was the either the "ESRI_Imagery_World_2D" map service (available online from ESRI Inc.[174]), or the Bing map service.[175]

F.4.3.3.2. Species Locations

FESTF Multi- Jurisdictional Database (MJD)

Threatened and endangered plant species location data at a sub-county level were obtained from the FIFRA Endangered Species Task Force Multi-Jurisdictional Database (FESTF MJD; NatureServe

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173 Overview Document (USEPA, 2004), p. 69.

174 Description of ESRI imagery source: Accessed through ESRI Inc, via the ArcMap GIS software. Described on the following website: http://www.arcgis.com/home/item.html?id=10df2279f9684e4a9f6a7f08febac2a9

175 Description of Bing imagery source: Accessed through ESRI Inc, via the ArcMap GIS software. http://www.esri.com/software/arcgis/arcgis-online-map-and-geoservices/bing-maps

2009, 2012). The FESTF MJD consists of a "licensed dataset" drawn from NatureServe's Multi-Jurisdictional Database (MJD) licensed to FESTF.[176] The MJD species observation records included additional data fields, such as date of last observation and observation notes; this information was evaluated and utilized when relevant to the proximity assessment.

The MJD location data were provided as polygons (areas representing where a listed plant species was observed; referred to as a "species observation"). The spatial dataset was provided in a format suitable for analysis and display using Geographic Information System (GIS) software. Polygons for listed dicots were are small as 10 square meters and as large as 700 square kilometers.

For the purposes of this analysis, species observations were considered "historic" if the "last observed date" for the observation (as reported by NatureServe in the MJD 2009 dataset) was prior to 1977.[177] Additional observation-specific data available in the MJD 2009 dataset (e.g. field notes) were examined to identify observations that are noted to be "historic" or "extirpated." In some cases, species with observations later than 1976 were flagged as "extirpated." In situations of historic or extirpated species observations, no further analysis was conducted.

State-Specific Location Data

New Jersey, Pennsylvania, and Maryland state heritage programs did not contribute data to the NatureServe program from which the FESTF MJD 2009 dataset was derived; where sub-county species location information was needed for these states, information was requested directly from the state heritage programs (New Jersey), or prior Monsanto company work products (Maryland; prepared when the program was a participant in the NatureServe program) were relied upon. In addition,

- For California, the California Natural Diversity Database (CNDDB, California Department of Fish and Game) was used as a supplement to the MJD 2009 dataset, to evaluate species presence at the sub-county level when the MJD 2009 dataset did not provide current species records.

- For North Carolina, a refined species location dataset was obtained in May 2010 from the North Carolina Natural Heritage (NCNH) Program; this information was used to refine proximity conclusions derived from the FESTF MJD 2009. At the request of the NCNH Program, the refined location information was used for the definition of proposed use limitation areas in North Carolina.

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176 Under the terms of the FESTF license with NatureServe, the sub-county threatened and endangered species location data are confidential information available only to FESTF member companies, companies having satisfied their data compensation obligations, and the U.S. EPA's Office of Pesticide Programs. Information based on the sub-county species location data may be shared with cooperating federal and state agencies for regulatory decision-making related to endangered species assessments for Monsanto products.

177 A time period for observations beginning in 1977 is considered a conservative time period for this analysis.

- Species location information for New Jersey was obtained from the New Jersey Department of Environmental Protection (NJDEP) and Office of Natural Lands Management (ONLM). These data were provided in a grid format – a grid layer with each grid section representing approximately 0.5 square miles. A corresponding table indicated which species were present in each grid section.

- For Washington State, prior Monsanto work products based on an earlier version of the FESTF dataset (FESTF MJD 2006) were considered for proximity analysis, since the MJD 2006 dataset contained higher resolution location information than the MJD 2009 dataset, and no new observation records for the plant species of interest were present in the MJD 2009 dataset (when compared to the MJD 2006 dataset).

F.4.3.3.3. Proximity Analysis Process

When the sub-county species location data was considered, the 838 county-species co-occurrences requiring further analysis resulted in 4,973 sub-county species observations from the FESTF MJD and state heritage program datasets; additional less well-defined species location information was available from other sources. Proximity distances from each observation (polygon) in the MJD 2009 dataset to NLCD Class 81 (Pasture/Hay) and Class 82 (Cultivated Crops) land area are available, and were used to evaluate potential proximity to land suitable for soybean production. As discussed above, both of these NLCD classes are considered relevant. The FIFRA Endangered Species Task Force used the MJD 2009 dataset to prepare a database entitled "FESTF 7/10/09 Multi-Jurisdictional Database (MJD) species occurrence/land cover proximity database", and Classes 81 and 82 were included in this database. From this database, the nearest distance of an observation to relevant land use in a soybean production county was extracted.

The proximity distance evaluated for each species observation to relevant land use for soybean production was 450 ft. The distance of 450 feet is a conservative distance that is greater than the distance from the edge of the dicamba application area to a point at which an effect on soybean plant height is no longer observed, when the proposed FIFRA label application requirements for the dicamba diglyolamine salt are employed (Orr, et al., 2012, Honegger, 2012b). Utilizing the EPA screening assessment approach as described in the EPA Overview Document (USEPA, 2004)[178], soybeans have been demonstrated to be the most sensitive species to the effects of dicamba ((Porch et al.: 2009a, 2009b), and plant height was the most sensitive endpoint in the vegetative vigor study. (Wright et al. (2013)).

F.4.3.3.4. Proximity Findings

Results of the proximity analysis indicate that there are 1,657 species observations representing 87 species in 27 states and 303 counties that are within 450 feet of a land area where soybeans could potentially be grown and dicamba applied (Table F-57, Data Row 4). In the detailed reports that describe the proximity determination (Carr and Leopold, 2012a and 2012b), the sub-county analysis

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178 Overview Document (USEPA, 2004), p. 31.

is described by county, with the counties being grouped by state, and the states being organized according to the U.S. Fish and Wildlife Service region.

According to the proposed mandatory FIFRA label requirements for application of the dicamba diglycolamine salt formulation on DT soybean, a no-spray buffer will be required when threatened and endangered plant species are downwind from a dicamba application area to DT soybean. The proposed label, which is currently pending before EPA, also mandates that the grower and/or applicator consult a hotline or a web-based application that is under development and will be implemented prior to product launch; this web-based application will ensure that the grower and/or applicator knows when threatened and endangered plant species may be located within potential proximity of land where soybeans could be grown and dicamba applied, and thus knows whether a no-spray buffer is required for each individual dicamba application. These label restrictions, and/or any other measures imposed by EPA, will ensure that there is no effect on threatened and endangered species from the use of dicamba on DT soybean. Because the locations of threatened and endangered species observations in the FESTF MJD are confidential by agreement with NatureServe, an area larger than the listed species observation must generally be defined to protect the species location information. These larger areas have been termed "potential use limitation areas." The process of defining these areas is described in Section IV.C.4.

F.4.3.4. Sub-county Areas for Potential Use Limitation and Mitigation Measures

Monsanto defined potential areas around threatened and endangered plant species locations where label restrictions related to threatened and endangered species may be required. These areas have been defined to ensure species protection. The three components needed for implementation of potential use limitation areas are:

1. definition of the sub-county areas that include threatened and endangered plant species locations, as well as additional area so that the listed species are protected from disturbance or collection by rare plant enthusiasts;

2. development of habitat descriptions for the listed plant species within these areas; and

3. definition of label requirements that provide listed plant species protection from potential dicamba exposure.

F.4.3.4.1. Sub-county Descriptions of Potential Use Limitation Areas

For the observations of threatened or endangered plant species that overlap or are within 450 feet of relevant land uses, the next step of the analysis is to identify these species observations in such a way that appropriate label restrictions can be applied. Because the sub-county species location information is confidential under the terms of the NatureServe licensing agreement, the species locations cannot be disclosed to the public (see Footnote 43). Therefore, each of the state-level agencies or programs that provided sub-county species location data to NatureServe was contacted to determine whether it was acceptable for the sub-county species location information to be available to the public with only an additional 450 feet distance applied as a "resolution distance" around the area identified as the species location. In some cases, this distance was acceptable. In most cases, the state programs requested that a larger area be identified to provide an additional layer of conservatism regarding the location of the species.

Proximity analysis tools available in GIS software were used to add the additional area requested by the state heritage programs to the species observation area. These "buffered" observations were then further expanded so that potential use limitation boundaries could be described using surrounding surface features, such as roads, creeks, rivers, and railroads, and land survey boundaries (sections), where available. Maps depicting each listed plant species observation with proximity to relevant land use and the subsequently derived potential use limitation area are presented in the confidential attachments of Carr and Leopold (2012a and 2012b).

F.4.3.4.2. Habitat Descriptions

Habitat descriptions have been developed for each threatened or endangered plant species for which areas of potential use limitation have been proposed. These descriptions were developed from plant species information available from government and academic sources. Within the areas described for potential use limitation, mandatory label restrictions are only considered necessary when the habitat for the listed species is present. These habitat descriptions are included in the detailed reports (Carr and Leopold, 2012a and 2012b).

F.4.3.4.3. Label Restrictions

A proposed label has been submitted for the dicamba diglycolamine salt formulation for the new use on DT soybeans. This proposed label, which is currently pending before EPA, includes mandatory application requirements to minimize off-site movement. These requirements include implementation of a buffer when listed plant species are downwind from application areas. A further explanation of these measures to reduce off-site movement is presented in Honegger (2012b).

F.4.3.4.4. Overall Process for Sub-county Analysis

Polygons depicting threatened and endangered plant species locations that are within 450 feet of agricultural land where soybeans could potentially be grown, based on Ag Census information, have been increased in size and geographically mapped to allow public presentation of areas where listed plant species may be present. In addition, while not making species names public, brief, clearly-worded habitat descriptions have been developed for each potential use limitation area to allow the applicator / grower to ascertain whether suitable habitat for the species is present in the area downwind from the planned application area. Because of the need to increase the size of the publicly identified area beyond the boundaries of the listed species location, it is proposed that only if the appropriate habitat is present would the buffer mandated by the label apply.

F.4.3.4.5. Web-Based System to Communicate Use Limitations

To provide a convenient mechanism to present the locations of potential use limitation areas to growers / applicators, a web-based system similar to the system developed for glyphosate (www.Pre-Serve.org) is under development for dicamba. This web site will guide growers and applicators through a simple step-wise process to determine whether their fields fall within potential use limitation areas – areas where threatened or endangered plant species and/or habitat for those species may be present. Where fields do fall within potential use limitation areas and appropriate habitat is present, the web-based system will reiterate to the growers the mandatory steps (as specified on the label) that must be taken to reduce exposure to threatened and endangered plant species and avoid effects on survival, growth, and reproduction of these species. As an alternative to using the web-based program, growers/applicators will be able to call a hotline to obtain this information.

F.4.3.5. Conclusions

In the EFED ecological risk assessment conducted for dicamba reregistration (USEPA, 2005), using a screening-level assessment, EPA scientists concluded that a "no effect" determination can be made for all dicamba uses for vascular aquatic plant species. The potential for adverse effects to non-vascular aquatic plants and terrestrial and semi-aquatic plants could not be excluded based on the EPA screening-level assessment, the initial phase of analysis. However, since there are currently no listed non-vascular aquatic plants and non-listed non-vascular aquatic plants have an RQ below the LOC, this taxon does not require further investigation at this time. Recognizing that screening-level analysis is only the first step in evaluating impacts on threatened and endangered species, the EFED Science Chapter (USEPA, 2005) indicates that "additional information on the biology of listed species, the locations of these species, and the locations of the use sites … could be considered along with available information on the fate and transport properties of the pesticide to determine the extent to which screening assumptions regarding an action area apply to a particular listed organism."

The above discussion summarizes the conclusions of four other reports (Wright et al., 2013; Frank and Kemman, 2012; and Carr and Leopold, 2012a and 2012b) that utilize some of the refinements described by EPA in the previous paragraph and in the Overview Document (USEPA, 2004) to evaluate the potential for adverse effects to listed plant species. When the properties of dicamba and species-specific information are taken into account, these reports demonstrate that monocotyledonous terrestrial and semi-aquatic plants outside the treated area also would not be affected (Wright et al., 2013). The other three reports listed above coupled with the proposed application requirements on the label provide a mechanism to prevent exposure that otherwise may affect other threatened and endangered terrestrial plant species.

Table F-57 summarizes the results of each step in this process. The analysis was initiated by considering all counties in the United States where soybean farms have been reported and in which threatened or endangered plant species have been observed. The presence of a single soybean farm in any one of three Censuses of Agriculture spanning a ten-year period resulted in inclusion of that county in the analysis. In addition, listed species from counties adjacent to soybean production counties were also included in the analysis. Exclusions for habitat, protections, proximity analysis, and observation notes were used to identify areas and species where a potential for effects from exposure to dicamba could not be excluded. These areas were defined with precision to protect species and not reveal their exact location. By providing a mechanism to identify these areas to applicators and growers, required application practices on the herbicide label can be used to avoid exposure that would affect these species.

Table F-57. Numbers of counties, listed plant species, and observations involved in the analysis for DT-soybeans at major steps in the analysis

Analysis Category	Number of:			
	States	Counties	Listed Plant Species	Species Observations
Soybean production counties & adjacent counties [b]	50	2,728	--	--
Soybean production counties & adjacent counties that have presence of listed plant species [b]	48	1,274	477	--
Species-county co-occurrences evaluated for potential proximity (450-ft) to relevant land use [c]	38	545	183	4,973 [a]
Species observations with potential proximity to relevant land use [d]	27	303	87	1,657 [a]
Proposed use limitation areas (ULA) [e]	27	307	87	-- [f]

a Numbers represent species observation data available from the FESTF MJD dataset or from other Heritage Program sources. These species observation numbers do not include species location information obtained from other sources.

b As reported in Frank and Kemman (2012).

c These co-occurrences are the records assigned a "Requires Further Analysis" determination in Frank and Kemman (2012).

d These values exclude species observations that are historic (pre-1977), extirpated, or not at risk from agriculture.

e Includes counties where proposed use limitation areas extend into that county from an adjacent county.

f Not reported since the proposed ULAs includes areas where species observations are not available.

F.4.4. Effects on Threatened or Endangered Animal Species From Dicamba Use on DT Soybean

F.4.4.1. Endangered Species Exposure and Effects Analysis

F.4.4.1.1. Screening Level Analysis

An initial analysis of the potential for exposure and effects to all taxa from dicamba use in DT soybean based on the use pattern pending at EPA was conducted (Wright et al., 2013) using the EPA deterministic risk quotient approach (USEPA, 2004).[179] The use pattern for dicamba utilized in this analysis was a pre-emergence application at a rate of 1.0 lb dicamba acid equivalents per acre (a.e/A) followed by two post-emergence applications each at a rate of 0.5 lb a.e./A with a 6-day

179 This approach calculates a risk quotient (RQ) by dividing the Estimated Environmental Concentration (EEC) by the appropriate toxicity endpoint, and then compares that value with the appropriate Level of Concern (LOC). The LOC is established by EPA policy as the criteria used by EPA in comparison to the calculated risk quotient (RQ) to assess the potential for a pesticide use to cause adverse effects to non-target organisms.

interval between the pre-emergence application and the first post-emergence application, and a 6-day interval between the two post-emergence applications, with all applications being made using ground application equipment.[180] The 6-day application intervals utilized in this analysis are expected to be shorter than the intervals actually used in practice, since a grower is expected to wait at least 7 days before deciding to make a subsequent application in order to allow evidence of dicamba efficacy to develop.

Initial exposure estimates using the above described use pattern were based on standard EPA exposure models and default assumptions; toxicity effects endpoints were taken from the EPA Environmental Fate and Effects Division (EFED) Science Chapter for the Reregistration Eligibility Decision for dicamba (USEPA, 2005). The conclusion from this initial analysis, based on risk quotients (RQs) being less than the EPA Levels of Concern (LOCs), is that dicamba use on DT soybean would not affect threatened and endangered species in the following taxa:

- Fish, aquatic phase amphibians, and aquatic invertebrates (acute or chronic exposure)
- Birds, terrestrial-phase amphibians, and reptiles (chronic exposure)
- Mammals (acute exposure)
- Insects[181]

These conclusions for aquatic animals, birds, mammals and insects are consistent with the risk conclusions presented in the EFED science chapter for dicamba reregistration (US EPA, 2005 and 2009).

The levels of concern considered by EPA for threatened and endangered (listed) species risk assessments are given in Table F-58.

180 The proposed dicamba label for DT soybeans will not permit aerial application.

181 RQ calculations for insects are based on acute contact exposure. The RQ for the honey bee, as a surrogate for terrestrial invertebrates, was not a definitive value. Since there was no mortality in the acute contact exposure study, a definitive LD_{50} could not be determined. The resulting RQ was <0.12. However, since there was no mortality in the study, and the dose tested was more than seven times greater than upper bound maximum default residue value for arthropods calculated from T-REX using the dicamba- specific foliar decline value, the initial assessment concluded that terrestrial invertebrates would not be affected by dicamba use on DT-soybeans. This is consistent with the dicamba science chapter (USEPA, 2005a) conclusion that dicamba is practically non-toxic to bees.

Table F-58. EPA Levels of Concern for Threatened and Endangered Species (USEPA, 2004)

Risk Presumption	Calculation for Risk Quotient	Level of Concern
Birds		
Acute Risk	EEC/LC_{50} (application of a liquid) or LD_{50}/ft^2 or LD_{50}/day (application as a granule, bait, or treated seed)	0.1
Chronic Risk	EEC/NOAEC	1.0
Wild Mammals		
Acute Risk	EEC/LC_{50} (application of a liquid) or LD_{50}/ft^2 or LD_{50}/day (application of a granule, bait, or treated seed)	0.1
Chronic Risk	EEC/NOAEC	1.0
Terrestrial Invertebrates		
Acute Risk	EEC/LD_{50}	0.05
Aquatic Animals		
Acute Risk	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/MATC or NOAEC	1.0

F.4.4.1.2. Refinement to the Screening Level Analysis - Use of Dicamba-specific Foliar Residue Values

Consistent with EPA guidance found in the Overview Document (USEPA, 2004), if screening-level assessments do not result in a "no effect" determination, EPA does not then conclude that an herbicide "may affect" threatened and endangered species; rather, more refined assessments must be conducted to ascertain if any effects are expected to occur. Accordingly, for threatened and endangered animal species and the exposure durations for which the risk quotient exceeded the LOC in the screening level analysis (acute exposure for birds, amphibians and reptiles, and chronic exposure for mammals), refined exposure estimates were developed utilizing measured dicamba residues on pasture grasses[182] as representative residues for the short grass component of animal diets (Wright et al., 2013). These data were from residue studies conducted under Good Laboratory Practices by dicamba registrants and were used to estimate dicamba-specific residues for the grass components of animal diets[183], instead of using the EPA default residue values based on the Kenaga nomogram (Hoerger and Kenaga, 1972) as revised by Fletcher (1994). In addition, a Monsanto soybean residue study and a grass residue study, and a wheat residue study, included forage sampling at several time points soon after application. From these studies, the rate of decline of dicamba

[182] Residue values from these studies were converted to values expressed as parts per million per pound dicamba acid from residues values for application rates of 0.5, 1.0, and 2.0 lb a.e./A for grasses.

[183] The ratio of Kenaga residue values for tall vs. short grass was used with the measured pasture grass residue value to calculate a corresponding tall grass residue value.

residues on soybean, grass, and wheat foliage could be determined, and the time required for dissipation of 50 percent of the Day Zero residues (DT_{50}) calculated.[184] The Overview Document (USEPA, 2004)[185] indicates that chemical-specific foliar dissipation values can be used for multiple application exposure modeling for wildlife; accordingly, as a conservative assumption, the longest of the representative dicamba-specific foliar DT_{50} values for these three crops (5.63 days, for pasture grass) was used in the calculation of the dicamba-specific residues for chronic exposure. For grass and broadleaf dietary items, both mean and upper bound residue values[186] were considered in the evaluation; these levels are suitable to estimate realistic (mean) and worst case (upper bound) levels of exposure. A comparison of the default upper bound residue values and dicamba-specific upper bound residue values is given in Table F-59.

Table F-59. Comparison of Default Kenaga Residues and Dicamba-specific Residues in Food-Items

	Maximum dicamba residues in food items (ppm a.e.) based on a 1 lb a.e./A pre-emergence application followed by two sequential post-emergence 0.5 lb a.e./A applications				
	Short Grass	**Tall Grass**	**Broadleaf Plants**	**Fruits/ Pods/Seeds**	**Arthropods**
Using upper bound Kenaga residues & default foliar DT_{50} (35 days)					
Day 0 (after 1st application)	240.0	110.0	135.0	15.0	94.0
Maximum residue[a] (after 3rd application)	415.8	190.6	233.9	26.0	162.9
Using upper bound Kenaga residues & dicamba-specific foliar DT_{50} (5.63 days)					
Day 0 and Maximum residue[a] (after 1st application)	240.0	110.0	135.0	15.0	94.0
Using Dicamba-specific maximum measured residues (short and tall grass) & foliar DT_{50} (5.63 days)					
Day 0 and Maximum residue[a] (after 1st application)	179.0	82.0	135.0	15.0	94.0
Using Dicamba-specific refined maximum measured residues (90th percentile value for short and tall grasses) & foliar DT_{50} (5.63 days)					
Day 0 and Maximum residue[a]	131.0	60.0	135.0	15.0	94.0

184 For the pasture grass and wheat residue studies, there were over 50 treatments per study for which a DT_{50} value could be calculated. In accordance with US EPA guidance, the 90th percentile upper confidence limit of the mean DT_{50} value was selected as an appropriate DT_{50} value to use for calculation of residue decline for these crops. For the soybean residue study only six treatments were available to calculate DT_{50} values; thus, the maximum value was considered to represent residue decline in soybean forage.

185 Overview Document (USEPA, 2004), pg. 13.

186 Considering the number of measured residue values available for pasture grasses to calculate the upper bound residue, for chronic exposures, use of a refined maximum residue value (90th percentile value) was still considered a "worst case" conservative approach and is consistent with probabilistic approaches outlined in ECOFRAM (1999).

(after 1st application)					

[a] Using the default foliar DT_{50}, the highest residue occurs immediately after the third application. Using the dicamba-specific DT_{50}, the highest residue occurs immediately after the first application.

These refined residue values for dietary items were considered when using the EPA model T-REX (v1.5.1) for the calculation of risk quotients and subsequent comparison to LOCs for acute exposures to birds, terrestrial amphibians, and reptiles, and for chronic exposures to mammals.[187]

Risk quotients for chronic exposure to mammals calculated using refined maximum measured upper bound residues slightly exceed the LOC for small and medium-sized mammals consuming short grass or broadleaf plants; however, utilizing mean residue values as a further refinement, risk quotients are all below the LOC (Table F-60) leading to a conclusion of no effect on these species. This is consistent with the finding in the EFED Science Chapter for dicamba (USEPA, 2005) and the revised RED (USEPA, 2009) for a single application rate of 1.0 lb a.e./A. Because there will be at most only three applications per year and dicamba dissipates rapidly, an individual small- or medium-sized mammal will not chronically consume foliage containing maximum residue levels from dicamba-treated fields. Therefore, reliance on dicamba-specific Day 0 mean residue values is also a conservative dietary exposure estimate for chronic exposure that is expressly countenanced by EPA.[188] Nonetheless, a refined county-level analysis was conducted for chronic exposure to mammals.

[187] The T-REX model is not designed to allow modification of the dietary food item residues. Thus, the dicamba-specific residues reported in Table F-59 were considered in the risk quotient calculations by applying a correction factor to the estimated environmental concentrations (EEC) values computed using the standard T-REX model for a single 1-lb/A application.

[188] Overview Document (USEPA, 2004), p. 40.

Table F-60. Risk Quotients for Chronic Exposure for Mammalian Species Based on Dicamba-Specific Residue Values and DT_{50}.

Diet	Mammal Size (g)	Risk Quotient[a,b] using Upper Bound Residues	Risk Quotient[a] using Mean Residues
Short Grass	15	**1.26**	0.75
	35	**1.08**	0.64
	1000	0.57	0.34
Tall Grass	15	0.58	0.32
	35	0.49	0.27
	1000	0.26	0.15
Broadleaf Plants	15	**1.30**	0.43
	35	**1.11**	0.37
	1000	0.60	0.20
Fruits/Pods	15	0.14	0.07
	35	0.12	0.06
	1000	0.07	0.03
Arthropods	15	0.91	0.63
	35	0.77	0.54
	1000	0.41	0.29
Seeds	15	0.03	0.02
	35	0.03	0.01
	1000	0.02	<0.01

[a] Dicamba-specific refined residue values based on a 1 lb a.e./A application rate were 131, 60.0, 135.0, 15.0, 94.0 and 15.0 mg a.e./kg diet, respectively, for upper bound values for short grass; tall grass; broadleaf plants; fruits/ pods; arthropods; and seeds, and 77.9, 33.0, 45.0, 7.0, 65.0 and 7.0 mg a.e./kg, respectively, for mean residues. The dicamba-specific residue decline DT_{50} of 5.63 days instead of the EPA default value of 35 days was also used in determining the peak residue value resulting from the three sequential applications.

[b] Numbers with Bold font indicate the RQ exceeds the LOC (1.0).

With respect to birds, analyses were performed using maximum measured dicamba residue values (Table F-59) for dose-based RQ calculations for acute exposure. The following could be excluded from concern (and, therefore, no effects would be expected to occur): birds of all sizes consuming only fruits/pods or seeds and large birds consuming tall grass or arthropods. Small and medium-sized birds consuming broadleaf plants, arthropods or grasses and large birds consuming short grass or broadleaf plants required further analysis. RQ values are presented in Table F-61. Refined analyses were conducted for birds for which the dose-based RQ values exceeded the LOC; however, this was a conservative approach since the subacute dietary-based RQ values, based on maximum measured upper bound residues (Table F-59), are all well below the LOC (0.1); except for birds consuming a short grass diet. The short grass RQ (<0.12) is not definitively below the LOC; however, considering that the toxicity value used in the dietary assessment (>1522 mg/kg_{diet}) is actually an unbounded NOEC value from the bobwhite quail study, there would be no effects from short-term exposure to dicamba used on DT-soybeans.[189]

Because birds are the surrogate species for terrestrial phase amphibians and reptiles, further analysis was also conducted to ensure that amphibians and reptiles could be excluded from concern for adverse effect.

Table F-61. Risk Quotients for Acute Exposure to Birds Using Maximum Measured Dicamba Residues and Dicamba-specific Residue Decline Values

Diet	Acute RQs: (Dose-based EEC/adjusted LD50)[a]		
	Upper Bound Residues		
	20 g Small	100 g Medium	1000 g Large
Short grass	**1.08**	**0.48**	**0.15**
Tall grass	**0.49**	**0.22**	0.07
Broadleaf plants	**0.81**	**0.36**	**0.12**
Fruits/pods	0.09	0.04	0.01
Arthropods	**0.57**	**0.25**	0.08
Seeds	0.02	<0.01	<0.01

[a] Bold numbers indicate the RQ exceeds the LOC (0.1).

F.4.4.1.3. Refined Analysis Considering Species County-level Location

Certain sizes of threatened and endangered birds, amphibians, reptiles, and mammals had risk quotients exceeding the LOC as a result of the use of dicamba on DT soybean based on a default exposure analysis or an analysis using refined residue and residue decline values. Consistent with guidance set forth in the EPA Overview Document[190], a more detailed evaluation of the locations of these threatened and endangered species relative to potential areas of soybean production was undertaken.

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[189] The toxicity value (>1522 mg/kg_{diet}) used to calculate the RQ is a concentration in feed at which no effect was observed rather than a concentration at which 50% mortality would be predicted. The short grass EEC from Table F-59 is 179 mg/kg_{feed}. This estimated concentration on short grass that birds might be consuming is less than one eighth of the dietary concentration at which no effects were observed; therefore, there will be no effect on these species from short-term exposure to dicamba used on DT-soybeans.

[190] Overview Document (USEPA, 2004), p. 69.

First, the co-occurrence of threatened and endangered species and the production of soybeans was determined at the county level. For completeness, all threatened and endangered avian, amphibian, reptile, and mammalian species were included in the county-level analysis (including species proposed for listing, but excluding wholly aquatic species). Listing status[191], species habitat and proximity data to soybean production at the county-level were evaluated for these identified species to determine which species in which counties can be excluded from further evaluation and which require further evaluation. This process is referred to as the "county-level analysis" (Frank and Kemman, 2013) and is discussed in more detail in Section IV.D.2 below. The sub-county location of threatened and endangered species observations and land relevant for soybean production was also considered for some species. This proximity evaluation is discussed in Section IV.D.3.

F.4.4.1.4. Refined Analysis Considering Species Biological Characteristics

Next, the Overview Document provides that – for those threatened and endangered species (avian, reptile, amphibian (terrestrial-phase), and mammalian) that require further evaluation – each species be considered individually to determine whether it can be excluded from concern for potential effects based on body weight or dietary considerations. Accordingly, for these animal species, refined risk quotient calculations were performed considering individual species body weight, food type and food intake rate, as described in Section IV.D.4 and in Schuler et al. (2013a), and consistent with EPA guidance found in the Overview Document (USEPA, 2004). Based on these refined county-level analyses, as discussed below, individual animal species were excluded from concern, and, therefore, would not be affected by dicamba use on DT soybeans.

F.4.4.2. County-level Analysis: Co-occurrence of Listed Species in Crop Production Areas

The procedures used in the county-level analysis to identify counties containing threatened or endangered species that require further evaluation and are described in detail in Frank and Kemman (2013a). The U.S. counties where soybean production was reported were identified using available data from the U.S. Census of Agriculture. Census data from 1997, 2002 and 2007 were utilized to identify counties with reported soybean farms.[192] Any county with a reported soybean farm (i.e. with a crop of "soybeans for beans") was considered in this analysis. [193] This information was supplemented with soybean pesticide application data available from the California Department of Pesticide Regulation for the years 2005-2007. Counties without soybean production, but adjacent to

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191 Listing status refers to whether the species is classified as threatened, endangered, no longer considered threatened or endangered (delisted), etc.

192 Conducted every five years, the USDA Census of Agriculture provides a detailed picture of U.S. farms and ranches and the people who operate them. It is the only source of uniform, comprehensive agricultural data for every state and county in the United States. The farm and acreage information for the 1997 census year was taken from the 2002 Census of Agriculture (USDA, 2004), which reports soybean information for both 1997 and 2002 census years.

193 This analysis assumed that the reported presence of a single soybean farm in any of the last three Censuses (1997, 2002, and 2007) was an indicator that the county contained land suitable for soybean production. Moreover, a review of the available data demonstrates that almost every county in the eastern two thirds of the U.S. is included (see Frank and Kemman 2013a). Thus, it is unlikely that any counties with soybean production were missed using this approach.

counties with soybean production were also identified. In total, there were 2,728 counties considered in this analysis (2,198 soybean counties, 530 adjacent counties).

In the identified counties, available county-level presence information for threatened or endangered avian, reptile, amphibian, and mammalian species was evaluated, using county-level location information compiled by the FIFRA Endangered Species Task Force (FESTF) and available in the FESTF Information Management System (IMS).[194] Species that were wholly aquatic (e.g. whales) were not included. Of the 2,728 counties initially considered, there were 2,418 counties with listed species in the taxa of interest for dicamba and where soybeans are produced (including counties adjacent to counties where soybeans are produced). These counties reflect the reported presence of 139 distinct species in 49 states (all states except Alaska). There were 5,744 species/county co-occurrence records considered across all animal taxa evaluated. In these counties, each species was evaluated with respect to the current listing status, county-level locations, species biology, species habitat requirements, and (when possible) species proximity to land relevant for soybean production, in order to determine whether exposure to dicamba from use on DT-soybean could potentially result in effects to the species. Some listed species could be removed from concern for effects based on exclusions that currently exist and are documented. Exclusions that have been employed include change in species listing status, not present due to extirpation[195], habitat not in proximity to agriculture, product properties (diet and feeding exclusions)[196], and species not in proximity to agriculture for other reasons.

The proximity analysis at the sub-county level as described in Section IV.D.3 and species-specific refinements as described in Section IV.D.4 have been utilized in conjunction with the county-level identification of co-occurrences to evaluate potential effects to threatened and endangered species as discussed in the EPA Overview Document.[197] T-REX was utilized for birds and mammals to calculate species- and diet-specific risk quotients. For amphibians and other relevant species, T-HERPS was utilized to calculate species- and diet-specific risk quotients for amphibians and reptiles with similar methods to those used in the assessments of the California red-legged frog. Diet information was utilized for individual species of birds, reptiles, and mammals to determine if actual diet considerations can justify removing a species from concern.

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194 The FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) Endangered Species Task Force (FESTF) Information Management System 2.7 (IMS) (referred to as the "FESTF IMS") was developed in order to meet the legal obligations of its member companies to submit data required by EPA/OPP under FIFRA (as described in Pesticide Registration Notice 2000-2) in support of the members' registration and re-registration actions. The purpose of the IMS is to meet the data requirements in a manner that significantly improves the consistency, quality, availability and use of existing information on threatened and endangered species and pesticide use. http://www.festf.org/visitors/default.asp.

195 An extirpated species is defined as "a species no longer surviving in regions that were once part of its range" (http://www.fws.gov/midwest/endangered/glossary/index.html).

196 This type of exclusion is based on a quantitative analysis of dicamba properties beyond the screening level analysis in the EFED Science Chapter. Specifically, this analysis involves assessing use of measured foliar residues and foliar decline rates following dicamba applications, adjusted to reflect the use pattern for DT-soybeans. The size, diet, and food consumption of the animal species are also considered (See Section F.4.4.3 and Section F.4.4.6).

197 Overview Document (USEPA, 2004) p. 69 and p. 67, respectively.

F.4.4.3. Sub-County Animal Species Observations versus Land Use Proximity Analysis

The analysis of proximity of relevant land use to sub-county locations of threatened or endangered animal species identified in the county-level analysis (Frank and Kemman, 2013a) is summarized in the sections that follow.

F.4.4.3.1. Land Use Information

For the contiguous U.S., land cover data considered in this analysis were obtained from the National Land Cover Dataset (minimum mapping unit: 30-meters)[198]. Data for the NLCD 2006 dataset were collected from 2001 and 2006 and represent the best comprehensive collection of national land use and land cover information for the U.S (NLCD, 2011). The land cover classes of pasture/hay (Class 81) and cultivated crops (Class 82) were considered "relevant land use" for this analysis (or, for California, counties where herbicide applications on soybeans have been reported), since land designated as cultivated crops could potentially be used for DT-soybean production, and some pasture/hay fields could be converted to cultivated cropland.

F.4.4.3.2. Species Locations

FESTF Multi- Jurisdictional Database (MJD)

Threatened and endangered animal species location data at a sub-county level were obtained from the FIFRA Endangered Species Task Force Multi-Jurisdictional Database (FESTF MJD; NatureServe 2012). The FESTF MJD consists of a "licensed dataset" drawn from NatureServe's Multi-Jurisdictional Database (MJD) licensed to FESTF.[199] The MJD species observation records included additional data fields, such as date of last observation and observation notes; this information was evaluated and utilized when relevant to the proximity assessment.

The MJD location data were provided as polygons (areas representing where a listed species was observed; referred to as a "species observation"). The spatial dataset was provided in a format suitable for analysis and display using Geographic Information System (GIS) software.

For the purposes of this analysis, species observations were considered "historic" if the "last observed date" for the observation (as reported by NatureServe in the FESTF MJD 2012 dataset) was prior to 1977 [200] or if the observation was noted to be "Historical" or "Extirpated" in the FESTF MJD 2012 dataset licensed from NatureServe.

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198 National Land Cover Database 2006 (NLCD 2006). URL: http://www.mrlc.gov/nlcd2006.php
For Hawaii, nearest distance to land use based on the NLCD 2001 dataset was considered.

199 Under the terms of the FESTF license with NatureServe, the sub-county threatened and endangered species location data are confidential information available only to FESTF, FESTF member companies, (including FESTF "Level II" companies), and the U.S. EPA's Office of Pesticide Programs staff reviewing FESTF member-company registrations. Information based on the sub-county species location data may be shared with cooperating federal and state agencies for regulatory decision-making related to endangered species assessments for Monsanto products.

200 A time period for observations beginning in 1977 is considered a conservative time period for this analysis.

F.4.4.3.3. Proximity Analysis Process

Proximity distances from each species observation (polygon) in the FESTF MJD 2012 dataset to NLCD 2006 Class 81 (Pasture/Hay) and Class 82 (Cultivated Crops) land area were available, and were used to evaluate potential proximity to land suitable for soybean production. The FIFRA Endangered Species Task Force used the MJD 2012 dataset to prepare a database entitled "FESTF MJD 2012/NLCD 2006 Species Occurrence/Land Cover Proximity Database – Classes 81 and 82", and Classes 81 and 82 were included in this database. From this database, the nearest distance of a species observation to relevant land use in a soybean production county was extracted for each species/county co-occurrence evaluated in Frank and Kemman (2013a).

The distance evaluated for potential proximity of each species observation to relevant land use for soybean production was determined based on each individual species home range, the area over which an animal normally travels and searches for food. Therefore, to remove a species from concern based on proximity, the home range for the individual species was determined as the minimum separation distance from the edge of the dicamba application area and the species observation.

Where relevant, land classified as soybean fields, based on 4 years of USDA Cropland Data Layer (CDL) data (2008 through 2011) (USDA2008, 2009,2010, 2011) was also considered in evaluating the proximity of a species observation to soybean production.

The California Pesticide Using Reporting database was also utilized to identify Public Land Survey Sections in the five California counties considered to have soybean production where pesticide applications had been made to soybeans, and hence were sections where soybeans have been grown. Pesticide Use Reports for the years 2001–2010 were used for this determination.

F.4.4.4. Species-specific Risk Quotient Calculations

Consistent with EPA's Overview Document, species-specific dietary exposure was assessed considering animal body weight and diet (Schuler et al., 2013a) for birds and mammals of certain sizes, where risk quotients exceeded the level of concern after the initial refinements described above. A similar assessment was conducted for amphibians and reptiles because birds serve as the surrogate for terrestrial phase amphibians and reptiles. Biological information was gathered from a number of sources, including U.S. Fish and Wildlife Service (USFWS) species recovery plans, primary literature, and other technical sources (e.g. NatureServe[201]).

F.4.4.4.1. Mammals

In the county-level endangered species analysis, 54 threatened or endangered mammalian species were identified as potentially being present in or adjacent to a county with soybean production (Frank and Kemman, 2013). Of the original 54 species, 12 species were removed from

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201 NatureServe is a non-profit conservation organization that collects detailed local information on plants, animals, and ecosystems. NatureServe has a public website available at http://www.natureserve.org .

consideration based on Habitat determinations and 7 species were deemed Not of Concern[202] across all the counties evaluated (Frank and Kemman, 2013a).

The remaining 35 species of mammals were examined for the potential for chronic effects based on proximity to land relevant for soybean production and biological characteristics (i.e., dietary preferences and body size). The analysis progressed in a step-wise fashion:

- The proximity of each species observation to relevant land use for soybean production was compared to species home range information. Of the 35 species evaluated in this refined analysis, 12 species were excluded from concern due to lack of proximity to land relevant for soybean production.[203]

- The 23 remaining species received Product Property determinations (Diet Exclusions)[204], since based on body size and diet, the RQs were less than LOC considering chronic exposure to upper bound residues.

- All calculations were based on the assumption that animals eat 100% of their diet at the upper bound residue levels. This is an extremely conservative assumption for a chronic exposure scenario. Based on the EPA Overview Document for Endangered and Threatened Species Effects Determinations (US EPA 2004), the use of the mean residue value is an appropriate refinement for chronic exposures. When consumption of food containing the mean residue value is assumed, the dose-based chronic risk quotients are well below the LOC of 1 (Table F-60) for all diet types and body sizes, indicating that threatened or endangered wild mammals can be excluded from concern and, therefore, would not be affected. [205]

- The Diet Exclusion was also applicable to the species assigned Proximity or Not of Concern determinations, resulting in a total of 35 mammalian species where a Diet Exclusion was applicable.

