Dow AgroSciences Petition for Determination of Nonregulated Status of Insect-Resistant DAS-81419-2 Soybean (12-272-01p)

OECD Unique Identifier: DAS-81419-2

Environmental Assessment

April 2014

Agency Contact
Cindy Eck
USDA, APHIS, BRS
4700 River Road, Unit 91
Riverdale, MD 20737-1237
Phone: (301) 851-3892
Fax: (301) 734-8910
Cynthia.A.Eck@aphis.usda.gov

Table of Contents

List of Tables.

1 PURPOSE AND NEED

1.1 Background

Dow AgroSciences (hereinafter "DAS") of Indianapolis, IN has submitted a petition, APHIS Number12-272-01p, to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in November 2012. The purpose of the petition is to support a decision of nonregulated status for DAS-81419-2 soybean (referred hereafter as DAS-81419-2 soybean) which is resistant[1] to the herbicide glufosinate and resistant to lepidopteran insects. The event DAS-81419-2 soybean is currently regulated under 7CFR part 340. Interstate movements and field trials of event DAS-81419-2 soybean have been conducted under permits issued or notifications acknowledged by APHIS since 2009. These field trials were conducted within thirteen US states and Puerto Rico. Data resulting from these field trials are described in the petition (Dow AgroSciences, 2012) and analyzed for plant pest risk in the USDA-APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2012).

The petition stated that APHIS should not regulate DAS-81419-2 soybean because it does not present a plant pest risk. If a determination of nonregulated status is made, it would include DAS-81419-2 soybean, any progeny derived from crosses between DAS-81419 soybean and conventional soybean, and crosses of DAS-81419-2 soybean with other biotechnology-derived soybean that are no longer subject to the regulatory requirements of 7 CFR (Code of Federal Regulations) Part 340 under the authority of the Plant Protection Act of 2000 (PPA).

1.2 Purpose of Product

A *pat* gene, from the bacterium *Streptomyces viridochromogenes* was transformed into soybean for resistance to the herbicide glufosinate. The protein expressed by the gene, phosphinothricin acetyltransferase (PAT) protein, confers resistance to the common herbicide glufosinate ammonium. Two other genes *cryF*, originally from *Bacillus thuringiensis* subsp. *aizawa* strain PS811and *cry1*Ac from *B. thuringiensis* subsp. *kurstaki* strain HD73 were also transformed into soybean for resistance to several lepidopteran pests of soybean, including the velvetbean caterpillar, *Anticarsia gemmatalis* and others. DAS has developed DAS-81419-2 soybean to

[1] "Resistance" to herbicides is defined by the HRAC (Herbicide Resistance Action Committee) as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type HRAC, "Guideline to the Management of Herbicide Resistance," (2013), <http://www.hracglobal.com/Overview/ManagementofResistance.aspx>.. Several technologies are available that can be used to develop herbicide resistance in plants including classical breeding, tissue culture, mutagenesis and genetic engineering. "Tolerance" is distinguished from resistance and defined by HRAC (2013) as the inherent ability of a plant to survive and reproduce following exposure to an herbicide treatment. This implies the circumstance in which there is no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. Throughout this EA (Environmental Assessment), APHIS has used the terms "resistance" and "tolerance" consistent with the definitions of the HRAC. It should be noted however, that different terms for the same concept may be used interchangeably in some instances. In its petition to USDA APHIS Dow AgroSciences referenced the subject as, "glufosinate-tolerant soybean," and used the term "herbicide tolerant" throughout its documentation to describe it (Dow AgroSciences, 2012). This terminology can be considered synonymous with "herbicide-resistant" (HR) used in this EA.

protect the plants from leaf-feeding damage by the larval stages of specific lepidopteran insects. In addition DAS-81419-2 will make available an additional variety of glufosinate resistant soybean to growers and seed suppliers for weed management. DAS-81419-2 soybean was developed for South America, where lepidopteran pest pressure exceeds economic thresholds. Soybean grown in regions of the U.S. (mainly the southeast) can experience economic damage by lepidopteran soybean pests; thus future use of DAS-81419-2 soybean may include U.S. commercialization under appropriate regulatory authorizations. To supply soybean seed for the South American market, DAS has obtained a breeding and seed increase registration with the EPA under FIFRA Section 3.

Availability of DAS-81419-2 soybean could reduce the need for insect scouting, preserve beneficial insect populations, as well as provide increased efficiency for soybean insect protection. Cry1Ac and Cry1F have been shown to bind to different receptors in the midgut of the target soybean insect pest tobacco budworm (*H. virescens*) (Jurat-Fuentes and Adang, 2001): Cry1Ac binds to at least three sets of receptors while Cry1F binds to at least two, only one of which also binds Cry1Ac. The major receptor in the insect gut for Cry1Ac does not bind Cry1F (Jurat-Fuentes and Adang, 2006). Bt gene pyramiding offered by DAS-81419-2 soybean offers potentially greater durability than Bt crops carrying a single Bt trait and provides deterrence to the development of insect resistance.

The PAT protein provides resistance to the herbicide glufosinate ammonium and was used as a selectable marker during product characterization and development. Glufosinate resistance allows growers to employ this ‘over-the-top’ broad spectrum herbicide that can control glyphosate resistant weeds. DAS has plans to cross DAS-81419-2 soybean with other deregulated herbicide resistant soybean varieties, such as those expressing glyphosate resistance.

1.3 **Coordinated Framework Review and Regulatory Review**

Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to Federal regulations published in the *Federal Register* (EOP-OSTP; US-FDA) entitled The Coordinated Framework for the Regulation of Biotechnology (henceforth referred to here as the Coordinated Framework). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). A summary of each role follows:

1.3.1 USDA-APHIS

APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (i.e., importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340, when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article 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 is also considered a plant pest. A GE organism is also regulated under 7 CFR 340, when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency for a determination that a particular regulated article is unlikely to pose a plant pest risk, and therefore, is no longer regulated under the plant pest provisions of the PPA or the regulations at 7 CFR 340. Under § 340.6(c)(4), the petitioner must provide information related to plant pest risk that the agency can 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 determines that it is unlikely to pose a plant pest risk.

1.3.2 Environmental Protection Agency

The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology. The EPA regulates plant incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) and certain biological control organisms under the Toxic Substances Control Act (TSCA) (15 U.S.C. 53 *et seq*.). Before planting a crop containing a PIP, a company must seek an experimental use permit from EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 registration with EPA.

Under FIFRA (7 U.S.C. 136 *et seq.*), EPA regulates the use of pesticides, and requires registration of all pesticide products for all specific uses prior to distribution for sale. EPA examines: the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, EPA must determine through testing that the pesticide does not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may only be legally used in accordance with directions and restrictions on its label. The overall intent of the label is to provide clear directions for effective product performance, while minimizing risks to human health and the environment. The Food Quality Protection Act (FQPA) of 1996 amended FIFRA, enabling EPA to implement periodic registration review of pesticides to ensure they are meeting current scientific and regulatory standards of safety and continue to have no unreasonable adverse effects (US-EPA, 2011).

EPA also sets tolerances (maximum residue levels) or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). A tolerance is the amount of pesticide residue that can remain on or in food for human consumption or animal feed. Before establishing a pesticide tolerance, EPA is required to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the FQPA. FDA enforces the pesticide tolerances set by EPA.

1.3.3 Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 et seq.). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, on May 29, 1992 (US-FDA). Under this policy, FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under Federal food safety laws prior to marketing.

More recently (June 2006), FDA published recommendations in “Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use” (US-FDA, 2006). This establishes voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

1.4 Purpose and Need for USDA-APHIS Action

As noted in the previous section any party can petition APHIS to seek a determination of nonregulated status for a GE organism that is regulated under 7 CFR 340. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as DAS-81419-2 Soybean. When a petition for nonregulated status is submitted, APHIS must determine if the GE organism is unlikely to pose a plant pest risk. 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 determines that it is unlikely to pose a plant pest risk.

USDA-APHIS must respond to the petition from DAS requesting a determination of nonregulated status for DAS-81419-2 Soybean. USDA-APHIS has prepared this Environmental Assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality’s (CEQ) National Environmental Policy Act of 1969 (NEPA) regulations and the USDA and USDA-APHIS NEPA implementing regulations and procedures (40 CFR Parts 1500-1508, 7 CFR Part 1b, and 7 CFR

Part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[2] that may result from a determination of nonregulated status for DAS-81419-2 Soybean.

1.5 Public Involvement

APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. APHIS does this through a notice published in the Federal Register. On March 6, 2012, APHIS published a notice[3] in the *Federal Register* advising the public that APHIS is implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for GE organisms to allow for early public involvement in the process. As identified in this notice, APHIS will publish two separate notices in the *Federal Register* for petitions for which APHIS prepares an EA. The first notice will announce the availability of the petition, and the second notice will announce the availability of APHIS' decision making documents. As part of the new process, with each of the two notices published in the *Federal Register,* there will be an opportunity for public involvement:

1.5.1 First Opportunity for Public Involvement

Once USDA-APHIS deems a petition complete, the petition will be made available for public comment for 60 days, providing the public an opportunity to raise issues regarding the petition itself and give input that will be considered by the Agency as it develops its EA and PPRA. USDA-APHIS will publish a notice in the Federal Register to inform the public that USDA-APHIS will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice. This availability of the petition for public comment will be announced in a Federal Register notice.

1.5.2 **Second Opportunity for Public Involvement**.

Assuming an EA is sufficient, the EA and PPRA are developed and a notice of their availability is published in a second *Federal Register* notice. This second notice follows one of two approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues:

Approach 1. GE organisms that do not raise substantive new issues.
This approach for public participation is used when APHIS decides, based on the review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition, that the petition involves a GE organism that *does not raise new biological, cultural, or ecological issues because of the nature of the modification or APHIS' familiarity with the recipient organism.* After developing its EA, finding of no significant impact

---

[2] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §1508.14).

[3] This notice can be accessed at: http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf

(FONSI), and PPRA, APHIS publishes a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the EA, FONSI, and PPRA for a 30-day public review period.

If APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination or FONSI, substantially changing the proposed action identified in the EA, or substantially changing the analysis of impacts in the EA, APHIS' preliminary regulatory determination becomes final and effective upon public notification through an announcement on its website. No further Federal Register notice is published announcing the final regulatory determination.

<u>Approach 2. For GE organisms that raise substantive new issues not previously reviewed by APHIS.</u> A second approach for public participation is used when APHIS determines that the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues. This could include petitions involving a recipient organism that has not previously been determined by APHIS to have nonregulated status or when APHIS determines that gene modifications raise substantive biological, cultural, or ecological issues not previously analyzed by APHIS. Substantive issues are identified by APHIS based on our review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition.

APHIS solicits comments on its draft EA and draft PPRA for 30 days through the publication of a *Federal Register* notice. APHIS reviews and evaluates comments and other relevant information, then revises the PPRA as necessary and prepares a final EA. Following preparation of these documents, APHIS approves or denies the petition, announcing in the *Federal Register* the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, National Environmental Policy (NEPA) decision document (either a FONSI or NOI to prepare an EIS), and regulatory determination. Enhancements to public input are described in more detail in the *Federal Register* notice[4] published on March 6, 2012.

USDA-APHIS has decided this EA will follow Approach 1 because this is another EA prepared for soybean genetically engineered for resistance to glufosinate herbicides with the same pat gene as several other soybean varieties, and also for resistance to lepidopterous insects with the same Cry protein-expressing genes as many other soybean, cotton, and corn varieties. The DAS petition was published for public comment on February 27, 2013, with comments accepted until April 29, 2013. As of that date, the docket file contained a total of 5 public submissions. One of the submissions to the docket contained multiple attached identical comments gathered by organizations from their members. Contained within the 5 submissions were a total of 561 identical public comments. Some of the comments expressed a general dislike of the use of GE organisms, health concerns for food or feed consumption or concerns for use of additional herbicides; some were form letters sent to all of the dockets which were open at the time that this docket was open. The form letter expressed a concern that there were too many dockets published on the same day. It also referenced other open dockets and potential effects from the use of the subjects of those petitions. These issues are outside the scope of this EA. The

[4] This notice can be accessed at: http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf

comments also encouraged a thorough review of all herbicide resistant crops, in the context of the potential for development of weed resistance to herbicides. Some comments were concerned about the development of insects resistant to the Cry proteins expressed by the variety, or concerned about admixture of GE soybean with organic soybean and admixture of GE lines with exported commodity soybean.

Issues raised in these public comments on the petition were focused on the nature of agronomic inputs associated with this new trait, potential impacts to plants from off-target drift, management of herbicide-resistant weeds, human health considerations from exposure to herbicides, and domestic and international economic impacts associated with the development and marketing of a new herbicide-resistant product. APHIS evaluated these raised issues and the submitted documentation. APHIS has also included a discussion of these issues in this EA.

1.6 Issues Considered

The list of resource areas considered in this Draft EA were developed by USDA-APHIS through experience in considering public concerns and issues raised in public comments submitted for this petition and other EAs of GE organisms. The resource areas considered also address concerns raised in previous and unrelated lawsuits, as well as issues that have been raised by various stakeholders for this petition and in the past. The resource areas considered in this EA can be categorized as follows:

Agricultural Production Considerations:

- Acreage and Areas of Soybean Production
- Soybean Seed Production
- Organic Soybean Production

Environmental Considerations

- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Soil Microorganisms
- Biological Diversity

Public Health Considerations

- Human Health
- Worker Safety

Livestock Health Considerations

- Animal Feed/Livestock Health

Socioeconomic Considerations

- Domestic Economics

- Trade Economics

1.7 Relevant Regulatory Background and Safety Assessments

USDA Review of Cry and PAT proteins
Cry proteins are highly specific, derived from a naturally occurring soil bacterium, *Bacillus thuringiensis* (*Bt*). Crops genetically engineered to produce Cry proteins have been widely adopted; Bt cotton now represents 75% of the cotton planted in the U.S and Bt corn is about 67% of the corn acreage (USDA-NASS 2012). The Cry1F and Cry1Ac proteins expressed in DAS-81419-2 soybean are the same as those present in the previously deregulated WideStrike® cotton events DAS-21023-5 and DAS-24236-5 (USDA-APHIS, 2004).

Other genetically engineered (GE) crops containing Cry technology include Monsanto's GE soybean, producing Cry1Ac (MON 87701), which was deregulated by APHIS in 2011 (USDA-APHIS, 2011b), and Monsanto's Bollgard® Cotton (Event 531), also producing Cry1Ac, which was deregulated by APHIS in 1995 (USDA-APHIS, 1995).

The PAT protein is encoded by the *pat* gene isolated from the soil bacterium *S. viridochromogenes* and inactivates the herbicide glufosinate ammonium. The *pat* gene has been widely used both as a selectable marker and an herbicide resistance trait in previously deregulated crops (USDA-APHIS, 1996; USDA-APHIS, 2001; USDA-APHIS, 2004; USDA-APHIS, 2005). Although there are commercial varieties of GE soybean with resistance to glufosinate ammonium available in the US, DAS-81419-2 soybean would be the first soybean product producing the Cry1Ac, Cry1F, and PAT proteins.

EPA Review of Cry and PAT Proteins
Substances that are pesticides, as defined under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) [7 U.S.C. §136(u)], are subject to regulation by the Environmental Protection Agency (EPA). Plant-incorporated protectants (PIPs), are also subject to regulation by the EPA under FIFRA.

Cry1Ac has an existing exemption from the requirement of a tolerance in all food and feed commodities granted by EPA in 1997 and published in the Code of Federal Regulations at 40 CFR §174.510 Cry1F has an exemption from tolerance for cotton and corn at 40 CFR §174.504 and 40 CFR §174.520, respectively (EPA, 2012a). Bt corn and Bt cotton expressing variations of Cry1Ac or Cry1F have been cultivated for commercial use in the U.S. and other countries for more than a decade. Exemptions from tolerance have been established based on safety assessments demonstrating a lack of allergenicity and toxicity to mammals. DAS has petitioned the U.S. EPA for an exemption from tolerance for Cry1F in soybean as a component of the application for registration for DAS-81419-2 Soybean.

Since the PAT protein has been included as an herbicide resistance marker in products containing PIPs, it has been reviewed by EPA as a PIP inert ingredient (EPA, 2005a). Based on

® WideStrike is a registered trademark of Dow AgroSciences LLC.
® Bollgard is a registered trademark of Monsanto Technology LLC.

its environmental risk assessment, the EPA determined that the PAT protein presents a low probability of risk to human health and the environment and granted an exemption from the requirement of a tolerance for this PIP inert ingredient (EPA, 1997; EPA, 2007b; EPA, 2012c).

DAS submitted an application for a FIFRA Section 3 seed increase registration of DAS-81419-2 soybean on July 27th, 2012. Under a seed increase registration, commercial sale of DAS-81419-2 soybean in the U.S. is prohibited by law. Should DAS decide to commercialize DAS-81419-2 soybean in the U.S., DAS will apply for an EPA FIFRA Section 3 registration for commercial use. The terms of EPA's Section 3 commercial use registrations for PIPs require the registrant to develop, administer and oversee an insect resistance management (IRM) program approved by the EPA.

EPA Review of Glufosinate Ammonium
Glufosinate ammonium was first registered by EPA for use in crops in 2000 as a non-selective foliar herbicide used for pre-plant and post-emergence control of broadleaf weeds (EPA, 2008b). It is currently registered for use on soybeans and other crops including apples, berries, canola, corn, cotton, currants, grapes, grass grown for seed, potatoes, rice, sugar beets, and tree nuts and for use in non-crop areas including lawns and residential areas (EPA, 2008b).

FDA Review of Cry and PAT Proteins
The FDA previously reviewed data on the Cry1Ac and Cry1F proteins as present in DAS-21023-5 and DAS-24236-5 (FDA, 2004a; FDA, 2004b). The FDA assessed the safety and nutritional data provided by DAS with regards to the use of the cotton in food and feed and concluded that it has no further questions (FDA, 2004a; FDA, 2004b). A biotechnology consultation on the PAT protein was conducted in 1998 and does not require additional evaluation by the FDA (FDA, 1998b).

DAS initiated the consultation process with FDA for DAS-81419-2 soybean and submitted a Biotechnology Notification File (BNF 00140) for safety and nutritional assessment of food and feed derived from DAS-81419-2 to the FDA on September 26, 2012. On February 7, 2014, FDA concluded the consultation stating that they have no further questions concerning food and feed derived from DAS-81419-2 soybean.

Global Assessment of Cry proteins
The food and feed safety of Cry proteins has been assessed by regulatory agencies worldwide, and *Bt* crops have been adopted in numerous countries (Betz et al., 2000). For example, WideStrike® cotton (DAS-21023-5; DAS-24236-5, expressing the same Cry1Ac and Cry1F proteins as DAS-81419-2 soybean) has received regulatory approval in Canada (import), Australia (food, feed), Brazil (cultivation, food, feed), Japan (import, food, feed), Mexico (food, feed); EU (food, feed) and Korea (food, feed) (Biotechnology Industry Organization, 2012).

1.8 Action

DAS requests determination of non-regulated status for DAS-81419-2 soybean, any progeny derived from crosses between DAS-81419-2 soybean and conventional soybean, and any progeny derived from crosses of DAS-81419-2 soybean with other biotechnology-derived soybean that has been granted non-regulated status under 7 CFR Part 340.

1.9 Action Area

Under the proposed EPA Section 3 seed increase registration, planting of DAS-81419-2 soybean will be on limited acreage throughout the U.S., with activity to support South American commercial soybean production market. If future application to EPA is made for commercial production/registration in the U.S., all areas of U.S. soybean cultivation will be considered, with highest adoption expected in areas experiencing economically significant insect pest pressure. This currently includes regions in Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Texas, and Virginia (Musser et al., 2010; USDA-APHIS, 2011b; Musser et al., 2012).

2 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of DAS-81419-2 soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that DAS-81419-2 is unlikely to pose a plant pest risk. Therefore APHIS must determine that DAS-81419-2 is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Based on its PPRA (USDA-APHIS, 2012), USDA-APHIS has concluded that DAS-81419-2 soybean is unlikely to pose a plant pest risk. Therefore, USDA-APHIS must determine that DAS-81419-2 soybean is no longer subject to 7 CFR Part 340 or the plant pest provisions of the PPA.

Two alternatives are evaluated in this Environmental Assessment: (1) no action and (2) determination of nonregulated status of DAS-81419-2 (preferred alternative). USDA-APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section. Other alternative actions were considered but not included in the detailed analysis (see Section 3.3).

2.1 No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. DAS-81419-2 soybeans and progeny derived from DAS-81419-2 soybeans would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of DAS-81419-2 soybeans and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS would choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of DAS-81419-2 soybean.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment that DAS-81419-2 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012). 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.

2.2 Preferred Alternative: Determination that DAS-81419-2 Soybean Is No Longer a Regulated Article

Under the Preferred Alternative, DAS-81419-2 soybean and progeny derived from them would no longer be regulated articles under 7 CFR part 340. DAS-81419-2 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of DAS-81419-2 soybean and progeny derived from this event. The preferred alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. Because the agency has concluded that DAS-81419-2 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of DAS-81419-2 soybean is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

2.3 Alternatives Considered, Not Included in Detailed Analysis

APHIS has assembled a list of alternatives that might be considered for DAS-81419-2 soybean. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the PPA, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for DAS-81419-2 soybean. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

2.3.1 Prohibit Any DAS-81419-2 from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of DAS-81419-2 soybean, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that DAS-81419-2 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012).

In enacting the PPA, Congress listed findings in Section 402(4), including the following one:

> "[D]ecisions affecting imports, exports, and interstate movement of products regulated under this title [the Plant Protection Act] shall be based on sound science;"

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide agencies that develop and implement policies for oversight of emerging technologies such as genetic engineering. In accordance with this memorandum, agencies should adhere to guidance in Executive Order 13563, and, consistent with it, apply the following principle, among others to the extent permitted by law when regulating emerging technologies:

"Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandate of each agency"

Based on the PPRA (USDA-APHIS, 2012), and the scientific data evaluated therein, APHIS concluded that DAS-81419-2 soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of DAS-81419-2 soybean.

2.3.2 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that DAS-81419-2 soybean is unlikely to pose a plant pest risk, (USDA-APHIS, 2012), and it is the only line described in the petition, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

2.3.3 Isolation Distance between DAS-81419-2 Soybean and Non-GE Soybean Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating DAS-81419-2 soybean from conventional or specialty soybean production. However, because APHIS has concluded that DAS-81419-2 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012), an alternative based on requiring isolation distances would be inconsistent with statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of DAS-81419-2 soybean based on the location of production of non-GE soybean in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' PPRA for DAS-81419-2 soybean, there are no geographic differences associated with any identifiable plant pest risks for DAS-81419-2 soybean (USDA-APHIS, 2012). This alternative was rejected and not analyzed in detail because APHIS has concluded that DAS-81419-2 soybean does not present a plant pest risk, and will not exhibit a greater plant risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the PPA and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. However, individuals might choose on their own to geographically isolate their non-GE production systems from DAS-81419-2 soybean or to use isolation distances and other management practices to minimize gene movement between soybean fields. Information to assist growers in making informed management decisions for DAS-81419-2 soybean is available from the Association of Official Seed Certifying Agencies (AOSCA, 2011).

2.3.4 Requirement of Testing for DAS-81419-2 Soybean

During the comment periods for other petitions for nonregulated status, some comments requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes that 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 DAS-81419-2 soybean does not pose a plant pest risk (USDA-APHIS, 2012), the imposition of any type of testing requirement is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340, and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for DAS-81419-2 soybean would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

2.4 Comparison of Alternatives

Table 1 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this Environmental Assessment. The impact assessment is presented in Section 3.

Table 1. Summary of issues of potential impacts and consequences of alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Preferred Alternative. Determination of Nonregulated Status
Meets Purpose and Need Objectives	No	Yes
Unlikely to Pose a Plant Pest Risk	Satisfied through use of regulated field trials	Satisfied by USDA-APHIS Plant Pest Risk Assessment
Management Practices		
Acreage and Areas of Soybean Production	Continuing under APHIS notification and EPA permits only, no change in current soybean acreage	Under EPA seed increase permits only, no large overall change in total soybean acreage is expected; existing soybean acres will be used for new seed production. If DAS chooses commodity production for DAS-81419-2, this will replace existing varieties.
Agronomic Practices	Standard practices will be maintained	Standard practices will be maintained for small scale seed production. If the crop is commercialized for the US market, less insecticide will be

		used in treating lepidopteran infestations. Some increase in glufosinate use may occur if the developer decides to pursue US commercialization of the trait.
Soybean Seed Production	Unchanged	Practices for seed production will remain similar to current seed production, including the unlikely use of glufosinate for weed control.
Organic Soybean Production	No expected changes in production of organic soybean varieties. 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 conventional or GE crops. Certified organic soybean acreage is a small but increasing percentage of overall soybean production.	No expected change in organic soybean practices or increase in present total acreage of GE soybean
Environment		
Water Resources	No expected changes to water resources	No expected changes to soybean seed production or to water resources; if used in areas with Lepidopteran pests, use could decrease insecticides in water
Soil Quality	Unchanged	If released commercially for commodity soybean production, some regions with economically important lepidopteran pests may have decreased insecticides in soil
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Biological		
Animal Communities	Unchanged. Under notifications test protocols are required that confine the seed and plant variety to prevent	DAS-81419-2 is not expected to have any effect on vertebrate animals or most invertebrate animals. DAS-

	environmental impacts	81419-2 exhibits insecticidal activity against certain lepidopteran insects. Those pests that feed directly on DAS-81419-2 soybeans would be expected to die or have delayed growth. If DAS-81419-2 soybean is commercialized in the U.S., there are potential benefits due to reduced insect pressure and reduced need for insecticide applications
Plant Communities	The most agronomically important members of the surrounding plant community are often those that behave as weeds. Soybean growers use production practices to manage weeds in and around fields. Resistant weeds will continue to increase because of the use of herbicides, especially glyphosate	No increased impacts because only seed production will be increased and glufosinate will likely not be used; if commercialized, may be a trend in some parts of the country for increased glufosinate use against glyphosate resistant weeds. No large increase in acres planted to DAS-81419-2 expected, so considerable change in glufosinate use is not likely.
Gene Flow and Weediness	Cultivated soybean varieties can cross-pollinate. Growers use various production practices to limit undesired cross-pollination	Unchanged from No Action Alternative
Soil Microorganisms	Unchanged	Unchanged
Biological Diversity	Unchanged	Unchanged
Human and Animal Health		
Risk to Human Health	Unchanged. EPA regulates the safe use, handling and exemptions from tolerances for all pesticides	Unchanged. EPA regulates the safe use, handling and exemptions from tolerances for all pesticides
Risk to Animal Feed	Unchanged. Processed soybeans are the largest source of protein in animal feed	Unchanged. A compositional analysis concluded that forage and grain from DAS-81419-2 soybean hybrids are considered similar in composition to forage and grain from both the non-transgenic comparator and

		conventional soybean hybrids. Therefore this is unchanged from the No Action Alternative.
Socioeconomic		
Domestic Economic Environment	No new impacts. The widespread adoption of herbicide-resistant soybean has been attributed to cost savings for production, and also non-monetary benefits.	If commercialized, then somewhat less use of insecticides in some parts of the country. Seed production may modestly increase
Trade Economic Environment	Likely no change of exported soybean seed for planting. Developer will not increase foreign sales of seed produced unless DAS-81419-2 is determined as nonregulated.	May increase exports of soybean seed for planting to some markets, especially South American markets. DAS intends to submit dossiers to request import approval of DAS-81419-2 soybean to the proper regulatory authorities of several countries that already have regulatory processes in place for GE soybean. These include, but are not limited to: Canada, Mexico, Japan, the EU, South Korea, and China.
Other Regulatory Approvals		
U.S.	FDA food consultation complete, EPA Cry1F tolerance exemptions and conditional pesticide registrations complete	FDA food consultation complete, EPA Cry1F tolerance exemptions and conditional pesticide registrations complete
Other Countries	Currently seeking foreign approvals for feed and food	Will seek approvals from South American countries for planting. Currently seeking foreign approvals for feed and food

3 AFFECTED ENVIRONMENT

3.1 Soybean Agricultural Production and Practices

3.1.1 Areas and Acreage of Soybean Production

Soybean (*Glycine max* (L.) Merr.) is an economically important leguminous crop, providing oil and protein. Domestically, soybean plants are grown for their seed, which is processed to yield oil and meal. Soybean is ranked number one in oil production (56 percent in 2011) among the major oil seed crops produced globally (The American Soybean Association, 2012a).

3.1.2 Land Use

As of 2007, there were about 406 million acres of cropland in the U.S., of which approximately 332 million acres (including harvested, failed crops, and cultivated fallow) were used for crop production (USDA NASS, 2007a). The remaining cropland was either idle or was used for pasture. From 1991 to 2011, acreage planted with soybean increased from just over 59 million acres to approximately 75 million acres (Figure 1) (USDA NASS, 2011b; USDA NASS, 2011c; USDA NASS, 2011a). The acreage planted in 2013 is estimated at 77.1 million acres (USDA-NASS, 2013c)

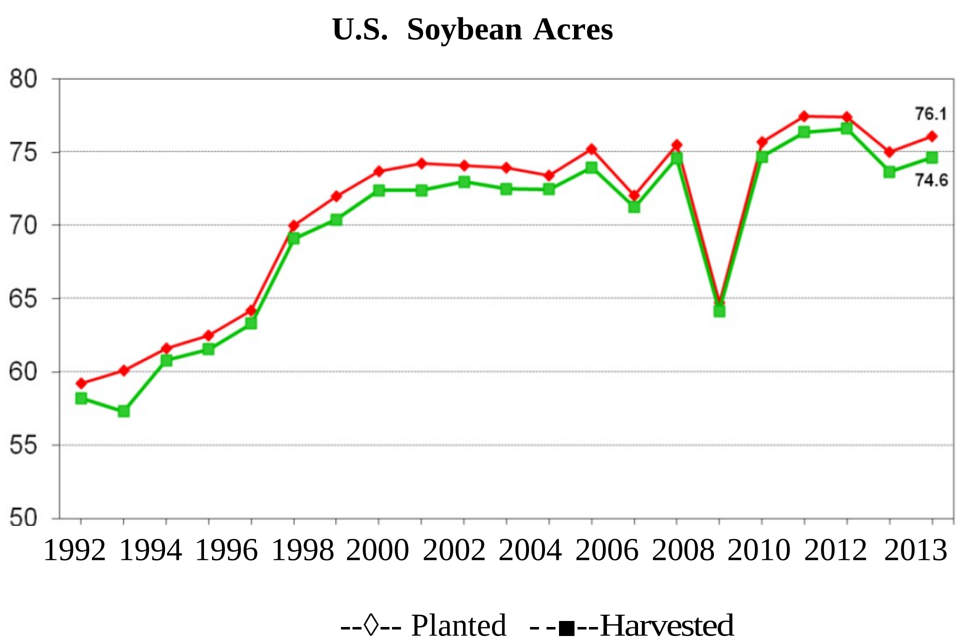

Figure 1. Planted and harvested acreage of soybeans in the U.S. (1991-2011). Source: (USDA NASS, 2011a)(2012f).

In the U.S., as cited 77.1 million acres of soybeans were planted by August 2013 (USDA-NASS, 2013d). Of these planted acres, about 75.7 million acres were harvested, valued at over $40 billion from estimates of $12.50-15.30/bu -and 3.26 billion bu production which is an 8% increase in soybean production from last year (USDA-NASS, 2013b). The majority of soybeans produced in the U.S. are grown in 31 states (Table 1), with about 80% of the planted soybean acres and 80% of the harvested soybean acres concentrated in 11 states: Iowa, Illinois, Minnesota, Indiana, Missouri, Nebraska, Ohio, South Dakota, North Dakota, Kansas, and Arkansas.

