Monsanto Company Petition 15-113-01 for Determination of Non-regulated Status for Dicambaand Glufosinate-Resistant Maize

OECD Unique Identifier: MON 87419 Maize

Final Environmental Assessment

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Acronyms and Abbreviations

AIA	advanced informed agreement
AMS	Agricultural Marketing Service
AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
Bt	Bacillus thuringiensis protein
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CH4	methane
СО	carbon monoxide
CO ₂	carbon dioxide
EA	environmental assessment
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act of 1973
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FFP	food, feed, or processing
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GE	genetically engineered
GHG	greenhouse gas
IPCC	Intergovernmental Panel on Climate Change
IPPC	International Plant Protection Convention
LMO	living modified organisms
N_2O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NOP	National Organic Program
NPS	Agricultural non-point source
OECD	Organization for Economic Cooperation and Development
PIP	plant incorporated protectants
PPRA	Plant Pest Risk Assessment
POST	Postemergent
PPA	Plant Protection Act
PRE	Pre-emergent

Acronyms and Abbreviations

TES	threatened and endangered species
TSCA	Toxic Substances Control Act
U.S.	United States
USDA	U.S. Department of Agriculture
USDA-ARMS	U.S. Department of Agriculture-Agricultural Resource Management Survey
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USC	United States Code
USFWS	U.S. Fish & Wildlife Service
WPS	Worker Protection Standard for Agricultural Pesticides

1 PURPOSE AND NEED

1.1 Background

Monsanto Company of St. Louis (henceforth referred to as Monsanto) submitted Petition 15-113-01p to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in April 2015 seeking a determination of nonregulated status of corn¹ event MON 87419 that has resistance to dicamba and glufosinate. MON 87419 corn is currently regulated under 7 CFR part 340. Interstate movements and field trials of MON 87419 corn have been conducted under notifications and permits acknowledged by APHIS since 2011. These field trials were conducted in diverse growing regions within the U.S., including Iowa, Illinois, Indiana, Kansas, Nebraska, Missouri, Ohio, Mississippi, Arkansas, Alabama, Louisiana, North Carolina, Pennsylvania, Wisconsin, Michigan, Arizona, California, Hawaii, and Puerto Rico. Details regarding and data resulting from these field trials are described in the MON 87419 corn petition (Monsanto 2015a) and analyzed for plant pest risk in the APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS 2015a).

The petition stated that APHIS should not regulate MON 87419 corn because it does not present a plant pest risk. In the event of a determination of nonregulated status, the nonregulated status would include MON 87419 corn, any progeny derived from crosses between MON 87419 corn and conventional corn, including crosses of MON 87419 corn with other biotechnology-derived corn varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (PPA).

1.2 Purpose of Product

MON 87419 corn is genetically engineered (GE) to express resistance to two herbicides, dicamba and glufosinate. This resistance will facilitate additional options for general weed control, with more options for control of problem weeds in corn production. By improving resistance of corn to dicamba, reduced damage will result from application of dicamba to corn. Providing corn with new resistance to dicamba and an additional variety with resistance to glufosinate will allow each to be used on MON 87419 corn for control of glyphosate resistant weeds, and to use these herbicides alternatively, either within seasons, or in one season and then the next.. Both herbicides can be used effectively alone or as mixtures; multiply effective herbicides used together for resistant weeds in corn production can prolong the usefulness of both and reduce the likelihood of development of resistance in weeds. MON 87419 corn was constructed by transforming an inbred line with the demethylase gene from *Stenotrophomonas maltophilia* that expresses a dicamba monooxygenase (DMO) protein to confer resistance to dicamba herbicide. MON 87419 corn also has the phosphinothricin N-acetyltransferase (pat) gene from *Streptomyces viridochromogenes* expresses the PAT protein and provides resistance to glufosinate herbicide. These bacteria from which the proteins derived are commonly found in soil or other environmental sources. The herbicides that can be used on MON 87419 can control 95 annual and biennial weed species and suppress over 100 perennial broadleaf and woody plant species (dicamba) or 120 species of broadleaf and grass weeds (glufosinate) (Monsanto 2015a).

¹ The terms, "maize" and "corn" are used interchangeably throughout this document for crops and products derived from *Zea mays*.

With MON 87419 corn, growers will gain improved tools for weed management and attain improved efficiency in the production of corn through increases in yield and quality.

1.3 Coordinated Framework Review and Regulatory Review

Since 1986, the United States (U.S.) government has regulated GE organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302; 57 FR 22984). 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 U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA). A summary of each role follows.

USDA-APHIS

APHIS regulations at 7 Code of Federal Regulations (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 (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 or if APHIS has reason to believe that the GE organism is a plant pest.

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 the EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 registration with the EPA.

Under FIFRA (7 U.S.C. 136 et seq.), the EPA regulates the use of pesticides (requiring registration of a pesticide for a specific use prior to distribution or sale of the pesticide for a proposed use pattern). The 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; and storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, the EPA must determine through testing that the pesticide will not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. The EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. 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. 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 of 1996 amended FIFRA, enabling the 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 2011d)The EPA also sets tolerances for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). The EPA is required, before establishing pesticide tolerance, to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the Food Quality Protection Act of 1996. The FDA enforces the pesticide tolerances set by the EPA.

Food and Drug Administration

The 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, in the *Federal Register* on May 29, 1992 (57 FR 22984). Under this policy, the 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 the FDA in complying with their obligations under Federal food safety laws prior to marketing.

More recently, in June 2006, the 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) for establishing 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 the FDA, but the information may be used later in the biotechnology consultation.

1.4 Purpose and Need for APHIS Action

Under the authority of the plant pest provisions of the PPA and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. Any party can petition APHIS to 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 MON 87419 corn. When a petition for nonregulated status is submitted, APHIS must make a determination 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 compare the plant pest risk of the regulated article to that of 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.

APHIS must respond to a petition from Monsanto requesting a determination of the regulated status of MON 87419 corn. APHIS has prepared this Environmental Assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with the Council of Environmental Quality's (CEQ) National Environmental Policy Act (NEPA) regulations and the USDA and 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 environment² that may result from a determination of nonregulated status of MON 87419 corn.

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 notice³ in the *Federal Register* to advise the public of 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.

1.5.1 First Opportunity for Public Involvement

Once APHIS deems a petition complete, the petition is made available for public comment for 60 days, providing the public an opportunity to raise issues regarding the petition itself and give input for consideration by the Agency as it develops its EA and PPRA. APHIS publishes a notice in the *Federal Register* to inform the public that 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.

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

 $^{^2}$ 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.

approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status 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 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 raises no substantive new issues, such as gene modifications that may present new biological, cultural, or ecological issues due to the nature of the modification, or APHIS' familiarity with the recipient organism. Under this approach, APHIS publishes a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the draft EA, preliminary FONSI, and PPRA for a 30-day public review period.

If no substantive information is received that would warrant substantial changes to APHIS' analysis or determination, APHIS' preliminary regulatory determination becomes effective upon public notification through an announcement on its website. No further *Federal Register* notice will be published announcing the final regulatory determination.

Approach 2. For GE organisms that raise substantive new issues not previously reviewed by <u>APHIS</u>

A second approach for public participation is used when APHIS determines that the petition for a determination of nonregulated status raises substantive new issues such as 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. APHIS reviews the petition, analyzes and evaluates comments received from the public during the 60-day comment period on the petition to determine if substantive issues have been identified.

APHIS solicits comments on its draft EA and draft PPRA for 30 days, as announced in a *Federal Register* notice. APHIS reviews and evaluates comments and other relevant information, after which it will revise the PPRA as necessary and prepare a final EA. Following preparation of these documents, APHIS either 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, and regulatory determination.

Enhancements to stakeholder input are described in more detail in the *Federal Register* notice⁴ published on March 6, 2012.

1.5.3 Public Involvement for Petition 15-113-01p

APHIS decided the EA for petition 15-113-01p will follow Approach 1. The issues discussed in this EA were developed by considering public input received from the *Federal Register* notice

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

published on August 13, 2015 announcing the availability of the petition, comments on the draft EA, issues raised in public comments submitted for other NEPA documents evaluating GE organisms, concerns raised in lawsuits, as well as issues of concern that have been raised by various stakeholders.

First Opportunity for Public Involvement

The public comment period for MON 87419 corn petition closed on October 13, 2015.⁵ At its closing the docket file contained a total of 21 public submissions. Some of the submissions to the docket contained multiple attached comments gathered by organizations from their members. Contained within the 21 submissions were a total of 23,867 signatures to a single unfavorable public comment. The majority of these comments expressed a general dislike of planting and use of GE crop plants. The issues that were raised in the public comments that were related to the MON 87419 corn petition included: development of dicamba-resistant weeds, increased herbicide use and environment and human health effects, human health effects from foods derived from GE plants, potential economic impacts on organic famers as a result of cross-pollination of MON 87419 corn with organic corn crops, and concerns that use of dicamba may result in drift of the herbicide to nearby horticultural and fruit crops.

Second Opportunity for Public Involvement

On February 17, 2016 APHIS announced in the *Federal Register* it was making available its draft EA, preliminary FONSI, and preliminary PPRA for a 30-day public review and comment period.⁶ At the end of the comment period, which closed Mar 18, 2016, APHIS had received 26 comments.⁷

Two of the commenters were in favor, or generally favored, deregulation of MON 87419 corn, while 24 commenters opposed APHIS deregulation of this corn variety, or had concerns. Commenters in favor expressed opinion that herbicide-tolerant corn hybrids have been a critical tool for farmers enabling them to increase yields of safe crops for use as food and feed while at the same time protecting the environment by decreasing crop inputs and expanding the use of conservation tillage. Commenters opposed expressed concerns that MON 87419 corn would increase the development of herbicide resistant weeds, that the long-term health effects of foods derived from GE crops were unknown, and that cross-pollination of GE crops and organic crops, and the unintended presence of GE material at levels exceeding market or organic certifier specifications, will result in economic losses for organic farmers.

APHIS evaluated the issues expressed in the comments and has provided a discussion of these issues in this final EA where appropriate. Various important topics were addressed by commenters during the review periods, both in favor and opposed to MON 87419 corn. However, there was no novel, substantive information received during the review periods for the

https://www.regulations.gov/#!documentDetail;D=APHIS-2015-0048-0001

⁵ 80 Federal Register No. 156 (August 13, 2015), pp. 48489 – 48490:

⁶ 81 Federal Register No. 31 (February 17, 2016), pp. 8035 -8037:

https://www.regulations.gov/#!documentDetail;D=APHIS-2015-0048-0024

⁷ https://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2015-0048

petition, the draft EA, and preliminary PPRA that would warrant substantial changes to these analyses and APHIS' preliminary regulatory determination. Hence, APHIS has developed and is issuing its final EA for MON 87419 corn.

1.6 Issues Considered

The list of resource areas considered in this final EA were developed in response to issues raised in the public comments submitted for this petition and draft EA, and the petitions and EAs of other GE organisms. The resource areas considered also address concerns raised in lawsuits, and issues that have been raised by various stakeholders regarding the deregulation and commercial production of GE crops. The resource areas considered in this EA can be categorized as follows:

Agricultural Production:

- Acreage and Range of Corn Production
- Agronomic Practices of Commercial Corn Production
- Organic Corn Production

Environmental:

- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Gene Flow and Weediness
- Microorganisms
- Biodiversity

Human Health:

- Consumer Health
- Worker Safety

Livestock Health:

• Animal Feed/Livestock Health

Socioeconomic Considerations:

- Domestic Economic Impacts
- Impacts on International Trade

2 AFFECTED ENVIRONMENT

The Affected Environment Section provides a discussion of the current conditions of those resources of the human environment potentially impacted by a determination of nonregulated status of MON 87419 corn. For the purposes of this EA, those resources of the human environment are: acreage and area of corn production, corn agronomic practices, the physical environment, biological resources, human health, animal feed, and socioeconomic issues.

2.1 Acreage and Area of Corn Production

Corn (*Zea mays* L.) is an economically important commodity and the most abundant crop planted and harvested in the United States. Its primary uses are for feed grain (accounting for 40 percent of total use) and fuel ethanol (35 percent of use). The remainder of harvested corn is processed into a variety of food and industrial products such as starch, sweeteners, corn oil, and beverage and industrial alcohol; only around 10 percent is typically used for direct human consumption (Barton and Clark 2014).

In 2012, there were 915 million acres of land in farms, just over 40 percent of all U.S. land (USDA-NASS 2014b). Of the 915 million acres, 45.4 percent was permanent pasture, 42.6 percent was cropland, and 8.4 percent was woodland. The remaining 3.6 percent was land in farmsteads, buildings, livestock facilities, etc. (USDA-NASS 2014b). Although the amount of cropland overall was down 4 percent, the amount of cropland harvested was nearly 2 percent more in 2012 than 2007.

While corn is grown in all states to some extent, the majority of production occurs in the Corn Belt, generally defined as including Illinois, Iowa, Indiana, southern and western Minnesota, eastern South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri. The leading corn-producing states of Illinois, Iowa, and Nebraska account for approximately 40 percent of the annual U.S. harvest (USDA-NASS 2015c). Significant production also occurs in the Pacific Northwest, California's Central Valley, along the Mississippi River, and up the Eastern Seaboard from Georgia to Upstate New York (Figure 1).

In the period from 2006 to 2012, planted corn acreage annually increased as market prices favored the planting of corn over alternative crops. The demand for feed grain, and increase in demand for fuel ethanol resulted in higher corn prices, providing incentive for growers to increase corn production and acreage (USDA-ERS 2015b). In many cases, farmers increased corn acreage by adjusting crop rotations between corn and soybeans, which caused soybean plantings to decrease. Other sources of land for increased corn plantings included acreage previously in fallow, acreage returning to production from expiring Conservation Reserve Program contracts, and shifts from other crops, such as cotton (USDA-ERS 2015b).



Figure 1. Corn Planted Acreage in the United States by County, 2014 Source: (USDA-NASS 2015b)

As corn acreage has increased, yields from corn production in the United States have also risen over time, particularly the last 20 years. The increase is a result of technological improvements, seed varieties, fertilizers, pesticides, and machinery. Production practices such as tillage, irrigation, crop rotations, and pest management systems have a role in the increases as well. Over the last seven years, around 85 to 95 million acres of corn have been harvested in the United States on an annual basis (USDA-NASS 2014b, Westcott and Hansen 2015) (Table 1, Figure 2). Acreage used for U.S. corn production is expected to remain steady over the next decade, at approximately 89 million acres annually (Westcott and Hansen 2015).

Table 1. Field	Table 1. Field Corn Production in the United States, 2000-2014								
Year			Average Yield (bushels/acre)	Total Production (×1000 bushels)	Value (billions \$)				
2014	90,597	83,136	171.1	14,215,532	52.38				
2012	97,291	87,375	123.4	10,780,296	74.33				
2010	88,192	81,446	152.8	12,446,865	64.64				
2008	85,982	78,570	153.9	12,091,648	49.31				
2006	78,327	70,638	149.1	10,531,123	32.08				
2004	80,929	73,631	160.3	11,805,581	24.38				
2002	78,894	69,330	129.3	8,966,787	20.88				
2000	79,551	72,440	136.9	9,915,051	18.50				

Source: Crop Production. Historical Track Records (USDA-NASS 2015d)



Figure 2. Planted and Harvested Acreage of Corn in the U.S., 1995-2015 Source: (USDA-NASS 2015d)

Adoption of GE corn expanded rapidly since introduction of GE varieties in 1996, and now comprises the majority of corn crops produced in the United States (Figure 3). Most GE-corn varieties are either herbicide-tolerant (HR) or insect-resistant (IR). In 2000, 25 percent of U.S. corn production was from GE varieties. IR (18 percent) and HR (6 percent) varieties accounted for most of this; only 1 percent of corn contained both traits (USDA-ERS 2014). In 2002, stacked-trait hybrids were introduced, and this led to a further increase in acreage of GE corn (Fernandez-Cornejo, Wechsler et al. 2014a). By 2014, 89 percent of the 87.6-million-acre U.S. corn crop was produced from GE HT corn and 80 percent from IR (Fernandez-Cornejo, Wechsler et al. 2014a).

Stacked-trait varieties with both IR and HR traits accounted for 76 percent of the 2014 crop. Only 13 percent contained just HR traits, and 4 percent were IR (USDA-ERS 2015a). Table 2 provides summary information on the percentage of acres planted with GE IR, HR, and stackedtrait corn varieties for selected states in 2014.