In summary, it can be concluded that no effects to mammalian species will result from the use of dicamba in DT-soybeans.

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202 "Not of Concern" Determination: *Species co-occurrences that are not of concern.* Physical or regulatory factors provide clear evidence that a species is not of concern in a particular county. Examples include delisted species, no current presence, and historical or extirpated species.

203 For all county co-occurrences that did not have applicable Not of Concern determinations.

204 This determination type identifies a particular species or taxon as not at risk based on the properties of the product (dicamba applied to DT-soybeans) when certain biological factors such as size (e.g. >1 kg) and diet (e.g., carnivorous, frugivorous, etc.) are considered.

205 Considering the rapid rate of dicamba foliar residue dissipation, even chronic RQs calculated for small mammals with the refined maximum measured residues only exceed the LOC for up to 2 days, not a sufficient duration to be considered a chronic exposure

F.4.4.4.2. Birds

In the county-level endangered species analysis, 52 threatened or endangered avian species were identified as potentially being present in or adjacent to a county with soybean production (Frank and Kemman 2013a).

- Of the original 52 species, 12 species were removed from consideration based on Habitat determinations (Frank and Kemman 2013a).

- The proximity of each species observation to relevant land use for soybean production was compared to species home range information. Of the 40 species evaluated in the refined analysis, 7 were removed from concern due to a lack of proximity to land relevant for soybean production.[206]

- Of the remaining species evaluated in this refined analysis, 20 were assigned Product Property determinations (Diet Exclusion) because their T-REX acute RQs were less than the LOC based on characteristics of diet and body weight or their diets did not include items considered in the T-REX model (e.g., aquatic animals).[207]

- Using measured upper-bound dicamba residue values, RQ values exceeded the acute LOC of 0.1 only for small and medium-sized birds that consume grasses, broadleaf plants, or arthropods, and large birds consuming short grass and broadleaf plants (Table F-61).

- Dose-based RQs calculated for 13 species using the acute LD50 value exceeded the acute LOC of 0.1 for the dose-based upper bound residues indicating that further refinement should be considered (described below).

- Based on the refinements, the remaining 13 species were assigned Product Property determinations (Feeding Exclusion)[208] because the upper bound EECs calculated for these species were lower than dose-based NOELs calculated from acute dietary exposure studies.

- The Diet and Feeding Exclusions were also applicable to the species assigned Proximity or Not of Concern determinations, resulting in totals of 21 species where a Diet Exclusion was applicable, and 19 species where a Feeding Exclusion was applicable.

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206 For all county co-occurrences that did not have applicable Not of Concern determinations.

207 Diet items not included in T-REX were aquatic animals and small- to medium-sized mammals as prey. Exposure to dicamba residues from the consumption of aquatic animals was not considered to be of concern due to low surface water concentrations (Wright et al., 2013) and a low bioconcentration factor (BCF). Consumption of small- to medium-sized wild mammals by large carnivorous mammals (i.e. 1 kg or larger) is not a concern because dicamba does not bioaccumulate in mammalian tissues (U.S. EPA, 2005) and residues from food items that a prey might have consumed would not result in RQs exceeding the LOC for species of 1 kg or larger.

208 This determination type identifies a particular species as not at risk based on the properties of the product (dicamba applied to DT-soybeans) when certain biological factors such as size (e.g. >1 kg) and diet (e.g., carnivorous, frugivorous, etc.) are considered.

Moreover, this analysis is conservative because it is likely that the birds would not be in soybean fields actively foraging, but rather foraging in the adjacent habitats (e.g., tree canopy) outside of the fields. Threatened and endangered species are "strongly associated" with their specific habitat type and, therefore, it is improbable that 100% of the bird's diet would consist of dietary items exposed in the field. Additionally, EPA's default approach to assessing acute risk is based on a single oral gavage dose (i.e., the entire dose is delivered to the animal at one time, typically after being dissolved in corn oil). In reality, of course, any pesticide exposure will not occur in this manner – but rather through dietary consumption of dicamba-exposed prey or food items. As a result, the gavage route of administration overestimates the exposure expected to occur in nature, and methods resulting in a dose-delivery over time (e.g., dietary exposure) are more environmentally relevant. Therefore, the use of the acute oral toxicity test (i.e., oral gavage) to predict risk of dicamba to birds in this case should be considered to be a screening-level approach that is expected to overestimate actual risk.

An acceptable refinement to the screening level risk assessment, based on guidance in the US EPA Overview Document on Ecological Risk Assessment Process for Endangered and Threatened Species Effects Determinations, is to determine the acute risk to birds from consuming dicamba exposed prey or food items from an estimate of the dose-based effect levels calculated from acute dietary toxicity studies.

- From short-term dietary toxicity tests using bobwhite quail chicks and mallard ducklings exposed to dicamba diglycolamine salt for 5 d, the dose-based NOEL values were determined (Grimes, 1986a; Grimes, 1986b). The use of the NOEL value in place of the LC_{50} for an acute assessment provides additional conservatism when assessing for potential effects on endangered species.

- For birds, the dose-based EECs were calculated based on the refined foliar residue and DT_{50}values and assuming 100% of the diet was obtained within the field. The short/tall grass residue values were refined based on the maximum measured Day 0 residues from 59 dicamba specific field trials in pasture grasses.

- From this analysis, the dose-based EECs for small passerine birds consuming a diet exposed in the field are below the dose-based NOEL values (Schuler et al., 2013a),

- Conservatively assuming that the avian species evaluated are passerine species (highest metabolic/ingestion rates, U.S. EPA, 1993), they cannot ingest enough food to achieve doses that would exceed the unbounded NOEL (highest dose tested).

- In addition, compared to the larger birds used in the gavage study (e.g., 178 g and 1,580 g for the bobwhite quail and mallard duck, respectively), the sizes of birds used in the dietary studies (e.g., 37 g and 264 g for the bobwhite quail and mallard duck, respectively) are much more relevant to birds considered in this analysis; thereby reducing uncertainty in the toxicity value adjustment.

In summary, it can be concluded that no effects to birds will result from the use of dicamba in DT-soybeans.

F.4.4.4.3. Amphibians and Reptiles

In the county-level endangered species analysis, 13 terrestrial-phase amphibian species and 20 reptile species were identified as potentially being in or adjacent to a county with soybean production (Frank and Kemman, 2013a). Of these species, 3 amphibian and 5 reptile species were removed from consideration based on Habitat determinations. Additionally, 2 reptile species were deemed Not of Concern across all counties evaluated (Frank and Kemman, 2013a).

The remaining 10 amphibian and 13 reptile species were evaluated based on their proximity to agriculture and species-specific refinements (Schuler et al, 2013a).

- The proximity of each species observation to relevant land use for soybean production was compared to species home range information. Five amphibian and three reptile species were removed from concern due to a lack of proximity to land relevant for soybean production.[209]

- The remaining species (5 amphibian species and 10 reptile species) all received Product Property determinations (Diet Exclusion) because their T-HERPS RQ values were less than the LOC based on characteristics of diet and body weight.

- The Diet Exclusion was also applicable to the species assigned Proximity or Not of Concern determinations, resulting in totals of 10 amphibian and 13 reptile species where a Diet Exclusion was applicable.

In summary, it can be concluded that no effects to terrestrial-phase amphibians or terrestrial reptiles will result from the use of dicamba in DT-soybeans.

F.4.4.5. Indirect Effects on Threatened and Endangered Species of Other Taxa Resulting from Direct Effects on Plant Species.

To assess the potential for indirect effects on threatened and endangered species, the EPA evaluates the risk of direct effects on non-endangered species from relevant taxonomic groups to make inferences concerning the potential for indirect effects upon threatened or endangered species that rely on non-endangered species in that category for critical resources (USEPA, 2004). The RQ values used to assess the potential for indirect effects from dicamba applications to DT-soybean indicate that indirect effects to other taxa resulting from effects on monocot plant species from application of dicamba at rates up to 1.0 lb a.e./A would not occur. Further, indirect effects to other taxa as a result of effects on dicot plant species from a combination of sheet runoff and spray drift to soil would also not occur (Wright et al., 2013). In addition, utilizing a refined exposure assessment, indirect effects to other taxa resulting from effects on dicot plant species exposed via a combination of channelized runoff and spray drift to soil would not occur (Wright et al., 2013). When RQ values are calculated for all six of the dicot species tested in the vegetative vigor study, RQs exceed the LOC for only two of the six species indicating that habitat and food sources from dicot plants will be present adjacent to areas treated with dicamba (Wright et al., 2013).

[209] For all county co-occurrences that did not have applicable Not of Concern determinations.

Furthermore, field studies demonstrate that even very sensitive plants at the edge of a field sprayed with dicamba are not affected to the extent that impacts on habitat would result. Additionally, effects from drift can be further minimized through the use of application requirements such as drift reducing technologies (e.g., low drift spray nozzles, boom height, deposition aides). A separate report (Schuler et al., 2013b) assesses the potential for indirect effects on threatened and endangered species.

F.4.4.6. Conclusions

In the EFED ecological risk assessment conducted for dicamba reregistration (USEPA, 2005), using a screening level assessment, EPA scientists concluded that a "no effect" determination can be made for all dicamba uses for listed fish, and aquatic invertebrates. The potential for adverse effects to listed birds and mammals could not be excluded based on the EPA screening level assessment, the initial phase of analysis. Recognizing that screening level analysis is only the first step in evaluating impacts on threatened and endangered species, the EFED Science Chapter (USEPA, 2005) indicates that "additional information on the biology of listed species, the locations of these species, and the locations of the use sites…could be considered along with available information on the fate and transport properties of the pesticide to determine the extent to which screening assumptions regarding an action area apply to a particular listed organism."

The above discussion summarizes the conclusions of three other reports (Wright et al., 2013; Frank and Kemman, 2013a; Schuler et al., 2013a) that utilize some of the refinements described by EPA in the previous paragraph to evaluate the potential for adverse effects to listed birds, mammals, amphibians, reptiles and terrestrial invertebrates. When the properties of dicamba and species-specific information are taken into account, these reports demonstrate that listed birds, mammals, amphibians, reptiles, and terrestrial invertebrates would not be affected by dicamba use in DT-soybean.

F.4.5. Impact on Threatened or Endangered Plant Species from Dicamba Use on DGT Cotton

F.4.5.1. Endangered Species Exposure and Effects Analysis

F.4.5.1.1. Screening-Level Analysis

An initial analysis was conducted of the potential for exposure and effects to all taxa (including plants) from dicamba use in cotton with the DT trait (Honegger et al., 2013) using the EPA deterministic risk quotient approach (USEPA, 2004). The analysis in Honegger et al. was based on a use pattern more conservative than that reflected in the proposed label whose approval is pending at EPA. The use pattern for dicamba utilized in this analysis was a pre-emergence application at a rate of 1.0 lb dicamba acid equivalents per acre (a.e./A) followed by two post-emergence applications each at a rate of 0.5 lb a.e./A with a 6-day interval between the pre-emergence application and the first post-emergence application, and a 6-day interval between the two post-emergence applications, with all applications being made using ground application equipment. The 6-day application intervals utilized in this analysis are shorter and more conservative than the 7-day interval specified on the proposed dicamba label for use in cotton with the DT trait, but were used for consistency with the analysis for DT-soybeans.

For aquatic plants, initial exposure estimates using the above described use pattern were based on the standard EPA exposure models GENEEC 2.0 and PRZM (3.12.2)/EXAMS (2.98.04.6) and toxicity effects endpoints taken from the EPA Environmental Fate and Effects Division (EFED) Science Chapter for the Reregistration Eligibility Decision for dicamba (USEPA, 2005).

For terrestrial plants, initial exposure estimates using the above described use pattern were based on the standard EPA exposure model TerrPlant 1.2.2 and default assumptions; toxicity effects endpoints were taken from EPA guideline studies conducted by BASF under an EPA data call-in (Porch et al., 2009a and 2009b).

The conclusion from this initial analysis (Honegger et al., 2013), based on risk quotients (RQs) being less than the EPA Levels of Concern (LOCs), is that dicamba use on cotton with the DT trait would not affect threatened and endangered plant species in the following taxa:

- Aquatic vascular plants
- Monocotyledonous terrestrial plant species (monocots)

Although the RQ for listed aquatic non-vascular plants exceeded the LOC, additional analysis was not conducted because there are no federally listed non-vascular aquatic plants. The RQ for non-listed aquatic non-vascular plants was less than the LOC, indicating that other taxa of threatened and endangered species would not incur indirect effects as a result of effects on non-listed non-vascular aquatic plants.

These conclusions for aquatic plants are consistent with the risk conclusions presented in the EFED science chapter for dicamba reregistration (USEPA, 2005 and 2009).

The conclusion for monocots is supported by more recent nontarget plant studies with a typical dicamba end use product containing the diglycolamine salt of dicamba. These studies were required by EPA during the reregistration process to assess the phytotoxicity of an end-use product containing the diglycolamine salt. Only endpoints for dicamba acid were available for consideration in the EFED science chapter (USEPA, 2005 and 2009) for which it was concluded that the RQ exceeded the LOC. Toxicity endpoints for the diglycolamine salt were not available at that time to calculate an RQ for comparison with the LOC (Porch et al., 2009a and 2009b). Using the no-observed-effect endpoints from these 2009 studies and the EPA model TerrPlant to calculate exposure and risk quotients, the RQs for monocots were below the LOC (Honegger et al., 2013), and thus result in a conclusion that monocots would not be affected by use of the diglycolamine salt of dicamba on cotton with the DT trait. The levels of concern considered by EPA for threatened and endangered (listed) species risk assessments are given in Table F-62.

Table F-62. EPA Levels of Concern for Threatened and Endangered Plant Species (USEPA, 2004)

Risk Presumption	Calculation for Risk Quotient	Level of Concern
Terrestrial and Semi-Aquatic Plants		
Acute Risk	EEC/EC_{05} or NOAEC	1.0
Aquatic Plants		
Acute Risk	EEC/EC_{05} or NOAEC	1.0

For threatened and endangered terrestrial plant species in classes other than monocotyledons, further analysis is required.

F.4.5.1.2. Refined Analysis for Listed Plants Considering County-Level Information

Consistent with EPA guidance found in the Overview Document (USEPA, 2004), if screening-level assessments do not result in a "no effect" determination, EPA does not then conclude that an herbicide "may affect" threatened and endangered species; rather, more refined assessments must be conducted to ascertain if any effects are expected to occur. Based on this guidance, a more detailed evaluation of the locations of threatened and endangered plant species relative to potential areas of cotton production, and, therefore, potential dicamba use was undertaken.

First, the co-occurrence of threatened and endangered plant species and the production of cotton was evaluated at the county level. Listing status , species habitat, species observation history in the county, and proximity data to cotton production at the county level were evaluated to determine: (1) which species in which counties can be excluded from further evaluation; and (2) which require further evaluation. This process is referred to as the "county-level analysis" (Frank and Kemman 2013) and is discussed in more detail in Section IV.E.2.

F.4.5.2. County Level Analysis: Co-occurrence of Listed Plant Species in Crop Production Areas

The procedures used in the county-level analysis to identify counties containing threatened or endangered species that require further evaluation are described in detail in Frank and Kemman (2013b). The U.S. counties where cotton production was reported were identified using available data from the U.S. Census of Agriculture. Census data from 1997, 2002 and 2007 were utilized to identify these counties. Counties without cotton production, but adjacent to counties with cotton production were also identified. In total, there were 1,198 counties considered in this analysis (733 cotton counties, 465 adjacent counties).

In the identified counties, available county-level presence information for threatened or endangered plant species was evaluated, using county-level location information compiled by the FIFRA Endangered Species Task Force (FESTF) in the FESTF Information Management System (IMS). Of the 1,198 counties initially considered, there were 355 counties in 18 states with reported cotton farms (or adjacent to counties with reported cotton farms) and reported presence of listed plant species. These counties represented 162 listed plant species. There were 1,697 species-county co-occurrence records considered across all plant taxa (see Table F-63).

In these counties, each species was evaluated with respect to the current listing status, county-level locations, species habitat requirements, and plant classification in order to determine whether exposure to dicamba from use on cotton with the DT trait could potentially result in effects to the species. Some listed species could be removed from concern for effects based on exclusions that currently exist and are documented. Exclusions that have been employed include change in species listing status, not present due to extirpation, historic observations (no observations since 1977 or earlier), habitat not in proximity to agriculture, product properties related to plant taxa selectivity, or species not in proximity to agriculture for other reasons. Table F-63, as reported in Frank and Kemman (2013), provides a summary of the results of the county-level analysis after exclusions have been considered. Species assigned a Not of Concern determination have information from a U.S. Fish & Wildlife Service (USFWS) or NatureServe source, or a state or local expert to indicate that the species is not present in the county or is not in proximity to cotton production.

Table F-63. Summary of Species Determinations for this Analysis (from Frank and Kemman, 2013)

Determination Type	Number of States	Number of Counties	Number of Species	Number of Co-Occurrences
Not of Concern	18	298	131	512[a]
Product-Property	14	151	39	207
Habitat	15	153	130	329
Species Management Practice[b]	2	2	2	2
Requires Further Analysis	18	357	162	647
Total				**1,697**
Total distinct[c]	**22**	**605**	**329**	

a Of the 512 co-occurrences with a Not of Concern determination, 507 of the determinations were supported by information from the U.S. Fish & Wildlife Service county list or a regional office expert; 5 determinations were supported by information from NatureServe or a state or local species expert.

b Species is present on public or private land protected by conservation plans or agreements.

c More than one determination type may be assigned to different county-level co-occurrences of the same species. Therefore, the total number of species (or counties) for all determination types is more than the total number of distinct species (or counties).

After considering co-occurrences for which exclusions apply, county-species co-occurrences remain in 18 states, in a total of 357 counties, and for 162 species, which require further analysis. As described in the EPA Overview Document (USEPA, 2004), the next step in the analysis is to consider these co-occurrences at the sub-county level evaluating the proximity of the species observation and the land areas that have the potential to be used for cotton production.

F.4.5.3. Sub-County Plant Species Observations Versus Land Use Proximity Analysis

The following discussion describes the analysis of proximity of relevant land use to sub-county locations of threatened or endangered plant species that have been identified as "requiring further analysis" in the county-level analysis (Frank and Kemman, 2013b). A summary of the spatial information used and the proximity analysis is provided in the sections that follow.

F.4.5.3.1. Land Use Information

Land cover data considered in this analysis were obtained from the National Land Cover Dataset (NLCD 2006) with a spatial resolution of 30-meters (NLCD, 2011). Data for the 2006 NLCD were collected from 2001-2006 and represent the best comprehensive collection of national land use and land cover information for the U.S (NLCD, 2011). "Relevant land use" considered were areas classified as Pasture/Hay (Class 81) or Cultivated Crops (Class 82) by the National Land Cover Database (NLCD) 2006 (NLCD 2011; Fry et al., 2011), in counties with reported cotton farms. This conservative approach considered that land designated as cultivated crops could potentially be used for production of cotton with the DT trait, and some pasture/hay fields could be converted to cultivated cropland.

For California, additional information regarding cotton production areas was obtained from the California Pesticide Use Reporting (PUR) database (California DPR 2013). Records from the PUR database were used to identify the Public Land Survey System (PLSS) sections where applications of pesticides to cotton were reported, as required by California regulations. As reported in Frank and Kemman (2013b), there were 13 California counties defined as having cotton production, based on Census of Agriculture information. For these counties, the PLSS sections with reported applications of pesticides to cotton for the California PUR reporting years of 2000 through 2011 were identified.

In some situations, available satellite imagery was used to verify the proximity of species observations to agricultural lands (a verification of the NLCD 2006 land use classification). The source of satellite imagery was either the dynamic map services provided by ESRI (including the "ESRI_Imagery_World_2D" map service), or the Bing map service.

F.4.5.3.2. Species Locations

FESTF Multi- Jurisdictional Database (MJD)

Threatened and endangered plant species location data at a sub-county level were obtained from the FIFRA Endangered Species Task Force Multi-Jurisdictional Database (FESTF MJD; NatureServe, 2012). The FESTF MJD consists of a "licensed dataset" drawn from NatureServe's Multi-Jurisdictional Database (MJD) licensed to FESTF. The MJD species observation records included additional data fields, such as date of last observation and observation notes; this information was evaluated and utilized when relevant to the proximity assessment.

The MJD location data were provided as polygons (areas representing where a listed plant species was observed; referred to as a "species observation"). The spatial dataset was provided in a format suitable for analysis and display using Geographic Information System (GIS) software. Polygons for listed dicots are as small as 5 square meters and as large as 377 square kilometers.

For the purposes of this analysis, species observations were considered "historic" if the "last observed date" for the observation (as reported by NatureServe in the MJD 2012 dataset) was prior to 1977. Additional observation-specific data available in the MJD 2012 dataset (e.g., field notes) were examined to identify observations that are noted to be "historic" or "extirpated." In some cases, species with observations later than 1976 were flagged as "extirpated." In situations of historic or extirpated species observations, no further analysis was conducted.

F.4.5.3.3. State-Specific Location Data

Spatial data depicting the locations of five plant species in selected Texas counties were obtained from the Texas Natural Diversity Database (TXNDD). This species location information was not included in the FESTF MJD 2012 datatset. Proximity between the TXNDD species observations and relevant land use was measured using tools available in the GIS software.

The Maryland state heritage program did not contribute data to the NatureServe MJD. Sub-county location information for species for Maryland was not available for this analysis. Additional research will be conducted to determine whether the Maryland plant species are near agriculture.

F.4.5.3.4. Proximity Database

For listed plant species observations available in the FESTF MJD 2012 dataset, proximity distances from each species observation (polygon) to NLCD 2006 Class 81 (Pasture/Hay) and Class 82 (Cultivated Crops) land area (or, for California, to survey sections in counties with reported pesticide applications to cotton; see further description below) were available, and were used to evaluate potential proximity to relevant land used for cotton production.

The FIFRA Endangered Species Task Force used the MJD 2012 dataset to prepare a database entitled "FESTF MJD 2012/NLCD 2006 Species Occurrence/Land Cover Proximity Database – Classes 81 and 82," and Classes 81 and 82 were included in this database (FESTF NatureServe 2012; Konkel and Frank 2012). From this database, the nearest distance of a species observation to relevant land use in a county with cotton farms was extracted for each species/county co-occurrence evaluated in Frank and Kemman (2013).

F.4.5.3.5. Proximity Analysis Process

It was concluded in the county-level evaluation for cotton with the DT trait (Frank and Kemman, 2013b) that certain listed plant species could not be excluded from concern (at the county level) due to potential exposure to dicamba during ground applications of dicamba to cotton with the DT trait. Therefore, it was necessary to assess the potential proximity of those listed plant species (those identified as "requiring further analysis" in the county-level evaluation) to agricultural land that could be used for cotton production. Proximity was also assessed for species assigned habitat determinations in Frank and Kemman (2013b).

The basic steps of the proximity analysis (as described in Carr and Orr, 2013a) were as follows:

1. Identify the plant species-county co-occurrences that were assigned a "requires further analysis" determination in the county-level evaluation (Frank and Kemman 2013b).

2. Obtain comprehensive spatial data regarding sub-county plant species locations, where available, for the states and counties identified in Step 1. Sub-county location information was not available for all species-county co-occurrences evaluated.

3. Identify land use suitable for cotton production, in counties with cotton production. Cotton production counties were defined in the same manner as was considered in the county-level analysis (Frank and Kemman 2013b). This definition was based on

three consecutive Censuses of Agriculture (for the years 1997, 2002, and 2007). If a cotton farm (or farms) was reported in a county for any of the three Censuses, then it was assumed that cotton production occurred in that county.

4. Using the FESTF Proximity Database (described in Section IV.E.3.d) in combination with GIS software, identify species observations that have overlap with or are within 450 feet of land use relevant for cotton production (i.e., have "potential proximity to relevant land use").

   The distance of 450 feet is greater than the distance from the edge of the dicamba application area to a point at which an effect on soybean plant height is no longer observed, when the proposed mandatory FIFRA application requirements for the dicamba diglycolamine salt are employed (Orr, et al., 2012; Honegger, 2012b). Utilizing the EPA screening assessment approach as described in the EPA Overview Document (USEPA, 2004), soybeans have been demonstrated to be the most sensitive species to the effects of dicamba (Porch et al., 2009a, 2009b), and plant height was the most sensitive endpoint in the vegetative vigor study (Honegger et al., 2013).

5. As indicated above, not all counties have sub-county species location information. In these cases, potential proximity was assumed , unless additional information was available to determine that the species was not within 450 feet of relevant land use. Thses records are referred to as "county-level record" in the tables summarizing the potential proximity results.

Where applicable, satellite imagery was used to assign a "no proximity" conclusion, even though the NLCD proximity distance was less than 450 feet. Generally, if the imagery indicated that the species location was not within 450 feet of tillable agricultural land, due either to mis-classification within the NLCD or due to land use change since the NLCD data were collected, then it was concluded that the species could be excluded from concern for effects of dicamba used on cotton containing the DT trait. Examples of non-agricultural land use that imagery could identify are developed residential areas, a grassy roadside, utility rights-of-way, shorelines, water bodies, and forest clear-cut areas.

Species and counties were identified as requiring further analysis at the conclusion of the county-level evaluation (Frank and Kemman 2013b). In this analysis, there were 162 distinct plant species in 357 counties in 18 states evaluated. Where species observations were available, there were 4,239 species observations evaluated for potential proximity to relevant land use for cotton production.

F.4.5.3.6. Conclusions of the Proximity Analysis

Table F-64 and Table F-65 present the results of the proximity analysis for the cotton production states included in this appendix, summarized in Table F-64 by U.S. FWS region and in Table F-65 by state.

Table F-64. Results of Proximity Analysis Presented (by Region)

US FWSRegion	Requires Further Analysis Number of:						With Potential Proximity to Relevant Land Use; Number of:				
	Species/ County Records [a]	States	Counties	Plant Species	Species Obs [b]	County-level Record[c]	States	Counties	Plant Species	Species Obs [b]	County-level Record[c]
Southwest (Region 2)	58[e]	3	40	28	333	4	3	16	14	38	4
Midwest (Region 3)	27	1	19	6	171	2	1	6	6	31	2
Southeast(Region 4)	358	9	225	61	2,438	28	9	113	30	475	25
Northeast (Region 5)	19	2	19	7	33	2	2	11	4	5	2
Mountain-Prairie(Region 6)	15	2	12	6	218	--	1	4	1	125	--
Pacific Southwest (Region 8)	170	2	42	68	1,048	27	1	9	9	11	4
Totals (unique)[d]	**648**	**18**	**357**	**162**	**4,239**	**63**	**16**	**159**	**58**	**685**	**37**

a As reported in the county-level analysis (Frank and Kemman, 2013b).

b Numbers represent species observation data available from the FESTF MJD dataset or from other Heritage Program sources. c Numbers represent species/county co-occurrences where sub-county location data was not available from the FESTF MJD 2012 dataset.

d This total may not equal the sum of the regional values, since some species are present in more than one county, state, or region.

e In the Southwest Region, one additional co-occurrence was evaluated, based on information obtained from the Texas Natural Diversity Database.

Table F-65. Results of Proximity Analysis Presented (by State)

State	Requires Further Analysis Number of:					With Potential Proximity to Relevant Land Use; Number of:			
	Species/ County Records [a]	Counties	Plant Species	Species Obs [b]	County-level Record[c]	Counties	Plant Species	Species Obs [b]	County-level Record[c]
Southwest (Region 2)									
Arizona	20	12	10	109	2	3	3	1	2
New Mexico	6	5	4	73	1	3	3	9	1
Texas	32[e]	23	12	151	1	10	9	28	1
Midwest (Region 3)									
Missouri	27	19	6	171	2	6	6	31	2
Southeast (Region 4)									
Alabama	58	36	14	151	20	26	14	40	18
Arkansas	12	12	3	83	--	3	1	27	--
Florida	64	19	32	767	2	5	3	5	1
Georgia	49	39	13	216	--	16	7	42	--
Louisiana	6	6	3	10	1	1	1	--	1
Mississippi	17	17	3	118	--	9	3	18	--
North Carolina	80	52	14	692	1	31	9	272	1
South Carolina	52	31	10	270	4	19	6	63	4
Tennessee	21	13	7	135	--	3	4	9	--
Northeast (Region 5)									
Maryland	2	2	2	--	2	2	2	--	2
Virginia	17	17	6	33	--	9	3	5	--
Mountain-Prairie (Region 6)									
Kansas	10	10	1	204	--	4	1	125	--
Utah	5	2	5	14	--	--	--	--	--
Pacific Southwest (Region 8)									
California	172	42	68	1,048	27	9	9	11	4
Totals	**648**	**357**	**162** [d]	**4,239** [d]	**63**	**17**	**159** [d]	**685** [d]	**37**

a As reported in the county-level analysis (Frank and Kemman, 2013b).

b Numbers represent species observation data available from the FESTF MJD 2012 dataset or from other Heritage Program sources. c Numbers represent species/county co-occurrences where sub-county location data was not available from the FESTF MJD 2012 dataset.

d This total may not equal the sum of the regional values, since some species or species observations are present in more than one region, state or county.

e In Texas, one additional co-occurrence was evaluated, based on information obtained from the Texas Natural Diversity Database.

F.4.5.4. Sub-county Areas for Potential Use Limitation and Mitigation Measures

Monsanto defined potential areas around threatened or endangered plant species locations where label restrictions related to threatened and endangered species may be required. These areas have been defined to ensure species protection. The three components needed for implementation of potential use limitation areas are:

4. definition of the sub-county areas that include threatened and endangered plant species locations, as well as additional area so that the listed species are protected from disturbance or collection by rare plant enthusiasts;

5. development of habitat descriptions for the listed plant species within these areas; and

6. definition of label requirements that provide listed plant species protection from potential dicamba exposure.

F.4.5.4.1. Sub-county Descriptions of Potential Use Limitation Areas

For the observations of threatened or endangered plant species that overlap or are within 450 feet of relevant land uses, the next step of the analysis is to identify these species observations in such a way that appropriate label restrictions can be applied. Because the sub-county species location information is confidential under the terms of the NatureServe licensing agreement, the species locations cannot be disclosed to the public (see Footnote 43). Therefore, each of the state-level agencies or programs that provided sub-county species location data to NatureServe was contacted to determine whether it was acceptable for the sub-county species location information to be available to the public with only an additional 450 feet distance applied as a "resolution distance" around the area identified as the species location. In some cases, this distance was acceptable. In most cases, the state programs requested that a larger area be identified to provide an additional layer of conservatism regarding the location of the species.

Proximity analysis tools available in GIS software were used to add the additional area requested by the state heritage programs to the species observation area. These "buffered" observations were then further expanded so that potential use limitation boundaries could be described using surrounding surface features, such as roads, creeks, rivers, and railroads, and land survey boundaries (sections), where available. Maps depicting each listed plant species observation with proximity to relevant land use and the subsequently derived potential use limitation area are presented in the confidential attachment of Carr and Orr (2013b).

F.4.5.4.2. Habitat Descriptions

Habitat descriptions have been developed for each threatened or endangered plant species for which areas of potential use limitation have been proposed. These descriptions were developed from plant species information available from government and academic sources. Within the areas described for potential use limitation, mandatory label restrictions are only considered necessary when the habitat for the listed species is present. These habitat descriptions are included in the detailed report (Carr and Orr, 2013b).

F.4.5.4.3. Label Restrictions

A proposed label has been submitted for the dicamba diglycolamine salt formulation for the new use on DGT cotton. This proposed label, which is currently pending before EPA, includes mandatory application requirements to minimize off-site movement. These requirements include implementation of a buffer when listed plant species are downwind from application areas. A further explanation of these measures to reduce off-site movement is presented in Honegger (2012b).

F.4.5.4.4. Overall Process for Sub-county Analysis

Polygons depicting threatened or endangered plant species locations that are within 450 feet of agricultural land where cotton could potentially be grown, based on Ag Census information, have been increased in size and geographically mapped to allow public presentation of areas where listed plant species may be present. In addition, while not making species names public, brief, clearly-worded habitat descriptions have been developed for each potential use limitation area to allow the applicator / grower to ascertain whether suitable habitat for the species is present in the area downwind from the planned application area. Because of the need to increase the size of the publicly identified area beyond the boundaries of the listed species location, it is proposed that only if the appropriate habitat is present would the buffer mandated by the proposed label apply.

F.4.5.4.5. Web-Based System to Communicate Use Limitations

To provide a convenient mechanism to present the locations of potential use limitation areas to growers/applicators, a web-based system similar to the system developed for glyphosate (www.Pre-Serve.org) is under development for dicamba. This web site will guide growers and applicators through a simple step-wise process to determine whether their fields fall within potential use limitation areas – areas where threatened or endangered plant species and/or habitat for those species may be present. Where fields do fall within potential use limitation areas and appropriate habitat is present, the web-based system will reiterate to the growers the mandatory steps (as specified on the proposed label) that must be taken to reduce exposure to threatened and endangered plant species and avoid effects on survival, growth, and reproduction of these species. As an alternative to using the web-based program, growers/applicators will be able to call a hotline to obtain this information.

F.4.5.5. Conclusion

The above discussion provides a summary of the multi-step process that has been used to assess potential effects to threatened and endangered plant species from the use of dicamba on cotton containing the DT trait. The process used to evaluate the potential proximity of listed plant species observations to relevant land use in U.S. counties with cotton production is described in detail. Comprehensive sub-county species location data and national land cover data were utilized.

In the 18 U.S. states where sub-county proximity was evaluated (listed in Table F-65), there are 58 listed plant species in 17 states (159 counties) where species observations are within 450 feet of relevant land use for cotton production (in counties with reported cotton farms), using best available data for species locations and land use. The observations within 450 feet of relevant land use were classified as having potential proximity to areas where dicamba could be used in production of DGT cotton.

The 450-foot proximity evaluation is considered conservative because of the possibility that unidentified local factors may render use limitations unnecessary in areas that this analysis identifies as having 450-foot proximity determinations.

In the EFED ecological risk assessment conducted for dicamba re-registration (USEPA, 2005), using a screening-level assessment, EPA scientists concluded that a "no effect" determination can be made for all dicamba uses for listed fish, aquatic invertebrates, and vascular aquatic plant species. The potential for adverse effects to listed birds and mammals, non-vascular aquatic plants and terrestrial and semi-aquatic plants could not be excluded based on the EPA screening-level assessment, the initial phase of analysis. However, since there are currently no listed non-vascular aquatic plants, and non-listed non-vascular aquatic plants have an RQ below the LOC, this taxon does not require further investigation at this time. Recognizing that screening-level analysis is only the first step in evaluating impacts on threatened and endangered species, the EFED Science Chapter (USEPA, 2005) indicates that "additional information on the biology of listed species, the locations of these species, and the locations of the use sites … could be considered along with available information on the fate and transport properties of the pesticide to determine the extent to which screening assumptions regarding an action area apply to a particular listed organism."

When the properties of dicamba and species-specific information are taken into account, these reports demonstrate that monocotyledonous terrestrial and semi-aquatic plants outside the treated area also would not be affected (Honegger et al., 2013). The identification of species observations with potential proximity to land relevant for cotton production, and the definition of use limitation areas for such observations that are readily available to the grower/applicator, coupled with the proposed mandatory application requirements on the proposed label, which is currently before EPA, provide a mechanism to minimize exposure to dicamba so that threatened and endangered terrestrial plant species in taxa other than monocots are not affected by dicamba application to cotton containing the dicamba tolerance trait.

Table F-66 summarizes the results of each step in this process. The analysis was initiated by considering all counties in the United States where cotton farms have been reported and in which threatened or endangered plant species have been observed. The presence of a single cotton farm in any one of three Censuses of Agriculture spanning a ten-year period resulted in inclusion of that county in the analysis. In addition, listed species from counties adjacent to cotton production counties were also included in the analysis. Exclusions for habitat protections, proximity analysis, and observation notes were used to identify areas and species where a potential for effects from exposure to dicamba could not be excluded. These areas were defined with precision to protect species and not reveal their exact location. By providing a mechanism to identify these areas to applicators and growers, required application practices on the proposed herbicide label can be used to avoid exposure so that these species would not be affected by dicamba use on DGT cotton.

Table F-66. Numbers of counties, listed plant species, and observations involved in the analysis for cotton with the DT trait at major steps in the analysis

Analysis Category	Number of:					
	States	Counties	Listed Plant Species	Species-County Co-occurrences	Species Observations[a]	County-level Presence[b]
Cotton production counties & adjacent counties [c]	22	1,198	--	--	--	
Cotton production counties & adjacent counties that have presence of listed plant species [c]	22	605	329	--	--	
Species-county co-occurrences evaluated for potential proximity (450-ft) to relevant land use [d]	18	357	162	648[e]	4,239 [a]	50
Species observations with potential proximity to relevant land use [f]	17	159	58	199	685 [a]	37

a Numbers represent species observation data available from the FESTF MJD dataset or from other Heritage Program sources.

b Numbers represent species/county co-occurrences where sub-county location data was not available from the FESTF MJD 2012 dataset.

c As reported in Frank and Kemman (2013b).

d These co-occurrences are the records assigned a "Requires Further Analysis" determination in Frank and Kemman (2013b).

e This includes 647 co-occurrences records (as reported in Frank and Kemman, 2013) and 1 additional record, to account for information received from the Texas heritage program, indicating presence of a species in an additional county not considered by Frank and Kemman (2013).

f These values exclude species observations that are Historic or Extirpated, or have a last observed date prior to 1977.

F.4.6. Impact on Threatened or Endangered Animal Species from Dicamba Use on DGT Cotton

F.4.6.1. Endangered Species Exposure and Effects Analysis

F.4.6.1.1. Screening Level Analysis

An initial analysis was conducted (Honegger et al., 2013) of the potential for exposure and effects to all animal taxa from dicamba use in DGT cotton based on a use pattern more conservative than that pending for cotton at EPA using the EPA deterministic risk quotient approach (USEPA, 2004).[210] The use pattern for dicamba utilized in this analysis was a pre-emergence application at a rate of 1.0 lb dicamba acid equivalents per acre (a.e/A) followed by two post-emergence applications each at a rate of 0.5 lb a.e./A with a 6-day interval between the pre-emergence application and the first post-emergence application, and a 6-day interval between the two post-emergence applications[211], with all applications being made using ground application equipment.[212] The 6-day application interval utilized in this analysis is shorter than the minimum interval mandated under the proposed label (7 days), and seven days is expected to be shorter than the interval actually used in practice, since a grower will typically allow weed regrowth to occur before making a new application – and that generally takes more than 7 days. Thus, the 6-day interval was assumed in an abundance of caution, to ensure a highly conservative exposure estimate, and to maintain consistency with the dicamba tolerant soy endangered species assessments.

Initial exposure estimates using the above described use pattern were based on standard EPA exposure models and default assumptions; toxicity effects endpoints were taken from the EPA Environmental Fate and Effects Division (EFED) Reregistration Chapter for Dicamba/Dicamba Salts (USEPA, 2005). The conclusion from this initial screening analysis, based on risk quotients (RQs) being less than the EPA Levels of Concern (LOCs), is that dicamba use on DGT cotton would not affect threatened and endangered species in the following taxa:[213]

- Fish, aquatic phase amphibians, and aquatic invertebrates (acute or chronic exposure)
- Birds, terrestrial-phase amphibians, and reptiles (chronic exposure)
- Mammals (acute exposure)
- Insects[214]

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210 This approach calculates a risk quotient (RQ) by dividing the Estimated Environmental Concentration (EEC) by the appropriate toxicity endpoint, and then compares that value with the appropriate Level of Concern (LOC). The LOC is established by EPA policy as the criteria used by EPA in comparison to the calculated risk quotient (RQ) to assess the potential for a pesticide use to cause adverse effects to non-target organisms.