Table 2. U.S. soybean production, 2012 and 2013.

State	Acres Planted (x 1,000)		Acres Harvested	
	2012	2013	2012	2013[1]
Alabama	340	430	335	420
Arkansas	3200	3250	3160	3200
Delaware	170	165	168	163
Florida	21	32	20	30
Georgia	220	230	215	220
Illinois	9050	9450	8920	9400
Indiana	5150	5200	5140	5180
Iowa	9350	9300	9300	9230
Kansas	4000	3600	3810	3540
Kentucky	1480	1654	1470	1640
Louisiana	1130	1120	1115	1080
Maryland	480	480	475	475
Michigan	2000	1900	1990	1980
Minnesota	7050	6700	6990	6630
Mississippi	1970	2010	1950	1980
Missouri	5400	5600	5260	5640
Nebraska	5050	4800	4990	4750
New Jersey	96	89	94	87
New York	315	275	312	272
North Carolina	1590	1460	1580	1440
North Dakota	4750	4650	4730	4610
Ohio	4600	4450	4580	4430
Oklahoma	420	345	260	310
Pennsylvania	530	520	520	510
South Carolina	380	320	370	310
South Dakota	4750	4600	4710	4550
Tennessee	1260	1560	1230	1520
Texas	125	105	110	90
Virginia	590	600	580	590
West Virginia	21	22	20	21
Wisconsin	1710	1580	1700	1570

United States	77,198	77,728	76,104	76,918

Source: USDA-NASS, 2013 Acreage Report and November 2013 Crop Production Report (USDA-NASS, 2013a; USDA-NASS, 2013c)

Over the last 20 years, soybean production has increased 35%, from nearly 2.0 billion bushels (43.1 million metric tons) in 1991 to approximately 3.0 billion bushels (64.6 million metric tons) in 2011. Average yield increased during this period approximately 17.6% from 34.2 bushels per acre in 1991 to 41.5 bushels per acre in 2011 (USDA NASS, 2011c). USDA agricultural projections for 2020 estimate about 3.5 billion bushels (76.3 metric tons) of soybean will be produced, of which approximately 2.0 billion bushels (43.1 million metric tons) will be for domestic consumption and 1.5 billion bushels (33.2 million metric tons) for export in that year (USDA, 2011b).

3.1.3 Agronomic Practices

3.1.3.1 Cultivation, Crop Rotation, Tillage and other Standard Agronomic Practices

Crop rotation is the successive planting of different crops in the same field over a particular period of years. Crop rotation has two primary goals: sustaining the productivity of the agricultural system and maximizing economic returns (Hoeft et al., 2000). Sustaining the agricultural system is achieved by rotating crops that may improve soil health and fertility with more commercially beneficial “cash crops”. Since soybean fixes nitrogen in soil, the yield of some crops following soybean, such as corn or wheat, may increase (Berglund and Helms, 2003). This shows for example that 64% of crops planted following soybean within the US in 2008 were corn, and for the southeastern states, 53% of crops planted were another planting of soybean.

Prior to planting, the soil must be stripped of weeds that would otherwise compete with the crop for space, water, and nutrients. 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 (Heatherly et al., 2009). Field preparation is accomplished through a variety of tillage systems, with each system defined by the remaining plant residue on the field. Types of tillage systems utilized include conventional, reduced, conservation (including mulch-till, strip-till, ridge-till, and no-till), and deep (primary). Various conservation tillage practices rely more or less primarily on use of herbicides for weed control.

3.1.3.2 Herbicide Use and Weed Management

Herbicide use is regulated by EPA, and the agency assesses the risks to human health as well as risks to nontarget organisms and the environment. EPA establishes use requirements to protect the health of humans and safety for the environment. Herbicides have been the primary tactic to manage weed communities in soybeans since the mid-1960s and will continue to be an important feature of row crop weed management for the foreseeable future. One study looked at aggregate data on crop yield losses and herbicide use and estimated that even if additional tillage and hand weeding labor replaced the use of herbicides, U.S. crop production would decline by 20% with a $16 billion loss in value if herbicides were not used (Gianessi and Reigner, 2007) and Reigner, 2007).

The presence of weeds in soybean fields is a primary detriment to soybean productivity. Weeds have been estimated to cause a potential yield loss of 37% in world-wide soybean production (Heatherly et al., 2009). Weeds compete with soybean for light, nutrients, and soil moisture, harbor insects and diseases, and interfere with harvest, causing extra wear on harvest equipment (Loux et al., 2008). In addition to weed density, the time period that weeds compete with the soybean crop influences the level of yield loss. The later the weeds emerge, the less impact they will have on yield. Soybean plants withstand early-season weed competition longer than corn, as the soybean canopy closes earlier (Boerboom, 2000). The extent of canopy closure restricts the light available for weeds and other plants growing below the soybean. In addition, canopy closure occurs more quickly when soybean is drilled or planted in narrow rows (Boerboom, 1999); however, in some studies it has also been observed that, depending on factors such as weed species, environmental conditions (i.e., rainfall amounts), and soybean cultivar, soybeans are able to compete with weeds with no resulting yield reduction (Krausz et al., 2001; Place et al., 2011). Place *et al.* have determined that larger soybean seeds produce a larger canopy more quickly and are, therefore, more successful at outcompeting weeds (Place et al., 2011).

Glufosinate ammonium

Primary responsibility for regulation of pesticides including herbicides is with the US EPA. “Pesticide registration is the process through which EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices. EPA evaluates the pesticide to ensure that it will not have unreasonable adverse effects on humans, the environment and non-target species. Pesticides must be registered or exempted by EPA's Office of Pesticide Programs before they may be sold or distributed in the U.S. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling.” (US-EPA, 2013c).

Glufosinate ammonium herbicides contain the active ingredient phosphinothricin and are in the phosphinic acid family of herbicides. The herbicide acts by blocking the plant enzyme glutamine synthetase, which is responsible for nitrogen metabolism and for detoxifying ammonia, a byproduct of plant metabolism. The exposed plant dies by the overproduction of ammonia, which leads to cessation of photorespiration (EPA, 2008b). It is a non-selective foliar herbicide that is used for the control of broadleaf and grass weeds in a variety of crops and non-crop areas. First registered with the EPA in 1993, initial glufosinate ammonium end-use products were for home owner, light industrial non-food, and farmstead weed control (OSTP, 2001). Glufosinate ammonium was first registered by EPA for use in crops in 2000 as a non-selective foliar herbicide used for pre-plant and post-emergence control of broadleaf weeds (EPA (US-EPA, 2008), 2008b). Glufosinate ammonium, a water soluble herbicide, is also approved for use on apples, berries, canola, corn, cotton, currants, grapes, grass grown for seed, potatoes, rice, soybeans, sugar beets, and tree nuts. Non-crop areas for which glufosinate ammonium is a registered use include residential lawns and industrial and public areas. Products include Rely®, Derringer® and Finale® (EPA, 2008b; US-EPA, 2008). Ignite® and Liberty® glufosinate ammonium products are registered for selective over-the-top use on GE LibertyLink® corn, cotton, canola, rice, and soybean.

The highest agricultural uses of glufosinate ammonium are in corn (900,000 lb a.i./yr), cotton (300,000 lb a.i./yr), canola (60,000 lb a.i./yr), almonds (30,000 lb a.i./yr), and grapes (20,000 lb a.i./yr) (EPA, 2008b). Potatoes, rice and soybeans account for 10,000 lbs ai/yr per crop (EPA, 2008b). Glufosinate ammonium-resistant soybean accounted for less than 1 percent of soybean acreage planted in the U.S. in 2009 with approximately 72,000 lb a.i. glufosinate ammonium applied (USDA-APHIS, 2012a). In 2011, the planted acreage of glufosinate ammonium-tolerant soybeans increased to 1.3 percent and glufosinate ammonium use rose to approximately 550,000 lb (USDA-APHIS, 2012a). By 2012, glufosinate ammonium use on glufosinate resistant soybean increased to nearly 3 million acres and 1.5 million pounds of active ingredient (Orr, G., DAS personal communication, 2013).

The EPA-registered use of glufosinate ammonium on LibertyLink® (i.e., glufosinate ammonium-resistant) soybean includes an initial application of glufosinate ammonium no higher than 0.66 lb a.i./A (36 fl oz/A) with a minimum of 0.40 lb a.i./A (22 fl oz/A) (Bayer CropScience, 2011, p. 14). A single second application of glufosinate ammonium up to 0.53 lb a.i./A (29 fl oz/A) is approved on LibertyLink® soybeans, with a seasonal maximum rate of 1.2 lb a.i./A (65 fl oz/A) permitted (Bayer CropScience, 2011). Glufosinate ammonium applications on LibertyLink® soybean should be made from emergence up to but not including the bloom growth stage and within 70 days of harvesting soybean (Bayer CropScience, 2011).

Weed resistance

Not unlike other agronomic practices, herbicide use may impart selection pressures on weed communities resulting in shifts in the weed community that favor those weeds that do not respond to the herbicide used (Owen, 2008). The shift to herbicide resistance in plants is largely a function of the selection of herbicide-resistant traits and is strongly related to the repeated use of one or a limited number of herbicides (Norsworthy et al., 2012; Shaw et al., 2012).

A variety of strategies have been proposed to help farmers deal with resistant weeds (Norsworthy et al., 2012; Shaw et al., 2012) including:

- The rotation of herbicides with different modes of action;
- Site specific herbicide applications;
- Use of full labeled application rates;
- Crop rotation;
- Use of tillage for supplemental weed control;
- Cleaning equipment between fields;
- Controlling weed escapes;
- Controlling weeds early; and
- Scouting for weeds before and after herbicide applications.

® Finale, Rely®, Ignite®, LibertyLink® and Derringer® are registered trademarks of Bayer CropScience.

3.1.3.3 Insecticide Use

Agricultural production of soybean is a relatively recent development; soybean did not become a major export crop in North America until the 1970s (Smith, 1994). Though insect injury has not traditionally resulted in economic losses in most North American growing regions, in recent years, losses have been severe in some southern regions of the United States (Catchot, 2011). Economic thresholds, defined as the level of insect pressure where benefits from treatment cover the cost of treatment, have traditionally been based on $4-6 per bushel soybeans. However, recent prices of $12-15 per bushel have significantly lowered economic thresholds associated with many soybean pests, expanding the area and number of insecticide treatments applied to soybeans (USDA ERS, 2011b). Increases in pest insect populations in soybean have also been observed; increases are attributed by some to global warming or insect adaptation to the soybean plant (Way, 1994). Lower economic thresholds coupled with higher insect populations favor more aggressive pest management strategies (Pedigo, 1996).

Insect injury can negatively impact yield, plant maturity, and seed quality. Insect injury is most often defined by the plant parts that are injured: roots, stems, foliage, or pods. Root- and stem-feeding insect groups typically remain undetected until damage has occurred. Although leaf-feeding insects are the most diverse group, pod-feeding insects are generally considered to be proportionately more important, because high-value soybean reproductive parts are affected.

Many soybean foliar feeders are caterpillars (Lepidoptera larvae) in the family Noctuidae. These include the soybean looper, *Chrysodeixis includens* formerly *Pseudoplusia includens* Walker, velvetbean caterpillar, *Anticarsia gemmatalis* Hübner and green cloverworm, *Hypena scabra* (Fab.). These species commonly occur sympatrically and procedures are being developed for making management decisions that acknowledge combined effects of these pests.

Soybean is attacked by many pests, some of which pose an economic threat. Damage is concentrated in certain production regions (Way, 1994). Nine insect species are responsible for most insect damage in U.S. soybean production:

Soybean aphid, *Aphis glycines* Matsumura
Velvetbean caterpillar (see earlier)
Soybean looper (see earlier)
Green cloverworm (see earlier)
Mexican bean beetle, *Epilachna varivestis* Mulsant (Coleoptera: Coccinellidae)
Southern green stinkbug, *Nezara viridula* (Linnaeus)
Bean leaf beetle, *Cerotoma trifurcata* Forster (Coleoptera: Coccinellidae)
Southern green podworm/corn earworm, *Helicoverpa zea* (Boddie) (formerly *Heliothis zea*) (Lepidoptera: Noctuidae) and
Green stink bug, *Chinavia halaris* (Say) (Hemiptera: Pentatomidae) (Higley, 1994; Purdue-University-Extension, 2009; Iowa-State-University, 2010) .

Soybean insect pest populations and the extent of soybean damage vary annually and regionally due to differences in climatic and weather conditions, species distributions and environmental tolerances and production practices (Way, 1994).

Midwestern States. Generally, soybean insect pest problems are less severe in the Midwest states of the U.S. than in other soybean producing areas (Way, 1994). Recently, the most serious soybean pest has been the soybean aphid (Purdue-University-Extension, 2009). Green cloverworm is the only known lepidopteran pest that occurs frequently in the Midwest; cutworms, *Agrostis ipsilon* (Hufnagel) and *Peridroma saucia* (Hübner) (Noctuidae) and Painted Lady, *Vanessa cardui* L. (Nymphalidae) have also been reported but are less economically important. Economic insect problems increased in the 1990s (Hammond, 2012) with greater increases in the north-central U.S. around 2000 (McWilliams et al., 1999). Generally, insect damage remains below economic threshold levels in the U.S. Midwest.

Northeastern States. Several insect pests have been reported in the northeastern United States and Southern Canada in numbers high enough to cause economic losses in soybean (Penn State Extension, 2012). In recent years, the foremost pest of soybean across the Northern US states has been the soybean aphid, and although important in states such as Pennsylvania, it is however not as prevalent as are economically actionable populations in the Midwest (Iowa-State-University, 2010; PennState-Entomology-Extension, 2014). Defoliators include: green cloverworm, Japanese beetle, *Popillia japonica* Newman (Coleoptera: Scarabaeidae), Mexican bean beetle, bean leaf beetle, and grasshoppers, *Melanoplus spp.* (Orthoptera: Acrididae). Sap-sucking insects include: soybean aphid, *Aphis glycines* Matsumura (Hemiptera: Aphididae), potato leafhopper, *Empoasca fabae* (Harris) (Hemiptera: Cicadellidae) and stink bugs (*Nezara viridula, Acrosternum hilare*, *Euschistus servus*). Stink bugs in particular will feed on both foliage and pods. Seedcorn maggots feed on seeds.

Southern States. Insect pressure is generally greatest in the southern U.S. states bordering the Gulf of Mexico and the Atlantic Ocean. Stink bugs are responsible for most infestations and greatest economic losses in the southeastern United States (McPherson et al., 1997; Guillebeau et al., 2008). Lepidopteran insects, primarily soybean looper, velvetbean caterpillar, corn earworm (soybean podworm), and lesser cornstalk borer, *Elasmopalpus lignosellus* (Zeller) (Lepidoptera: Pyralidae) are responsible for most of the remaining damage (McPherson et al., 1997; Guillebeau et al., 2008). Velvetbean caterpillar and soybean looper are considered the most damaging defoliating insects in the South (Way, 1994; Hammond, 2012). Insecticides are used on approximately 50% of the soybean acreage in Georgia for lepidopteran pests, with velvetbean caterpillar being the most targeted pest (Gianessi et al., 2002). Approximately 40% of the soybean acreage in Louisiana is treated with insecticides for lepidopteran pests, with soybean looper being the main target (Gianessi et al., 2002).

Insect infestation thresholds have been established to indicate when insecticide applications are economically justified. The thresholds are commonly based on number of insects found in field sampling surveys or on established standard defoliation thresholds, such as those provided pest management strategic plans (North Central Integrated Pest Management Center, 2012). In the case of insecticides, these economic damage thresholds are used to determine whether the control method should be applied. For insect resistant crops, the decision to plant an IR variety is made before the crops are planted; some input for this decision may be derived from the insect infestation level of the previous season, since the insect eggs or other diapausing stages may be found directly in the soil of the field site, such as eggs of corn rootworms that may be laid on plant parts. However, velvetbean caterpillars arrive on southern fields as late season arrivals from Central and South America (Mississippi-State-University, 2004), so their incidence is difficult to anticipate.

Summary data of the latest available USDA-NASS chemical insecticide usage statistics for U.S. soybeans from a 2006 survey found that insecticides were applied to 16% of the 72.9 million soybean acres planted in surveyed states (excludes restricted use pesticides) in 2006 and 18% in 2012 (USDA-NASS, 2013e). Of the 12 reported insecticides, the three most common, lambda-cyhalothrin, chlorpyrifos, and esfenvalerate, were applied to 6%, 5%, and 3% of the planted acres in 2007 and 6%, 6%, and <0.5% respectively in 2012 in surveyed program states (USDA NASS, 2007b; USDA-NASS, 2013e). Variability in the historical level of insecticide use from year to year may be considerable, and reflects the unpredictability in the U.S. soybean growing regions of economic damage from insect pest populations. Use of one chemical, chlorpyrifos, attained a usage rate that varied between 2 and 27% on all US soybean between 2004 and 2006 (USDA-NASS, 2007). Lambda cyhalothrin attained a similar range of use during the interval 1997-2006 (USDA-NASS, 2007).

Soybean can withstand 20-35% defoliation before yields are impacted; thus, pesticides are only applied when damage reaches economic thresholds. Approximately 15% of the soybean acreage in the Midwest region and approximately 25% of the soybean acreage in the Southeast and Eastern Coastal regions received an insecticide treatment in 2006, with some states in the Southeast requiring treatments on up to 84% of their acreage (USDA-NASS, 2013e).

Regulation and Environmental Oversight of Insecticides by EPA

Insecticide use is regulated by EPA, which addresses product characterization, human health risk, ecological risk, and insect resistance management for chemical products as well as products expressing plant incorporated protectants, such as the Cry proteins. Insecticides generally provide effective and economical means of control or suppression of soybean insect pests that reach economic thresholds. However, chemical insecticides have limited efficacy in controlling lepidopteran infestations in soybean. Narrow application windows, the emergence of insecticide resistance, and public pressure for reduced pesticide use limit the desirability of this approach to pest management (Thomas and Boethel, 1994). Velvetbean caterpillar and soybean looper are considered the most damaging defoliating insects in the South (Way, 1994; Gianessi, 2009). Soybean looper has developed extensive insecticide resistance (Thomas and Boethel, 1994), and resistance to pyrethroids is widespread across the southern U.S. (Felland et al., 1990; Leonard et al., 1990). Insecticides remain effective against velvetbean caterpillar.

Replacing insecticides with GE plants that produce insect specific toxins (especially the Cry proteins) has been shown to reduce the overall volume of insecticide used against target pests. For insecticides targeted at larvae of moths and beetles feeding above-ground and on roots, the use of GE Insect Resistant (IR) corn by producers through 2010 had reduced the volume of applied insecticide active ingredient (ai) by 4.1 million kilograms, or 83.8% (Brookes and Barfoot, 2012). Since 1996, the cumulative decrease in insecticide use has been 36.6 million kg, a 40% reduction (Brookes and Barfoot, 2012). Efficacy trials of *Bt* corn hybrids against black cutworm, corn earworm, and corn rootworm larvae demonstrate that the addition of pesticides to *Bt* crops does not further increase yield (Estes et al., 2011). For *Bt* cotton, the reduction in volume of applied insecticide active ingredient was 1.19 million kg, or 23% (Brookes and

Barfoot, 2012). Since 1996, the cumulative decrease in insecticide ai use has been 8.67 million kg, a reduction of 9.7% (Brookes and Barfoot, 2012). While those cotton pests not susceptible to the currently deployed Cry proteins require insecticide treatments (i.e., *Lygus* bugs), GE lepidopteran-resistant cotton sometimes also require supplementary insecticides when cotton bollworm (Lepidoptera) populations have been high enough to require it (Stewart, 2007).

Crops genetically engineered to produce Cry proteins have been widely adopted; *Bt* cotton now represents 75% of the cotton planted in the U.S and *Bt* corn is about 67% of the corn acreage (USDA NASS, 2012c; USDA NASS, 2012b). No soybean engineered with cry proteins have been made commercially available in the US at present, although one such soybean line has been recognized with nonregulated status, and it expresses the Cry1Ac protein.

Regulation of Cry1F and Cry1Ac proteins. Cry1F *Bt* proteins are expressed in several US GE crop species including corn (DAS 01507-1 and DAS 0675-8) and in cotton (DAS 24236-5), and cry1Ac proteins in cotton (DAS-21023-5, MON-15985-7 and MON-00531-6) and corn (DKB-89614-9), and soybean which is not presently available in the US (MON-87701-2) (Biosafety Clearinghouse, 2013) and in some countries, canola, rapeseed and melons. The cry1F gene (cry1Fv3) which is transformed into DAS-81419 is the same gene as that was recognized as non-regulated by USDA in 2004, petition 03-036-01 (USDA-APHIS, 2004), and the cry1Ac (*synpro*) was nonregulated also as of 2004, petition 03-036-02, and together these are commercially produced as WideStrike cotton.

DAS asserts that Cry1Ac and Cry1F provide protection against several lepidopteran pests of soybean, including soybean looper (*Chrysodeixis includens* (Walker), formerly *Pseudoplusia includens*), velvetbean caterpillar (*Anticarsia gemmatalis*), fall armyworm (*Spodoptera frugiperda*) and tobacco budworm (*Heliothis virescens*). Soybean-damaging Lepidoptera that are economically the most important species in Brazil for which this product may be directed similarly include *Chrysodeixis includens* (Walker), *Anticarsia gemmatalis* (Hubner), but also *Spodoptera cosmioides* (Walker), *Spodoptera eridania* (Stoll), and *Spodoptera albula* (Walker) (Rolim et al., 2013).

For the stacked Cry1Ac/Cry1F cotton (WideStrike™) whose Bt components are the same as those in DAS- 81419-2, EPA addressed product characterization, human health risk, ecological risk, and insect resistance management for the Bt cotton products. EPA concluded in their assessment of ecological risk and insect resistance management:

1) no synergistic effects or increase in non-target host range were seen as a result of combining these two proteins in the same product,
2) aquatic and terrestrial wildlife were not likely to be harmed and WideStrike cotton was not likely to threaten the long-term survival of any non-target wildlife populations,
3) the Agency has sufficient information to conclude that there is no hazard from the proposed uses of WideStrike cotton to non-target wildlife, aquatic and soil organisms, but they are requesting additional, primarily long term effects data that were recommended by previous Panels for PIP corn to lend additional weight to their conclusion.

4) incomplete shared binding of Cry1Ac and Cry1F receptors, in TBW and CBW, is expected to lead to incomplete cross-resistance and thus the likelihood of enhanced survival on WideStrike cotton is expected to be small. (US-EPA, 2005a)

EPA assessed the potential for possible environmental impacts of the two Cry proteins in combination in cotton plants, and as noted, concluded there were "no unreasonable adverse effects on the environment" associated with their deployment in cotton. However, the EPA initially requested additional information over a longer term (US-EPA, 2005a). Since then, there have been additional studies, such as one assessing the impacts of green lacewing predators feeding on insects that had fed on plants expressing the Cry 1Ac and Cry 1F proteins, and no deleterious effects were detected (Tian et al., 2013). A common pest species, fall armyworm, was fed on Cry1F producing corn, and after two generations of feeding on these larvae by the common and abundant ladybird beetle, *Coleomegilla maculata*, no effects were seen on the ladybird; transfer of the toxin could be directly demonstrated from the prey species into this predator (Tian et al., 2012). Similarly, a predator species *Podisus maculiventris* (spined soldier bug) was fed larvae of the pest lepidopteran species *Spodoptera exigua* and these had been raised on cotton plants expressing cry1Ac. The Bt can disrupt development and reduce feeding of the *Spodoptera* larvae. The *Podisus* also took up the toxin, and could not be shown to be affected by the exposure (Torres and Ruberson, 2008) .

Multiple Bt proteins may have additive or synergistic effects on susceptible lepidopteran species such as those observed for the cotton pests *H. zea* and *S. frugiperda* (Stewart et al., 2001). However, for insects not susceptible to single cry proteins, no effects were observed from feeding up to three simultaneous cry proteins. For example, larval honeybees consume Cry proteins in pollen within honeybee cells and when fed multiple cry proteins show no effects (Hendriksma et al., 2012). Likewise, risk assessment of the effects on nontarget predators show a low likelihood of Cry1Ac and Cry1F protein effects on nontarget individuals (Wolt, 2011). In a review of population surveys made of predators and parasites found in a variety of crops expressing Cry proteins, Lu (Yu et al., 2011) concluded that no consistent effects can be seen on non-target species found on Bt-expressing crops. The more recent observations in scientific literature continue to be consistent with the conclusion of the EPA in the 2005 BRAD that the "non-target organism effects data are considered sufficient for the period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the product and the risk of resistance developing to the *Bacillus thurigiensis* Cry1F (synpro) or *Bacillus thuringiensis* Cry1Ac (synpro) protein(s) during the conditional registration is not expected." (US-EPA, 2005a). Similarly, the EPA concluded in the 2013 document that "based on extrapolating from previous studies on Bt proteins… the cultivation of event DAS-81419-2 soybean will not result in adverse effects to nontarget organisms (US-EPA, 2013b).

Global Assessment of Cry proteins

The food and feed safety of Cry proteins has been assessed by regulatory agencies worldwide, and Bt crops have been adopted in numerous countries (Betz et al., 2000). For example, WideStrike® cotton (DAS-21023-5; DAS-24236-5, expressing the same Cry1Ac and Cry1F proteins as DAS-81419-2 soybean) has received regulatory approval in Canada (import), Australia (food, feed), Brazil (cultivation, food, feed), Japan (import, food, feed), Mexico (food, feed); EU (food, feed) and Korea (food, feed) (Biotechnology Industry Organization, 2012).

Insect Resistance Management

EPA considers protection of insect pest susceptibility to *Bt* to be in the "public good" (EPA, 2001). In order to delay the development of insect resistance to *Bt* crop plant-incorporated protectants, EPA has mandated specific requirements on registered PIPs that are intended to reduce the potential for insect pests to become resistant to the *Bt* proteins (EPA, 2001). These requirements are part of the terms and conditions of the registrations (EPA, 2001). These provisions include the following items:

- Additional field research on pest biology;
- Monitoring for the development of resistance or increased tolerance to the Bt protein;
- Grower education;
- Development of a remedial action plan in case resistance is identified;
- Increased communication among growers, producers, researchers, and the public; and
- Use of refuges to provide non-resistant insects to dilute the genes of any resistant insects in the pest population.

Another key component of IRM is the planting of refuges. An example of a refuge is a block of non-*Bt* corn planted near a *Bt* corn field. For many PIP products, EPA registrations require that such a refuge be planted by growers of the PIP crop. The aim of this strategy is to provide an ample supply of insects that remain susceptible to the *Bt* toxin. The non-*Bt* refuge will greatly decrease the odds that a resistant insect can emerge from a Bt field and choose another resistant insect as a mate. The likelihood that two insects with a resistant gene will find each other and mate is greatly decreased. By preventing the pairing of resistant genes, these refuges help ensure that susceptibility is passed on to offspring (EPA, 2002a).

Integrated Pest Management (IPM) programs integrate preventive pest management with additional pest control tools, including insecticides when warranted. IPM practice includes monitoring fields for insect growth stage, insect development and population density, and occasionally natural enemy development and population density. Management decisions for insect populations in individual fields are based on economic injury level, which is defined as the lowest population density of each insect likely to cause economic damage. The economic injury level usually changes during the growing season, with later stages of development warranting action at a lower level of defoliation. IPM programs integrate chemical control and biological control, cultural control, and plant resistance to minimize insecticide resistance and reduce dependence on insecticides (Pedigo, 1996).

3.2 Soybean Seed Production

In 2012, 76.1 million soybean acres were planted (USDA NASS, 2012a). Several factors influence optimal planting rate for soybean such as row spacing, seed germination rate, soil conditions, climate, disease and pest pressure, past tillage practices and crop rotation (Robinson and Conley, 2007). Seeding rate is also determined by the plant population desired by the grower. Since 93% of the 76 million soybean acres planted in the U.S. in 2012 were GE varieties (USDA NASS, 2012a), at least 70.8 million acres were planted with certified seeds.

The four largest producers of GE seed combined (Monsanto, DuPont Pioneer, DAS and Syngenta) have about 70% of the GE soybean seed market (AgWeb, 2013). Besides seed from these companies, regional and local suppliers sell seed and farm supply brand seed may also be available to growers.

The U.S. Federal Seed Act of 1939 requires accurate labeling and purity standards for seeds in commerce, and prohibits the importation and movement of adulterated or misbranded seeds (7 C.F.R. Part 201). The Act recognizes classes of certified seed (USDA, 2012f) seed certification and official certifying agencies (USDA, 2012d), and varietal purity standards for seed (USDA, 2012e). States have also developed laws to regulate the quality of seed available to farmers (Bradford, 2006). Most of the laws are similar in nature and have general guidelines for providing information on the label for the following:

- Commonly accepted name of agricultural seed;
- Approximate total percentage by weight of purity;
- Approximate total percentage of weight of weed seeds;
- Name and approximate number per pound of each kind of noxious weed seeds;
- Approximate percentage of germination of the seed; and
- Month and year the seed was tested.

Various seed associations have standards to help maintain the quality of soybean seed. The Association of Official Seed Certifying Agencies defines the classes of seed as follows (AOSCA, 2012):

- *Breeder* seed is directly controlled by the plant breeder that developed the variety.
- *Foundation* seed is the progeny of Breeder or Foundation seed that is handled to most nearly maintain specific genetic identity and purity.
- *Registered* seed is a progeny of Breeder or Foundation seed that is so handled as to maintain satisfactory genetic identity and purity.
- *Certified* seed is the progeny of Breeder, Foundation, or Registered seed that is so handled as to maintain satisfactory genetic identity and purity.

These definitions are in accord with those set forth in the Federal Seed Act (USDA, 2012f).

Production of all classes of certified seed requires that:

1. each certifying agency shall determine that genetic purity and identity are maintained at all stages of certification including seeding, harvesting, processing, and labeling of the seed;
2. the unit of certification shall be a clearly defined field or fields;
3. one or more field inspection shall be made prior to harvest and when genetic purity and identity can best be determined; and
4. a certification sample shall be drawn in a manner approved by the certifying agency from each cleaned lot of seed eligible for certification (USDA, 2012g).

Federal regulation 7 CFR §201.76 specifies minimum land, isolation, field, and seed standards required for soybean Foundation, Registered and Certified seed (USDA, 2012h). To produce all classes of certified seed, the land requirement is that the crop shall not be grown on land where soybeans were grown the previous year unless the preceding soybean crop was planted with a class of certified seed of the same variety or unless the preceding soybean crop and the variety being planted have an identifiable character difference. The Federal Seed Act does not specify a numerical measurement for isolation distances in the production of Foundation, Registered and Certified soybean seeds, but states that the distance from any potential contaminating source must be adequate to prevent mechanical mixing (USDA, 2012f, Table 5).

Isolation requirement varies somewhat among states and seed producers. Some states require an isolation distance of five feet while other states and seed producers require 10 feet of isolation distance (Iowa Crop Improvement Association, 2000; Virginia Crop Improvement Association, 2012). Under 7 CFR §201.76, to qualify as Certified seed, only one plant of another variety in 200 soybean plants and 0.5% of seed of other varieties or off-types are permitted. To qualify as Registered seed, only one plant of another variety in 500 soybean plants and 0.2% of seed of other variety or off-types are permitted. To be certified as Foundation seed, only one plant of another variety in 1,000 soybean plants and 0.1% of seed of other variety or off-types are permitted (USDA, 2012h).

3.3 Organic Soybean Production

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, 2012). Organic certification involves oversight by an accredited, third-party certifying agent of the materials and practices used to produce or handle an organic agricultural product (USDA, 2012j). 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 (USDA, 2012i), they do not require testing for the presence of excluded methods. Thus, NOP certification is dependent on process and not product. For more details of the production of organic soybean, see APHIS Final EAs for other soybean varieties.