Figure 3. GE Corn Traits Planted in the United States between 2000-2013
Source: (USDA-ERS 2014)

Table 2. Adoption of GE Corn in the United States in 2014								
State	Corn Acreage Planted (1,000 acres)	Insect- resistant (Bt) only (%)	Herbicide- tolerant only (%)	Stacked gene varieties* (%)	All GE varieties (%)	Total acreage planted to GE varieties (1,000 acres)		
Illinois	11900	3	5	83	91	10,829		
Indiana	6000	2	8	78	88	5,280		
lowa	13600	4	8	83	95	12,920		
Kansas	4300	5	18	72	95	4,085		
Michigan	2600	2	15	76	93	2,418		
Minnesota	8600	2	10	81	93	7,998		
Missouri	3350	4	10	79	93	3,115		
Nebraska	9950	4	15	77	96	9,552		
North Dakota	3850	6	22	68	96	3,696		
Ohio	3900	3	14	69	86	3,354		
South Dakota	6200	3	14	80	97	6,014		
Texas	2350	12	17	62	91	2,138		
Wisconsin	4100	3	17	72	92	3,772		
Other States	9897	6	19	66	91	9,006		
U.S.	90597	4	13	76	93	84,255		

Source: (USDA-ERS 2015a)

2.2 Agricultural Production of Corn

2.2.1 Agronomic Practices: Tillage, Crop Rotation, and Agronomic Inputs

The agriculture in current practice incorporates a wide variety of inputs to maximize crop yield and judiciously use the land and environmental resources. Conventional farming covers a broad scope of farming practices, including the use synthetic fertilizers and pesticides. Conventional farming also includes the use of GE varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. Organic systems exclude certain production methods, such as synthetic agricultural inputs and GE crops. (Organic corn production is discussed further in Section 2.3.)

Tillage, crop rotation, and inputs, such as pesticides, are selected from a range of options by each grower to achieve their desired outcomes of yield and environmental stewardship. Key production practices are described in the following sections. Although specific crop production practices vary according to region and end-use market, they commonly include tillage, crop rotation, and agricultural inputs. The following introduces the agronomic practices commonly employed to produce corn in the United States.

2.2.1.1 Tillage

Prior to planting, the soil is typically stripped of weeds that would otherwise compete with the crop for space, water, and nutrients. Field preparation is accomplished through a variety of tillage systems, with each system defined by the remaining crop residue on the field. Crop residues are materials left in an agricultural field after the crop has been harvested, including stalks and stubble (stems), leaves and seed pods (USDA-NRCS 2005).

Conventional tillage is associated with intensive plowing and leaving less than 15 percent crop residue in the field (US-EPA 2010d). In contrast, reduced tillage is associated with 15 to 30 percent crop residue. Conservation tillage relies on methods that result in less soil disruption and leaves at least 30 percent of crop residue on the surface. These residues aid in conserving soil moisture and reduce wind and water-induced soil erosion (USDA-ERS 1997, USDA-NRCS 2005, Heatherly, Dorrance et al. 2009).

Conservation and reduced tillage practices include: mulch-till, eco-fallow, strip-till, ridge-till, zero-till, and no-till (IPM 2007). No-till farming only disturbs the soil between crops. The new crop is planted into residue or in narrow strips of tilled soil, which results in less soil disruption. Under no-till practices, there is no turning of the soil to break up compacted areas (USDA-NRCS 1996). In general, soil conservation practices, such as conservation tillage, reduce field tillage and corresponding soil loss (Tyler, Wagger et al. 1994, Papendick and Moldenhauer 1995, USDA-NRCS 2006c). Increases in total acres dedicated to conservation tillage were facilitated in part by an increased use of HR GE crops, reducing the need for mechanical weed control (USDA-NRCS 2006c, Towery and Werblow 2010, USDA-NRCS 2010a).

The choice to till is dependent upon a variety of factors (Hoeft, Nafziger et al. 2000), such as:

- Desired yields
- Soil type and moisture storage capacity

- Crop rotation pattern
- Prevalence of insect and weed pests
- Risk of soil compaction and erosion
- The need for crop residue or animal waste disposal
- Management and time constraints

In general, despite variable adoption rates before 2001, use of conservation tillage, especially notill practices, has increased in U.S. corn production compared to conventional tillage (Horowitz, Ebel et al. 2010).

Conservation tillage, although highly valued as a means to enhance soil quality and preserve soil moisture, has been identified as a potential challenge for corn disease management as well as pest management. The surface residues have been identified as an inoculum source for certain plant pathogens (Robertson, Nyvall et al. 2009). This is especially a problem for growers who cultivate corn-to-corn rotations with minimal tillage (Robertson, Nyvall et al. 2009). Corn-to-corn cultivation refers to the cultivation of corn in consecutive years in the same field (Erickson and Lowenberg-DeBoer 2005). Diseases associated with corn residues include Anthracnose (caused by the fungus *Colletotrichum graminicola*), Eyespot (caused by the fungus *Kabatiella zeae*), Goss's wilt (caused by the bacteria *Corynebacterium nebraskense*), Gray leaf spot (caused by the fungus *Cercospora zeae-maydis*), and Northern corn leaf blight (caused by the fungus *Helminthosporium turcicum*) (Robertson, Nyvall et al. 2009). For each of these diseases, the disease agent overwinters in the cool and moist soil, and the pathogenic inoculum from the corn residue then infects the new crop (Robertson, Nyvall et al. 2009). Disease control measures include cultivation of resistant hybrids, crop rotation, and more careful balancing of conservation tillage with residue management (Robertson, Nyvall et al. 2009).

2.2.1.2 Crop Rotation

Crop rotation is the successive planting of different crops in the same field over a specific number of years. The goals of crop rotation include maximizing economic returns and sustaining the productivity of the agricultural system (Hoeft, Nafziger et al. 2000). Sustaining the agricultural system is achieved by rotating crops that may improve soil health and fertility with more commercially beneficial commodity crops. Crop rotations are used to diversify farm income, spread labor requirements throughout the year, and spread the crop loss risk associated with weather and pest damage across two or more crops. Maximizing economic returns is realized by rotating crops in a sequence that efficiently produces the greatest net returns for a producer over a multi-year period.

Rotations are used for soil and pest management to 1) manage weed, insect, and disease pests, 2) reduce soil erosion by wind and water, 3) maintain or increase soil organic matter, 4) provide biologically fixed nitrogen when legumes are used in the rotation, and 5) manage excess nutrients (Singer and Bauer 2009). Moreover, the rotation of crops can effectively reduce weediness and selection pressure for selecting weeds resistant to herbicides (USDA-ERS 1997, Berglund and Helms 2003). Many factors at the individual farm level affect the crop rotation system chosen, including the soil type present in an individual field, the expected commodity

price, the need to hire labor, the price of fuel, the availability of capital to buy seed, and the price of agricultural inputs (Langemeier 1997, Hoeft, Nafziger et al. 2000, Duffy 2011).

In 1996, at least 85 percent of corn planted acreage was in some form of rotation in the United States (Osteen and Fernandez-Cornejo 2013) and in 2014 remained at 84 percent of corn acreage in 15 surveyed principal corn states (USDA-NASS 2015a) or possibly as low as 70 percent (Table 3) . Crops used in rotation with corn vary regionally in the United States and may include alfalfa, oats, soybean, wheat, rye, and forage (Peel 1998, IPM 2004). Approximately 30 percent of the U.S. corn acres are rotated back to corn and 57 percent are rotated to soybean the following year (Figure 4, Table 3). Wheat and cotton also are key rotational crops of corn with approximately 5 percent and 2 percent acres rotated to these crops, respectively. Additionally, crop rotation may also include fallow periods, or sowing with cover crops to prevent soil erosion and to provide livestock forage between cash crops (Hoeft, Nafziger et al. 2000, USDA-NRCS 2010a).



Figure 4. Cropping Patterns for Corn in the United States, 1996-2010 Source: (Osteen and Fernandez-Cornejo 2013)

Rotational	Rotational Crop Following Corn (acres) (% of Rotational Crop Acres) Region (acreage) ¹							
Crop Following Cotton	United States (95,365)	Midwest (55,680)	Northeast (4,175)	Southeast (5,535)	Plains (28,580)	West (1,395)		
Corn	28,291 (29.7)	13,261 (23.6)	2,204 (52.8)	1,753 (31.7)	10,337 (36.2)	735 (52.7)		
Soybean	54,451 (57.1)	38,785 (69.7)	836 (20.0)	1,513 (27.3)	13,317 (46.6)			
Wheat	4,527 (4.7)	1076 (1.9)	417 (10.0)	476 (8.6)	2,352 (8.2)	206 (14.8)		
Cotton	1,870 (2)			1,331 (24.1)	521 (1.8)	18 (1.3)		
Alfalfa ³	1,303 (1.4)	908 (1.6)	144 (3.4)		83 (0.3)	168 (12)		
Other Hay	1,118 (1.2)	735 (1.3)	272 (6.5)		54 (0.2)	56 (4.0)		
Sorghum	799 (0.8)	12 (<0.1)		20 (0.4)	766 (2.7)			
Oats	469 (0.5)	229 (0.4)	156 (3.7)		62 (0.2)	22 (1.5)		
Sugar Beets	455 (0.5)	216 (0.4)			239 (0.8)			
Sunflower	453 (0.5)				453 (1.6)			
Barley	320 (0.3)	21 (0)	109 (2.6)		128 (0.4)	64 (4.6)		
Peanut	281 (0.3)			281 (5.1)				
Vegetables	283 (0.3)	213 (0.4)	37 (0.9)	5 (0.1)	1 (0.002)	27 (1.9)		
Dry Beans	273 (0.3)	151 (0.3)			93 (0.3)	29 (2.1)		
Potatoes	213 (0.2)	73 (0.1)			77 (0.3)	64 (4.6)		

Source: (Monsanto 2015c)

1. All acreage expressed as 1,000s of acres. Corn acreage based on USDA-NASS planting data.

2. "—" = no reported production in this region

3. Newly seeded alfalfa

4. Vegetables may include sweet corn, tomatoes, snap beans, cantaloupe, watermelon, cucumbers, green peas, carrots, and cabbage

Recently, there has been an increase in continuous corn rotations because of high corn commodity prices and the strong demand for corn grain (USDA-ERS 2011b). About 30 percent of corn farmers grow continuous corn (Figure 4). Consecutive plantings of corn frequently require at-planting or pre-plant pesticide treatments to control corn pests and pathogens as well

as supplemental fertilizer treatments (IPM 2004, Erickson and Lowenberg-DeBoer 2005, Sawyer 2007, Stockton 2007). Corn-to-corn rotations also may require a change in tillage practices. Corn-to-corn cultivation may produce substantially greater quantities of field residue, requiring additional tillage prior to planting (Erickson and Lowenberg-DeBoer 2005). Additionally, continuous corn rotations generally require more fertilizer treatments to replace diminished soil nitrogen levels and more pesticide applications (Bernick 2007, Laws 2007, Erickson and Alexander 2008).

Studies in U.S. Corn Belt states indicate corn yield is about 10-15 percent higher in corn grown following soybean than corn grown following corn (Singer and Bauer 2009). While there are tangible benefits from crop rotations, many other factors such as crop price fluctuations, input costs, rental agreements, government price supports, weather, choice of farming system and on-farm resources, and other factors all contribute to decisions regarding crop rotations (Monsanto 2015a).

2.2.1.3 Nutrient and Fertilizer Use

Fertilizers are generally defined as any material, organic or inorganic, natural or synthetic, that supply any of the chemical elements required for the plant growth. Commercially available fertilizers usually contain a mixture of the macronutrients nitrogen (N), phosphorus, and potassium which are essential for plant growth (Vitosh 1996). To fill specific crop needs in soils that are deficient, various concentrations of micronutrients may be included in fertilizer formulations (Jones and Jacobsen 2003). Fertility needs also can be met by applying organic matter which may alter the soil's naturally occurring level of nutrients that are available for plant growth (Jones and Jacobsen 2003). Nevertheless, about half of the N applied in a chemical form is not taken up by plants, but is lost to the atmosphere and to above- and below-ground water supplies (Smil 1997).

Given the importance of nutrient availability to corn agronomic performance, fertilization is widely practiced in order to maximize corn grain yield (Hoeft, Nafziger et al. 2000). Soil and foliar macronutrient applications to corn primarily include nitrogen, phosphorous (phosphate), potassium (potash), calcium, and sulfur, with other micronutrient supplements such as zinc, iron, and magnesium applied as needed (Espinoza and Ross 2006).

A 2014 survey of 15 corn producing states conducted by USDA-NASS found that nitrogen was the most widely used fertilizer on corn, applied to 97 percent of planted acres at an average rate of 144 pounds per acre (lb/acre) (USDA-NASS 2015f). Phosphate was applied at an average rate of 64 lb/acre to 80 percent of planted corn and potash was applied to 65 percent of planted acres at the rate of 82 lb/acre (USDA-NASS 2015f).

2.2.1.4 Insect and Pest Management

Pest management is an integral part of any corn production system and is used to maintain yield and quality of the grain. Corn pests may include microbes (e.g., nematodes, fungi, or bacterial), insects, or weeds. Corn pest management strategies are often dependent on the corn variety cultivated. Fungicides, insecticides, and herbicides are the primary pesticides applied on U.S. corn acres.

Pesticides – Fungicides

In addition to pesticide inputs to control invertebrates (insecticides) and weeds (herbicides), rowers may also apply fungicides to control certain fungal diseases on corn. These treatments include both foliar fungicide applications to treat certain diseases as well as seed treatments to manage both insect pests of corn seed as well as certain fungal diseases. This practice is not universal, and varies by grower and region depending upon the specific disease (Hoeft, Nafziger et al. 2000, Ruhl 2007). Some of the common fungal diseases on corn include Anthracnose leaf blight (*C. graminicola*), common rust (*Puccinia sorghi*), eyespot (*K. zeae*), gray leaf spot (*C. zea-maydis*), northern corn leaf blight (*Exserohilum turcicum*), northern corn leaf spot (*Bipolaris zeicola*), and seed rot (multiple causes, fungal and bacterial, see, e.g., (Hoeft, Nafziger et al. 2000, Ruhl 2007)).

Historically, foliar applications of fungicides were not common, and fungal disease management was focused on selection of disease-resistant hybrids, crop rotation to break the disease cycle, and tillage to encourage decomposition of crop residues that were reservoirs for the disease (see, e.g., (Purdue 2012)). The corn-to-corn rotations discussed previously in Subsection 2.2.2 – Crop Rotation, along with conservation tillage, have resulted in an increased disease risk in some areas (Robertson, Abendroth et al. 2007, Robertson and Mueller 2007). Corn yields have been reported to increase as a result of these foliar applications of fungicides (Robertson and Mueller 2007).

Pesticides – Insecticides

Corn is subject to insect pests throughout its development, with several groups and types of insects capable of feeding on the seeds, roots, stalk, leaf, or ears (Hoeft, Nafziger et al. 2000). Insect pests causing damage to corn may be managed by growers through the use of GE insect-tolerant traits, insecticide treatment of seeds or soil, over-the-top application of insecticides, or use of a number of crop rotation or integrated pest management practices.

The introduction of Cry proteins from *B. thuringiensis* into corn plants has transformed insect pest management. There has been a steady decline in the application of insecticides in recent years attributed, in part, to the adoption of corn varieties incorporating these Cry proteins (Brookes and Barfoot 2010, Benbrook 2012). The Cry proteins from *Bt* are generally target specific (e.g., Lepidoptera vs. Coleoptera) (OECD 2007). This specificity allows a grower to select a corn variety containing a Cry protein specific to an insect pest. The advantage of this target specificity is that the grower can then avoid the application of broad-spectrum insecticides, allowing corn growers to reduce insecticide applications (Brookes and Barfoot 2010). This provides benefits to growers and the environment from the reduction of exposure to insecticides and a corresponding reduction in costs to the grower associated with insecticide purchases and applications (US-EPA 2010b, US-EPA 2010a, US-EPA 2010e).

In 2014, 80 percent of the total U.S. corn acreage was planted corn varieties containing at least one Bt trait (USDA-NASS 2014c). The EPA reviews PIPs, such as the Cry proteins, pursuant to FIFRA, and publishes tolerances or exemptions from a tolerance pursuant to its authority under FFDCA. Since 1995, the EPA has registered over 39 crops expressing one or more proteins

derived from Bt (US-EPA 2011c). The EPA has published tolerance exemptions for the Cry proteins (US-EPA 2007)⁸. Weed Management

Effective weed control requires grower implementation of management practices that limit the introduction and spread of weeds, help the crop to compete with weeds, and prevent weeds from adapting. The key components to successfully manage weeds are: 1) knowing the exact identity of all weeds in the field; 2) treating fields (if necessary) while the weeds are small; 3) tailoring control measures to the type of weed and its size (Loux, Doohan et al. 2013).