211 This use pattern is referred to in subsequent reports as the 6-day interval maximum-use pattern (6diMUP).

212 The proposed dicamba label for DGT cotton will not permit aerial application.

213 "If assumptions associated with the screening level action area result in RQs that are below the listed species LOCs, a "no effect" determination conclusion is made with respect to listed species in that taxa, and no further refinement of the action area is necessary." EFED Reregistration Chapter for Dicamba/Dicamba Salts, p. 72.

214 RQ calculations for insects are based on acute contact exposure. The RQ for the honey bee, as a surrogate for terrestrial invertebrates, was not a definitive value. Since there was no mortality in the acute contact exposure study, a definitive LD_{50} could

These conclusions for aquatic animals, birds, mammals and insects are consistent with the risk conclusions presented in the EFED Reregistration Chapter for Dicamba/ Dicamba Salts (USEPA, 2005 and 2009).

The levels of concern considered by EPA for threatened and endangered (listed) species risk assessments are given in Table F-67.

Table F-67. EPA Levals of Concern for Threatened and Endangered Species (US EPA, 2004)

Risk Presumption	Calculation for Risk Quotient	Level of Concern
Birds		
Acute Risk	EEC/LC_{50} (application of a liquid) or LD_{50}/ft^2 or LD_{50}/day (application as a granule, bait, or treated seed)	0.1
Chronic Risk	EEC/NOAEC	1.0
Wild Mammals		
Acute Risk	EEC/LC_{50} (application of a liquid) or LD_{50}/ft^2 or LD_{50}/day (application of a granule, bait, or treated seed)	0.1
Chronic Risk	EEC/NOAEC	1.0
Terrestrial Invertebrates		
Acute Risk	EEC/LD_{50}	0.05
Aquatic Animals		
Acute Risk	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/MATC or NOAEC	1.0

F.4.6.1.2. Refinement to the Screening Level Analysis - Use of Dicamba-specific Foliar Residue Values

Consistent with EPA guidance found in the Overview Document (USEPA, 2004), if screening-level assessments do not result in a "no effect" determination, EPA does not then conclude that an herbicide "may affect" threatened and endangered species; rather, more refined assessments must be conducted to ascertain if any effects are expected to occur. Accordingly, for threatened and endangered animal species and the exposure durations for which the risk quotient exceeded the LOC in the screening level analysis (acute exposure for birds, amphibians and reptiles, and chronic exposure for mammals), refined exposure estimates were developed utilizing measured dicamba

not be determined. The resulting RQ was <0.12. However, since there was no mortality in the study, and the dose tested was more than seven times greater than upper bound maximum default residue value for arthropods calculated from T-REX using the dicamba- specific foliar decline value, the initial assessment concluded that terrestrial invertebrates would not be affected by dicamba use on DT-soybeans. This is consistent with the dicamba science chapter (USEPA, 2005a) conclusion that dicamba is practically non-toxic to bees.

residues on pasture grasses[215] as representative residues for the short grass component of animal diets (Honegger et al., 2013). These data were from an extensive battery of residue studies conducted under Good Laboratory Practices by dicamba registrants. These data were used to estimate dicamba-specific residues for the grass components of animal diets[216], instead of using the EPA default residue values based on the Kenaga nomogram (Hoerger and Kenaga, 1972) as revised by Fletcher (1994). This approach is consistent with the approach described in the Overview Document for certain types of pesticides (US EPA, 2004).

In addition, a Monsanto soybean residue study, and a grass residue study and a wheat residue study from a dicamba registrant, included forage sampling at several time points soon after application. From these studies, the rate of decline of dicamba residues on soybean, grass forage, and wheat foliage could be determined, and the time required for dissipation of 50 percent of the Day Zero residues (DT_{50}) calculated.[217] The Overview Document (USEPA, 2004)[218] indicates that chemical-specific foliar dissipation values can be used for multiple application exposure modeling for wildlife; accordingly, as a conservative assumption, the longest of the representative dicamba-specific foliar DT_{50} values for these three crops (5.63 days, for pasture grass) was used in the calculation of the dicamba-specific residues for chronic exposure. For grass and broadleaf dietary items, both mean and upper bound residue values[219] were considered in the evaluation; these levels are suitable to estimate realistic (mean) and worst case (upper bound) levels of exposure. A comparison of the default upper bound residue values and dicamba-specific upper bound residue values is given in Table F-68.

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215 Residue values from these studies were converted to values expressed as parts per million per pound dicamba acid from residues values for application rates of 0.5, 1.0, and 2.0 lb a.e./A for grasses.

216 The ratio of Kenaga residue values for tall vs. short grass was used with the measured pasture grass residue value to calculate a corresponding tall grass residue value.

217 For the pasture grass and wheat residue studies, there were over 50 treatments per study for which a DT_{50} value could be calculated. In accordance with USEPA guidance, the 90th percentile upper confidence limit of the mean DT_{50} value was selected as an appropriate DT_{50} value to use for calculation of residue decline for these crops. For the soybean residue study, only six treatments were available to calculate DT_{50} values; thus, the maximum value was considered to represent residue decline in soybean forage.

218 Overview Document (USEPA, 2004), pg. 13.

219 Considering the number of measured residue values available for pasture grasses to calculate the upper bound residue, for chronic exposures, use of a refined maximum residue value (90th percentile value) was still considered a "worst case" conservative approach and is consistent with probabilistic approaches outlined in ECOFRAM (1999).

Table F-68. Comparison of Default Kenaga Residues and Dicamba-specific Residues in Food-Items

	Maximum dicamba residues in food items (ppm a.e.) based on a 1 lb a.e./A pre-emergence application followed by two sequential post-emergence 0.5 lb a.e./A applications assuming 6-day intervals between applications (6diMUP)				
	Short Grass	Tall Grass	Broadleaf Plants	Fruits/ Pods/Seeds	Arthropods
Using upper bound Kenaga residues & default foliar DT_{50} (35 days)					
Day 0 (after 1st application)	240.0	110.0	135.0	15.0	94.0
Maximum residue[a] (after 3rd application)	415.8	190.6	233.9	26.0	162.9
Using upper bound Kenaga residues & dicamba-specific foliar DT_{50} (5.63 days)					
Day 0 and Maximum residue[a] (after 1st application)	240.0	110.0	135.0	15.0	94.0
Using Dicamba-specific maximum measured residues (short and tall grass) & foliar DT_{50} (5.63 days)					
Day 0 and Maximum residue[a] (after 1st application)	179.0	82.0	135.0	15.0	94.0
Using Dicamba-specific refined maximum measured residues (90th percentile value for short and tall grasses) & foliar DT_{50} (5.63 days)					
Day 0 and Maximum residue[a] (after 1st application)	131.0	60.0	135.0	15.0	94.0

a Using the default foliar DT50, the highest residue occurs immediately after the third application. Using the dicamba-specific DT50, the highest residue occurs immediately after the first application.

These refined residue values for dietary items were considered when using the EPA model T-REX (v1.5.2; USEPA, 2013) for the calculation of risk quotients and subsequent comparison to LOCs for acute exposures to birds, terrestrial amphibians, and reptiles, and for chronic exposures to mammals.[220]

Risk quotients for chronic exposure to mammals calculated using refined maximum measured upper bound residues slightly exceed the LOC for small and medium-sized mammals consuming short grass or broadleaf plants; however, utilizing mean residue values as a further refinement, risk quotients are all below the LOC (Table F-69) leading to a conclusion of no effect on these species. This is consistent with the finding in the EFED Science Chapter for dicamba (USEPA, 2005) and the revised RED (USEPA, 2009) for a single application rate of 1.0 lb a.e./A. Because there will be

220 The T-REX model is not designed to allow modification of the dietary food item residues. Thus, the dicamba-specific residues reported in Table F-68 were considered in the risk quotient calculations by applying a correction factor to the estimated environmental concentrations (EEC) values computed using the standard T-REX model for a single 1-lb/A application.

at most only three applications per year and dicamba dissipates rapidly, an individual small- or medium-sized mammal will not chronically consume foliage containing maximum residue levels from dicamba-treated fields. Therefore, reliance on dicamba-specific Day 0 mean residue values is also a conservative dietary exposure estimate for chronic exposure that is expressly countenanced by EPA.[221] Nonetheless, a refined county-level analysis was conducted for chronic exposure to mammals.

Table F-69. Risk Quotients for Chronic Exposure for Mammalian Species Based on Dicamba-Specific Residue Values and DT_{50}.

Diet	Mammal Size (g)	Risk Quotient[a,b] using Upper Bound Residues	Risk Quotient[a] using Mean Residues
Short Grass	15	**1.26**	0.75
	35	**1.08**	0.64
	1000	0.57	0.34
Tall Grass	15	0.58	0.32
	35	0.49	0.27
	1000	0.26	0.15
Broadleaf Plants	15	**1.30**	0.43
	35	**1.11**	0.37
	1000	0.60	0.20
Fruits/Pods	15	0.14	0.07
	35	0.12	0.06
	1000	0.07	0.03
Arthropods	15	0.91	0.63
	35	0.77	0.54
	1000	0.41	0.29
Seeds	15	0.03	0.02
	35	0.03	0.01
	1000	0.02	<0.01

a Dicamba-specific refined residue values based on a 1 lb a.e./A application rate were 131, 60.0, 135.0, 15.0, 94.0 and 15.0 mg a.e./kg diet, respectively, for upper bound values for short grass; tall grass; broadleaf plants; fruits/ pods; arthropods; and seeds, and 77.9, 33.0, 45.0, 7.0, 65.0 and 7.0 mg a.e./kg, respectively, for mean residues. The dicamba-specific residue decline DT_{50} of 5.63 days instead of the EPA default value of 35 days was also used in determining the peak residue value resulting from the three sequential applications.

b Bold font indicates that the RQ exceeds the LOC (1.0).

221 Overview Document (USEPA, 2004), p. 40.

With respect to birds, analyses were performed using maximum measured dicamba residue values (Table F-68) for dose-based RQ calculations for acute exposure. The following could be excluded from concern (and, therefore, no effects would be expected to occur): birds of all sizes consuming only fruits/pods or seeds and large birds consuming tall grass or arthropods. Small and medium-sized birds consuming broadleaf plants, arthropods or grasses and large birds consuming short grass or broadleaf plants required further analysis (Table F-70).

Refined analyses were conducted for birds for which the dose-based RQ values exceeded the LOC; however, this was a conservative approach since the subacute dietary-based RQ values, based on maximum measured upper bound residues (Table F-68), are all well below the LOC (0.1); except for birds consuming a short grass diet. The short grass RQ (<0.12) is not definitively below the LOC; however, considering that no listed species in the continental U.S. consume grasses as the primary diet item (Sullivan and Wisk, 2012) and taking into account the toxicity value used in the dietary assessment (>1522 mg/kg_{diet}) is actually an unbounded NOEC value, effects from short-term exposure to dicamba used on DGT cotton can be excluded from concern.[222]

Because birds are the surrogate species for terrestrial phase amphibians and reptiles, further analysis was also conducted to ensure that amphibians and reptiles could be excluded from concern for adverse effect.

Table F-70. Risk Quotients for Acute Exposure to Birds Using Maximum Measured Dicamba Residues and Dicamba-specific Residue Decline Values

Diet	Acute RQs: (Dose-based EEC/adjusted LD50)[a]		
	Upper Bound Residues		
	20 g Small	100 g Medium	1000 g Large
Short grass	**1.08**	**0.48**	**0.15**
Tall grass	**0.49**	**0.22**	0.07
Broadleaf plants	**0.81**	**0.36**	**0.12**
Fruits/pods	0.09	0.04	0.01
Arthropods	**0.57**	**0.25**	0.08
Seeds	0.02	<0.01	<0.01

222 The toxicity value (>1522 mg/kg_{diet}) used to calculate the RQ is a concentration in feed at which no effect was observed rather than a concentration at which 50% mortality would be predicted. The short grass EEC from Table F-68 is 179 mg/kg-food item. This estimated concentration on short grass that birds might be consuming is less than one eighth of the dietary concentration at which no effects were observed; therefore, there will be no effect on these species from short-term exposure to dicamba used on DGT cotton.

Food Item	Dietary-based RQs (Dietary-based EEC/LC50 or NOAEC)			
	Upper Bound Residues		Mean Residues	
	Subacute	Chronic	Subacute	Chronic
Short grass	**<0.12**	0.26	<0.05	0.11
Tall grass	<0.05	0.12	<0.02	0.05
Broadleaf plants	<0.09	0.19	<0.03	0.06
Fruits/pods/seeds	<0.01	0.02	<0.01	0.01
Arthropods	<0.07	0.14	<0.04	0.09

[a] Bold numbers indicate the RQ exceeds the LOC (0.1).

F.4.6.1.3. Refined Analysis Considering Species County-level Location

Certain sizes of threatened and endangered birds, amphibians, reptiles, and mammals had risk quotients exceeding the LOC as a result of the use of dicamba on DGT cotton based on a default exposure analysis or an analysis using refined residue and residue decline values. Consistent with guidance set forth in the EPA Overview Document[223], a more detailed evaluation of the locations of these threatened and endangered species relative to potential areas of cotton production was undertaken.

First, the co-occurrence of threatened or endangered species and the production of cotton was determined at the county level. For completeness, all threatened or endangered avian, amphibian, reptile, and mammalian species were included in the county-level analysis (including species proposed for listing, but excluding wholly aquatic species). Listing status[224], species habitat and proximity data to cotton production at the county-level were evaluated for these identified species to determine which species in which counties can be excluded from further evaluation and which require further evaluation. This process is referred to as the "county-level analysis" (Frank and Kemman, 2013b) and is discussed in more detail in Section IV.F.2 below. The sub-county location of threatened and endangered species observations and land relevant for cotton production was also considered for some species. This proximity evaluation is discussed in Section IV.F.3.

F.4.6.1.4. Refined Analysis Considering Species Biological Characteristics

Next, the Overview Document provides that – for those threatened or endangered species (avian, reptile, amphibian (terrestrial-phase), and mammalian) that require further evaluation – each species be considered individually to determine whether it can be excluded from concern for potential

223 Overview Document (USEPA, 2004), p. 69.

224 Listing status refers to whether the species is classified as threatened, endangered, or no longer considered threatened or endangered (delisted).

effects based on body weight or dietary considerations. Accordingly, for these animal species, refined risk quotient calculations were performed considering individual species body weight, food type and food intake rate, as described in Section IV.F.4 and in Schuler et al. (2013a), and consistent with EPA guidance found in the Overview Document (USEPA, 2004). Based on these refined species-specific analyses, as discussed below, individual animal species were excluded from concern, and, therefore, would not be affected by dicamba use on DGT cotton.

F.4.6.2. County-level Analysis: Co-occurrence of Listed Species in Crop Production Areas

The procedures used in the county-level analysis to identify counties containing threatened or endangered species that require further evaluation are described in detail in Frank and Kemman (2013b). The U.S. counties where cotton production was reported were identified using available data from the U.S. Census of Agriculture. Census data from 1997, 2002 and 2007 were utilized to identify counties with reported cotton farms.[225] Any county with a reported cotton farm was considered in this analysis.[226] This information was supplemented with cotton pesticide application data available from the California Department of Pesticide Regulation for the years 2000-2011. Counties without cotton production, but adjacent to counties with cotton production were also identified. In total, there were 1,198 counties considered in this analysis (733 cotton counties, 465 adjacent counties).

In the identified counties, available county-level presence information for threatened or endangered avian, terrestrial reptile, terrestrial-phase amphibian, and mammalian species was evaluated, using county-level location information compiled by the FIFRA Endangered Species Task Force (FESTF) and available in the FESTF Information Management System (IMS).[227] Species that were wholly aquatic (e.g. whales) were not included. Of the 1,198 counties initially considered, there were 1,063 counties with listed species in the taxa of interest for dicamba and where cotton is produced (or in counties adjacent to cotton production counties). These counties reflect the reported presence of 118 distinct species in 24 states. There were 3,181 species/county co-occurrence records considered across all animal taxa evaluated. In these counties, each species was evaluated with respect to the current listing status, county-level locations, species biology, species habitat requirements, and (when possible) species proximity to land relevant for cotton production, in order to determine whether exposure to dicamba from use on DGT cotton could potentially result in effects to the species.

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225 Conducted every five years, the USDA Census of Agriculture provides a detailed picture of U.S. farms and ranches and the people who operate them. It is the only source of uniform, comprehensive agricultural data for every state and county in the United States. The farm and acreage information for the 1997 census year was taken from the 2002 Census of Agriculture (USDA, 2004), which reports cotton information for both 1997 and 2002 census years.

226 This analysis assumed that the reported presence of a single cotton farm in any of the last three Censuses (1997, 2002, and 2007) was an indicator that the county contained land suitable for cotton production.

227 The FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) Endangered Species Task Force (FESTF) Information Management System 2.7 (IMS) (referred to as the "FESTF IMS") was developed in order to meet the legal obligations of its member companies to submit data required by EPA/OPP under FIFRA (as described in Pesticide Registration Notice 2000-2) in support of the members' registration and re-registration actions. The purpose of the IMS is to meet the data requirements in a manner that significantly improves the consistency, quality, availability and use of existing information on threatened and endangered species and pesticide use. http://www.festf.org/visitors/default.asp.

Some listed species could be removed from concern for effects based on exclusions that currently exist and are documented in Frank and Kemman (2013b). Exclusions that have been employed include change in species listing status, species not present due to extirpation[228], habitat not in proximity to agriculture, lack of proximity to agricultural lands in counties with cotton farms[229], product properties[230], and species not in proximity to agriculture for other reasons.

The proximity analysis at the sub-county level as described in Section IV.F.3 and species-specific refinements as described in Section IV.F.4 have been utilized in conjunction with the county-level identification of co-occurrences to evaluate potential effects to threatened and endangered species as discussed in the EPA Overview Document.[231] T-REX was utilized for birds and mammals to calculate species- and diet-specific risk quotients. For amphibians and other relevant species, was utilized to calculate species- and diet-specific risk quotients for amphibians and reptiles with similar methods to those used in the assessments of the California red-legged frog (US EPA, 2008b). Diet information was utilized for individual species of birds, reptiles, and mammals to determine if actual diet considerations can justify removing a species from concern.

F.4.6.3. Sub-County Animal Species Observations versus Land Use Proximity Analysis

The analysis of proximity of relevant land use to sub-county locations of threatened or endangered animal species identified in the county-level analysis (Frank and Kemman, 2013c) is reported in Schuler et al. (2013a) and is summarized in the sections that follow.

F.4.6.3.1. Land Use Information

For the contiguous U.S., land cover data considered in this analysis were obtained from the National Land Cover Dataset (NLCD 2006) (minimum mapping unit: 30-meters)[232]. Data for the NLCD 2006 dataset were collected from 2001 and 2006 and represent the best comprehensive collection of national land use and land cover information for the U.S (NLCD, 2011). The land cover classes of pasture/hay (Class 81) and cultivated crops (Class 82) were considered "relevant land use" for this analysis since land designated as cultivated crops could potentially be used for production of DGT cotton, and some pasture/hay fields could be converted to cultivated cropland. In addition, for California, sections where herbicide applications on cotton have been reported were also considered a source of land use information.

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228 An extirpated species is defined as "a species no longer surviving in regions that were once part of its range" (http://www.fws.gov/midwest/endangered/glossary/index.html).

229 Based on National Land Cover Database (NLCD) 2006 land use information.

230 A Product Property exclusion is based on a quantitative analysis of dicamba properties beyond the screening level analysis in the EFED Reregistration Chapter (USEPA, 2005). Specifically, this analysis involves assessing use of measured foliar residues and foliar decline rates following dicamba applications, adjusted to reflect the use pattern for DGT cotton. The size and diet of the animal species are also considered.

231 Overview Document (USEPA, 2004), p. 69 and p. 67, respectively.

232 National Land Cover Database 2006 (NLCD 2006). URL: http://www.mrlc.gov/nlcd2006.php

F.4.6.3.2. Species Locations

FESTF Multi- Jurisdictional Database (MJD)

Threatened and endangered animal species location data at a sub-county level were obtained from the FIFRA Endangered Species Task Force Multi-Jurisdictional Database (FESTF MJD; NatureServe 2012). The FESTF MJD consists of a "licensed dataset" drawn from NatureServe's Multi-Jurisdictional Database (MJD) licensed to FESTF.[233] The MJD species observation records included additional data fields, such as date of last observation and observation notes; this information was evaluated and utilized when relevant to the proximity assessment.

The MJD location data were provided as polygons (areas representing where a listed species was observed; referred to as a "species observation"). The spatial dataset was provided in a format suitable for analysis and display using Geographic Information System (GIS) software.

For the purposes of this analysis, species observations were considered "historic" if the "last observed date" for the observation (as reported by NatureServe in the FESTF MJD 2012 dataset) was prior to 1977 [234] or if the observation was noted to be "Historical" or "Extirpated" in the FESTF MJD 2012 dataset licensed from NatureServe.

F.4.6.3.3. Proximity Analysis Process

Proximity distances from each species observation (polygon) in the FESTF MJD 2012 dataset to NLCD 2006 Class 81 (Pasture/Hay) and Class 82 (Cultivated Crops) land area were available, and were used to evaluate potential proximity to land suitable for cotton production. The FIFRA Endangered Species Task Force used the MJD 2012 dataset to prepare a database entitled "FESTF MJD 2012/NLCD 2006 Species Occurrence/Land Cover Proximity Database – Classes 81 and 82", and Classes 81 and 82 were included in this database. From this database, the nearest distance of a species observation to relevant land use in a cotton production county was extracted for each species/county co-occurrence evaluated in Frank and Kemman (2013c).

Under the proximity analysis process, the distance evaluated for proximity of a species to relevant land use for cotton production was determined based on each species' home range, i.e., the area over which an animal normally travels and searches for food. A species may be excluded from concern in a particular county if the nearest distance of current species observations[235] in that county to land

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233 Under the terms of the FESTF license with NatureServe, the sub-county threatened and endangered species location data are confidential information available only to FESTF, FESTF member companies (including FESTF "Level II" companies), and EPA-OPP (Office of Pesticide Programs) staff reviewing FESTF member-company registrations. Information based on the sub-county species location data may be shared with cooperating federal and state agencies for regulatory decision-making related to endangered species assessments for Monsanto products.

234 A time period for observations beginning in 1977 is considered a conservative time period for this analysis.

235 For the purposes of this analysis, species observations were not considered current if the last observed date was prior to 1977, or the observation was classified as Historical or Extirpated (as reported by NatureServe in the MJD 2012 dataset).

relevant for cotton production was greater than the species' home range, based on best available information (on home range and on cotton production areas).

The California Pesticide Using Reporting database was also utilized to identify Public Land Survey Sections in the 13 California counties considered to have cotton production, based on Census of Agriculture information, where pesticide applications had been made to cotton, and hence were sections where cotton has been grown. Pesticide Use Reports for the years 2000–2011 were used for this determination.

F.4.6.4. Species-specific Risk Quotient Calculations

Consistent with EPA's Overview Document, species-specific dietary exposure was assessed considering animal body weight and diet (Schuler et al., 2013a) for birds and mammals of certain sizes, where risk quotients exceeded the level of concern after the initial refinements described above. A similar assessment was conducted for amphibians and reptiles because birds serve as the surrogate for terrestrial phase amphibians and reptiles. Biological information was gathered from a number of sources, including U.S. Fish and Wildlife Service (USFWS) species recovery plans, primary literature, and other technical sources (e.g. NatureServe[236]).

F.4.6.4.1. Mammals

In the county-level endangered species analysis, 51 threatened or endangered mammalian species were identified as potentially being present in or adjacent to a county with cotton production (Frank and Kemman, 2013c). Of the original 51 species, 11 species were removed from consideration based on Habitat determinations and 6 species were deemed Not of Concern[237] across all the counties evaluated (Frank and Kemman, 2013c).

The remaining 34 species of mammals were examined for the potential for chronic effects based on proximity to land relevant for cotton production and biological characteristics (i.e., dietary preferences and body size). The analysis progressed in a step-wise fashion (see Schuler et al., 2013c):

- The proximity of each species observation to relevant land use for cotton production was compared to species home range information. Of the 34 species evaluated in this refined analysis, 5 species were excluded from concern due to lack of proximity to land relevant for cotton production,[238] and 6 additional species were excluded from concern based on a combination of Not of Concern and Proximity determinations.

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236 NatureServe is a non-profit conservation organization that collects detailed local information on plants, animals, and ecosystems. NatureServe has a public website available at http://www.natureserve.org .

237 "Not of Concern" Determination: *Species co-occurrences that are not of concern.* Physical or regulatory factors provide clear evidence that a species is not of concern in a particular county. Examples include delisted species, no current presence, and historical or extirpated species.

238 For all county co-occurrences that did not have applicable Not of Concern determinations.

- The 23 remaining species received Product Property determinations (Diet Exclusions)[239], since based on body size and diet, the RQs were less than LOC considering chronic exposure to upper bound residues.

- All calculations were based on the assumption that animals eat 100% of their diet at the upper bound residue levels. This is an extremely conservative assumption for a chronic exposure scenario. Based on the EPA Overview Document for Endangered and Threatened Species Effects Determinations (US EPA 2004), the use of the mean residue value is an appropriate refinement for chronic exposures. When consumption of food containing the mean residue value is assumed, the dose-based chronic risk quotients are well below the LOC of 1 (Table F-69) for all diet types and body sizes, indicating that threatened or endangered wild mammals can be excluded from concern and, therefore, would not be affected. [240]

- The Diet Exclusion was also applicable to the species assigned Proximity or Not of Concern determinations, resulting in a total of 34 mammalian species where a Diet Exclusion was applicable.

In summary, it can be concluded that no effects to mammalian species will result from the use of dicamba on DGT cotton.

F.4.6.4.2. Birds

In the county-level endangered species analysis, 37 threatened or endangered avian species were identified as potentially being present in or adjacent to a county with cotton production (Frank and Kemman 2013b).

- Of the original 37 species, 4 species were removed from consideration based on Habitat determinations, and 1 species was deemed Not of Concern[237] across all the counties evaluated (Frank and Kemman 2013c).

- For the remaining species, the proximity of each species observation to relevant land use for cotton production was compared to species home range information. Of the 32 species evaluated in the refined analysis, 3 were removed from concern due to a lack of proximity to land relevant for cotton production,[241] and an additional 4 species were excluded from

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239 This determination type identifies a particular species or taxon as not at risk based on the properties of the product (dicamba applied to DGT cotton) when certain biological factors such as size (e.g. >1 kg) and diet (e.g., carnivorous, frugivorous, etc.) are considered.

240 Considering the rapid rate of dicamba foliar residue dissipation, even chronic RQs calculated for small mammals with the refined maximum measured residues only exceed the LOC for up to 2 days, not a sufficient duration to be considered a chronic exposure

241 For all county co-occurrences that did not have applicable Not of Concern determinations.

concern based on a combination of Not of Concern and Proximity determinations (Schuler et al, 2013c).

- Of the remaining species evaluated in this refined analysis, 14 were assigned Product Property determinations (Diet Exclusion) as the primary determination because their T-REX acute RQs were less than the LOC based on characteristics of diet and body weight or their diets did not include items considered in the T-REX model (e.g., aquatic animals) (Schuler et al., 2013c).[242]

- Using measured upper-bound dicamba residue values, RQ values exceeded the acute LOC of 0.1 only for small and medium-sized birds that consume grasses, broadleaf plants, or arthropods, and large birds consuming short grass and broadleaf plants.

- Dose-based RQs calculated for 11 species using the acute LD50 value exceeded the acute LOC of 0.1 for the dose-based upper bound residues indicating that further refinement should be considered (described below).

- Based on the refinements (see Schuler et al., 2013a), these remaining 11 species were assigned Product Property determinations (Feeding Exclusion)[243] because the upper bound EECs calculated for these **s**pecies were lower than dose-based NOELs calculated from acute dietary exposure studies.

- The Diet and Feeding Exclusions were also applicable to the species assigned Proximity or Not of Concern determinations, resulting in totals of 15 species where a Diet Exclusion was applicable, and 17 species where a Feeding Exclusion was applicable.

Moreover, this analysis is conservative because it is likely that the birds would not be in cotton fields actively foraging, but rather foraging in the adjacent habitats (e.g., tree canopy) outside of the fields. Threatened and endangered species are strongly associated with their specific habitat type and, therefore, it is improbable that 100% of the bird's diet would consist of dietary items exposed to dicamba in the field. Additionally, EPA's default approach to assessing acute risk is based on a single oral gavage dose (i.e., the entire dose is delivered to the animal at one time, typically after being dissolved in corn oil). In reality, of course, any pesticide exposure will not occur in this manner – but rather through dietary consumption of dicamba-exposed prey or food items. As a result, the gavage route of administration overestimates the exposure expected to occur in nature,

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242 Diet items not included in T-REX were aquatic animals and small- to medium-sized mammals as prey. Exposure to dicamba residues from the consumption of aquatic animals was not considered to be of concern due to low surface water concentrations (Honegger et al., 2013) and a low bioconcentration factor (BCF). Consumption of small- to medium-sized wild mammals by large carnivorous mammals (i.e. 1 kg or larger) is not a concern because dicamba does not bioaccumulate in mammalian tissues (U.S. EPA, 2005) and residues from food items that a prey might have consumed would not result in RQs exceeding the LOC for species of 1 kg or larger.

243 This determination type identifies a particular species as not at risk based on the properties of the product (dicamba applied to DGT cotton) when certain biological factors such as size (e.g. >1 kg) and diet (e.g., carnivorous, frugivorous, etc.) are considered.

and methods resulting in a dose-delivery over time (e.g., dietary exposure) are more environmentally relevant. Therefore, the use of the acute oral toxicity test (i.e., oral gavage) to predict risk of dicamba to birds in this case should be considered to be a screening-level approach that is expected to overestimate actual risk.

An acceptable refinement to the screening level risk assessment, based on guidance in the US EPA Overview Document on Ecological Risk Assessment Process for Endangered and Threatened Species Effects Determinations (USEPA, 2004), is to determine the acute risk to birds from consuming dicamba exposed prey or food items from an estimate of the dose-based effect levels calculated from acute dietary toxicity studies.

- From short-term dietary toxicity tests using bobwhite quail chicks and mallard ducklings exposed to dicamba diglycolamine salt for 5 d, the dose-based NOEL values were determined (Grimes, 1986a; Grimes, 1986b). The use of the NOEL value in place of the LC_{50} for an acute assessment provides additional conservatism when assessing for potential effects on endangered species.

- For birds, the dose-based EECs were calculated based on the refined foliar residue and DT_{50} values and assuming 100% diet was obtained within the field. The short/tall grass residue values were refined based on the maximum measured Day 0 residues from 59 dicamba specific field trials in pasture grasses.

- From this analysis, the dose-based EECs for small passerine birds consuming a diet exposed in the field are below the dose-based NOEL values (Schuler et al., 2013c).

- Conservatively assuming that the avian species evaluated are passerine species (highest metabolic/ingestion rates, U.S. EPA, 1993), they cannot ingest enough food to achieve doses that would exceed the unbounded NOEL (highest dose tested).

- In addition, compared to the larger birds used in the gavage study (e.g., 178 g and 1,580 g for the bobwhite quail and mallard duck, respectively), the sizes of birds used in the dietary studies (e.g., 37 g and 264 g for the bobwhite quail and mallard duck, respectively) are much more relevant to birds considered in this analysis; thereby reducing uncertainty in the toxicity value adjustment.

In summary, it can be concluded that no effects to birds will result from the use of dicamba on DGT cotton.

F.4.6.4.3. Amphibians and Reptiles

In the county-level endangered species analysis, 13 terrestrial-phase amphibian species and 17 reptile species were identified as potentially being in or adjacent to a county with cotton production (Frank and Kemman, 2013c). Of these species, 1 amphibian and 4 reptile species were removed from consideration based on Habitat determinations. Additionally, 1 reptile species was deemed Not of Concern across all counties evaluated (Frank and Kemman, 2013c).

The remaining 12 amphibian and 12 reptile species were evaluated based on their proximity to agriculture and species-specific refinements (Schuler et al, 2013c).

- The proximity of each species observation to relevant land use for cotton production was compared to species home range information. Two reptile species were removed from concern due to a lack of proximity to land relevant for cotton production.[244] Three amphibian species and two additional reptile species were excluded from concern based on a combination of Not of Concern and Proximity determinations (Schuler et al, 2013c).

- The remaining species (9 amphibian species and 8 reptile species) all received Product Property determinations (Diet Exclusion) because their T-HERPS RQ values were less than the LOC based on characteristics of diet and body weight.

- The Diet Exclusion was also applicable to the species assigned Proximity or Not of Concern determinations, resulting in totals of 12 amphibian and 12 reptile species where a Diet Exclusion was applicable.

In summary, it can be concluded that no effects to terrestrial-phase amphibians or terrestrial reptiles will result from the use of dicamba on DGT cotton.

F.4.6.5. Indirect Effects on Threatened and Endangered Species of Other Taxa Resulting from Direct Effects on Plant Species

To assess the potential for indirect effects on threatened and endangered species, the EPA evaluates the risk of direct effects on non-endangered species from relevant taxonomic groups to make inferences concerning the potential for indirect effects upon threatened or endangered species that rely on non-endangered species in that category for critical resources. For threatened and endangered species that have an obligate relationship with another species, EPA evaluates the risk of direct effects on the listed species from relevant taxonomic groups to make inferences concerning the potential for indirect effects upon threatened or endangered species (USEPA, 2004).

Through a combination of screening level and refined exposure analyses (Honegger, et al., 2013; Schuler et al., 2013c), all terrestrial and aquatic animal taxa have been excluded from concern for potential effects on threatened and endangered species of these taxa from the use of dicamba on cotton with the DT trait. Similarly, vascular aquatic plants and monocotyledonous terrestrial plants have been excluded from concern for potential effects on threatened and endangered species of these taxa. There are currently no listed non-vascular aquatic plants, and the RQ is below the LOC for non-listed non-vascular plants. These results indicate that these taxa can be removed from concern for indirect effects on other taxa from the use of dicamba on cotton with the DT trait.

The RQ values used to assess the potential for indirect effects from dicamba applications to cotton with the DT trait indicate that indirect effects to other taxa as a result of effects on dicot plant species from a combination of sheet runoff and spray drift to soil would not occur (Honegger et al., 2013). In addition, utilizing a refined exposure assessment, indirect effects to other taxa resulting from effects on dicot plant species exposed via a combination of channelized runoff and spray drift

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[244] For all county co-occurrences that did not have applicable Not of Concern determinations.

to soil would be extremely unlikely (Honegger et al., 2013). When RQ values are calculated for all six of the dicot species tested in the vegetative vigor study, RQs exceed the LOC for only two of the six species indicating that habitat and food sources from dicot plants will be present adjacent to areas treated with dicamba (Honegger et al., 2013). Furthermore, field studies demonstrate that even very sensitive plants at the edge of a field sprayed with dicamba are not affected to the extent that impacts on habitat would result. Additionally, effects from drift can be further minimized through the use of application requirements such as drift reducing technologies (e.g., low drift spray nozzles, boom height, deposition aides).

To be conservative in the analysis of potential risk of indirect effects, a separate report (Schuler et al., 2013d) further assesses the potential for indirect effects on threatened or endangered terrestrial animal species and concludes that none of the 159 listed animal species in or adjacent to cotton production counties will be subject to indirect effects resulting from direct effects to terrestrial plants from exposure to dicamba use on cotton containing the DT-trait. This analysis considered proximity data (home range to agricultural land relevant for cotton production) and species-specific biological and habitat information, in addition to an evaluation of dicamba-specific impacts to off-target terrestrial plants for dependent species, to more accurately describe the risk associated with dicamba use on cotton containing the DT-trait. This analysis also concluded that there would be no effects to the designated critical habitat for any of the species evaluated based on a proximity analysis of the separation distance between critical habitat locations and agricultural lands relevant for cotton production or a determination that the vegetation-based PCEs of the listed animal species critical habitat would not be affected by dicamba.

F.4.6.6. Conclusions

In the EFED ecological risk assessment conducted for dicamba reregistration (USEPA, 2005), using a screening level assessment, EPA scientists concluded that a "no effect" determination can be made for all dicamba uses for listed fish and aquatic invertebrates. The potential for adverse effects to listed birds and mammals could not be excluded based on the EPA screening level assessment, the initial phase of analysis. Recognizing that screening level analysis is only the first step in evaluating impacts on threatened and endangered species, the EFED Reregistration Chapter (USEPA, 2005) indicates that "additional information on the biology of listed species, the locations of these species, and the locations of the use sites…could be considered along with available information on the fate and transport properties of the pesticide to determine the extent to which screening assumptions regarding an action area apply to a particular listed organism."

This discussion summarizes the conclusions of other reports submitted to EPA (Honegger et al., 2013; Frank and Kemman, 2013c; Schuler et al., 2013c & d) that utilize some of the refinements described by EPA in the previous paragraph to evaluate the potential for adverse effects to listed birds and mammals as well as amphibians, reptiles, and terrestrial invertebrates. When the properties of dicamba and species-specific information are taken into account, these reports demonstrate that listed birds, mammals, amphibians, reptiles and terrestrial invertebrates would not be affected directly or indirectly by dicamba use in cotton with the DT trait.

F.4.7. Potential for GE Plant to Affect Threatened or Endangered Species

APHIS' regulatory authority over genetically engineered (GE) organisms under the PPA is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which

APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR 340.1). EPA has sole authority to regulate the use of any herbicide. After completing a plant pest risk analysis, if APHIS determines that the GE organism does not pose a plant pest risk, then the GE organism would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 and, therefore, APHIS will grant a determination of nonregulated status.

In accordance with the ESA, APHIS will review its action under the PPA relative to the GE organism to determine if its action may affect listed species or critical habitat, just as EPA reviews and regulates herbicides to determine impact on threatened and endangered species and/or critical habitats. Monsanto has prepared the information in this environmental report to assist APHIS in making this determination from DT soybean and DGT cotton. In it review, for each GE plant, APHIS considers the following information, data, and questions:

- A review of the biology and taxonomy of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant, including disease and pest susceptibilities, weediness potential, and agronomic and environmental impacts;
- Determination of the concentrations of known plant toxicants (if any are known in the plant);
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species or a host of any threatened or endangered plant or animal species; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

F.4.8. Potential for DT Soybean to Affect Threatened or Endangered Species

To identify any potential effects of DT soybean on threatened or endangered plant species, the potential for DT soybean to cross with a listed species was evaluated. Soybean is not native to the U.S., and DT soybean is not sexually compatible with any federally listed TES or a species proposed for listing. Like other *G. max*, DT soybean will likely be a poor competitor with native vegetation and will not survive outside of cultivation (Baker, 1965). Thus, DT soybean is not expected to interbreed with any plant species or displace natural vegetation in the U.S.

To identify potential effects on threatened or endangered animal species, the risks to threatened or endangered animals from consuming DT soybean or vegetative materials are considered. In this analysis, the biology of DT soybean and the agricultural practices associated with the cultivation of DT Soybean have been considered for potential adverse impact on TES and their critical habitats. As explained in Appendices H and I, bioinformatics analysis determined that MON 87708 DMO does not share amino acid sequence similarities with known allergens, gliadins, glutenins, or protein toxins. MON 87708 DMO was rapidly digested in *in vitro* assays using simulated gastric and intestinal fluids and did not show any adverse effects when administered to mice via oral gavage at levels far in excess of that reasonably expected to be consumed by humans or animals. Compared to commercially cultivated soybean, DT soybean does not express any additional proteins or natural toxicants that are known to directly or indirectly affect a listed TES or species proposed for listing by the U.S. Fish and Wildlife Service. Compositional analysis of DT soybean for nutrients and anti-nutrients indicated that the harvested seed and forage from DT soybean were compositionally equivalent to commercially cultivated soybean. Thus, DT soybean would not be expected to have any impacts on TES that would differ from commercially cultivated soybean.