3.3.1 Organic Practices

Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (NCAT, 2003). 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, 2012). 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 (Ronald and Fouche, 2006; USDA-AMS, 2011; USDA-AMS, 2012).

3.3.2 Weed, Pest, and Disease Control in Organic Agriculture

Weed control in organic systems is accomplished with delayed seeding to avoid spring weeds, applying fertilizer to growing plants to outcompete weeds, increasing seeding rates, sowing cover crops, crop rotation, intercropping, flame weeding, hand weeding, and mechanical means (e.g., tillage) (Kuepper, 2003; Heatherly et al., 2009; Place et al., 2011). Organic crop production historically employed mulch and ridge tillage practices (NCAT, 2003); however, no till may be unsustainable in some long-term organic systems because of increasingly poor weed control (Teasdale et al., 2007).

Pest control in organic systems is accomplished with application of natural pesticides, integrated pest management techniques (e.g. introduction of beneficial organisms such soil predator and parasitic organisms), and some weed control practices, such as crop rotation, intercropping, and use of cover crops (Fouche et al., 2000; NCAT, 2003; Michigan State University Extension, 2012) .

Diseases are primarily controlled in organic systems by planting disease-resistant varieties and with management practices that promote healthy soil, rotating crops, diligently removing diseased plant material, and plant canopy management (NCAT, 2003; Michigan State University Extension, 2012). When physical, mechanical, or biological controls are not sufficient for controlling weeds, pests, or disease, only a biological, botanical or synthetic substance approved on the national list may be used (USDA, 2011a).

3.3.2.1 Organic Pesticides

There are a number of insecticides approved for use in certified organic production systems, mainly non-synthetic compounds or biocontrols. Conditions for use of an insecticide must be documented under the National Organic Standard. Generally speaking, pesticides that derive from natural materials or living organisms are allowed in organic production if they do not contain synthetic additives or are not specifically disallowed on the National List of Allowed and Prohibited Substances under(USDA, 2012b) Most synthetic pesticides are not allowed; those few that are can be found on the National List under (USDA, 2012a). The Organic Crops Workbook lists the approved classes of insecticides used for organic production; the largest classes are botanicals, biologicals, oils, fatty acids, minerals, and pheromones (NCAT, 2003).

3.3.3 Economic/Market Data for Organic Agriculture

USDA-Economic Research Service (ERS) reported the organic crop production data collected in 2008 (USDA ERS, 2010a). In that year, 125,621 acres of organic soybeans in 28 states were harvested (USDA ERS, 2010a), compared to approximately 74.5 million harvested acres of conventionally produced soybean (USDA NASS, 2011b). In 1995, prior to introduction of glyphosate resistant soybeans, organic soybean acreage was 47,200 (USDA ERS, 2010a). Total U.S. soybean acres that year totaled approximately 63.1 million (USDA NASS, 2012b), thus organic soybean acres made up about 0.007% of acres. In 2008, organic soybean production consisted of about 0.13% of total U.S. soybean production and was valued at approximately $50.2 million, capturing roughly 0.17% of the overall soybean crop value for that year (USDA NASS, 2008). Organic soybean producers generally harvest lower yields than other producers

(McBride and Greene, 2008; Heatherly et al., 2009). McBride and Greene also found total operating costs averaged $30 more per acre and capital costs averaged $60 per acre higher for organic soybean producers than for other conventional soybean producers.

Organic soybean markets typically enjoy a market premium offsetting the additional production and record-keeping costs associated with this production method. The study also found that while organic soybean costs range from $1 to $6 more per bushel, the average premium is $9 bushel compared to other production systems (McBride and Greene, 2008).

Table 3. U.S. certified organic soybean acres by state, 2008.

State	Soybeans (acres)		State	Soybeans (acres)	
	2007	2008		2007	2008
Arizona	241	241	Missouri	7,893	6,441
Arkansas	8,374	11,172	Nebraska	5,672	8,825
Colorado	488	3,502	New York	1,324	5,038
Connecticut	9	9	North Carolina	165	94
Delaware	25	25	North Dakota	3,308	3,773
Idaho	1	1	Ohio	3,665	3,951
Illinois	6,277	7,225	Oklahoma	80	165
Indiana	888	1,104	Oregon	--	141
Iowa	6,989	19,913	Pennsylvania	1,589	1,753
Kansas	639	2,141	South Dakota	4,531	4,786
Maine	144	194	Texas	2,093	2,141
Maryland	416	437	Vermont	--	337
Michigan	11,320	11,251	Virginia	360	363
Minnesota	25,518	21,229	Wisconsin	8,381	9,369
U.S. Total				100,390	125,621

Source: (USDA-ERS, 2010)

3.4 Physical Environment

The types of possible impacts of DAS-81419-2 on physical resources of soil quality, water resources, air quality and relationship to climate change are no different than those of other soybean crops, and of agriculture in general. These issues have been previously surveyed in numerous APHIS EAs. Use of herbicides may impose some potential for environmental impacts on soil, water and possibly air resources, but EPA has assessed these for each herbicide, including glufosinate, and determined that under FIFRA, use of glufosinate will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. An ecological impact analysis of environmental fate, transport and degradation has been prepared in 2013 for glufosinate in soils, groundwater, surface water (US-EPA, 2013a).

3.5 Biological Resources

3.5.1 Animal Communities

Animal communities in this discussion include wildlife species and their habitats. Wildlife refers to both native and introduced species of mammals, birds, amphibians, reptiles, invertebrates, and fish or shellfish. Agriculture dominates human uses of land (Robertson and Swinton, 2005). In 2011, 917 million acres (approximately 47%) of the contiguous 48 states were devoted to farming, including: crop production, pasture, rangeland, Conservation Reserve Program, Wetlands Reserve Program, or other government program uses (USDA-ERS, 2012). How these lands are maintained influences the function and integrity of ecosystems and the wildlife populations that they support.

A wide array of wildlife species occur within the 31 major soybean-producing U.S. states. During the spring and summer months, soybean fields provide browse for rabbits, deer, rodents, other mammals; birds such as upland gamebirds, while also providing a forage base for insects (Palmer et al., 2012). During the winter months, leftover and unharvested soybeans provide a food-source for wildlife; however, soybeans are poorly suited for meeting nutrient needs of wildlife, such as waterfowl, that require a high-energy diet (Krapu et al., 2004).

Some insects and other invertebrates can be beneficial to soybean production, providing services such as nutrient cycling and preying on plant pests. But many insects and invertebrates are detrimental to soybean crops, including: bean leaf beetle (*Cerotoma trifurcata*); beet armyworm (*Spodoptera exigua*); blister beetle (*Epicauta* spp.); corn earworm (*Helicoverpa zea*); grasshopper (*Acrididae* spp.); green cloverworm (*Hypena scabra*); seed corn beetle (*Stenolophus lecontei*); seedcorn maggot (*Delia platura*); soybean aphid (*Aphis glycines*); soybean looper (*Pseudoplusia includens*); soybean stem borer (*Dectes texanus*); spider mites (*Tetranychus urticae*); stink bug (green [*Acrosternum hiliare*]; brown [*Euschistus* spp.]); and velvetbean caterpillar (*Anticarsia gemmatalis*) (Palmer et al., 2012; Whitworth et al., 2012). The principle lepidopteran pests for which this variety was constructed are listed in Section 3.1.3.3 of this EA.

While insects are considered less problematic than weeds in U.S. soybean production, insect injury can impact yield, plant maturity, and seed quality. Consequently, insect pests are managed during the growth and development of soybean to enhance soybean yield (Higley, 1994; Aref and Pike, 1998). Conventional broad-spectrum insecticides are potentially toxic to invertebrates and vertebrates. The US-EPA requires application control measures for certain Restricted Use insecticides to limit human and environmental exposure (EPA, 2012e). *Bt* foliar sprays contain Cry proteins and are approved insecticides for use in organic production systems to control moths, beetles, mosquitoes, and flies (Lepidoptera, Coleoptera, and Diptera), and exhibit low toxicity to non-target organisms (EPA, 2011b).

Insect-resistant crop varieties are targeted to certain invertebrate species that negatively impact the crop. Currently, GE varieties with nonregulated status are Lepidopteran resistant (European corn borer and other species in corn, and additional lepidopteran species in cotton and soybean) or Coleopteran resistant (corn rootworm in corn).

Transgenic *Bt* crops containing Cry proteins could potentially affect non-target invertebrates that directly consume *Bt* plant material or are exposed via Cry protein residues in soil, water, or prey species. However, for a Cry protein to exert toxicity, the appropriate activating enzyme(s) and receptor binding sites would need to exist in the midgut of the non-target species, and sufficiently high concentrations of active Cry protein would have to reach these binding sites. Reviews of commercially established GE crops have summarized the general lack of impact of Bt expressing varieties on non-target organisms (Yu et al., 2011).

Multiple indicator species have been exposed to purified *Bt* proteins in direct feeding studies; these studies have typically not shown any hazard to the tested species, despite exposure to very high test concentrations under “no choice” conditions where the species was continually exposed through its diet. Some laboratory studies have found an effect, but concluded through refinement of exposure models and estimates, or via field studies, that the effect was not adverse or not representative of field conditions (Duan et al., 2009).

GE insect-resistant products may reduce broad-spectrum insecticide use. Since the commercialization of *Bt* crops, there have been a substantial number of field studies that have demonstrated that non-target invertebrates are generally more abundant in *Bt* cotton and *Bt* corn fields than in non-GE fields managed with chemical insecticides (Marvier et al., 2007; Lu et al., 2012; Mannion and Morse, 2012). These studies demonstrate that *Bt* crops do not cause unreasonable or unexpected adverse effects in the environment and that arthropod prevalence and diversity is actually greater in *Bt* crop fields (EPA, 2010a).

3.5.2 Plant Communities

The plant community surrounding a soybean field is dependent on physical geography of the farm and the context of larger areas. Soybean fields can be bordered by other agricultural fields (including those of other soybean varieties), woodlands, or pasture and grasslands. From an agronomic perspective, the most relevant members of a surrounding plant community are those that can behave as weeds. Just as with other plants, weeds and theirpressure on agricultural crops are also dependent on geography. Two known weed biotypes have been identified and confirmed to be resistant to glufosinate ammonium, a glutamine synthase inhibitor herbicide, namely goosegrass (*Eleusine indica*) and Italian ryegrass (*Lolium multiflorum*). Glufosinate ammonium resistant goosegrass has not been identified in the U.S. In 2010, Italian ryegrass with resistance to both glyphosate and glufosinate ammonium was confirmed in Oregon (Heap, 2011). For a detailed description of weeds and development of weed resistance to herbicides, see additional APHIS EAs for other herbicide resistant soybean varieties.

3.5.3 Gene Flow and Weediness

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). Soybean is considered a highly self-pollinated species, propagated by seed (OECD, 2000b).

3.5.4 Microorganisms

Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). *Bt* (*Bacillus thuringiensis)* is a naturally occurring soil bacterium, commonly present in soil (Shelton, 2012). Nitrogen fixing species such as *Bradyrhizobium japonica*, which are important components of soybean yield and enhancing soil nitrogen, are also found in soil and associated with soybean. For a discussion of soil microorganisms, including soybean mutualists, effects of GE crops, and impacts of herbicides, see recent APHIS EAs for soybean traits.

3.5.5 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem. Biodiversity provides valuable genetic resources for crop improvement (Harlan, 1975) and also provides other functions beyond food, fiber, fuel, and income. These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). The loss of biodiversity results in a need for costly management practices in order to provide these functions to the crop (Altieri, 1999).

3.6 Human Health

3.6.1 FDA Review

Public health concerns surrounding crops genetically engineered to accumulate *Bt* focus primarily on human and animal consumption. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. FDA evaluates the submission and responds to the developer by Biotechnology Consultation Note (and Memo) to File (BNF) (FDA, 1997).

3.6.2 EPA Review

Pursuant to FFDCA, before a pesticide can be used on a food crop, EPA must establish the tolerance value which is the maximum amount of pesticide residue that can remain on the crop or in foods processed from that crop (EPA, 2010b). In addition, the FDA and the USDA monitor foods for pesticide residues and enforce these tolerances (USDA, 2011a). If pesticide residues are found to exceed the tolerance value, the food is considered adulterated and may be seized. The USDA has implemented the Pesticide Data Program (PDP) in order to collect data on pesticides residues on food (USDA-AMS, 2010). The EPA uses PDP data to prepare pesticide dietary exposure assessments pursuant to the 1996 FQPA. Pesticide tolerance levels for glufosinate ammonium have been established for a wide variety of commodities; the tolerance for soybean seed is 0.02 parts per million (ppm) (EPA, 2007a).

Pesticides, including herbicides and insecticides, are used on most soybean acreage in the U.S. Changes in acreage, crops, or farming practices can affect the amounts and types of pesticides used. This in turn affects potential risks to farm workers. Common farm practices, however, can mitigate exposure to pesticides by farm workers. Choosing from less toxic groups of insecticides to control soybean insects is a good common agricultural practice.

3.7 Animal Feed

Animal feed is the major product derived from soybean meal produced in the U.S. (Soyatech, 2012). In 2011, approximately 39 million metric tons of soybean meal was produced, about 25 million tons of which was marketed for animal feed, with the largest volumes consumed by poultry (48%), swine (26%), and beef (12%). In 2011, about 12 million metric tons of meal was used in poultry rations, with 6.3 and 3 million tons in hog and beef rations, respectively (The American Soybean Association, 2012b; The American Soybean Association, 2012c).

Similar to the regulatory control for direct human consumption of soybean 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 must comply with all applicable legal and regulatory requirements, which in turn protects human health. To help ensure compliance, GE plants used for feed may undergo a voluntary consultation process with FDA before release onto the market, which provides the applicant with any needed direction regarding the need for additional data or analysis, and allows for interagency discussions regarding possible issues.

3.8 Socioeconomics

3.6.1 Domestic Economic Environment

Soybean is one of the most important crops in the U.S., used for both animal feed and human consumption (Heatherly et al., 2009). The top ten producing states (Iowa, Illinois, Minnesota, Indiana, Nebraska, Ohio, Missouri, South Dakota, Kansas, and North Dakota) accounted for more than 80% of this production (USDA, 2012c). 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, which vary in terms of land productivity and cost of production. The most productive of these regions are the Heartland and Northern Crescent (USDA ERS, 2012a). While these regions have higher production costs, their higher productivity still results in greater profitability (USDA ERS, 2012a). In 2012, the U.S. total gross average value of soybean production per planted acre was $388.49 and the average price of a bushel of soybeans at harvest was $11.94 (USDA ERS, 2012a).

As discussed in Section 2.1.2, several insect pests have been reported in the northeastern United States and Southern Canada in numbers high enough to cause economic losses in soybean (Penn State Extension, 2012). Insect pressure is generally greatest in the southern U.S. states bordering the Gulf of Mexico and the Atlantic Ocean; soybean insect pest problems in the Midwest are generally less severe (Way, 1994).

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. In 2010, typical operating costs are reported in dollars per planted acre and included purchased seed ($59.20), fertilizer and soil amendments ($17.87), other chemicals ($17.04), and irrigation water ($0.16) (USDA ERS, 2012a). Total 2010 operating costs were $131.89 per planted soybean acre (USDA ERS, 2012a). In comparison, 2011 typical U.S. soybean production operating costs per planted acre total 136.87, including $55.55 for purchased seed, $22.84 for fertilizer and soil amendments, and $16.42 for other chemicals, and costs for irrigation water were $0.15 (USDA ERS, 2012a). The rise in crop production input prices is attributed to the increased use of more expensive seeds with complex genetic traits, increased use of fertilizer that has increased in price primarily in response to rising natural gas prices, and a 4% rise in pesticide costs coupled with an increase in overall crop acreage (USDA ERS, 2011a).

3.6.2 Trade Economic Environment

Soybean exports in the form of bulk beans, meal, and oil are a major share of the total agricultural exports for the U.S. The value of U.S. agricultural exports was $135.77 billion in 2012 (USDA ERS, 2012h). Bulk soybeans accounted for $19.8 billion of this total, ranking first among all agricultural commodities, while soybean meal, at a value of $3.84 billion, and soybean oil, at a value of $1.82 billion, ranked 6th and 16th, respectively (ERS, 2012). 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 (USDA, 2012k; USDA ERS, 2012d; USDA FAS, 2013).

In 2010, the U.S. was responsible for 35.1% of the world's soybean production, 22.9% of world's soybean meal production, and 23.0% of the world's soybean oil production (USDA ERS, 2012d; USDA FAS, 2013). The U.S., China, Argentina, and Brazil are the major producers of soybean, soybean meal and soybean oil (USDA, 2012k; USDA FAS, 2013).

The U.S., along with Brazil, Argentina, Paraguay, and Canada, account for 97% of the bulk soybean exported worldwide; Argentina, Brazil, the U.S., India, and Paraguay account for 94.1% of the soybean meal exported worldwide (USDA, 2012k; USDA FAS, 2013). Argentina, the U.S., and Brazil are the dominant countries in terms of soybean oil exports (USDA, 2012k; USDA FAS, 2013). China, Mexico, and the 27 European Union member countries (EU-27) were the top 3 importers for U.S. soybean by volume for 2010 and 2011 (USDA, 2012k; USDA FAS, 2013).

Currently, soybean seeds for planting are a small percentage of U.S. soybean exports (USDA-APHIS, 2011a; USDA, 2013). From 2005-2010, Chile and Argentina were the largest South American importers of U.S. soybean seed for planting (USDA-APHIS, 2011a).

4 ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this environmental assessment. A cumulative effects analysis is presented for each potentially affected environmental concern.

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for DAS-81419-2 soybean are described in detail throughout this section. An impact would be any change, positive or negative, from the existing (baseline) conditions of the affected environment (described for each resource area in Section 3.0). 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. Examples could 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. Examples could include surface water quality changes resulting from soil erosion due to increased tillage, and worker safety impacts resulting from a change in herbicide use.

A cumulative effects analysis is also included for each environmental issue in Section 5. A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Examples include breeding DAS-81419-2 soybean with other events that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340,or impacts result from third-party actions (e.g. EPA, growers). If there are no direct or indirect impacts identified for a resource area, then there can be no cumulative impacts. Where it is not possible to quantify impacts, a qualitative assessment of potential impacts can be provided. Certain aspects of this product and its cultivation may be no different between the alternatives; those are described below.

4.1 Scope of Analysis

4.1.1 Herbicide use

The conferred resistance of DAS-81419-2 soybean to glufosinate ammonium and use of glufosinate ammonium on DAS-81419-2 soybean is considered in the assessment. Use of the herbicide is permitted by the EPA on commercially-available resistant soybean varieties. Glufosinate ammonium is registered by EPA for use on soybeans at an initial application rate no higher than 0.66 lb ai/A (36 fl oz/A) and a single second application up to 0.53 lb ai/A (29 fl oz/A) (EPA, 2008b). Glufosinate ammonium applications on glufosinate ammonium-resistant soybean may be made from emergence up to but not including the bloom growth stage and within 70 days of harvesting. A seasonal glufosinate ammonium maximum rate of 1.2 lb ai/A (65 fl oz/A of) is the approved use pattern on glufosinate ammonium-resistant soybeans (Bayer CropScience, 2011). For seed production, DAS notes that they do not expect that glufosinate will be used regularly (L. Han, personal communication, 2013)

4.1.2 Stacking

DAS intends to develop a stacked variety through conventional breeding techniques combining the insect resistance from DAS-81419-2 soybean with herbicide resistance from another nonregulated genetically engineered soybean variety. Environmental consequences associated with potential future stacking in which additional herbicide resistance is incorporated with DAS-81419-2 soybean are presented and discussed in the cumulative impacts analyses where appropriate.

4.2 Agricultural Production of Soybean

4.2.1 Acreage and Area of Soybean Production

Soybean acreage over the long term is not expected to change much, as the USDA Office of the Chief Economist indicates 76 million acres for 2013/2014, with the same acreage for 2022/2023 (USDA-OCE 2013 (USDA-OCE, 2013). While increased export demand for soybean is forecast in the projection, OCE predicts no pressure for increased acreage.

4.2.1.1 No Action Alternative: Acreage and Area of Soybean Production

Under the No Action Alternative, DAS-81419-2 would continue to be regulated by APHIS under 7 C.F.R. Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introduction of DAS-81419-2 soybean, and measures to ensure physical and reproductive confinement would continue. Activities for DAS 81419-2 would be limited, with no expected change to acreage and area of soybean production.

4.2.1.2 Preferred Alternative: Acreage and Area of Soybean Production

Similar to the No Action Alternative, breeding and seed increase activities would have no impact on acreage. Other than resistance to a specific order of pests, DAS-81419-2 soybean confers no special agronomic benefit compared to other soybean varieties (12-272-01p a2 Sections 8, 9), and no change in commercial soybean production area or in total amount of soybean acreage in the U.S. is expected. Soybean acres in the US have remained in the range of 75-77 million acres between 2004 and 2012 (USDA-ERS, 2013) and production from 2.7-3.3 million bushels. The USDA (USDA-OCE, 2013) estimated that soybean acreage will remain about 76 million acres through at least 2018. Accordingly, the impacts under the Preferred Alternative are unchanged from the No Action Alternative. Area of production of soybean for seed production may increase, but overall soybean production area for seed destined for South America would at maximum be 250,000 acres of the total commodity soybean production of 77.1 million acres (0.3% of the total). DAS has specified that the geographic areas assigned to DAS-81419-2 seed increase would likely be the same as that presently being used for DAS seed increase, using contract seed producers selected by a third party. The current area in which seed is produced thus would not likely change.

4.2.2 Agronomic Practices

Locations where DAS might produce seed are not determined, nor is the maturity group known for the soybean line containing the trait presented for determination of nonregulated status. If we can assume that the highest yielding sites will be selected for seed production, we suggest that it is likely that production of this variety would be within the center of the Corn Belt, such as Indiana, Iowa and Illinois. Practices common in these states would be chosen, and since there are no details of production of DAS-81419-2 that differ from those needed for other, similar GE soybean varieties, practices would be similar to those common in these areas.

4.2.2.1 No Action Alternative: Agronomic Practices

Under the No Action Alternative, DAS-81419-2 soybean could be produced under APHIS notification or permit in the states and counties identified by EPA in the seed increase registration. While the scope of activity would be limited, similar agronomic practices that are currently used for commercially available soybean seed production would also be used by growers of DAS-81419-2.

A variety of herbicide choices are available to growers, including those used for preplant only, pre-emergent herbicides often with residual activity, those used as post-emergent herbicides, and combinations of both (Loux et al., 2013). Growers under third party contract for DAS seed are not required under their growing contracts to use specific herbicides for seed production. However, the soybean seed production leader for DAS (personal communication, through Lei Han, 2013) states that the following herbicides would be typically used for seed production:

Preplant herbicide use:

Valor (Flumioxazin)

Postplant herbicide use:

Classic (Chlorimuron-methyl)

First Rate (Chloransulum-methyl)

Select (Clethodim)

Marvel (contains active ingredients Fluthiacet-methyl and Fomesafen);

Marvel and tank mix with Select (active ingredient Clethodim);

Flex Star (Fomesafen)

4.2.2.2 Preferred Alternative: Agronomic Practices

Cultivation Area

Under the Preferred Alternative, the planting of DAS-81419-2 would continue to be limited by the EPA to a seed increase registration, but would not be regulated by APHIS.

Insecticide Use

DAS-81419-2 soybean expresses Cry1Ac and Cry1F which are active against lepidopteran pests and could reduce the localized use of insecticides for these pests. If DAS were to seek and obtain EPA registration for commercial use in the U.S., adoption of DAS-81419-2 soybean would be expected in areas where lepidopteran pest pressure exceeds economic thresholds. While there is a potential for reduced insecticide use with DAS-81419-2 soybean, any potential reduction is unlikely to negatively impact the overall environment, and any effects would likely be beneficial. Accordingly, no adverse impacts from insecticide use are expected from a determination of non-regulated status.

Herbicide Use

With production of seed only, DAS asserts that the seed growers would likely use herbicides that are listed in the No Action Alternative (personal communication, L. Han, DAS, 2013). The use of glufosinate would be unlikely, since the herbicides used for past seed increases have been adequate for the soybean seed production process. Additionally, the glufosinate resistant variety was designed for use in fields where glyphosate resistant weeds are a significant issue (Dow-Agrosciences, 2011) and other herbicides may have either more flexibility for acceptable weed height at application to attain control, and other herbicides may better target the more important weeds, (M. Krieger, DAS, personal communication, 2013) or the others are possibly more economical (see Appendix 1). Thus, no changes in herbicide applications from the No Action alternative are expected.

Herbicide resistant soybeans were grown on 93% of the total U.S. soybean acreage in 2012 (USDA ERS, 2012b). Glufosinate ammonium is registered by the U.S. EPA for use on soybeans; glufosinate resistant soybeans have been available to growers since 1996. As use of herbicide resistant soybeans is common practice for growers in the U.S., impacts under the preferred alternative are the same as under the no action alternative. No action by EPA is necessary to approve a new label for the use of glufosinate on the DAS-81419 soybean, and the label would be the same as that for Liberty soybean varieties.

Production Methods

DAS-81419-2 soybean is agronomically equivalent to commercial soybean (Petition 12-272-01p a2 Sections 7, 8). Thus, no changes in production methods are expected under the Preferred Alternative.

Refugia Required by EPA

EPA will not set requirements for refuge acres for *Bt* susceptible insects when planting DAS-81419 soybean for seed, since the EPA has accepted DAS' proposal that the total acreage of plantings for seed production will be maintained at reduced levels with reference to existing soybean or cotton acreage. Consequently, with small plantings, there will be little selection pressure on lepidopteran populations for new resistance to Cry 1Ac and Cry 1F. Further, the pyramided trait reduces the potential for development of resistance to the Bt Cry proteins (L.Han, 2013, personal communication). Planting limits of 20,000 acres per county were accepted for soybean growing areas without cotton, 10,000 acres for soybean growing areas with at 25,000 or less soybean acres, and 1,000 acres in cotton growing areas where soybean has 25,000 acres or greater (US-EPA, 2013e).

4.2.3 Soybean Seed Production

While no published estimates of acreage of soybean seed production in the US are known to USDA-APHIS, estimates can be made of minimal acreage needed to plant U.S. commodity soybean[5]. From typical current values APHIS estimates that at least 1.58 million acres of soybean seed are minimally required to produce sufficient soybean seed for planting of the U.S. soybean commodity.

4.2.3.1 No Action Alternative: Soybean Seed Production

Under the No Action alternative, any seed production of DAS-81419-2 would require notification or permit under APHIS. Accordingly, activities would be highly limited in scope. No change to current soybean seed production practices is expected.

4.2.3.2 Preferred Alternative: Soybean Seed Production

Under the Preferred Alternative, planting of DAS-81419-2 soybean would not be regulated by APHIS. However, current management practices for the production of high quality seed, such as those set forth by AOSCA, would also be used for DAS-81419-2 soybean. Land use requirements and restrictions on other crops cultivated specified by AOSCA or state certifying agencies would be followed (See Section 2.1.3). Isolation distances beyond those needed to prevent mechanical mixing are not specified under the Federal Seed Act (USDA, 2012h), though some state regulations do specify isolation distances (See Section 2.1.3). As earlier noted, DAS plans to continue soybean seed production using contracted acres in the same areas in which that work is currently accomplished.

Accordingly, the Preferred Alternative would have no impact on seed production practices.

4.2.4 Organic Soybean Production

Organic production plans prepared pursuant to the NOP include practical methods to prevent the unintended presence of GE materials. Typically, organic growers use multiple methods to prevent unwanted material from entering their fields, many of them following the same system utilized for the cultivation of certified seed under the AOSCA procedures. These include planting organic seed only, planting at times earlier or later than neighbors, and using field isolation practices (NCAT, 2003).

This analysis is based on the premise that producers of non-GE soybean who sell products to sensitive markets (e.g., organic or some export markets) use practices that protect their crop from unwanted substances. As discussed in sections 2.1.3 and 2,1,4, specialty markets have specific

[5] Assuming a seeding rate of 125,000 seeds per acre, 2500 seeds per pound, then about 50 pounds of seed might be needed for an average field. If 76 million acres are planted, then 3.8 billion pounds of seeds for planting are needed. If 42 bushels of seed were the average production of soybean seed then this would be a rate of 2400 pounds per acre. The seed production could be met by total weight of seed needed divided by the weight produced per acre (3.8 billion #/ 2400#/acre).

requirements, and growers receive a premium for their products (McBride and Greene, 2008). Thus, the expectation that specialty growers observe standard protective practices is reasonable.

4.2.4.1 No Action Alternative: Organic Soybean Production

The availability of soybean seed developed for organic production is expected to remain the same under the No Action Alternative. Under USDA and U.S. EPA regulation, DAS-81419-2 soybean acreage would be limited to a small percentage of U.S. soybean growing acreage, and company activities would be limited. No changes to organic soybean production are expected.

4.2.4.2 Preferred Alternative: Organic Soybean Production

Agronomic practices employed to produce organic soybean would remain unaffected by selection of the Preferred Alternative. 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 (Ronald and Fouche, 2006; USDA-AMS, 2011; USDA-AMS, 2012). However, certain markets or contracts may have defined thresholds (The Non-GMO Project, 2012).

When compared to other GE varieties of soybean, DAS-81419-2 soybean should not present any new and different issues and impacts for organic and other specialty soybean producers and consumers. As detailed in Section 2.4.1., organic producers employ a variety of measures to manage identity and preserve the integrity of organic production systems (NCAT, 2003). Agronomic tests conducted by DAS found DAS-81419-2 soybean substantially equivalent to the non-GE control variety (12-272-01p a2, Section 8). Therefore, pollination characteristics of DAS-81419-2 soybean are expected to be similar to other soybean varieties currently available to growers. Given the largely self-fertilized nature and the limited pollen movement of soybean (Caviness, 1966; OECD, 2000b; Ray et al., 2003; Abud et al., 2007; Yoshimura, 2011), and that 93% of soybeans grown in the U.S. are GE (USDA NASS, 2012a), no impact on organic farmers is expected following a determination of nonregulated status of DAS-68416-soybean when organic soybeans are produced in accordance with agronomic practices designed to meet National Organic Standards.

Organic soybean farmers would continue to use 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. Acreage devoted to organic soybean production is small relative to that of GE varieties and has remained relatively steady, only fluctuating between 122,217 to 125,621 acres between 2005 and 2008 (USDA ERS, 2010a; USDA ERS, 2010b); this amount would not be expected to change under the No Action Alternative.

For these reasons, a determination of nonregulated status of DAS-81419-2 will not result in adverse impacts to organic soybean production.

4.3 Physical Environment

4.3.1 Soil Quality

The USDA National Resource Conservation Service has identified significant reductions in the loss of soil from croplands in the U.S., finding that total soil loss on highly erodible croplands and non-highly erodible cropland decreased by 39.2% from 1982 to 2003 (USDA-NRCS, 2006c). Herbicide-resistant soybean has contributed to this reduction in soil loss through a shift towards conservation tillage and the use of cover crops where the cultivation of herbicide-resistant varieties and attendant use of post-emergent herbicides replaces manual weed control techniques (Cerdeira and Duke, 2006; University of Illinois, 2006). Other benefits to soil of conservation tillage or no-till systems include lower dust generation, decreased fertilizer and pesticide use, reduced fuel and labor costs, and conservation of soil moisture.

4.3.1.1 No Action Alternative: Soil Quality

Under the No Action Alternative, DAS-81419-2 soybean would remain regulated by APHIS and restricted under its EPA registration. No impacts to soil quality are expected.