Weed control programs vary by crop, weed problem, geography, and cropping system (e.g., no-till, conventional-till, etc.). There are five general weed management strategies: preventive, cultural, mechanical, biological, and chemical. A combination of methods is recommended instead of relying on one particular method of weed control (Burgos, Culpepper et al. 2006, Ashigh, Mosheni-Moghadam et al. 2012, Monsanto 2013b). The combination of weed control practices that a grower chooses depends upon the weed spectrum, size of weed populations, soil type, cropping system, weather, and time and labor available for the treatment option.

Weed management is an integral component of any corn production system. If weeds in a corn field are left unmanaged, grain yield may be reduced as much as 50 percent (Smith and Scott 2006). Individual weed species, including glyphosate-resistant species, are discussed in Section 2.4.2. The management of weeds in corn production generally involves the application of herbicides. Growers choose pesticides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Heiniger 2000, Farnham 2001). In selecting an herbicide, a grower must consider, among other factors, whether an herbicide can be used on the crop (herbicides are registered by the EPA for specific uses/crops), the potential adverse effects on the crop, residual effects that can limit crops that can be grown in rotation, effectiveness on expected weeds, and cost.

In 2014, 97 percent of all U.S. corn acreage was subjected to herbicide applications (USDA-NASS 2015f). The most commonly applied herbicide in corn during 2014 was atrazine, with approximately 45,200 lb applied over 55 percent of all planted corn acreage in surveyed states (USDA-NASS 2015a). This amount is approximately 12 percent less than the atrazine used on corn in 2010 which was applied on 61 percent of corn acreage planted that year. Other often used corn herbicides include acetochlor (28,685,000 lb) applied on 29 percent of corn acreage, glyphosate isopropylamine salt (27,221, 000 lb) applied on 38 percent of corn acreage (all glyphosate formulations, 73% of corn acreage, 61,300,000 pounds), S-metolachlor (23,600,000 lb) applied on 27 percent of corn acreage, mesotrione (2,529,000 lb) applied on 27 percent of corn acreage

⁸ Under its FFDCA authority, the EPA will publish an exemption from the requirement for a tolerance when it has completed comprehensive review of the toxicity and exposure data and completed health and animal risk assessment studies US-EPA (2012c). Setting Tolerances for Pesticide Residues in Foods. **2012**.. An exemption from tolerance for the Cry proteins means that the EPA completed its review and found a reasonable certainty of no harm under the FFDCA, as amended by the FQPA.

(USDA-NASS 2015a). These and other commonly applied herbicides on U.S. corn acres in 2014 are summarized in Table 4 (USDA-NASS 2015a).

Table 4. Corn: Total Herbicide Applications, 2010 ¹								
Herbicide	Total Applied (x thousand pounds)	Area Applied (percent of total planted acres)	Applications (number)	Rate per Application (pounds per acre per application)	Rate per Crop Year (pounds per acre per year)			
2,4-D, 2-EHE	2,601	4	1.1	0.561	0.599			
2,4-D, dimeth. salt	1,630	3	1	0.595	0.62			
Acetochlor	28,685	29	1	1.202	1.256			
Alachlor	444	<0.5	1.6	1.488	2.348			
Atrazine	45,231	55	1.1	0.950	1.018			
Bromoxynil Octanoate	45	<0.5	1	0.335	0.335			
Clethodim	15	<0.5	1	0.073	0.073			
Clopyralid	752	<0.5	1	0.071	0.072			
Clopyralid, mono salt	21	13	1.1	0.077	0.083			
Clopyralid, potassium	17	<0.5	1	0.084	0.084			
Dicamba	19	<0.5	1	0.126	0.126			
Dicamba, digly. salt	117	1	1	0.194	0.194			
Dicamba, dimet. salt	513	2	1.2	0.209	0.249			
Dicamba, pot. salt	183	<0.5	1.7	0.246	0.145			
Dicamba, sodium salt	472	3	1.1	0.088	0.097			
Diflufenzopyr-sodium	177	2	1.1	0.035	0.04			
Dimethenamid-P	2,130	5	1.1	0.593	0.63			
Flumetsulam	315	5	1	0.033	0.034			
Flumioxazin	24	<0.5	1	0.154	0.154			
Fluroxypyr 1-MHE	25	<0.5	1.1	0.082	0.087			
Fluthiacet-methyl	2	1	1	0.004	0.004			
Fomesafen	68	<0.5	1.1	0.189	0.207			
Glufosinate-Ammonium	234	2	1	0.296	0.298			
Glyphosate	7,979	7	1.1	0.843	0.931			
Glyphosate dim. salt	3,604	4	1.2	0.925	1.113			
Glyphosate iso. salt	27,221	38	1.2	0.824	1.065			
Glyphosate pot. salt	22,560	24	1.2	0.936	1.204			
Imazethapyr	5	<0.5	1	0.02	0.02			
Isoxaflutole	506	11	1	0.065	0.066			
Mesotrione	2,529	27	1	0.116	0.121			
Metolaclor	935	1	1	1.234	1.276			
Nicosulfuron	12	1	1.1	0.016	0.016			
Paraquat	227	1	1	0.641	0.699			
Pendimethalin	553	1	1.2	1.154	1.154			
Primisulfuron	5	<0.5	1	0.023	0.023			
Prosulfuron	1	<0.5	1	0.008	0.008			
Pyroxasulfone	66	1	1	0.139	0.139			
Rimsulfuron	60	4	1.2	0.014	0.015			
S-Metolachlor	23,600	27	1.1	1.076	1.159			
Saflufenacil	178	4	1	0.059	0.075			

Table 4. Corn: Total Herbicide Applications, 2010 ¹								
Herbicide	Total Applied (x thousand pounds)	Area Applied (percent of total planted acres)	Applications (number)	Rate per Application (pounds per acre per application)	Rate per Crop Year (pounds per acre per year)			
Simazine	1,430	2	1	1.038	1.169			
Sulfentrazone	46	<0.5	1.1	0.173	0.196			
Tembotrione	336	6	1	0.064	0.064			
Thiencarbazone-methy	167	9	1	0.025	0.025			
Thifensulfuron	10	2	1.1	0.007	0.007			
Topramezone	31	3	1	0.014	0.014			
Trifluralin	169	<0.5	1	0.608	0.608			

Source: (USDA-NASS 2015a)

¹ Program states surveyed - Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, Pennsylvania, South Dakota, Texas, and Wisconsin

The use of glyphosate in U.S. corn production has increased since 1994, a trend associated with the increasing adoption of herbicide-resistant (primarily glyphosate-resistant) corn varieties (Figure 5). Although glyphosate-resistant corn has not substantially affected the percentage of corn acreage managed with herbicides, the introduction of glyphosate-resistant corn varieties has resulted in the substitution of glyphosate for some other corn herbicides (Brookes and Barfoot 2012, Vencill, Nichols et al. 2012).



Figure 5. Herbicide Use on Corn, 1996-2008

HR crops have become adopted widely since their introduction in the mid-late 1990s for several reasons. Increased selection pressure caused by wide-spread adoption of HR crops, reduction in the use of other herbicides and weed management practices, resulted in both weed population shifts and growing numbers of HR individuals among some weed populations (Owen 2008, Duke and Powles 2009). With HR corn planted on 89 percent of U.S. acres in 2014, herbicides are the primary basis of weed management programs (USDA-ERS 2014).

The continued emergence of GR weeds will likely require modifications of crop management practices to address these weeds. Herbicide use may increase to meet the need for additional integrated weed management tactics to control HR weeds in different cropping systems (Owen and Zelaya 2005b, Culpepper 2008).

2.2.2 Organic Corn Production

In the United States, 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 2015b). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

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

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

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

(a) Synthetic substances and ingredients,

(e) Excluded methods

Excluded methods are then defined at 7 CFR Section 205.2 as:

A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods (USDA-AMS 2015b).

The use of biotechnology, such as that used to produce MON 87419 corn, is an excluded method under the National Organic Program [7 CFR § 205.2]. 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 2015b). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods as detailed in their approved organic system plan (Ronald and Fouce 2006, USDA-AMS 2015b).

Although conventional corn yields tend to be higher than organic yields, net returns from organic acres continues to be greater than net return from conventional acres, with a 16 percent premium received by organic growers as reported in 2008 (Kuepper 2002, Coulter, Sheaffer et al. 2010, Roth 2011b). In 2008, USDA Economic Research Services (USDA-ERS) reported that 194,637 acres out of a total 93.5 million (0.21 percent) planted corn acres were certified organic (USDA-ERS 2010b). Wisconsin, Iowa, Minnesota, Michigan, New York, Texas, and Nebraska each had more than 10,000 acres of certified organic corn, totaling approximately 68 percent of all certified organic acreage in the United States (Table 5). Generally, acreage increased from 2007 to 2008, although, in some instances, certain states showed a decrease in the number of certified organic corn acres. The most recent survey showed that total acres of organic corn have declined from earlier surveys, although a few states have shown increased plantings. Organic corn was produced on 134,877 acres in 2011 and yielded 14.2 million bushels, equal to approximately 0.1 percent of U.S. corn production (USDA-NASS 2012a).

Table 5: Certi	fied Organic Corn Acreage by	State with More th	nan 1,000 Acres of Certified Land in
2007, 2008, a	nd 2011		

State	Acreage			Acreage			
State	2007	2008	2011	State	2007	2008	2011
California	1,305	2,765	1,370	New Mexico	2,700	1,552	NA

2007, 2008,	and 2011			1	T		
State		Acreage		State	Acreage		
	2007	2008	2011		2007	2008	2011
Colorado	2,445	3,043	887	New York	11,909	11,459	13,150
Illinois	7,319	8,739	6,983	North Dakota	3,292	4,761	1,194
Indiana	2,414	2,998	1,502	Ohio	8,786	8,969	6,899
lowa	24,944	25,419	18,984	Oregon	1,072	1,712	2,734
Kansas	2,067	4,637	3,688	Pennsylvania	4,482	5,918	3,262
Maine	1,025	1,237	310	South Dakota	5,779	5,564	4,410
Maryland	1,009	1,239	1,568	Texas	7,710	11,202	1,109
Michigan	12,722	12,663	13,266	Virginia	1,286	1,472	289
Minnesota	26,849	27,565	20,432	Washington	1,970	2,265	1,266
Missouri	7,144	3,765	13,226	Wisconsin	27,431	33,619	20,059
Nebraska	12,226	10,568	9,111	U.S. Total	170,905	193,637	134,877

Table 5: Certified Organic Corn Acreage by State with More than 1,000 Acres of Certified Land in

Source: (USDA-ERS 2010b) and (USDA-NASS 2012a)

2.2.3 Specialty Corn

Specialty corn varieties have been developed and marketed as Value Enhanced Corn Varieties cultivated as specialty corn included high oil, white, waxy, blue corn, hard endosperm/food grade, high-amylose, high lysine, high oleic oil, low phytate, nutritionally enhanced, high extractable starch, high total fermentable (for ethanol), popcorn, pharmaceutical and industrial corns, and organic (Thomison and Geyer 2004, U.S. Grains Council 2006). It was estimated that in 2005 approximately 8 percent of the total U.S. corn produced was devoted to specialty corn varieties (U.S. Grains Council 2006). The leading specialty corn states include Illinois, Iowa, Nebraska, and Indiana (Thomison and Geyer 2004, U.S. Grains Council 2006).

Similar to the production of conventional seed, industry quality standards for specialty crop products have prompted these seed producers and growers to use a variety of techniques to ensure that their products are not pollinated by or commingled with conventional or GE crops (Bradford 2006). Common practices include maintaining isolation distances to prevent pollen movement from other corn sources, planting border or barrier rows to intercept pollen, and employing natural vegetative barriers to pollen, including fallow fields and hedgerows (Wozniak 2002, NCAT 2003).

Regulations (7 CFR §201, et seq.) of the Federal Seed Act provide additional details on seed production and certification. Field monitoring for off-types is generally carried out by company staff and state crop improvement associations (Bradford 2006). Seed handling standards are established by the American Organization of Seed Certifying Agencies (AOSCA) to reduce the likelihood of seed source mixing during planting, harvesting, transporting, storage, cleaning, and ginning (AOSCA 2004). In general, the conventional management practices used for conventional seed production are sufficient to meet standards for the production of specialty crop seed (Bradford 2006).

2.3 Physical Environment

Resources within the physical environment that may be affected by corn production include soil and water resources, air quality, and nonregulated status for MON 87419 corn may potentially impact climate change or conversely, the variety may be affected by climate consequences.

2.3.1 Soil Quality

USDA-APHIS 2,4-D-Resistant Corn and Soybean Varieties FEIS: Soil and land resources in U.S. corn growing regions were assessed in more detail by the USDA in the 2014 FEIS (USDA-APHIS 2014e) in Sections 3.2.2, and 3.2.7. That information is incorporated here by reference. Soil resources remain essentially unchanged from that described in the 2014 2,4-D-Resistant Corn and Soybean Varieties FEIS.

Corn is cultivated in a wide variety of soils across the United States. Tillage practices and agronomic inputs may affect soil fertility, erosion, and cause off-site transport of sediments into aquatic ecosystems in agricultural ecosystems, consequently affecting soil quality. The various agronomic practices used in crop production affect the biological, physical, and chemical properties of soil differently, and impact soil fertility and sustainability.

Soil erosion can occur through natural processes, and the rate of erosion is determined by soil type, local ecology, and weather, certain tillage practices. Conventional tillage contributes to erosion and to the degradation of soil quality. Soil quality losses occur through declines in organic matter, nutrient reduction, and physical removal of soil structure (Berhe and Kleber 2013, Brevik 2013, Gomiero 2013). Conversely, soils under conservation tillage systems exhibit higher soil quality and less erosion, as compared with conventionally tilled soils (Roger-Estrade, Anger et al. 2010, He, Li et al. 2011, Sharma and Abrol 2012, Abdalla, Osborne et al. 2013, Van Eerd, Congreves et al. 2014). Thus, soil management and conservation strategies are key to current agronomic practices, particularly in the Corn Belt region, and many U.S. farmers have been moving away from conventional to conservation tillage practices (USDA-NRCS 2006c, CTIC 2015).

Conservation tillage methods include no-till, strip-till, ridge-till, and mulch-till. These practices reduce erosion and runoff; preserve soil organic matter, beneficial biota, and nutrients; improve water-retention capacity; and require less time and labor in preparation of the field for planting (Roger-Estrade, Anger et al. 2010, He, Li et al. 2011, Sharma and Abrol 2012, Van Eerd, Congreves et al. 2014). Over the last three decades while conservation tillage practices were increasing, total soil loss on erodible croplands in the United States decreased from 462 million tons per year to 281 million tons per year, or by 39 percent (USDA-NRCS 2006b). This decrease in soil erosion carried with it a corresponding decrease in non-point source (NPS) pollution runoff containing fertilizer and pesticides (NCGA 2007a). In 2012, farmers applied tillage practices on 278.8 million acres of cropland, which included no-till on 96.5 million acres, conservation tillage on 76.6 million acres, and conventional tillage on 105.7 million acres (USDA-NASS 2012b).

While erosion has decreased through adoption of conservation tillage and other practices, erosion remains a key issue in some areas of the United States. Excessively eroding cropland soils are

concentrated in Midwest and Northern Plains States and in the Southern High Plains of Texas (Figure 6). Farmers producing crops on highly erodible land, including corn growers, are required by law to maintain a soil conservation plan approved by the USDA National Resources Conservation Service (USDA-ERS 2012). These soil conservation plans are prepared by the grower following requirements of the programs to minimize soil erosion in the 1985 Food Security Act, Highly Erodible Land Conservation Compliance and Sodbuster provisions. Corn farmers also are actively involved in state, local, and national programs that idle environmentally sensitive land set aside from crop production; these programs include the Conservation Reserve Program, the Conservation Reserve Enhancement Program, and the Farmable Wetlands Program FSA (USDA-FSA 2015)



Figure 6. Status of Eroding U.S. Croplands 2007 Source: (USDA-NRCS 2011)

In many cases, crop and soil management practices impart beneficial changes to soil. Some practices such as conservation tillage may increase soil organic matter and plant residues. For example, herbicide application may provide soils with plant matter from dead weeds, and the new organic matter would be beneficial to omnivores in the soil, such as bacteria and nematodes, which would consume the organic matter as food (Zhao, Neher et al. 2013). Enhanced organic matter also hinders pesticide movement and facilitates pesticide degradation (Locke and Zablotowicz 2004).