The only TES animal listed that occupies habitat that is likely to include soybean fields and that might feed on soybean is the Federally Endangered Delmarva Peninsula Fox Squirrel, *Sciurus niger cinereus*, found in areas of the mid-Atlantic Eastern seaboard.[245] It is known to utilize certain agricultural lands readily, and its diet includes acorns, nuts/seeds of hickory, beech, walnut, and loblolly pine, buds and flowers of trees, fungi, insects, fruit, and an occasional bird egg. Given its varied diet, the safety of MON 87708 DMO, and the demonstrated compositional, agronomic and phenotypic equivalence of DT soybean to commercially cultivated soybean, it is concluded that no biologically significant changes to the habitat or diet of the Delmarva Peninsula Fox Squirrel are expected. Consequently, the planting of DT soybean is not expected to impact the Delmarva Peninsula Fox Squirrel.

As part of the analysis for TES and critical habitat, Monsanto considered whether DT soybean has any characteristics that may allow the plant to naturalize in the environment and potentially have an effect on TES. In doing so, Monsanto assessed whether DT soybean is any more likely to become a weed than commercially cultivated soybean. Weediness could potentially affect TES or critical habitat if DT soybean were to become naturalized in the environment. As discussed in Appendix G, cultivated soybean is largely self-pollinating, with minimal gene movement. With the exception of its tolerance to dicamba, DT soybean has been shown to be no different from commercially cultivated soybean in its phenotypic, agronomic and ecological characteristics, including pollen diameter, viability, and morphology. In addition, DT soybean is not different from commercially cultivated soybean in terms of seed dormancy and germination, susceptibility to or tolerance of disease or insect pests, and response to abiotic stressors (such as compaction, drought, high winds, nutrient deficiency, etc.), and would, therefore be no different than commercially cultivated soybean in its potential for volunteers and feral populations. In particular, the lack of hard seed, a well-accepted characteristic often associated with plants that are weeds, supports a conclusion of no increased weediness of DT soybean compared to commercially cultivated soybean. Collectively, this information indicates that DT soybean is no different from commercially cultivated soybean in its weediness potential.

In summary, no stressor associated with the introduction of DT soybean is expected to affect the reproduction, numbers, or distribution of a listed TES, candidate species, or species proposed for listing. As a result, a detailed site-specific (or spatially explicit) exposure analysis for individually listed TES is not necessary. Collectively, all the laboratory and field trial data on DT soybean

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[245] Source is from website http://ecos.fws.gov/tess_public/SpeciesReport.do.

support the conclusion that there would be no difference with cultivation of DT soybean from effects that would occur from the production of commercially cultivated soybean. Soybean is not native to the U.S., and DT soybean is not sexually compatible with any federally listed TES or a species proposed for listing. Like other *G. max*, DT soybean will likely be a poor competitor with native vegetation and will not survive outside of cultivation (Baker, 1965). Thus, DT soybean is not expected to interbreed with any plant species or displace natural vegetation in the U.S.

F.4.9. Potential for DGT Cotton to Affect Threatened or Endangered Species

To identify any potential effects of DGT cotton on threatened or endangered plant species, the potential for DGT cotton to cross with a listed species was evaluated. Cotton is in the genus *Gossypium* and has the ability to cross with some other species of cotton in the same genus (OECD 2008). A review of the list of threatened or endangered plant species in the U.S. shows that DGT cotton would not be sexually compatible with any listed threatened or endangered plant species, species proposed for listing, or candidate species, as none of these listed, proposed, or candidate species are in the same genus or known to cross pollinate with species of the genus *Gossypium* (USFWS 2012; 2013). As discussed in Appendix G, there is only one native *Gossypium* species found in U.S. cotton-growing regions, in Arizona, and cross-pollination of that species with commercial cotton would not produce fertile offspring (Fryxell 1984; Waghmare et al. 2005).

To identify potential effects on threatened and endangered animal species, the risks to threatened and endangered animals from consuming DGT cotton, cottonseed or vegetative materials are considered. As discussed in Appendix G, there is no difference in the composition and nutritional quality of DGT cottonseed compared with commercially cultivated cottonseed. The allergenicity and toxicity of the MON 88701 DMO and PAT(*bar*) proteins were also evaluated. The research summarized and referenced in Appendices H and I found no differences in allergenicity and toxicity compared to the analogous protein in commercially cultivated cotton. Both types of proteins are ubiquitous in nature and normally present in food and feeds derived from these plant and microbial sources. As discussed in Appendix G, during field trials with DGT cotton, no biologically relevant changes in arthropod feeding damage were observed, indicating similar arthropod susceptibility for DGT cotton compared to commercially cultivated cotton. As DGT cotton exhibits no toxic effects on insects or other animals it is concluded that they will not be affected. In addition, the cultivation of DGT cotton does not impact the nutritional quality, safety or availability of animal feed. Based on these results, no effects to any TES animal species (or candidate species, or species proposed for listing) that may feed on DGT cotton plant parts would be expected.

As part of the analysis for TES and critical habitat, Monsanto considered whether DGT cotton has any characteristics that may allow the plant to naturalize in the environment and potentially have an effect on TES. In doing so, Monsanto assessed whether DGT cotton is any more likely to become a weed than commercially cultivated cotton. Weediness could potentially affect TES or critical habitat if DGT cotton were to become naturalized in the environment. As discussed under Appendix G, cultivated cotton is largely self-pollinating, and no wild (native) or feral species of *Gossypium* have been found in cotton-growing areas. With the exception of its tolerances to both dicamba and glufosinate, DGT cotton has been shown to be no different from commercially cultivated cotton in its phenotypic, agronomic and ecological characteristics, including pollen diameter, viability, and morphology. In addition, DGT cotton is not different from commercially cultivated cotton in terms of seed dormancy and germination, susceptibility to or tolerance of disease or insect pests, and response to abiotic stressors (such as compaction, drought, high winds, nutrient deficiency, etc.), and would, therefore be no different than commercially cultivated cotton in its potential for volunteers and feral populations. In particular, the lack of hard seed, a well-accepted characteristic often associated with plants that are weeds, supports a conclusion of no increased weediness of DGT cotton compared to commercially cultivated cotton. Collectively, this information indicates that DGT cotton is no different from commercially cultivated cotton in its weediness potential.

In summary, no stressor associated with the introduction of DGT cotton is expected to affect the reproduction, numbers, or distribution of a listed TES, candidate species, or species proposed for listing. As a result, a detailed site-specific (or spatially explicit) exposure analysis for individually listed TES is not necessary. Collectively, all the laboratory and field trial data on DGT cotton support the conclusion that there would be no difference with cultivation of DGT cotton from effects that would occur from the production of commercially cultivated cotton. Cotton is not sexually compatible with, nor does it serve as a host species for, any listed species, candidate species or species proposed for listing. Based on the characteristics of the introduced protein and comparative compositional assessments, consumption of DGT cotton by any listed species or species proposed for listing will not result in a toxic or allergic reaction.

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APPENDIX G: CHARACTER AND QUALITY OF DT SOYBEAN AND DGT COTTON TRAITS

Table of Contents

G.1. Introduction

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has responsibility under the Plant Protection Act (Title IV Pub. L. 106-224, 114 Stat. 438, 7 U.S.C. § 7701-7772) to prevent the introduction and dissemination of plant pests into the U.S. APHIS regulation 7 CFR § 340.6 provides that an applicant may petition APHIS to evaluate submitted data to determine that a particular regulated article does not present a plant pest risk and no longer should be regulated. If APHIS determines that the regulated article does not present a plant pest risk, the petition is granted, thereby allowing unrestricted introduction of the article.

Monsanto Company has submitted requests to APHIS for determinations of nonregulated status for two new biotechnology-derived products, soybean MON 87708 (DT soybean) and cotton MON 88701 (DGT cotton). These requests include DT soybean, DGT cotton, any progeny derived from crosses between DT soybean and conventional soybean and DGT cotton and conventional cotton, and any progeny derived from crosses of DT soybean and DGT cotton with biotechnology-derived soybean or cotton, respectively, that have previously been granted nonregulated status under 7 CFR Part 340.

G.2. Dicamba-Tolerant Soybean (DT Soybean)

G.2.1. Product Description

Monsanto Company has developed biotechnology-derived soybean MON 87708 (DT soybean) that is tolerant to dicamba (3,6-dichloro-2-methoxybenzoic acid) herbicide. DT soybean offers growers an expanded use of dicamba in soybean production from the current preplant and preharvest labeled uses. The tolerance of DT soybean to dicamba facilitates a wider window of application in soybean, allowing preemergence application up to the day of crop emergence and in-crop postemergence applications through the early reproductive (R1/R2) growth stage. Dicamba provides effective control of over 95 annual and biennial weed species, and suppression of over 100 perennial broadleaf and woody plant species. Dicamba is efficacious on broadleaf weeds that are hard-to-control with glyphosate, such as common lambsquarters, hemp sesbania, morning glory species, nightshade, Pennsylvania smartweed, prickly sida, velvetleaf, waterhemp and wild buckwheat. Hard-to-control weeds generally require a higher rate and/or application at a smaller growth stage in order to consistently achieve commercially acceptable control. Refer to the Roundup WeatherMax label (U.S. EPA Reg. No. 524-537) for a listing of these weeds.

Additionally, dicamba provides effective control of herbicide-resistant broadleaf weeds, including glyphosate-resistant weeds such as marestail, common ragweed, giant ragweed, palmer pigweed, and waterhemp. Herbicide resistant weeds are those listed on the International Survey of Resistant Weeds website (www.weedscience.org).

DT soybean will be combined with MON 89788 (Roundup Ready 2 Yield® soybean) utilizing traditional breeding techniques. Dicamba is an effective broadleaf herbicide and the potential use of dicamba and glyphosate herbicides at the same time in mixtures for weed control will provide growers greater application flexibility prior to planting as well as in-crop for greater consistency of control in both conventional and conservation tillage situations. Use of dicamba, in addition to glyphosate and the other herbicide options currently labeled for use on soybean, provides more options to implement diversified weed management programs to control a broad spectrum of grass and broadleaf weed species. Successful adoption of the dicamba tolerance trait, into the Roundup Ready® soybean system, will provide: 1) growers with an opportunity for an efficient, effective weed management system; 2) an option to mitigate the potential for further resistance to glyphosate and other critically important soybean herbicides, in particular, herbicides in the ALS and PPO class of chemistry; 3) excellent crop safety, and 4) continue to provide soybean growers with effective weed control systems necessary for production yields to meet the growing needs of the food, feed, and industrial markets. The combination of dicamba and glyphosate tolerance in soybeans will also provide the basis for mitigating the potential for the evolution of further weed resistance to glyphosate, dicamba, and herbicides in general, because of the ability to use these two modes of action in mixtures and sequences.

DT soybean contains a gene from *Stenotrophomonas maltophilia* that expresses a mono-oxygenase enzyme that rapidly demethylates dicamba rendering it inactive, thereby conferring tolerance to dicamba. The demethylation of dicamba produces 3,6-dichlorosalicylic acid (DCSA), a known soybean, soil, and livestock metabolite whose safety has been evaluated by the Environmental Protection Agency (U.S. EPA). DCSA, in addition to dicamba, is included in the current 10 ppm pesticide residue tolerance for soybean seed that supports the existing uses of dicamba on commercial soybean (40 CFR § 180.227). Even with the expanded use of dicamba on DT soybean, compared to commercial soybean uses, the rapid metabolism of dicamba results in residues in dicamba-treated DT soybean seed, including the DCSA metabolite, that are well below the established 10 ppm tolerance, and therefore no modification to the existing soybean seed tolerance is needed. Consequently, only approval for the expanded use pattern of dicamba on DT soybean has been requested of EPA.

G.2.2. Data and Information Presented Confirm the Lack of Plant Pest Potential of DT soybean Compared to Conventional Soybean

The data and information presented in petition #10-188-01p demonstrate DT soybean is agronomically, phenotypically, and compositionally comparable to conventional soybean with the exception of its tolerance to dicamba. Moreover, the data presented demonstrate DT soybean is unlikely to pose an increased plant pest risk, including weediness or adverse environmental impact, compared to conventional soybean. The food, feed, and environmental safety of DT soybean was confirmed based on multiple, well-established lines of evidence:

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1. Soybean is a familiar crop that does not possess any of the attributes commonly associated with weeds and has a history of safe consumption.

2. A detailed molecular characterization of the inserted DNA demonstrated a single, intact copy of the T-DNA insert in a single locus within the soybean genome.

3. Data confirmed that the dicamba mono-oxygenase (DMO) in DT soybean (MON 87708 DMO) is unlikely to be a toxin or allergen based on extensive information collected.

4. A compositional assessment of seed and forage confirmed that DT soybean is compositionally equivalent to conventional soybean.

5. An extensive evaluation on phenotypic and agronomic characteristics and environmental interactions of DT soybean demonstrated no increased plant pest potential compared to conventional soybean.

6. An assessment of potential impact on non-target organisms (NTOs) and endangered species indicated that, under normal agricultural conditions, DT soybean is unlikely to have adverse effects on these organisms compared to conventional soybean.

7. Evaluation of DT soybean using current cultivation and management practices for soybean concluded that deregulation of DT soybean will not significantly impact soybean agronomic practices or land use, with the exception of the expanded window of dicamba application.

G.2.3. Soybean is a Familiar Crop Lacking Weedy Characteristics

There is a longstanding history of safe use and consumption of conventional soybean and processed products. Soybean is grown as a commercial crop in over 35 countries. Domestication occurred as early as 1000 B.C. and soybean is now the most widely grown oilseed crop in the world, with approximately 211 million metric tons of harvested seed produced in 2008, which represented 56% of world oilseed seed production that year.

The commercial soybean species in the U.S. (*Glycine max* L. Merr.) does not exhibit weedy characteristics, does not invade established ecosystems, and does not outcross to weedy relatives. Soybean is not listed as a weed in major weed references, nor is it present on the lists of noxious weed species distributed by the federal government (7 CFR Part 360). During 2004 to 2008, U.S. growers planted between 64.7 and 75.7 million acres of soybean. Soybean does not possess any of the attributes commonly associated with weeds, such as long persistence of the seed in the soil, ability to disperse, invade, or become a dominant species in new or diverse landscapes, or the ability to compete well with native vegetation. However, due to a pronounced lack of dormancy it is known that soybean seed can germinate quickly under adequate temperature and moisture conditions, and can potentially grow as a volunteer plant. However, a volunteer soybean plant likely would be killed by frost during the autumn or winter of the year it germinated. Furthermore, if a volunteer plant were to survive, it would not compete well with the succeeding crop, and would be controlled readily via mechanical or other chemical means. Twenty commonly used agricultural herbicides, representing eight modes-of-action (*i.e.*, ALS-inhibitor, chloroacetamide, EPSPS, PPO inhibitor, PSI disruption, PSII inhibitor, synthetic auxin, and tubulin inhibitor classes) were tested as DT soybean potential substrates for MON 87708 DMO. Other than dicamba, none of the herbicides tested were found to affect the tolerance of DT soybean at commercial application rates, therefore, herbicides effective for control of volunteer soybean can still be used to control DT soybean volunteers. Finally, since wild populations of *Glycine* species are not known to exist in the U.S., there is no potential for DT soybean to outcross to wild or weedy relatives.

G.2.4. Conventional Soybean A3525 is an Appropriate Comparator to DT Soybean

Soybean variety A3525 is the near isogenic line to DT soybean and was used as the conventional soybean comparator to support the safety assessment of DT soybean. DT soybean and the near isogenic conventional soybean control A3525 have similar genetic backgrounds with the exception of the *dmo* expression cassette, thus, the effect of the *dmo* expression cassette and the expressed MON 87708 DMO could be assessed in an unbiased manner.

G.2.5. Molecular Characterization Verifies the Integrity and Stability of the Inserted DNA in DT Soybean

MON 87708 was developed through *Agrobacterium*-mediated transformation of conventional soybean A3525 meristem tissue with the 2T-DNA plasmid vector PV-GMHT4355. PV-GMHT4355 contains two separate T-DNAs that are each delineated by Left and Right Border sequences. The first T-DNA, designated as T-DNA I, contains the *dmo* expression cassette regulated by the peanut chlorotic streak virus (*PC1SV*) promoter and the pea *E9* 3' non-translated region. The second T-DNA, designated as T-DNA II, contains the *cp4 epsps* expression cassette under the regulation of the figwort mosaic virus (*FMV*) promoter and the pea *E9* 3' non-translated region. During transformation, both T-DNAs were inserted into the soybean genome, where T-DNA II, containing the *cp4 epsps* expression cassette, functioned as a marker gene for the selection of transformed plantlets. Subsequently, conventional self-pollination breeding methods and segregation were used to isolate a plant containing the *dmo* expression cassette but not containing the *cp4 epsps* expression cassette, resulting in the production of marker-free, dicamba-tolerant soybean MON 87708.

Molecular characterization by Southern blot analyses determined that DT soybean contains one copy of the T-DNA I at a single integration locus and all expression elements are present. These data also demonstrated that DT soybean does not contain detectable backbone sequences from the plasmid vector or T-DNA II sequences. The complete DNA sequence of the insert and adjacent genomic DNA sequence in DT soybean confirmed the integrity of the inserted *dmo* expression cassette within the inserted sequences and identified the 5' and 3' insert-to-genomic DNA junctions. Furthermore, Southern blot analysis demonstrated that the insert in DT soybean has been maintained through at least five generations of breeding, thereby confirming the stability of the insert over multiple generations.

G.2.6. Data Confirm DT Soybean DMO Safety

DT soybean contains a *dmo* expression cassette that results in two forms of the DMO protein; referred to as DMO and DMO+27 (See Appendix I.). The active form of these proteins, necessary to confer dicamba tolerance, is a trimer comprised of three DMO monomers. In DT soybean, the trimer can be comprised of DMO, DMO+27, or a combination of both. Therefore, this document will refer to both forms of the protein and all forms of the trimer as MON 87708 DMO.

A multistep approach was used to characterize MON 87708 DMO. This detailed characterization and assessment confirmed that MON 87708 DMO is safe for human and animal consumption. The assessment involved: 1) characterization of the physicochemical and functional properties of MON 87708 DMO; 2) quantification of MON 87708 DMO levels in plant tissues; 3) comparison of the amino acid sequence of MON 87708 DMO to known allergens, gliadins, glutenins, toxins, and other biologically active proteins known to have adverse effects on mammals; 4) evaluation of the digestibility of MON 87708 DMO in simulated gastric and intestinal fluids; 5) endogenous and exogenous substrate specificity of DMO; 6) documentation of the history of safe consumption of mono-oxygenases (the class of enzymes to which MON 87708 DMO belongs); and 7) investigation of the potential mammalian toxicity through an oral gavage assay.

DMO was found to be specific to dicamba when tested using structurally similar endogenous substrates and exogenous herbicide substrates representing a wide range of modes-of-action. MON 87708 DMO has no relevant amino acid sequence similarities with known allergens, gliadins, glutenins, toxins, and other biologically active proteins that may have adverse effects on mammals. MON 87708 DMO was rapidly degraded in simulated gastric and intestinal fluids and a high dose of this protein in a mouse acute oral toxicity evaluation demonstrated that it is not acutely toxic, and does not cause any adverse effect. The safety assessment supports the conclusion that exposure to MON 87708 DMO poses no meaningful risk to the environment, or human and animal health.

G.2.7. DT Soybean is Compositionally Equivalent to Conventional Soybean

Detailed compositional analyses in accordance with OECD guidelines were conducted to assess whether levels of key nutrients and anti-nutrients in DT soybean were comparable to levels present in the aforementioned near isogenic conventional soybean control A3525 and several commercial reference soybean varieties. Seed and forage were harvested from five individual sites in which DT soybean (both treated with dicamba herbicide at the V2-V3 growth stage and not treated with dicamba herbicide), the conventional control, and a range of commercial reference varieties were grown concurrently in the same field trial. The commercial reference varieties used to establish a range of natural variability for the key nutrients and anti-nutrients in commercial soybean varieties have a history of safe consumption. Nutrients assessed in this analysis included proximates (ash, carbohydrates by calculation, moisture, protein, and fat), fiber, amino acids (18 components), fatty acids (FA, C8-C22), and vitamin E (α-tochopherol) in seed, and proximates (ash, carbohydrates by calculation, moisture, protein, and fat) and fiber in forage. The anti-nutrients assessed in seed included raffinose, stachyose, lectin, phytic acid, trypsin inhibitors, and isoflavones (daidzein, genistein, and glycitein).

The combined-site analysis was conducted to determine statistically significant differences (5% level of significance) between DT soybean and the near isogenic conventional control A3525. The results from the combined-site data were reviewed using considerations relevant to food and feed safety and nutritional quality. These considerations included assessments of: 1) the relative magnitudes of the difference in the mean values of nutrient and anti-nutrient components of DT soybean and the conventional control, 2) whether the DT soybean component mean value was within the range of natural variability of that component as represented by the 99% tolerance interval of the commercial reference varieties grown concurrently in the same field trial, 3) analyses of the reproducibility of the statistically significant combined-site component differences at individual sites, and 4) assessing the differences within the context of natural variability of commercial soybean composition published in the scientific literature and in the International Life Sciences Institute (ILSI) Crop Composition Database.

Assessment of the analytical results confirmed that the differences observed in the combined-site analysis were not meaningful to food and feed safety or the nutritional quality of DT soybean soybean. In addition, the levels of assessed components in DT soybean were compositionally equivalent to the conventional control and within the range of variability of the commercial reference varieties that were grown concurrently in the same field trial.

G.2.8. DT Soybean Does Not Change Soybean Plant Pest Potential or Environmental Interactions

"Familiarity" is an important consideration in assessing the plant pest potential of a biotechnology-derived crop. Conceptually, "familiarity" is based upon the fact that the new biotechnology-derived plant is developed from a conventional plant variety whose biological properties and plant pest potential are well known. Familiarity considers the biology of the plant, the introduced trait, the receiving environment, and the interactions among these factors that provides a basis for comparative risk assessment between a biotechnology-derived plant and the conventional control. Following this concept, the phenotypic, agronomic, and environmental interaction assessment of DT soybean included the near isogenic conventional soybean control A3525 and the commercial reference varieties. Characteristics assessed included: seed dormancy and germination, pollen morphology, and symbiont interactions conducted in the laboratory and greenhouse; and plant phenotypic and agronomic evaluations and environmental interaction observations conducted in the field. The commercial soybean reference varieties grown concurrently were used to establish a range of natural variability for each assessed characteristic in soybean. The phenotypic, agronomic, and environmental interaction assessment demonstrated that DT soybean is equivalent to the conventional control. Thus, DT soybean is unlikely to have a changed plant pest potential compared to conventional soybean.

Seed dormancy and germination characterization demonstrated that DT soybean seed had germination characteristics similar to seed of the conventional control. In particular, the lack of hard seed, a well-accepted characteristic of weediness affecting seed germination, supports a conclusion of no increased weediness of DT soybean when compared to the conventional control. For pollen characteristics and symbiont interactions, there were no statistically significant differences (5% level of significance) observed between DT soybean and the conventional control for any of the parameters measured, including pollen viability and diameter, nodule number and dry weight, shoot total nitrogen, and shoot and root dry weight. Collectively, these results support the conclusion that DT soybean is not likely to exhibit increased plant pest potential compared to conventional soybean.

The field evaluation of phenotypic, agronomic, and environmental interaction characteristics of DT soybean also support the conclusion that DT soybean is not likely to have an increased plant pest potential compared to conventional soybean. The evaluations were conducted at 18 replicated field sites across North American soybean production regions. These assessments included plant growth and development characteristics, as well as observations for plant responses to abiotic stressors and plant-disease and plant-arthropod interactions. The observed phenotypic characteristics were similar between DT soybean and the conventional control.

In a combined-site analysis, data show no statistically significant differences (5% level of significance) between DT soybean and the conventional control for early stand count, seedling vigor, days to 50% flowering, lodging, pod shattering, final stand count, seed moisture, seed test weight, or yield. Two statistically significant differences were detected between DT soybean and the conventional control for plant height and 100 seed weight. DT soybean was slightly taller and had a lower 100 seed weight than the conventional control. However, both differences were small in magnitude. Additionally, DT soybean and the conventional control were within the same range of plant growth stages for 131 out of the 132 growth stage observations among the sites. Except for the differences in plant height, 100 seed weight, and a single growth stage observation at one site, all values for DT soybean fell within the range of the commercial reference varieties grown concurrently. None of these differences were considered biologically meaningful in terms of increased plant pest potential of DT soybean compared to conventional soybean.

In an individual-site assessment of abiotic stress response and disease damage, no differences were observed between DT soybean and the conventional control for 193 out of 194 comparisons for the assessed abiotic stressors or for any of the 215 comparisons for the assessed diseases among all observations at the 18 sites. One difference was observed between DT soybean and the conventional control for wind damage during a single observation at one site. The damage rating for v (slight damage) was outside the range of the commercial reference varieties (no damage); however, the difference was not observed during any of the other 29 wind damage observations among the sites. Thus, the slight difference in wind damage rating was not indicative of a consistent plant response associated with DT soybean and is not considered biologically meaningful in terms of increased plant pest potential or an altered environmental impact from DT soybean compared to conventional soybean.

In an assessment of arthropod-related damage, no statistically significant differences (5% level of significance) were detected between DT soybean and the conventional control for 89 out of 95 comparisons for the assessed arthropods. Lack of variability in the data precluded statistical comparisons between DT soybean and the conventional control for 121 additional comparisons; however, the means for DT soybean and the conventional control were the same value for these comparisons, indicating no biological differences. For each of the six statistically significant differences between DT soybean and the conventional control, the severity of arthropod-related damage to DT soybean was within or slightly outside the range of the commercial reference varieties. The differences between DT soybean and the conventional control were small in magnitude and were not consistent across observations or sites. Thus, the differences in arthropod-related damage are not indicative of a consistent plant response associated with DT soybean and are not considered biologically meaningful in terms of increased plant pest potential or an altered environmental impact from DT soybean compared to conventional soybean.

In an assessment of pest and beneficial arthropod abundance, no statistically significant differences (5% level of significance) were detected between DT soybean and the conventional control for 142 out of 151 comparisons (including 74 arthropod pest and 77 beneficial arthropod comparisons) among the multiple collections conducted during the season at four sites. For the nine detected differences in arthropod abundance, seven were arthropod pests (green cloverworm, Japanese beetles, and stink bugs) and two were beneficial arthropods (spiders and *Nabis* spp). The differences detected in pest and beneficial arthropod abundance were small in magnitude and were not consistent with other collection times at the individual sites or across the sites. Consequently, it is concluded that the differences in pest and beneficial arthropod abundance are not indicative of a consistent plant response associated with DT soybean and are not biologically meaningful in terms of increased plant pest potential or an altered environmental impact from DT soybean compared to conventional soybean.

Field evaluations of phenotypic, agronomic, and environmental interaction characteristics of DT soybean treated with dicamba herbicide were also conducted. Data were collected from field trials conducted at eight sites within the U.S. soybean producing regions. These assessments included plant growth and development characteristics, as well as observations for plant responses to abiotic stressors, plant-disease and plant-arthropod interactions. The phenotypic, agronomic, and environmental interaction assessment demonstrated that treated DT soybean is equivalent to the conventional control. Thus, DT soybean is unlikely to have an altered plant pest potential compared to conventional soybean.

The observed phenotypic characteristics were similar between the dicamba-treated DT soybean and the conventional control. In a combined-site assessment, no statistically significant differences were detected between treated DT soybean and the conventional control for early stand count, seedling vigor, days to 50% flowering, plant height, lodging, pod shattering, final stand count, seed moisture, or yield. One statistically significant difference was detected between treated DT soybean and the control, for 100 seed weight. The difference in 100 seed weight was relatively small in magnitude and the mean 100 seed weight of treated DT soybean was slightly below the reference range. It is unlikely that this small difference in 100 seed weight would contribute to increased weed potential of DT soybean when treated with dicamba compared to conventional soybean. Additionally, treated DT soybean and the control were within the same range of plant growth stages for all growth stage observations among the sites. None of these differences were considered biologically meaningful in terms of increased plant pest potential of treated DT soybean compared to conventional soybean.

In an assessment of plant response to abiotic stressors and disease damage, no differences were observed between treated DT soybean and the conventional control for 181 of 182 comparisons among all observations at the eight sites. One difference was observed between treated DT soybean and the control for white mold during a single observation (slight vs. none). The damage rating for treated DT soybean was outside of the reference range (no damage was observed in the references). This difference was not observed in any of the other two white mold evaluations across the sites and is not considered biologically meaningful in terms of increased plant pest potential or an altered environmental impact from treated DT soybean compared to conventional soybean.

In an assessment of arthropod-related damage, there were no statistically significant differences detected between treated DT soybean and the control for 56 out of 59 comparisons. Lack of variability in the data precluded statistical comparisons between treated DT soybean and the conventional control for 34 additional comparisons. The mean damage ratings for bean leaf beetle and grasshopper damage was outside the reference range however the response was not consistent across observations or sites. Thus, the results are not considered biologically meaningful in terms of adverse environmental impacts of treated DT soybean compared to the conventional soybean.

In summary, the phenotypic, agronomic, and environmental interaction data were collected to provide a detailed characterization of DT soybean and to assess whether the introduction of the dicamba tolerance trait in DT soybean and the associated application of dicamba herbicide alters the plant pest potential compared to conventional soybean. The analysis considered the comparisons of DT soybean to the conventional control, the reproducibility, magnitude, and direction of detected differences (trends), and comparison to the range of the commercial reference varieties. Results from the phenotypic, agronomic, and environmental interactions assessment indicated that DT soybean does not possess weedy characteristics, increased susceptibility or tolerance to specific abiotic stress, diseases, or arthropods, or characteristics that would confer a plant pest risk or a significant environmental impact compared to conventional soybean.

G.2.9. DT Soybean Will Not Adversely Affect NTOs or Threatened and Endangered Species

Evaluation of the impacts of a biotechnology-derived crop on Non-Target Organisms (NTOs) and threatened and endangered species is a component of the plant pest risk assessment. Since DT soybean does not possess pesticidal activity, all organisms that interact with DT soybean are considered to be NTOs. The environmental assessment demonstrated that the presence of the dicamba tolerance trait in DT soybean and the associated application of dicamba did not alter plant-arthropod interactions, including beneficial arthropods, or alter disease susceptibility compared to the conventional control.

The biochemical information and experimental data for evaluation of DT soybean included molecular characterization, MON 87708 DMO safety assessments, the history of environmental exposure to mono-oxygenases (the class of enzymes to which MON 87708 DMO belongs), information from the environmental interaction assessment, demonstration of compositional equivalence to conventional soybean, and demonstration of agronomic and phenotypic equivalence to conventional soybean. Taken together, these data support the conclusion that DT soybean has no reasonable mechanism for harm to NTOs, or to pose an additional risk to threatened and endangered species compared to the cultivation of conventional soybean.

The potential for outcrossing and gene introgression from DT soybean to sexually-compatible species in the U.S. is unlikely since no known wild *Glycine* species related to cultivated soybean are known to be present in North America. Furthermore, should cross-pollination occur, DT soybean and its progeny are not expected to exhibit a significant environmental impact because, as described above, evaluations have shown that the presence of the dicamba tolerance trait is not likely to enhance weediness or plant-pest potential. Therefore, the environmental consequence of pollen transfer from DT soybean to other *Glycine* species is considered negligible.

G.2.10. Deregulation of DT Soybean Will Not Significantly Impact Soybean Agronomic Practices or Land Use

Soybean fields are typically highly managed agricultural areas that are dedicated to crop production for many years. Cultivation of DT soybean would not be expected to differ from typical soybean cultivation, with the sole exception of an expanded window of dicamba applications due to the presence of the dicamba tolerance trait in DT soybean. DT soybean likely would be used in common rotations on land currently used for agricultural purposes. As demonstrated, DT soybean is similar to conventional soybean in its agronomic, phenotypic, ecological, and compositional characteristics and has comparable levels of resistance to insects and diseases as compared to commercial soybean. Therefore, the introduction of DT soybean into the Roundup Ready soybean system is not expected to have a significant impact on current cultivation and management practices for soybean. The adoption of DT soybean into the Roundup Ready soybean system will provide growers with another herbicide mode-of-action and the means to control broadleaf weeds, including hard-to-control and herbicide-resistant broadleaf weeds, and will help preserve conservation tillage practices by providing growers with an additional weed management tool. Based on these considerations, there is no apparent potential for significant impacts on agronomic practices or land use, with the exception of the expanded application window of dicamba.

G.2.11. Conclusion

Based on the data and information presented in petition #10-188-01p, it is concluded that DT soybean is not likely to be a plant pest. Therefore, Monsanto Company requests a determination from APHIS that DT soybean and any progeny derived from crosses between DT soybean and conventional soybean or previously deregulated biotechnology-derived soybean, be granted nonregulated status under 7 CFR Part 340.

G.3. Dicamba and Glufosinate-Tolerant Cotton (DGT Cotton)

G.3.1. Product Description

Monsanto Company has developed dicamba and glufosinate-tolerant cotton, MON 88701, which will allow in-crop applications of dicamba herbicide for the control of broadleaf weeds from preemergence to seven days preharvest and glufosinate herbicide for broad spectrum weed control from emergence through early bloom growth stage. DGT cotton provides a wider dicamba window of application beyond the current preplant cotton uses and glufosinate application rates and timings that are equivalent to current commercial glufosinate-tolerant cotton. The combination of these two unique herbicide modes-of-action provides an effective weed management system for cotton production. Dicamba provides effective control of over 95 annual and biennial weed species, and suppression of over 100 perennial broadleaf and woody plant species. Glufosinate, a broad-spectrum contact herbicide, provides nonselective control of approximately 120 broadleaf and grass weeds. Additionally, dicamba and glufosinate provide control of herbicide-resistant weeds, including glyphosate-resistant biotypes of Palmer amaranth (*Amaranthus palmeri*), marestail (*Conyza canadensis*), common ragweed (*Ambrosia artemisiifolia*), giant ragweed (*Ambrosia trifida*) and waterhemp (*Amaranthus tuberculatus*).

DGT cotton contains a demethylase gene from *Stenotrophomonas maltophilia* that expresses a dicamba mono-oxygenase (DMO) protein to confer tolerance to dicamba herbicide. DMO protein rapidly demethylates dicamba to the herbicidally inactive metabolite 3,6-dichlorosalicylic acid (DCSA). DCSA has been previously identified as a metabolite of dicamba in cotton, soybean, livestock, and soil. Monsanto will request a registration from U.S. EPA for the expanded use of dicamba on DGT cotton, an increase in the dicamba residue tolerance for cottonseed, the establishment of a tolerance for cotton gin by-products, and the inclusion of DCSA in the residue definitions for both cottonseed and gin by-products. No other revisions to the dicamba pesticide residue tolerances are necessary including animal products such as meat, eggs, and milk. Furthermore, the use of dicamba on DGT cotton does not present any new environmental exposure scenarios not previously evaluated and deemed acceptable by U.S. EPA.

DGT cotton also contains a bialaphos resistance (*bar*) gene from *Streptomyces hygroscopicus* that expresses the phosphinothricin N-acetyltransferase (PAT) protein to confer tolerance to glufosinate herbicide. PAT (*bar*)[246] protein acetylates the free amino group of glufosinate to produce non-herbicidal N-acetyl glufosinate, a well known metabolite in glufosinate-tolerant plants. The use pattern and rate of glufosinate on DGT cotton will follow the existing glufosinate-tolerant cotton uses outlined on the glufosinate herbicide label. The glufosinate residues in DGT cotton treated with commercial glufosinate rates are below the established pesticide residue tolerances for both cottonseed and gin by-products. Therefore, Monsanto will not seek any changes in the glufosinate label or the established tolerances for its use on DGT cotton.

DGT cotton will be combined, through traditional breeding methods, with other deregulated herbicide-tolerant (*e.g.*, glyphosate-tolerant) events. The in-crop use of dicamba and glufosinate herbicides, in addition to glyphosate herbicide, provides improved weed management options in cotton to control a broad spectrum of grass and broadleaf weed species and effective control of weeds resistant to several herbicide families. Successful integration of DGT cotton into glyphosate-tolerant cotton systems will provide: 1) an opportunity for an efficient, effective weed management system for hard-to-control and herbicide-resistant weeds; 2) a flexible system for two additional herbicide modes-of-action for in-crop application in current cotton production systems as recommended by weed science experts to manage future weed resistance development; 3) an option to mitigate the potential for development of further resistance to glyphosate and other critically important cotton herbicides; in particular, herbicides in the acetolactate synthase inhibitor (ALS) and protoporphyrinogen oxidase inhibitor (PPO) class of chemistry; 4) crop safety to dicamba, glufosinate, and glyphosate; and 5) additional weed management tools to enhance weed management systems necessary to maintain yield and quality to meet the growing needs of the food, feed, and industrial markets.

G.3.2. Data and Information Presented Confirms the Lack of Plant Pest Potential and the Food and Feed Safety of DGT Cotton Compared to Conventional Cotton

The data and information presented in petition #12-185-01p demonstrate MON 88701 is agronomically, phenotypically, and compositionally comparable to commercially cultivated cotton, with the exception of its tolerances to both dicamba and glufosinate. Moreover, the data presented demonstrate DGT cotton is unlikely to pose an increased plant pest risk, including weediness, or adverse environmental impact, compared to commercially cultivated cotton. The food, feed, and environmental safety of DGT cotton was confirmed based on multiple, well-established lines of evidence:

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[246] PAT (*bar*) indicates the PAT protein encoded by the *bar* gene isolated from *S. hygroscopicus*. The *pat* gene from *S. viridochromogenes* also encodes a PAT protein that confers glufosinate tolerance.

- Cotton is a familiar crop that does not possess any of the attributes commonly associated with weeds, and has a history of safe usage and consumption.

- A detailed molecular characterization of the inserted DNA demonstrated a single, intact copy of the T-DNA insert in a single locus within the cotton genome.

- Extensive evaluation of the proteins expressed in DGT cotton, dicamba mono-oxygenase (MON 88701 DMO) and phosphinothricin acetyltransferase [PAT (*bar*)], confirmed they are unlikely to be toxins or allergens. In addition, PAT proteins are in several other commercially-available crops that have been reviewed and previously deregulated by USDA, including those in cotton, corn, soy, canola, sugarbeet, and rice.

- A compositional assessment of cottonseed confirmed that DGT cotton is compositionally equivalent to commercially cultivated cotton.

- An extensive evaluation of phenotypic, agronomic, and plant mapping characteristics, as well as environmental interactions of DGT cotton, demonstrated no increased plant pest potential compared to commercially cultivated cotton.

- An assessment of potential impact on non-target organisms (NTOs) indicated that, under anticipated agricultural conditions, DGT cotton is unlikely to have adverse effects on these organisms compared to commercially cultivated cotton.

- Evaluation of DGT cotton using current agronomic management practices for cotton concluded that deregulation of DGT cotton is not likely to impact cotton agronomic practices or land use, with the exception of the expanded window of dicamba application.

G.3.3. Cotton is a Familiar Crop Lacking Weedy Characteristics

Cotton, as a commodity crop, has a longstanding history of cultivation; its by-products, including processed fractions, also have a history of safe use and consumption. Cotton is grown in 17 states across the southern U.S. and in over 80 countries world-wide. In 2011, U.S. growers planted approximately 14.7 million acres of cotton.