4.3.1.2 Preferred Alternative: Soil Quality

Under the Preferred Alternative, DAS-81419-2 soybean would not be regulated by APHIS. No changes to agronomic practices are required for cultivation of DAS-81419-2 soybean. There are no expected increases in land acreage, cultivation, planting, pesticide use, fertilizer use, harvesting, or volunteer control compared to planted soybean. Agronomic practices currently used for commercially available soybean seed production will also be used by growers of DAS-81419-2 soybean, should it be made available for commodity production, for which there are no announced plans at present. Glufosinate ammonium is weakly adsorbed to and is highly mobile in soil. The herbicide undergoes rapid microbial degradation in soil, and has a short soil residual half-life of seven days (WSSA, 2007).

DAS-81419-2 soybean provides resistance to glufosinate ammonium. As glufosinate ammonium is registered by the EPA for use on soybean, growers could apply glufosinate ammonium to DAS-81419-2 soybean in those situations where its use was most economically appropriate. As noted in the discussion of seed production, however, the use of glufosinate for that use may be infrequent and inconsequential.

Agronomic performance for DAS-81419-2 soybean is equivalent to conventional soybean (12-272-01p a2, Section 8); thus agronomic practices will be no different between DAS-81419-2 soybean and conventional varieties. No-till and reduced tillage systems adopted by soybean growers will likely continue with cultivation of DAS-81419-2 soybean. These systems have resulted in reduced surface water run-off and soil erosion (Locke et al., 2008).

No adverse impacts are expected for the soil microbial populations that maintain soil quality and are associated with conventional soybean cultivation. In particular, mutual symbiotic relationships between soybean and the *Rhizobiaceae* and *Bradyrhizobiaceae* are unlikely to be negatively affected. Cry proteins from *B. thuringiensis* are rapidly degraded in a variety of soil types and these proteins do not accumulate (Head et al., 2002; Mendelsohn et al., 2003; Dubelman et al., 2005). For some Cry proteins residual amounts of Bt proteins may persist for extended periods (Feng et al., 2011), but at biologically insignificant quantities. The EPA concluded that available data indicates that there should be minimal short term accumulation of Cry1F and Cry1Ac protein in agricultural soil (US-EPA, 2005b). The EPA risk assessment for support of a Section 3 seed increase registration for DAS-81419-2 likewise concludes that Cry proteins have a short half-life, and are unlikely to affect soil invertebrates or significantly impact soil microbiota (US-EPA, 2013b).

Based on the above, no negative impacts to soil quality are expected from deregulation of DAS-81419-2 soybean.

4.3.2 Water Resources

Because drought is the most damaging abiotic stress factor, irrigation is the most important factor in soybean production (CAST, 2009). The majority of the irrigated soybean acreage occurs in the western Corn Belt and mid-southern regions of the U.S. (USDA NASS, 2013). A recent agricultural practice aiming to reduce water stress is early planting of early-maturing soybeans groups II-V. This practice avoids a large portion of the drought period during the most sensitive reproductive stages of this crop (CAST, 2009).

4.3.2.1 No Action Alternative: Water Resources

Under the No Action Alternative, DAS-81419-2 production would be limited to soybean-growing states where it is approved for regulated release by APHIS and EPA. The use of DAS-81419-2 in this region under the No Action Alternative is unlikely to change any water use requirements.

4.3.2.2 Preferred Alternative: Water Resources

Under the Preferred Alternative, DAS-81419-2 soybean would not be regulated by APHIS. As production of DAS-81419-2 soybean does not require any changes to standard soybean cultivation practices (12-272-01p a2, Section 8), a determination of nonregulated status would not change the use of irrigation practices. Needs for additional volumes of water are not expected; DAS-81419-2 soybeans will likely replace acres already used for soybean production.

In regard to water quality, planting of DAS-81419-2 soybean may locally reduce the amount of insecticides applied to control lepidopteran pests. To the extent that DAS-81419-2 soybean reduces the application of insecticides, it could reduce chemical runoff into surface water and groundwater.

DAS-81419-2 soybean provides resistance to glufosinate ammonium, and glufosinate ammonium is registered by U.S. EPA for use on soybeans. EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). When EPA registers a pesticide, it approves product composition and label language that provides precautionary information and use directions. As part of the registration process, the Agency also approves one or more particular uses for the pesticide product. No changes to the currently authorized use of glufosinate on soybean are proposed.

Glufosinate ammonium is highly water soluble, relatively non-persistent in soil, persistent in water, and highly mobile (EPA, 2000). Based on laboratory data, EPA has determined that glufosinate-ammonium is not volatile (EPA, 2000). Adsorption to suspended solids and sediment has been observed to be low to high (EPA, 2000). Biodegradation occurs in anaerobic water bodies with a half-life greater than 64 days (EPA, 2000). Surface water may be impacted by glufosinate ammonium residues transported by runoff, but EPA label restrictions require actions be taken to minimize impacts, such as not applying the herbicide when rainfall is forecasted to occur within 48 hours (EPA, 2007c). Glufosinate ammonium has not been found to be a source of impairment for any water body designated as impaired under section 303(d) of the Clean Water Act (EPA, 2008b). Glufosinate ammonium may leach to groundwater under certain conditions (such as soils with high permeability and shallow groundwater), but generally, because it degrades, it is rarely found deeper than 15 centimeters (approximately 6 inches) from the soil surface (EPA, 2008b), minimizing its potential to enter groundwater. Glufosinate ammonium does not bioaccumulate in fish and has low potential for bioconcentration in aquatic organisms (EPA, 2008b).

Based on the above, DAS-81419-2 soybean is not expected to impact water quality or water resources. Accordingly no adverse impacts to water resources are expected under the Preferred Alternative.

4.3.3 Air Quality

Traditional agricultural practices have the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from agricultural burning, tillage, traffic and harvest emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer (USDA-NRCS, 2006a; Aneja et al., 2009). Other greenhouse gas (GHG) emission sources associated with agricultural production include equipment emissions (contributing carbon monoxide, nitrogen oxides, and reactive organic gases), particulate matter, sulfur oxides, and direct emissions of N2O from fertilizer application (US-EPA, 2010a).

4.3.3.1 No Action: Air Quality

Under the No Action Alternative, DAS-81419-2 soybean would remain regulated by APHIS and subject to limited acreage under EPA seed increase registration. No impacts to air quality are expected.

4.3.3.2 Preferred Alternative: Air Quality

No impacts are expected to air quality under this alternative. Based on its agronomic characteristics, cropping practices for DAS-81419-2 soybean will not differ from those used for conventional soybean (12-272-01p a2, Section 8.4).

Where infestations of lepidopteran pests exceed economic thresholds, the use of insecticides on these fields of DAS-81419-2 soybean could be less than that for conventional soybeans. Areas where DAS-81419-2 soybean is planted may receive reduced insecticide applications. Though localized areas may realize some benefit, nationwide impact is not expected to be significant.

Glufosinate ammonium has a low volatility and a short residual half-life of about 7 days. (WSSA, 2007). Thus, glufosinate ammonium is not considered an atmospheric contaminant with potential impacts to air quality. No adverse environmental impacts to air quality are expected under the Preferred Alternative.

4.3.4 Climate Change

The adoption of herbicide-resistant soybean has reduced air emissions, including GHG, following the increased adoption of conservation practices (NRC, 2010). Conservation practices, including conservation tillage associated with GE soybean production, requires fewer tractor passes across a field (Baker et al., 2005; USDA-NRCS, 2006a). This results in a decrease in dust generation and tractor emissions (Baker (Baker et al., 2005; USDA-NRCS, 2006a). Surface residues and untilled organic matter physically hold the soil in place thus decreasing wind erosion of soils and pesticide drift in wind-eroded soils (Baker et al., 2005; USDA-NRCS, 2006a). Reduced tillage also increases sequestration rates of potential carbon emissions from soils (Causarano et al., 2006).

4.3.4.1 No Action Alternative: Climate Change

Under the No Action Alternative, environmental releases of DAS-81419-2 would be limited under APHIS regulation and EPA registration. Accordingly, no impacts to climate change are expected.

4.3.4.2 Preferred Alternative: Climate Change

DAS-81419-2 soybeans will be managed similarly to other soybeans grown for seed, with herbicides and insecticides used as needed. While some decrease in insecticide use could occur due to the lepidopteran resistance conferred by DAS-81419-2, there is unlikely to be a measurable change in agricultural practice that might affect climate change. No significant change in herbicide use is expected with the addition of glufosinate resistance in DAS-81419-2, as herbicides are already applied to the majority of soybean acres produced in the U.S. today. Agronomic practices associated with soybean production such as tillage, cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment will be the same for DAS 81419-2 soybean as for commercial soybean today.

Localized areas may experience a decrease in certain insecticide use on DAS-81419-2 soybeans, however, the cultivation, agronomic practices, and/or agricultural land acreage associated with growing DAS-81418-2 soybeans is not expected to have any overall negative adverse impact on climate change.

4.4 Biological Resources

4.4.1 Animal Communities

Plants genetically engineered to express Cry proteins have a history of safe use in the U.S. Since the mid-1990s, corn and cotton lines that express these proteins have been commercialized without deleterious impacts on non-target organisms (Mendelsohn et al., 2003; EPA, 2008a; USDA-APHIS, 2011c). The use of transgenic cotton and maize producing Cry1 proteins, including Cry1F and Cry1Ac, has been shown to reduce the use of broad spectrum insecticides without significant impacts on the diversity of non-target insects (Romeis et al., 2006; Marvier et al., 2007; Wolfenbarger et al., 2008; Higgins et al., 2009; Naranjo, 2009).

DAS-81419-2 similarly demonstrates low probability of potential harm to the environment (12-272-01p a2, Section 9). Toxicity of *Bt* proteins results from specific activation through proteolytic cleavage at an active site in the protein core; *Bt* proteins must bind to specific receptors in the gut membrane, leading to pore formation and, ultimately, death of the larva (Arora et al., 2007). Most *Bt* proteins require an alkaline environment to remain stable. (Arora et al., 2007; Bravo et al., 2011). Because Cry1 receptors are not present in non-target birds and mammals, this insecticidal protein is not expected to adversely affect vertebrate organisms (Pigott and Ellar, 2007).

Bt crops exhibit high specificity of the *Bt* toxins, which minimize the potential toxic effects on non-target insects. The use of insecticides, other than *Bt* crops, may affect non-target organisms including honey bees, soil invertebrates, or culturable microbial flora (EPA, 2005c).

Soybean production systems in agriculture are host to many animal species. Mammals and birds may use soybean fields and the surrounding vegetation for food and habitat throughout the year. There is ample information indicating that Cry *Bt* toxins do not negatively affect mammals or birds (Betz et al., 2000). Invertebrates can feed on soybean plants or prey upon other insects living on soybean plants, as well as in the vegetation surrounding soybean fields. Because the Cry proteins expressed by *Bacillus thuringiensis* are very specific for Lepidoptera, other arthropods are not likely to be affected (van Frankenhuyzen, 2009).

4.4.1.1 No Action Alternative: Animal Communities

Under the No Action Alternative, DAS-81419-2 soybean would continue to be regulated by USDA and EPA, and therefore produced on limited acreage. Accordingly, no negative impacts to animal communities are expected.

4.4.1.2 Preferred Alternative: Animal Communities

Under the Preferred Alternative, agronomic practices used to produce DAS-81419-2 soybeans will be the same as those used to produce other conventionally grown GE and non-GE soybeans. DAS-81419-2 soybean production will not change total acreage or any cultivation practices for conventional, GE, or non-GE soybean production. The Cry1Ac, Cry1F and PAT proteins expressed in DAS-81419-2 soybean are not derived from organisms that are known for pathogenic or toxic effects and have an established history of safe use in multiple GE crops. Cry proteins are specific for insects, and no work has shown effects on other groups of animals when animal exposure occurs within the expected range of environmental concentrations. The PAT protein present in DAS-81419-2 soybean is equivalent to that produced in other GE crops that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (USDA-APHIS, 1996; USDA-APHIS, 2001; USDA-APHIS, 2004; USDA-APHIS, 2005). The food and feed safety of the protein was reviewed as part of these previous assessments and was shown to present no significant food or feed safety risk. A biotechnology consultation on the PAT protein as expressed in glufosinate resistant soybean lines was conducted by U.S. FDA in 1998 and does not require additional evaluation

(FDA, 1998a; FDA, 1998b). DAS has also submitted DAS-81419-2 soybean to FDA for a food and feed safety and nutritional evaluation. On February 7, 2014, FDA concluded the consultation stating that they have no further questions concerning food and feed derived from DAS-81419-2 soybean.

Cry1Ac has an existing exemption from the requirement of a tolerance in all food and feed commodities granted by EPA in 1997, as published in the Code of Federal Regulations (EPA, 2009a). Cry1F has an exemption from tolerance for cotton and corn (EPA, 2012a; EPA, 2012b). The FDA previously reviewed data on the Cry1Ac and Cry1F proteins as present in DAS-21023-5 and DAS-24236-5 (FDA, 2004a; FDA, 2004b). The FDA assessed the safety and nutritional data provided by DAS with regards to the use of the cotton in food and feed and concluded that they have no further questions (FDA, 2004a; FDA, 2004b). DAS petitioned the U.S. EPA for an exemption from tolerance for Cry1F in soybean as a component of the application for registration for DAS-81419-2 soybean and tolerance for Cry1F proteins in soybean has been issued by the EPA (Federal Register 79, 8293, February 12, 2014). Additionally, a biotechnology consultation on the Cry1Ac protein in soybean was completed for MON 87701 soybean in 2010 and does not require additional evaluation by the FDA (USFDA 2010, BNF 000119).

DAS completed tests and produced data for the required and voluntarily developed indicator and host range species on WideStrike™ cotton, which contained both Cry proteins. Supplementary field data from observations of WideStrike cotton compared to non-Bt cotton showed no environmental impacts. EPA concluded that the levels of Cry1F and Cry1Ac protein in the cotton variety would not pose unreasonable adverse effects to cotton agroecosystem flora and fauna (US-EPA 2005. Available data also indicate that there should be minimal short term accumulation of Cry1F and Cry1Ac protein in agricultural soil. In addition, no adverse effect on listed endangered and threatened species listed by the US Fish and Wildlife Service was expected from the WideStrike™ cotton registration. More recently, EPA has approved the previous toxicity testing done for WideStrike cotton as adequate for the similar levels of Cry proteins expressed in DAS-81412-2 (US-EPA, 2013b).

EPA at the time of registration for WideStrike cotton stated that the Agency was not aware of identified significant adverse effects of Cry1F and Cry1Ac proteins on the abundance of non-target beneficial organisms in any population in the field, whether they were pest parasites, pest predators, or pollinators (US-EPA 2005). Field census data submitted to the Agency for Widestrike cotton showed minimal to undetectable changes in the beneficial insect abundance or diversity. In cotton fields densities of predatory and non-target insects were generally higher on Bt crops than non-Bt crops primarily because the Bt crops were not subjected to the same number of applications of nonspecific pesticides.

Research has shown no direct adverse effects on insectivorous insects in field and laboratory studies with GE plants expressing Cry proteins (Romeis et al., 2006; Marvier et al., 2007; Wolfenbarger et al., 2008; Naranjo, 2009). DAS conducted field studies to determine the potential for adverse effect on non-target organisms and found that, across study sites, arthropod populations associated with DAS-81419-2 soybeans were similar to non-GE near isogenic soybean. Based on this data, no adverse effects from cultivation of DAS-81419-2 soybean, expressing the Cry1F, Cry1Ac, and PAT proteins, are expected.

EPA's Environmental Risk Assessment and Biotechnology Risk Assessment Document for both Bt proteins expressed in soybean was bridged to DAS' Non-Target Arthropod Field study, and the previously reviewed toxicity studies of select nontarget organisms in the BRAD for WideStrike cotton Bt proteins, and concluded that Cry1F and Cry1Ac proteins are not expected to have adverse effects on mammals, birds, plants, freshwater and estuarine/marine fish and invertebrates, nontarget insects and other invertebrate species at the environmentally effective concentration (US-EPA, 2013b) (US-EPA, 2014). From a recent review of literature related to the two Bt proteins, APHIS agrees that the absence of adverse effects on nontarget arthropods is consistent with no likely impacts.

Therefore, potential impacts from deregulation of DAS-81419-2 soybean on animal communities would be unchanged from the No Action Alternative.

4.4.2 Plant Communities

Plant communities are varied and adapted to local climate and soil, as well as the frequency of natural or human-induced disturbance (Clements et al., 2004). Non-crop vegetation in soybean fields is limited by farmers' cultivation and weed control practices. Plant communities adjacent to soybean fields commonly include other crops, borders, hedgerows, windbreaks, pastures, and other natural vegetation. The majority of U.S. soybean acres is planted with GE herbicide-resistant soybean cultivars, and genetically engineered traits do not change the adaptation to the various agronomic environments in which soybean can be produced.

Agricultural practices affect plant communities by exerting selection pressures that influence the type and composition of plants present in a community. Preparation of fields for planting of crops removes other plants that compete for light and nutrients. Natural selection in frequently disturbed environments enables colonization by plants exhibiting early germination and rapid growth from seedling to sexual maturity, and the ability to reproduce sexually and asexually (Baucom and Holt, 2009). These weedy characteristics enable such plants to spread rapidly into areas undesired by humans.

Weeds are the most important pests in agriculture, competing for light, nutrients, and water and can significantly affect yields (Gibson et al., 2005; Baucom and Holt, 2009). Weeds commonly encountered in soybean production include water hemp, giant ragweed, common lambsquarters, and others. Agronomic practices common in soybean production, such as tillage and herbicide use, impart selection pressures on the weed community that can result in shifts in the relative importance of specific weeds (Owen, 2008). In aggressive tillage systems, weed diversity tends to decline and annual grasses and broadleaf plants are the dominant weeds; whereas, in no-till fields, greater diversity of annual and perennial weed species may occur (Baucom and Holt, 2009), . The most common weed management tactic in U.S. soybean production is to use herbicides and for soybean that is most frequently glyphosate.

Herbicide resistance occurs when a plant survives the application of an herbicide and reproduces, passing on its resistance to new generations. Herbicide-resistant weeds can become agronomically important as they out-compete crops and require additional resources to affect control. Weed species resistant to glyphosate are becoming more prevalent in crop production. For example, glyphosate-resistant Palmer pigweed (amaranth) is a major weed problem in the

Southeast U.S. although increasingly present in the Corn Belt, while glyphosate-resistant waterhemp is a problematic weed in Midwestern states (Culpepper et al., 2006) (Owen, 2008; Heap, 2013). In response, producers are diversifying weed management tactics in soybean production to include alternating crops resistant to different herbicide modes of action that are grown on the same field, alternating the herbicide modes of action used with the same crop, practicing more crop rotation, and increasing tillage to effect control of herbicide-resistant weeds (Owen et al., 2011). Weeds are developing resistance to multiple herbicides, but are also controlled with adjustments to standard practices, so as to include crop rotation and tillage (Owen et al., 2011) when overreliance on herbicides obviates such changes.

4.4.2.1 No Action Alternative: Plant Communities

Under the No Action Alternative, cultivation of DAS-81419-2 soybean would be under APHIS regulation and in limited acreage under EPA registration. No adverse impacts to plant communities are expected under this alternative.

4.4.2.2 Preferred Alternative: Plant Communities

A determination of nonregulated status of DAS-81419-2 soybean is not expected to affect plant communities. Risks to wild plants and agricultural productivity from weedy soybean populations are low, as volunteer soybean populations can be easily managed (Carpenter et al., 2002). Plant species that typically inhabit soybean production systems will be managed through the use of mechanical, cultural, and chemical control methods. The landscape surrounding a soybean field varies depending on the region. In certain areas, soybean fields may be bordered by other soybean fields (or any other crop) or may also be surrounded by woodland, rangelands, or pasture or grassland areas. These plant communities may be natural or managed plant habitats for the control of soil and wind erosion or allocated to serve as wildlife habitats.

Because DAS-81419-2 soybean contains resistance for applied glufosinate ammonium, growers could select this herbicide for use on DAS-81419-2 soybean. Any potential use would remain consistent with the per-application and per-year rates approved by EPA, and application would be in soybean growing areas where glufosinate ammonium may already be in use. As part of the registration of glufosinate use on soybeans, EPA considered the impact on plant communities (EPA, 2008b). In addition, 93 percent of soybeans today are treated with herbicides; (USDA ERS, 2012f) and in 2012, glufosinate was applied to as much as 4% of soybean acres (G.Orr, DAS, 2013). Thus, glufosinate will not be a new herbicide, and because this product is not likely to require the herbicide for seed production, no changes in impact on plant communities are expected from the introduction of glufosinate resistance in DAS-81419-2 soybean.

Based on the above, no negative impacts to plant communities are expected from deregulation of DAS-81419-2 soybean.

4.4.3 Gene Flow and Weediness

Two forms of gene flow can be evaluated: Vertical gene flow and horizontal gene flow. Vertical gene flow, or hybridization and associated introgression, is the movement of genes to sexually compatible relatives (Ellstrand, 2003; Quist, 2010). The soybean is considered self-pollinating, and has no wild relatives in the U.S. (OECD, 2000b; USDA-APHIS, 2013). Although some cross-pollination can occur, AOSCA identity protection practices have been found adequate to protect against such gene flow (OECD, 2000b; USDA-APHIS, 2013) . The only relatives of soybean are other varieties currently cultivated. In assessing the risk of gene introgression from MON 87769 soybean to its sexually compatible relatives, APHIS considered two primary issues: 1) the potential for gene flow and introgression to soybean relatives; and 2) the potential impact of introgression. Vertical gene flow is discussed below in the analysis of the Preferred Alternative.

4.4.3.1 No Action Alternative: Gene Flow and Weediness

Under the No Action Alternative, DAS-81419-2 would be grown under APHIS and EPA regulatory authority. Any gene flow from commercially available GE cultivars to non-GE soybean cultivars is expected to remain unchanged from current conditions.

4.4.3.2 Preferred Alternative: Gene Flow and Weediness

Under the Preferred Alternative, no impact on other soybean varieties or production systems is anticipated due to gene flow or weediness characteristics of DAS-81419-2 soybean. Agronomic properties of DAS-81419-2 soybean have demonstrated equivalence to conventional soybean (Petition, Section 8), indicating DAS-81419-2 soybean does not have increased weediness potential compared to conventional soybean.

As discussed in Section 3.5.3, soybean is considered a highly self-pollinated species, with heavy seeds that are not naturally dispersed, not transported by animals, and lack dormancy. The insect resistance traits of DAS-81419-2 soybean do not alter its reproductive characteristics, as the genes encoding Cry1F, Cry1Ac, and PAT proteins do not impart any reproductive advantage that would increase the probability of weediness.

A measure of the reproductive capacity of plants that are propagated by seed is the number of seeds that are produced and the germination and viability of those seeds. Overall, DAS-81419-2 soybean produced similar percentages of viable seed when compared to controls (12-272-01p a2, Section 8.3). These results on growth characteristics, seed production and germination indicate that DAS-81419-2 soybean is substantially equivalent to conventional soybean (12-272-01p a2, Section 8). There is no indication that DAS-81419-2 soybean possesses a selective advantage that would result in increased weediness: DAS-81419-2 soybean lacks the ability to persist as a troublesome weed and there will be no direct impact on current weed management practices for soybean cultivation.

The PAT protein is unlikely to increase the weediness potential of any plant species, as demonstrated by previous agency determinations (USDA-APHIS, 1996; USDA-APHIS, 2001; USDA-APHIS, 2004; USDA-APHIS, 2005). The agency has reached the same determination regarding *Bt* proteins Cry1Ac and Cry1F (USDA-APHIS, 1995; USDA-APHIS, 2004; USDA-APHIS, 2011a). Based on all the factors discussed above, a determination of nonregulated status of DAS-81419-2 soybean will not impact other soybean varieties through gene flow or introgression, nor will it present a greater risk of weediness or invasive characteristics. Deregulation of DAS-81419-2 soybean is not expected to have an effect on gene movement.

4.4.4 Microorganisms

An adequate soil population of nodulation-inducing bacteria is an important part of soybean production. These bacteria must be supplied if a soybean crop has not been recently grown on the planted field (Section 4.3.2). Although the bacteria persist for several years in soil, their numbers may not be sufficient to insure adequate nodulation (Bottomley, 1992). Various commercial sources of inoculants such as multiple strains of *Bradyrhizobium* can be spread in soybean fields around the time of planting, many with similar results (Beuerlein, 2005). From one season to the next, the inoculated bacteria in soil may change characteristics or phenotypes and diverge from traits expressed by the original culture (Farooq and Vessey, 2009).

Bt corn and cotton are known to produce exudates of Cry proteins that can be detected in the soil (Sun et al., 2007; Icoz et al., 2008; Lawhorn et al., 2009). The presence of these toxins, ubiquitous in the soil under normal conditions, have not shown a negative effect on soil microbes (Blackwood and Buyer, 2004; Baumgarte and Tebbe, 2005; Icoz et al., 2008) or on litter decomposition processes (Zurbrügg et al., 2010). Additionally, Cry proteins derived from *Bt* are rapidly degraded in a variety of soil types and the proteins typically do not accumulate in soil (Head et al., 2002; Mendelsohn et al., 2003; Dubelman et al., 2005).

Soil type has a large effect on the microbial community and availability of Cry proteins (Blackwood and Buyer, 2004). Certain Cry proteins may adsorb rapidly to clay minerals, on the clay-sized fraction of soil, on humic soils, and on complexes of montmorillonite-humic acids aluminum hydroxypolymers (Saxena and Stotzky, 2001). Some field studies on the persistence of Cry proteins released by GE plants showed that Cry proteins do not persist and degrade rapidly in soil, although a small fraction may be protected from biodegradation in the plant matrix or bound on surface-active particles (Icoz et al., 2008).

4.4.4.1 No Action Alternative: Microorganisms

DAS may continue confined trials under both APHIS and EPA regulations, so that the limited production of DAS-81419-2 soybean under the No Action Alternative is not expected to have an effect on soil microbes.

4.4.4.2 Preferred Alternative: Microorganisms

A determination of nonregulated status of DAS-81419-2 soybean would not change the effects of planting DAS-81419-2 soybean on soil organisms. Because of the universal existence of proteases in microbes, proteins only exceptionally persist in the environment (Satyanarayana and Getzin, 1973). The Cry1Ac protein has been used in sprayable Bt formulations for over half a century and is present in both WideStrike® cotton event DAS-21023-5 (also described as 3006-210-23) and Bollgard® cotton event MON 531, as well as a discontinued corn event: DBT418Cry1Ac corn) (Mendelsohn et al., 2003; Sanahuja et al., 2011). The Cry1F protein has also been used in sprayable Bt formulations and is present in WideStrike® cotton event DAS-24236-5 (also described as 281-24-236), as well as, in Herculex® and SmartStax®corn (event TC1507) (Mendelsohn et al., 2003; Sanahuja et al., 2011). Laboratory experiments have shown that both Cry1Ac and Cry1F are quickly inactivated, and field studies have shown no accumulation of the proteins as a result of continuous planting of crops containing these proteins (Head et al., 2002; Herman et al., 2002; Shan et al., 2008). It has further been suggested that the

Cry proteins in general are unlikely to represent a significant risk in the soil environment (Icoz et al., 2008).

While *Bt* exudates can be found in the soil when GE crops that produce *Bt* toxins are grown, this has not had a negative effect on soil microbes in corn or cotton systems. Planting of DAS-81419-2 soybean is anticipated in current soybean-growing areas. These are areas where Bt corn and Bt cotton that express the two cry proteins are currently grown today with no discernable impacts. Consequently, no negative impacts to soil microorganisms are expected under the Preferred Alternative.

4.4.5 Biodiversity

Many studies over the last 10 years have investigated the differences in biological diversity and abundance between GE and non-GE crop fields, particularly those GE crops that are resistant to insects (e.g., *Bt* crops) or herbicides (e.g., glyphosate- or glufosinate ammonium-resistant). Some studies have found negligible to modest decreases in biological diversity or abundance attributed to crops genetically engineered to produce insecticidal proteins or tolerate herbicide application for weed management (Ponsard et al., 2002; Pilcher et al., 2005). Other studies compared *Bt* crops to non-GE crops that were unsprayed or sprayed with insecticides and found that *Bt* crops do not cause any overall changes in arthropod abundance or diversity (Torres and Ruberson, 2005; Romeis et al., 2006; Chen et al., 2008; Wolfenbarger et al., 2008). A review of over 360 research papers concluded that there is no evidence of landscape-level effects from *Bt* crops (Carpenter, 2011), other than area-wide reduction in pest populations under particular circumstances (Hutchison et al., 2010). Compared to the use of broad-spectrum insecticides in agriculture, *Bt* crops may increase biological diversity in agroecosystems by reducing broad-spectrum insecticide use, thus allowing more non-target species to survive (Romeis et al., 2006; Marvier et al., 2007). GE crops may generally increase the productivity of cultivated lands, so biodiversity is protected because additional land is not needed for the same volume of crop production (Raven, 2010).

The use of broad-spectrum insecticides imposes one of the most severe constraints for biological diversity in crops (Naranjo, 2005). One of the benefits of *Bt* crops has been the reduction of broad-spectrum insecticide use during production. The use of GE crops producing the Cry proteins has been shown to reduce the use of broad spectrum insecticides without significant impact on the diversity of non-target insects (Romeis et al., 2006; Marvier et al., 2007; Wolfenbarger et al., 2008; Higgins et al., 2009; Naranjo, 2009).

The presence and release of *Bt* toxins from the aboveground and below ground parts of *Bt* plants may influence microbial diversity. *Bt* toxin has been found to be present in every major part of *Bt* plants (Sivasupramaniam et al., 2008). However, the presence of *Bt* toxin in the soil may not influence microbial diversity or activity. Studies regarding the effects of *Bt* on non-target soil microorganisms in *Bt* maize and *Bt* cotton cultivation found that microbial biodiversity and activity were no different than that of their non-*Bt* counterparts (Shen et al., 2006; Icoz et al., 2008).

4.4.5.1 No Action Alternative: Biodiversity

Under the No Action Alternative, DAS-81419-2 soybean and its progeny would continue to be regulated by USDA-APHIS under 7 CFR part 340, and production restricted under U.S. EPA Section 3 Seed Increase Registration. Given the limited acreage and regulated plantings, no impacts to biodiversity are expected under this alternative.

4.4.5.2 Preferred Alternative: Biodiversity

A determination of nonregulated status of DAS-81419-2 soybean will not change the cultivation, agronomic practices, or agricultural land acreage associated with growing soybeans. Cry and PAT proteins have a history of safe use, with numerous published studies demonstrating that *Bt* crops have not had a negative impact on non-target organisms and soil activity.

In 2005, the EPA in the BRAD for WideStrike cotton with the two *Bt* genes, concluded that " in general invertebrate abundance studies in Bt crop fields do not show a shift in biodiversity, except in cases where the predators are dependent on the pest insect as prey (US-EPA, 2005)".

> *"In contrast, treatment with chemical pesticides, when studied, had significant effects on the total numbers of insects and on the numbers within the specific groups. To date the available field test data show that compared to crops treated with conventional chemical pesticides, the transgenic crops have no detrimental effect on the abundance of non-target insect populations. However, annual insect monitoring of representative commercial fields will continue for long term biodiversity effects assessment (US-EPA, 2013)."*

There is a potential benefit to biodiversity at the regional level due to a reduced use of broad spectrum insecticides where DAS-81419-2 soybean is planted (USDA-ERS, 2006; Wolfenbarger et al., 2008). A determination of nonregulated status for DAS-81419-2 soybean is not expected to have negative impacts on biodiversity.

4.5 Human Health

Human health concerns surrounding GE products center on possible toxic, nutritional, or allergic effects. Insecticidal Cry proteins from *B. thuringiensis* have a long history of safe use in food crops (EPA, 2001). Their modes of action are highly specific within narrow ranges of related insect species; *Bt* toxins have no mechanism of action on mammals or other vertebrates (Pigott and Ellar, 2007; Bravo et al., 2011).