In summary, agronomic practices used in corn production can beneficially or adversely affect the quality and erosional tendencies of soils. Conservation tillage, crop rotation, soil amendment, and other practices can improve and sustain soils. Growers must repeatedly choose sound resource management practices to avoid degrading soil quality and to deter soil erosion (Montgomery 2007, Berhe and Kleber 2013, Gomiero 2013, USDA-NRCS 2015b).

2.3.2 Water Resources

USDA-APHIS 2,4-D-Resistant Corn and Soybean Varieties FEIS: Water resources in U.S. corn growing regions were assessed by USDA in the 2014 FEIS (USDA-APHIS 2014b), in Section 3.2.4, and that is incorporated here by reference. Additional assessments are provided in Section 2.3.2 and as an extension to the previous analysis of the similar auxinic herbicide trait.

2.3.2.1 Crop Irrigation

Corn is a water-sensitive crop with a low tolerance for drought. Consequently, irrigation is a significant source of water consumption in U.S. corn production. Water requirements for corn vary during different stages of development. Adequate water supply, particularly during critical periods of development, is a basic requirement for both optimal crop quality and yield.

In general, corn requires around 20 to 22 inches of rainfall for optimal yield, which must be met by irrigation if rainfall is inadequate (US-EPA 2015e). In other terms, corn requires approximately 4,000 gallons through the growing season to produce 1 bushel of grain (U-Illinois 2015). Approximately 88 percent of irrigation water for corn production is from groundwater sources, with the remainder from on-farm and off-farm surface water sources (USDA-NASS 2013). Groundwater sources are particularly important for irrigation in the western U.S. and Mississippi River Valley corn growing regions, with seven states (California, Nebraska, Arkansas, Texas, Idaho, Kansas, and Colorado) typically accounting for over 70 percent of total groundwater withdrawals (Figure 7).



Figure 7. U.S. Irrigated Corn Acreage, 2012 Source: (USDA-NASS 2014a)

Irrigation water used in corn production rose from 15.4 million acre-feet in 2008 to 17.9 million acre-feet in 2013 (USDA-NASS 2013). Increases in irrigation were due in part to the increased use of corn for ethanol production (e.g., roughly 30 percent of U.S. corn is currently used for ethanol), and resulting growth in harvested acres of corn, which increased by roughly 15.2 million acres between 2000 and 2013 (USDA-NASS 2015d). Most of this expansion occurred in Western States that can be unpredictably arid and vulnerable to water stress (USDA 2008). Another factor driving irrigation is that irrigated corn yields are typically 30 percent higher than non-irrigated yields. Irrigated corn accounts for approximately 20 percent of total U.S. corn production but occupies less than 15 percent of total agriculture acres (USDA-ERS 2012).

Irrigation of corn crops is likely to remain important to corn production, with commensurate demands on surface and ground water resources. Pursuit of water-use efficiency gains in corn by intensive selection of existing genes, or by transgenic means is an industry-wide goal (Lovell 2014). The need for new resources for irrigation may be greater for crops such as corn with relatively higher water needs, relative to less water-intensive crops, such as wheat (Kenny, Strawn et al. 2012, Schaible and Aillery 2012). Efficient irrigation can not only increase corn yields, it can also help reduce runoff and deep percolation (leaching) losses. However, continued changes in the irrigation sector are anticipated in response to increasing water demands for public and environmental uses, as well as evolving policy among institutions governing farm programs and water allocations.

2.3.3 Water Quality

About 66 percent of water withdrawn for all public uses in the U.S. is from surface waters, and the remainder is from groundwater (Schaible and Aillery 2012). Surface waters provide for drinking, non-agricultural irrigation, industrial, recreational, and other public uses. Almost half of the U.S. population, around 47 percent, depend on groundwater as their drinking water supply, be it from either a public source or private well (Maupin, Kenny et al. 2014).

Crop production can potentially impair surface water quality through soil erosion and run-off, and can impair ground water through leaching of nitrogen and pesticides. Agricultural run-off is the primary source of non-point source (NPS) contaminants impacting U.S. surface waters such as rivers and streams, and the third most significant cause of impairment of water quality in estuaries (US-EPA 2008e, US-EPA 2015a). The most common contaminants in agricultural run-off are sediment, nitrogen and other soil nutrients deriving from fertilizers, and also pesticides, which can similarly impact adversely aquatic and terrestrial wildlife, and ecosystem dynamics (e.g., see (US-EPA 2015f)). The EPA has documented over 3 million acres and 100 thousand miles of water bodies impaired or threatened by nutrient loads, and lists sediments as the second most frequent cause of impairment of U.S. stream sand rivers, nutrients second, and pesticides sixteenth (US-EPA 20151).

Agricultural nutrient losses to streams are a primary concern in the U.S. Corn Belt (Ribaudo, Delgado et al. 2011), particularly in relation to the adverse effects of nutrient loads on hypoxia in the Gulf of Mexico (Wiebe and Gollehon 2006). Nitrogen in particular, when in excess, can fuel harmful algal blooms, which deplete dissolved oxygen with resultant detrimental effects on aquatic ecosystems. In total, agricultural sources contribute more than 70 percent of the nitrogen and phosphorus delivered to the Gulf, versus only 9 to 12 percent from urban sources (Alexander, Smith et al. 2008). For the 2014 crop year, farmers applied nitrogen to 97 percent of planted acres at an average rate of 144 pounds per acre, for a total of 11.2 billion pounds. They applied phosphate to 80 percent of planted acres and potash to 65 percent (USDA-NASS 2014d). Nitrogen run-off from cornfields, in particular, is the single largest source of nutrient pollution to the Gulf of Mexico's "dead zone" (Ribaudo, Delgado et al. 2011).

Agricultural management practices and factors that determine erosion and NPS pollution include tillage and irrigation practices; pesticide, herbicide, and fertilizer application practices (e.g., type, quantity, methods); weather; and the local environment (i.e., the biotic and abiotic conditions governing the transport and fate of environmental chemicals) (US-EPA 2008e, US-EPA 2015a).

Where corn production operations are sustainably managed, they can preserve and restore critical habitats, help protect watersheds, reduce run-off, and improve soil health and water quality. The effectiveness of public water conservation programs depends on how well the environmental results of state nutrient reduction activities are monitored and tracked and then are responsive to the extent of progress (EPA 2014). Effectiveness of initiated Corn Belt agricultural operations also depend on whether these programs complement other watershed conservation and environmental programs and policies (US-EPA 2014c). Because of concerns about potential impacts of agriculture on water resources, various National and regional efforts are underway to reduce NPS contaminants in agricultural run-off, and run-off itself (US-EPA 2008e, USDA-NRCS 2015b, USDA-NRCS 2015c, USDA-NRCS 2015a, USDA 2015b).

2.3.4 Air Quality

USDA-APHIS Dicamba-Resistant Soybean and Cotton Varieties FEIS: Air Quality in U.S. corn growing regions was assessed by USDA in the 2014 FEIS (USDA-APHIS 2014c), Section 3.3.4, and that information is incorporated here by reference. Air Quality considerations in 2015 are similar to those described in the 2014 Dicamba-Resistant Soybean and Cotton Varieties FEIS.

The EPA establishes National Ambient Air Quality Standards (NAAQSs) pursuant to the Clean Air Act (CAA) that are intended to protect public health and the environment. NAAQS are established for six criteria pollutants: ozone (O₃), nitrogen dioxide (NO₂), carbon monoxide (CO), sulfur dioxide (SO₂), lead (Pb), and particulate matter (PM). In addition to criteria pollutants, the EPA regulates hazardous air pollutants (HAPs) such as ammonia and hydrogen sulfide. States enforce the NAAQS s through creation of state implementation plans (SIPs), which are designed to achieve EPA established NAAQS.

Crop production practices can generate air pollutants that can potentially affect the environment and human health, and challenge regional NAAQS (US-EPA 2013c, US-EPA 2015c). Agricultural emission sources from corn production include: smoke from agricultural burning (PM); fossil fuel consumption associated with equipment used in tillage and harvest (CO₂, NOx, SOx); soil particulates from tillage (PM); pesticide volatilization or drift; and soil nitrous oxide (N₂O) emissions from the use of fertilizers (Aneja, Schlesinger et al. 2009, US-EPA 2013c).

Drift, and volatilization of pesticides from soil and plant surfaces, can result in introduction of these chemicals to the atmosphere. Herbicide loss through volatilization loss can be up to 25 times larger than losses from surface runoff, and largely dependent on soil wetness and temperature (Gish, Prueger et al. 2011). Drift is dependent on wind conditions and applicator practices, to include application equipment features such as nozzle size (US-EPA 2015k). Drift and volatilization of pesticides can be a concern due to the potential effects of pesticides on non-target organisms and human health.

The EPA's Office of Pesticide Programs (OPP), which regulates the use of pesticides, including herbicides, introduced initiatives to help pesticide applicators minimize off-target drift. The EPA's voluntary Drift Reduction Technology (DRT) Program was developed to encourage the manufacture, marketing, and use of spray technologies experimentally verified to significantly reduce pesticide drift (US-EPA 2015k). EPA is also working with pesticide manufacturers through the registration and registration review programs on improvements to pesticide label instructions to reduce drift (US-EPA 2015k).

The USDA and EPA provide regional, state, and local regulatory agencies technical tools and information on how to manage agricultural air emissions with USDA approved measures and USDA and EPA expertise. These measures allow stakeholders the flexibility in choosing which measures are best suited for their specific situations or conditions and desired purposes (USDA-EPA 2012). In October of 2012 the EPA and USDA published a reference manual that further provides guidance for improving air quality on agricultural lands (USDA-NRCS 2012).
Over the past several years, the EPA has also developed USDA-approved measures to manage air emissions from cropping systems and to help satisfy SIP requirements. In the 2006 Particulate Matter (PM) National Ambient Air Quality Standards (NAAQS) and 2008 Ozone NAAQS preambles, EPA recommended that in areas where agricultural activities have been identified as a contributor to a violation of the NAAQS, when properly implemented to control airborne emissions of the desired NAAQS pollutant, USDA-approved conservation systems and activities may be implemented to achieve reasonably available control measure (RACM) and best available control measure (BACM) levels of control (USDA-NRCS 2012).

Current practices used in corn production to minimize emissions include conservation tillage, residue management, wind breaks, burn management, manure management, integrated pest management, nutrient management, fertilizer injection, chemigation and fertigation (inclusion in irrigation systems), and conservation irrigation (USDA-NRCS 2006b, USDA-NRCS 2006a).

2.3.5 Climate Change

USDA-APHIS 2,4-D-Resistant Corn and Soybean Varieties FEIS: Impacts of climate change as related to U.S. corn production and impacts of agriculture on climate are assessed by USDA in the 2014 FEIS, Section 3.2.6 (USDA-APHIS 2014b), and that information is incorporated here by reference. Climate change considerations remain similar to those described in 2014 within the 2,4-D-Resistant Corn and Soybean Varieties FEIS.

Agriculture can influence climate change through stages and segments of the production process, which include combustion of fossil fuels in farm equipment, pesticide and fertilizer applications, tillage and manure management practices, and decomposition of agricultural waste products which can all result in emission of greenhouse gases (GHG) to the atmosphere. The major sources of GHG emissions associated with corn production are soil derived nitrous oxide (N₂O) emissions, particulate matter (PM) derived from tillage and agricultural inputs, and carbon dioxide (CO₂) emissions associated with fossil fuel burning farm equipment.

Greenhouse gas emissions from agriculture have increased by approximately 17 percent since 1990, and agriculture is currently responsible for an estimated 8 percent of total GHG emissions in the U.S. (US-EPA 2013c). Methane and N₂O are the primary greenhouse gases emitted by agricultural activities. Methane from emissions from enteric fermentation and manure management represents 25.9 percent of emissions from anthropogenic activities (US-EPA 2013c). Agricultural soil management activities such as fertilizer application and other cropping practices are the largest source of N₂O emissions nationally, accounting for 74.2 percent (US-EPA 2013c). CO₂ is also a significant GHG associated with agricultural land uses and energy consumption.

Corn crops can both contribute to GHG emissions, as well as result in carbon capture and sequestration. The factors influencing agricultural GHG emissions and carbon sequestration are those related to the agronomic practices used in a corn production system, the soil types, and individual grower decisions. For example, emissions of N₂O, produced naturally in soils through microbial nitrification and denitrification processes, can be significantly influenced by fertilizer application practices, cultivation of nitrogen-fixing crops and forage, retention of crop residues (e.g., conservation tillage), irrigation, and fallowing of land (US-EPA 2013c).

Conservation tillage, in particular, can enhance soil carbon sequestration on croplands through the conservation of biomass and incorporation of plant residue (Franzluebbers 2005). In general, the carbon footprint for corn production has been estimated to be approximately 300 pounds of carbon equivalent emission per acre (Nelson, Hellwinckel et al. 2009). Where corn cultivation has been estimated to produce higher total CO₂ emissions than soybean, on-site emissions can be reduced by half for some crops by replacing conventional with no-till systems (Nelson, Hellwinckel et al. 2009). Similarly, rotation of corn crops, such as with legumes, may reduce carbon footprint⁹ of corn crops and also reduce GHG production (Ma, Liang et al. 2012) and simultaneously reduce needs for input of chemical nitrogen to corn. The relationship of conservation tillage and possible benefits to carbon sequestration are however, disputed by some soil experts (VandenBygaart 2016).

Climate change can also affect agricultural crop production when precipitation, temperature, and duration of growing season may be altered; notably, weed and pest pressure may require altered control practices as may the lack thereof (Backlund 2008, IPCC 2014). Current species of agricultural weeds and pests of crops are expected to shift in response to changes in regional climates, which could present new challenges to crop production in certain areas (Backlund 2008). On the other hand, Field et al. found that most studies projected likely climate-related yield increases of 5 to 20 percent on the agricultural output of corn, rice, sorghum, soybean, wheat, common forages, cotton, some fruits, and irrigated grains (Field, Mortsch et al. 2007a). However, such a beneficial impact would not likely be evenly distributed across all geographic areas; certain regions of the U.S. are expected to be negatively impacted by substantial reductions or experience variability of available water resources (Field, Mortsch et al. 2007b, Johnston, Sandefur et al. 2015).

2.4 Biological Resources

2.4.1 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 and shellfish. Wildlife may feed on corn in the field or use habitat surrounding fields for nesting and refuge. Mammals and birds may seasonally consume corn, and invertebrates can feed on the plant during the entire growing season. How agricultural and other lands are managed influences the function and integrity of ecosystems and the wildlife populations that they support.

2.4.1.1 Mammals and Birds

Cornfields are generally considered poor habitat for mammals (Table 6) and birds (Table 7) in comparison with uncultivated lands, but the use of cornfields by birds and mammals is not uncommon. Some birds and mammals use cornfields at various times throughout the corn production cycle for feeding and reproduction. Most of these using cornfields are ground

⁹ Calculated according to Gan et al. Gan, Y., C. Liang, C. Hamel, H. Cutforth and H. Wang (2011). "Strategies for reducing the carbon footprint of field crops for semiarid areas. A review." <u>Agronomy for Sustainable Development</u> **31**(4): 643-656.

foraging omnivores that feed on corn seed, sprouting corn, and the corn remaining in the fields following harvest.

Table 6. Mammal Species of Importance in Cornfield Environments			
Common Name Scientific Name			
Deer mouse	Peromyscus maniculatus		
Feral hog	Sus scrofa		
House mouse	Mus musculus		
Meadow vole	Microtus pennsylvanicus		
Raccoon	Procyon lotor		
Thirteen- lined ground squirrel Spermophilus tridecemlineatus			
White-tailed deer	Odocoileus virginiana		
Woodchuck	Marmota monax		

White-tailed deer are responsible for more corn damage than any other wildlife which impacts yield (Stewart, McShea et al. 2007) Deer use woodlots adjacent to cornfields for both food and cover, especially in mid-summer (Vercauteren and Hygnstrom 1993). In addition to deer, significant damage to corn by raccoons also has been documented (DeVault, Beasley et al. 2007, Humberg, DeVault et al. 2007). Corn has been shown to constitute up to 65 percent of the diet of raccoons during the late summer and fall (MacGowan et al., 2006).

Small mammal use of cornfields for shelter and forage varies regionally and includes the deer mouse, meadow vole, house mouse, and the thirteen-lined ground squirrel (Nielsen, 2005). Throughout the U.S., the deer mouse is the most common small mammal in agricultural fields (Stallman and Best, 1996; Sterner et al., 2003). Deer mice feed on a wide variety of plant and animal matter depending on availability, but primarily feed on seeds and insects. As well as being a seed predator on corn, deer mice can also been considered beneficial in agroecosystems because they consume both weed and insect pests (Smith 2005).