The commercial cotton species in the U.S. (*Gossypium hirsutum* and *Gossypium barbadense* L. Merr.) do not exhibit weedy characteristics as defined by USDA, and neither invade established ecosystems, nor outcross to weedy relatives. Cotton is not listed as a weed in major weed references, nor is it present on the lists of noxious weed species distributed by the federal government (7 CFR Part 360). Cotton does not possess any of the attributes commonly associated with weeds, such as long persistence of the seed in the soil, ability to disperse, invade, or become a dominant species in new or diverse landscapes, or the ability to compete well with native vegetation. It is recognized that in some agricultural systems, cotton can volunteer in a subsequent rotational crop. However, volunteers are easily controlled through tillage or the use of appropriate herbicides with diverse modes-of-action (*e.g.*, ALS inhibitor, chloroacetamide, EPSPS, PPO inhibitor, PSI disruption, PSII inhibitor, synthetic auxin, and tubulin inhibitor classes). Specificity studies using the aforementioned herbicides as potential substrates for MON 88701 DMO showed similar injury levels for DGT cotton compared to the conventional control, indicating that these herbicides do not serve as a substrate for MON 88701 DMO at commercial application rates. Additionally, the specificity of PAT (*bar*) has been established in the published scientific literature. Therefore, herbicides effective for control of volunteer conventional cotton can still be used to control DGT cotton volunteers.

In the continental U.S., wild populations of *Gossypium* species and some feral populations of cultivated variants of *G. hirsutum* exist, but these species, which are able to cross with cultivated cotton, are not known to exist in cotton growing areas. Importantly, DGT cotton would not be expected to confer a selective advantage to, or enhance the pest potential of, progeny resulting from such a cross if it were to occur, and could easily be controlled through current agronomic practices used to control conventional cotton. Thus, with environmental and biological limitations and varying chemical and agronomic practices available in the areas with wild and/or feral populations, there is limited probability for DGT cotton or any *Gossypium* species to outcross with wild or feral plants.

G.3.4. Conventional Cotton Coker 130 is an Appropriate Comparator to DGT Cotton

Cotton variety Coker 130 is the near isogenic line to DGT cotton and was used as the conventional cotton comparator to support the safety assessment of DGT cotton. DGT cotton and the near isogenic conventional cotton control Coker 130 have similar genetic backgrounds with the exception of the *dmo* and *bar* expression cassettes; thus, the effect of the *dmo* and *bar* expression cassettes and the expressed MON 88701 DMO and PAT (*bar*) proteins could be evaluated.

G.3.5. Molecular Characterization Verified the Integrity and Stability of the Inserted DNA in DGT Cotton

DGT cotton was developed through *Agrobacterium*-mediated transformation of hypocotyls from cotton variety Coker 130 utilizing vector PV-GHHT6997. PV-GHHT6997 contains one T-DNA that is delineated by Left and Right Border regions. The T-DNA contains the *dmo* and *bar* expression cassettes. The *dmo* expression cassette is regulated by the *PC1SV* promoter, the *TEV* 5' leader sequence, and the *E6* 3' untranslated region. The chloroplast transit peptide CTP2 directs transport of the MON 88701 DMO protein to the chloroplast and is derived from *CTP2* target sequence of the *Arabidopsis thaliana shkG* gene. The *bar* expression cassette is regulated by the *e35S* promoter, the *Hsp70* leader, and the *nos* 3' untranslated region. After transformation, self pollination and segregation were used to select those plants containing a single homozygous copy of the T-DNA, including both the *dmo* and *bar* expression cassettes, resulting in the selection of DGT cotton.

Molecular characterization determined that DGT cotton contains one copy of the T-DNA at a single integration locus and all genetic elements are present. These data also demonstrated that DGT cotton does not contain detectable backbone sequences from the plasmid vector. The complete DNA sequence of the insert and adjacent genomic DNA sequences in DGT cotton confirmed the integrity of the inserted *dmo* and *bar* expression cassettes and identified the 5' and 3' insert to flank DNA junctions. Molecular characterization analysis also demonstrated that the insert in DGT cotton has been maintained over five consecutive generations of breeding, thereby confirming the stability of the insert. Furthermore, results from segregation analyses show inheritance and stability of the insert were as expected across multiple generations, which corroborates the molecular insert stability analysis determination that the DGT cotton T-DNA resides at a single chromosomal locus within the cotton genome.

G.3.6. Data Confirms MON 88701 DMO and PAT (*bar)* Protein Safety

A multistep approach was used to characterize and assess the safety of the MON 88701 DMO and PAT (*bar*) proteins expressed in DGT cotton resulting from the genetic modification. The expression levels of the MON 88701 DMO and PAT (*bar*) proteins in selected tissues of DGT cotton were determined. An assessment of the allergenic potential of the MON 88701 DMO and PAT (*bar*) proteins supports the conclusion that neither protein poses a significant allergenic risk to humans or animals. In addition, the donor organisms for the MON 88701 DMO and PAT (*bar*) protein coding sequences, *Stenotrophomonas maltophilia* and *Streptomyces hygroscopicus*, respectively, are ubiquitous in the environment and are not commonly known for human or animal pathogenicity or allergenicity. Bioinformatics analysis determined that the MON 88701 DMO and PAT (*bar*) proteins lack structural similarity to known allergens, gliadins, glutenins, or protein toxins. The MON 88701 DMO and PAT (*bar*) proteins are rapidly digested in simulated gastrointestinal fluids and neither protein demonstrates acute oral toxicity in mice at the levels tested. Hence, the consumption of the MON 88701 DMO and PAT (*bar*) proteins from DGT cotton or its progeny poses no meaningful risk to the environment or human and animal health.

G.3.7. DGT Cotton is Compositionally Equivalent to Conventional Commercial Cotton

Detailed compositional analyses were conducted in accordance with OECD guidelines to assess whether levels of key nutrients and anti-nutrients in DGT cotton cottonseed were comparable to levels in the conventional control, Coker 130, and several commercial reference cotton varieties. These compositional comparisons were made by analyzing cottonseed harvested from eight U.S. field sites in which DGT cotton was treated with dicamba and glufosinate, with the conventional control, and a range of commercial reference varieties that were grown concurrently in the same field trial. Compositional comparisons of DGT cotton not treated with dicamba or glufosinate herbicides were also conducted to further support the assessment of DGT cotton traits. The commercial reference varieties used to establish a range of natural variability for key nutrients and anti-nutrients have a history of safe consumption. Nutrients assessed in this analysis included proximates (ash, carbohydrates, and calories by calculation, moisture, protein, and fat), fibers (ADF, crude fiber, NDF, and TDF), amino acids (18 components), fatty acids (C8-C22), minerals (calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium, and zinc) and vitamin E. The anti-nutrients assessed in this analysis included gossypol and the cyclopropenoid fatty acids dihydrosterculic, malvalic, and sterculic.

Combined-site analyses were conducted to determine if there were any statistically-significant differences (5% level of significance) between DGT cotton and the conventional control cottonseed samples. Significant differences noted from the combined-site statistical comparison were assessed using considerations relevant to the safety and nutritional quality of DGT cotton when compared to the conventional control. Considerations used to assess the relevance of each combined-site statistically significant difference included: 1) the relative magnitude of the difference in the mean values of nutrient and anti-nutrient components between DGT cotton and the conventional control; 2) whether the DGT cotton component mean value is within the range of natural variability of that component as represented by the 99% tolerance interval of the commercial reference varieties grown concurrently in the same trial; 3) evaluation of the reproducibility of the statistical ($p < 0.05$) combined-site component differences at individual sites; and 4) an assessment of the differences within the context of natural variability of commercial cotton composition published in the scientific literature and in the International Life Sciences Institute (ILSI) Crop Composition Database.

Based on these criteria, the observed differences were not meaningful to food and feed safety or nutritional value, and led to the conclusion that DGT cotton is compositionally equivalent to commercially cultivated cotton that has a history of safe consumption. These results support the overall food and feed safety of DGT cotton.

G.3.8. DGT Cotton Does Not Change Cotton Plant Pest Potential or Environmental Interactions

Plant pest potential of a biotechnology-derived crop is assessed from the basis of familiarity that the USDA recognizes as an important underlying concept in risk assessment. The concept of familiarity is based on the fact that the biotechnology-derived plant is developed from a conventional plant hybrid or variety whose biological properties and plant pest potential are well known. Familiarity considers the biology of the plant, the introduced trait(s), the receiving environment, and the interactions among these factors. This provides a basis for comparative risk assessment between a biotechnology-derived plant and the conventional control. Thus, the phenotypic, agronomic, plant mapping, and environmental interaction assessment of DGT cotton included the parental conventional control as a comparator. This evaluation used a weight-of-evidence approach and considered statistical differences between DGT cotton and the conventional control with respect to reproducibility, magnitude, and directionality. The observations were taken on plants not treated with dicamba or glufosinate, in order to evaluate the impact of the introduced traits in DGT cotton. To further support the trait assessment, similar supplemental observations were also conducted on the agronomic system that includes DGT cotton treated with dicamba and glufosinate herbicides. Comparison to a range of commercial reference varieties established the range of natural variability for cotton, and provided a context from which to further evaluate any statistical differences. Characteristics assessed included: seed dormancy and germination, pollen morphology, plant phenotypic observations, plant mapping, and environmental interaction evaluations conducted in the field. The phenotypic, agronomic, and environmental interaction assessment demonstrated that DGT cotton is comparable to conventional cotton. Thus, DGT cotton is unlikely to have increased weediness or plant pest potential compared to commercially cultivated cotton.

Seed dormancy and germination characterization demonstrated that DGT cotton cottonseed had germination characteristics similar to cottonseed of the conventional control. In particular, the lack of hard seed, a well-accepted characteristic of weediness affecting seed germination, supports a conclusion of no increased weediness of DGT cotton when compared to the conventional control. Additionally, there were no statistically significant (5% level of significance) differences observed between DGT cotton and the conventional control for pollen viability and diameter, and no visual differences in general pollen morphology were observed. Collectively, these results support the conclusion that DGT cotton is not likely to exhibit increased plant pest potential compared to commercially cultivated cotton.

The field evaluation of phenotypic, agronomic, plant mapping, and environmental interaction characteristics of DGT cotton also support the conclusion that DGT cotton is not likely to have an increased plant pest potential compared to commercially cultivated cotton. The evaluations were conducted at 26 replicated field sites across the U.S. cotton producing region. These assessments included plant growth and development characteristics, including cotton plant mapping evaluations at harvest, as well as observations for plant responses to abiotic stressors and plant-disease and plant-arthropod interactions. The observed phenotypic characteristics were similar between DGT cotton and the conventional control.

In a combined-site analysis of plant growth and development characteristics, data showed no statistically significant differences (5% level of significance) between DGT cotton and the conventional control for stand count at 14 and 30 days after planting (DAP), final stand count, number of nodes above white flower at one of three observations, seed cotton yield, immature seed per boll, weight per boll, micronaire, fiber elongation, fiber uniformity, and fiber length. The mean values for DGT cotton were statistically different from the conventional control for eight parameters in the combined-site analysis. DGT cotton had shorter plants at 30 DAP and harvest, an increased number of nodes above white flower at two observations, a lower seed index, increased seed per boll, increased mature seeds per boll, and increased fiber strength. However, the mean values of DGT cotton were within the range of values observed for the commercial reference varieties for each of the characteristics listed above. Therefore, none of these differences were considered biologically meaningful in terms of increased plant pest potential of DGT cotton compared to commercially cultivated cotton.

Plant mapping is a process commonly used by cotton agronomists and breeders to quantify growth and development parameters of a cotton plant, including boll retention. Plant mapping parameters, which include delineation of boll position and spatial retention of bolls, are used to measure crop productivity and are influenced by abiotic and biotic stressors. In the combined-site analysis of plant mapping parameters, no statistically significant differences were detected between DGT cotton and the conventional control for number of mainstem nodes, number of nodes to first fruiting branch, total number of bolls per plant, number of vegetative bolls per plant, percent retention of first-position bolls, and percent first-position bolls. One statistically significant difference was detected between DGT cotton and the conventional control in the combined-site analysis. The mean value for first-position bolls per plant was higher for DGT cotton than the conventional control. However, the mean value of the number of first-position DGT cotton bolls was within the range of the commercial reference varieties. Thus, DGT cotton is similar to commercially cultivated cotton varieties and unlikely to have increased plant pest potential, increased weediness, or an adverse environmental impact compared to commercially cultivated cotton.

In an individual site assessment of abiotic stress response and disease damage, no differences were observed between DGT cotton and the conventional control for any of the 296 comparisons for the assessed abiotic stressors or for any of the 299 comparisons for the assessed diseases among all observations at the 26 sites. In an assessment of arthropod-related damage, no differences were detected between DGT cotton and the conventional control for any of the 288 comparisons for the assessed arthropods. The lack of significant biological differences in plant responses to abiotic stress, disease damage, and arthropod-related damage for DGT cotton support the conclusion that the introduction of the dicamba and glufosinate tolerance traits are unlikely to result in increased plant pest potential or an altered environmental impact from DGT cotton compared to commercially cultivated cotton.

In an assessment of pest- and beneficial-arthropod abundance, no statistically significant differences (5% level of significance) were detected between DGT cotton and the conventional control for 173 out of 178 comparisons (including 89 arthropod-pest and 89 beneficial-arthropod comparisons) among the multiple collections conducted during the season at five geographically diverse sites. For the five detected differences in arthropod abundance, two were arthropod pests (stink bugs and tarnished plant bugs) and three were beneficial arthropods (*Nabis* spp. and *Orius* spp.). The differences detected in pest- and beneficial-arthropod abundance were small in magnitude and were not consistent with other collections at the individual sites or across the sites. Consequently, it is concluded that the differences in pest- and beneficial-arthropod abundance are not indicative of a consistent plant response associated with DGT cotton and are not biologically meaningful in terms of increased plant pest potential or an altered environmental impact from DGT cotton compared to commercially cultivated cotton.

Field evaluations of phenotypic, agronomic, and plant mapping characteristics of DGT cotton treated with dicamba and glufosinate herbicides were also conducted to further support the assessment of DGT cotton traits. Data were collected from field trials conducted at eleven sites within the U.S. cotton-producing region. These assessments included plant growth and development characteristics, as well as plant mapping evaluations at harvest. The phenotypic, agronomic, and plant mapping assessments demonstrated that herbicide-treated DGT cotton is not different than the conventional control, which further supports that DGT cotton, whether treated or not with dicamba and glufosinate, is unlikely to have an altered plant pest potential compared to commercially cultivated cotton.

In summary, the phenotypic, agronomic, plant mapping and environmental interaction data were evaluated to characterize DGT cotton, and to assess whether the introduction of the traits in DGT cotton alters the plant pest potential compared to conventional cotton. The evaluation, using a weight-of-evidence approach, considered the reproducibility, magnitude, and direction of detected differences between DGT cotton and the conventional control, and comparison to the range of the commercial reference varieties. Results from the phenotypic, agronomic, plant mapping, and environmental interactions assessment indicated that DGT cotton does not possess weedy characteristics, increased susceptibility or tolerance to specific abiotic stress, diseases, or arthropods, or characteristics that would confer a plant pest risk or a significant environmental impact compared to commercially cultivated cotton.

G.3.9. DGT Cotton Will Not Adversely Affect NTOs or Threatened and Endangered Species

Evaluation of the impacts of a biotechnology-derived crop on non-target organisms (NTOs) is a component of the plant pest risk assessment. Since MON 88701 does not possess pesticidal activity, all organisms that interact with DGT cotton are considered to be NTOs. The environmental assessment demonstrated that the presence of the dicamba and glufosinate-tolerance traits in DGT cotton did not alter plant-arthropod interactions, including beneficial arthropods, or alter disease susceptibility compared to the conventional control. In addition, plant mapping data, which is utilized to determine crop productivity in relation to abiotic and biotic stresses affecting yield, demonstrated that both DGT cotton plots treated and not treated with dicamba and glufosinate herbicides each had only a single significant difference from the conventional control, an increased number of first-position bolls that was within the range of the commercial reference varieties. From these data it can be concluded that both DGT cotton plants treated and not treated with dicamba and glufosinate responded to stressors in a similar manner.

The biochemical information and experimental data for evaluation of DGT cotton included molecular characterization, MON 88701 DMO and PAT (*bar*) safety assessments, the history of environmental exposure to mono-oxygenases (the class of enzymes to which MON 88701 DMO belongs) and the PAT proteins in several commercial glufosinate-tolerant events, information from the environmental interaction assessment, demonstration of compositional equivalence to conventional cotton, and demonstration of agronomic and phenotypic equivalence to conventional cotton. Overall, these data support the conclusion that DGT cotton has no reasonable mechanism for harm to NTOs and does not pose any additional risk to NTOs compared to commercially cultivated cotton.

The potential for outcrossing and gene introgression from DGT cotton to sexually compatible species in the U.S. is unlikely, since the only known wild *Gossypium* species related to cultivated cotton do not grow in areas where cotton is cultivated, cotton pollen movement by wind is limited due to it is large and sticky nature, and several studies have demonstrated that cross-pollination, even in the presence of high pollinator activity is limited by distance. Furthermore, should cross-pollination occur, DGT cotton and its progeny are not expected to exhibit a significant environmental impact because, as described above, evaluations have shown that the presence of the dicamba and glufosinate-tolerance traits are not likely to enhance weediness or plant-pest potential. Therefore, the environmental consequence of pollen transfer from DGT cotton to other *Gossypium* species is considered negligible.

G.3.10. Deregulation of DGT Cotton is Not Likely to Impact Cotton Agronomic Practices or Land Use

Cotton fields are typically highly managed agricultural areas that are dedicated to crop production for many years. Cultivation of DGT cotton would not be expected to differ from typical cotton cultivation, with the sole exception of an expanded window of dicamba application, due to the presence of the dicamba-tolerance trait in DGT cotton. As glufosinate is already utilized within the U.S. cotton-growing areas, no change in agronomic practices or land use would occur with the cultivation of DGT cotton and the presence of the glufosinate-tolerance trait. DGT cotton likely would be used in common rotations on land currently used for agricultural purposes. As demonstrated, DGT cotton is similar to commercially cultivated cotton in its agronomic, phenotypic, ecological, and compositional characteristics, and has comparable levels of resistance to insects, diseases, and abiotic stresses as compared to commercial cotton. Therefore, the introduction of DGT cotton into the existing cotton system is not expected to have a significant impact on current cultivation and pest management practices for cotton. The adoption of DGT cotton into glyphosate-tolerant cotton systems will provide growers with two additional herbicide modes-of-action and the means to control broadleaf weeds, including hard-to-control and herbicide-resistant broadleaf weeds, and will help preserve conservation tillage practices by providing growers with an additional weed management tool. Based on these considerations, DGT cotton is not likely to impact agronomic practices or land use, with the exception of the expanded application window of dicamba.

G.3.11. Conclusion

Based on the data and information presented in petition #12-185-01p, it is concluded that DGT cotton is not likely to be a plant pest. Therefore, Monsanto Company requests a determination from USDA-APHIS that DGT cotton and any progeny derived from crosses between DGT cotton and conventional *Gossypium* cotton species or deregulated biotechnology-derived cotton be granted nonregulated status under 7 CFR Part 340.

G.4. Adverse Consequences of Introduction

Monsanto does not know of any results or observations associated with DT soybean, DGT cotton, or the MON 87708 DMO, MON 88701 DMO or PAT (*bar*) proteins indicating that there would be an adverse environmental consequence from the introduction of DT soybean or DGT cotton. DT soybean contains DMO that confers dicamba tolerance to the soybean plant and DGT cotton contains DMO and PAT that confers dicamba and glufosinate tolerance to the cotton plant, respectively. As demonstrated by field results and laboratory tests, the only phenotypic differences between DT soybean and DGT cotton and their conventional counterparts are there herbicide tolerances.

The data and information presented in petition #10-188-01p demonstrate that DT soybean is unlikely to pose an increased plant pest risk or to have an adverse environmental consequence compared to conventional soybean. This conclusion is based on multiple lines of evidence developed from a detailed characterization of the product compared to conventional soybean, followed by risk assessment on detected differences: 1) characterization evaluations included molecular analyses, which confirmed the insertion of a single functional copy of the *dmo* expression cassette at a single locus within the soybean genome; 2) measurement of the MON 87708 DMO levels in various soybean tissues; 3) characterization of the MON 87708 DMO confirming it is not novel and is structurally and functionally similar to oxygenase homologs widely present in bacteria and plants, where a history of safe use is established; and 4) extensive characterization of the plant phenotype, including compositional analysis of key nutrients and antinutrients, and environmental interactions. Therefore, based on the lack of increased pest potential or adverse environmental consequences compared to conventional soybean, the risks for humans, animals, and other NTOs from DT soybean are negligible under the conditions of use. Additionally the introduction of DT soybean will not adversely impact cultivation practices or the management of weeds, diseases, and insects in soybean production systems, other than the use of dicamba postemergence in soybean.

The data and information presented in petition #12-185-01p demonstrate that DGT cotton is unlikely to pose an increased plant pest risk or to have an adverse environmental consequence compared commercially cultivated cotton. This conclusion is reached based on multiple lines of evidence developed from a detailed characterization of the product compared to commercially cultivated cotton, followed by a risk assessment on detected differences. The characterization evaluation included molecular analyses, which confirmed the insertion of a single functional copy of the *dmo* and *bar* expression cassettes at a single locus within the cotton genome. The amino acid sequence of the MON 88701 DMO and PAT (*bar*) proteins expressed in DGT cotton are identical to the amino acid sequences of the respective *E. coli*-produced proteins utilized in the protein safety studies supporting the safety of the proteins. Analyses of key nutrients and, anti-nutrients of DGT cotton seed demonstrate that DGT cotton is compositionally equivalent to commercially cultivated cotton. The phenotypic evaluations of DGT cotton, including an assessment of seed germination and dormancy characteristics, plant growth and development characteristics, plant mapping parameters, pollen characteristics, and environmental interactions also indicated that DGT cotton is no more weedy than commercially cultivated cotton. There is no indication that DGT cotton would have an adverse impact on beneficial or non-target organisms. Therefore, based on the lack of increased plant pest potential or adverse environmental consequences compared to commercially cultivated cotton, the risks for humans, animals, and other NTOs from introducing DGT cotton are negligible under the conditions of use.

Successful integration of DT soybean and DGT cotton into the glyphosate-tolerant soybean and cotton systems will provide growers with an opportunity for an efficient, effective weed management system for the management of glyphosate's hard-to-control and resistant broadleaf weeds; provide flexible systems for inclusion of a second and/or third herbicide mode-of-action in soybean and/or cotton production practices as recommended by weed science experts to manage weed resistance development; and continue to provide soybean and cotton growers with effective weed control systems necessary for production yields to meet the growing needs of the food, feed, and industrial markets.

APPENDIX H: PRESENCE OF DICAMBA-TOLERANT SOYBEAN AND DICAMBA-AND-GLUFOSINATE-TOLERANT COTTON IN HUMAN FOOD OR ANIMAL FEED

Table of Contents

Tables and Figures

H.1. Dicamba-Tolerant Soybean

H.1.1. Introduction

The scope of this section covers how DT soybean could be present in human food and animal feed and the potential health impacts of that presence.

Soybean is the most widely grown oilseed in the world, with approximately 211 million metric tons of harvested seed produced in 2008. This represents 56% of world oilseed seed production that year (ASA 2012). Soybean is grown as a commercial crop in over 35 countries. The major producers are the U.S., Brazil, Argentina, China, India, and Paraguay, accounting for approximately 94% of the global soybean production in 2008. Approximately one-third of the 2008 world soybean production was in the U.S. (Soyatech, 2010). The U.S. was also the largest soybean seed exporting country in 2008 (ASA, 2009).

H.1.1.1. Soy Biology and Usage

Cultivated soybean, *Glycine max* (L.) Merr., is a diploidized tetraploid (2n=40), in the family Leguminosae, the subfamily Papilionoideae, the tribe Phaseoleae, the genus Glycine Willd. and the subgenus Soja (Moench) (OECD, 2000). It is an erect, bushy herbaceous annual that can reach a height of 1.5 metres.

Soybean is grown as a commercial crop in over 35 countries and is one of the most valued agricultural commodities because of its high protein and oil content. In 2008, soybean represented 57% of world oilseed production, and approximately 33% of those soybean were produced in the U.S. In 2008, the U.S. exported 1.16 billion bushels (31.6 million metric tons) of soybean, which accounted for 40% of the world's soybean exports and was valued at $15.5 billion (ASA, 2009).

Approximately 94% of the world's soybean seed supply was crushed to produce soybean meal and oil in 2008 (Soyatech, 2010), and the majority was used to supply the feed industry for livestock use or the food industry for edible vegetable oil and soybean protein isolates.

The U.S. soybean acreage in the past 10 years has varied from approximately 64.7 to 77.5 million acres. Average soybean yields have varied from 33.9 to 44.0 bushels per acre over this same time period. According to data from USDA-NASS (2013a), soybean was planted on approximately 77.2 million acres in the U.S. in 2012, producing 3.0 billion bushels of soybean with a value of $43.19 billion (USDA-NASS, 2913a).

In the U.S., soybean production occurs in three major soybean growing regions accounting for 99.1% of the soybean acreage: Midwest region (IL, IN, IA, KS, KY, MI, MN, MO, NE, ND, OH, SD, and WI), Southeast region (AL, AR, GA, LA, MS, NC, SC, and TN) and the Eastern Coastal region (DE, MD, NJ, NY, PA, and VA). Table H-1 shows the relative productivity of the three regions in 2008.

Table H-1. 2012 Soybean Productivity by Region

Region	% 2012 U.S. Soybean Acreage	2008 Average Yield (bushels per acre)	Range of Average State Yields (bushels per acre)
Midwest/Plains	84.1	39.0	22.0 – 45.0
Southeast	13.1	42.1	34.0 – 46.0
Eastern Coastal	2.9	45.1	39.0 – 49.0

Source: USDA-NASS (2013a).

H.1.1.2. Conventional Soy Crop

Soybean has a long history of planting and production in North America. Soybean was originally introduced into North America from China in 1765 and has since been reintroduced several times by scientists, seed dealers, merchants, military expeditions, and various individuals (Singh and Hymowitz, 1999). Conventional plant breeding is based on the interplay and combination of genes present in the particular crop genome, and soybean is limited with regard to genetic diversity (Chung and Singh, 2008).

Soybean is one of eight allergenic foods that are responsible for approximately 90% of all food allergies (Cordle, 2004). Soybean is less allergenic than other foods in this group and is rarely responsible for severe, life-threatening reactions (Cordle, 2004). Allergy to soybean is more prevalent in children than adults and is considered a transient allergy of infancy/childhood (Sicherer et al., 2000).

The conventional soybean variety A3525, used as the recipient for the *dmo* expression cassette insertion that produced DT soybean, was developed by Asgrow Seed Company. A3525 is a mid−maturity group III soybean variety with very high yield potential. A3525 has superior yields relative to varieties of similar maturity and has excellent agronomic characteristics (Steffen, 2004).

H.1.1.3. Gene and Gene Product

Production of a GE organism involves integration of a DNA cassette that is novel to a host plant into the host plant's genomic DNA, called a transformation event. The DNA construct contains all the genetic information needed to produce the new characteristic or trait and, in most instances, this includes production of a protein. DT soybean contains a gene from *Stenotrophomonas maltophilia* that expresses a mono-oxygenase enzyme that rapidly demethylates dicamba and renders it inactive, thereby conferring tolerance to dicamba. The demethylation of dicamba produces 3,6-dichlorosalicylic acid (DCSA), a known soybean, cotton, soil, and livestock metabolite whose safety has been evaluated by the Environmental Protection Agency (U.S. EPA, 2009), and formaldehyde, a compound that is naturally present in many plants and in the human body.

FDA enforces laws regarding the safety and labeling of food and feed. In 2011, Monsanto completed a voluntary consultation with FDA regarding the food and feed safety of DT soybean (see appendix I). FDA considers a consultation to be completed when all food and feed safety issues and any regulatory issue are resolved (see appendix I; also see http://www.fda.gov/food/foodscienceresearch/biotechnology/submissions/default.htm). As part of this consultation, Monsanto discussed its findings that MON 87708 DMO is similar to the amino acid sequences of bacterial mono-oxygenases. MON 87708 DMO belongs to a common class of mono-oxygenases present in bacteria and plants currently widely prevalent in the environment and consumed by human and animals alike. Monsanto explained that: (1) there is an absence of known reports of allergies to *S. maltophilia*, which is the source of the *dmo* gene transferred to the recipient plant lines; (2) there is a lack of both structurally and immunologically relevant similarities between the amino acid sequences of MON 87708 DMO and known allergens, gliadins, and glutenins; (3) all forms of MON 87708 DMO are rapidly degraded in vitro in simulated gastric fluid and in simulated intestinal fluid.

H.1.1.4. Herbicides

Dicamba was approved by the U.S. EPA for agricultural uses in 1967 (U.S. EPA, 2009). Dicamba is formulated as a stand-alone herbicide product and marketed by several companies under various trade names such as Banvel®, Clarity®, Diablo®, Rifle®, and Sterling® that are various salt formulations of dicamba. These dicamba products can be tank mixed with one or more active ingredients depending on the treated crop. For example, Clarity can be tank mixed with over 75 herbicide products in labeled crops. Additionally, dicamba is formulated as a registered premix product with one or more other herbicide active ingredients such as glyphosate, 2,4-D, diflufenzopyr, atrazine, nicosulfuron, metsulfuron, primsulfuron, triazulfuron, rimsulfuron and halosulfuron. Dicamba herbicide (*e.g.*, Clarity – diglycolamine (DGA) salt of dicamba) is currently labeled for weed control in soybean, corn, cotton, sorghum, wheat, barley, oats, millet, pasture, rangeland, asparagus, sugarcane, turf, grass grown for seed, conservation reserve programs, and fallow croplands.

Dicamba is currently labeled for use in conventional or Roundup Ready soybean, although dicamba use is extremely limited because applications are restricted to very early preplant and/or preharvest applications due to soybean tolerance concerns. The dicamba-treated acreage in 2011 soybean production was approximately 870,000 acres, representing 1.2% of the total soybean acreage. Upon integration of DT soybean into the Roundup Ready soybean system, dicamba herbicide use will be expanded to in-crop postemergence applications for those hard-to-control and herbicide-resistant broadleaf weeds found in U.S. soybean production. The impact that DT soybean will have on overall dicamba use will be dependent upon the level of DT soybean adoption by growers. Thus, the extent of dicamba-treated soybean acreage following the deregulation of DT soybean is difficult to forecast. Monsanto estimates dicamba-treated acres to ultimately be in the range of 30 to 50% of the total U.S. soybean acres. See Appendix A.

H.1.2. Dicamba-Tolerant Soy Hazard Identification

Soybean (*Glycine max* (L.) Merr.) is the most widely grown oilseed in the world. Soybean is grown primarily for the production of seed, has a multitude of uses in the food and industrial sectors, and represents one of the major sources of edible vegetable oil and of proteins for livestock feed use. Monsanto Company developed DT soybean to be tolerant to the herbicide dicamba.

H.1.2.1. Dicamba-Tolerant Soy Biology

DT soybean contains a *dmo* expression cassette that upon translation results in two forms of DMO protein; referred to as DMO and DMO+27. The active form of the proteins, necessary to confer dicamba tolerance, is a trimer comprised of three DMO monomers. In DT soybean, the trimer can be comprised of DMO, DMO+27, or a combination of both. Therefore, this document will refer to both forms of the protein and all forms of the trimer as MON 87708 DMO.

DMO is an enzyme that catalyzes the demethylation of dicamba into the non-herbicidal compound DCSA and formaldehyde. DCSA is a known soybean, cotton, soil, and livestock metabolite whose safety has been evaluated by the EPA. Formaldehyde is found naturally in many plants at levels up to several hundred ppm.

DT soybean was developed through Agrobacterium-mediated transformation of soybean meristem tissue using the binary transformation plasmid PV-GMHT4355. DT soybean contains one copy of the insert at a single integration locus. No additional genetic elements from the transformation vector were detected in the genome of DT soybean, including backbone sequence from plasmid PV-GMHT4355. Additionally, the data confirm the organization and sequence of the insert, and demonstrate the stability of the insert over several generations. On the basis of these data, it is concluded that only the MON 87708 DMO is produced from the inserted DNA. Additionally, analyses of nutrient and anti-nutrient levels in both dicamba-treated and untreated DT soybean and a near-isogenic conventional control support the conclusion that soybean seed and forage produced from DT soybean are compositionally equivalent to that of conventional soybean.

H.1.2.1.1. Characterization of DT soybean

The safety assessment of crops derived through biotechnology includes characterization of the functional and physicochemical properties, and confirmation of the safety of the introduced protein. As stated previously, both forms of the protein and all forms of the trimer are referred to as the MON 87708 DMO. MON 87708 DMO was purified in sufficient quantities directly from the seed of DT soybean and used in subsequent safety assessment studies. Typically protein safety studies are conducted on proteins produced in heterologous expression systems, such as *E. coli*. Since the MON 87708 DMO used in the subsequent safety studies was purified directly from MON 87708 DMO, equivalence evaluations between plant-produced and bacterial-produced MON 87708 DMO was not necessary. The physicochemical characteristics and functional activity of the MON 87708 DMO were determined by a panel of analytical techniques, including: 1) western blot analysis to establish identity and immunoreactivity of MON 87708 DMO using an anti-DMO antibody, 2) N-terminal sequence analysis, 3) matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) to generate a tryptic peptide map of the MON 87708 DMO, 4) sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) to establish the apparent molecular weight of MON 87708 DMO, 5) glycosylation status of MON 87708 DMO, and 6) MON 87708 DMO activity analysis to demonstrate functional activity. The details of the materials, methods, and results are described in Appendix C of the Monsanto petition (Monsanto 2010), while the conclusions of the MON 87708 DMO characterization are summarized below.

The identities of both forms of the DMO protein produced in DT soybean that constitute MON 87708 DMO were confirmed by western blot analysis by probing with an anti-DMO antibody, N-terminal sequencing, and MALDI-TOF MS analysis of peptides produced after trypsin digestion. The antibody specifically detected DMO and DMO+27 on a western blot. The N-terminal sequence of the first 15 amino acid residues of both DMO and DMO+27 was identical to the predicted amino acid sequence, with the exception of the N-terminal methionine residue. MALDI-TOF MS analyses of DMO and DMO+27 yielded peptide masses consistent with their expected sequence. The apparent molecular weights of DMO and DMO+27 were 39.8 and 42.0 kDa, respectively and neither were glycosylated. The MON 87708 DMO activity was determined by measuring the production of DCSA using dicamba as the substrate, resulting in a specific activity of 62.21 nmoles DCSA/min/mg of MON 87708 DMO. Taken together, these data provide a detailed characterization of the MON 87708 DMO isolated from the seed of DT soybean.

H.1.2.1.2. Expression Levels of MON 87708 DMO

The levels of MON 87708 DMO in various tissues of DT soybean that are relevant to the risk assessment were determined by a validated ELISA. Tissues of DT soybean and the near isogenic conventional soybean control A3525 were collected during the 2008 growing season from five field sites in the U.S.: Jefferson County, Iowa; Stark County, Illinois; Clinton County, Illinois; Parke County, Indiana; and Berks County, Pennsylvania. These field sites were representative of soybean producing regions suitable for commercial production. At each site, three replicated plots containing DT soybean, as well as the conventional control, were planted using a randomized complete block field design. Over-season leaf (OSL 1-4), root, forage, and seed tissues were collected from each replicated plot at all field sites (except for the conventional control from Berks County, Pennsylvania where only two replicates were collected). A description of tissues collected is provided in Table H-2.

Table H-2. Tissues Collected and Analyzed for MON 87708 DMO

Tissue	Soybean Development Stage[1]	Days After Planting
OSL-1	V3-V4	21-30
OSL-2	V5-V8	31-42
OSL-3	R2-V12	43-58
OSL-4	R5-V16	55-78
Root	R6	70-91
Forage	R6	70-91
Seed	R8	109-147

[1]Soybean plant growth stages described in Soybean Growth and Development (ISU, 2004).

The levels of MON 87708 DMO were determined in all seven tissue types as described in Table H-3. The ELISA assay detected all forms of MON 87708 DMO and therefore the levels represent the total of MON 87708 DMO. The results obtained from the ELISA analysis are summarized in Table H-3 and the details of the materials and methods are described in Appendix D to the Monsanto petition (Monsanto 2010). In summary, expression analysis of the samples from the 2008 U.S. field trial showed that MON 87708 DMO was detected in all tissue types across all five sites ranging from 3.9 – 180 μg/g dry weight (dwt). The mean levels of the MON 87708 DMO across the five sites were highest in leaf (ranging from OSL-1 at 17 μg/g dwt, to OSL-4 at 69 μg/g dwt), followed by forage (53 μg/g dwt), seed (47 μg/g dwt), and root (6.1 μg/g dwt). As expected for the conventional control, the ELISA values for MON 87708 DMO were less than the limit of quantitation (LOQ) of the assay in all tissue types.

Table H-3. Summary of the Levels of MON 87708 DMO[1] in Leaf, Root, Forage, and Seed from DT soybean Grown in 2008 U.S. Field Trials

Tissue Type	Mean (SD)[2] (µg/g fwt)[3]	Range[4] (µg/g fwt)	Mean (SD) (µg/g dwt)[5]	Range (µg/g dwt)	LOQ/LOD (µg/g fwt)[6,7]
OSL-1	3.1 (1.9)	0.87 – 6.8	17 (7.7)	6.2 – 29	0.63/0.20
OSL-2	5.2 (2.6)	1.4 – 9.8	31 (13)	12 – 54	0.63/0.20
OSL-3	6.0 (2.2)	3.5 – 11	44 (14)	25 – 71	0.63/0.20
OSL-4	16 (12)	4.6 – 43	69 (46)	23 – 180	0.63/0.20
Root	1.9 (0.73)	1.2 – 3.6	6.1 (2.1)	3.9 – 11	0.031/0.015
Forage	12 (2.5)	7.0 – 17	53 (18)	25 – 84	0.63/0.10
Seed	43 (7.7)	31 – 55	47 (8.7)	34 – 59	1.3/0.21

1 Represents total for MON 87708 DMO

2 The mean and standard deviation (SD) were calculated (n=15). The "n" values for the calculated mean and standard deviations represent the number of samples figured into the calculation.

3 Protein levels are expressed as microgram (µg) of protein per gram (g) of tissue on a fresh weight (fwt) basis.

4 Minimum and maximum values were determined for each tissue type.

5 Protein levels are expressed as µg/g dwt. The dry weight values were calculated by dividing the µg/g fwt by the dry weight conversion factors obtained from moisture analysis data.

6 The limit of quantitation (LOQ) was calculated based on the lowest DMO standard concentration. The "ng/ml" value was converted to "µg/g fwt" using the respective dilution factor and tissue-to-buffer ratio.

7 The limit of detection (LOD) was calculated as the mean value plus three SD using the data generated with conventional control sample extracts for each tissue type. The LOD value in "ng/ml" was converted to "µg/g fwt" using the respective dilution factor and tissue-to-buffer ratio.

H.1.2.1.3. Compositional Assessment

Monsanto conducted analyses of nutrient and anti-nutrient levels in both dicamba-treated and untreated DT soybean and the near isogenic conventional control A3525 to assess compositional equivalence. The tissues analyzed included seed and forage harvested from plants grown at five field sites in the U.S. during the 2008 field season. The composition analysis, conducted in accordance with OECD guidelines, also included measurement of nutrients and anti-nutrients in the commercial reference varieties concurrently grown with DT soybean to provide data on natural variability of each compositional component. All soybean plants including DT soybean, the conventional control, and the commercial reference varieties were treated with maintenance pesticides as necessary throughout the growing season. In addition, DT soybean plots were either treated at the V2-V3 growth stage with dicamba herbicide at the maximum in-crop label rate (0.5 lb a.e./acre) or not treated with dicamba herbicide.