The US-EPA requires seed registrants to submit tests of potential toxicity and allergenicity of the GE proteins in PIPs before they can be approved for human consumption. Tests conducted for adverse mammalian impact from ingesting Cry proteins have been negative, even at extremely high doses (Wu, 2006). The toxicity of insecticidal *Bt* proteins depends on binding to specific receptors present in the insect midgut (Pigott and Ellar, 2007; Bravo et al., 2011). With regard to the specific Cry proteins produced in *Bt* crops, research demonstrates that this specificity limits each protein's toxic effect to certain insect species (Pigott and Ellar, 2007; Bravo et al., 2011).

Because Cry1Ac and Cry1F are pesticidal substances, EPA has responsibility for setting tolerances or issuing exemptions from the requirement of a tolerance for food and feed products. Tolerance exemptions are already in place for Cry1Ac in all crops and Cry1F in corn and cotton (EPA, 2009a; EPA, 2012a). DAS has submitted an exemption from tolerance for Cry1F in soybeans, including toxicology and allergenicity data on the Cry1F protein. The amino acid sequences of both the Cry1Ac and Cry 1F protein expressed in DAS-81419-2 soybean are identical to those expressed in WideStrike® Cotton (12-272-01_p2, Section 6.1). EPA also conducted reviews of the food and feed safety of Cry1F and Cry1Ac proteins for registration of WideStrike® cotton comprising DAS-21023-5 and DAS-24236-5. The EPA determined that there is a reasonable certainty that no harm to human health will result from exposure to Cry1F and Cry1Ac and that no unreasonable adverse effects on the flora and fauna of the cotton agroecosystems are expected (EPA, 2005b). Another assessment of DAS-81419-2 concludes that no harm will result from aggregate exposure of the US population to the two Cry proteins or genetic material for its expression (US-EPA, 2013d).

EPA also has regulatory oversight for establishing safety of the PAT protein responsible for herbicide resistance. Based on a review of toxicity and digestibility data, the EPA has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the PAT protein and the genetic material necessary for its introduction; EPA has consequently established an exemption from tolerance requirement pursuant to FFDCA section 408(j)(3) for PAT and the genetic material necessary for its production in all plants (EPA, 1997).

The PAT protein present in DAS-81419-2 soybean is equivalent to that produced in other GE crops that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act (USDA-APHIS, 1996; USDA-APHIS, 2001; USDA-APHIS, 2004; USDA-APHIS, 2005). The food and feed safety of the protein was reviewed as part of these previous assessments and was shown to present no significant food or feed safety risk. A biotechnology consultation on GE soybean expressing the PAT protein was conducted in 1998: the FDA reviewed the safety and composition data and determined that there were no further questions (FDA, 1998a; FDA, 1998b). DAS has also submitted its DAS-81419-2 soybeans to the FDA for a safety and nutritional evaluation and provided the results of the assessment when the FDA completed its review. On February 7, 2014, FDA concluded that it had no further questions about use of DAS-81419-2 in food or feed (BNF-000140).

4.5.1.1 No Action Alternative: Human Health

Under the No Action Alternative, any field production of DAS-81419-2 soybean will be confined by USDA by notification permit regulations and restricted by EPA permit regulations. Consumers are expected to have limited exposure to DAS-81419-2 soybean, and no impacts on human health are expected.

4.5.1.2 Preferred Alternative: Human Health

Under the Preferred Alternative, a determination of nonregulated status of DAS-81419-2 soybean by APHIS would not result in any negative impacts to human health when compared to the No Action Alternative. DAS-81419-2 soybean is compositionally equivalent to currently available soybeans on the market with the exception of Cry1Ac, Cry1F, and PAT protein expression (12-272-01p a2, Section 6, 7, 8). As discussed in Section 1.2, Bt corn and Bt cotton expressing variations of Cry1Ac or Cry1F have been cultivated for commercial use in the U.S. and other countries for more than a decade. Exemptions from tolerance have been established based on safety assessments demonstrating a lack of allergenicity and toxicity to mammals.

APHIS considers the voluntary FDA regulatory assessment in making its determination of the potential impacts of a determination on nonregulated status of the new agricultural product. DAS initiated the consultation process with FDA for the DAS-81419-2 soybean and submitted a safety and nutritional assessment of food and feed derived from DAS-81419-2 soybean to the FDA on October 15, 2012. On February 7, 2014, FDA concluded that it had no further questions about the use of DAS-81419-2 in food or feed (BNF-000140).

The FDA previously reviewed safety data for the Cry1Ac and Cry1F proteins as present in event DAS-21023-5 x DAS-24236-5 (WideStrike® cotton: BNF 0092; BNF 0085) regarding:

Applications and uses;
Source, identity, and function of the introduced genetic materials;
The intended effect of the modifications;
The compositional and nutritional equivalence of the GE lines and their non-GE counterparts.

Following completion of the consultation processes and their data reviews, CFSAN confirmed that they had no further questions (FDA, 2004a; FDA, 2004b).

DAS-81419-2 soybean is compositionally equivalent to currently available soybeans on the market with the exception of Cry1Ac, Cry1F, and PAT protein expression (see petition12-272-01p a2, Section 7). The amino acid sequences of both the Cry1Ac and Cry 1F protein expressed in DAS-81419-2 soybean are identical to those expressed in WideStrike® Cotton (see petition 12-272-01p a2).

A biotechnology consultation on the PAT protein was conducted in 1998 and does not require additional evaluation by the FDA (FDA, 1998b; FDA, 1998c).

Based on compositional equivalency to conventional soybean and the safety assessment of the expressed proteins, there is no expected change or impact to human health and safety from a determination of nonregulated status of DAS-81419-2 as compared to the No Action Alternative.

4.6 Animal Feed

The majority of the soybean cultivated in the U.S. is grown for animal feed, and is usually fed as soybean meal (Soyatech, 2012). Animal agriculture consumes 98% of the U.S. soybean meal produced (Soyatech, 2012). Under FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from DAS-81419-2 soybean must be in compliance with all applicable legal and regulatory requirements. GE organisms for feed typically undertake a voluntary consultation process with the FDA prior to release onto the market.

DAS submitted a summary of its safety and nutritional assessment of DAS-81419-2 soybean to FDA on October 15, 2012. DAS has provided the FDA with information on the identity, function, and characterization of the genes, including expression of the gene products in DAS-81419-2 soybean. On February 7, 2014, FDA concluded that it had no further questions about use of DAS-81419-2 in food or feed (BNF-000140). Additionally, EPA tolerance exemptions are already in place for Cry1Ac in all crops and Cry1F in corn and cotton (40 CFR §174.510; 40 CFR §174.504; 40 CFR §174.520). DAS has submitted an exemption from tolerance for Cry1F in soybeans, including toxicology and allergenicity data on the Cry1F protein. The tolerance was published in the Federal Register (v 29, pp 8293-8295, February 12, 2014). EPA exemptions from a tolerance apply to both food and feed.

DAS analyzed the composition of forage and seed from DAS-81419-2 soybean and compared it to a non-GE soybean control variety, Maverick, which has a genetic background similar to DAS-81419-2 soybean. DAS also evaluated the composition of forage and seed from six commercial non-GE soybean varieties ("reference varieties") grown under the same field conditions as DAS-81419-2 soybean and control soybeans. Samples were analyzed for nutrient and anti-nutrient content, and the results compared to values reported in scientific literature. The data demonstrate compositional equivalence to conventional soybean.

4.6.1.1 No Action Alternative: Animal Feed

Under the No Action Alternative, DAS-81419-2 soybean would continue to be regulated by USDA and EPA. There would be no commercial scale planting of DAS-81419-2 soybean in the U.S. and DAS-81419-2 soybean would have limited use in animal feed. No additional risks or benefits to livestock feed safety from DAS-81419-2 soybean are expected under the No Action Alternative.

4.6.1.2 Preferred Alternative: Animal Feed

While planting of DAS-81419-2 soybean under this alternative would not be regulated by APHIS, impacts will be unchanged from the No Action Alternative. The safety of the Cry1F, Cry1Ac, and PAT proteins as expressed in GE crops is well established; deregulation of DAS-81419-2 soybean would not result in novel animal exposure to these proteins, since have been similarly present in both commercial corn and cotton plant parts or products. Additionally, DAS-81419-2 soybean demonstrates compositional equivalence to conventional soybean.

Based on the information presented above, a determination of nonregulated status of DAS-81419-2 soybean will have no negative impacts on animal feed or animal health. Overall impacts are unchanged from the No Action Alternative.

4.7 Socioeconomic Impacts

4.7.1 Domestic Economic Environment

GE soybeans are cultivated on 93% of the U.S. soybean acreage as earlier noted in Section 2. The U.S. acreage of soybeans planted has varied over time, but the USDA has noted that the acreage dedicated to soybean has declined in recent years as returns on investment favored corn production (USDA-ERS, 2008). Although acreage has declined, the yield per acre has continued to increase (USDA-ERS, 2008).

4.7.1.1 No Action Alternative: Domestic Economic Environment

Under the No Action Alternative, DAS-81419-2 would continue to be regulated by APHIS under 7 C.F.R. Part 340, with limited acreage under EPA registration. The product developer would not produce commercial seed. Accordingly, there would be no effect on the U.S. domestic soybean market under this alternative.

4.7.1.2 Preferred Alternative: Domestic Economic Environment

Under this alternative, DAS-81419-2 soybean would not be regulated by APHIS. Under the EPA registration for seed increase, less than 250,000 acres of DAS-81419-2 soybean would be expected to be produced, and most of this would not enter the domestic soybean market.

In 2012, 93% of soybeans planted were herbicide resistant (USDA-NASS 2012b). DAS-81419-2 soybean is expected to replace existing soybean acres in areas where lepidopteran pest pressure exceeds economic thresholds, if DAS decides to fully register the variety for commercial production. DAS studies demonstrate agronomic and compositional equivalence of DAS-81419-2 soybean to commercially available soybean varieties. Given the equivalence of DAS-81419-2 soybean to herbicide resistant commercial soybean, and the expectation of no new soybean acreage, impacts from a determination of non-regulated status are the same as for the No Action Alternative.

4.7.2 Trade Economic Environment

The U.S. produces approximately 35% of the global soybean supply (Soy Stats, 2011, Introduction). In 2010, the U.S. exported 1.6 billion bushels of soybean, which accounted for 44 percent of the world's soybean exports (The American Soybean Association, 2012a). China is expected to account for nearly 80 percent of the increased demand (USDA ERS, 2012c). China and India are predicted to import 46 percent of the total soybean market by 2018/2019 (Food and Agricultural Policy Research Institute, 2009). The USDA has predicted that U.S. exports will remain flat during much of this period, as a result of an increase in domestic consumption and competition from South America (Food and Agricultural Policy Research Institute, 2009; USDA ERS, 2012c).

The majority of exported soybean seed for planting is sold to other countries in North America, with only about 2 percent of this current market (about 1,100 metric tons in 2012) is exported to South American countries (USDA-APHIS, 2011a; USDA, 2013) and the five year average attains to 700 metric tons (BICO-10 FAS converted data) (USDA-FAS, 2013).

4.7.2.1 No Action Alternative: Trade Economic Environment

Under this alternative DAS-81419-2 soybean would remain a regulated article by APHIS. Under these restrictions, seed would not be produced for export. Accordingly, there would be no impacts to trade under the No Action Alternative.

4.7.2.2 Preferred Alternative: Trade Economic Environment

Under this alternative, DAS-81419-2 soybean would not be regulated by APHIS.

DAS-81419-2 soybean was developed for lepidopteran pest control, with primary target markets in South America. Increases in exports to South American markets as the result of a determination of nonregulated status of DAS-81419-2 soybean are not likely to change the current export amounts to other regions, but could increase the overall export of soybean seed to South America. The addition of new export markets by DAS-81419-2 soybean to the overall soybean seed export market will likely be minor in the near term (USDA-APHIS, 2011a; USDA, 2013). If all the DAS-81419-seed on the 250k acres requested of EPA for seed increase and production were sold to South America markets, 272,800 metric tons of seed would be produced (assuming average US production, 43bu soybean/acre, and 39.5bu equivalency to one ton), which would be considerably higher than the present total exports to that region (Table 4). Total world exports of US seed for soybean planting were 28,700 tons in 2012 (USDA-FAS (USDA-FAS, 2014).

Table 4. Metric Tons of US Seed for Planting Exported to South America (Jan-Dec) by Year

2008	2009	2010	2011	2012
520	1,058	372	384	1,172

From: USDA-FAS 2014.

Beginning in 2012, DAS intends to submit dossiers to the regulatory authorities of trade partners for import clearance and production approval. This may include Canada, Japan, Korea, Taiwan, European Union, Australia/New Zealand, South Africa, Brazil, Argentina and Mexico. DAS intends to submit for regulatory approval in South America for import and planting of DAS-81419-2 soybean in 2013. Argentina and Chile, the countries that currently import the most soybean seed for planting, have not yet approved DAS-81419-2 soybean. Because DAS-81419-2 soybean represents such a small portion of the total soybean seed production in the U.S., it will not impact the availability of other seed varieties that meet the current export needs.

Under the restrictions of a seed increase registration, DAS-81419-2 soybean is not expected to impact trade. Accordingly, impacts to trade economic environment under the No Action Alternative will be similar to the No Action alternative.

5 CUMULATIVE IMPACTS

A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. For example, the potential effects associated with approval of nonregulated status for a GE crop in combination with the future production of crop seeds with multiple approved traits (i.e., “stacked” traits), including drought tolerance, herbicide resistance, and pest resistance, would be considered a cumulative impact.

5.1 Assumptions Used for Cumulative Impacts Analysis

DAS has applied for a Section 3 seed increase registration with U.S. EPA for DAS-81419-2 soybean and a registration was granted January 20,, 2014). The application and subsequent registration did not include commercial registration. While DAS-81419-2 soybean was developed for use in South America, lepidopteran pest pressure in the U.S. may demonstrate a need for DAS-81519-2. Accordingly, the cumulative impacts analysis includes the possibility that DAS will commercialize DAS-81419-2 soybean in the future. Before selling DAS-81419-2 seed in the U.S., DAS would be required to obtain from EPA a FIFRA Section 3 registration for commercial planting. In that document, EPA will announce data requirements, including the need for an Insect Resistance Monitoring program. For example, requirements for *Bt* corn and cotton are set forth in the 2001 BRAD for *Bt*-PIPs; requirements for *Bt* soybean are set forth in the 2011 BRAD for Mon 87701 (EPA, 2001; EPA, 2011a).

GE soybeans currently are planted on the majority of soybean acres in the U.S; 93% of soybean acres in 2012 were planted to GE varieties, and all which are herbicide resistant. (USDA ERS, 2012g). The use of herbicide resistant soybean systems is the most common method in the U.S. for management of weeds in soybean fields. DAS has plans to cross DAS-81419-2 soybean with other deregulated herbicide resistant soybean varieties, such as those expressing glyphosate tolerance. Therefore, the possibility of stacked traits is presented in the cumulative impacts analysis.

Nonregulated GE glyphosate-resistant (e.g., Roundup Ready®) crop varieties have been in the market since 1996, when glyphosate-resistant soybean became commercially available. Potential effects from cultivation of glyphosate-resistant crops and corresponding regarding implications of the use of glyphosate have been thoroughly evaluated in other APHIS Environmental Assessments since the 1993 introduction of the first glyphosate-resistant crop product (see http://www.aphis.usda.gov/biotechnology/not_reg.html).

DAS-81419-2 soybean expresses PAT, which provides resistance to glufosinate ammonium. Glufosinate ammonium is registered with EPA for use on soybeans. Thus, there is a potential for increased glufosinate ammonium use resulting from commercial production of DAS-81419-2 soybean.

5.2 Cumulative Impacts: Acreage and Area of Soybean Production

No cumulative impacts to acreage and area of soybean production are expected under the Preferred Alternative, where DAS-81419-2 soybean will be limited to breeding and seed increase activities. Should DAS pursue commercial registration, DAS-81419-2 soybean is expected to replace existing GE soybean acres, with adoption likely limited to areas under economically significant lepidopteran pest pressure. Projecting possible modest increases in the existing populations of pest Lepidoptera, the area of cultivation could eventually include Georgia and Louisiana where the total acres treated for Lepidoptera already has reached 40-50%. In other Southern and possibly some Midwestern states, these pest populations may not attain greater importance. The two states (Georgia and Louisiana) encompass together less than 1.8% of total planted soybean acres in the U.S. Replacement of existing soybean acres with DAS-81419 would be likely, not addition of new acres that were not previously used for soybean production. Thus, no cumulative impacts to acreage are expected under potential future commercialization of DAS-81419-2 soybean.

DAS-81419-2 soybean may be conventionally crossed with other GE soybean varieties that are not regulated pursuant to Part 340 and the Plant Protection Act. Because 93% of soybeans grown in the U.S. today are already herbicide-resistant, crossing of DAS-81419-2 with an herbicide resistant soybean variety is not expected to expand the range or change land use patterns for soybean cultivation in the U.S. Like other commercial varieties, DAS-81419-2 soybean is a domesticated crop that will not likely be cultivated outside areas of current agronomic management where soil and climate conditions are optimal. The addition of glyphosate herbicide resistance to DAS-81419-2 soybean would not expand the potential area of cultivation. Additionally, displacement of all currently adopted soybean varieties by DAS-81419-2 soybean and any progeny is unlikely.

Because of the high adoption rate of herbicide resistant soybeans already in the market place, and the agronomic equivalence between DAS-81419-2 soybean and other commercial varieties, commercial production of DAS-81419-2 soybean alone or stacked with other herbicide resistant varieties will not result in increased adoption of herbicide resistant soybean in the U.S. The cumulative effect on land use is expected to be minimal. Impacts are further minimized because adoption is expected only in areas experiencing significant lepidopteran pest pressure.

5.3 Cumulative Impacts: Agronomic Practices

No cumulative impacts on agronomic practices are expected from determining non-regulated status for DAS-81419-2 soybean. Potential approval of DAS-81419-2 soybean under a commercial use registration by EPA or the generation of soybean varieties stacked with a commercially approved DAS-81419-2 soybean and herbicide resistant events are not expected to result in any cumulative effects on soybean agronomic practices.

Herbicides have been the primary tactic used to manage weed communities in soybeans since the mid-1960s and will continue to be an important feature of row crop weed management for the foreseeable future. Glyphosate has become the most often-used herbicide on U.S. soybean: in 2006, nearly 92 million pounds of glyphosate were applied on 92% of the planted acres (USDA NASS, 2007b). Prior to 1995, glyphosate was primarily used for pre-plant weed control in soybean (Young, 2006). After 1995, annual glyphosate usage increased due to post-emergence application on Monsanto's Roundup Ready® Soybean (GTS 40-3-2) which became commercially available to growers in 1996. In 2006, an estimated 98 percent of the planted soybeans were treated with at least one type of herbicide (USDA NASS, 2007b). It is common practice today for growers to make use of herbicide resistance in soybeans, particularly glyphosate resistance. No changes in current agronomic practices would be required if DAS-891419-2 were to be stacked with a deregulated glyphosate resistance trait.

Commercial plans for DAS 81419 soybean are at present confined to seed production on less than 250,000 acres in the US (Dow-Agrosciences, 2013) and that seed will be mostly exported. No commercial use can be made of the variety unless EPA has issued a permit for unrestricted commercial sale of the variety and for various stacks or combinations of traits including DAS-81419-2 that are licensed for that stack. As noted however, seed production could reach 0.3% of total acreage of all planted soybean acres. Use of glufosinate is not anticipated on these seed production acres, but overall use of glufosinate may increase should the variety be offered for commercial commodity soybean production. Glufosinate will likely be used when incorporated into widely sold glyphosate resistant soybean varieties if growers have no economical alternatives for control of glyphosate resistant weeds, and primarily if the trait for glyphosate resistance becomes in some measure ineffective. While glyphosate remains highly effective on a broad range of weeds, has flexibility in application windows, and is more economical than many herbicides, it will continue to be a high use herbicide. Glufosinate will be used where glyphosate resistant weeds are prevalent, but will not likely attain to the usage rate of glyphosate for the reasons noted.

If DAS-81419-2 soybean is commercialized in the U.S. market, growers in soybean areas experiencing high lepidopteran pest pressure may choose to adopt DAS-81419-2 soybean, possibly reducing insecticide applications in these fields. It is expected that growers will still monitor fields for insect damage and apply other insecticides, due to the presence of soybean insect pests not affected by Cry1Ac and Cry1F. Therefore, the only anticipated change in current agronomic practices for insect control with commercialization of DAS-81419-2 is the potential reduction of insecticide applications for specific lepidopteran pests. As pest pressure varies across regions, no cumulative impacts to agronomic practices from adoption of DAS-81419-2 soybean is expected.

An estimate of the potential market for this lepidopteran resistant product is bounded by the likely number of acres for which present lepidopteran pest levels are highest. At present, these acres are apparently not sufficient to justify producing and marketing the product in the US for commercial soybean production. As noted in the Affected Area discussion, about 50% of the soybean acreage in Georgia and 40% of that in Louisiana are treated for lepidopteran pests with conventional insecticides. The other areas of the US where soybeans are planted at present have not received the same level of lepidopteran infestation that would consistently require an insect resistant soybean. If all the soybean acres presently receiving insecticides (for any insect pest) would be planted to a Cry-expressing soybean for lepidopteran resistance, the total IR soybean would be as much as 40% of US soybean acres (USDA-NASS, 2013e). Of course, the total need for lepidopteran control would be much less because the USDA data is for control of all insect pests. Stinkbugs and beetles are the most important pests in Southeastern and Northeastern farms respectively, while Midwestern farms generally see economically important damage from soybean aphids, and do not have economically important lepidopteran populations on soybean. The USDA data is also listed by insecticide used, so multiple applications of different insecticides to the same field and which insects were primary targets could not be discerned from the application data.

Besides the value of the insect resistance trait, commercial soybean growers may also consider the usefulness of the glufosinate trait. Glufosinate would likely be an adjunct soybean resistance that would be used if glyphosate resistant weeds were present in the soybean fields. Thus, a glufosinate resistance trait would augment the control potential for glyphosate, but only when growers needed the variety's IR trait for locally important lepidopteran pests. Heap (Heap, 2013) estimates that in the U.S., 6 million hectares have glyphosate resistant weeds (14.83 million acres) and if these were found predominately in the soybean and corn production areas, would represent about 9% of all acres on which soybean might be grown. A survey from 2012 indicates that the total land with glyphosate resistant weeds may have reached 61.2 million acres; Georgia growers have an infestation on 92% of their acres (Stratus-Agri-Marketing, 2013). Consequently, 9-40% of soybean production land (corn-planted acres plus soybean-planted acres together total 168 million acres) may potentially have glyphosate resistant weeds. If the potential need for an IR (insect resistant) soybean (assume 15% of acres) were considered as a subset of those that may also need an herbicide mode of action such as glufosinate to control glyphosate resistant weeds (9-40% of acres), then the product of the two represents the possible market penetration; 1.35-6% would be a general estimate of the possible adoption of the product. The market penetration could be larger if the general pest status of the various lepidopterous pests of soybean were to markedly increase beyond the two state area so that a higher percentage of growers would have an economic reason to request and plant a commodity soybean variety with such lepidopteran pest resistance traits.

Although glufosinate resistant varieties are at least one strategy for control of glyphosate resistant weeds in soybeans, other herbicide regimes can also be used, either with glyphosate use or without (Hager, 2013; Monsanto, 2013). Considering that lepidopteran resistance traits might be needed in the cited areas, and that glufosinate also were needed in only some of the glyphosate weed resistant acres, a minimal adoption might be even less than 1-6% of total soybean acres. The total impact of the crop, should it be commercialized, would not be a substantial number of acres.

5.4 Cumulative Impacts: Soybean Seed Production

No cumulative impacts on production of soybean seed are expected following a determination of non-regulated status for DAS-81419-2 soybean. Based on current trends, GE soybean are likely to continue to dominate soybean production. GE soybean varieties were grown on more than 93% of soybean acres in 2012.

Should DAS-81419-2 soybean become commercially available, no change in U.S. soybean cultivation and seed production is expected. The percentage of soybean seed exports for planting is presently small and growth of seed production would not be large compared to soybean commodity production (Section 4.7.2). Since high value soybean production areas are likely already used for commercial production, any new seed production is likely to use these existing acres, especially since growers would receive a premium for soybean seed production compared to commercial production.

Potential commercialization of DAS-81419-2 soybean is not expected to create new acres for seed production. If growers see value in the traits offered by a DAS-81419-2 soybean or stacked progeny, this variety may replace existing soybean varieties. Because changes in the agronomic practices or locations for soybean seed production are not expected from potential future commercialization of DAS-81419-2 soybean, there are no cumulative effects identified for production of either GE or non-GE seed if DAS-81419-2 soybean is commercialized in the U.S. Similarly, no cumulative effects are expected upon possible future commercialization of any stacked progeny of DAS 81419-2 and other non-regulated soybean varieties, such as herbicide-resistance, for standard commodity soybean production.

Management practices for the production of high quality seed, such as AOSCA or state standards for production of soybean seed of the desired class, would continue under the Preferred Alternative. These practices further support a finding of no cumulative effects upon deregulation and possible future commercialization of 1) DAS 81419-2 soybean; and 2) stacked progeny.

5.5 Cumulative Impacts: Organic Soybean Production

No cumulative impacts to organic soybean production are expected under the Preferred Alternative. A determination of nonregulated status of DAS-68416-4 soybean is not expected to change the market demands for GE soybean or soybean produced using organic methods. Data from USDA-ERS indicates that in 2012, 93% of all soybean grown in the U.S. were herbicide-resistant GE varieties (USDA ERS, 2012b). In 2008, organic soybean varieties were grown on less 0.2% of soybean acres planted in the U.S; in 2005, the organic soybean market share was 0.17% (USDA ERS, 2010b).

Since 1994, nine GE soybean events or lines have been determined by APHIS as 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 (USDA ERS, 2010b). 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), not the adoption rate of GE soybean. Based on the trend in the cultivation of GE soybean, non-GE, and organic soybean varieties, and the expectation that corresponding production systems to preserve varietal integrity are both likely to remain the same, no cumulative impacts are expected in the event of commercial production of 1) DAS-81419-2 soybean; nor 2) any stacked progeny.

5.6 Cumulative Impacts: Water Resources

Approval of DAS petition for deregulation and potential commercial production in the U.S. of DAS-81419-2 soybean for seed is not expected to have cumulative impacts on water resources. Generation of stacked herbicide resistant varieties from DAS-81419-2 soybean and other herbicide resistant soybean varieties is also not expected to have a cumulative effect on water resources. Use of herbicides on DAS-81419-2 soybean either 1) alone or 2) stacked with other traits such as herbicide resistance is not expected to increase the overall number of acres where herbicide would be applied. Herbicide resistant soybeans currently comprise 93% of U.S. soybean varieties produced (USDA ERS, 2012b). DAS-81419-2 soybean, either alone or stacked with other traits, would likely replace to a limited extent currently cultivated herbicide resistant soybeans.

Acceptability of herbicide accumulation in water is the responsibility of EPA to assess, and the potential of impacts of commercially available herbicides have been examined by EPA. Glyphosate is already used on soybean 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 (EPA, 1993; Giesy et al., 2000). 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” (EPA, 2002b).

Glufosinate ammonium is weakly adsorbed and highly mobile in soil, rapidly degrading in soil and water and having a short soil residual half-life of seven days (WSSA, 2007). Glufosinate ammonium has a high leaching potential in soil, but because it degrades so rapidly, it is rarely found deeper than 15 centimeters (approximately 6 inches) from the soil surface (WSSA, 2007), and thus has little potential impact to groundwater. Implementation of best management practices to slow soil erosion and filter pollutants from surface runoff, such as vegetated strips, control of spray drift, and adherence to label restrictions governing safe application and equipment cleanup, minimize the potential for pesticide impacts to surface and groundwater.

There may be potential reduction in insecticide use in areas where DAS-81419-2 soybean or stacked progeny is adopted. As current insecticide applications to soybean are few, any change is expected to be small. Overall, there are no cumulative effects on water resources from deregulation and possible commercial production of: 1) DAS-81419-2 soybean; or 2) any progeny of DAS-81419-2 soybean stacked with other traits such as herbicide resistance.

5.7 Cumulative Impacts: Soil Quality

No cumulative impacts to soil quality are expected under the Preferred Alternative. Due to the lack of economically significant lepidopteran insect pressure, DAS-81419-2 soybean is unlikely to replace large amounts of currently planted GE soybean varieties across U.S. cultivation areas. Similarly the use of tillage, agriculture equipment, irrigation, and fertilizer applications would not likely change as a result of a determination of nonregulated status (Section 4.2.2).

Commercial production of DAS-81419-2 soybean in the U.S. is not expected to contribute to increases of soil loss or degradation in comparison to the No Action Alternative, thus there are no expected cumulative impacts to soil quality upon potential commercialization of DAS-81419-2 soybean.

Safety and use profiles for glyphosate and glufosinate are well documented (EPA, 2002b; US-EPA, 2013). Therefore, no cumulative effects on soil quality are expected from commercialization of any stacked progeny of DAS-81419-2 soybean.

5.8 Cumulative Impacts: Air Quality

There are no expected cumulative impacts on air quality resulting from a determination of nonregulated status for DAS-81419-2 soybean. In the event of product commercialization, adoption of DAS-81419-2 soybean across the entire U.S. soybean cultivation range is unlikely because adoption is expected only in areas where lepidopteran insect pressure reaches economic levels. While adoption could result in fewer insecticide applications in these areas, any change is not expected to impact air quality: insect pressure from non-lepidopteran pests may still require insecticide applications, and insect pressure varies by year and location. Currently, insecticides are applied to a small percentage of soybean acres, so the overall change in insecticide applications is expected to be small.

DAS-81419-2 soybean expresses resistance to glufosinate ammonium. Glufosinate ammonium has low volatility and a short soil residual life (average half-life of 7 days) (WSSA, 2007); thus, it is not considered an atmospheric contaminant with any potential impacts to air quality.

Combining the DAS-81419-2 soybean event with a nonregulated herbicide resistant trait such as glyphosate enables continued adoption and use of reduced- or no till strategies in soybean cultivation. Therefore, there are also no anticipated negative cumulative effects on air quality from U.S. commercialization of DAS-81419-2 soybean nor from any stacked progeny.

5.9 Cumulative Impacts: Climate Change

Nonregulated status of DAS-81419-2 soybean is not expected to result in any cumulative impacts on climate change. While some agricultural practices can contribute to climate change through greenhouse gas emissions, these will not change as a result of a determination of nonregulated status of DAS-81419-2 soybeans. Accordingly, potential commercialization of DAS-81419-2 soybean is unlikely to result in cumulative impacts on climate change. Similarly, if DAS-81419-2 soybean were stacked with other nonregulated soybean varieties, such as herbicide resistant varieties, cumulative impacts are also unlikely.

5.10 Cumulative Impacts: Animal Communities

No cumulative impacts to animal communities are expected under the Approval the Petition Alternative. DAS-81419-2 soybean is not toxic to vertebrate animals. Cry1F and Cry1Ac, are specific to certain lepidopteran species: caterpillars that eat plants expressing the proteins typically die (Pigott and Ellar, 2007; British Columbia Ministry of Environment, 2012). Other orders of insects are not affected by the Cry1F and Cry1Ac toxins and thus would not be affected by DAS-81419-2 soybean. Cry proteins are naturally occurring, and present in common, non-pathogenic soil bacteria. Cry1Ac and Cry1F are also expressed in commercially available corn and cotton products, either alone or in combination with other insecticidal proteins (EPA, 2001; Mendelsohn et al., 2003; EPA, 2008a; EPA, 2010a). There have been no impacts on nontarget insects from WideStrike cotton which also expresses both IR Bt traits of DAS-81419-2 soybean but instead in cotton varieties.