The meadow vole feeds primarily on fresh grass, sedges, and herbs, and also on seeds and grains of field crops. Although the meadow vole may be considered beneficial as a consumer of weeds, this rodent can be a significant agricultural pest when it consumes seeds in the field, and population levels are high. Meadow vole populations are kept in check by high intensity agriculture methods, including conventional tillage; this vole is often associated with cover surrounding the edge of field, and in limited tillage agriculture and strip crops (Smith, 2005). The thirteen-lined ground squirrel feeds primarily on seeds of weeds and available crops, such as corn and wheat. This species has the potential to damage agricultural crops, but can also be beneficial by eating pest insects, such as grasshoppers and cutworms (Smith, 2005).

Table 7. Bird Species of Significance in and Around Cornfields				
Common Name Scientific Name				
American crow	Corvus brachyrhynchos			
Brown-headed cowbird	Molothrus ater			
Canada goose Branta canadensis				
grouse species family Phasianidae				

Horned lark	Eremophila alpestris
Nuttall's woodpecker	Dryobates nuttallii
Red-winged blackbird	Agelaius phoeniceus
Ring-necked pheasant	Phasianus colchicus
Sandhill crane	Grus canadensis
Snow goose	Chen caerulescens
Vesper sparrow	Pooecetes gramineus
Wild turkey	Meleagris gallopavo

Corn fields provide both food and cover for a variety of birds (Vercauteren and Hygnostrom 1993, Palmer, Bromley et al. 2011). The types and numbers of birds that inhabit cornfields vary regionally and seasonally, but numbers are general low (Patterson and Best 1996). Most of the birds that use cornfields are ground foraging omnivores that feed on corn seed, sprouting corn, and the corn remaining in the fields following harvest. It is also common to find large flocks of Canada goose, snow goose, Sandhill cranes, and other migratory waterfowl foraging in cornfields (Sparling and Krapu 1994, Taft and Elphick 2007, Sherfy, Anteau et al. 2011) after corn harvest.

2.4.1.2 Invertebrates

Invertebrate communities in cornfields (Table 8) represent a diverse assemblage of feeding strategies including predators, crop-feeders, saprophages, parasites, and polyphages (Stevenson et al., 2002). Numerous insects and related arthropods perform valuable functions: they pollinate plants, contribute to the decay and processing of organic matter, reduce weed seed populations through predation, cycle soil nutrients, and attack other insects and mites that are considered to be pests. Although many arthropods in agricultural settings are considered pests there are many beneficial arthropods which are natural enemies of both weeds and insect pests (Hoeft, Nafziger et al. 2000, Landis, Menalled et al. 2005). Insects and other invertebrates can be beneficial to corn production, providing services such as nutrient cycling and preying on plant pests. Insect injury can impact yield, plant maturity, and seed quality.

Table 8. Invertebrate Pests and Beneficial Invertebrates					
Common Name Scientific Name					
Pests					
Billbug	Sphenophorus venatus vestitus				
Brown stink bug	Halyomorpha halys				
Corn earworm	Heliothis zea				
Corn flea beetle	Chaetocnema pulicaria				
Corn leaf aphid	Rhopalosiphum maidis				
Corn leafhopper	Dalbulus maidis				
Corn rootworm	Diabrotica spp.				
Corn (dusky) sap beetle	Carpophilus dimidiatus				
Cutworms	Noctuidae				
European corn borer	Ostrinia nubilalis				

Fall armyworm	Spodoptera frugiperda
Grasshoppers	Family Acrididae
Japanese beetle	Popillia japonica
Seedcorn maggot	Delia platura
Slug	several genera
Stalk borer	Elasmopalpus lignosellus
Thrips	Frankliniella occidentalis, F. williamsi
Two-spotted spider mite	Tetranychus urticae
Wireworms	Limonius spp.; Conoderus vespertinus
Beneficial Invertebrates	
Assassin bug	Family Reduviidae
Big-eyed bug	Geocoris spp.
Caterpillar parasitoids	Meteorus communis, Glyptapanteles militaris
Convergent lady beetle	Hippodamia convergens
Crane fly (larvae)	Family Tipulidae
Damsel bug	Family Nabidae
Ground beetles	Family Carabidae
Insidious flower bug, minute pirate bug	Family Anthocoridae
Lacewings	Family Chrysopidae
Predatory mite	Phytoseiulus persimilis
Spined soldier bug	Podisus maculiventris
Spiders	Order Araneae

Many insects are also considered beneficial, as are a multitude of spiders (Order: Araneae) which may benefit corn production by preying on plant pests (Stewart, Layton et al. 2007, Iowa State University n.d.). Other soil dwelling fauna such as earthworms and arthropods play critical roles in the aeration and turn-over of soil, processing of wastes and detritus, and nutrient cycling (USDA-NRCS 2004). Earthworms, termites, ants, beetles, and millipedes contribute to the decay of organic matter and the cycling of soil nutrients (Ruiz, Lavelle et al. 2008).

All agricultural practices have been employed to simplify the agricultural landscape, a consequence of which is that beneficial arthropods may be adversely affected (Landis et al., 2005). Intensively cultivated lands, such as those used in corn production, provide less suitable habitat for wildlife use than that found in fallow fields or adjacent natural areas. Consequently, the types and numbers of animal species found in cornfields are less diverse by comparison with adjacent areas. Greater complexity and plant diversity of surrounding fields can improve arthropod diversity. Windbreaks, shrubs and hedgerows, and even grassy strips can be the source of predatory invertebrates for planted fields in the spring and useful sheltered sites in the winter to stabilize these populations (Dennis and Fry, 1992;(Thomas and Marshall 1999)

2.4.2 Soil Microorganisms

The inorganic and organic matter comprising soil is both home to a wide variety of fungi, bacteria, and arthropods, as well as the growth medium for terrestrial plant life (USDA-NRCS, 2004). Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Young and Ritz 2000, Jasinski, Eisley et al. 2003, Garbeva, van Veen et al. 2004) They also suppress soil-borne plant diseases and promote plant growth (Doran, Sarrantonio et al. 1996).

The main factors affecting microbial population size and diversity include plant type (providers of specific carbon and energy sources into the soil), soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation)(Young and Ritz 2000) (Garbeva, van Veen et al. 2004). Some types of soil micro-organisms share metabolic pathways with plants and might be affected by herbicides. Tillage disrupts multicellular relationships among micro-organisms, and crop rotation changes soil conditions in ways that favor different microbial communities.

Diseases affecting corn include those caused by the fungal pathogens northern leaf spot; northern corn leaf blight; southern corn rust; common corn rust, (*Puccinia sorghi*); anthracnose leaf blight; and gray leaf spot (Ruhl 2007). Management to control disease outbreaks varies by region and pathogen, but includes common practices such as crop rotation, weed control, planting resistant cultivars, and proper planting and tillage practices.

Table 9. Pathogens of Corn				
Common Name Scientific Name				
Fungal Diseases				
Anthracnose leaf blight	Colletotrichum sublineolum			
Anthracnose stalk rot	Colletotrichum graminicola			
Anthracnose top dieback	Colletotrichum graminicola			
Aspergillus ear rot	Aspergillus flavus			
Carbonum leaf spot	Cochliobolus carbonum			
Charcoal rot	Macrophomina phaseolini			
Cladosporium ear rot	Cladosporium spp.			
Common rust	Puccinia sorghi			
Common smut	Ustilago maydis			
Crazy top	Sclerophthora macrospora			
Diplodia ear rot	Fusarium graminearum			
Diplodia stalk rot	Diplodia zeae			
Exserohilum root rot	Exserohilum pedicellatum			
Eyespot	Aureobasidium zeae			
Fusarium ear rot, seedling blight	Fusarium verticillioides			
Fusarium stalk rot	Fusarium spp.			

Gibberella ear rot	Gibberella zeae		
Gibberella stalk rot	Gibberella moniliformis		
Gray leaf spot	Pyricularia grisea		
Head smut	Sphacelotheca reiliana		
Nigrospora ear rot	Nigrospora sphaerica		
Northern corn leaf blight	Setosphaeria turcica		
Penicillium ear rot	Penicillium spp.		
Physoderma brown spot	Physoderma maydis		
Root rot	Phoma terrestris		
Southern corn leaf blight	Cochliobolus heterostrophus		
Southern rust	Puccinia polysora		
Bacterial Diseases			
Bacterial soft rot	Erwinia (Pectobacterium) spp.		
Corn stunt	Spiroplasma kunkelii		
Goss' wilt	Clavibacter michiganensis subsp. nebraskensis		
Holcus leaf spot	Pseudomonas syringae		
Stewart's bacterial wilt	Pantoea stewartii		
Oomycetal Disease			
Pythium stalk rot	Pythium spp.		
Viral Diseases			
Maize chlorotic dwarf virus	family Sequiviridae		
Maize dwarf mosaic virus	family Potyviridae		

2.4.3 Plant Communities

Vegetation surrounding corn producing areas varies by region, and may be naturally occurring or components of an intentional landscape. Surrounding plant communities could be other crops, forest, hedgerows, rangelands, wetlands, pasture, and grassland or shrub land areas. For example, the Western Corn Belt Plains, whose growers lead U.S. corn production, within the area which includes Iowa, southern Minnesota, eastern Nebraska, northeast Kansas, northwest Missouri, and small areas of west-central Wisconsin and southeast South Dakota, is dominated by agricultural land cover including animal pasture land (Auch 2014)). Western Corn Belt growers are also the leading U.S. producers of soybean, wheat, and alfalfa (Auch 2014)). In recent years, the Western Corn Belt has seen an increasing conversion of grasslands to corn or soybean production that over a 6-year period attained to 1.3 million acres(Wright and Wimberly 2013). This grassland conversion could adversely impact erosion rates, as well as wetlands, and have subsequent impacts on wildlife (Wright and Wimberly 2013, Johnston 2014)). Land use can shift for many reasons, but an increase in prices following increased use of commodity crops in biofuels was likely responsible for this trend (Wright and Wimberly 2013, USDA-ERS 2015c)).

Several factors can influence the structure of the plant community including the overall health of the field, taxa present, mechanization level, and use of herbicides (Egan, Bohnenblust et al. 2014, Egan, Graham et al. 2014) (Egan, 2014). Plant and arthropod diversity can be impacted by herbicides; however, the level of herbicide impact was found to vary widely dependent on the species, the stage of development, as well as abiotic stresses (Egan, Graham et al. 2014). Given the number and dynamic nature of these influencing factors, the impact of the herbicide has been identified as a potential secondary factor of influence (Egan, Graham et al. 2014)).

Corn fields also include plant species commonly referred to as weeds. Corn is adversely impacted by weed competition, particularly at critical phases of development (Soltani, Nurse et al. 2013). Frequently occurring weeds of corn fields will vary depending on the region, but the most common weeds include waterhemp, giant ragweed, marestail, foxtail, velvetleaf and morning glory (Pocock 2011)). Tillage practices can determine the diversity of weeds that will populate a field. In aggressive tillage systems, weed diversity tends to decline and annual grasses and broadleaf plants are the dominant weeds; but in no-till fields, there may be a greater diversity of annual and perennial weed species (Baucom and Holt 2009)).

The most common weed management tactic in U.S. corn production is use of herbicides. Herbicide usage can also affect weed diversity, and drive weed shifts (Wilson, Miller et al. 2007, Webster and Nichols 2012). In 2014 it was estimated that 89 percent of the corn grown in the U.S. was herbicide resistant (Fernandez-Cornejo, Wechsler et al. 2014a)) which facilitates use of herbicides in weed control. Weeds can develop resistance to herbicides following frequent exposure to a single herbicide. This exposure exerts selective pressure on weed populations leading to development of weed resistance. Potential transference of weed resistance traits may derive from intercrosses of herbicide-resistant crops (GE or naturally-resistant plants) with weedy relatives. This trait transference is not possible in U.S. corn, however.

2.4.3.1 Gene Flow, Weediness and Outcrossing

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

The rate and success of gene flow is dependent on numerous factors. General factors related to pollen-mediated gene flow include the presence, abundance, and 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 (Zapiola, Campbell et al. 2008). Seed-mediated gene flow also depends on many factors, including the absence, presence, and magnitude of seed dormancy; contribution and participation in various dispersal pathways; and environmental conditions and events (Zapiola, Campbell et al. 2008).

The potential for outcrossing or gene escape is defined as the ability of the gene to escape to wild relatives and APHIS's preliminary Plant Pest Risk Assessment determined that there is no likely route for commercial corn gene flow (USDA-APHIS 2015a)). Corn plants do not produce clonal

structures nor can corn plants produce vegetative propagules. Therefore, asexual reproduction and gene flow as a result of dispersal of vegetative tissues does not occur with corn.

2.4.3.2 Weeds and Resistance to Herbicides

The development of herbicide resistance in weeds is not unique to a particular crop or herbicide, or to the use to genetically engineered plants. Best management practices are critical to control the development of herbicide resistant weeds (Norsworthy, Ward et al. 2012). Strategies to control weeds in corn are detailed in Appendix 6 of the FEIS for Monsanto Petitions (10-188-01p and 12-185-01p) and include using more than one mode of action, properly timing herbicide applications, proper dosage, establishing weed free fields at planting (USDA-APHIS 2014d). Weeds resistant to glyphosate, dicamba, and glufosinate-ammonium are detailed below in Tables 10-13, respectively. Table 10 focuses on weed species that can occur in corn fields. Tables 11 and 12 are dicamba and glufosinate-ammonium resistant weeds that were identified in the United States. There are two weed species that have been identified as resistant to dicamba in the U.S., and one weed species with resistance to glufosinate-ammonium in the U.S. (Heap 2015). In 2013, approximately 13.9 percent of U.S. corn fields were sprayed with dicamba, 1.2 percent of corn fields were sprayed with glufosinate-ammonium, and 83.7 percent were sprayed with gluphosate (Table 15).

As of June, 2015, 14 glyphosate resistant weed species have been identified at 146 locations within the U.S. (Heap 2015). Specifically in U.S. corn fields, 9 glyphosate resistant weed species have been identified in 23 states, see Table 10. MON 87419 corn will provide growers with additional and enhanced pre-emergence and in-crop weed management option to control a broad spectrum of broadleaf weeds, including glyphosate resistant broadleaf weed species. Significant glyphosate resistant weeds such as Palmer amaranth, marestail, common ragweed, giant ragweed, and waterhemp can be controlled by dicamba and glufosinate (Monsanto 2015a,b). The exclusive use of glyphosate for weed control has been identified as the main cause of glyphosate resistant weeds (Livingston, Fernandez-Cornejo et al. 2015). Potentially due to the evolution of glyphosate resistant weeds, the percentage of corn acres receiving only glyphosate declined to 23 percent in 2010, down from 44 percent in 2005 (Livingston, Fernandez-Cornejo et al. 2015). Herbicide resistant weeds impact cultivation practices. Researchers have concluded that glyphosate resistant weeds, resistant Palmer amaranth in particular, have also negatively impacted the number of acres cultivated under conservation or reduced tillage practices (Price, Balkcom et al. 2011).