For DT soybean treated, the combined-site analysis of both seed and forage showed no statistically significant differences between DT soybean and conventional control for 21 (42.0%) of the 50 mean value comparisons. Of the statistically significant differences observed, one was from the forage analysis, and 28 were from the seed analysis. Nutrient component differences in seed included mean values for ash, carbohydrates by calculation, protein and 12 amino acids, five fatty acids, ADF, NDF, crude fiber, and vitamin E. In the combined-site analysis, all nutrient component differences in seed between DT soybean and the conventional control were of small relative magnitude with respect to the conventional control and, whether increased or decreased, ranged from 1.51% to 12.37% for the three proximates, amino acids, fatty acids, and fibers, and 15.13% for vitamin E. Two of the nutrient components in the combined-site analysis (decreased levels of 18:1 oleic acid and increased levels of 18:3 linolenic acid) were also observed to be statistically different at all five individual sites, and one nutrient component (vitamin E) was observed to be increased at four of the five individual sites as in the combined-site analysis. The other combined-site differences occurred at fewer or none of the individual sites. Anti-nutrient component differences in seed were observed in mean values for phytic acid, raffinose, stachyose, and daidzein. In the combined-site analysis, all anti-nutrient component differences in seed between DT soybean and the conventional control were of small relative magnitude with respect to the conventional control, and ranged from a 6.14% decrease (phytic acid) to an 11.51% increase (daidzein). None of the anti-nutrient components were observed to be statistically different at more than two of the five individual sites. The only nutrient component difference in forage for the combined-site analysis was observed in ADF and its relative magnitude of difference, with respect to the conventional control, was 10.45%. No differences between DT soybean and the conventional control ADF mean values were observed at any of the five individual sites. Mean values of DT soybean components with statistically significant differences to the conventional control were all within the 99% tolerance interval established from the commercial reference varieties grown concurrently and at the same field sites, as well as ranges in the scientific literature and the ILSI Crop Composition Database.

For DT soybean (untreated) the combined-site analysis of both seed and forage showed no statistically significant differences between DT soybean (untreated) and conventional control for 30 (60.0%) of the 50 mean value comparisons. Of the statistically significant differences observed, none were from the forage analysis, and 20 were from the seed analysis. Nutrient component differences in seed included mean values for protein and eight amino acids, five fatty acids, ADF, NDF, and vitamin E. In the combined-site analysis, all nutrient component differences in seed between DT soybean (untreated) and the conventional control were of small relative magnitude with respect to the conventional control and, whether increased or decreased, ranged from 1.45% to 7.60% for protein and amino acids, fatty acids, and fibers, and 18.16% for vitamin E. None of the nutrient components in the combined-site analysis were observed to be statistically different at all five individual sites. Anti-nutrient component differences in seed were observed in mean values for trypsin inhibitor, daidzein, and genistein. In the combined-site analysis, all anti-nutrient component differences in seed between DT soybean (untreated) and the conventional control were of small relative magnitude, with respect to the conventional control, and ranged from an 11.59% increase (genistein), 15.37% increase (trypsin inhibitor), and a 17.24% increase (daidzein). None of the anti-nutrient components from the combined-site analysis were observed to be statistically different at more than one of the five individual sites. No nutrient component differences in forage for the combined-site analysis were observed. Mean values of DT soybean components with statistically significant differences to the conventional control were all within the 99% tolerance interval established from the commercial reference varieties grown concurrently and at the same field sites, as well as ranges in the scientific literature and the ILSI Crop Composition Database.

In summary, a comprehensive evaluation of key nutrients and anti-nutrients in seed and key nutrients in forage for both dicamba-treated and untreated DT soybean supports the conclusion that soybean seed and forage produced from DT soybean are compositionally equivalent to that of conventional soybean and that neither the dicamba tolerance trait in DT soybean, nor the dicamba herbicide treatment, applied according to maximum in-crop label rates (including the associated dicamba residue levels) have a meaningful impact on the composition and therefore on the food and feed safety or the nutritional quality of DT soybean compared to conventional soybean.

H.1.2.2. MON 87708 DMO and Gene Sequence Detection

Monsanto has committed to best industry practices on seed quality assurance and control to ensure the purity and integrity of DT soybean seed. Before commercializing DT soybean in any country, Monsanto has pledged to make a DT soybean detection method available to soybean producers, processors, and buyers.

H.1.2.2.1. MON 87708 DMO and Gene Sequence Detection Methods

Methods for detecting GE materials range in their limits of detection. In many situations, a test will be required that not only detects the presence of GE material, but also measures the amount of GE content in the sample. All testing methodologies detect either the inserted DNA or the expressed protein resulting from the inserted DNA. The major detection methods for transgenic proteins are Enzyme Linked Immunosorbent Assays (ELISAs), and make use of the properties of antibodies. ELISAs are easy to use, robust and cheaper than DNA detection methods but generally less sensitive (Griffiths et al., 2002). In contrast to protein detection assays, assays designed to detect transgenic DNA are more sensitive. The most commonly used DNA amplification method is the Polymerase Chain Reaction (PCR), though there are other amplification methods to suit specific applications.

For each testing method, a Limit of Detection (LOD) is defined to show the sensitivity of the method. For example, a method with an LOD of 1 percent (w/w) for GT soy would be able to detect GT soy in a batch of soy flour when present as 1 percent (w/w) of the total soy flour (Griffiths et al., 2002). It is important to note that this LOD value written in an abbreviated form means the LOD for GT soy is 1 percent (w/w) of total soy flour if the product is comprised of 100 percent soy (Griffiths et al., 2002). For food products containing several ingredients, estimation of the LOD is less reliable. Using the previous example, if the 1 percent (w/w) GE soy flour were used as a baking ingredient in cake, the soy flour may make up only 0.5 percent (w/w) of the total cake ingredients. The GE soy would thus be only 0.005 percent (w/w) of the total sample, which would be well below the LOD for this method (Griffiths et al., 2002). The LOD is normally defined on a percent (w/w) basis, the actual measurement of GE ingredients is based on either DNA or protein and this DNA- or protein-based measurement is not necessarily directly transferable to a percent (w/w) measurement (Griffiths et al., 2002). Some highly processed foods contain no traces of DNA and/or protein. In these cases, there is no analytical method available to identify whether these products are derived from GE materials.

H.1.2.2.2. Labeling Standards

In the United States, foods derived from GE plants are not required to indicate on the food label that they were derived from plants produced through the use of biotechnology with the exception of resultant foods that have a change in composition. While Australia has a labeling threshold level of 1 percent for unintended GE material, other countries such as Japan and Korea currently have a higher labeling threshold level of 5 percent (Griffiths et al., 2002). At present, European Union

Regulations 2003/1829/EC and 2003/1830/EC govern the use of GE ingredients intended for food, feed, and food additives. The threshold for labeling of food and feed is 0.9% for presence of approved GE material. Unapproved events are managed with zero tolerance (Alexander et al., 2007), however the EU has implemented a technical threshold for feed that is set at 0.1%. Products such as milk, meat, and eggs, and that are derived from livestock fed transgenic feeds are exempt from labeling laws in the EU and other countries with mandatory GE food labeling provisions. Other foods produced with GM technology, such as cheese produced with GM enzymes, wine and beer produced with GE yeasts, are exempted from EU-labeling as well. Currently, only the EU and Switzerland have labeling regulations specifically pertaining to GE feed (Griffiths et al., 2002; Alexander et al., 2007; ISAAA, 2005).

H.1.2.2.3. Detection in Food Products

There is some literature available on the detection and quantification of GE material in various foods. In an Australian monitoring study (Griffiths et al., 2002), the GT trait was detected in soy flour, soy protein isolate, soy milk, snack foods, biscuits, powdered bread, and corn flour as illustrated in Figure H-1 below.

Round	Number	Test Material	Ingredient	GM Ingredient[a]			Laboratory results		
				GM Trait	% of GM Ingredient	% in Test Product	No. Results	% of results present	% of results absent
1	2301A	Soy flour	Soy flour	Roundup Ready	1	1	85	94	6
	2301 B	Soy flour	Soy flour	Roundup Ready	0.2	0.2	81	89	11
	2301 C	Soy protein isolate	Soy protein isolate	-	0	0	91	91	9
	2301 D	Soy protein isolate	Soy protein isolate	Roundup Ready	1	1	94	99	1
	2301 E	Soy protein isolate	Soy protein isolate	Roundup Ready	0.5	0.5	92	98	2
2	2302 A	Maize flour	Maize flour	Bt176	0.75	0.75	74	97	3
	2302 B	Maize flour	Maize flour	-	0	0	74	26	74
	2302 C	Maize flour	Maize flour	Bt176	1.5	1.5	74	99	1
3	2303 A	Soy flour	Soy flour	-	0	0	63	16	84
	2303 B	Soy flour	Soy flour	Roundup Ready	2	2	63	92	8
	2303 C	Wheat flour/soy flour	Soy flour	Roundup Ready	10	0.5	63	97	3
4	2304 A	Maize flour	Maize flour	Bt176	0.5	0.5	98	99	1
5	GMO-05A	Soy milk powder with soy protein isolate	Soy protein isolate	Roundup Ready	1	0.15	67	100	0
6	GMO-06A	Snack Food Crumbs	Soy flour	Roundup Ready	0	0	57	14	86
	GMO-06B	Snack Food Crumbs	Soy flour	Roundup Ready	2	Unknown	58	95	5
7	GMO-07	Maize/soy flour mix	Soy flour	Roundup Ready	1	0.5	78	96	4
			Maize flour	Bt176	0.25	0.125	67	91	9
			Maize flour	Bt11	0	0	43	53	47
8	GMO-08A	Soy-based baked biscuit crumbs	Soy flour	Roundup Ready	2.5	0.05	91	98	2
9	GMO-09A	Soy in canned meat	Soy flour	Roundup Ready	5	0.1	81	67	33
10[b]	GMO-10A	Maize flour/wheat flour	Soy flour	Roundup Ready	0	0	92	4	96
			Maize flour	Bt176	0.5	0.025	97	86	14
			Maize flour	Bt11	0	0	65	6	94
	GMO-10B	Soya flour/maize flour	Soy flour	Roundup Ready	1	0.25	107	97	3
			Maize flour	Bt176	1	0.025	91	84	16
			Maize flour	Bt11	0	0	65	38	62
11[b]	GM11A	Soy flour/ wheat flour	Soy flour	Roundup Ready	1.5	0.075		90	10
			Maize flour	Bt176	0	0		8	92
			Maize flour	Bt11	0	0		0	100
	GM11B	Soy flour/ wheat flour	Soy flour	Roundup Ready	0.5	0.025		82	18
			Maize flour	Bt176	0	0		10	90
			Maize flour	Bt11	0	0		0	100
12	GM12	Powdered bread	Soy flour	Roundup Ready	3	0.01		81	19

[a] '% of GM Ingredient' is calculated as % (w/w) GM ingredient in total ingredient. '% in Test Product' is calculated as % (w/w) GM ingredient in total Test Material.
[b] Results for information only as IRMM Maize Reference Materials withdrawn due to degradation

Figure H-1: Australian Detection of Genetically Engineered Material in Various Foods (Griffiths et al., 2002)

H.1.2.2.4. Detection of MON 87708 DMO and Gene Sequence in Downstream Animals

The European Food Safety Authority (EFSA) has reported that a large number of experimental studies have shown that recombinant DNA consumed by livestock has not been subsequently detected in tissues, fluids, or edible products of these farm animals (EFSA 2007). DNA has always been present in food and, upon consumption, is quickly degraded by restriction nucleases present in the gastrointestinal tract of humans and animals to nucleic acids. According to the U.S. FDA (1992), nucleic acids are present in the cells of every living organism, do not raise concerns as a component of food, and are generally recognized as safe. Results from an International Life Sciences Institute (ILSI) workshop on safety considerations of DNA in food were reported (Jonas et al., 2001) and confirmed that: 1) all DNA, including recombinant DNA, is composed of the same four nucleotides; 2) there are no changes to the chemical characteristics or the susceptibility to degradation by chemical or enzymatic hydrolysis of recombinant DNA as compared to non-recombinant DNA; and 3) there is no evidence that DNA from dietary sources has ever been incorporated into the mammalian genome.

As described by the European Food Safety Authority (EFSA) in 2007 the fate of recombinant DNA from genetically engineered plants or resultant proteins are dependent on the following four factors:

- the fate of the recombinant DNA and protein during the feed processing and ensilaging;
- the fate of the recombinant DNA and protein in the gastrointestinal tract of animals fed with the GE feed;
- the potential absorption of the digested pieces of DNA or protein into animal tissues/products; and
- the potential of biological functionality of absorbed DNA and protein fragments.

No study has found that mechanical treatment (e.g., baling, chopping, processing) of animal feed has effect on DNA stability (EFSA). Digestion in the gut generally causes DNA and protein to be broken down to the original nucleotides and amino acids respectively. The inserted DNA and protein expressed from the inserted DNA are not expected to be digested in any different manner simply because they are present in the food due to the use of biotechnology.

For example, in field tests, CP4 EPSPS, the inserted gene sequence in glyphosate-tolerant (GT) soybeans, was found in GT soybean at 0.1 percent in chicken feed (Ash et al., 2003) by an ELISA method; no detectable amounts of CP4 EPSPS protein were in whole egg, egg albumen, liver, or feces of the chickens fed GT soybeans.

Conventional PCR/Southern Blot and an ELISA method were utilized to determine if transgenic DNA or protein were detectable in pigs fed GT soybeans (Jennings et al., 2003). The authors report that there was an absence of detectable levels of fragments of either transgenic DNA or protein. By contrast Sharma (2006) reported detection of transgenic DNA in intestinal tissue.

Quantitative real-time PCR and conventional PCR were used to evaluate GT canola cp4 *epsps* transgene in the intestines, rumen, or feces of sheep feed canola meal (Alexander et al., 2004). Digestion of plant material and release of tDNA (including transgenic DNA) can occur in the small intestine of sheep. The free transgenic DNA is rapidly degraded at neutral pH in small intestine duodenal fluid, thus reducing the likelihood that intact transgenic DNA would be available for absorption through the Peyer's Patches further down in the distal ileum of the small intestine (Alexander et al., 2004).

The persistence of plant-derived recombinant DNA in sheep and pigs fed GE (GT) canola was assessed by Sharma et al. (2006) utilizing PCR and Southern hybridization analysis of DNA extracted from digesta, GI tract tissues, and visceral organs. This study confirmed that DNA fragments ingested in feed do survive to the terminal GI tract and that uptake into gut epithelial tissues does occur. A very low frequency of transmittance to visceral tissue was confirmed in pigs, but not in sheep. There was no evidence to suggest that recombinant DNA would be processed in the gut in any manner different from endogenous feed-ingested genetic material.

A study by Netherwood et al. (2004) and the discussion by Heritage (2004) address the finding by Netherwood et al. of evidence of low-frequency EPSPS gene transfer from genetically engineered soya to the microflora of the small bowel. However, the microflora contained only fragments EPSPS; the full length gene was not detected, and it could not be determined whether it was the bacteria themselves that contained the fragments.

H.1.2.3. DT Soybean Safety Assessment

H.1.2.3.1. MON 87708 DMO Safety Assessment

FDA enforces laws regarding the safety and labeling of food and feed. In 2011 Monsanto completed a voluntary consultation with FDA regarding the food and feed safety of DT soybean. *See* Appendix I. FDA considers a consultation to be completed when all safety and regulatory issues are resolved. *See* Appendix I. As part of the consultation, Monsanto discussed its finding that the MON 87708 DMO belongs to a common class of mono-oxygenases present in bacteria and plants currently widely prevalent in the environment and consumed.

Regarding the food and feed safety of MON 87708 DMO, the available data demonstrate that harvested seed is as safe as conventional soybean for food and feed uses; thus it is safe and wholesome for consumption. To assess the impact of MON 87708 DMO on food and feed safety, bioinformatic analyses were used to establish the lack of both structurally and immunologically-relevant similarities between DT soybean and allergens or toxins, based on the amino acid sequence of MON 87708 DMO. Furthermore, digestive fate experiments conducted with MON 87708 DMO demonstrate rapid digestion in simulated gastric fluid (SGF), a characteristic shared among many proteins with a history of safe consumption. Rapid digestion of MON 87708 DMO in SGF indicates that it is highly unlikely that MON 87708 DMO will reach absorptive cells of the intestinal mucosa. This, combined with the history of safe consumption of mono-oxygenases (the class of enzymes to which MON 87708 DMO belongs) and the lack of homology of the amino acid sequence to known allergens and toxins, supports a conclusion that MON 87708 DMO has low allergenic and toxic potential. Finally, a high dose of MON 87708 DMO in a mouse acute oral toxicity evaluation demonstrated that it is not acutely toxic, and does not cause any adverse effect. The safety assessment supports the conclusion that exposure to MON 87708 DMO poses no meaningful risk to human or animal health.

H.1.2.3.1.1. Donor Organism Safety

The safety of the donor organism was discussed in Monsanto's consultation with the FDA. In this consultation, Monsanto explained that the *dmo* gene is derived from the bacterium *Stenotrophomonas maltophilia* (Palleroni and Bradbury, 1993).

S. maltophilia is ubiquitous in the environment and is found associated with the rhizosphere of plants. *S. maltophilia* can be found in a variety of foods and feeds, and is widespread in the home environment (Berg et al., 1999; Denton and Kerr, 1998; Echemendia, 2010). Exposure to *S. maltophilia* is incidental to its presence in food. It has been isolated from "ready to eat" salads, vegetables, frozen fish, milk, and poultry (Qureshi et al., 2005; Ryan et al., 2009). *S. maltophilia* can be found in healthy individuals without causing any harm to human health (Denton et al., 1998) and infections caused by *S. maltophilia* are extremely uncommon (Cunha, 2010). Strains have been found in the transient flora of hospitalized patients as a commensal organism (Echemendia, 2010) and, similar to the indigenous bacteria of the gastrointestinal tract, *S. maltophilia* can be an opportunistic pathogen (Berg, 1996). As such, *S. maltophilia* is of low virulence in immuno-compromised patients where a series of risk factors (severe debilitation, the presence of indwelling devices such as ventilator tubes or catheters, for prolonged periods of time and prolonged courses of antibiotics) must occur for colonization by *S. maltophilia* in humans (Ryan et al., 2009). Therefore, infections by *S. maltophilia* almost exclusively occur in hospital settings, in which case they are only present in a minimal percentage of infections (Ryan et al., 2009). Finally, *S. maltophilia* has not been reported to be source of allergens.

The ubiquitous presence of *S. maltophilia* in the environment, the presence in healthy individuals without causing infections, the incidental presence in foods without any adverse safety reports, and the lack of reported allergenicity establishes the safety of the donor organism.

H.1.2.3.1.2. MON 87708 DMO Belongs to a Common Class of Mono-Oxygenases

In its consultation with FDA, Monsanto also discussed the similarity of MON 87708 DMO to a common class of mono-oxygenases regularly consumed by humans and animals. MON 87708 DMO is classified as an oxygenase. Oxygenases are enzymes that incorporate one or two oxygen atoms into substrates and are widely distributed in many universal metabolic pathways (Harayama et al., 1992). Within this large enzymatic class are mono-oxygenases that incorporate a single oxygen atom as a hydroxyl group with the concomitant production of water and oxidation of NAD(P)H (Harayama et al., 1992). Non-heme iron oxygenases, where iron is involved in the catalytic site, are an important class of oxygenases. Within this class are Rieske oxygenases, which contain a Rieske iron-sulfur [2Fe-2S] cluster. All Rieske non-heme iron oxygenases contain two catalytic domains, a non-heme iron domain (nh-Fe) that is a site of oxygen activation, and a Rieske [2Fe-2S] domain (Ferraro et al., 2005). MON 87708 DMO belongs to this class of oxygenases which are found in diverse phyla ranging from bacteria to plants (Ferraro et al., 2005; Schmidt and Shaw, 2001).

The crystal structure of a DMO has been solved (D'Ordine et al., 2009; Dumitru et al., 2009). The crystallography results demonstrated that, similar to all Rieske non-heme iron oxygenases, DMO contains two catalytically important and highly conserved domains; a mononuclear non-heme iron domain (nh-Fe) that is a site of oxygen activation, and a Rieske [2Fe-2S] domain (D'Ordine et al., 2009; Dumitru et al., 2009; Ferraro et al., 2005). The amino acids binding the non-heme iron and those that constitute the Rieske [2Fe-2S] domain in the DMO protein are also highly conserved in these plant proteins, as is their spatial orientation (D'Ordine et al., 2009; Ferraro et al., 2005). Rieske domains are ubiquitous in numerous bacterial and plant proteins, like the iron-sulfur protein of the cytochrome bc1 complex, chloroplast cytochrome b6/f complex, and choline mono-oxygenases (Breyton, 2000; Darrouzet et al., 2004; Gray et al., 2004; Hibino et al., 2002; Rathinasabapathi et al., 1997; Russell et al., 1998). The presence of two conserved domains, a Rieske [2Fe-2S] domain and a mononuclear iron domain, suggests that all Rieske type non-heme iron oxygenases share the same reaction mechanism, by which the Rieske domain transfers electrons from the ferredoxin to the mononuclear iron to allow catalysis (Chakraborty et al., 2005; Dumitru et al., 2009; Ferraro et al., 2005). The structure and mechanistic homologies are further evidence of the evolutionary relatedness of all Rieske non-heme iron oxygenases to each other (Nam et al., 2001; Rosche et al., 1997; Werlen et al., 1996). Additionally, a FASTA alignment search of publicly available databases using the DMO+27 sequence as a query yielded homologous sequences from many different species, predominantly bacteria, with amino acid sequence identity ranging up to approximately 42%. Homologous oxygenases are also present in plants, including such crops as rice (*Orysa sativa*), canola (*Brassica napus*), and corn (*Zea mays*), with sequence identity up to 24%. The highest homology was observed to pheophorbide A oxygenases from corn, canola and pea (*Pisum sativum*). Pheophorbide A oxygenase is also a Rieske-type oxygenase that plays a key role in the overall regulation of chlorophyll degradation in plants (Rodoni et al., 1997). The protein is constitutively present in all green tissues and, at slightly lower levels, in etiolated and non-photosynthetic tissues including seeds (Yang et al., 2004).

Therefore, MON 87708 DMO shares sequence identity and many catalytic and domain structural similarities with a wide variety of oxygenases present in bacteria and plants currently widely prevalent in the environment and consumed, establishing that animals and humans are extensively exposed to these types of enzymes.

H.1.2.3.1.3. DMO is a Dicamba-Specific Mono-Oxygenase

DMO converts dicamba to DCSA. In Monsanto's consultation with FDA, Monsanto described its research demonstrating that this demethylation is very specific to dicamba, where both the carboxylate moiety and the chlorine atoms help position the substrate at the active site of the enzyme (D'Ordine et al., 2009; Dumitru et al., 2009). Crystallography studies of the substrate in the active site demonstrated that these chlorines function as steric "handles" that position the substrate in the proper orientation in the binding pocket (Dumitru et al., 2009). Potential substrates abundant in soybean (o-anisic acid, vanillic acid, syringic acid, ferulic acid and sinapic acid) that are structurally similar to dicamba, were not metabolized by an *E. coli*-produced DMO in laboratory tests indicating that the DMO enzyme is specific for dicamba (Monsanto 2010). The *E. coli*-produced DMO is similar in sequence and function to MON 87708 DMO; therefore, it is appropriate to extend specificity data generated with the *E. coli*-produced DMO to MON 87708 DMO. Given the limited amount of chlorinated metabolites with structures similar to dicamba in plants and other eukaryotes (Wishart, 2010; Wishart et al., 2009), it is unlikely that MON 87708 DMO will catalyze the conversion of other endogenous substrates. Therefore, the activity of the enzyme is specific for dicamba, while maintaining many structural properties common to oxygenases that are ubiquitous to all organisms.

H.1.2.3.1.4. DT soybean Allergenicity

The potential allergenicity of DT soybean was evaluated in Monsanto's consultation with the FDA. The allergenic potential of an introduced protein is assessed by comparing the biochemical characteristics of the introduced protein to biochemical characteristics of known allergens (Codex Alimentarius, 2003). A protein is not likely to be associated with allergenicity if: 1) the protein is from a non-allergenic source, 2) the protein represents a very small portion of the total plant protein, 3) the protein does not share structural similarities to known allergens based on the amino acid sequence, and 4) the protein is rapidly digested in mammalian gastrointestinal systems. MON 87708 DMO, as defined above, refers to all forms of the protein and the resulting trimer, and has been assessed for its potential allergenicity according to these safety assessment guidelines.

1) MON 87708 DMO originates from *S. maltophilia*, an organism that has not been reported to be a source of known allergens.
2) MON 87708 DMO represents no more than 0.01% of the total protein in the seed of DT soybean.
3) Bioinformatics analyses demonstrated that the DMO+27 form of MON 87708 DMO, that also contains the DMO sequence, does not share amino acid sequence similarities with known allergens and, therefore, is highly unlikely for DMO or DMO+27 to contain immunologically cross-reactive allergenic epitopes.
4) *In vitro* digestive fate experiments conducted with the MON 87708 DMO demonstrate that the proteins are rapidly digested in simulated gastric fluid (SGF) and in simulated intestinal fluid (SIF).

Taken together, these data support the conclusion that MON 87708 DMO does not pose a significant allergenic risk to humans or animals.

H.1.2.3.1.5. MON 87708 DMO is Labile in *in vitro* Digestion Assays

MON 87708 DMO was readily digestible in SGF and SIF. Rapid degradation of the MON 87708 DMO in SGF and SIF makes it highly unlikely that the MON 87708 DMO would be absorbed in the small intestine and have any adverse effects on human or animal health.

H.1.2.3.1.6. MON 87708 DMO Toxicity

Monsanto's consultation with the FDA also included an evaluation of the potential toxicity of MON 87708 DMO. Monsanto explained that an acute oral toxicology study was conducted with MON 87708 DMO. Results indicate that MON 87708 DMO did not cause any adverse effects in mice, with a No Observable Adverse Effect Level (NOAEL) of 140 mg/kg body weight (BW), the highest dose level tested.

Potential human health risks from consumption of foods derived from DT soybean were evaluated using a Margin of Exposure (MOE) approach. The MOE is a ratio of two factors which assesses for a given population the dose at which a small but measurable adverse effect is first observed and the level of exposure to the substance considered. A MOE was calculated between the acute mouse NOAEL (140 mg/kg BW) for the MON 87708 DMO and 95th percentile "eater-only" estimates of acute dietary exposure determined using the Dietary Exposure Evaluation Model (DEEM-FCID version 2.03, Exponent Inc.). DEEM food consumption data are obtained from the 1994-1996 and

1998 USDA Continuing Survey of Food Intakes by Individuals (CSFII). The MOEs for acute dietary intake of MON 87708 DMO were estimated to be 24,800 and 600 for the general population and non-nursing infants, the sub-population with the highest estimated exposure, respectively. These very large MOEs, in addition to the above mentioned protein safety data for MON 87708 DMO, support the conclusion that there is no meaningful risk to human health from dietary exposure to MON 87708 DMO.

Potential health risks to animals from the presence of MON 87708 DMO in feed were evaluated by calculating an estimate of daily dietary intake (DDI). In the worst case scenario, the percentage of MON 87708 DMO consumed from DT soybean as a percentage of the daily protein intake for a dairy cow is 0.0396% and for both the broiler and pig is less than 0.0121%. These very small levels of exposure of animals to MON 87708 DMO in their feed, in addition to the above mentioned safety data for MON 87708 DMO, support the conclusion that there is no meaningful risk to animal health when DT soybean is present in their diets.

H.1.2.3.1.7. DT soybean Safety Assessment Conclusions

MON 87708 DMO is an oxygenase that catalyzes the O-demethylation of the herbicide dicamba. MON 87708 DMO was derived from *S. maltophilia*, which is an environmentally ubiquitous bacterium that does not pose a health risk to healthy individuals. MON 87708 DMO is a Rieske-type mono-oxygenase that has homologs in bacteria and plants that share many of the typical structural and functional characteristics of these types of oxygenases, while maintaining specificity for its substrate. MON 87708 DMO was fully characterized confirming both the N-terminal and internal amino acid sequence and the lack of glycosylation. MON 87708 DMO was isolated from DT soybean and was used for the described safety studies; therefore an equivalence evaluation to the protein produced in a heterologous expression system was not required. Expression studies using ELISA demonstrated that MON 87708 DMO was expressed in all tissues assayed at levels ranging from 3.9 – 180 μg/g dwt, representing a low percentage of the total protein in soybean. Bioinformatics analysis determined that MON 87708 DMO does not share amino acid sequence similarities with known allergens, gliadins, glutenins, or protein toxins. MON 87708 DMO was rapidly digested in *in vitro* assays using simulated gastric and intestinal fluids and did not show any adverse effects when administered to mice via oral gavage at levels that resulted in large MOEs. Together with the safety data, these data support a conclusion that there is no meaningful risk to human health from dietary exposure to MON 87708 DMO.

Using the guidance provided by the FDA in its 1992 Policy Statement regarding the evaluation of New Plant Varieties, a conclusion of "no concern" is reached for the donor organism and MON 87708 DMO. The food and feed products containing DT soybean or derived from DT soybean are as safe as soybean currently on the market for human and animal consumption.

H.1.2.3.2. Dicamba Reaction Product Safety Assessment

MON 87708 DMO rapidly demethylates dicamba rendering it inactive, thereby conferring tolerance to dicamba in DT soybean. In dicamba-treated DT soybean, the demethylation of dicamba produces 3,6-dichlorosalicylic acid (DCSA), a known soybean, cotton, soil, and livestock metabolite whose safety has been evaluated by the Environmental Protection Agency (U.S. EPA), and formaldehyde. In the absence of a dicamba treatment on DT soybean, DCSA and formaldehyde would not be produced. DCSA is structurally similar to salicylic acid (SA). Numerous studies have reported on the stress defense activities of SA, although most studies have looked at the protective effects of exogenously applied SA (Janda et al, 2007). Formaldehyde has a potential linkage to apoptosis in plants (Szende and Tyihak, 2010), and formaldehyde concentrations in plants have been found to increase under certain stress conditions (Szabo et al, 2003). The National Toxicology Program (NTP) 12th Report on Carcinogens has reclassified formaldehyde as a known human carcinogen (USHHS-NTP, 2011). The relevant route of exposure for this health risk is from repeated inhalation at levels associated with indoor or occupational environments, which are generally higher than outdoor environments (USHHS-NTP, 2011). Formaldehyde is present in food and in the human body naturally, and there is no evidence to suggest that dietary intake of formaldehyde is important (USHHS-NTP, 2011).

A full discussion on DCSA, and the safety of this metabolite, is provided in Appendices M and L of the Monsanto petition (Monsanto 2010). DCSA as well as other dicamba metabolite products were measured in the residue study provided to the EPA to demonstrate that dicamba and dicamba metabolite residues are well below the current MRL set for dicamba in soybeans in the U.S.

Formaldehyde is ubiquitous in the environment and present in plants and animals. Formaldehyde was not considered a relevant metabolite in the demethylation of dicamba by the EPA. According to the guidelines published by Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency (US EPA OPPTS 860.1300), the methoxy sidechain that is cleaved from dicamba to form formaldehyde would specifically not be chosen to be labeled in a metabolism study (U.S. EPA, 1996). This is because it is not metabolically stable and would not be considered a significant moiety, as it would be readily metabolized and incorporated into the 1-carbon pool of the plant through known pathways. Therefore, formaldehyde was not measured in the residue study when dicamba was applied to DT soybean.

Data from both dicamba-treated and non-treated DT soybean compared to a conventional control are available from multiple sites across the U.S. where agronomic, phenotypic and observational environmental interaction data were collected. The results of this assessment demonstrate no biologically meaningful difference between DT soybean treated with dicamba, or DT soybean not treated with dicamba compared to the conventional control, and support a conclusion that the formation of DCSA and formaldehyde does not alter the weedy characteristics, or increased susceptibility and tolerance to diseases, insects or abiotic stresses. Therefore, DT soybean, as cultivated, is no more likely to be a plant pest risk or have a biologically meaningful change in environmental impact than conventional soybean.

Further, the metabolism of formaldehyde in plants is well understood, and there are a number of natural occurring sources of formaldehyde in plants. For example, it is produced during the process of photorespiration (Oliver, 1994) and during oxidative demethylation of DNA (Zhu, 2009), which supports why formaldehyde is not considered a byproduct of interest as dicamba is demethylated. It is well known and understood that formaldehyde is rapidly metabolized in plants through two basic routes: 1) it can be incorporated into the one-carbon folate pool via spontaneous or enzyme-mediated formation of methylene tetrahydrofolate (Hanson and Roje, 2001); or 2) it can be oxidized to formate by a detoxification pathway that begins with spontaneous formation of the glutathione adduct *S*-hydroxymethylglutathione (Hanson and Roje, 2001). In each case, formaldehyde is further metabolized to carbon dioxide or entered into the 1C folate pool (Hanson and Roje, 2001; Giese et al., 1994). The maximum theoretical production of formaldehyde produced from dicamba-treated DT soybean is estimated to be 16.7 and 37.5 mg/kg[247]. This is well within the range of formaldehyde concentrations measured for a variety of agricultural commodities – up to 60 mg/kg in fruits and vegetables (WHO-IPCS, 1989). Plants have a large capacity to metabolize formaldehyde naturally produced from internal processes (A. Hanson (2011), C.V. Griffin, Sr. Eminent Scholar, Horticulture Department, University of Florida, Personal Communication), and any additional amount of formaldehyde that could be theoretically produced in the plant by dicamba treatment in DT soybean would be metabolized very quickly. Additionally, as dicamba would not be instantaneously absorbed and metabolized, the incremental increase in formaldehyde over and above the levels already presumed to be present in the soybean plant would be small and transient. Further, since current literature supports that formaldehyde is only emitted from foliage under certain conditions (Nemecek-Marshall et al., 1995; Cojocariu et al., 2004; Cojocariu et al., 2005) and that emission rates are low (Nemecek-Marshall et al., 1995), little opportunity exists for formaldehyde to be released from DT soybean after dicamba treatment.

In addition to formaldehyde production in plants, plants and animals are constantly exposed to low levels of formaldehyde. Formaldehyde is already present in the environment and the atmosphere from a variety of biogenic (e.g. plant and animal) and anthropogenic (e.g. automotive or industrial emissions) sources. Additionally, formaldehyde degrades rapidly in environmental compartments (air, soil, and water). In water, formaldehyde dissipates through biodegradation to low levels in a few days (USHHS-ATSDR, 1999). Aerobic biodegradation half-lives are estimated to be 1-7 days for surface water and 2-14 days for ground water (US EPA, 2008). The half-life of formaldehyde in air is dependent on a number of factors (light intensity, temperature and location). Through reaction with hydroxyl radical, the half-life of formaldehyde in air varies from 7 to 70 hours (US EPA, 2008). The photolytic half-life of formaldehyde in air (e.g., in the presence of sunlight) is estimated to be 1.6-6 hours (US EPA, 2008; USHHS-ATSDR, 1999). The rapid degradation of formaldehyde in the environment, combined with the understanding that formaldehyde is widely used by living organisms as a 1C source, support a conclusion that any environmental effects of formaldehyde, including effects on other plants and NTO's, resulting from dicamba-treated DT soybean would be negligible.

Humans are also constantly exposed to low levels of formaldehyde. Human exposure to formaldehyde is primarily due to indoor and occupational air exposures (USHHS-ATSDR, 1999). Formaldehyde is also found in a variety of consumer products such as cosmetics and paints, often as an antimicrobial agent, and is used extensively in urea-formaldehyde "slow-release" fertilizer formulations and adhesives (USHHS-ATSDR, 1999). Indoor formaldehyde air concentrations are

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[247] Calculation based on an assumption that the entire 0.56 kg/ha (0.5 lb/acre a.e.) application of dicamba to MON 87708 soybean at the V3 growth stage is intercepted by the soybean plants, is instantaneously and completely absorbed, and then instantaneously metabolized by the DMO enzyme. Complete demethylation of 560 g (2.5 mol)/ ha dicamba would yield 2.5 mol/ha formaldehyde. Above-ground biomass of V3 plants is estimated at 2 metric tons/ha, and results in 37.5 mg/kg formaldehyde in plants. For dicamba applications at R1 growth stage, the crop biomass is estimated to be 4.5 metric tons/ha, and level of formaldehyde produced in plants is 16.7 mg/kg.

generally significantly higher than outdoor air concentrations (USHHS-ATSDR, 1999) as a result of combustion (cooking, heating, tobacco use) and the emission of formaldehyde from a variety of construction materials (e.g., particle board, plywood or foam insulation) as well as permanent press fabrics (clothing or draperies) (US CPSC, 1997). Formaldehyde present in outdoor air results from a number of sources, and levels of formaldehyde are generally higher in urban areas than in rural areas (WHO-IPCS, 1989). Direct contributions of formaldehyde to the atmosphere (i.e., those in the form of formaldehyde itself) from man-made sources are present, but are generally considered to be small relative to natural sources or indirect production of formaldehyde in the atmosphere (WHO, 2002). Formaldehyde is rapidly consumed in the atmosphere through direct photolysis or by oxidation with hydroxyl or nitrate radicals (USHHS-ATSDR, 1999).

The National Toxicology Program (NTP) 12th Report on Carcinogens has reclassified formaldehyde as a known human carcinogen (USHHS-NTP, 2011). However, the relevant route of exposure for this health risk is from repeated inhalation of concentrated levels associated with indoor or occupational environments. As previously discussed, formaldehyde may only be released by plants in very small quantities and under certain conditions. Any incremental exposure to formaldehyde associated with the application of dicamba to DT soybean would occur outdoors, would be minimal, and also would be transient in nature. Therefore human safety concerns of formaldehyde released from dicamba treated DT soybean are considered to be negligible. USHHS-NTP (2011) has already stated that there is no evidence to suggest that dietary intake of formaldehyde is important. In addition, commodity soybean seed is not directly consumed by humans, and would be processed into food products, limiting potential exposure to humans to any formaldehyde in dicamba-treated DT soybean seed.

H.1.2.4. Summary of Findings

Trace amounts of MON 87708 DMO and dicamba reaction products are likely to be present in food and feed generated from DT soybean. Substantial analyses of the safety of these compounds have revealed no evidence of toxicity or allergenicity. These analyses suggest that the presence of DT soybean in human food and animal feed presents negligible risks.

H.1.3. Dicamba-Tolerant Soy Presence in Food or Animal Feed

Monsanto intends to market DT soybean for the same commercial purposes as current transgenic and non-transgenic soybean varieties. Soybean seeds are processed primarily into oil and meal.

Soybean oil constitutes nearly 70% of consumption of edible fats and oils in the United States, and is the second largest source of vegetable oil worldwide. Soybean products are also used as human foods and sources of food ingredients.

Soybean meal is the predominant use of soybeans in animal feed and is the most common supplemental protein source in U.S. livestock and poultry rations due to its nutrient composition, availability, and price. Soybean forage is occasionally used in animal feed.

Thus, the food and animal feed uses of soybean and its processed products remain the predominant uses of soybeans.

In efforts to assess the human health, livestock, and wildlife risks of exposure to DT soybean, potential impacts from MON 87708 DMO and dicamba reaction products are evaluated in this report.

H.1.3.1. Probability of Presence

As discussed above, only the MON 87708 DMO is produced from the inserted DNA. In the expression level studies conducted by Monsanto, MON 87708 DMO was found in some amount in the leaf, root, forage, and seed of DT soybean. See Part 1.2.1.2. When exposed to dicamba, the MON 87708 DMO catalyzes the demethylation of dicamba to the non-herbicidal compound DCSA and formaldehyde. As a result, the probability of human and animal dietary exposure to at least trace levels of MON 87708 DMO, DCSA, and formaldehyde is high.

H.1.3.2. Health Effects of MON 87708 DMO

H.1.3.2.1. Health Effects of MON 87708 DMO and Dicamba Reaction Products on Humans

As discussed above, both the MON 87708 DMO and dicamba reaction products have been assessed for safety for human consumption. See Part 1.2.3. These assessments examined the donor organism safety, the similarity of MON 87708 DMO to a common class of mono-oxygenases, the dicamba-specificity of MON 87708 DMO, potential allergenicity issues, MON 87708 DMO digestibility, and the toxicity of MON 87708 DMO and the dicamba reaction products.[248] These assessments concluded that the food and feed products containing DT soybean or derived from DT soybean are as safe as soybean currently on the market for human consumption.