Should DAS-81419-2 soybean be commercialized, growers that consistently use insecticides to control lepidopteran pests in soybeans are the most likely to adopt DAS-81419-2 soybean. In cotton growing areas, DAS-81419-2 soybeans could increase the acreage of crops expressing Cry1Ac and Cry1F. Insect populations that feed on both cotton and soy could experience greater exposure, resulting in a possible reduction in the target lepidopteran pest populations. Though adoption of DAS-81419-2 soybean may increase exposure of animals to Cry1Ac and Cry1F in the environment, vertebrate animals are not affected by the Cry proteins. Thus, the change in exposure will not impact animals.

Non-target invertebrates could also experience greater exposure to the Cry1Ac and Cry1F endotoxins. However, as described in Section 4.4.1, non-target invertebrate populations are not likely to be affected by Cry1 endotoxins. The increase in exposure would not change the effects on these populations compared to the current situation.

Commercial production of DAS-81419-2 soybean would require registration under Section 3 of FIFRA, under EPA jurisdiction. EPA data requirements for registration would include implementation of an Insect Resistance Management Program (IRM). The 2001 Biopesticides Registration Action Document (BRAD) for *Bt* Plant Incorporated Protectants (PIP) sets forth requirements for an IRM plan (EPA, 2001). The BRAD for Monsanto's IR soybean (expressing Cry1Ac) states that information on pest biology, dose, simulation modeling, and cross resistance would be required to assess the risks for an unlimited commercial registration (EPA, 2011a). DAS must satisfy EPA requirements prior to undertaking commercial production. In particular, should DAS submit for and obtain full commercial cultivation registration of DAS-81419-2 soybean from EPA, widespread adoption of the product may reduce the current natural refuge for lepidopteran pests of cotton. Any future action to change the area where DAS-81419-2 soybean is EPA registered to be grown would take into account the other Bt crops in the area as well as any natural refuge in designing an IRM plan. DAS submitted a proposal to the EPA to allow seed production on small acreages without refuges, whose size is determined by proximity to other soybean, and to cotton acreage, where targeted insects are likely to be present. The proposal was accepted by (US-EPA, 2013e).

Use of herbicides on DAS-81419-2 soybean alone or stacked with other traits is not expected to increase the overall number of acres receiving herbicide treatment. Ninety-three percent of soybean acres are herbicide resistant (USDA NASS, 2012b); it is reasonable to assume that nearly all receive herbicide treatments. Any herbicides applied to DAS-81419-2 soybean or progeny would be used in accordance with per-application and per-year rates approved by EPA. While there is a possibility of increased glufosinate ammonium use upon adoption of DAS-81419-2 soybean, no impacts from potential use are expected.

On an acute exposure basis, glufosinate is considered practically nontoxic to birds, mammals, and insects; slightly non-toxic to freshwater fish; slightly toxic to estuarine/marine fish; moderately toxic to freshwater and estuarine/marine invertebrates; and toxic to terrestrial and aquatic plants. For birds, glufosinate is practically non-toxic on an acute and subacute dietary basis; therefore, the risk potential is presumed to be low (EPA, 2008b).

Glyphosate is already in use in soybean in both conventional and Roundup Ready varieties. The herbicide has been previously reviewed by EPA for impacts on non-target organisms and is currently being evaluated as part of the reregistration review process, scheduled to be completed in 2015 (EPA, 2009b). EPA's process ensures that each registered pesticide continues to meet the highest standards of safety to protect human health and the environment

5.11 Cumulative Impacts: Plant Communities

No cumulative impacts to plant communities are expected upon determination of nonregulated status of DAS-81419-2 soybean. Except for expression of the Cry1Ac, Cry1F, and PAT proteins, DAS-81419-2 soybean is agronomically and compositionally equivalent to commercially available varieties (12-272-01p a2, Sections 8.4). The Cry proteins are toxic to certain lepidopteran insects, with no effect on plants. Use of herbicides on DAS-81419-2 soybean alone or stacked with other herbicide resistant traits is not expected to increase the overall number of acres on which herbicide would be applied. Any herbicides applied to DAS-81419-2 soybean or stacked varieties would be used in accordance with rates approved by EPA. Therefore, commercialization of DAS-81419-2 soybean in the U.S. is not expected to have any cumulative impacts on plants. Commercial production of any stacked progeny of DAS 81419-2 soybean, such as herbicide tolerant stacked progeny, is also not expected to result in any cumulative impacts for the reasons described above.

5.12 Cumulative Impacts: Gene Flow and Weediness

No cumulative impacts on gene flow and weediness are expected from a determination of nonregulated status for DAS-81419-2 soybean. Agronomic characteristics of DAS-81419-2 soybean are substantially equivalent to other GE and non-GE varieties (Petition, Section 8). Given the reproductive characteristics of soybean, the probability for cross-pollination is low (Caviness, 1966; Ray et al., 2003). Additionally, the soybean industry has identity protection measures in place to restrict pollen movement and gene flow between soybean fields through the use of isolation distances, border and barrier rows, the staggering of planting dates and various seed handling and transportation procedures (Sundstrom et al., 2002; NCAT, 2003; Bradford, 2006). Under both the No Action and Preferred Alternatives, DAS-81419-2 soybean will be grown using these practices.

There is no evidence that horizontal gene transfer and expression of DNA occurs between soybean and soil bacteria or unrelated plant species under natural field conditions (see Section 2.3.3). Due to its agronomic equivalence to other soybean varieties, there is no greater potential for gene movement between sexually compatible soybean varieties (vertical gene flow) in DAS-81419-2 soybean compared to other non-GE or GE cultivars. Accordingly, no cumulative impacts on gene flow or weediness are expected from potential commercialization of: 1) DAS-81419-2 soybean; or 2) stacked progeny of DAS-81419-2 soybean with other nonregulated GE soybean events.

5.13 Cumulative Impacts: Microorganisms

No cumulative impacts to microorganisms are expected under the Preferred Alternative. *Bt* from root exudates occurs in soils where GE *Bt* crops are planted; these exudates do not affect soil quality (see Section 4.3.2). Regarding potential future commercialization in the U.S., use of herbicides on 1) DAS-81419-2 soybean or 2) DAS-81418-2 progeny stacked with other traits is not expected to increase the overall number of acres receiving herbicide treatment. Herbicide resistant soybeans currently comprise 93% of U.S. soybean cultivars (USDA-ERS, 2012b). DAS-81419-2 soybean, either alone or stacked with other traits such as glyphosate resistance, would likely replace herbicide resistant soybeans currently cultivated.

As soybean is often rotated with other crops, rotation of *Bt* soybean with another *Bt* crop, such as corn, is possible. *Bt* is a ubiquitous, naturally occurring soil bacterium, with no negative effects on soil microbes (see Section 4.3.2). Therefore, the production of DAS-81419-2 soybean, even in rotation with other *Bt* crops, will not cumulatively impact soil quality or microorganisms.

Glufosinate ammonium is rapidly degraded in soil, acted upon by microbes that degrade it to CO_2 and natural phosphorus compounds (EPA, 2008b). Studies of the effects of glufosinate ammonium on the microbial community have yielded varying results: several found no differences in the microbial community from the application of glufosinate ammonium compared to either those treated with different herbicides or those left untreated (Schmalenberger and Tebbe, 2002; Lupwayi et al., 2004; Wibawa et al., 2010). However, Gyamfi et al. found the application of glufosinate ammonium caused minor, transient shifts in the bacterial community structure, potentially caused by the increase of herbicide-degrading microbes (Gyamfi et al., 2002). Other research found that the use of glufosinate ammonium inhibits the activity of cultivar pathogens such as Bacterial Blight (Pline, 1999) and Grapevine Downy Mildew (*Plasmopara viticola*) (Albrecht and Kortekamp, 2009).

Glufosinate ammonium is currently registered by EPA for use on soybeans; thus use could increase by grower adoption of DAS-81419-2 soybeans.

For the reasons described above no cumulative impacts on soil microbes are expected upon potential future commercialization of 1) DAS-81419-2 soybean; or 2) stacked progeny of DAS-81419-2 soybean containing other non-regulated GE traits, such as herbicide resistance.

5.14 Cumulative Impacts: Biodiversity

Under the Preferred Alternative, no cumulative impacts to biodiversity are expected.

DAS-81419-2 soybean is similar in all respects to other soybeans except for the expression of Cry1Ac, Cry1F, and PAT. Cry proteins demonstrate high specificity and toxicity to certain lepidopteran insects, are naturally occurring in soil bacteria, and present in other commercially available crops (see Section 4). *Bt* crops have been cultivated since 1996; the lack of adverse impacts on biodiversity is well documented in the scientific literature (see, e.g., Sections 4.4; 4.5).

A determination of non-regulated status and U.S. commercial production of DAS-81419-2 soybean is not expected to result in new acres upon which herbicides are applied. Ninety-three percent of current soybean acres are herbicide resistant, with both glyphosate and glufosinate ammonium registered for use on soybeans. For these reasons, no new cumulative impacts to biodiversity are expected from deregulation of DAS-81419-2 soybean. Additionally, no cumulative impacts are expected upon potential commercialization of 1) DAS-81419-2 soybean alone, or 2) any stacked progeny, including progeny containing herbicide resistant traits.

5.15 Cumulative Impacts: Human Health

DAS-81419-2 soybean expresses proteins Cry1Ac, Cry1F and PAT. Cry1Ac and Cry1F proteins are toxic to certain lepidopteran species; they are not toxic to vertebrate animals, including humans, and have no similarities to known allergens (see Section 4.5). Cry1Ac and Cry1F have an exemption from tolerance from the EPA and are deemed safe for human consumption (EPA, 2005c). DAS initiated the consultation process with FDA for DAS-81419-2 soybean and submitted a safety and nutritional assessment of food and feed derived from DAS-81419-2 soybean to the FDA on October 15, 2012. On February 7, 2014, FDA concluded that it had no further questions about use of DAS-81419-2 in food or feed (BNF-000140).

DAS intends to develop a stacked variety with DAS-81419-2 soybean and commercially available soybean varieties expressing glyphosate resistance. A major source of glyphosate resistance in crops is the CP4 EPSPS protein derived from *Agrobacterium* spp. 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 (EPA, 2007d) EPA has also determined that the PAT protein presents a low probability of risk to human health and the environment and granted an exemption from the requirement of a tolerance for this PIP inert ingredient (EPA, 2007b).

Herbicide resistant soybeans account for 93% of U.S. acreage and both glyphosate and glufosinate ammonium are registered with the EPA for use on soybeans. Should DAS seek and obtain commercial use registration with EPA, it is possible that some growers may apply glufosinate to DAS-81419-2 soybean. No overall change in herbicide use patterns is expected if DAS-81419-2 soybean is granted nonregulated status.

For glufosinate ammonium, the 2003 EPA risk assessment based the occupational risk assessment on the highest supported application rates for cotton, bushberry, and rice (0.79, 0.52 and 0.44 lb ai/A per application, respectively), which are greater or equal to the approved application rate of 0.44 lb ai/A per application for soybean (EPA, 2008b). This assessment concluded the modeled exposure levels were adequate for the determination of potential adverse human health effects posed by glufosinate ammonium (EPA, 2008b). Potential human health effects from glufosinate ammonium use are currently under review in the EPA reregistration review process for this herbicide (EPA, 2008b). The current EPA-approved label for glufosinate ammonium includes precautions and measures to protect human health. Applications of pesticides in accordance with the registered use and label instructions minimize the potential for human health impacts.

For all the reasons described above, no cumulative impacts on human health are expected from a determination on non-regulated status of DAS-81419-2 soybean. Similarly, commercialization of 1) DAS-81419-2 soybean alone; or 2) any stacked progeny of DAS-81419-2 soybean containing, for example, herbicide resistance traits, is also expected to have no cumulative impacts on human health.

5.16 Cumulative Impacts: Animal Feed

The Cry1Ac and Cry1F proteins expressed in DAS-81419-2 soybeans are toxic to certain lepidopteran species, but not toxic to vertebrate animals, including livestock, and have no similarities to known allergens (see Section 4.5). These proteins have an exemption from tolerance from the EPA. There are no anticipated effects on livestock health from the consumption of this protein.

Based on previous FDA food and feed assessments of commercial products expressing Cry1Ac and Cry1F proteins (FDA, 2004a; FDA, 2004b), DAS-81419-2 soybean is not materially different in any respect relevant to feed safety compared to commercially available soybean varieties. Thus, no cumulative effects on animal feed are anticipated from a determination of non-regulated status for DAS-81419-2 soybean. Further, no cumulative effects are expected should DAS commercialize DAS-81419-2 soybean in the U.S.

Regarding a glyphosate resistant stacked variety of DAS 81419-2 soybean, glyphosate has been widely used on soybean since 1996. The use of glyphosate herbicide does not appear to 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 (EPA, 2012d).

Glufosinate ammonium was first registered by EPA for use in crops in 2000 as a non-selective foliar herbicide used for pre-plant and post-emergence control of broadleaf weeds (EPA, 2008b). It is currently registered for use on many crops including apples, berries, canola, corn, cotton, currants, grapes, grass grown for seed, potatoes, rice, soybeans, sugar beets, and tree nuts and for use in non-crop areas including lawns and residential areas (EPA, 2008b). GE glufosinate resistant soybean treated with glufosinate ammonium must not be grazed or cut for hay (Bayer CropScience, 2011). This is a minor use of soybeans and the commercialization of DAS-81419-2 is not expected to impact this limited use.

Based on the above, no cumulative effects on animal feed are anticipated with regards to commercialization of: 1) DAS-81419-2 soybean alone or 2) any stacked progeny, including progeny containing herbicide resistance.

5.17 Cumulative Impacts: Domestic Economic Environment

For reasons discussed throughout this document, no cumulative impacts to the domestic economic environment are expected under the Preferred Alternative. Adoption of DAS-81418-2 soybean is expected in current soybean growing areas under economically significant pest pressure if DAS decides to make it available for commodity soybean production. No new soybean acres are expected with commercial production of DAS-81419-2 soybean. The same is true for any stacks of DAS-81419-2 soybean with other commercially available GE soybean varieties. Accordingly, no cumulative impacts on the domestic economic environment are anticipated upon potential commercialization of either: 1) DAS-81419-2 or; 2) any stacked progeny.

5.18 Cumulative Impacts: Trade Economic Environment

DAS-81419-2 soybean is engineered to control lepidopteran pests of soybeans. These pests are more economically important in tropical and semi-tropical areas of the world than in temperate climates. The primary market for DAS-81419-2 soybean is currently South America.

Soybean seed exports for crop cultivation are a minor part of the current soybean export market, the vast majority of soybeans are exported for processing (USDA ERS, 2012e; USDA, 2013). See also section 2.6.2 of this document. The contribution of DAS-81419-2 soybean to the overall soybean export market will not be significant; most soybean seed is exported for processing not planting (USDA ERS, 2012e). Any increase in seed exports that may result from a determination of nonregulated status of DAS-81419-2 soybean would be small compared to the total export commodity soybean market, but would nevertheless represent a major increase in seed export shipment. However, no likely impact can be anticipated to the economic environment. Similarly, no cumulative impacts to trade economic environment are expected from commercial production of either: 1) DAS-81419-2 soybean, or 2) stacked progeny of DAS-81419-2 soybean, such as those expressing herbicide resistance traits. Accordingly no cumulative impacts on soybean exports are expected from a determination of non-regulated status for DAS-81419-2 soybean.

6 THREATENED AND ENDANGERED SPECIES

6.1 Scope of Analysis

The Endangered Species Act (ESA) of 1973, as amended, is one of the most far-reaching wildlife conservation laws ever enacted by any nation. Congress passed the ESA to prevent extinctions facing many species of fish, wildlife and plants. The purpose of the ESA is to conserve endangered and threatened species and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the U.S. Fish & 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 it is determined by the USFWS/NMFS 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.

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 designated critical habitat. To facilitate their ESA consultation requirements, 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 (PPA) of 2000 (Title IV of Public Law 106-224). APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

APHIS met with USFWS officials on June 15, 2011, to discuss whether APHIS has any obligations under the ESA regarding analyzing the effects of herbicide use associated with all GE crops on TES. As a result of these joint discussions, 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 currently planted because EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under FIFRA. APHIS has no statutory authority to authorize or regulate the use of glufosinate or any other herbicide, by soybean growers. Under APHIS' current Part 340 regulations, APHIS only has the authority to regulate DAS-81419-2 soybean or any GE organism as long as APHIS believes they may pose a plant pest risk (7 CFR § 340.1). APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms.

After completing a plant pest risk analysis, if APHIS determines that DAS-81419-2 soybean seeds, plants, or parts thereof do not pose a plant pest risk, then this article 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 must reach a determination that this article is no longer regulated. As part of its EA analysis, APHIS is analyzing the potential effects of DAS-81419-2 soybean on the environment including, as required by the ESA, any potential effects to threatened and endangered species and critical habitat. As part of this process, APHIS thoroughly reviews the GE product information and data related to the organism (generally a plant species, but may also be other genetically engineered organisms). For each transgene/transgenic plant, APHIS considers the following:

- 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 species (TES) of plants or a host of any TES; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

In following this review process, APHIS, as described below, has evaluated the potential effects that a determination of nonregulated status of DAS-81419-2 soybean may have, if any, on federally-listed TES species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation.

Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, APHIS reviewed the USFWS list of TES species (listed and proposed) for each state where soybean is commercially produced from the USFWS Environmental Conservation Online System (ECOS; as accessed 1-20-2014 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp). Prior to this review, APHIS considered the potential for DAS-81419-2 soybean to extend the range of soybean production and also the potential to extend agricultural production into new natural areas. This product was developed for growers in South America and is not expected to be grown in the United States to any great extent. APHIS has determined that agronomic characteristics and cultivation practices required for DAS-81419-2 soybean are essentially indistinguishable from practices used to grow other soybean varieties, including other herbicide-resistant varieties. (Dow-AgroSciences, 2012; USDA-APHIS, 2013). If grown in the US, DAS-81419-2 soybean may be expected to replace other varieties of soybean currently cultivated, and APHIS does not expect the cultivation of these to result in new soybean acres to be planted in areas that are not already devoted to agriculture. Accordingly, the issues discussed herein focus on the potential environmental consequences of the determination of nonregulated status of DAS-81419-2 soybean on TES species in the areas of the US where soybean is currently grown.

For its analysis on TES plants and critical habitat, APHIS focused on the agronomic differences between the regulated articles and soybean varieties currently grown; the potential for increased weediness; and the potential for gene movement to native plants, listed species, and species proposed for listing.

For its analysis of effects on TES animals, APHIS focused on the implications of exposure to the novel proteins expressed in the plants as a result of the transformation, and the ability of the plants to serve as a host for a TES. The novel proteins associated with DAS-81419-2 soybean are listed in Table 4.

Table 4. Proteins expressed in the Event DAS-81419-2 Soybean.

Protein	Phenotypic Effects
phosphinothricin acetyltransferase (PAT)	Resistance to glufosinate
Cry1Ac	Resistance to feeding by larval stages of specific lepidopteran insects
Cry1F	Resistance to feeding by larval stages of specific lepidopteran insects

6.2 Potential Effects of DAS-81419-2 Soybean on TES and Critical Habitat

6.2.1 Threatened and Endangered Plant Species and Critical Habitat

The agronomic and morphologic characteristics data provided by DAS were used in the APHIS analysis of the weediness potential for DAS-81419-2 soybean, and further evaluated for the potential to impact TES and critical habitat. Agronomic studies conducted by DAS tested the hypothesis that the weediness potential of DAS-81419-2 soybean is unchanged with respect to conventional soybean produced by DAS (Dow-AgroSciences, 2012). No differences were detected between DAS-81419-2 soybean and nontransgenic soybean in growth, reproduction, or interactions with pests and diseases, other than the intended effect of herbicide resistance (Dow-AgroSciences, 2012; USDA-APHIS, 2013). Soybean possesses few of the characteristics of successful weeds, and has been cultivated around the globe without any report that it is a serious weed or that it forms persistent feral populations (USDA-APHIS, 2013) Soybean cannot survive in the majority of the United States without human intervention (USDA-APHIS, 2013), and it is easily controlled if volunteers appear in subsequent crops. The expression of the PAT protein providing herbicide resistance, and the Cry1Ac, and Cry1F proteins providing insect resistance in DAS-81419-2 soybean are unlikely to appreciably improve seedling establishment or increase weediness potential. APHIS has concluded the approval of a petition of nonregulated status for DAS-81419-2 soybean does not present a risk of weediness, and does not present an increased risk of gene flow when compared to other currently cultivated soybean varieties (USDA-APHIS, 2013).

APHIS evaluated the potential of DAS-81419-2 soybean to cross with listed species. As previously discussed in the analysis of Gene Movement and Weediness and Plants, APHIS has determined that there is no risk to unrelated plant species from the cultivation of DAS-81419-2 soybean. Soybean is highly self-pollinating and can only cross with other members of *Glycine* subgenus *Soja*. Wild soybean species are endemic in China, Korea, Japan, Taiwan and the former USSR; in the U.S. there are no *Glycine* species found outside of cultivation and the potential for outcrossing is minimal (OECD, 2000a; OECD, 2000b). After reviewing the list of threatened and endangered plant species in the U.S. states where soybean is grown, APHIS determined that DAS-81419-2 soybean would not be sexually compatible with any listed threatened or endangered plant species proposed for listing, as none of these listed plants are in the same genus nor are known to cross pollinate with species of the genus *Glycine*.

Based on agronomic field data, literature surveyed on soybean weediness potential, and no sexually compatibility of TES with soybean, APHIS has concluded that DAS-81419-2 soybean will have no effect on threatened or endangered plant species or critical habitat.

Threatened and Endangered Animal Species

For its effects analysis on TES animal species, APHIS focused on the likelihood of the species to be exposed to the toxins expressed in DAS-81419-2 soybean. Exposure of TES species to Cry1Ac and Cry1F is only likely if the species occur in the areas where soybean is grown, because soybean plant parts (seeds, pollen, crop debris) are not readily transported long distances without human intervention. Threatened and endangered animal species that may be exposed to the gene products in DAS-68416-4 soybean would be those TES that inhabit soybean fields and feed on DAS-68416-4 soybean. Few if any TES are likely to use soybean fields because they do not provide suitable habitat. Only whooping crane (*Grus americana*), sandhill crane (*Grus canadensis pulla*), piping plover (*Charadrius melodus*), interior least tern (*Sterna antillarum*), and Sprague's pipit (*Anthus spragueii;* a candidatespecies) occasionally feed in farmed sites (US Fish and Wildlife Service, 2011). These bird species may visit soybean fields during migratory periods, but would not be present during normal farming operations (Krapu et al., 2004; US Fish and Wildlife Service, 2011) . In a study of soybean consumption by wildlife in Nebraska, results indicated that soybeans do not provide the high energy food source needed by cranes and waterfowl (Krapu et al., 2004). The Delmarva fox squirrel (*Sciurus niger cinereus*), which inhabits mature forests of mixed hardwoods and pines, may be found adjacent to agricultural areas of the Delmarva Peninsula (US Fish and Wildlife Service, 2008). The squirrel forages for food in woodlots and openings, such as farm fields, with a diet that mainly includes acorns, nuts/seeds of hickory, beech, walnut, and loblolly pine. They also feed on tree buds and flowers, fungi, insects, fruit, and seeds in the spring and mature, green pine cones in the summer and early fall (US Fish and Wildlife Service, 2008). The Louisiana black bear (*Ursus americanus luteolus*), occurring in Louisiana, Mississippi, and Texas has been found to consume corn, berries, grasses, acorns, herbaceous vegetation, and other species of soft mast (Benson and Chamberlain, 2006).

The use of GE crops expressing Cry proteins has been shown to reduce the use broad spectrum insecticides without significant impacts on diversity of non-target insects (Romeis et al., 2006; Marvier et al., 2007; Wolfenbarger et al., 2008; Naranjo, 2009). *Bt* toxins expressed in transgenic plants for pest management are generally regarded as safe due to their mode of action, specificity, and fast degradation in the environment (Glare and O'Callaghan, 2000; Sanvido et al., 2007; Romeis et al., 2008). The specificity of *Bt* crystalline proteins to lepidopteran insect larvae, and not for other insects, birds, and mammals, results from the highly specific receptors for these proteins in the larvae midgut (Arora et al., 2007). Once activated by insect-specific proteases in the insect midgut, Cry proteins bind to receptors in the midgut. Binding leads to the formation of pores in the midgut membranes and ultimately to cell lysis and death. The specific binding of *Bt*-based Cry proteins to midgut membrane receptors is a key determinant of pest specificity (Showalter et al., 2009).

Given the narrow spectrum of activity observed for Cry proteins (Pigott and Ellar, 2007; Wolfenbarger et al., 2008) the TES analysis is focused on taxa within the order Lepidoptera. Proximity relationships between potential growing sites where DAS-81419-2 could be planted and locations of T/E lepidopteran species were determined from the information contained in the FIFRA Endangered Species Task Force (FESTF) databases. Ecology and life history information for species identified as being present in soybean-growing counties was accessed from the U.S. Fish and Wildlife Service and NatureServe Explorer databases (NatureServe Explorer, 2012).

Four lepidopteran butterfly species (Karner blue, *Lycaeides melissa samuelis*; Mitchell's satyr, *Neonympha mitchellii mitchellii*; Saint Francis' satyr, *Neonympha mitchellii francisci*; and Uncompahgre fritillary, *Boloria acrocnema*) were indicated to co-occur with soybean use sites in 66 counties located in 13 states. Ecology and life history information demonstrated that habitat requirements for larvae and adults of three of the identified species (Mitchell's satyr, Saint Francis' satyr, and Uncompahgre fritillary) do not overlap with commercial soybean acreage, and are therefore not expected to be impacted by DAS-81419-2 cultivation. There is a possible overlap between the geographic range for Karner blue butterfly and soybean use sites; however, the potential for direct exposure to the Cry proteins produced by DAS-81419-2 soybean is negligible. Karner blue larvae feed only on lupines (*Lupinus* spp.). Soybean is neither identified as a larval food source, nor is soybean open-pollinated; thus DAS-81419-2 soybean pollen is highly unlikely to be deposited on lupine leaves. Furthermore, soybean is not identified as a nectaring source for Karner blue adults. Therefore, the risk posed to the Karner blue butterfly is considered negligible.

Cry1Ac, Cry1F, and PAT have been reviewed by USDA, U.S. EPA, and U.S. FDA regulatory agencies, with no safety implications under specified use (Section 1.2). In agreement with previous TES assessments for PAT, Cry1F, and Cry1Ac products, the assessment for DAS-81419-2 supports a determination of no effect on threatened or endangered animal species. (USDA-APHIS, 1995; USDA-APHIS, 2004; USDA-APHIS, 2011a).

APHIS considered the possibility that DAS-81419-2 soybean could serve as host plant for a threatened or endangered species. A review of the species list reveals that there are no members of the genus *Glycine* that serve as a host plant for any threatened or endangered species.

Combining the above information, cultivation of DAS-81419-2 soybean and its progeny are expected to have no effect on threatened or endangered animals.

Summary

After reviewing the possible effects of allowing the environmental release of DAS-81419-2 soybean, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. APHIS also considered the potential effect of a determination of nonregulated status of DAS-81419-2 soybean on designated critical habitat and habitat proposed for designation, and could identify no differences from effects that would occur from the production of other soybean varieties. Soybean is not considered a particularly competitive plant species and has been selected for domestication and cultivation under conditions not normally found in natural settings (US-EPA, 2010b). Soybean is not sexually compatible with, or serves as a host species for, any listed species or species proposed for listing. Consumption of DAS-81419-2 soybean by any listed species or species proposed for listing will not result in a toxic or allergic reaction. Based on these factors, APHIS has concluded that a determination of nonregulated status of DAS-81419-2 soybean, and the corresponding environmental release of these soybean varieties will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or NMFS is not required.

References

Abud, S, P I M de Souza, G R Vianna, E Leonardecz, C T Moreira, F G Faleiro, J N Júnior, P M F O Monteiro, E L Rech, and F J L Aragão. (2007). "Gene flow from transgenic to nontransgenic soybean plants in the Cerrado region of Brazil." *Genetics and Molecular Research* 6 (2): p 445 - 52.

AgWeb. (2013). "Inside the Seed Industry." Last Accessed: 11-19-13 < http://www.agweb.com/article/inside_the_seed_industry/default.aspx?print=y >.

Albrecht, M, and A. Kortekamp. (2009). "The *in Vitro* Effect of the Herbicide Basta® (Glufosinate Ammonium) on Potential Fungal Grapevine Pathogens." *European Journal of Horticultural Science* 74 (3): p 112 - 17.

Altieri, M. (1999). "The ecological role of biodiversity in agroecosystems." *Agriculture, Ecosystems and Environment* 74 p 19-31.

Aneja, V.P. , W.H. Schlesinger, and J.W. Erisman. (2009). "Effects of agriculture upon the air quality and climate: Research, policy, and regulations." *Environmental Science & Technology* 43 (12): p 4234–40.

AOSCA. (2012). "Seed Certification." http://www.aosca.org/seed%20certification.htm >.

Aref, Susanne, and David R Pike. (1998). "Midwest Farmers' Perceptions of Crop Pest Infestation." *Agronomy Journal* 90 p 819 - 25.

Arora, Naresh, Neema Agrawal, Vimala Yerramilli, and Raj K Bhatnagar. (2007). "Biology and Applications of Bacillus Thuringiensis in Integrated Pest Management." *General Concepts in Integrated Pest Management and Disease Management*. Springer. p 227 - 44.

Baker, J., R. Southard, and J. Mitchell. (2005). "Agricultural dust production in standard and conservation tillage systems in the San Joaquin Valley." *Journal of Environmental Quality* 34 p 1260-69.

Baucom, R., and J. Holt. (2009). "Weeds of agricultural importance: Bridging the gap between evolutionary ecology and crop and weed science." *New Phytologist* (184): p 741-43.

Baumgarte, Susanne, and Christoph C Tebbe. (2005). "Field studies on the environmental fate of the Cry1Ab Bt-toxin produced by transgenic maize (MON810) and its effect on bacterial communities in the maize rhizosphere." *Molecular Ecology* 14 (8): p 2539 - 51.

Bayer CropScience. "Ignite 280 SL Herbicide label." 2011. fs1.agrian.com/pdfs/Ignite_280_SL_Herbicide_Label3.pdf.

Benson, John F, and Michael J Chamberlain. (2006). "Food Habits of Louisiana Black Bears (Ursus americanus luteolus) in Two Subpopulations of the Tensas River Basin." *The American Midland Naturalist* 156 (1): p 118 - 27.

Berglund, Duane R., and Ted C. Helms. (2003). "Soybean Production (Report: A-250 Revised)." North Dakota State University Extension Service. http://www.ag.ndsu.edu/pubs/plantsci/rowcrops/a250w.htm >.

Betz, Fred S., B.G. Hammond, and Roy L. Fuchs. (2000). "Safety and Advantages of *Bacillus thuringiensis* - Protected Plants to Control Insect Pests." *Regulatory Toxicology and Pharmacology* 32 p 156 - 73.

Beuerlein, Jim. (2005). "2005 Ohio Soybean Inoculation Report." The Ohio State University. http://agcrops.osu.edu/specialists/soybean/resources/current-research-projects/2005SoyInoculationReport.pdf/view >.

Biotechnology Industry Organization. (2012). "Biotrade Status - WideStrike Cotton."

Blackwood, Christopher B, and Jeffrey S Buyer. (2004). "Soil Microbial Communities Associated with Bt and Non-Bt Corn in Three Soils." *Journal of Environmental Quality* 33 (3): p 832 - 36.

Boerboom, Chris. (1999). "Nonchemical Options for Delaying Weed Resistance to Herbicides in Midwest Cropping Systems." *Weed Technology* 13 (3): p 636 - 42.