Table 10. Gly	Table 10. Glyphosate-Resistant Weeds Found in the United States					
Species	Common Name	State	Year Identified	Herbicide Site of Action		
<u>Amaranthus</u> <u>palmeri</u>	Palmer Amaranth	Florida	2013	EPSP synthase inhibitors (G/9)		
				Multiple Resistance: 3 Sites of Action		
<u>Amaranthus</u>	Amaranthus Palmer Coordin 2010	ALS inhibitors (B/2)				
<u>palmeri</u>	Amaranth	Georgia	orgia 2010	Photosystem II inhibitors (C1/5)		
				EPSP synthase inhibitors (G/9)		
<u>Amaranthus</u>	Palmer	Illinois	2013	Multiple Resistance: 2 Sites of Action		
<u>palmeri</u>	Amaranth	minois	2013	ALS inhibitors (B/2)		

Table 10. Glyphosate-Resistant Weeds Found in the United States					
				EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> palmeri	Palmer Amaranth	Illinois	2010	EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>palmeri</u>	Palmer Amaranth	Indiana	2012	EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>palmeri</u>	Palmer Amaranth	Missouri	2008	EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>palmeri</u>	Palmer Amaranth	North Carolina	2005	EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>palmeri</u>	Palmer Amaranth	South Carolina	2010	Multiple Resistance: 2 Sites of Action ALS inhibitors (B/2) EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>palmeri</u>	Palmer Amaranth	Tennessee	2006	EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>palmeri</u>	Palmer Amaranth	Wisconsin	2013	EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>tuberculatus</u> <u>(=A. rudis)</u>	Tall Waterhemp	Illinois	2006	Multiple Resistance: 2 Sites of Action ALS inhibitors (B/2) EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>tuberculatus</u> <u>(=A. rudis)</u>	Tall Waterhemp	Illinois	2009	Multiple Resistance: 4 Sites of Action ALS inhibitors (B/2) Photosystem II inhibitors (C1/5) PPO inhibitors (E/14) EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>tuberculatus</u> (=A. rudis)	Tall Waterhemp	lowa	2011	Multiple Resistance: 4 Sites of Action ALS inhibitors (B/2) Photosystem II inhibitors (C1/5) HPPD inhibitors (F2/27) EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>tuberculatus</u> <u>(=A. rudis)</u>	Tall Waterhemp	lowa	2009	EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>tuberculatus</u> <u>(=A. rudis)</u>	Tall Waterhemp	Missouri	2009	Multiple Resistance: 2 Sites of Action ALS inhibitors (B/2) EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>tuberculatus</u> (=A. rudis)	Tall Waterhemp	Missouri	2005	Multiple Resistance: 3 Sites of Action ALS inhibitors (B/2) PPO inhibitors (E/14) EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>tuberculatus</u> <u>(=A. rudis)</u>	Tall Waterhemp	North Dakota	2010	EPSP synthase inhibitors (G/9)	
<u>Amaranthus</u> <u>tuberculatus</u> <u>(=A. rudis)</u>	Tall Waterhemp	South Dakota	2010	EPSP synthase inhibitors (G/9)	

Table 10. Gly	Table 10. Glyphosate-Resistant Weeds Found in the United States					
<u>Amaranthus</u> <u>tuberculatus</u> <u>(=A. rudis)</u>	Tall Waterhemp	Texas	2006	EPSP synthase inhibitors (G/9)		
<u>Amaranthus</u> <u>tuberculatus</u> <u>(=A. rudis)</u>	Tall Waterhemp	Wisconsin	2013	EPSP synthase inhibitors (G/9)		
<u>Ambrosia</u> <u>artemisiifolia</u>	Common Ragweed	South Dakota	2007	EPSP synthase inhibitors (G/9)		
<u>Ambrosia</u> <u>trifida</u>	Giant Ragweed	lowa	2009	EPSP synthase inhibitors (G/9)		
<u>Ambrosia</u> <u>trifida</u>	Giant Ragweed	Missouri	2011	Multiple Resistance: 2 Sites of Action ALS inhibitors (B/2) EPSP synthase inhibitors (G/9)		
<u>Ambrosia</u> <u>trifida</u>	Giant Ragweed	Wisconsin	2011	EPSP synthase inhibitors (G/9)		
<u>Conyza</u> <u>bonariensis</u>	Hairy Fleabane	California	2009	Multiple Resistance: 2 Sites of Action PSI Electron Diverter (D/22) EPSP synthase inhibitors (G/9)		
<u>Conyza</u> <u>canadensis</u>	Horseweed	Alabama	2013	EPSP synthase inhibitors (G/9)		
<u>Conyza</u> <u>canadensis</u>	Horseweed	California	2005	EPSP synthase inhibitors (G/9)		
<u>Conyza</u> <u>canadensis</u>	Horseweed	lowa	2011	EPSP synthase inhibitors (G/9)		
<u>Conyza</u> <u>canadensis</u>	Horseweed	Mississippi	2003	EPSP synthase inhibitors (G/9)		
<u>Conyza</u> <u>canadensis</u>	Horseweed	Missouri	2002	EPSP synthase inhibitors (G/9)		
<u>Conyza</u> <u>canadensis</u>	Horseweed	South Dakota	2010	EPSP synthase inhibitors (G/9)		
<u>Conyza</u> <u>canadensis</u>	Horseweed	West Virginia	2007	EPSP synthase inhibitors (G/9)		
<u>Echinochloa</u> <u>colona</u>	Junglerice	California	2008	EPSP synthase inhibitors (G/9)		
<u>Kochia</u> <u>scoparia</u>	Kochia	Idaho	2014	EPSP synthase inhibitors (G/9)		
<u>Kochia</u> <u>scoparia</u>	Kochia	Kansas	2013	Multiple Resistance: 2 Sites of Action EPSP synthase inhibitors (G/9) Synthetic Auxins (O/4)		
<u>Kochia</u> <u>scoparia</u>	Kochia	Kansas	2013	Multiple Resistance: 4 Sites of Action ALS inhibitors (B/2) Photosystem II inhibitors (C1/5) EPSP synthase inhibitors (G/9) Synthetic Auxins (O/4)		
<u>Kochia</u> <u>scoparia</u>	Kochia	Kansas	2007	EPSP synthase inhibitors (G/9)		

Table 10. Glyp	Table 10. Glyphosate-Resistant Weeds Found in the United States					
<u>Kochia</u> <u>scoparia</u>	Kochia	Nebraska	2011	EPSP synthase inhibitors (G/9)		
<u>Kochia</u> <u>scoparia</u>	Kochia	North Dakota	2012	EPSP synthase inhibitors (G/9)		
<u>Kochia</u> <u>scoparia</u>	Kochia	Oklahoma	2013	EPSP synthase inhibitors (G/9)		
<u>Kochia</u> <u>scoparia</u>	Kochia	Oregon	2014	EPSP synthase inhibitors (G/9)		
<u>Kochia</u> <u>scoparia</u>	Kochia	South Dakota	2009	EPSP synthase inhibitors (G/9)		
<u>Lolium</u> perenne ssp. multiflorum	Italian Ryegrass	Louisiana	2014	EPSP synthase inhibitors (G/9)		
<u>Lolium</u> perenne ssp. multiflorum	Italian Ryegrass	North Carolina	2009	EPSP synthase inhibitors (G/9)		
<u>Lolium</u> perenne ssp. multiflorum	Italian Ryegrass	Tennessee	2012	EPSP synthase inhibitors (G/9)		
Parthenium hysterophorus	Ragweed	Florida	2014	EPSP synthase inhibitors (G/9)		
Pao annua	Annual Bluegrass	Missouri Tennessee	2010 2011	EPSP synthase inhibitors (G/9)		
Salsola tragus	Russian- thistle	Montana	2015	EPSP synthase inhibitors (G/9)		
Sorghum halepense	Johnsongrass	Arkansas Mississippi Louisiana	2007 2008 2010	EPSP synthase inhibitors (G/9)		

Source: Heap, I. The International Survey of Herbicide Resistant Weeds. Online. Internet. March 22, 2015 . Available <u>www.weedscience.com</u>.

Table 11. Dicamba-Resistant Weeds Found in the United States						
Species	Common Name	State	Year Identified	Herbicide Site of Action		
Kochia scoparia	Kochia	Montana	1994	Synthetic Auxins (O/4)		
Kochia scoparia	Kochia	North Dakota	1995	Synthetic Auxins (O/4)		
Kochia scoparia	Kochia	Idaho	1997	Synthetic Auxins (O/4)		
Kochia scoparia	Kochia	Colorado	1999	Synthetic Auxins (O/4)		
Kochia scoparia	Kochia	Nebraska	2009	Synthetic Auxins (O/4)		
				Multiple Resistance, 4 sites of action:		
Kochia scoparia	Kochia	Kansas	2013	ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), Photosystem II inhibitors (C1/5), Synthetic Auxins (O/4)		
				Multiple Resistance, 2 sites of action:		
Kochia scoparia	Kochia	Kansas	2013	EPSP synthase inhibitors (G/9), Synthetic Auxins (O/4)		
Lactuca serriola	Prickly lettuce, Milk thistle	Washington	2007	Synthetic Auxins (O/4)		

Source: Heap, I. The International Survey of Herbicide Resistant Weeds. Online. Internet. Tuesday, June 9, 2015. Available www.weedscience.com

Table 12. Glufosinate-Ammonium-Resistant Weeds Found in the United States						
Species	Common Name	State	Year Identified	Herbicide Site of Action		
Lolium perenne ssp. multiflorum	Italian Ryegrass	Oregon	2010	Multiple resistance, 2 sites of action: EPSP synthase inhibitors (G/9), Glutamine synthase inhibitors (H/10)		

Source: Heap, I., The International Survey of Herbicide Resistant Weeds. Online. Internet. Tuesday, June 9, 2015. Available at www.weedscience.com

2.4.4 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson 1988)) and so includes the sum of all organisms, the genes they express and the ecosystem which they form (EPA-NSW 2012). Biodiversity provides valuable genetic resources for human innovations, including crop improvement and also provides systemic and necessary ecological supporting functions besides the resources for food, fiber, fuel, and income (Harlan 1975). 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).

The complexity of biodiversity in an agroecosystem depends on four primary characteristics of the landscape and of grower practices: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management; and 4) extent of isolation of the agroecosystem from natural vegetation (Southwood and Way 1970).

Agricultural land subject to intensive farming practices used in crop production generally has low levels of biodiversity compared with adjacent natural areas. Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvesting limit the diversity of plants and animals (Lovett, Price et al. 2003). Improved biodiversity has been linked with use of no-till in production agriculture (Lal 2013) and sometimes density and diversity of specific populations was emphasized, such as seed-feeding carabid beetles (Menalled, Smith et al. 2007). In corn cultivation, planting of herbicide resistant corn at least appears directly correlated with adoption of no-till practices (Young 2006) but may have increased simultaneously with this tillage practice; other authors see adoption of no-till practices over conventional tillage practices as linked (Givens, Shaw et al. 2009b, NRC 2010). The opposite correlation can be made that populations of glyphosate resistant weeds have increased with increasing adoption of herbicide resistant crops and this has led to reductions in tillage practices in some areas. For example, as mentioned above, glyphosate resistant weeds, particularly resistant Palmer amaranth, have negatively impacted the number of acres cultivated under conservation or reduced tillage practices (Price, Balkcom et al. 2011) but these are often associated with soybean or cotton production.

Biodiversity can be maintained or reintroduced into agroecosystems through the ecologically conscious design of farms and surrounding fields and their cropping practices. Agronomic practices that may be employed to support biodiversity include intercropping (the planting of two or more crops simultaneously to occupy the same field), crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (compost, green manure, animal manure, etc.), agroforestry, and windbreaks, wetlands, hedgerows and woodlots (Altieri 1999).

2.5 Human Health

Human health considerations are those related to (1) the safety and nutritional value of corn to consumers, and (2) the potential health effects of pesticides that may be used in association with corn production. As for GE corn, health concerns are in regard to the potential toxicity or allergenicity of the introduced genes and their products, the expression of new antigenic proteins, or altered levels of existing allergens or plant constituents. Some consumers may also be concerned about potential consumption of pesticide residues on food crops.

Foods derived from genetically modified plants undergo a comprehensive safety evaluation before entering the market, including reviews under the CODEX Alimentarius, the European Food Safety Agency, and the World Health Organization (FAO 2009, Hammond and Jez 2011). Food safety reviews frequently will compare the compositional characteristics of the GE crop with non-GE, conventional varieties of that crop. These analyses will also evaluate the composition of the modified crop under actual agronomic conditions, including various agronomic inputs, is the case for MON 87419 corn (see (Monsanto 2015a)).

In the U.S., GE plants are regulated and evaluated for public health and environmental safety under the Coordinated Framework for the Regulation of Biotechnology (51 FR 23302; 57 FR 22984) described in Section 1.3. The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA APHIS, the EPA, and the FDA. The safety assessment of crops derived through biotechnology includes characterization of the physicochemical and functional properties of the protein(s) produced from the inserted DNA, and confirmation of the safety of the protein(s).

Under the Federal Food Drug and Cosmetics Act (FFDCA) it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and labeled properly. Food and feed derived from GE organisms must be in compliance with the FFDCA, Food Safety Modernization Act (FSMA), and all other applicable legal and regulatory requirements. Developers of GE organisms the will be used for food or feed may undergo a voluntary consultation process with the FDA prior to release of the food or feed into commerce. Although a voluntary process, thus far all applicants who have wanted to commercialize a GE product that would be included in the food or feed supply have completed a consultation with the FDA. In a consultation, a developer meets with the FDA to identify and discuss relevant safety, nutritional, and other regulatory assessment of the food. The FDA evaluates the submission and responds to the developer by letter.

Under the FIFRA, all pesticides (which is inclusive of herbicides, insecticides, and fungicides) sold or distributed in the U.S. must be registered by the EPA. Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to human health, workers, or the environment. In addition, the FDA and the USDA monitor foods for pesticide residues and enforce these tolerances.

The EPA's registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects.

The USDA conducts the Pesticide Data Program collecting data on pesticides residues on food (USDA-AMS 2015a). The EPA uses Pesticide Data Program data to prepare pesticide dietary exposure assessments pursuant to the 1996 Food Quality Protection Act. Pesticide tolerance levels for dicamba and glufosinate have been established for a wide variety of commodities, including field corn for grain and forage. The dicamba tolerance levels established for field corn forge, grain, and stover are 3.0, 0.1, and 3.0 parts per million (ppm), respectively (40 CFR § 180.227 - Dicamba; tolerances for residues). Those for glufosinate are 4.0, 0.2, and 6.0 ppm, respectively (40 CFR §180.473 - Glufosinate ammonium; tolerances for residues 4.0, 0.2, 6.0 ppm). These tolerance limits are expected to be protective of livestock health (see 40 CFR Part 80, Tolerances and Exemptions for Pesticide Chemical Residues in Food).

2.5.1 Worker Safety

Agriculture is one of the most hazardous industries for U.S. workers. Farm workers are at a high risk for fatal and nonfatal injuries. The most common hazards are those associated with operation of machinery and vehicles, although pesticide application, as a potential route of exposure for farm workers, is also a concern.

Both dicamba and glufosinate may be used on MON 87419 corn during production. As discussed above, pesticides labeled for use on crops in the U.S. must be evaluated for safety and registered by the EPA. Among other elements, the EPA pesticide registration process involves the development of use restrictions that, when followed, have been determined to be protective of worker health. These may include instructions on personal protective equipment, specific handling requirements, and field reentry procedures. These label restrictions carry the weight of law and are enforced by the EPA and the states (FIFRA 7 U.S.C. 136j (a)(2)(G) Unlawful Acts); consequently, it is expected that use of dicamba and glufosinate on MON 87419 corn would be consistent with the EPA-approved label requirements. Used in accordance with the label, these herbicides have been determined to not present a health risk to workers.

The EPA updated labeling and use instructions for dicamba in the 2008 and amended 2009 RED (US-EPA 2009b). In 2013, the EPA updated their occupational assessment for glufosinate to include: (1) handler exposure and risk estimates for spot/directed treatments to citrus, pome, stone fruits, and olives, (2) handler exposure and risk estimates for the representative crops of corn, cotton, sorghum, and canola, and (3) a new summary of estimated post-application risks for various crops (US-EPA 2013e)

EPA's Worker Protection Standard (WPS) (40 CFR Part 170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. On February 20, 2014, the EPA announced proposed changes to the agricultural WPS to increase protections from pesticide exposure for agricultural workers and their families 10. The EPA is proposing to strengthen the protections provided to agricultural workers and handlers under the WPS by improving elements of the existing regulation, such as training, notification, communication materials, use of personal protective equipment, and decontamination supplies. The proposed changes to the current WPS requirements, specifically improved training on reducing pesticide residues brought from the treated area to the home on workers and handlers' clothing and bodies and establishing a minimum age for handlers and early entry workers, help to mitigate the potential for children to be exposed to pesticides directly and indirectly. The EPA expects the revisions, once final, to prevent unreasonable adverse effects from exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations, child farmworkers, and farmworker families; and the general public.

2.6 Animal Feed

Corn is the most widely cultivated feed grain in the United States, accounting for more than 95 percent of total value and production of feed grains. It is a primary feed source due to its nutrient

¹⁰ For the proposed changes see: <u>http://www.epa.gov/oppfead1/safety/workers/proposed/index.html</u>

composition, with beef cattle, poultry, hogs, and dairy cattle, consuming the largest volume feed harvested (NCGA 2014). Animal feed derived from corn comes not only from the unprocessed grain, but also from silage (the above-ground portions of the corn plant), stalk residues in fields that might be grazed, and residuals derived from corn refining and milling, such as corn gluten feed, corn gluten meal, corn germ meal, corn steep liquor, and amino acids.