Studies on the persistence of plant-derived native DNA and recombinant DNA in livestock have indicated that feed-ingested DNA fragments do survive in the terminal gastrointestinal (GI) tract and that uptake into the gut epithelium does occur (Sharma, 2006). However, recombinant DNA fragments were not found in visceral tissues, like the kidney. There is no evidence thus far to indicate that the recombinant DNA that encodes the inserted gene would be processed in a manner any differently from the endogenous feed-ingested genetic material.

H.1.3.2.2. Health Effects of MON 87708 DMO and Dicamba Reaction Products on Livestock

Monsanto has completed the biotechnology consultation process with FDA for the safety and nutritional assessment of food and feed derived from DT soybean. This consultation did not identify biologically meaningful differences between the composition of DT soybean and conventional soy. As discussed above, MON 87708 DMO belongs to a common class of mono-oxygenases, regularly consumed by humans and animals. Additionally, MON 87708 DMO did not cause any adverse effects in mice, with a No Observable Adverse Effect Level (NOAEL) of

[248] The dicamba reaction byproducts are considered pesticidal substances under EPA regulations. Monsanto has submitted a regulatory submission to EPA requesting the establishment of a tolerance for the use of dicamba on MON 87708 soybean.

140 mg/kg body weight (BW), the highest dose level tested. At the conclusion of the FDA consultation, FDA had no questions about the safety of DT soybean and for use in food or feed.

The dicamba reaction byproducts are considered pesticidal substances under EPA regulations. Monsanto has submitted a regulatory submission to EPA requesting the establishment of a tolerance for the use of dicamba on DT soybean.

H.1.3.2.3. Health Effects of MON 87708 DMO and Dicamba Reaction Products on Non-livestock Animals (Wildlife)

No specific data or scientific literature were found relating to the health effects of MON 87708 DMO on non-livestock animals. As discussed above, MON 87708 DMO belongs to a common class of mono-oxygenases, regularly consumed by humans and animals. Additionally, MON 87708 DMO did not cause any adverse effects in mice, with a No Observable Adverse Effect Level (NOAEL) of 140 mg/kg body weight (BW), the highest dose level tested.

There is no evidence that MON 87708 DMO or dicamba reaction products will exhibit adverse biological activity toward wildlife. Because use of DT soybean is compatible with conservation tillage practices, usage of DT soybean may have a positive impact on wildlife. Conservation tillage practices can have a positive impact on wildlife, including beneficial arthropods (Altieri, 1999; Landis et al., 2005; Towery and Werblow, 2010). Conservation tillage practices benefit biodiversity due to decreased soil erosion leading to improved surface water quality, retention of vegetative cover, crop residues serving as a food source, and increased populations of invertebrates which can serve as food sources to other organisms (Landis et al. 2005; Sharpe, 2010).

H.1.3.3. Summary of Findings

There is little evidence that MON 87708 DMO and dicamba reaction products have any direct toxic effect on livestock or any deleterious outcome on nutritional parameters. The information evaluated suggests that the presence of MON 87708 DMO and dicamba reaction products in human food and animal feed pose negligible risks to humans, livestock, and wildlife.

H.2. Dicamba and Glufosinate-Tolerant Cotton

H.2.1. Introduction

The scope of this section covers how Dicamba and-Glufosinate-Tolerant cotton ("DGT Cotton") could be present in human food and animal feed and the potential health impacts of that presence.

H.2.1.1. Cotton Biology and Usage

Cotton belongs to the genus *Gossypium* that currently has approximately 50 species which are widely cultivated in tropical and subtropical regions around the world (OECD, 2008; Percival et al., 1999). There are four cultivated species that were domesticated independently, two of which account for greater than 95% of world cotton production. *Gossypium hirsutum* (often called upland, American, Mexican, or Acala cotton) accounts for 90% and *Gossypium barbadense* (often called extra long-staple, Pima, and Egyptian cotton) accounts for 5% of world cotton production. Due to the utility of the fibers for the production of textiles, human selection pressure on cotton has altered the plant from essentially perennial shrubs or trees with small impermeable seeds and sparse hairs to a compact annual row crop, yielding large, easily germinating seeds with white, thick, long, and strong fibers (Brubaker et al., 1999).

Cotton is a crop that produces two commodities: fiber and seed. The fiber is the more valuable product of the crop, normally accounting for approximately 85% of the value. For every 100 pounds of fiber produced by the cotton plant, it also produces about 162 pounds of cottonseed (NCCA, 2010). Cottonseed is crushed for oil and meal used in both food products and in livestock feed.

The four cultivated species, which are widely cultivated across the entire globe, are comprised of two diploid species *G. arboretum* and *G. herbaceum*, which evolved from Africa and the Middle East, and two allotetraploid species *G. barbadense* and *G. hirsutum*, which evolved in the Americas (Brubaker et al., 1999).

Improved modern varieties of *G. hirsutum* and *G. barbadense* are currently cultivated in the southern U.S., with *G. barbadense* grown primarily in the western states of Arizona, California, New Mexico, and Texas; and *G. hirsutum* produced throughout the 17 states comprising the U.S. cotton growing region, commonly referred to as the Cotton Belt. *G. hirsutum* comprises the vast majority of U.S. cotton production with nearly 11 million acres planted and 18 million bales harvested, whereas *G. barbadense* varieties accounted for approximately 200,000 acres and half a million bales in 2010 (USDA-NASS, 2011b). Commercial cotton, including *G. hirsutum* and *G. barbadense*, has a long history of agricultural production (Lee, 1984; USDA-AMS, 2001; USDA-NASS, 2012). Extralong staple lint from *G. barbadense* is segregated and classed separately from *G. hirsutum* and is sold at a premium (USDA-AMS, 2001). However, cottonseed and cottonseed by-products (e.g., oil and meal) are not generally distinguished by species (OECD, 2008; USDA-FAS, 2005).

The majority of the value of the producer's cotton crop is based on the quality and quantity of the lint produced, and with the exception of contracted acres for planting seed production. Little consideration is given by growers to the disposition of the cottonseed and its by-products. Most of the world's cotton production (116.40 million bales annually) is grown in China (30.5 million bales), India (26.4 million bales), United States (18.1 million bales), Pakistan (8.6 million bales) and Brazil (9.0 million bales). Figures are from the 2010/2011 cotton season (USDA-FAS, 2012). In 2010/2011, the U.S. supplied over 14 million bales of the world's cotton exports, accounting for approximately 40% of the total world export market for cotton (USDA-FAS, 2011). Cottonseed production currently results in approximately 10% of the world's oilseed production (USDA-FAS, 2010), and is exceeded by soybean (58%) and rapeseed (13%).

Cotton (*Gossypium* spp.) is grown in the U.S. across southern states where the climate is warmer and the season is longer. The total U.S. cotton acreage in the past 10 years has varied from approximately 9.15 to 15.77 million planted acres, with the lowest acreage recorded in 2009 and the highest in 2001. Average cotton yields have varied from 632 to 879 pounds per acre over this same time period. Total annual cotton production ranged from 12.19 to 23.89 million bales (480 pounds/bale) over the past ten years. The variations observed in cotton acreage and production are driven by current market conditions, rather than agronomic considerations. According to data from USDA-NASS (USDA-NASS, 2011a), cotton was planted on approximately 11 million acres in the U.S. in 2010, producing approximately 18 million bales of cotton. The value of cotton production reached $7.32 billion in the U.S. in 2010 (USDA-NASS, 2011a).

H.2.1.2. Conventional Cotton Crop

The *G. hirsutum* cotton variety used as the recipient for the DNA insertion to create DGT cotton was Coker 130, a non-transgenic, conventional, upland inbred variety developed by Coker Pedigreed Seed Co., commercialized in 1990 in the U.S. (Bowman et al., 2006).

H.2.1.3. Gene and Gene Product

Production of a GE organism involves integration of a DNA cassette that is novel to a host plant into the host plant's genomic DNA, called a transformation event. The DNA construct contains all the genetic information needed to produce the new characteristic or trait and, in most instances, this includes production of a protein. DGT cotton contains a demethylase gene from *Stenotrophomonas maltophilia* that expresses a dicamba mono-oxygenase (DMO) protein to confer tolerance to dicamba herbicide. DMO protein rapidly demethylates dicamba to the herbicidally inactive metabolite 3,6-dichlorosalicylic acid (DCSA). DCSA has been previously identified as a metabolite of dicamba in cotton, soybean, livestock, and soil.

DGT cotton also contains a bialaphos resistance (*bar*) gene from Streptomyces hygroscopicus that expresses the phosphinothricin N-acetyltransferase (PAT) protein to confer tolerance to glufosinate herbicide. PAT (bar)[249] protein acetylates the free amino group of glufosinate to produce non-herbicidal N-acetyl glufosinate, a well-known metabolite in glufosinate-tolerant plants.

H.2.1.4. Herbicides

Dicamba was approved by the U.S. EPA for agricultural uses in 1967 (U.S. EPA, 2009). Dicamba is formulated as a stand-alone herbicide product and marketed by several companies under various trade names such as Banvel®, Clarity®, Diablo®, Rifle®, and Sterling® that are various salt formulations of dicamba. These dicamba products can be tank mixed with one or more active ingredients depending on the treated crop. For example, Clarity can be tank mixed with over 75 herbicide products in labeled crops. Additionally, dicamba is formulated as a registered premix product with one or more other herbicide active ingredients such as glyphosate, 2,4-D, diflufenzopyr, atrazine, nicosulfuron, metsulfuron, primsulfuron, triazulfuron, rimsulfuron and halosulfuron. Dicamba herbicide (*e.g.*, Clarity – diglycolamine (DGA) salt of dicamba) is currently labeled for weed control in soybean, corn, cotton, sorghum, wheat, barley, oats, millet, pasture, rangeland, asparagus, sugarcane, turf, grass grown for seed, conservation reserve programs, and fallow croplands.

Dicamba-treated acreage has ranged from 17.4 to 36.3 million acres between 1990 and 2011. Usage of dicamba peaked during the period of 1994 through 1997, where 1994 was the peak year when 36 million crop acres were treated with 9.4 million pounds of dicamba. Since then, the use of dicamba has steadily declined to 17.4 million treated acres with 2.7 million pounds applied in 2006. The reduction in dicamba use has been attributed to the competitive market introductions of

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249 PAT (bar) indicates the PAT protein encoded by the bar gene isolated from *S. hygroscopicus*. The pat gene from *S. viridochromogenes* also encodes a PAT protein that confers glufosinate tolerance.

sulfonylurea herbicides (chlorsulfuron, metsulfuron-methyl, and thifensulfuron-methyl) in wheat, new broadleaf herbicide active ingredients in corn, and introduction of glyphosate-tolerant corn. More recently, however, dicamba treated acres have been on the rise and have increased by as much as 7.9 million acres from 2006 to 2011. Most of this increase has occurred in fallow, pastureland, sorghum, and cotton (preplant) (Monsanto 2012). Currently, 364,000 pounds of dicamba are applied pre-plant on cotton, although use would be expected to rise if DGT cotton is deregulated. See Appendix A for more details.

Glufosinate was approved by the U.S. EPA for agricultural uses in 1989 (U.S. EPA 2013). Glufosinate is a non-selective foliar herbicide that is used for preplant and postemergence control of grass and broadleaf weeds. Glufosinate is formulated as a stand-alone herbicide product and marketed under the trade names Liberty®, Ignite™, Ignite®280, Rely™ 200, and Rely®280. All products contain either 1.67 or 2.34 lbs per gallon of glufosinate-ammonium. Glufosinate (Rely®280 and Ignite®280) is used for postemergence weed control in canola, corn, cotton, and soybean varieties that are glufosinate-tolerant. Glufosinate may be used for weed control in non-glufosinate-tolerant cotton when applied with a hood sprayer in-crop. It may also be applied as a preplant burndown application in commercial varieties of canola, corn, cotton, soybean, or sugar beet. In addition, glufosinate (Rely®200 and Rely®280) may be used for postemergence weed control in apples, berries, grapes, tree nuts, and applied for potato vine desiccation. Glufosinate products can be tank mixed with other active ingredients depending on the treated crop. For example, Ignite™ can be tank mixed with metolachlor or fluometuron for in-crop applications in glufosinate-tolerant cotton. However, reduced weed control has been observed when glufosinate is tank mixed with glyphosate (Dotray et al. 2011; Reed et al 2011; Reed et al. 2012).

Glufosinate-treated acreage across all crops has steadily increased from 1.6 million acres in 1998 to 7.0 million acres in 2011. Increased weed resistance is one factor responsible for the increased use of glufosinate (Robertson 2012). Glufosinate is currently labeled for in-crop application on glufosinate-tolerant cotton from emergence through early bloom growth stage at 0.402 to 0.530 lbs a.i. per acre, seasonal maximum of 1.59 lbs a.i. per acre (Bayer Crop Science 2007). The average application rate in cotton is 0.39 pounds of glufosinate per acre with an average of 1.5 applications per season.

H.2.2. Dicamba-and-Glufosinate-Tolerant Cotton Hazard Identification

Cotton is grown in 17 states across the southern U.S. and in over 80 countries world-wide. Cotton is grown primarily for its fiber, but also produces seed which can be used as animal feed or processed to serve as an ingredients in human food and animal feed. Monsanto Company developed DGT cotton to be tolerant to the herbicides dicamba and glufosinate.

H.2.2.1. DGT Cotton Biology

DGT cotton contains *dmo* and *bar* expression cassettes that, when transcribed and translated, result in the expression of the MON 88701 DMO and PAT (*bar*) proteins, respectively.

DMO is an enzyme that catalyzes the demethylation of dicamba into the nonherbicidal compound DCSA and formaldehyde (Chakraborty et al., 2005). DCSA is a known cotton, soybean, soil, and livestock metabolite whose safety has been evaluated by the EPA. Formaldehyde is found naturally in many plants at levels up to several hundred ppm.

The mode-of-action for the PAT protein has been extensively assessed, as numerous glufosinate-tolerant products including those in cotton, corn, soy, canola, sugarbeet and rice have been reviewed by the FDA and several other regulatory agencies (ILSI-CERA, 2011; OECD, 1999a; 2002). PAT, including the PAT (bar) protein produced in DGT cotton, is an enzyme classified as an acetyltransferase which acetylates glufosinate to produce non-herbicidal N-acetyl glufosinate. Glufosinate is a racemic mixture of the D- and L- forms of phosphinothricin, though only the L-form has herbicidal activity. The herbicidal activity of glufosinate results from the binding of L-phosphinothricin to glutamine synthetase (OECD, 1999b; 2002). Glutamine synthetase is responsible for the assimilation of ammonia generated during photorespiration. The binding of L-phosphinothricin to glutamine synthetase results in the inactivation of glutamine synthetase and a subsequent toxic build-up of ammonia within the plant, resulting in death of the plant (Manderscheid and Wild, 1986; OECD, 1999b; 2002; Wild and Manderscheid, 1984).

The PAT (*bar*) protein produced in DGT cotton acetylates the free amine group of the L-phosphinothricin form of glufosinate to produce non-herbicidal N-acetyl glufosinate. The acetylated glufosinate is unable to bind to glutamine synthetase and therefore does not disrupt photorespiration and avoids the build-up of ammonia. Therefore, the production of PAT (bar) protein in DGT cotton confers glufosinate herbicide tolerance through this mechanism.

Molecular characterization determined that DGT cotton contains one copy of the T-DNA at a single integration locus and all genetic elements are present. These data also demonstrated that DGT cotton does not contain detectable backbone sequences from the plasmid vector. The complete DNA sequence of the insert and adjacent genomic DNA sequences in DGT cotton confirmed the integrity of the inserted *dmo* and *bar* expression cassettes. Molecular characterization analysis also demonstrated that the insert in DGT cotton has been maintained over five consecutive generations of breeding, thereby confirming the stability of the insert. Furthermore, results from segregation analyses show inheritance and stability of the insert were as expected across multiple generations, which corroborates the molecular insert stability analysis determination that the DGT cotton T-DNA resides at a single chromosomal locus within the cotton genome.

H.2.2.1.1. Characterization of DGT Cotton

The safety assessment of crops derived through biotechnology includes characterization of the physicochemical and functional properties of the protein(s) produced from the inserted DNA, and confirmation of the safety of the protein(s). For the safety data generated using *E. coli*-produced protein(s) to be applied to plant-produced protein(s), the equivalence of the plant- and *E. coli*-produced proteins must be assessed. For DGT cotton the physicochemical and functional characteristics of the MON 88701 DMO and MON 88701-produced PAT (*bar*) proteins were determined and each was shown to be equivalent to its respective *E. coli*-produced protein.

The MON 88701 DMO protein purified from cottonseed of DGT cotton was characterized and the equivalence of the physicochemical and functional properties between the MON 88701 DMO and the *E. coli*-produced MON 88701 DMO proteins was established using a panel of analytical tests: 1) the identity could not be confirmed by N-terminal sequence analysis; however, MALDI-TOF MS analysis of peptides derived from tryptic digested MON 88701 DMO established the N-terminal sequence of MON 88701 DMO; 2) MALDI-TOF MS analysis yielded peptide masses consistent with the expected peptide masses from the theoretical trypsin digest of the MON 88701 DMO sequence; 3) MON 88701 DMO protein was detected on a western blot probed with antibodies specific for DMO protein and the immunoreactive and physiochemical properties of the MON 88701 DMO and E. coli-produced MON 88701 DMO proteins were shown to be equivalent; 4) the electrophoretic mobility and apparent molecular weight of the MON 88701 DMO and *E. coli*-produced MON 88701 DMO proteins were shown to be equivalent; 5) glycosylation status of MON 88701 DMO and *E. coli*-produced MON 88701 DMO proteins were determined to be equivalent; and 6) functional activity of the MON 88701 DMO and the *E. coli*-produced MON 88701 DMO proteins were demonstrated to be equivalent (Monsanto 2012).

The MON 88701-produced PAT (*bar*) protein purified from cottonseed of DGT cotton was characterized and the equivalence of the immunoreactive and physicochemical characteristics and functional activity between the MON 88701- and the *E. coli*-produced PAT (*bar*) proteins was established using a panel of analytical tests: 1) N-terminal sequence analysis of the MON 88701-produced PAT (*bar*) protein established identity; 2) MALDI-TOF MS analysis yielded peptide masses consistent with the expected peptide masses from the theoretical trypsin digest of the MON 88701-produced PAT (*bar*) sequence; 3) MON 88701-produced PAT (*bar*) protein was detected on a western blot probed with antibodies specific for PAT (*bar*) protein and the immunoreactive properties of the MON 88701-produced and *E. coli*-produced PAT (*bar*) proteins were shown to be equivalent; 4) the electrophoretic mobility and apparent molecular weight of the MON 88701-produced and *E. coli*-produced PAT (*bar*) proteins were shown to be equivalent; 5) glycosylation status of MON 88701- and *E. coli*-produced MON 88701 PAT (*bar*) proteins were determined to be equivalent; and 6) functional activity of the MON 88701- and *E. coli*-produced PAT (*bar*) proteins were demonstrated to be equivalent. (Monsanto 2012)

Taken together, these data provide a detailed characterization of the MON 88701 DMO and PAT (*bar*) proteins and establish their respective equivalence to *E. coli*-produced MON 88701 DMO protein and *E. coli*-produced PAT (*bar*) protein. This equivalence justifies the use of the *E. coli*-produced proteins as test substances in the protein safety studies.

H.2.2.1.2. Expression Levels of MON 88701 DMO and PAT (*bar*) Proteins in DGT Cotton

MON 88701 DMO and PAT (*bar*) protein levels in various tissues of DGT cotton relevant to the risk assessment were determined by a validated enzyme-linked immunosorbent assay (ELISA). Tissues of DGT cotton were collected from four replicate plots planted in a randomized complete block field design during the 2010 growing season from the following eight field sites in the U.S.: Arkansas (ARTI), Georgia (GACH), Kansas (KSLA), Louisiana (LACH), North Carolina (NCBD), New Mexico (NMLC), South Carolina (SCEK), and Texas (TXPL). DGT cotton plots were treated at the 3-5 leaf stage with glufosinate herbicide at the label rate (0.5 lbs active ingredient [a.i.]/acre) and at the 6-10 leaf stage with dicamba herbicide at the proposed label rate (0.5 lbs acid equivalent [a.e.]/acre). The field sites were representative of cotton-producing regions suitable for commercial production. Seed, pollen, root, and overseason leaf (OSL-1 through OSL-4) tissue samples were collected from each replicated plot at all field sites. (Monsanto 2012)

MON 88701 DMO protein levels were determined in all seven tissue types. The results obtained from ELISA are summarized in Table H-5 and the details of the materials and methods are described in Appendix D to the Monsanto petition. (Monsanto 2012). Due to a limited amount of tissue, moisture content was not measured for pollen; therefore, pollen is reported on a fresh weight (fw) basis only. MON 88701 DMO protein levels in DGT cotton across tissue types ranged from <LOD to 410 μg/g dw. The mean MON 88701 DMO protein levels were determined across eight

sites, with the exception of OSL-1 (7 sites) and OSL-4 (7 sites). Samples <LOD were not included in mean determinations. The mean MON 88701 DMO protein levels were highest in leaf (ranging from OSL-2 and OSL-3 at 240 μg/g dw, OSL-4 at 230 μg/g dw to OSL-1 at 180 μg/g dw), followed by root at 43 μg/g dw, seed at 21 μg/g dw, and pollen at 14 μg/g fw.

Table H-4. Summary of MON 88701 DMO Protein Levels in Tissues from DGT Cotton Grown in 2010 U.S. Field Trials

Tissue Type[1]	Development Stage[2]	Days After Planting (DAP)	PAT (*bar*) Mean (SD) Range (µg/g fw)[3]	PAT (*bar*) Mean (SD) Range (µg/g dw)[4]	LOQ/LOD (µg/g fwt)[6,7]
OSL-1	2-4 leaf	14-25	27 (7.6) 13 – 42	180 (52) 110 – 280	0.168/0.313
OSL-2	4-7 leaf	25-37	41 (12) 19 – 65	240 (69) 110 – 380	0.168/0.313
OSL-3	9 leaf – Full flower	35-99	52 (17) 24 – 97	240 (75) 91 – 410	0.168/0.313
OSL-4	Cutout – Full flower	70-121	57 (18) 0.70 – 91	230 (59) 2.8 – 310	0.168/0.313
Root	50% open flower-Full flower	70-121	14 (3.7) 8.2 – 21	43 (12) 26 – 72	0.168/0.313
Pollen	50% open flower – Full flower	68-99	14 (28) 0.31 – 110	NA (NA) NA	0.043/0.125
Seed	Maturity	148-183	20 (4.6) 8.2 – 29	21 (5.0) 8.9 – 33	0.059/0.313

[1]OSL= over-season leaf. Seed = black seed (ginned and delinted).
[2]The crop development stage each tissue was collected (Ritchie et al., 2007).
[3]Protein levels are expressed as the arithmetic mean and standard deviation (SD) as microgram (µg) of protein per gram (g) of tissue on a fresh weight basis (fw). The means, SD, and ranges (minimum and maximum values) were calculated for each tissue across all sites (n=32, except OSL-3 n=31 due to one sample <LOD, OSL-1 and OSL-4 n=28 due to missed sample collections, and pollen n=29 due to two samples expressing <LOD and one being inconclusive).
[4]Protein levels are expressed as µg/g on a dry weight (dw) basis. The dry weight values were calculated by dividing the µg/g fw by the dry weight conversion factors obtained from moisture analysis data. NA= Not Applicable.
[5]LOQ=limit of quantitation; LOD=limit of detection. Note: In the DGT cotton petition (Monsanto 2012) the column heading was incorrectly labeled LOQ/LOD.

PAT (*bar*) protein levels were determined in all seven tissue types. The results obtained from ELISA are summarized in Table H-6 and the details of the materials and methods are described in Appendix D to the Monsanto petition. (Monsanto 2012). Due to a limited amount of tissue, moisture content was not measured for pollen; therefore, pollen is reported on a fresh weight (fw) basis only. PAT (*bar*) protein levels in DGT cotton across tissue types ranged from <LOQ to 10 μg/g dw. The mean PAT (*bar*) protein levels were determined across eight sites, with the exception of OSL-1 (7 sites) and OSL-4 (7 sites). Samples <LOD were not included in mean determinations. The mean PAT (*bar*) protein levels were highest in seed at 6.6 μg/g dw, followed by leaf (ranging from OSL-2 at 6.4 μg/g dw to OSL-4 at 3.2 μg/g dw), root at 1.8 μg/g dw, and pollen at 0.56 μg/g fw.

Table H-5. Summary of PAT (bar) Protein Levels in Tissues from DGT Cotton Grown in 2010 U.S. Field Trials

Tissue Type[1]	Development Stage[2]	Days After Planting (DAP)	PAT (*bar*) Mean (SD) Range (µg/g fw)[3]	PAT (*bar*) Mean (SD) Range (µg/g dw)[4]	LOQ/LOD (µg/g fwt)[6,7]
OSL-1	2-4 leaf	14-25	0.84 (0.21) 0.46 - 1.4	5.5 (1.5) 3.7 – 9.1	0.162/0.188
OSL-2	4-7 leaf	25-37	1.1 (0.26) 0.68 – 1.6	6.4 (1.4) 3.8 – 9.4	0.162/0.188
OSL-3	9 leaf – Full flower	35-99	1.0 (0.34) 0.34 – 1.7	4.8 (2.0) 1.3 - 10	0.162/0.188
OSL-4	Cutout – Full flower	70-121	0.78 (0.29) 0.42 – 1.7	3.2 (1.2) 2.0 – 6.7	0.162/0.188
Root	50% open flower-Full flower	70-121	0.56 (0.18) 0.27 – 0.89	1.8 (0.75) 0.93 – 3.3	0.162/0.188
Pollen	50% open flower – Full flower	68-99	0.56 (0.24) 0.27 – 0.90	NA (NA) NA	0.021/0.188
Seed	Maturity	148-183	6.1 (0.95) 4.8 – 8.8	6.6 (1.1) 5.2 – 9.6	0.032/0.188

[1]OSL= over-season leaf. Seed = black seed (ginned and delinted).
[2]The crop development stage each tissue was collected (Ritchie et al., 2007).
[3]Protein levels are expressed as the arithmetic mean and standard deviation (SD) as microgram (µg) of protein per gram (g) of tissue on a fresh weight basis (fw). The means, SD, and ranges (minimum and maximum values) were calculated for each tissue across all sites (n=32, except OSL-1 n=28 due to missed sample collections, OSL-4 n=27 due to missed sample collections and one sample expressing <LOD, OSL-3 n=31 due to one sample expressing <LOD, and pollen n=6 due to 26 samples expressing <LOQ).
[4]Protein levels are expressed as µg/g on a dry weight (dw) basis. The dry weight values were calculated by dividing the µg/g fw by the dry weight conversion factors obtained from moisture analysis data. NA= Not Applicable.
[5]LOQ=limit of quantitation; LOD=limit of detection.

H.2.2.1.3. Compositional Assessment

Monsanto conducted detailed analyses on nutrient and anti-nutrient levels in DGT cottonseed from plants treated with dicamba and glufosinate, reported above, and plants not treated with dicamba or glufosinate. See petition (Monsanto 2012). Component levels for DGT cotton were compared to levels in the conventional control. The analytes evaluated are consistent with those identified by the OECD as important to understanding the safety and nutrition of new varieties of biotechnology-derived cotton (OECD, 2009). These compositional comparisons were made by analyzing the acid-delinted cottonseed harvested from plants grown at each of eight field sites in the U.S. during the 2010 field season. Composition analyses of all samples, conducted in accordance with OECD guidelines, were performed for nutrients including proximates (ash, carbohydrates, and calories by calculation, moisture, protein, and fat), fibers (ADF, CF, NDF, and TDF), amino acids, fatty acids (C8-C22), minerals (calcium, copper, iron magnesium, manganese, phosphorus, potassium, sodium, and zinc), and vitamin E. The anti-nutrients assessed in this analysis included total and free gossypol and cyclopropenoid fatty acids (dihydrosterculic, malvalic, and sterculic). These analyses also included measurements of the same nutrients and anti-nutrients in conventional commercial cotton varieties, known as reference varieties, to provide data on natural variability of each compositional component analyzed. All cotton plants including DGT cotton, the conventional control, and the conventional commercial reference varieties, were treated with maintenance pesticides as necessary throughout the growing season. In addition, DGT cotton plots were treated at the 3-5 leaf stage with glufosinate herbicide at the label rate (0.5 lbs a.i./acre) and at the 6-10 leaf stage with dicamba herbicide at the label rate (0.5 lbs a.e./acre).

For DGT cotton compared to the conventional control, the combined-site analysis of cottonseed showed no statistically significant differences ($p<0.05$) between nutrient and anti-nutrient components of DGT cotton and the control for 30 (57.7%) of the 52 mean value comparisons. Cottonseed nutrient component differences included mean values for five proximates (ash, calories, carbohydrates, moisture, and total fat), three types of fiber (ADF, NDF, and TDF), three amino acids (arginine, methionine, and proline), two fatty acids (14:0 myristic acid and 18:2 linoleic acid), five minerals (calcium, magnesium, manganese, potassium and zinc), and vitamin E. Cottonseed anti-nutrient component differences included mean values for dihydrosterculic acid, free and total gossypol. All nutrient and anti-nutrient component differences observed in the combined-site statistical analysis, whether reflecting increased or decreased DGT cotton mean values with respect to the conventional control, were 14.09% or less. Mean values for all significantly different nutrient and anti-nutrient components from the combined-site analysis of DGT cotton, with the exception of methionine, were within the 99% tolerance interval established from the conventional, commercial reference varieties grown concurrently in the same trial. All combined-site mean values, including methionine, and individual site mean values of DGT cotton for all nutrient and anti-nutrient components were within the context of the natural variability of commercial cotton composition as published in the scientific literature and/or available in the ILSI Crop Composition Database (ILSI, 2011).

Overall, for DGT cotton mean component values observed to be significantly different from those of the conventional control, the differences with the control were generally shown to be of small relative magnitudes. All DGT cotton mean component values in the combined-site analysis, with the exception of methionine, were within the 99% tolerance interval established from the conventional commercial references varieties grown concurrently and at the same field sites. All combined-site mean values including methionine and individual site mean values of DGT cotton for all nutrient and antinutrient components were within the context of the natural variability of commercial cotton composition as published in the scientific literature and/or available in the ILSI Crop Composition Database (ILSI, 2011).

For DGT cotton treated with dicamba and glufosinate, compared to the conventional control, most of the combined-site differences were not reproducible among the individual sites, with the exception of ash and calcium; however, all of the combined-site component values were within the range of values reported in the scientific literature and/or in the ILSI Crop Composition Database. Additionally, the concentrations of key nutrients and anti-nutrients of cottonseed from DGT cotton that was not treated with dicamba or glufosinate were also analyzed. Results from this analysis were similar to those of the dicamba and glufosinate treated analysis. Based on the results of this composition analysis, it is concluded that cottonseed from DGT cotton is compositionally equivalent to conventional cotton and therefore the food and feed safety and nutritional quality of this product is comparable to that of the commercially cultivated cotton.

The processing of DGT cotton is not expected to be any different from that of conventional cotton. As described in this section, detailed compositional analyses of key components of DGT cotton have been performed and have demonstrated that DGT cotton is compositionally equivalent to conventional cotton. Additionally, the mode of action of the MON 88701 DMO and PAT (*bar*) proteins is well understood, and there is no reason to expect interactions with important nutrients or known anti-nutrients that are present in cotton. Therefore, when DGT cotton and its progeny are used on a commercial scale as a source of food or feed, these products are not expected to be different from the equivalent foods or feeds originating from commercially cultivated cotton.

H.2.2.1.4. MON 88701, PAT (*bar*), and Gene Sequence Detection

Monsanto has committed to best industry practices on seed quality assurance and control to ensure the purity and integrity of DGT cotton seed. Before commercializing DGT cotton in any country, Monsanto has pledged to make a DGT cotton detection method available to cotton producers, processors, and buyers.

H.2.2.1.4.1. MON 88701 DMO, PAT (*bar*), and Gene Sequence Detection Methods

Methods for detecting GE materials range in their limits of detection. In many situations, a test will be required that not only detects the presence of GE material, but also measures the amount of GE content in the sample. All testing methodologies detect either the inserted DNA or the expressed protein resulting from the inserted DNA. The major detection methods for transgenic proteins are Enzyme Linked Immunosorbent Assays (ELISAs), and make use of the properties of antibodies. ELISAs are easy to use, robust and cheaper than DNA detection methods but generally less sensitive (Griffiths et al., 2002). In contrast to protein detection assays, assays designed to detect transgenic DNA are more sensitive. The most commonly used DNA amplification method is the Polymerase Chain Reaction (PCR), though there are other amplification methods to suit specific applications.

For each testing method, a Limit of Detection (LOD) is defined to show the sensitivity of the method. For example, a method with an LOD of 1 percent (w/w) for GT soy would be able to detect GT soy in a batch of soy flour when present as 1 percent (w/w) of the total soy flour (Griffiths et al., 2002). It is important to note that this LOD value written in an abbreviated form means the LOD for GT soy is 1 percent (w/w) of total soy flour if the product is comprised of 100 percent soy (Griffiths et al., 2002). For food products containing several ingredients, estimation of the LOD is less reliable. Using the previous example, if the 1 percent (w/w) GE soy flour were used as a baking ingredient in cake, the soy flour may make up only 0.5 percent (w/w) of the total cake ingredients. The GE soy would thus be only 0.005 percent (w/w) of the total sample, which would be well below the LOD for this method (Griffiths et al., 2002). The LOD is normally defined on a percent (w/w) basis, the actual measurement of GE ingredients is based on either DNA or protein and this DNA- or protein-based measurement is not necessarily directly transferable to a percent (w/w) measurement (Griffiths et al., 2002). Some highly processed foods contain no traces of DNA and/or protein. In these cases, there is no analytical method available to identify whether these products are derived from GE materials.

H.2.2.1.4.2. Labeling Standards

In the United States, foods derived from GE plants are not required to indicate on the food label that they were derived from plants produced through the use of biotechnology. While Australia has a tolerance level of 1 percent unintended GE material, other countries such as Japan and Korea currently have a higher tolerance level of 5 percent (Griffiths et al., 2002). On the other hand, the European Commission (EC), on behalf of the European Union (EU), has proposed new legislation to drop the threshold for the presence of unintended GE content from 1 percent to 0.5 percent. The EU is also planning to adopt a process-based rather than the product-based GE food labeling approach, so that any product derived from gene technology would have to be labeled, even if the novel DNA and/or protein were completely removed. The commercial feed producer is required by EU legislation to label feed containing GE feed ingredients. At present, European Market Regulations 2003/1829/EC and 2003/1830/EC govern the use of GE ingredients intended for food, feed, and food additives. Threshold labeling at 9 g/kg (0.9 percent) for the unintended presence of approved GE material and 5 g/kg for GE materials not approved in Europe is required (Bakke-McKellep et al., 2007). In addition, a 0.5 percent labeling threshold has been mandated for GE crops that have been given a favorable risk assessment but are not yet approved within the EU. Unapproved varieties are managed with zero tolerance (Alexander et al., 2007). Products such as milk, meat, and eggs, and that are derived from livestock fed transgenic feeds are exempt from EU-labeling laws. Currently, only the EU and Switzerland have labeling regulations specifically pertaining to GE feed (Griffiths et al., 2002; Alexander et al., 2007; ISAAA, 2005).

H.2.2.1.4.3. Detection in Food Products

There is some literature available on the detection and quantification of GE material in various foods. In an Australian monitoring study (Griffiths et al., 2002), the GT trait was detected in soy flour, soy protein isolate, soy milk, snack foods, biscuits, powdered bread, and corn flour as illustrated in figure H-7 below.

Round	Number	Test Material	Ingredient	GM Ingredient[a]			Laboratory results		
				GM Trait	% of GM Ingredient	% in Test Product	No. Results	% of results present	% of results absent
1	2301A	Soy flour	Soy flour	Roundup Ready	1	1	85	94	6
	2301 B	Soy flour	Soy flour	Roundup Ready	0.2	0.2	81	89	11
	2301 C	Soy protein isolate	Soy protein isolate	-	0	0	91	91	9
	2301 D	Soy protein isolate	Soy protein isolate	Roundup Ready	1	1	94	99	1
	2301 E	Soy protein isolate	Soy protein isolate	Roundup Ready	0.5	0.5	92	98	2
2	2302 A	Maize flour	Maize flour	Bt176	0.75	0.75	74	97	3
	2302 B	Maize flour	Maize flour	-	0	0	74	26	74
	2302 C	Maize flour	Maize flour	Bt176	1.5	1.5	74	99	1
3	2303 A	Soy flour	Soy flour	-	0	0	63	16	84
	2303 B	Soy flour	Soy flour	Roundup Ready	2	2	63	92	8
	2303 C	Wheat flour/soy flour	Soy flour	Roundup Ready	10	0.5	63	97	3
4	2304 A	Maize flour	Maize flour	Bt176	0.5	0.5	98	99	1
5	GMO-05A	Soy milk powder with soy protein isolate	Soy protein isolate	Roundup Ready	1	0.15	67	100	0
6	GMO-06A	Snack Food Crumbs	Soy flour	Roundup Ready	0	0	57	14	86
	GMO-06B	Snack Food Crumbs	Soy flour	Roundup Ready	2	Unknown	58	95	5
7	GMO-07	Maize/soy flour mix	Soy flour	Roundup Ready	1	0.5	78	96	4
			Maize flour	Bt176	0.25	0.125	67	91	9
			Maize flour	Bt11	0	0	43	53	47
8	GMO-08A	Soy-based baked biscuit crumbs	Soy flour	Roundup Ready	2.5	0.05	91	98	2
9	GMO-09A	Soy in canned meat	Soy flour	Roundup Ready	5	0.1	81	67	33
10[b]	GMO-10A	Maize flour/wheat flour	Soy flour	Roundup Ready	0	0	92	4	96
			Maize flour	Bt176	0.5	0.025	97	86	14
			Maize flour	Bt11	0	0	65	6	94
	GMO-10B	Soya flour/maize flour	Soy flour	Roundup Ready	1	0.25	107	97	3
			Maize flour	Bt176	1	0.025	91	84	16
			Maize flour	Bt11	0	0	65	38	62
11[b]	GM11A	Soy flour/ wheat flour	Soy flour	Roundup Ready	1.5	0.075		90	10
			Maize flour	Bt176	0	0		8	92
			Maize flour	Bt11	0	0		0	100
	GM11B	Soy flour/ wheat flour	Soy flour	Roundup Ready	0.5	0.025		82	18
			Maize flour	Bt176	0	0		10	90
			Maize flour	Bt11	0	0		0	100
12	GM12	Powdered bread	Soy flour	Roundup Ready	3	0.01		81	19

[a] '% of GM Ingredient' is calculated as % (w/w) GM ingredient in total ingredient. '% in Test Product' is calculated as % (w/w) GM ingredient in total Test Material.
[b] Results for information only as IRMM Maize Reference Materials withdrawn due to degradation

Figure H-2: Australian Detection of Genetically Engineered Material in Various Foods (Griffiths et al., 2002)

H.2.2.1.4.4. Detection of MON 88701 DMO, PAT (bar) and Gene Sequence in Downstream Animals

The European Food Safety Authority (EFSA) has reported that a large number of experimental studies have shown that recombinant DNA consumed by livestock has not been subsequently detected in tissues, fluids, or edible products of these farm animals (EFSA 2007). DNA has always been present in food and, upon consumption, is quickly degraded by restriction nucleases present in the gastrointestinal tract of humans and animals to nucleic acids. According to the U.S. FDA (1992), nucleic acids are present in the cells of every living organism, do not raise concerns as a component of food, and are generally recognized as safe. Results from an International Life Sciences Institute (ILSI) workshop on safety considerations of DNA in food were reported (Jonas et al., 2001) and confirmed that: 1) all DNA, including recombinant DNA, is composed of the same four nucleotides; 2) there are no changes to the chemical characteristics or the susceptibility to degradation by chemical or enzymatic hydrolysis of recombinant DNA as compared to non-recombinant DNA; and 3) there is no evidence that DNA from dietary sources has ever been incorporated into the mammalian genome.