Boerboom, Chris. (2000). "Timing Postemergence Herbicides in Corn and Soybeans." *Wisconsin Crop Management Conference*.

Bottomley, Peter J. (1992). "Ecology of *Bradyrhizobium* and *Rhizobium*." *Biological Nitrogen Fixation*. New York, NY: Routledge, Chapman and Hall, Inc. p 293 - 348.

Bradford, Kent J. (2006). "Methods to Maintain Genetic Purity of Seed Stocks." *ANR Publication* 8189 p 5.

Bravo, Alejandra, Supaporn Likitvivatanavong, Sarjeet S Gill, and Mario Soberón. (2011). "*Bacillus thuringiensis*: A Story of a Successful Bioinsecticide." *Insect Biochemistry and Molecular Biology* 41 p 423 - 31.

British Columbia Ministry of Environment. (2012). "Fact Sheets: Bt: An Alternative to Chemical Pesticides." http://www.env.gov.bc.ca/epd/ipmp/publications/fact_sheets/bt.htm >.

Brookes, Graham, and Peter Barfoot. "GM Crops:global socio-economic and environmental impacts 1996-2010." Dorchester UK: PG Economics Ltd UK, 2012.

Carpenter, J (2011). "Impact of GM Crops on Biodiversity Landes Bioscience." http://www.landesbioscience.com/journals/36/article/15086/ >.

Carpenter, Janet E, Allan Felsot, Timothy Goode, Michael Hammig, David Onstad, and Sujatha Sankula. (2002). "Comparative Environmental Impacts of Biotechnology-derived and Traditional Soybean, Corn, and Cotton Crops." Council for Agricultural Science and Technology.

CAST. (2009). "U.S. Soybean Production: A Comparison of Sustainable Production Systems for Conventional, Biotech, and Organic Soybeans." p 15 pages. http://www.soyconnection.com/pdf/9001_USB_CAST_V1r1May11.pdf >.

Catchot, Angus. (2011). "Soybean Insect Pest Problems In The Mid-South, What To Watch For In 2011." *14th Annual National Conservation Systems Cotton & Rice Conference*.

Causarano, H. J., A. J. Franzluebbers, D. W. Reeves, and J. N. Shaw. (2006). "Soil organic carbon sequestration in cotton production systems of the Southeastern United States: A review." *Journal of Environmental Quality* 35 (4): p 1374-83.

Caviness, C. E. (1966). "Estimates of Natural Cross-Pollination in Jackson Soybeans in Arkansas." *Crop Science* 6 (2): p 211-12. http://crop.scijournals.org/cgi/content/abstract/cropsci;6/2/211 >.

Cerdeira, A. L. , and S. O. Duke. (2006). "The Current Status and Environmental Impacts of Glyphosate-Resistant Crops: A Review." *J. Environmental Quality* 35 p 1633-58. https://www.agronomy.org/publications/jeq/pdfs/35/5/1633 >.

Chen, Mao, Jian-Zhou Zhao, Hilda L Collins, Elizabeth D Earle, Jun Cao, and Anthony M Shelton. (2008). "A Critical Assessment of the Effects of Bt Transgenic Plants on Parasitoids." *PLoS ONE* 3 (5): p e2284.

Clements, D. R., A. DiTommaso, N. Jordan, B. D. Booth, J. Cardina, D. Doohan, C. L. Mohler, S. D. Murphy, and C. J. Swanton. (2004). "Adaptability of plants invading North American cropland." *Agriculture, Ecosystems & Environment* 104 (3): p 379-98. http://www.sciencedirect.com/science/article/pii/S0167880904001203 >.

Culpepper, A.L., T.L. Grey, W.K. Vencill, J.M. Kichler, T.M. Webster, S.M. Brown, A.C. York, J.W. Davis, and W.W. Hanna. (2006). "Glyphosate-resistant Palmer (*Amaranthus palmeri*) confirmed in Georgia." *Weed Technology* 54 p 620-26.

Doran, J W, M Sarrantonio, and M A Liebig. (1996). "Soil Health and Sustainability." *Advances in Agronomy* 56 p 1 - 54.

Dow-Agrosciences. (2011). "Dow AgroSciences, M.S. Technologies Submit for Approval First Ever Three-Gene Herbicide-Tolerant Soybean Will Provide Growers New, Improved Choice for Glyphosate

Tolerance in Soybean." http://www.dowagro.com/newsroom/corporate/2011/20110822a.htm >.
Dow-AgroSciences. (2012). "Petition for Determination of Nonregulated Status for Insect-Resistant DAS-81419-2 Soybean." Submitted by Registration Manager. http://www.aphis.usda.gov/brs/aphisdocs/12_27201p.pdf >.
Dow-Agrosciences. (2013). "Insect Resistance Management Implications." EPA, Letter submitted to.
Duan, Jian J., Jonathan G. Lundgren, Steve Naranjo, and Michelle Marvier. (2009). "Extrapolating non-target risk of *Bt* crops from laboratory to field." *Biology Letters* 6 p 74-77. http://rsbl.royalsocietypublishing.org/content/early/2009/09/08/rsbl.2009.0612.abstract >.
Dubelman, Samuel, Bonnie R Ayden, Brenda M Bader, Christopher R Brown, Changjian Jiang, and Demetra Vlachos. (2005). "Cry1Ab Protein Does Not Persist in Soil After 3 Years of Sustained Bt Corn Use." *Environmental Entomology* 34 (4): p 915 - 21.
Ellstrand, N. C. (2003). "Current knowledge of gene flow in plants: Implications for transgene flow." *Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences* 358 (1434): p 1163-70. http://www.ncbi.nlm.nih.gov/pubmed/12831483 >.
EOP-OSTP. (1986). "Coordinated Framework for Regulation of Biotechnology." *51 Federal Register 23302, June 26, 2006* p Executive Office of the President, Office of Science and Technology Policy. http://usbiotechreg.epa.gov/usbiotechreg/ >.
EPA. (1993). "Glyphosate Reregistration Eligibility Decision (RED)." www.epa.gov/oppsrrd1/REDs/factsheets/0178fact.pdf >.
EPA. (1997). "Phosphinothricin Acetyltransferase and the Genetic Material Necessary for Its Production in All Plants; Exemption From the Requirement of a Tolerance On All Raw Agricultural Commodities." http://www.gpo.gov/fdsys/pkg/FR-1997-04-11/html/97-9373.htm >.
EPA. (2000). "EFED Risk Assessment for Use of Glufosinate-ammonium on Canola, Potatoes, and Sugar Beets." http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0190-0006 >.
EPA. (2001). "Biopesticides Registration Action Document: *Bacillus thuringiensis* (*Bt*) Plant-Incorporated Protectants." http://www.epa.gov/opp00001/biopesticides/pips/bt_brad.htm >.
EPA. (2002a). "EPA's Regulation of Bacillus thuringiensis (Bt) Crops." http://www.epa.gov/oppbppd1/biopesticides/pips/regofbtcrops.htm >.
EPA. (2002b). "Glyphosate: Pesticide Tolerances." http://www.gpo.gov/fdsys/pkg/FR-2002-09-27/pdf/02-24488.pdf >.
EPA. (2005a). "Attachment III: Environmental Risk Assessment of Plant Incorporated Protectant (PIP) Inert Ingredients." http://www.epa.gov/scipoly/sap/meetings/2005/december/pipinertenvironmentalriskassessment11-18-05.pdf >.
EPA. (2005b). "Bacillus thuringiensis Cry1F (synpro and Cry1Ac (synpro) Construct 281/3006 Insecticidal Crystal Proteins as expressed in cotton) (Chemical PC Codes 006512 and 006513, respectively." BRAD.
EPA. (2005c). "Biopesticide Registration Action Document - *Bacillus thuringiensis* Cry1F (synpro) and Cry1Ac (synpro) Construct 281/3006 Insecticidal Crystal Proteins as expressed in cotton." U.S. Envrionmental Protection Agency Office of Pesticide Programs Biopesticides and Pollution Prevention Division. http://www.epa.gov/oppbppd1/biopesticides/ingredients/tech_docs/brad_006512.pdf >.
EPA. (2007a). "40 CFR § 174.523 CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase in all plants; exemption from the requirement of a tolerance." http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=686fa49e307a01ab5515323f43b928e2&rgn=div8&view=text&node=40:25.0.1.1.24.14.19.23&idno=40 >.

EPA. (2007b). "40 CFR § 180.1151 Phosphinothricin Acetyl-transferase (PAT) and the genetic material necessary for its production all plants; exemption from the requirement of a tolerance." http://www.gpo.gov/fdsys/pkg/CFR-2007-title40-vol23/xml/CFR-2007-title40-vol23-sec180-1151.xml >.

EPA. (2007c). "Environmental Fate and Ecological Risk Assessment in Support of the Proposed Addition of Hooded Sprayers and Pre-plant Burndown to Glufosinate-ammonium Labels for Corn, Soybeans and Canola." http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0190-0012 >.

EPA. (2007d). "Glufosinate-ammonium; Pesticide Tolerance." http://www.gpo.gov/fdsys/pkg/FR-2007-12-21/pdf/E7-24841.pdf >.

EPA. (2008a). "*Bacillus Thuringiensis* modified Cry1Ab (SYN-IR67B-1) and Vip3Aa19 (SYN-IR102-7) insecticidal protiens and the genetic material necessary for their production in COT102 X COT67B cotton." Agency, US Environmental Protection. http://www.epa.gov/opp00001/chem_search/reg_actions/registration/decision_PC-006529_12-Aug-08.pdf >.

EPA. (2008b). "Glufosinate Summary Document Registration Review: Initial Docket (Report: EPA-HQ-OPP-2008-0190)." EPA,. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0190-0003 >.

EPA. (2009a). "40 CFR § 174.510 Bacillus thuringiensis Cry1Ac protein in all plants; exemption from the requirement of a tolerance." http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=649c72152c33476c1969424c35402e09&r=PART&n=40y25.0.1.1.24#40:25.0.1.1.24.14.19.10 >.

EPA. (2009b). "Glyphosate Final Work Plan (FWP) Registration Review Case No. 0178." http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0361-0042;oldLink=false >.

EPA. (2010a). "Biopesticides Registration Action Document: Cry1Ab and Cry1F Bacillus thuringiensis (Bt) Corn Plant-Incorporated Protectants." http://www.epa.gov/pesticides/biopesticides/pips/cry1f-cry1ab-brad.pdf >.

EPA. (2010b). "Pesticide Registration Manual: Chapter 11 - Tolerance Petitions U.S. Environmental Protection Agency. ." http://www.epa.gov/pesticides/bluebook/chapter11.html >.

EPA. (2011a). "Bacillus thuringiensis Cry1Ac in MON 87701 Soybean Biopesticide Registration Action Document." EPA.

EPA. (2011b). "*Bacillus thuringiensis*: Preliminary work plan and summary document for registration review." http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0705-0002 >.

EPA. (2012a). "40 CFR § 174.504 *Bacillus thuringiensis* Cry1F protein in cotton; exemption from the requirement of a tolerance." http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=649c72152c33476c1969424c35402e09&r=PART&n=40y25.0.1.1.24#40:25.0.1.1.24.14.19.10 >.

EPA. (2012b). "40 CFR § 174.520 Bacillus thuringiensis Cry1F protein in corn; exemption from the requirement of a tolerance." http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=4a70c5905f08047d42b9f07b2b325728&rgn=div8&view=text&node=40:25.0.1.1.24.14.19.20&idno=40 >.

EPA. (2012c). "40 CFR § 174.522 Subpart W—Tolerances and Tolerance Exemptions; Phosphinothricin Acetyltransferase (PAT); exemption from the requirement of a tolerance." http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=f488b9fbd992d67b381711589a9efc3b&rgn=div5&view=text&node=40:25.0.1.1.24&idno=40#40:25.0.1.1.24.14.19.22 >.

EPA. (2012d). "40 CFR § 180.364 Tolerances and Exemptions for Pesticide Chemical Residues in Food, Glyphosate: tolerances for residue." http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=a16a9e2977e1f4cef315d779cfcfcc9f&rgn=div5&view=text&node=40:25.0.1.1.28&idno=40#40:25.0.1.1.28.3.19.131 >.

EPA. (2012e). "Pesticides: Regulating Pesticides." EPA. http://www.epa.gov/pesticides/regulating/ >.

ERS, USDA. (2012). "Top 25 Agricultural Export Commodities, With Level of Processing, by Fiscal Year, Current Dollars. Retrieved from U.S. Department of Agriculture–Economic Research Service." http://www.ers.usda.gov/data-products/foreign-agricultural-trade-of-the-united-states-(fatus)/fiscal-year.aspx >.

Estes, Ronald E, Michael E Gray, and Nicholas A Tinsley. (2011). "Annual Summary of Field Crop Insect Management Trials." University of Illinois, Department of Crop Sciences. http://ipm.illinois.edu/ontarget/ >.

Farooq, Faisal T, and J Kevin Vessey. (2009). "Genetic diversity of *Bradyrhizobium japonicum* within soybean growing regions of the north-eastern Great Plains of North America as determined by REP-PCR and ERIC-PCR profiling." *Symbiosis* 48 p 131 - 42.

FDA. (1997). "Guidance on Consultation Procedures, New Plant Varieties." http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096126.htm >.

FDA. (1998a). "Biotechnology Consultation Agency Response Letter BNF No. 000055." http://www.fda.gov/Food/Biotechnology/Submissions/ucm161092.htm >.

FDA. (1998b). "Biotechnology Consultation Note to the File BNF No. 00055." http://www.fda.gov/Food/Biotechnology/Submissions/ucm161170.htm >.

FDA. (1998c). "Guidance for Industry Use of Antibiotic Resistance Marker Genes in Transgenic Plants." http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096135.htm >.

FDA. (2004a). "Biotechnology Consultation Agency Response Letter BNF No. 000085." http://www.fda.gov/Food/Biotechnology/Submissions/ucm155756.htm >.

FDA. (2004b). "Biotechnology Consultation Agency Response Letter BNF No. 0000092." http://www.fda.gov/Food/Biotechnology/Submissions/ucm155750.htm >.

Felland, C. M., H. N. Pitre, R. G. Luttrell, and J. L. Hamer. (1990). "Resistance to Pyrethroid Insecticides in Soybean Looper (Lepidoptera: Noctuidae) in Mississippi." *Journal of Economic Entomology* 83 (1): p 35 - 40.

Food and Agricultural Policy Research Institute. (2009). "FAPRI, 2009, World Oilseeds and Products, Agricultural Outlook." Food and Agricultural Policy Research Institute.

Fouche, Calvin, Mark Gaskell, Steven T Koike, Jeff Mitchell, and Richard Smith. (2000). "Insect Pest Management for Organic Crops." University of California ANR Communication Services.

Garbeva, P, J A van Veen, and J D van Elsas. (2004). "Microbial Diversity in Soil: Selection of Microbial Populations by Plant and Soil Type and Implications for Disease Suppressiveness." *Annual Review of Phytopathology* 42 p 243 - 70.

Gianessi, L. , and N. T. Reigner. (2007). "The Value of Herbicides in U.S. Crop Production." *Weed Technology* 21 p 559-66.

Gianessi, Leonard P. (2009). "The Benefits of Insecticide Use: Soybeans." CropLife Foundation.

Gianessi, Leonard P, Cressida S Silvers, Sujatha Sankula, and Janet E Carpenter. (2002). "Plant Biotechnology: Current and Potential Impact for Improving Pest Management in U.S. Agriculture - An Analysis of 40 Case Studies." National Center for Food & Agricultural Policy.

Gibson, K. D., W. G. Johnson, and D.E. Hillger. (2005). "Farmer perceptions of problematic corn and soybean weeds in Indiana." *Weed Technology* 19 p 1065-70.

Giesy, John P, Stuart Dobson, and Keith R Solomon. (2000). "Ecotoxicological Risk Assessment for Roundup® Herbicide." *Reviews of Environmental Contamination and Toxicology* 167 p 35 - 120.

Glare, Travis, and Maureen O'Callaghan. (2000). *Bacillus thuringiensis:Biology, Ecology, and Safety*. New York: Wiley.

Guillebeau, Paul, Nancy Hinkle, and Phillip Roberts. (2008). "Summary of Losses from Insect Damage and Cost of Control in Georgia 2006." University of Georgia.

Gyamfi, Stephen, Ulrike Pfeifer, Michael Stierschneider, and Angela Sessitsch. (2002). "Effects of Transgenic Glufosinate-tolerant Oilseed Rape (*Brassica napus*) and the Associated Herbicide Application on Eubacterial and *Pseudomonas* Communities in the Rhizosphere." *FEMS Microbiology Ecology* 41 p 181 - 90.

Hager, A. (2013). "Controlling Large Horseweed and Waterhemp in Soybean." Illinois, University of. http://bulletin.ipm.illinois.edu/?p=1336 >.

Hammond, Ronald B. (2012). "Soybean Insect IPM." *Radcliffe's IPM World Textbook*. St. Paul, MN: University of Minnesota. http://ipmworld.umn.edu >.

Harlan, JR. . (1975). "Our vanishing genetic resources. ." *Science,* 188 (4188): p 618-21.

Head, Graham, James B. Surber, Jon A. Watson, John W. Martin, and Jian J. Duan. (2002). "No Detection of Cry1Ac Protein in Soil After Multiple Years of Transgenic Bt Cotton (Bollgard) Use." *Environmental Entomology* 31 (1): p 30-36. Last Accessed: 2012/05/18 < http://dx.doi.org/10.1603/0046-225X-31.1.30 >.

Heap, I. "Overview of Global Herbicide Resistance Cases and Lessons Learned." GHRC Conference 2013, Perth: Grains Research and Development Corporation, 2013. http://www.weedsmart.org.au/ian-heap-overview-of-global-herbicide-resistance-cases-and-lessons-learnt/.

Heatherly, Larry, Anne Dorrance, Robert G. Hoeft, David Onstad, James Orf, Paul Porter, Stan Spurlock, and Bryan Young. "Sustainability of U.S. Soybean Production: Conventional, Transgenic, and Organic Production Systems (Report: Special Publications No. 30)." Ames, IA: Council for Agricultural Science and Technology, 2009. 1-106 of *CAST*.

Hendriksma, H , S Härtel, D Babendreier, W Ohe, and I Steffan-Dewenter. (2012). "Effects of multiple Bt proteins and GNA lectin on in vitro-reared honey bee larvae." *Apidologie* 43 (5): p 549-60. http://dx.doi.org/10.1007/s13592-012-0123-3 >.

Herman, Rod A., Peter N. Scherer, Debra L. Young, Charles A. Mihaliak, Thomas Meade, Aaron T. Woodsworth, Brian A. Stockhoff, and Kenneth E. Narva. (2002). "Binary Insecticidal Crystal Protein from *Bacillus thuringiensis*, Strain PS149B1: Effects of Individual Protein Components and Mixtures in Laboratory Bioassays." *Journal of Economic Entomology* 95 (3): p 635-39. Last Accessed: 2012/04/19 < http://dx.doi.org/10.1603/0022-0493-95.3.635 >.

Higgins, Laura S, Jonathan Babcock, Paul Neese, Raymond J Layton, Daniel J Moellenbeck, and Nicholas P Storer. (2009). "Three-Year Field Monitoring of Cry1F, Event DAS-Ø15Ø7–1, Maize Hybrids for Nontarget Arthropod Effects." *Environmental Entomology* 38 (1): p 281 - 92.

Higley, Leon G. (1994). "Insect Injury to Soybean." *Handbook of Soybean Insect Pests*. Lanham, MD: Entomological Society of America. p 11-13.

Hoeft, Robert G., Emerson D. Nafziger, Richard R. Johnson, and Samuel R. Aldrich. (2000). *Modern Corn and Soybean Production*. Savoy, IL: MCSP Publications.

HRAC. (2013). "Guideline to the Management of Herbicide Resistance." Last Accessed: January 22 2013 < http://www.hracglobal.com/Overview/ManagementofResistance.aspx >.

Hutchison, W. D., E. C. Burkness, P. D. Mitchell, R. D. Moon, T. W. Leslie, Shelby J Fleischer, M. Abrahamson, K. L. Hamilton, K. L. Steffey, M. E. Gray, Richard L Hellmich, L. V. Kaster, Thomas E. Hunt, R. J. Wright, K. Pecinovsky, T. L. Rabaey, B. R. Flood, and E. S. Raun. (2010). "Areawide

Suppression of European Corn Borer with Bt Maize Reaps Savings to Non-Bt Maize Growers." *Science* 330 p 222 - 25.

Icoz, I., D. Saxena, D. A. Andow, C. Zwahlen, and G. Stotzky. (2008). "Microbial Populations and Enzyme Activities in Soil In Situ under Transgenic Corn Expressing Cry Proteins from." *J. Environ. Qual.* 37 (2): p 647-62. https://www.agronomy.org/publications/jeq/abstracts/37/2/647 >.

Iowa-State-University. (2010). "Soybean Aphid Management Field Guide." Service, Cooperative Extension. http://www.ent.iastate.edu/soybeanaphid/files/AphidGuide3(5-3).pdf >.

Iowa Crop Improvement Association. (2000). "Current soybean certification requirements from the Iowa Seed Certification Requirements Handbook." p 47 - 49. http://www.agron.iastate.edu/icia/PDFs/SOYBEAN%20Requirements.DOC >.

Jurat-Fuentes, Juan Luis, and Michael J Adang. (2001). "Importance of Cry1 delta-endotoxin domain II loops for binding specificity in *Heliothis virescens* (L.)." *Applied and Environmental Microbiology* 67 (1): p 323-29.

Jurat-Fuentes, Juan Luis, and Michael J Adang. (2006). "The *Heliothis virescens* cadherin protein expressed in *Drosophila* S2 cells functions as a receptor for *Bacillus thuringiensis* Cry1A but not Cry1Fa toxins." *Biochemistry* 45 (32): p 9688-95.

Krapu, Gary L, David A Brandt, and Robert R Cox Jr. (2004). "Less Waste Corn, More Land in Soybeans, and the Switch to Genetically Modified Crops: Trends with Important Implications for Wildlife Management." *Wildlife Society Bulletin, 2004* 32 (1): p 127 - 36.

Krausz, Ronald F., Bryan G. Young, G. E. O. R. Kapusta, and Joseph L. Matthews. (2001). "Influence of Weed Competition and Herbicides on Glyphosate-Resistant Soybean (*Glycine max*)." *Weed Technology* 15 (3): p 530-34. http://dx.doi.org/10.1614%2F0890-037X%282001%29015%5B0530%3AIOWCAH%5D2.0.CO%3B2 >.

Kuepper, George. (2003). "Organic Soybean Production." *Appropriate Technology Transfer for Rural Areas* p 5 pages. http://counties.cce.cornell.edu/oneida/Agriculture/Ag/crops/organic%20soybean.pdf >.

Lawhorn, C Nicole, Deborah A Neher, and Galen P Dively. (2009). "Impact of coleopteran targeting toxin (Cry3Bb1) of Bt corn on microbially mediated decomposition." *Applied Soil Ecology* 41 (3): p 364 - 68.

Leonard, B. Rogers, David J. Boethel, Alton N. Sparks Jr., M. Blake Layton, Jeffrey S. Mink, Anthony M. Pavloff, Eugene Burris, and Jerry B. Graves. (1990). "Variations in Response of Soybean Looper (Lepidoptera: Noctuidae) to Selected Insecticides in Louisiana." *Journal of Economic Entomology* 83 (1): p 27 - 34.

Locke, Martin A, Robert M Zablotowicz, and Krishna N Reddy. (2008). "Integrating soil conservation practices and glyphosate-resistant crops: impacts on soil." *Pest Management Science* 64 p 457 - 69.

Loux, M. M., D. Doohan, A. F. Dobbels, B. Reeb, W. G. Johnson, and T. R. Legleite. (2013). "2013 Weed Control Guide for Ohio and Indiana." Extension, Horticulture and Crop Science: Ohio State University Extension and Botany and Plant Pathology: Purdue. Last Accessed: 11-29-13 < http://agcrops.osu.edu/publications >.

Loux, Mark M, Jeff M Stachler, William G Johnson, Glenn R W Nice, and Thomas T Bauman. (2008). "Weed Control Guide for Ohio Field Crops (Report: Bulletin 789)." Ohio State University Extension. http://ohioline.osu.edu/b789/index.html >.

Lu, Yanhui, Kongming Wu, Yuying Jiang, Yuyuan Guo, and Nicolas Desneux. (2012). "Widespread adoption of Bt cotton and insecticide decrease promotes biocontrol services." *Nature* 487 p 362 - 67.

Lupwayi, N Z, K N Harker, G W Clayton, T K Turkington, W A Rice, and J T O'Donovan. (2004). "Soil Microbial Biomass and Diversity After Herbicide Application." *Canadian Journal of Plant Science* 84 (2): p 677 - 85.

Mallory-Smith, Carol, and Maria Zapiola. (2008). "Gene flow from glyphosate-resistant crops." *Pest Management Science* 64 p 428-40.

Mannion, A M, and Stephen Morse. (2012). "Biotechnology in agriculture: Agronomic and environmental considerations and reflections based on 15 years of GM crops." *Progress in Physical Geography* 36 (6): p 747 - 63.

Marvier, Michelle, Chanel McCreedy, James Regetz, and Peter Kareiva. (2007). "A Meta-Analysis of Effects of Bt Cotton and Maize on Nontarget Invertebrates." *Science* 316 (5830): p 1475-77. http://www.sciencemag.org/content/316/5830/1475.abstract >.

McBride, William D, and Catherine Greene. (2008). "The Profitability of Organic Soybean Production." *American Agricultural Economics Association Annual Meeting, July 27 - 29, 2008*. http://ageconsearch.umn.edu/bitstream/6449/2/465035.pdf >.

McPherson, R. M., R. D. Hudson, and D. C. Jones. (1997). "Summary of Losses from Insect Damage and Costs of Control in Georgia." The Bugwood Network. http://www.bugwood.org/sl97/soybean.97.htm >.

McWilliams, D.A., D.R. Berglund, and G.J. Endres. "Soybean Growth and Management Quick Guide." Ed. Service, NDSU Extension. Fargo, North Dakota: North Dakota State University, 1999.

Mendelsohn, M., J. Kough, Zigfridas Vaituzis, and K. Matthews. (2003). "Are Bt crops safe?" *Nature Biotechnology* 21 (9): p 1003-09.

Michigan State University Extension. (2012). "Organic Weed Control in Field Crops." http://msue.anr.msu.edu/news/organic_weed_control_in_field_crops >.

Mississippi-State-University. (2004). "Soybean Insect Management Guide." msucares.com/insects/soybeans/pubs/insect_management.pdf >.

Monsanto. (2013). "Crop Recommendations. ." Last Accessed: 12-10-13 < http://www.roundupreadyplus.com/Pages/croprecommendations.aspx#/Crop-Recommendations=Soy >.

Musser, F R, Angus L Catchot Jr., J A Davis, D A Herbert, B R Leonard, G M Lorenz, T Reed, D D Reisig, and S D Stewart. (2012). "2011 Soybean Insect Losses in the Southern US." *Midwest Entomologist* 5 p 11 - 22.

Musser, F R, Angus L Catchot Jr., G M Lorenz, and S D Stewart. (2010). "2010 Soybean Insect Losses for Mississippi, Tennessee, and Arkansas." *Midwest Entomologist* 4 p 22 - 28.

Naranjo, Steven E. (2005). "Long-Term Assessment of the Effects of Transgenic *Bt* Cotton on the Function of the Natural Enemy Community." *Environmental Entomology* 34 (5): p 1211 - 23.

Naranjo, Steven E. (2009). "Impacts of Bt crops on non-target invertebrates and insecticide use patterns " *CAB Reviews:Perspectives in Agriculture, Veterinary Science, Nutrition, and Natural Resources* 4 (11).

NatureServe Explorer. (2012). www.natureserve.org/explorer >.

NCAT. (2003). "NCAT's Organic Crops Workbook: A Guide to Sustainable and Allowed Practices." https://attra.ncat.org/attra-pub/summaries/summary.php?pub=67 >.

Norsworthy, Jason K, Sarah M Ward, David R Shaw, Rick S Llewellyn, Robert L Nichols, Theodore M Webster, Kevin W Bradley, George Frisvold, Stephen B Powles, Nilda R Burgos, William W Witt, and Michael Barrett. (2012). "Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations." *Weed Science* 60 p 31 - 62.

North Central Integrated Pest Management Center. (2012). "Pest Management Strategic Plans." http://www.ncipmc.org/pmsp/ >.

NRC. (2010). *The Impact of Genetically Engineered Crops on Farm Sustainability in the United States*. Washington, DC: National Academies Press. http://www.nap.edu/catalog.php?record_id=12804 >.

OECD. (2000a). "Consensus Document on the Biology of *Glycine max* (L.) Merr. (Soybean)." Organisation for Economic Co-operation and Development http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2000)9&docLanguage=En >.

OECD. (2000b). "Consensus Document on the Biology of *Glycine max* (L.). Merr. (Soybean)." http://www.oecd.org/dataoecd/16/56/46815668.pdf >.

OSTP. (2001). "Case Studies of Environmental Regulation for Biotechnology: Soybean plus sidebar (Report: Case Study III)." http://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study4.pdf >.

Owen, M. D., B. G. Young, D. R. Shaw, R. G. Wilson, D. L. Jordan, P. M. Dixon, and S. C. Weller. (2011). "Benchmark study on glyphosate-resistant crop systems in the United States. Part 2: Perspectives." *Pest Management Science* 67 (7): p 747-57. http://www.ncbi.nlm.nih.gov/pubmed/21452168 >.

Owen, Michael D. K. (2008). "Weed species shifts in glyphosate-resistant crops." *Pest Management Science* 64 (4): p 377-87. ISI:000254497600011 >.

Palmer, William E, Peter T Bromley, and John R Anderson Jr. . (2012). "Pesticides and Wildlife - Soybeans." North Carolina Extension Integrated Pest Management Program. http://ipm.ncsu.edu/wildlife/soybeans_wildlife.html >.

Pedigo, Larry P. (1996). "Pest Management Theory." *Entomology and Pest Management*. Upper Saddle River, NJ: Prentice Hall. p 279-300.

Penn State Extension. (2012). "Soybean Insect Control." College of Agricultural Sciences, The Pennsylvania State University, PA. http://extension.psu.edu/agronomy-guide/pm/sec4/sec43a >.

PennState-Entomology-Extension. (2014). "Fact Sheets. Soybean Aphid, Aphis glycines." http://ento.psu.edu/extension/factsheets/soybean-aphid-1 >.

Pigott, Craig R, and David J Ellar. (2007). "Role of Receptors in *Bacillus thuringiensis* Crystal Toxin Activity." *Microbiology and Molecular Biology Reviews* 71 (2): p 255-81.

Pilcher, Clinton D, Marlin E Rice, and John J Obrycki. (2005). "Impact of Transgenic *Bacillus thuringiensis* Corn and Crop Phenology on Five Nontarget Arthropods." *Environmental Entomology* 34 (5): p 1302 - 16.

Place, G. T., S. C. Reberg-Horton, T. E. Carter Jr., and A. N. Smith. (2011). "Effects of Soybean Seed Size on Weed Competiton." *Agronomy Journal* 103 (1): p 175 - 81.

Pline, W. (1999). " Effect of Temperature and Chemical Additives on the Efficacy of the Herbicides Glufosinate and Glyphosate in Weed Management of Liberty-Link and Roundup-Ready Soybeans." Virginia Tech. *Dissertations and Theses*. http://scholar.lib.vt.edu/theses/available/etd-041299-151856/ >.

Ponsard, Sergine, Andrew P Gutierrez, and Nicholas J Mills. (2002). "Effect of *Bt*-toxin (Cry1Ac) in Transgenic Cotton on the Adult Longevity of Four Heteropteran Predators." *Environmental Entomology* 31 (6): p 1197 - 205.