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

Under Section 408 of the FFDCA, the EPA regulates the levels of pesticide residues that can remain on food or food commodities from pesticide applications (US-EPA, 2010e). The EPA establishes tolerance levels¹⁸ for feed to ensure the safety of raw or processed commodities for animal feed and may include conventional pesticides (e.g., herbicides) and genetic elements resulting from genetic engineering, such as PIPs (e.g., Cry proteins) or proteins conferring herbicide resistance (e.g., EPSPS protein) (US-EPA, 2012c). With regard to pesticides and pesticide residues, growers must adhere to the EPA label use restrictions for pesticides used to produce a corn crop before using it as forage, hay, or silage.

2.7 Socioeconomics

2.7.1 Domestic Economic Environment

2.7.1.1 GE Corn Production

U.S. corn production has increased over time following technological improvements in seed varieties, pesticides, and machinery, and production practices such as tillage, irrigation, crop rotations, and pest management systems (USDA-ERS 2015b). Corn acreage in the U.S. has risen over the last 10 years, with 91.6 million acres (37.4 million hectares) planted in 2014 (Figure 8). Where this represents the lowest planted corn acreage since 2010, it is the fifth largest corn acreage planted in the U.S. since 1944 (USDA-NASS 2014c). The increase in acreage has involved all varieties of corn and is occurring throughout corn growing areas in the U.S. Planting of GE corn has significantly increased (mostly for herbicide tolerance and insect resistance) and accounted for over 90 percent of planted corn acres in the U.S. in 2013; a trend that is expected to continue (Fernandez-Cornejo, Wechsler et al. 2014b).



Figure 8. Corn Acreage and Yield from 1926 to 2014

Strong demand for ethanol production has resulted in generally higher corn prices, and consequently, the incentive to increase corn acreage (USDA-ERS 2015b). In many cases, farmers have increased corn acreage by adjusting crop rotations between corn and soybeans, resulting in a decrease in soybean plantings. Other sources of land for increased corn plantings include pasture, acreage returning to production from expiring Conservation Reserve Program contracts, and shifts from other crops, such as cotton. In general, since 2006, U.S. corn acreage has increased as market prices have favored the planting of corn over alternative crops. Corn used to produce ethanol in 2015/16 is expected to be unchanged as projected gasoline consumption during the 2015/16 marketing year is nearly identical to 2014/15 (USDA-OCE 2015).

Herbicide tolerant (HT) corn accounted for 89 percent of corn acreage in 2014 (USDA 2015a). Producers who plant HT crops expect to achieve at least the same yield while lowering weed control costs (e.g., chemicals and mechanical methods), and minimizing the need for weed scouting. In return, producers pay more for HT seeds. The price of GE soybean and corn seeds grew by about 50 percent in real terms (adjusted for inflation) between 2001 and 2010. (Fernandez-Cornejo, Wechsler et al. 2014b).

In the absence of pests, commercially available GE seeds do not increase maximum crop yields. However, while the evidence of the impact of HT crops (for corn, cotton, and soybeans) on net returns has been somewhat mixed, the benefits appear to largely outweigh costs. The adoption of GE corn in the U.S. has been found to reduce costs and improve profitability on the farm (Brookes and Barfoot 2013, Fernandez-Cornejo, Wechsler et al. 2014b). These cost reductions are a attributed to reductions in average herbicide and pesticide use per field, and corresponding reductions in tillage and associated field cultivation costs. Other benefits to the grower from adoption of GE crops have included (Carpenter, Felsot et al. 2002, Brookes and Barfoot 2010):

- Reduced harvesting costs;
- Higher quality harvested crop;
- An improvement in soil quality as growers expand practices of limited tillage; and
- Overall improvements in human health costs associated with use of less toxic pesticides.

Relative to MON 87419 corn, stacked-trait seeds have higher yields than conventional seeds or seeds with only one GE trait (Fernandez-Cornejo, Wechsler et al. 2014b). USDA data indicate that conventional corn seeds had an average yield of 134 bushels per acre, while seeds with two types of herbicide tolerance (glyphosate and glufosinate) and three types of insect resistance (corn borer, corn rootworm, and corn earworm) had an average yield of 171 bushels per acre (Fernandez-Cornejo, Wechsler et al. 2014b). Adoption rates of stacked-trait varieties have increased in recent years, with stacked-trait corn expanding from 1 percent of planted acres in 2000, to 76 percent in 2014. GE varieties incorporating three or four traits are now common.

2.7.1.2 Weed Control Costs and Stacked Traits

Approximately 97 percent of U.S. acreage devoted to major crops was treated with herbicides in 2014 (USDA-NASS 2014d). Historically, adoption of a GE HT weed control system has reduced grower costs and increased profitability; however, an important concern currently facing U.S. farmers, including corn farmers, is the emergence of herbicide-resistant weeds; a result of the repeated, wide spread, and sometimes exclusive use of a single pesticide on corn, cotton, and soybean crops resistant to the pesticide, primarily glyphosate.

As of 2014, there were 14 different weed species with glyphosate-resistant populations, 2 different species resistant to dicamba, and 1 species resistant to glufosinate (Heap 2015). Stacked trait crops are planted to combat weed resistance, and stacked seeds are more costly. The extent to which HT adoption affects net returns is mixed and depends primarily on how much weed control costs are reduced and seed costs are increased. It may be possible that employment of management strategies utilizing crop rotation and stacked trait corn as a tool to manage weed density, could potentially decrease management costs and environmental impacts, and improve overall cropping system sustainability (Dunn 2009, Garrison, Miller et al. 2014).

Other recent analyses suggest that where weed management costs are higher with more intensive management with herbicides, reduced weed pressure resulted in a trend toward higher crop yields, which offset the higher weed management costs. It has also been noted that managing glyphosate resistance is more cost effective than ignoring it, and after about 2 years, the cumulative impact of the returns received is higher when managing instead of ignoring weed resistance (Livingston, Fernandez-Cornejo et al. 2015). Similarly, Weirich *et al.* investigated the effect of grower adoption of alternative glyphosate weed resistance management programs, finding weed resistance management more costly, but it provided similar yields and economic returns (Weirich, Shaw et al. 2011). Findings from this study, and Fernandez-Cornejo *et al.*

(2015) suggest that implementing weed resistance management systems net returns can be equivalent in the short run, and, in the long term, can result in substantial savings.

2.7.1.3 Conventional and Organic Corn Production

Growers can choose from a large number of conventional and organic corn hybrids produced from traditional breeding. As summarized previously, GE varieties of corn have been widely adopted during the past decade, and USDA recognizes that producers of non-GE corn, particularly producers who sell their products to markets sensitive to GE traits (e.g., organic and some export markets), desire to maintain the genetic purity of the crop product.

Corn is a cross-pollinating crop in which most pollination results from pollen dispersed by wind and gravity. Insects, and farmer's actions themselves, can also be the cause of cross-pollination. Either instance may result in economic losses to conventional or organic farmers. According to a Food and Water Watch survey, one third of surveyed organic farmers had dealt with contamination on their farms, and of those, over half had product rejected by their buyers for that reason (FWW 2014).

Practices to prevent contamination of non-GE corn include isolation of the farm; physical barriers or buffer zones between GE production and non-GE production; planting border or barrier rows to intercept pollen; changing planting schedules to ensure flowering at different times; and formal cooperative communications between neighboring farms to ensure crop protection (Baier 2008, Roth 2011a). These are the types of practices utilized for the cultivation of "certified" seed under the Association of Official Seed Certifying Agencies (AOSCA) procedures. During the cultivation period, cross-pollination is managed by recognizing corn pollen dispersal patterns, and maintaining adequate distances and controls between fields where cross-pollination is not desired (Mallory-Smith and Sanchez Olguin 2011).

Organic systems are usually certified organic according to USDA National Organic Program standards (USDA-AMS 2015b). In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards.

The NOP recognizes the economic importance of protecting organically-produced crops from accidental contamination by GE crops, and require that organic production plans include practical methods to protect organically produced crops. The NOP requires organic production operations to have a management plan approved by an accredited certifying agent, which may include measures such as distinct, defined boundaries and buffer zones to prevent unintended contact with adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan, approved by their accredited certifying agent, to prevent genetic commingling due to pollen flow, as well as post-harvest commingling. Plans under the approved operating system enable the production operator to achieve and document compliance with the National Organic Standards, including the

prohibition on the use of excluded methods. In NOP organic systems, the use of GE crops is excluded.

USDA assumes non-GE crop producers use practices on their farm to protect their crop from unwanted substances and thus maintain their price premium, and that growers of non-GE corn are already using, or have the ability to use, those common practices as prescribed by NOP and AOSCA.

Organic corn in particular carries a price premium. While organic corn accounted for only 0.3 percent of total 2011 corn acres, acres planted to organic corn nearly tripled between 2001 and 2010. In contrast, total corn acres increased only 11 percent during the same period. The growth in organic corn acres was likely the result of high returns to organic corn production, but its share in total corn acres remains low possibly due to fixed costs and 3 years of time needed to convert land from conventional to organic production. Data from USDA-ERS and the 2010 Agriculture Management Resource Survey (ARMS) were used to compare costs and production practices for organic and conventional producers planting at least 1 acre of corn with the intent of harvesting it for grain. Producers saw average returns of \$307 per acre for conventional corn compared with \$557 per acre for organic corn in 2010. The gross value of production per acre from organic corn exceeded that from conventional corn in 2010, due primarily to higher organic corn prices that outweighed the effects of lower yields (Foreman 2014).

Although organic yields tend be lower than conventional corn yields, around some 80 percent (de Ponti, Rijk et al. 2012, Ponisio, M'Gonigle et al. 2015), net returns from organic acres continue to be greater than that from conventional acres, with a around a 60 percent premium received for organic corn growers reported in 2010 (USDA-ERS 2015d).

Similar to the production of conventional seed, industry quality standards for specialty crop products have led these seed producers and growers to employ a variety of techniques to ensure that their products are not pollinated by or commingled with conventional or GE crops. Common practices include maintaining isolation distances to prevent pollen movement from other corn sources, planting border or barrier rows to intercept pollen, and employing natural barriers to pollen (NCAT 2003).

Considering producers of non-GE corn, and GE corn producers, have available production and handling strategies in place to ensure that their product meets standards specified either in the USDA NOP, AOSCA, or through contracts, as relevant, USDA assumes that producers of GE and non-GE corn will use practices to protect their crop from pollen and seed in order to maintain crop purity, certification, and/or price premium.

2.7.2 Trade Economic Environment

Corn is the dominant feed grain traded internationally and in 2014 the U.S. produced approximately 36 percent of the total world corn supply (USDA-FAS 2015). Corn exports in recent years have accounted for about 20 percent of U.S. production, although corn is expected to gain an increasing share of world coarse grain trade, with its market share of global trade projected to grow to almost 45 percent over the next decade, with annual corn exports projected to be 63.5 million tons by 2024/25 (Westcott and Hansen 2015).

Identity protection is important in international trade. The low level presence (LLP) and adventitious presence (AP) of GE corn in internationally traded conventional or organic food and feed crops are important considerations in the trade of corn. Asynchronous Approvals (AA) and zero tolerance policy (Van Eenennaam and Young 2014) can result in diversion of trade by some of exporters, and rejection or market withdrawals by importers of corn (e.g., see (FOEU, Frisvold 2015, WTO 2015)). These incidents can have impacts on producers, consumers, and agribusiness firms (Atici 2014). Consequently, incidents of LLP or AP can lead to income loss for exporters and consequently for producers, and consumers in importing countries can potentially face higher domestic corn prices when import is deterred or directed to another trading partner.

The challenges associated with maintaining variety identity in international commodity movement can increase costs, as well as the premiums paid, for some GE crops. GE corn is excluded by some countries sensitive to the importation of GE crops, and other countries may lag approval of new GE corn varieties. In general, LLP or compromise of corn identity can cause disruptions in international trade when GE corn is inadvertently incorporated into food or feed grain shipments, or specialty corn fractions such as corn gluten. As such, GE crop producing countries are required to take all measures necessary in production, harvesting, transportation, storage, and marketing of GE crops to avoid the potential identity related conflicts.

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of MON 87419 corn. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87419 corn is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS 2015a) APHIS has concluded that MON 87419 corn is unlikely to pose a plant pest risk. Therefore, APHIS must determine that MON 87419 corn is no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA.

Two alternatives are evaluated in this EA: (1) No Action: Continuation as a Regulated Article and (2) Preferred Alternative: Determination of nonregulated status of MON 87419 corn. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

3.1 No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. MON 87419 corn and progeny derived from MOON 87419 corn 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 MON 87419 corn and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MON 87419 corn.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRA that MON 87419 corn is unlikely to pose a plant pest risk(USDA-APHIS 2015a). 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.

3.2 Preferred Alternative: Determination that MON 87419 Corn is No Longer a Regulated Article

Under this alternative, MON 87419 corn and progeny derived from it would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87419 corn is unlikely to pose a plant pest risk (USDA-APHIS 2015a). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87419 corn and progeny derived from this event. This 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 MON 87419 corns 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.

Under this alternative, growers may have future access to MON 87419 corn and progeny derived from this event if the developer decides to commercialize MON 87419 corn.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 87419 corn. 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 MON 87419 corn. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

3.3.1.1 Prohibit Any MON 87419 Corn 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 MON 87419 corn, including denying any permits associated with field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MON 87419 corn is unlikely to pose a plant pest risk (USDA-APHIS 2015a)In enacting the PPA, Congress found that

[D]ecisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science...§ 402(4).

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 the development and implementation of policies for oversight of emerging technologies (such as genetic engineering) at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principle, among others, to the extent permitted by law, when regulating emerging technologies:

"[D]ecisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency"

Based on the PPRA (USDA-APHIS 2015a) and the scientific data evaluated therein, APHIS concluded that MON 87419 corn is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87419 corn.

3.3.1.2 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 MON 87419 corn is unlikely to pose a plant pest risk (USDA-APHIS 2015a), it would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340 to consider approval of the petition only in part.

3.3.1.3 Isolation Distance between MON 87419 Corn and Non-GE CROP 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 MON 87419 corn from non-GE corn production. However, because APHIS has concluded that MON 87419 corn is unlikely to pose a plant pest risk (USDA-APHIS 2015a), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of MON 87419 corn based on the location of production of non-GE corn 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 MON 87419 corn, there are no geographic differences associated with any identifiable plant pest risks for MON 87419 corn. This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87419 corn does not pose a plant pest risk, and will not exhibit a greater plant pest 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 7 CFR part 340.

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. Individuals might choose on their own to geographically isolate their non-GE corn production systems from MON 87419 corn or to use isolation distances and other management practices to minimize gene movement between CROP fields. Information to assist growers in making informed management decisions for MON 87419 corn is available from the Association of Official Seed Certifying Agencies (AOSCA 2010).

3.3.1.4 Requirements of Testing for MON 87419 Corn

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes 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 MON 87419 corn does not pose a plant pest risk (USDA-APHIS 2015a), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA and the regulations at 7 CFR part 340. Therefore, imposing such a requirement for MON 87419 corn would not meet APHIS' purpose and need to respond appropriately to the petition.

3.4 Comparison of Alternatives

Table 13 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this EA. The impact assessment is presented in Section 4 of this EA.