As described by the European Food Safety Authority (EFSA) in 2007 the fate of recombinant DNA from genetically engineered plants or resultant proteins are dependent on the following four factors:

- the fate of the recombinant DNA and protein during the feed processing and ensilaging;

- the fate of the recombinant DNA and protein in the gastrointestinal tract of animals fed with the GE feed;
- the potential absorption of the digested pieces of DNA or protein into animal tissues/products; and
- the potential of biological functionality of absorbed DNA and protein fragments.

No study has found that mechanical treatment (e.g., baling, chopping, processing) of animal feed has effect on DNA stability (EFSA). Digestion in the gut generally causes DNA and protein to be broken down to the original nucleotides and amino acids respectively. The inserted DNA and protein expressed from the inserted DNA are not expected to be digested in any different manner simply because they are present in the food due to the use of biotechnology.

For example, in field tests, CP4 EPSPS, the inserted gene sequence in glyphosate-tolerant (GT) soybeans, was found in GT soybean at 0.1 percent in chicken feed (Ash et al., 2003) by an ELISA method; no detectable amounts of CP4 EPSPS protein were in whole egg, egg albumen, liver, or feces of the chickens fed GT soybeans.

Conventional PCR/Southern Blot and an ELISA method were utilized to determine if transgenic DNA or protein were detectable in pigs fed GT soybeans (Jennings et al., 2003). The authors report that there was an absence of detectable levels of fragments of either transgenic DNA or protein. By contrast Sharma (2006) reported detection of transgenic DNA in intestinal tissue.

Quantitative real-time PCR and conventional PCR were used to evaluate GT canola cp4 epsps transgene in the intestines, rumen, or feces of sheep feed canola meal (Alexander et al., 2004). Digestion of plant material and release of tDNA (including transgenic DNA) can occur in the small intestine of sheep. The free transgenic DNA is rapidly degraded at neutral pH in small intestine duodenal fluid, thus reducing the likelihood that intact transgenic DNA would be available for absorption through the Peyer's Patches further down in the distal ileum of the small intestine (Alexander et al., 2004).

The persistence of plant-derived recombinant DNA in sheep and pigs fed GE (GT) canola was assessed by Sharma et al. (2006) utilizing PCR and Southern hybridization analysis of DNA extracted from digesta, GI tract tissues, and visceral organs. This study confirmed that DNA fragments ingested in feed do survive to the terminal GI tract and that uptake into gut epithelial tissues does occur. A very low frequency of transmittance to visceral tissue was confirmed in pigs, but not in sheep. There was no evidence to suggest that recombinant DNA would be processed in the gut in any manner different from endogenous feed-ingested genetic material.

A study by Netherwood et al. (2004) and the discussion by Heritage (2004) address the finding by Netherwood et al. of evidence of low-frequency EPSPS gene transfer from genetically engineered soya to the microflora of the small bowel. However, the microflora contained only fragments EPSPS; the full length gene was not detected, and it could not be determined whether it was the bacteria themselves that contained the fragments.

H.2.2.2. DGT Cotton Safety Assessment

H.2.2.2.1. MON 88701 DMO and PAT (*bar*) Safety Assessment

FDA enforces laws regarding the safety and labeling of food and feed. In 2013 Monsanto completed a voluntary consultation with FDA regarding the food and feed safety of DGT cotton. See Appendix I of this Environmental Report. FDA considers a consultation to be completed when all safety and regulatory issues are resolved. See Appendix I of this Environmental Report. As part of the consultation, Monsanto discussed its finding that the MON 88701 DMO belongs to a common class of mono-oxygenases present in bacteria and plants currently widely prevalent in the environment and consumed, and that PAT (*bar*) is well understood and included in existing deregulated glufosinate-tolerant crops. Available data demonstrate that harvested seed is as safe as conventional cotton seed for food and feed uses.

H.2.2.2.1.1. DMO Donor Organism Safety

The *dmo* gene is derived from the bacterium *Stenotrophomonas maltophilia* (Palleroni and Bradbury, 1993). *S. maltophilia* is ubiquitous in the environment and is found associated with the rhizosphere of plants. *S. maltophilia* can be found in a variety of foods and feeds, and is widespread in the home environment (Berg et al., 1999; Denton and Kerr, 1998; Echemendia, 2010). Exposure to *S. maltophilia* is incidental to its presence in food. It has been isolated from "ready to eat" salads, vegetables, frozen fish, milk, and poultry (Qureshi et al., 2005; Ryan et al., 2009). *S. maltophilia* can be found in healthy individuals without causing any harm to human health (Denton et al., 1998) and infections caused by *S. maltophilia* are extremely uncommon (Cunha, 2010). Strains have been found in the transient flora of hospitalized patients as a commensal organism (Echemendia, 2010) and, similar to the indigenous bacteria of the gastrointestinal tract, *S. maltophilia* can be an opportunistic pathogen (Berg, 1996). As such, *S. maltophilia* is of low virulence in immuno-compromised patients where a series of risk factors (severe debilitation, the presence of indwelling devices such as ventilator tubes or catheters, for prolonged periods of time and prolonged courses of antibiotics) must occur for colonization by *S. maltophilia* in humans (Ryan et al., 2009). Therefore, infections by *S. maltophilia* almost exclusively occur in hospital settings, in which case they are only present in a minimal percentage of infections (Ryan et al., 2009). Finally, *S. maltophilia* has not been reported to be source of allergens.

The ubiquitous presence of *S. maltophilia* in the environment, the presence in healthy individuals without causing infections, the incidental presence in foods without any adverse safety reports, and the lack of reported allergenicity establishes the safety of the donor organism.

H.2.2.2.1.2. MON 88701 DMO Belongs to a Common class of Mono-Oxygenases

MON 88701 DMO is classified as an oxygenase. Oxygenases are enzymes that incorporate one or two oxygen atoms into substrates and are widely distributed in many universal metabolic pathways (Harayama et al., 1992). Within this large enzymatic class are mono-oxygenases that incorporate a single oxygen atom as a hydroxyl group with the concomitant production of water and oxidation of NAD(P)H (Harayama et al., 1992). Non-heme iron oxygenases, where iron is involved in the catalytic site, are an important class of oxygenases. Within this class are Rieske oxygenases, which contain a Rieske iron-sulfur [2Fe-2S] cluster. All Rieske non-heme iron oxygenases contain two catalytic domains, a non-heme iron domain (nh-Fe) that is a site of oxygen activation, and a Rieske

[2Fe-2S] domain (Ferraro et al., 2005). MON 88701 DMO belongs to this class of oxygenases which are found in diverse phyla ranging from bacteria to plants (Ferraro et al., 2005; Schmidt and Shaw, 2001).

As discussed previously, the crystal structure of a DMO has been solved (D'Ordine et al., 2009; Dumitru et al., 2009). The crystallography results demonstrated that, similar to all Rieske non-heme iron oxygenases, DMO contains two catalytically important and highly conserved domains; a mononuclear non-heme iron domain (nh-Fe) that is a site of oxygen activation, and a Rieske [2Fe-2S] domain (D'Ordine et al., 2009; Dumitru et al., 2009; Ferraro et al., 2005). The amino acids binding the non-heme iron and those that constitute the Rieske [2Fe-2S] domain in the DMO protein are also highly conserved in these plant proteins, as is their spatial orientation (D'Ordine et al., 2009; Ferraro et al., 2005). Rieske domains are ubiquitous in numerous bacterial and plant proteins like the iron-sulfur protein of the cytochrome bc1 complex, chloroplast cytochrome b6/f complex, and choline mono-oxygenases (Breyton, 2000; Darrouzet et al., 2004; Gray et al., 2004; Hibino et al., 2002; Rathinasabapathi et al., 1997; Russell et al., 1998). The presence of two conserved domains, a Rieske [2Fe-2S] domain and a mononuclear iron domain, suggests that all Rieske type non-heme iron oxygenases share the same reaction mechanism, by which the Rieske domain transfers electrons from the ferredoxin to the mononuclear iron to allow catalysis (Chakraborty et al., 2005; Dumitru et al., 2009; Ferraro et al., 2005). The structure and mechanistic homologies are further evidence of the evolutionary relatedness of all Rieske non-heme iron oxygenases to each other (Nam et al., 2001; Rosche et al., 1997; Werlen et al., 1996). Additionally, a FASTA alignment search of publicly available databases using the MON 88701 DMO protein sequence as a query yielded homologous sequences from many different species, predominantly bacteria, with amino acid sequence identity ranging up to approximately 42%. Alignments of MON 88701 DMO with plant proteins revealed homologous oxygenases present in crops such as canola (Brassica napus), corn (Zea mays), pea (Pisum sativum), rice (Orysa sativa), and soy (Glycine max), which were determined to have sequence identities up to approximately 27%. The highest homology was observed to proteins that are involved in chlorophyll metabolism. Chlorophyllide A oxygenase (Accession number: ACG42449) is Rieske-type oxygenase that is required for the formation of chlorophyll b, which is present in all plants (Tanaka et al., 1998). Pheophorbide A oxygenase (Accession number: ABD60316) is also a Rieske-type oxygenase that plays a key role in the overall regulation of chlorophyll degradation in plants (Rodoni et al., 1997). Pheophorbide A oxygenase is constitutively present in all green tissues and, at slightly lower levels, in etiolated and non-photosynthetic tissues including seeds (Yang et al., 2004). As a Rieske-type oxygenase, Pheophorbide A oxygenase is expected to have high degree of secondary and tertiary structure homology to similar structural elements in DMO as described above. The presence of these conserved structural domains in these plant proteins is further evidence that exposure to a structural homolog of MON 88701 DMO has occurred through consumption of these crops.

Therefore, MON 88701 DMO shares sequence identity and many catalytic domain structural similarities with a wide variety of oxygenases present in bacteria and plants currently widely prevalent in the environment and consumed, establishing that animals and humans are extensively exposed to these types of enzymes.

H.2.2.2.1.3. DMO is a Dicamba-Specific Mono-Oxygenase

DMO converts dicamba to DCSA. This demethylation is very specific to dicamba, where both the carboxylate moiety and the chlorine atoms help position the substrate at the active site of the enzyme (D'Ordine et al., 2009; Dumitru et al., 2009). Crystallography studies of the substrate in the active site demonstrated that these chlorines function as steric "handles" that position the substrate in the proper orientation in the binding pocket (Dumitru et al., 2009). Potential substrates abundant in cotton (o-anisic acid, vanillic acid, syringic acid, ferulic acid and sinapic acid) that are structurally similar to dicamba, were not metabolized by an *E. coli*-produced N-terminal histidine DMO. In addition, *E. coli*-produced MON 88701 DMO did not metabolize o-anisic acid, the endogenous compound that has the greatest structural similarity to dicamba. These laboratory tests indicate that DMO, including MON 88701 DMO protein, is specific for dicamba. See Appendix I, section VI.A.3. Given the limited amount of chlorinated metabolites with structures similar to dicamba in plants and other eukaryotes (Wishart, 2010; Wishart et al., 2009), it is unlikely that MON 88701 DMO will catalyze the conversion of other endogenous substrates. Therefore, the activity of the enzyme is specific for dicamba while it maintains many structural properties common to oxygenases that are ubiquitous to all organisms with a history of safe consumption.

H.2.2.2.1.4. *bar* Donor Organism Safety

S. hygroscopicus is a saprophytic, soil-borne bacterium with no known safety issues. *Streptomyces* species are widespread in the environment and present no known allergenic or toxicity issues (Kämpfer, 2006; Kutzner, 1981) though human exposure is quite common (Goodfellow and Williams, 1983). *S. hygroscopicus* is not considered pathogenic to plants, humans or other animals (Cross, 1989; Goodfellow and Williams, 1983; Locci, 1989). The history of safe use of *S. hygroscopicus* is discussed previously (Hérouet et al., 2005), and this organism has been extensively reviewed during the deregulation of several glufosinate-tolerant events with no safety or allergenicity issues identified.

The ubiquitous presence of *S. hygroscopicus* in the environment, the widespread human exposure without any adverse safety or allergenicity reports, and the successive reviews resulting from the deregulation of several glufosinate-tolerant events with no safety or allergenicity issues identified establishes the safety of the donor organism.

H.2.2.2.1.5. PAT Protein has a History of Safe Use

The PAT (*bar*) protein expressed in DGT cotton is identical to the wild-type protein produced in *S. hygroscopicus* and is analogous to the PAT proteins in commercially available glufosinate-tolerant products in several crops including cotton, corn, soybean, and canola. Based on studies characterizing the kinetic and chemical mechanisms of PAT proteins (Wehrmann et al., 1996), OECD recognizes PAT proteins produced from different genes to be equivalent with regard to function and safety (OECD, 1999b).

The safety of PAT protein present in biotechnology-derived crops has been extensively assessed (ILSI-CERA, 2011) and in 1997 a tolerance exemption was issued for PAT proteins by U.S. EPA (U.S. EPA, 1997). This exemption was based on a safety assessment that included rapid digestion in simulated gastric fluids, lack of significant homology to known toxins and known allergens, and lack of toxicity in an acute oral mouse gavage study. Numerous glufosinate-tolerant products including those in corn, soy, canola, sugarbeet and rice have been reviewed by the USDA and FDA with no concerns identified. Further, a comprehensive study on the safety of PAT proteins present in biotechnology-derived crops (Hérouet et al., 2005) demonstrated structural similarity only with other acetyltransferases known to not cause adverse effects after consumption, lack of sequence homology to know allergens and toxins, lack of glycosylation sites, rapid degradation in gastric and intestinal fluids, and no adverse effects in mice treated with high doses of PAT proteins. Hérouet et al. concluded that there is a reasonable certainty of no harm resulting from the inclusion of PAT proteins in human food or animal feed (2005).

The history of safe use of PAT is supported by the lack of any documented reports of adverse effects related to this protein since the introduction of glufosinate-tolerant crops in 1995 (Duke and Powles, 2009). Since then, approvals have been issued by regulatory agencies of 11 different countries for the environmental release of greater than 38 transformation events, including 8 different species of plants expressing the PAT protein (ILSI-CERA, 2011).

H.2.2.2.1.6. PAT (*bar*) Catalyzes a Specific Enzyme Reaction

The mode-of-action for PAT protein has been extensively assessed, as numerous glufosinate-tolerant products, including those in corn, soy, canola, sugarbeet, and rice, have been reviewed by the FDA and several other regulatory agencies (ILSI-CERA, 2011; OECD, 1999b; 2002). PAT, including the PAT (*bar*) protein produced in DGT cotton, is an enzyme classified as an acetyltransferase which acetylates glufosinate to produce non-herbicidal N-acetyl glufosinate. Glufosinate is a racemic mixture of the D- and L- forms of phosphinothricin. The herbicidal activity of glufosinate results from the binding of L-phosphinothricin to glutamine synthetase (OECD, 1999b; 2002). Glutamine synthetase is responsible for the assimilation of ammonia generated during photorespiration. The binding of L-phosphinothricin to glutamine synthetase results in the inactivation of glutamine synthetase and a subsequent toxic build-up of ammonia within the plant, resulting in death of the plant (Manderscheid and Wild, 1986; OECD, 1999b; 2002; Wild and Manderscheid, 1984).

The PAT (*bar*) protein produced in DGT cotton acetylates the free amine group of Lphosphinothricin form of glufosinate to produce non-herbicidal N-acetyl glufosinate. The acetylated glufosinate is unable to bind to glutamine synthetase and therefore does not disrupt photorespiration and avoids the build-up of ammonia. Therefore, the production of PAT (*bar*) protein in DGT cotton confers glufosinate herbicide tolerance through this mechanism.

The PAT proteins, including PAT (*bar*), are highly specific for glufosinate in the presence of acetyl-CoA (Thompson et al., 1987; Wehrmann et al., 1996). While the herbicidal activity of glufosinate comes from the L-amino acid form, other L-amino acids are unable to be acetylated by PAT protein and competition assays containing glufosinate, high concentrations of other amino acids and PAT showed no inhibition of glufosinate acetylation (Wehrmann et al., 1996). Furthermore, L-glutamate, an analogue of glufosinate, also showed no inhibition of glufosinate acetylation in competition assays (Wehrmann et al., 1996). In addition, the PAT (*bar*) protein has more than 30-fold higher affinity towards L-phosphinothricin over other plant analogues (Thompson et al., 1987). Thus, the PAT (*bar*) protein has high substrate specificity for L-phosphinothricin, the herbicidal component of glufosinate, and is unlikely to affect the metabolic system of DGT cotton. Numerous glufosinate-tolerant products, including those in corn, soy, canola, sugarbeet, and rice have been reviewed with no concerns identified (ILSI-CERA, 2011).

H.2.2.2.1.7. DGT Cotton Allergenicity

Assessing the potential allergenicity of the expressed proteins is less relevant to DGT cotton since only cottonseed oil and linters from cotton are used in food applications, which have undetectable or negligible amounts of total protein (Reeves and Weihrauch, 1979; Sims et al., 1996). Nonetheless, the allergenic potential of MON 88701 DMO and PAT (*bar*) proteins was assessed by comparing the biochemical characteristics of these introduced proteins to biochemical characteristics of known allergens (Codex Alimentarius, 2009). A protein is not likely to be associated with allergenicity if: 1) the protein is from a non-allergenic source; 2) the protein represents a very small portion of the total plant protein; 3) the protein does not share structural similarities to known allergens based on the amino acid sequence; and 4) the protein is rapidly digested in mammalian gastrointestinal systems.

MON 88701 DMO has been assessed for its potential allergenicity according to the safety assessment guidelines described above (see Appendix I), and conclusions were as follows:

> 1) MON 88701 DMO originates from *S. maltophilia*, an organism that has not been reported to be a source of known allergens.
>
> 2) MON 88701 DMO represents no more than 0. 008% of the total protein in the cottonseed of DGT cotton.[250] Therefore, the MON 88701 DMO protein represents a very small portion of the total protein in the cottonseed of DGT cotton and due to the harsh conditions used in cottonseed processing is most likely absent in the oil and linters that are used for food production.
>
> 3) Bioinformatics analyses demonstrated that the MON 88701 DMO does not share amino acid sequence similarities with known allergens and, therefore, is highly unlikely to contain immunologically cross-reactive allergenic epitopes.
>
> 4) In vitro digestive fate experiments conducted with the MON 88701 DMO demonstrate that the proteins are rapidly digested in simulated gastric fluid (SGF) and in simulated intestinal fluid (SIF).

Taken together, these data support the conclusion that MON 88701 DMO does not pose a significant allergenic risk. See Appendix I.

The non-allergenic nature of PAT (*bar*) protein is established in the scientific literature (Hérouet et al., 2005) and by the tolerance exemption set by U.S. EPA (1997). Furthermore, the safety of PAT proteins, including the PAT (*bar*) protein produced in DGT cotton, has been assessed extensively by regulatory agencies in 11 different countries for more than 38 biotechnology-derived events in eight different species (ILSI-CERA, 2011). In addition, potential allergenicity of PAT (*bar*) protein produced in DGT cotton has been assessed according to the safety assessment guidelines described above (see Appendix I), and conclusions were as follows.

> 1) PAT (*bar*) originates from *S. hygroscopicus*, an organism that has not been reported to be a source of known allergens.

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[250] % protein = (Mean level of protein expression (µg/g)/ Mean dry weight of total protein in seed µg/g) x 100 %

2) PAT (*bar*) represents no more than 0. 002% of the total protein in the cottonseed of DGT cotton.[251] Therefore, the PAT (*bar*) protein represents a very small portion of the total protein in the cottonseed of DGT cotton and due to the harsh conditions used in cottonseed processing is most likely absent in the oil and linters that are used for food production.

3) Bioinformatics analyses demonstrated that the PAT (*bar*) does not share amino acid sequence similarities with known allergens and, therefore, is highly unlikely to contain immunologically cross-reactive allergenic epitopes.

4) In vitro digestive fate experiments conducted with the PAT (*bar*) demonstrate that the proteins are rapidly digested in simulated gastric fluid (SGF) and in simulated intestinal fluid (SIF).

Taken together, these data support the conclusion that PAT (*bar*) does not pose a significant allergenic risk.

H.2.2.2.1.8. MON 88701 DMO and PAT (*bar*) are Labile in *in vitro* Digestion Assays

MON 88701 DMO and PAT (*bar*) were readily digestible in simulated gastric fluid (SGF) and simulated intestinal fluid (SIF). Rapid degradation of the MON 88701 DMO and PAT (*bar*) proteins in SGF and SIF makes it highly unlikely that either protein would be absorbed in the small intestine and have any adverse effects on human or animal health. (Monsanto 2012).

H.2.2.2.1.9. MON 88701 DMO and PAT (*bar*) Toxicity

Acute oral toxicology studies were conducted with MON 88701 DMO and PAT (*bar*) proteins individually. Results indicate that neither MON 88701 DMO or PAT (*bar*) caused any adverse effects in mice, with No Observable Adverse Effect Levels (NOAELs) for MON 88701 DMO at 283 mg/ kg bw and PAT (*bar*) at 1086 mg/kg bw, respectively, the highest doses tested. (Monsanto 2012).

Cottonseed is not consumed by humans because the majority of commercial cotton varieties contain the anti-nutrients gossypol and cyclopropenoid fatty acids. The primary human food currently produced from cottonseed is refined, bleached, and deodorized (RBD) oil, and to a smaller extent, linters. RBD oil contains undetectable amounts of protein (Reeves and Weihrauch, 1979); therefore, oil produced from DGT cotton will contain extremely low levels of MON 88701 DMO and PAT (*bar*) proteins. Linters are an industrial by-product of ginning, and can be consumed as a highly processed product composed of nearly pure (i.e., >99%) cellulose (NCPA, 2002; Nida et al., 1996). Cottonseed RBD oil and linters are processed fractions that contain undetectable or negligible amounts of protein there is minimal, if any, dietary exposure to MON 88701 DMO and PAT (*bar*) proteins from consumption of foods derived from DGT cotton. Therefore, MOE values were not calculated for the MON 88701 DMO or PAT (*bar*) proteins. Furthermore, the safety of PAT (*bar*)

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[251] % protein = (Mean level of protein expression (µg/g)/ Mean dry weight of total protein in seed µg/g) x 100 %

has been extensively assessed (Hérouet et al., 2005), several glufosinate-tolerant crops that produce PAT proteins have been reviewed by FDA and other regulatory agencies (ILSI-CERA, 2011) and in 1997 a tolerance exemption was issued for PAT proteins by U.S. EPA (1997).

Estimated exposure of MON 88701 DMO and PAT (*bar*) proteins in animal feed were evaluated by calculating an estimate of daily dietary intake (DDI) for dairy cows. Exposure was calculated for the worst-case scenario, which assumes: 1) the source of cottonseed in the diet is cottonseed meal; 2) cottonseed meal is only derived from DGT cotton and contains no other cottonseed sources; 3) the protein expression level is the maximum expression level measured for each protein; and 4) there would be no loss of protein due to heat. The maximum daily amount of MON 88701 DMO or PAT (*bar*) proteins consumed from DGT cotton would be for the dairy cow and would be 0.00043 g/kg of body weight for MON 88701 DMO and 0.000124 g/kg of body weight for PAT (*bar*). These values represent 0.007 and 0.002% of protein consumed, respectively. These very small levels of exposure of animals to MON 88701 DMO and PAT (*bar*) in their feed, in addition to the above mentioned safety data for both MON 88701 DMO and PAT (*bar*), support the conclusion that there is no risk to animal health when MON 88701 DMO or PAT (*bar*) are present in their diets.

H.2.2.2.1.10. DGT Cotton Safety Assessment Conclusions

In April of 2013 Monsanto concluded consultations with the FDA regarding the safety of DGT cotton in food and feed. After considering the above-described findings, along with comprehensive submissions of data and research, the FDA concluded that it had no further questions about food and feed derived from DGT cotton. Food and feed products containing DGT cotton or derived from DGT cotton are as safe as cotton currently on the market for human and animal consumption. See Appendix I.

H.2.2.2.2. Dicamba Reaction Product Safety Assessment

MON 88701 DMO rapidly demethylates dicamba rendering it inactive, thereby conferring tolerance to dicamba in DGT cotton. In dicamba-treated DGT cotton, the demethylation of dicamba produces 3,6-dichlorosalicylic acid (DCSA), a known cotton, soybean, soil, and livestock metabolite whose safety has been evaluated by the Environmental Protection Agency (U.S. EPA), and formaldehyde. In the absence of a dicamba treatment on DGT cotton, DCSA and formaldehyde would not be produced. DCSA is structurally similar to salicylic acid (SA). Numerous studies have reported on the stress defense activities of SA, although most studies have looked at the protective effects of exogenously applied SA (Janda et al, 2007). Formaldehyde has a potential linkage to apoptosis in plants (Szende and Tyihak, 2010), and formaldehyde concentrations in plants have been found to increase under certain stress conditions (Szabo et al, 2003). The National Toxicology Program (NTP) 12th Report on Carcinogens has reclassified formaldehyde as a known human carcinogen (USHHS-NTP, 2011). The relevant route of exposure for this health risk is from repeated inhalation at levels associated with indoor or occupational environments, which are generally higher than outdoor environments (USHHS-NTP, 2011). Formaldehyde is present in food and in the human body naturally, and there is no evidence to suggest that dietary intake of formaldehyde is important (USHHS-NTP, 2011).

A full discussion on DCSA, and the safety of this metabolite, is provided in Appendix L of the Monsanto Petition for Determination of Nonregulated Status for DT Soybean (Monsanto 2010). DCSA residue levels were measured in dicamba-treated DGT cotton to support Monsanto's registration request for the inclusion of DCSA in the cottonseed and gin byproduct dicamba residue definitions. DCSA is structurally similar to salicylic acid (SA). Numerous studies have reported on the stress defense activities of SA, although most studies have looked at the protective effects of exogenously applied SA (Janda et al, 2007).

Formaldehyde is ubiquitous in the environment and present in plants and animals. Formaldehyde was not considered a relevant metabolite in the demethylation of dicamba by the EPA. According to the guidelines published by Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency (US EPA OPPTS 860.1300), the methoxy sidechain that is cleaved from dicamba to form formaldehyde would specifically not be chosen to be labeled in a metabolism study (U.S. EPA, 1996). This is because it is not metabolically stable and would not be considered a significant moiety, as it would be readily metabolized and incorporated into the 1-carbon pool of the plant through known pathways. Therefore, formaldehyde was not measured in the residue study when dicamba was applied to DGT cotton.

Data from both dicamba and glufosinate-treated and not treated DGT cotton compared to a conventional control are available from multiple sites across the U.S., where agronomic, phenotypic and environmental interaction data were collected. The results of this assessment demonstrate no biologically meaningful difference between DGT cotton treated with and without dicamba and glufosinate and the conventional control, and support a conclusion that the formation of DCSA and formaldehyde does not alter the weedy characteristics or increase susceptibility or tolerance to diseases, insect pests or abiotic stresses. Therefore, DGT cotton, as cultivated, is no more likely to be a plant pest risk or have a biologically meaningful change in environmental impact than conventional cotton.

Further, the metabolism of formaldehyde in plants is well understood, and there are a number of natural occurring sources of formaldehyde in plants. For example, it is produced during the process of photorespiration (Oliver, 1994) and during oxidative demethylation of DNA (Zhu, 2009), which supports why formaldehyde is not considered a byproduct of interest as dicamba is demethylated. It is well known and understood that formaldehyde is rapidly metabolized in plants through two basic routes: 1) it can be incorporated into the one-carbon folate pool via spontaneous or enzyme-mediated formation of methylene tetrahydrofolate (Hanson and Roje, 2001); or 2) it can be oxidized to formate by a detoxification pathway that begins with spontaneous formation of the glutathione adduct *S*-hydroxymethylglutathione (Hanson and Roje, 2001). In each case, formaldehyde is further metabolized to carbon dioxide or entered into the 1C folate pool (Hanson and Roje, 2001; Giese et al., 1994).

The maximum theoretical production of formaldehyde produced from dicamba-treated DGT cotton is estimated to be 6.3 mg/kg and 33 mg/kg.[252] This is well within the range of formaldehyde

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[252] Calculation based an assumption that the entire 0.56 kg/ha (0.5 lb/acre a.e.) application of dicamba that is intercepted by the DGT cotton plant at the 6-leaf or first bloom plus 15 day growth stage is instantaneously and completely absorbed, and then instantaneously metabolized by the DMO enzyme (Complete demethylation of 560 g (2.5 mol)/ ha dicamba would yield 2.5 mol/ha formaldehyde). Canopy closure, and thus spray interception, is estimated at 30% at the 6-leaf stage (Krutz et al., 2012), resulting in production of 23 g/ha formaldehyde. Canopy closure is near complete at the first bloom plus 15 day growth stage (Reddy et al., 2009), so no adjustment is applied. Above-ground biomass of 6-leaf plants is estimated to be 0.7 metric tons/ha (Ducamp et al., 2012), and the estimated maximum theoretical concentration is 33 mg/kg formaldehyde in plants. For dicamba

concentrations measured for a variety of agricultural commodities, including up to 60 mg/kg in fruits and vegetables (WHO-IPCS, 1989). Plants have a large capacity to metabolize formaldehyde naturally produced from internal processes (A. Hanson (2011), C.V. Griffin, Sr. Eminent Scholar, Horticulture Department, University of Florida, Personal Communication), and any additional amount of formaldehyde that could be theoretically produced in the plant by dicamba treatment in DGT cotton would be metabolized very quickly. Thus the incremental increase in formaldehyde over and above the levels already presumed to be present in the cotton plant would be small and transient and associated with an outdoor application of dicamba herbicide. Further, since current literature supports that formaldehyde is only emitted from foliage under certain conditions (Nemecek-Marshall et al., 1995; Cojocariu et al., 2004; Cojocariu et al., 2005) and that emission rates are low (Nemecek-Marshall et al., 1995), little opportunity exists for formaldehyde to be released from DGT cotton after dicamba treatment. Therefore human safety concerns of formaldehyde released from dicamba-treated DGT cotton are considered to be negligible and the most relevant route of exposure is from repeated inhalation of concentrated levels associated with indoor or occupational environments. USHHS-NTP (2011) has already stated that there is no evidence to suggest that dietary intake of formaldehyde is important, despite NTP's 12th Report on Carcinogens reclassifying formaldehyde as a known human carcinogen by (USHHS-NTP, 2011). In addition, the only human food currently produced from cottonseed is refined, bleached, and deodorized (RBD) oil, and to a smaller extent, linters. Therefore, the potential for human exposure to any formaldehyde in dicamba-treated DGT cotton cottonseed is highly unlikely.

In addition to formaldehyde production in plants, plants and animals are constantly exposed to low levels of formaldehyde. Formaldehyde is already present in the environment and the atmosphere from a variety of biogenic (e.g. plant and animal) and anthropogenic (e.g. automotive or industrial emissions) sources. Additionally, formaldehyde degrades rapidly in environmental compartments (air, soil, and water). In water, formaldehyde dissipates through biodegradation to low levels in a few days (USHHS-ATSDR, 1999). Aerobic biodegradation half-lives are estimated to be 1-7 days for surface water and 2-14 days for ground water (US EPA, 2008). The half-life of formaldehyde in air is dependent on a number of factors (light intensity, temperature and location). Through reaction with hydroxyl radical, the half-life of formaldehyde in air varies from 7 to 70 hours (US EPA, 2008). The photolytic half-life of formaldehyde in air (e.g., in the presence of sunlight) is estimated to be 1.6-6 hours (US EPA, 2008; USHHS-ATSDR, 1999). The rapid degradation of formaldehyde in the environment, combined with the understanding that formaldehyde is widely used by living organisms as a 1C source, support a conclusion that any environmental effects of formaldehyde, including effects on other plants and NTO's, resulting from dicamba-treated DGT cotton would be negligible.

Humans are also constantly exposed to low levels of formaldehyde. Human exposure to formaldehyde is primarily due to indoor and occupational air exposures (USHHS-ATSDR, 1999). Formaldehyde is also found in a variety of consumer products such as cosmetics and paints, often as an antimicrobial agent, and is used extensively in urea-formaldehyde "slow-release" fertilizer formulations and adhesives (USHHS-ATSDR, 1999). Indoor formaldehyde air concentrations are

applications at first bloom plus 15 day growth stage, the crop biomass is estimated to be 12 metric tons/ha (Boquet and Breitenbeck, 2000), and the estimated maximum theoretical formaldehyde concentration produced in planta is 6.3 mg/kg.

generally significantly higher than outdoor air concentrations (USHHS-ATSDR, 1999) as a result of combustion (cooking, heating, tobacco use) and the emission of formaldehyde from a variety of construction materials (e.g., particle board, plywood or foam insulation) as well as permanent press fabrics (clothing or draperies) (US CPSC, 1997). Formaldehyde present in outdoor air results from a number of sources, and levels of formaldehyde are generally higher in urban areas than in rural areas (WHO-IPCS, 1989). Direct contributions of formaldehyde to the atmosphere (i.e., those in the form of formaldehyde itself) from man-made sources are present, but are generally considered to be small relative to natural sources or indirect production of formaldehyde in the atmosphere (WHO, 2002). Formaldehyde is rapidly consumed in the atmosphere through direct photolysis or by oxidation with hydroxyl or nitrate radicals (USHHS-ATSDR, 1999).

The National Toxicology Program (NTP) 12th Report on Carcinogens has reclassified formaldehyde as a known human carcinogen (USHHS-NTP, 2011). However, the relevant route of exposure for this health risk is from repeated inhalation of concentrated levels associated with indoor or occupational environments. As previously discussed, formaldehyde may only be released by plants in very small quantities and under certain conditions. Any incremental exposure to formaldehyde associated with the application of dicamba to MON 88701 would occur outdoors, would be minimal, and also would be transient in nature. Therefore human safety concerns of formaldehyde released from dicamba treated DGT cotton are considered to be negligible. USHHS-NTP (2011) has already stated that there is no evidence to suggest that dietary intake of formaldehyde is important. In addition, cotton seed is not directly consumed by humans, and would be processed into food products, limiting potential exposure to humans to any formaldehyde in dicamba-treated DGT cotton seed.

H.2.2.3. Summary of Findings

Because direct human dietary exposure to cotton is generally limited to processed products that contain undetectable or negligible amounts of protein, there is minimal, if any, dietary exposure to MON 88701 DMO and PAT (*bar*) proteins from consumption of foods derived from DGT cotton. Although livestock are likely to be ingest these proteins or their byproducts, substantial analyses of the safety of these compounds has revealed that there is no reason to suspect that DGT cotton is any less safe than conventional cotton as an ingredient in food and feed. The presence of DGT cotton in food and feed presents negligible risks.

H.2.3. Dicamba-and-Glufosinate-Tolerant Cotton Presence in Food or Animal Feed

In efforts to assess the human health, livestock, and wildlife risks of exposure to DGT cotton, potential impacts from MON 88701 DMO, dicamba reaction byproducts, and PAT (*bar*) are evaluated in this report.

H.2.3.1. Probability of Presence

As discussed above, the inserted DNA in DGT cotton causes the production of MON 88701 DMO and PAT (*bar*) within the plant. In the expression level studies conducted by Monsanto, MON 88701 DMO and PAT (*bar*) were found in some amount in all tissue types. See Part 2.2.1.2. When exposed to dicamba, the MON 88701 DMO catalyzes the demethylation of dicamba to the non-herbicidal compound DCSA and formaldehyde. As a result, the probability of presence of these proteins and reaction byproducts in unprocessed cotton seed products is high. However, humans generally do not consume unprocessed cotton sed. Human dietary exposure to cotton is generally limited to processed products that contain undetectable or negligible amounts of protein. Thus, the likelihood of direct human dietary exposure to these proteins is negligible.

H.2.3.2. Health Effects of MON 88701 DMO, Dicamba Reaction Products, and PAT (*bar*)

H.2.3.2.1. Health Effects of MON 88701 DMO, Dicamba Reaction Products, and PAT (*bar*) on Humans

As discussed above, the MON 88701 DMO, dicamba reaction products, and PAT (*bar*) have been assessed for safety for human consumption. See Part 2.2.2. These assessments examined the donor organism safety, the similarity of MON 88701 DMO to a common class of mono-oxygenases, the dicamba-specificity of MON 88701 DMO, the specificity of PAT (*bar*), the history of safe use of the PAT protein, potential allergenicity issues, the digestibility of MON 88701 DMO and PAT (*bar*), and the toxicity of MON 88701 DMO, PAT (*bar*), and the dicamba reaction byproducts.[253] These assessments concluded that the food and feed products containing DGT cotton or derived from DGT cotton are as safe as cotton currently on the market for human consumption. Additonally, Monsanto has completed the biotechnology consultation process with FDA for the safety and nutritional assessment of food and feed derived from DGT cotton, and FDA concluded that it had no additional questions.

Studies on the persistence of plant-derived native DNA and recombinant DNA in livestock have indicated that feed-ingested DNA fragments do survive in the terminal gastrointestinal (GI) tract and that uptake into the gut epithelium does occur (Sharma, 2006). However, recombinant DNA fragments were not found in visceral tissues, like the kidney. There is no evidence thus far to indicate that the recombinant DNA that encodes the inserted gene would be processed in a manner any differently from the endogenous feed-ingested genetic material. The risks associated with transgene fragment presence in feed and food is considered to be negligible.

H.2.3.2.2. Health Effects of MON 88701 DMO, Dicamba Reaction Products, and PAT (*bar*) on Livestock

Monsanto has completed the biotechnology consultation process with FDA for the safety and nutritional assessment of food and feed derived from DGT cotton. This consultation did not identify any biologically meaningful differences between the composition of DGT cotton and conventional cotton. As discussed above, MON 88701 DMO belongs to a common class of mono-oxygenases, regularly consumed by humans and animals, and PAT (*bar*) has a history of safe consumption. At the conclusion of the FDA consultation, FDA had no questions about the safety of DGT cotton for use in food or feed.

H.2.3.2.3. Health Effects of MON 88701 DMO, Dicamba Reaction Products, and PAT (*bar*) on Non-Livestock Animals (Wildlife)

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[253] Monsanto has submitted a request for the inclusion of DCSA in the cottonseed and gin byproduct dicamba residue definitions.

No specific data or scientific literature were found relating to the health effects of MON 88701 DMO or PAT (*bar*) on non-livestock animals. As discussed above, MON 88701 DMO belongs to a common class of mono-oxygenases, regularly consumed by humans and animals, and PAT (*bar*) has a history of safe consumption. Additionally the results of acute oral toxicology studies for MON 88701 DMO and PAT (*bar*) indicated that neither MON 88701 DMO or PAT (*bar*) caused any adverse effects in mice, with No Observable Adverse Effect Levels (NOAELs) for MON 88701 DMO at 283 mg/ kg bw and PAT (*bar*) at 1086 mg/kg bw, respectively, the highest doses tested.

There is no evidence that MON 88701 DMO, PAT (*bar*), or dicamba reaction products will exhibit adverse biological activity toward wildlife. Because use of DGT cotton is compatible with conservation tillage practices, usage of DGT cotton may have a positive impact on wildlife. Conservation tillage practices can have a positive impact on wildlife, including beneficial arthropods (Altieri, 1999; Landis et al., 2005; Towery and Werblow, 2010). Conservation tillage practices benefit biodiversity due to decreased soil erosion leading to improved surface water quality, retention of vegetative cover, crop residues serving as a food source, and increased populations of invertebrates which can serve as food sources to other organisms (Landis et al. 2005; Sharpe, 2010).

H.2.3.3. Summary of Findings

There is little evidence that MON 88701 DMO, dicamba byproducts, or PAT (*bar*) have any direct toxic effect on livestock or any deleterious outcome on nutritional parameters. The information evaluated suggests that the presence of DGT cotton in human food and animal feed poses negligible risks to humans, livestock, and wildlife.

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