Purdue-University-Extension. (2009). "Field Crops IPM. Speed Scouting Worksheet." http://extension.entm.purdue.edu/fieldcropsipm/insects/soybean-aphid.php >.

Quist, David. (2010). "Vertical (Trans)gene Flow: Implications for Crop Diversity and Wild Relatives." *Biotechnology & Biosafety Series 11*. Penang, Malaysia: Third World Network.

Raven, Peter H. (2010). "Does the Use of Transgenic Plants Diminish or Promote Biodiversity." *New Biotechnology* 27 (5): p 528 - 33.

Ray, J.D., T.C. Kilen, C.A. Abel, and R.L. Paris. (2003). "Soybean natural cross-pollination rates under field conditions." *Environmental Biosafety Research* 22 (2): p 133-38.

Robertson, G.P., and S.M. Swinton. (2005). "Reconciling agricultural productivity and environmental integrity: A grand challenge for agriculture." *Frontiers in Agriculture and the Environment* 3 p 38-46.

Robinson, A.P., and S.P. Conley. (2007). "Plant populsation and seeding rates for soybeans." Last Accessed: 1-16-14 < https://www.extension.purdue.edu/extmedia/AY/AY-217-W.pdf >.

Rolim, A. A. S. Gomez, S. A. Cavaguchi Yano, A. Specht, C. G.Tardelli De Jesus Andrade, and D. R. Sosa-Gómez. (2013). "Morphological and Molecular Characterization of the Eggs of Some Noctuid Species Associated with Soybean in Brazil." *Annals of the Entomological Society of America* 106 (5): p 643-51. Last Accessed: 2013/11/22 < http://www.bioone.org/doi/abs/10.1603/AN13049 >.

Romeis, Jorg, Detlef Bartsch, Franz Bigler, Marco P. Candolfi, Marco M. C. Gielkens, Susan E. Hartley, Richard L. Hellmich, Joseph E. Huesing, Paul C. Jepson, Raymond Layton, Hector Quemada, Alan Raybould, Robyn I. Rose, Joachim Schiemann, Mark K. Sears, Anthony M. Shelton, Jeremy Sweet, Zigfridas Vaituzis, and Jeffrey D. Wolt. (2008). "Assessment of risk of insect-resistant transgenic crops to nontarget arthropods." *Nat Biotech* 26 (2): p 203-08. http://dx.doi.org/10.1038/nbt1381 >.

Romeis, Jorg, Michael Meissle, and Franz Bigler. (2006). "Transgenic crops expressing *Bacillus thuringiensis* toxins and biological control." *Nature Biotechnology* 24 (1): p 63-71. http://dx.doi.org/10.1038/nbt1180 >.

Ronald, Pamela, and Benny Fouche. (2006). "Genetic Engineering and Organic Production Systems." *University of California - Division of Agriculture and Natural Resources* Publication 8188 p 5 pages. http://ucanr.org/freepubs/docs/8188.pdf >.

Sanahuja, Georgina, Raviraj Banakar, Richard M. Twyman, Teresa Capell, and Paul Christou. (2011). "*Bacillus thuringiensis*: a century of research, development and commercial applications." *Plant Biotechnology Journal* 9 (3): p 283-300. http://dx.doi.org/10.1111/j.1467-7652.2011.00595.x >.

Sanvido, Olivier, Jörg Romeis, and Franz Bigler. (2007). "Ecological Impacts of Genetically Modified Crops: Ten Years of Field Research and Commercial Cultivation." *Advances in Biochemical Engineering/Biotechnology* 107 p 235 - 78.

Satyanarayana, T. , and L. W. Getzin. (1973). "Properties of a Stable Cell-Free Esterase from Soil." *Biochemistry* 12 (8,): p 1566-71. http://pubs.acs.org/doi/pdf/10.1021/bi00732a016 >.

Saxena, D, and Guenther Stotzky. (2001). "Bacillus thuringiensis (Bt) toxin released from root exudates and biomass of Bt corn has no apparent effect on earthworms, nematodes, protozoa, bacteria, and fungi in soil." *Soil Biology and Biochemistry* 33 (9): p 1225 - 30.

Schmalenberger, Achim, and Christoph C Tebbe. (2002). "Bacterial community composition in the rhizosphere of a transgenic, herbicide-resistant maize (*Zea mays*) and comparison to its non-transgenic cultivar *Bosphore*." *FEMS Microbiology Ecology* 40 p 29 - 37.

Shan, G, S. K. Embrey, R.A. Herman, and R. McCormick. (2008). "Cry1F protein not detected in soil after three years of transgenic Bt corn (1507 corn) use." *Environmental Entomology* 37 p 255-62.

Shaw, D.R., S. Culpepper, M. Owen, A. Price, and R. Wilson. (2012). "Herbicide-resistant Weeds Threaten Soil Conservation Gains: Finding a Balance for Soil and Farm Sustainability." *CAST Issue Paper* 49.

Shelton, Anthony M. (2012). "Biological Control: A Guide to Natural Enemies in North America." Cornell University. http://www.biocontrol.entomology.cornell.edu/pathogens/bacteria.html >.

Shen, Ren, Hong Cai, and Wan Gong. (2006). "Transgenic Bt cotton has no apparent effect on enzymatic activities or functional diversity of microbial communities in rhizosphere soil." *Plant and Soil* 285 (1): p 149-59. http://dx.doi.org/10.1007/s11104-006-9000-z >.

Showalter, Ann M, Shannon Heuberger, Bruce E Tabashnik, and Yves Carrière. (2009). "A Primer for Using Transgenic Insecticidal Cotton in Developing Countries." *Journal of Insect Science* 9 (22): p 1 - 22.

Sivasupramaniam, Saku, W J Moar, L G Ruschke, J A Osborn, C Jiang, J L Sebaugh, G R Brown, Z W Shappley, Mark E Oppenhuizen, J W Mullins, and J T Greenplate. (2008). "Toxicity and Characterization of Cotton Expressing *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 Proteins for Control of Lepidopteran Pests." *Journal of Economic Entomology* 101 (2): p 546 - 54.

Smith, Keith. (1994). "Status of Soybean Insect Pests in the United States." *Handbook of Soybean Insect Pests*. Lanham, MD: Entomological Society of America. p 3.

Soyatech. (2012). "Soy Facts." http://soyatech.com/soy_facts.htm >.

Stewart, S. D., J. J. Adamczyk, K. S. Knighten, and F. M. Davis. (2001). "Impact of Bt Cottons Expressing One or Two Insecticidal Proteins of Bacillus thuringiensis Berliner on Growth and Survival of Noctuid (Lepidoptera) Larvae." *Journal of Economic Entomology* 94 (3): p 752-60. Last Accessed: 2013/11/21 < http://dx.doi.org/10.1603/0022-0493-94.3.752 >.

Stewart, S.D. (2007). "Bt Cotton." Last Accessed: 12-23-13 < http://www.utcrops.com/cotton/cotton_insects/btcotton.htm >.

Stratus-Agri-Marketing. (2013). "Glyphosate Resistant Weeds – Intensifying." Last Accessed: 12-2-13 < http://www.stratusresearch.com/blog07.htm >.

Sun, C X, L J Chen, Z J Wu, L K Zhou, and H Shimizu. (2007). "Soil persistence of *Bacillus thuringiensis* (Bt) toxin from transgenic Bt cotton tissues and its effect on soil enzyme activities." *Biology and Fertility of Soils* 43 (5): p 617 - 20.

Sundstrom, F.J., J. Williams, A. Van Deynze, and K.J. Bradford. (2002). "Identity Preservation of Agricultural Commodities." *ANR Publication* 8077.

Teasdale, John R, Charles B Coffman, and Ruth W Mangum. (2007). "Potential Long-Term Benefits of No-Tillage and Organic Cropping Systems for Grain Production and Soil Improvement." *Agronomy Journal* 99 p 1297 - 305.

The American Soybean Association. (2012a). "Soy Stats 2012." http://www.soystats.com/2012/Default-frames.htm >.

The American Soybean Association. (2012b). "U.S. Soybean Meal Production 1986 - 2011." Soy Stats. http://www.soystats.com/2012/Default-frames.htm >.

The American Soybean Association. (2012c). "U.S. Soybean Meal Use by Livestock 2011." http://www.soystats.com/2012/Default-frames.htm >.

The Non-GMO Project. (2012). "Overview of the Standard - The Goals of the Non-GMO Project Standard." http://www.nongmoproject.org/product-verification/non-gmo-project-standard/overview-of-the-standard/ >.

Thomas, James D, and David J. Boethel. (1994). "Synergism of Insecticides in Tests with Resistant Soybean Looper Larvae (Lepidoptera: Noctuidae) in the Laboratory and Field." *Journal of Economic Entomology* 87 (6): p 1416-22.

Tian, J. C., X. P. Wang, L. P. Long, J. Romeis, S. E. Naranjo, R. L. Hellmich, P. Wang, E. D. Earle, and A. M. Shelton. (2013). "Bt Crops Producing Cry1Ac, Cry2Ab and Cry1F Do Not Harm the Green Lacewing, Chrysoperla rufilabris." *PLoS ONE* 8 (3). http://www.scopus.com/inward/record.url?eid=2-s2.0-84875478145&partnerID=40&md5=7e4539f701fd94e4626a3588adae759b >.

Tian, J.C. , H. L. Collins, J. Romeis, S. E. Naranjo, R. L. Hellmich, and A. M. Shelton. (2012). "Using field-evolved resistance to Cry1F maize in a lepidopteran pest to demonstrate no adverse effects of Cry1F on one of its major predators." *Transgenic Research* 21 p 1303-10.

Torres, J B, and J R Ruberson. (2008). "Interactions of Bacillus thuringiensis Cry1Ac toxin in genetically engineered cotton with predatory heteropterans." *Transgenic Research* 17 (3): p 345-54. http://dx.doi.org/10.1007/s11248-007-9109-8 >.

Torres, Jorge B., and John R. Ruberson. (2005). "Canopy- and Ground-Dwelling Predatory Arthropods in Commercial *Bt* and non-*Bt* Cotton Fields: Patterns and Mechanisms." *Environmental Entomology* 34 (5): p 1242-56.

University of Illinois. (2006). "No-till is now the "Conventional" Tillage System for Illinois Farmers " http://web.extension.illinois.edu/state/newsdetail.cfm?NewsID=4991 >.

US-EPA. (2005a). "Biopesticide Registration Action Document. Bacillus thuringiensis Cry1F (synpro) and Cry1Ac (synpro). Construct 281/3006 Insecticidal Crystal Proteins as expressed in cotton " US Environmental Protection Agency, Office of Pesticide Programs http://www.epa.gov/oppbppd1/biopesticides/ingredients_keep/tech_docs/brad_006512.pdf >.

US-EPA. (2005b). "Biopesticide Registratoin Action Document (Bacillus thuringiensis Cry1F (synpro and Cry1Ac (synpro) Construct 281/3006 Insecticidal Crystal Proteins as expressed in cotton " US Environmental Protection Agency, Office of Pesticide Programs http://www.epa.gov/oppbppd1/biopesticides/ingredients_keep/tech_docs/brad_006512.pdf >.

US-EPA. (2008). "Glufosinate Summary Document
Registration Review: Initial Docket
March 2008." http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0190-0003;oldLink=false >.

US-EPA. (2010a). "Agriculture."

US-EPA. (2010b). "Introduction to Biotechnology Regulation for Pesticides." US-EPA. http://www.epa.gov/oppbppd1/biopesticides/regtools/biotech-reg-prod.htm >.

US-EPA. (2011). "Pesticides: Registration Review." http://www.epa.gov/oppsrrd1/registration_review/ >.

US-EPA. (2013a). "Environmental Fate and Ecological Risk Assessment for the Registration Review of Glufosinate." http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0190-0023 >.

US-EPA. (2013b). "ERA for Support of Seed increase Sec 3 for PIP in DAS 81419-2." Last Accessed: 1-15-2014 < http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2013-0703-0004 >.

US-EPA. (2013c). "Registering Pesticides." http://www.epa.gov/opp00001/regulating/registering/ >.

US-EPA. (2013d). "Review of Human Health and Product Characterization Data for registration of Bt Cry1Ac and Cry1F in DAS-81419-2." Last Accessed: 1-15-14 <

US-EPA. (2013e). "Review of Insect Management Considerations for Bt Soybean Event DAS-81419-2." http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2013-0703-0005 >.

US-EPA. (2014). "Draft Biopesticides Registration Action Document (BRAD) Plant-Incorporated Protectants: Cry1Ac Protein and Cry1F Protein " Environmental Protection Agency, Office of Pesticide Programs. Last Accessed: 1-15-14 < http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2013-0703-0003 >.

US-FDA. (1992). "Guidance to Industry for Foods Derived from New Plant Varieties." *Federal Register* 57 (104): p 22984. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096095.htm >.

US-FDA. (2006). "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use." http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/biotechnology/ucm096156.htm >.

US Fish and Wildlife Service. (2008). "Delmarva Peninsula Fox Squirrel *Sciurus niger cinereus*." www.fws.gov/endangered/esa-library/pdf/squirrel.pdf >.

US Fish and Wildlife Service. (2011). "Environmental Assessment - Use of Genetically Modified, Glyphosate-Tolerant Soybeans and Corn on National Wildlife Refuge Lands in the Mountain - Prairie Region (Region 6)."

USDA-AMS. (2010). "PDP Program Overview." http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?more=G.OptionalText2&template=TemplateG&navID=PDPDownloadNav2Link2&rightNav1=PDPDownloadNav2Link2&topNav=&leftNav=ScienceandLaboratories&page=PDPProgramOverview&resultType=&acct=pestcddataprg >.

USDA-AMS. (2011). "Agricultural Marketing Service memo, "Clarification of Existing Regulations Regarding the Use of Genetically Modified Organisms in Organic Production and Handling"." Last Accessed: March 7, 2012 < http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5090396 >.

USDA-AMS. (2012). "USDA Agricultural Marketing Service - National Organic Program." http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateA&navID=NationalOrganicProgram&leftNav=NationalOrganicProgram&page=NOPNationalOrganicProgramHome&acct=AMSPW >.

USDA-APHIS. (1995). "Availability of Determination of Nonregulated Status for Genetically Engineered Cotton." http://www.gpo.gov/fdsys/pkg/FR-1995-07-13/pdf/95-17080.pdf >.

USDA-APHIS. (1996). "Availability of Determination of Nonregulated Status for Soybeans Genetically Engineered for Glufosinate Herbicide Tolerance." http://federalregister.gov/a/96-20921 >.

USDA-APHIS. (2001). "Availibility of Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance and Glufosinate Herbicide Tolerance." Inspection, Animal and Plant Health. http://www.gpo.gov/fdsys/pkg/FR-2001-08-14/pdf/01-20307.pdf >.

USDA-APHIS. (2004). "Availability of Determination of Nonregulated Status for Cotton Lines Genetically Engineered for Insect Resistance." http://www.gpo.gov/fdsys/pkg/FR-2004-08-13/pdf/04-18523.pdf >.

USDA-APHIS. (2005). "Availability of Determination of Nonregulated Status for Genetically Engineered Corn (Corn line DAS-59122-7)." http://www.gpo.gov/fdsys/pkg/FR-2005-10-07/html/05-20194.htm >.

USDA-APHIS. (2011a). "Final Environmental Assessment, Monsanto Company Petition (09-SY-194U) for Determination of Non-regulated Status of Event MON 87701." http://www.aphis.usda.gov/brs/aphisdocs/09_08201p_fea.pdf >.

USDA-APHIS. (2011b). "Monsanto Co,; Determination of Nonregulated Status for Soybean Genetically Engineered for Insect Resistance." http://www.aphis.usda.gov/brs/fedregister/BRS_20111012b.pdf >.

USDA-APHIS. (2011c). "Plant Pest Risk Assessment for Monsanto MON 87701 Soybean." http://www.aphis.usda.gov/brs/aphisdocs/09_08201p_dpra.pdf >.

USDA-APHIS. (2012a). "Draft Environmental Assessment for Dow AgroSciences Petition for Nonregulated Status of DAS-68416-4 Soybean." http://www.aphis.usda.gov/brs/aphisdocs/09_34901p_dea.pdf >.

USDA-APHIS. (2013). "Draft Plant Pest Risk Assessment for Insect Resistant Soybean (Glycine max) event DAS-81419-2. Petition 12-272-01p." Services, Biotechnology Regulatory.

USDA-ERS. (2006). "The First Decade of Genetically Engineered Crops in the United States." http://www.ers.usda.gov/publications/eib-economic-information-bulletin/eib11.aspx >.

USDA-ERS. (2008). "Soybeans and Oil Crops: Market Outlook. Economic Research Service." Last Accessed: January 21, 2011 < http://www.ers.usda.gov/briefing/soybeansoilcrops/2008baseline.htm. >.

USDA-ERS. (2010). "Table 3: Certified organicand total U.S. acreage, selected crops and livestock, 1995-2008." http://www.ers.usda.gov/data-products/organic-production.aspx >.
USDA-ERS. (2012). "Major Uses of Land in the United States, 2002 (updated 2012)."
USDA-ERS. (2013). "Agricultural Baseline Projections. Baseline Related Historical Data." http://www.ers.usda.gov/topics/farm-economy/agricultural-baseline-projections/baseline-related-historical-data.aspx >.
USDA-FAS. (2013). "Exports-Planting Seeds. BICO-10 FAS Converted." http://www.fas.usda.gov/gats/ExpressQuery1.aspx >.
USDA-FAS. "BICO-10 Export Data to S. America Dec-Nov."
USDA-NASS. (2007). "NASS Database Agricultural Chemical Statistics Search--By Crop " http://www.pestmanagement.info/nass/app_statcs3_crop.cfm >.
USDA-NASS. (2013a). "Acreage." http://www.usda.gov/nass/PUBS/TODAYRPT/acrg0613.pdf >.
USDA-NASS. (2013b). "Agricultural Prices " http://usda01.library.cornell.edu/usda/current/AgriPric/AgriPric-11-27-2013.pdf >.
USDA-NASS. (2013c). "Crop Production-b." http://www.usda.gov/nass/PUBS/TODAYRPT/crop1113.pdf >.
USDA-NASS. (2013d). "Crop Production August 11." http://usda01.library.cornell.edu/usda/nass/CropProd//2010s/2013/CropProd-08-12-2013.pdf >.
USDA-NASS. "Quick Stats 2.0. Soybean Insecticide use." National Agricultural Statistics Service. http://quickstats.nass.usda.gov/ >.
USDA-NRCS. (2006a). "Conservation Resource Brief: Air Quality, Number 0605." National Resources Conservation Service. http://www.nrcs.usda.gov/feature/outlook/Air%20Quality.pdf >.
USDA-NRCS. (2006c). "Conservation Resource Brief: Soil Erosion, Number 0602." National Resources Conservation Service. http://www.nrcs.usda.gov/feature/outlook/Soil%20Erosion.pdf >.
USDA-OCE. (2013). "USDA Agricultural Projections to 2022." http://www.usda.gov/oce/commodity/projections/USDAAgriculturalProjections2022.pdf >.
USDA. (2011a). "Organic Production and Handling Standards U.S. Department of Agriculture-Agricultural Marketing Service. ." http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3004445&acct=nop
geninfo >.
USDA. (2011b). "USDA Agricultural Projections to 2020." USDA. http://www.usda.gov/oce/commodity/archive_projections/USDAAgriculturalProjections2020.pdf >.
USDA. (2012a). "7 CFR § 205.601 National Organic Program - Synthetic substances allowed for use in organic crop production." http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=6a416fef1cd12d31c433622a4f2c095e&n=7y3.1.1.9.32&r=PART&ty=HTML#7:3.1.1.9.32.7.354.3 >.
USDA. (2012b). "7 CFR § 205.602 National Organic Program - Nonsynthetic substances prohibited for use in organic crop production." http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=6a416fef1cd12d31c433622a4f2c095e&n=7y3.1.1.9.32&r=PART&ty=HTML#7:3.1.1.9.32.7.354.3 >.
USDA. (2012c). "Crop Values 2011 Summary." Service, National Agricultural Statistics. http://usda01.library.cornell.edu/usda/current/CropValuSu/CropValuSu-02-16-2012.pdf. >.
USDA. (2012d). "Federal Seed Act 7 CFR § 201.67: Seed Certifying Agency Standards and Procedures." http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2f1a62d0bcb927d31f492e59d47b40ec&rgn=div8&view=text&node=7:3.1.1.7.29.0.345.100&idno=7 >.

USDA. (2012e). "Federal Seed Act 7 CFR § 201.68: Eligibility requirements for certification of varieties." http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=2483c6e45df6967754e3fe197e8bec8b;rgn=div5;view=text;node=7%3A3.1.1.7.29;idno=7;cc=ecfr#7:3.1.1.7.29.0.345.102 >.

USDA. (2012f). "Federal Seed Act 7 CFR § 201.69: Classes of Certified Seed." http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=2483c6e45df6967754e3fe197e8bec8b;rgn=div5;view=text;node=7%3A3.1.1.7.29;idno=7;cc=ecfr#7:3.1.1.7.29.0.345.102 >.

USDA. (2012g). "Federal Seed Act 7 CFR § 201.72: Production of all classes of certified seed." http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=2483c6e45df6967754e3fe197e8bec8b;rgn=div5;view=text;node=7%3A3.1.1.7.29;idno=7;cc=ecfr#7:3.1.1.7.29.0.345.102 >.

USDA. (2012h). "Federal Seed Act 7 CFR § 201.76: Minimum Land, Isolation, Field and Seed Standards." http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2f1a62d0bcb927d31f492e59d47b40ec&rgn=div8&view=text&node=7:3.1.1.7.29.0.345.109&idno=7 >.

USDA. (2012i). "National Organic Program 7 C.F.R. § 205.272 Commingling and contact with prohibited substance prevention practice standard." http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;rgn=div5;view=text;node=7%3A3.1.1.9.32;idno=7;sid=bf165925f395353921ec628f936e9f2d;cc=ecfr#7:3.1.1.9.32.3.354.3 >.

USDA. (2012j). "National Organic Program 7 C.F.R. § 205.300 Use of Term Organic." http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=aaa529f77569b2ebd4e9d9cecb66bbdc&rgn=div8&view=text&node=7:3.1.1.9.32.4.354.1&idno=7 >.

USDA. (2012k). "Oilseeds: World Market and Trade. Circular Series, FOP 12-12, December 2012." http://usda01.library.cornell.edu/usda/fas/oilseed-trade//2010s/2012/oilseed-trade-12-11-2012.pdf >.

USDA. (2013). "Global Agricultural Trade Systems Online." Last Accessed: February 8, 2013 < http://www.fas.usda.gov/gats/default.aspx >.

USDA ERS. (2010a). "Table 3: Certified organicand total U.S. acreage, selected crops and livestock, 1995-2008." http://www.ers.usda.gov/data-products/organic-production.aspx >.

USDA ERS. (2010b). "Table 7: U.S. Certified organic beans. Acres of soybeans, dry beans, dry peas/lentils, by State, 1997 and 2000 - 2008." http://www.ers.usda.gov/datafiles/Organic_Production/StateLevel_Tables_/Beans.xls >.

USDA ERS. (2011a). "Agricultural Income and Finance Outlook Department of Agriculture–Economic Research Service." http://www.ers.usda.gov/publications/ais-agricultural-income-and-finance-outlook/ais91.aspx >.

USDA ERS. (2011b). "Futures Price Forecast Model: estimates for the season-average price and counter-cyclical payment rate for soybeans " http://www.ers.usda.gov/data-products/season-average-price-forecasts.aspx >.

USDA ERS. (2012a). "Commodity Costs and Returns - Soybean Production Costs and Returns per Planted Acre by Region, Excluding Government Payments, 2010-2011. ." http://www.ers.usda.gov/data-products/commodity-costs-and-returns.aspx#historic2 >.

USDA ERS. (2012b). "Genetically engineered varieties of corn, upland cotton, and soybeans, by State and for the United States, 2000-12." USDA ERS. . http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx >.

USDA ERS. (2012c). "Market Outlook - USDA Soybean Baseline, 2010-19." Last Accessed: February 7, 2013 < http://www.ers.usda.gov/topics/crops/soybeans-oil-crops/market-outlook/usda-soybean-baseline,-2010-19.aspx >.

USDA ERS. (2012d). "Oil Crops Year Book 2012." Service, Economic Research. http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1290 >.

USDA ERS. (2012e). "Soybean & Oil Crops: Trade." http://www.ers.usda.gov/topics/crops/soybeans-oil-crops/trade.aspx#US >.

USDA ERS. (2012f). "Soybeans & Oil Crops." http://www.ers.usda.gov/topics/crops/soybeans-oil-crops/background.aspx >.

USDA ERS. (2012g). "USDA Economic Research Service Adoption of Genetically Engineered Crops in the U.S.: Recent Trends in GE Adoption." http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx >.

USDA ERS. (2012h). "Value of U.S. Agricultural Trade, by Fiscal Year. Retrieved Jan. 2013 from U.S. Department of Agriculture–Economic Research Service." http://www.ers.usda.gov/data-products/foreign-agricultural-trade-of-the-united-states-(fatus)/fiscal-year.aspx >.

USDA FAS. (2013). "Oilseeds: World Markets and Trade. Circular Series, FOP 02-13, February 2013." Table 7 Soybeans: http://www.fas.usda.gov/psdonline/psdreport.aspx?hidReportRetrievalName=BVS&hidReportRetrievalID=706&hidReportRetrievalTemplateID=8 ; Table 8 Soybean Meal: http://www.fas.usda.gov/psdonline/psdreport.aspx?hidReportRetrievalName=BVS&hidReportRetrievalID=707&hidReportRetrievalTemplateID=8 ; Table 9 Soybean Oil: http://www.fas.usda.gov/psdonline/psdreport.aspx?hidReportRetrievalName=BVS&hidReportRetrievalID=708&hidReportRetrievalTemplateID=8 ; Table 10 Soybeans and Products: http://www.fas.usda.gov/psdonline/psdreport.aspx?hidReportRetrievalName=BVS&hidReportRetrievalID=709&hidReportRetrievalTemplateID=11 >.

USDA NASS. (2007a). "2007 Census of Agriculture, United States Summary and State Data." http://www.agcensus.usda.gov/Publications/2007/Full_Report/ >.

USDA NASS. (2007b). "Agricultural Chemical Usage 2006 Field Crops Summary." http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1560 >.

USDA NASS. (2008). "2008 Organic Survey - Organic Field Crops Harvested from Certified and Exempt Organic Farms: 2008." http://www.agcensus.usda.gov/Publications/2007/Online_Highlights/Organics/index.php >.

USDA NASS. (2011a). "U.S. Soybean Acres." http://www.nass.usda.gov/Charts_and_Maps/graphics/soyac.pdf >.

USDA NASS. (2011b). "USDA National Agricultural Statistics Service. Acreage Report." http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1000 >.

USDA NASS. (2011c). "USDA National Agricultural Statistics Service: Quick Stats." http://www.nass.usda.gov/Data_and_Statistics/Quick_Stats/ >.

USDA NASS. (2012a). "Acreage Report - Soybean." www.usda.gov/nass/PUBS/TODAYRPT/acrg0612.pdf >.

USDA NASS. (2012b). "USDA National Agricultural Statistics Service. Acreage Report " http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1000 >.

USDA NASS. (2012c). "USDA National Agricultural Statistics Service. Acreage Report - Corn Biotechnology Varieties as a Percent of All Corn Planted - States and United States: 2011 and 2012." USDA.

USDA NASS. (2013). "USDA National Agricultural Statistics Service, Statistics by Subject." http://www.nass.usda.gov/Statistics_by_Subject/result.php?02724256-DFB8-3BB1-953C-4E665A5E7612&sector=CROPS&group=FIELD%20CROPS&comm=SOYBEANS >.

van Frankenhuyzen, Kees. (2009). "Insecticidal activity of *Bacillus thuringiensis* crystal proteins." *Journal of Invertebrate Pathology* 101 p 1 - 16.

Virginia Crop Improvement Association. (2012). "Soybean Certification Requirements." http://www.virginiacrop.org/vcia.soy.std.htm >.

Way, M. O. (1994). "Status of Soybean Insect Pests in the United States." *Handbook of Soybean Insect Pests*. Lanham, MD: Entomological Society of America. p 15-16.

Whitworth, R. Jeff, J P Michaud, and Holly N Davis. (2012). "Soybean Insect Management (Report MF743)." Kansas State University. www.ksre.ksu.edu/library/entml2/mf743.pdf >.

Wibawa, Wahyu, Rosli B Mohamad, Dzolkhifli Omar, Nurmasirah Mohd Zain, Adam B Puteh, and Yahya Awang. (2010). "Comparative impact of a single application of selected broad spectrum herbicides on ecological components of oil palm plantation." *African Journal of Agricultural Research* 5 (16): p 2097 - 102.

Wolfenbarger, L. LaReesa, Steven E. Naranjo, Jonathan G. Lundgren, Royce J. Bitzer, and Lidia S. Watrud. (2008). "Bt Crop Effects on Functional Guilds of Non-Target Arthropods: A Meta-Analysis." *PLoS ONE* 3 (5): p e2118. http://dx.plos.org/10.1371%2Fjournal.pone.0002118 >.

Wolt, J. D. (2011). "A mixture toxicity approach for environmental risk assessment of multiple insect resistance genes." *Environmental Toxicology and Chemistry* 30 (3): p 763-72. http://www.scopus.com/inward/record.url?eid=2-s2.0-79551597446&partnerID=40&md5=7850331adbf701e548ec163f68a60210 >.

WSSA. (2007). "Glufosinate." *Herbicide Handbook*. Lawrence, KS: Weed Science Society of America. p 247 - 48.

Wu, Felicia. (2006). "Mycotoxin Reduction in Bt Corn: Potential Economic, Health, and Regulatory Impacts." *Transgenic Research* 15 (3): p 277 - 89.

Yoshimura, Yasuyuki. (2011). "Wind tunnel and field assessment of pollen dispersal in Soybean [Glycine max (L.) Merr.]." *Journal of Plant Research* 124 (1): p 109-14. http://dx.doi.org/10.1007/s10265-010-0357-y >.

Young, Bryan. (2006). "Changes in Herbicide Use Patterns and Production Practices Resulting from Glyphosate-Resistant Crops." *Weed Technology* 20 p 301 - 07.

Yu, Hui-Lin, Yun-He Li, and Kong-Ming Wu. (2011). "Risk Assessment and Ecological Effects of Transgenic Bacillus thuringiensis Crops on Non-Target OrganismsF." *Journal of Integrative Plant Biology* 53 (7): p 520-38. http://dx.doi.org/10.1111/j.1744-7909.2011.01047.x >.

Zurbrügg, Corinne, Linda Hönemann, Michael Meissle, Jörg Romeis, and Wolfgang Nentwig. (2010). "Decomposition dynamics and structural plant components of genetically modified Bt maize leaves do not differ from leaves of conventional hybrids." *Transgenic Research* 19 (2): p 257 - 67.

7 Appendix A. Relative Costs of Herbicides for Application

The relative cost of various herbicides or herbicide combinations cited by DowAgrosciences as typical of those used by their contract growers for soybean seed production. Reported as cost per acre based on small quantities, survey limited to North Dakota. (North Dakota State, 2012)

Herbicide-trade name	Chemical name	Cost per acre (mid-dose range)
Preplant herbicide use:		
Valor	Flumioxazin	12.00
Postplant herbicide use:		
Classic	Chlorimuron-methyl	6.75
First Rate	Chloransulum-methyl	5.00
Marvel	Fluthiacet-methyl and Fomesafen	N/A
Select	Clethodim	8.45
Cadet	Fluthiacet-methyl	7.65
FlexStar	Fomesafen	13.15
FlexStar + Cadet+ Select		24.45
Liberty	Glufosinate	19.25

Price per acre of a midrange herbicide application (unless none presented and then the lowest recommended rate was listed for each)