Table 13. Summary of Issues of Potential Impacts and Consequences of Alternatives				
Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status		
Meets Purpose and Need and Objectives	No	Yes		
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied—risk assessment USDA- APHIS (USDA-APHIS 2015a)		
Management Practices				
Acreage and Areas of Corn Production	Acreage of soybean plantings are anticipated to increase somewhat through 2020 (USDA-OCE 2013). Corn plantings are anticipated to fluctuate as market prices change. Locations of corn production are not expected to change.	Acreage of plantings likely unchanged. The nonregulated varieties might replace other corn varieties currently grown in the United States. Locations of corn production unchanged.		
Agronomic Practices	Weeds resistant to glyphosate and other herbicides will continue to increase. As HR weeds become more prevalent, growers are expected to shift to more costly alternative weed control measures, additional herbicide combinations or other crops that are economically viable.	Use of dicamba and glufosinate in corn cropping systems is expected to increase, but changes in dicamba use are contingent on EPA's decision to approve the new uses of dicamba on these crop varieties. More efficient weed control is expected to reduce the need for more complex herbicide combinations to control resistant weeds. Conventional growers are likely to continue use of herbicides and retain conservation tillage practices if resistant weeds do not develop over time.		
Organic Corn Production	Planting of organic corn is not likely to change.	Planting of organic corn is not likely to change.		
Use of GE Crops	Planting of existing varieties of GE HR crops is likely already at a maximum, because the percentage of these crops has not been changing in recent years.	Planting of new GE HR corn will likely remain the same or increase only slightly as multiply-resistant weeds increase.		
Physical Environment	1	1		
Soil Quality	One strategy for dealing with herbicide resistant weeds is to increase tillage and cultivation, which can disrupt conservation tillage patterns	A new option, dicamba resistant corn, would provide growers an additional strategy for weed control		
Water Resources	Increased tillage to manage HR weeds may be one option in corn in some regions of the United States. This could increase evaporative water loss and	MON 87419 corn will support continued or increased use of current conservation tillage practices in the short term. In the long term,		

Table 13. Summary of Issue	Table 13. Summary of Issues of Potential Impacts and Consequences of Alternatives			
Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status		
	demand for water resources by irrigation, and cause increased soil erosion accompanied by diminished water quality from sedimentation	development of more HR weeds may be accompanied by increased tillage with negative impacts (as described in the No Action Alternative).		
Air Quality	Increased use of herbicides may occur to manage HR weeds. This would increase drift from herbicides that would reduce air quality. Increased tillage to manage HR weeds is one option in SE regions of the United States for cropping systems	Overall use of herbicides will remain the same or be reduced by better management of HR weeds. Drift from herbicides will remain the same or be reduced, resulting in no change or improved air quality.		
	that include corn. This could reduce air quality from increased air particulates and exhaust from farm equipment.	Use of MON 87419 corn is expected to stabilize current tillage. This will be accompanied by a reduction in airborne particulates and exhaust emissions, which will increase air quality.		
Climate Change	Increased tillage to manage HR weeds (as in a limited portion of the United States) is an option in cropping systems that include corn. This would increase the release of GHGs (primarily CO ₂ and methane).	Use of MON 87419 corn is expected to stabilize current conservation tillage. This will be accompanied by averting the release of additional GHGs (primarily CO ₂ and methane).		
Biological Resources				
Animal Communities	Cultivated corn currently provides limited food and habitat for wildlife in regular cropping situations.	Expected to be the same as No Action because toxicological studies and studies of allergenicity of the added traits did not reveal any impacts on animals.		
Plant Communities	The most important plant communities interacting with corn production are competing weeds. Production practices including herbicides are used to manage weeds. Under the No Action Alternative, selection for herbicide resistant weeds will continue, some with resistance against multiple herbicides that are used.	Selection pressure to develop dicamba resistance in weed populations will increase, including the potential for development of weeds with multiple resistance to more than one herbicide mode of action. MON 87419 corn is not a potential plant pest because it does not compete with native plant species and lacks the potential to do so, so will not adversely impact natural plant communities.		
Gene Flow and Weediness	Gene flow from corn to wild plants does not occur; Volunteers can easily be controlled with herbicides.	Many herbicide options exist for control of various HR volunteer corn varieties including MON 87419 corn.		

Table 13. Summary of Issues of Potential Impacts and Consequences of Alternatives			
Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status	
Microorganisms	Soil organisms provide for organic material breakdown, nutrient transformations, soil structure, and supporting or inhibiting plant pathogens.	Traits of GE corn have not consistently been shown to support changes in soil microbial diversity or abundance.	
Biodiversity	Cropping systems generally are not expected to change, so biodiversity in regions where corn is produced will not change. Herbicide use may decrease weed prevalence or modify the weed species complex in some regions. These changes could modify the species complex of organisms that rely on these weeds as a food source or habitat.	Crop biodiversity is not expected to substantially change relative to the No Action Alternative Use of MON 87419 corn will allow for stable levels of conservation tillage in areas with weeds resistant to herbicides such as glyphosate, which will not decrease biodiversity and might increase it. Use of MON 87419 corn will likely not require increased overall herbicide use, which will not reduce biodiversity and might increase it. Selection pressure for dicamba and glufosinate resistance in weed populations may modify the weed species complex in some regions, which might modify the species complex of organisms that rely on these weeds as a food source or habitat.	
Human and Animal Health			
Risk to Human Health	Corn varieties are associated with all the normal risks of agricultural production. The EPA label use restrictions are designed to protect humans during herbicide use in corn cropping systems to achieve a standard of a "reasonable certainty of no harm".	MON 87419 corn does not present any additional risks to workers. The revised EPA label use restrictions for corn will be designed to achieve the same level of human health and safety as those that currently exist for non-GE varieties.	
Risk to Animal Feed	Risks of new gene expression in GE crops are assessed through FDA biotechnology consultations; EPA provides tolerances for genes and pesticides in crops and their derivative commodities.	The DMO protein is not allergenic, has no toxicity, and an orthologue has been assessed for safety by FDA. The PAT protein has already received a tolerance in several other GE crops.	
Socioeconomic Environment			
Trade Economic Environment	The U.S. will continue to be an exporter of GE corn.	Monsanto has submitted or is planning to submit requests for regulatory approvals in the main	

Table 13. Summary of Issues of Potential Impacts and Consequences of Alternatives				
Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status		
Domestic Economic Environment	The percentage of GE varieties in the market is not expected to change.	export markets for these varieties of corn. The U.S. will continue to be an exporter of GE corn. MON 87419 is not substantially different from those varieties already in commerce. MON 87419 corn is not expected to change the overall percentage of GE varieties in the market; other auxinic		
		class herbicide-resistant corn varieties will also be available, as will corn varieties resistant to several other herbicides.		
Other Regulatory Approvals				
FDA	All products of biotechnology that are offered in the United States have undergone a consultation with the FDA.	Monsanto submitted a food and feed safety document to FDA as part of a biotech consultation.		
EPA	EPA must approve all uses of herbicides and all pesticide residues on food and feed.	Application of glufosinate and dicamba on corn is already a use registered by EPA. Approval of an increase and maximum application rate of dicamba on corn will be determined by the EPA.		
Compliance with Other Laws	Fully compliant	Fully compliant		
Executive Orders and Other Enviro	nmental Regulations			
Executive Orders	All presently commercialized GE corn varieties have complied with existing EOs.	MON 87419 corn will be in compliance with existing EOs.		

4 ENVIRONMENTAL CONSEQUENCES

This chapter examines the environmental effects associated with the alternatives on the affected environment (as identified in Chapter 2). In this chapter, APHIS examines the direct and indirect effects of its decision regarding the regulatory status of MON 87419 corn. While the Agency recognizes that these varieties were engineered to be resistant to applications of the herbicide dicamba, the EPA has the regulatory authority to approve new uses of all pesticides, including those for dicamba on MON 87419 corn. The EPA is currently evaluating the proposed new uses of dicamba for this variety, and is the Federal agency which determines possible human health and environmental consequences of dicamba use in agriculture. The EPA registers herbicide use when consistent with a conclusion of no unreasonable environmental impacts. In this chapter, we assume that any use of dicamba should be discussed as a cumulative effect of APHIS' action combined with future actions that may be taken by the EPA or other agencies. Thus, the analysis of these possible cumulative effects is discussed in Section 5 of the EIS.

4.1 Scope of Analysis

Although the preferred alternative would allow for new plantings of MON 87419 corn to occur anywhere in the United States, APHIS will limit the environmental analysis to those areas that currently support corn production. To determine areas of corn production, APHIS used data from various official USDA sources.

4.2 Agricultural Production of Corn

Best management practices (BMP) are commonly accepted, practical ways to grow corn, regardless of whether the corn farmer is using organic practices or conventional practices with non-GE or GE varieties. These management practices consider crop-specific planting dates, seeding rates, and harvest times, among others. Over the years, corn production has resulted in well-established management practices that are available through local Cooperative Extension Service offices and their respective websites. The National Information System for the Regional Integrated Pest Management Centers publishes crop profiles for major crops on a state-by-state basis. These crop profiles provide production guidance for local growers, including recommended practices for specific pest control. Crop profiles for many of the corn production states can be reviewed at www.ipmcenters.org/cropprofiles/index.cfm.

4.2.1 Acreage and Area of Corn Production

4.2.1.1 No Action Alternative: Acreage and Area of Corn Production

Under the No Action Alternative, existing trends related to area and acreage of corn is expected to continue. Corn is expected to continue being commercially cultivated in 48 U.S. States, with the majority of production centered in the Midwestern Corn Belt (USDA-NASS 2014c). As discussed in Subsection 2.1 – Agricultural Production of Corn, this trend towards increase in corn cultivation is not a result of cultivation of new farm land or conversion of conservation reserves to corn, but is instead a consequence of the grower's substitution of corn for other crops to take advantage of current crop pricing (Wallander, Claasen et al. 2011).

Since 2006, U.S. corn planted acreage has increased as market prices have favored the planting of corn over alternative crops, such as cotton (USDA-NASS 2014c). The increase in corn acreage has been linked to the increase in demand for corn as a feed stock for ethanol for biofuel (Hart 2006, USDA-ERS 2013a). The increase in acreage has involved all varieties of corn and is occurring throughout the corn growing areas (USDA-ERS 2013a). The USDA has estimated that over 90 million acres of corn will be required to meet the demands of ethanol, livestock, and export (Hart 2006). The increased acreage to fulfill the added requirements for ethanol production is expected to come from the upper Midwest and eastern Great Plains areas (Hart 2006).

4.2.1.2 Preferred Alternative: Acreage and Area of Corn Production

A determination of nonregulated status of MON 87419 corn under the Preferred Alternative is unlikely to substantially impact projected trends in U.S. corn acreage (USDA-OCE 2014) relative to the No Action Alternative; corn with herbicide resistance traits shows increasing adoption rates (USDA-ERS 2014). Monsanto studies have demonstrated that with the exception of the traits for resistance to dicamba and glufosinate, MON 87419 corn is phenotypically and agronomically equivalent to other commercially cultivated corn (Monsanto 2015a). There are no changes in agronomic characteristics in MON 87419 corn that would result in an increase in acreage devoted to corn or a change in the range where corn is already cultivated in the U.S. (USDA-APHIS 2015a). As previously discussed, both market forces (i.e., demand for U.S. corn products) and government policies (e.g., reduction in Conservation Reserve Program land enrollment or increased funding for Environmental Quality Incentives Program) strongly affect domestic levels of corn production. MON 87419 corn is unlikely to substantially increase U.S. corn acreage under the Preferred Alternative, as increases in U.S. corn acreage and production generally reflects commercial demand for U.S. corn products and not the cultivation of any one corn variety.

The Preferred Alternative, a determination of nonregulated status of MON 87419 corn, is therefore not expected to increase corn production, either by its availability alone or associated with other factors, or result in an increase in overall acreage of GE corn. Potential impacts would be similar to the No Action Alternative.

4.2.2 Agronomic Practices

4.2.2.1 No Action Alternative: Agronomic Practices

Under the No Action Alternative, MON 87419 corn would continue to be regulated by APHIS. The current availability and usage of commercially-available (both GE and non-GE) corn varieties are expected to continue under the No Action Alternative. General agronomic practices such as planting and harvesting times, crop nutrition, and pre-harvest and harvest practices are expected to remain the same. Specialized agronomic practices such as row spacing, the use of cover crops and crop rotation practices, as well as adoption of precision agriculture may change over time.

As noted in the APHIS Dicamba-Resistant Soybean and Cotton FEIS (USDA-APHIS 2014a), under the No Action Alternative, if hard-to-control or GR weeds continue to be problematic or

become new problems where not previously at issue, growers may consider increases or reversion to conventional tillage or hand-weeding, as has been the case with cotton producers in Southern states with GR palmer amaranth (Sosnoskie and Culpepper 2014).

However, corn growers have reported a lower degree of GR weed presence in corn acres than have soybean and cotton growers on those crops, and in 2010, populations of GR weeds occurred on 5.6 percent of corn acres, mainly on acreage in the Corn Belt and Northern Plains as indicated in USDA ARMS data (Livingston, Fernandez-Cornejo et al. 2015). In 2012, growers were reporting that on 43.7 percent of soybean acres glyphosate effectiveness was declining (Livingston, Fernandez-Cornejo et al. 2015). Corn growers may be reporting fewer issues with GR weeds in part because tillage is used on a greater percentage of corn than soybean acreage, while, conversely, no-till is used on more soybean acreage than corn (Livingston, Fernandez-Cornejo et al. 2015); tillage among other outcomes can be a good mechanism for weed control with no consequence for development of weed resistance (United-Soybean-Board 2014). In addition, corn producers have more options of inexpensive herbicides that can be used for control of annual, perennial, and herbicide-resistant weeds than with other crops (Iowa-State-Extension 2015), so that one recommendation for control of glyphosate- and ALS class-herbicides is to grow corn as a rotation crop, with more effective herbicide choices. GR weeds have posed less of a problem to corn production most likely because herbicides other than glyphosate accounted for most of the herbicides applied to corn acres. In contrast, weeds in soybean fields are far more frequently managed with glyphosate alone (Livingston, Fernandez-Cornejo et al. 2015), because the next best alternative herbicides to control soybean weeds, especially broadleaf weeds, are more expensive, less effective, and can injure soybean plants (NRC, 2010). In some states such as Iowa, only herbicide group 14 and glufosinate can be used on soybean for POST weed control (Iowa-State-University 2015).

Approximately 98 percent of the corn acreage in the U.S. receives an herbicide application (USDA-NASS 2010c). USDA-ERS found that corn growers used other herbicides in addition to glyphosate to manage glyphosate-resistant weeds on over 84 percent of corn acres with GR weeds (see Figure 9). Glyphosate accounted for only 1 percent of herbicide use in 1996, but as HT corn varieties were planted to more acres, glyphosate use grew to 35 percent of total herbicides applied in 2010. In 2010, herbicide use on corn acres was consistent with glyphosate-resistance management on over 82 percent of corn acres where glyphosate was combined with at least one herbicide with a different mechanism of action (MOA), or not used (Livingston, Fernandez-Cornejo et al. 2015).

It is expected that the current trends in herbicide use and tillage in U.S. corn production would not change under the No Action Alternative. It is expected that corn growers will continue to rely on diversified herbicide treatment programs by utilizing additional modes of action.



Figure 9. Corn Acreage Herbicide Application, Surveyed States, 1996-2012 Source: (Livingston, Fernandez-Cornejo et al. 2015)

4.2.2.2 Preferred Alternative: Agronomic Practices

Under the Preferred Alternative, agronomic practices associated with U.S. corn production are likely to continue as described in the analysis of the No Action Alternative and the USDA-APHIS 2,4-D-Resistant Corn and Soybean Varieties FEIS. MON 87419 corn is essentially indistinguishable from non-GE corn plants or other GE corn plants that are no longer regulated by the Agency in terms of agronomic characteristics, cultivation practices, and disease susceptibility.

MON 87419 corn has resistance to both dicamba and glufosinate which are currently labelled for use in corn (Clarity®: EPA Reg No. 7969-137, Liberty®: EPA Reg No. 264-660). Monsanto has indicated that it will petition the EPA to increase the maximum use rate of dicamba in corn from 0.5 to 1.0 lbs. a.e. of dicamba per acre for preemergence applications and up to two applications of 0.5 lbs. a.e. of dicamba per acre for postemergence applications through the V8 growth stage or corn height of 30 inches, whichever comes first. The combined maximum annual application rate of dicamba on MON 87419 corn would be 2.0 lbs. a.e. dicamba per acre per year; currently, the maximum annual application rate of dicamba on corn is 1.5 lbs a.e. per acre.

Glufosinate use on corn is currently approved by the EPA and labeled for preplant applications prior to planting or prior to emergence on conventional and herbicide-tolerant corn hybrids and for in-crop postemergence applications on glufosinate-tolerant hybrids only (CDMS 2015). Glufosinate use in MON 87419 corn will not change from the current EPA-approved uses.

APHIS' selection of a particular alternative does not in itself allow the use of dicamba on MON 87419 corn plant varieties. The EPA regulates the use of herbicides under FIFRA and is making a separate decision which may or may not allow use of dicamba on corn variety.

Therefore, the introduction of MON 87419 corn is not expected to have adverse impacts on current agronomic, cultivation, and management practices for corn. APHIS considers EPA's action regarding the potential approval of the new use of dicamba on MON 87419 corn in Section 5, Cumulative Impacts.

4.2.3 Organic Corn Production

4.2.3.1 No Action Alternative: Organic Corn Production

Current availability of seed for conventional (both GE and non GE) corn varieties and those corn varieties that are developed for organic production are expected to remain the same under the No Action Alternative. Commercial production of conventional and organic corn is not expected to change and likely will remain the same under the No Action Alternative. Organic growers are already coexisting with commercial production of conventional and GE corn. The grower strategies employed to support this coexistence are not expected to change and likely will remain the same under the No Action Alternative. Planting and production of GE, non-GE, and organic corn will continue to fluctuate with market demands, as it has over the last 10 years, and these markets are likely to continue to fluctuate under the No Action Alternative (USDA-ERS 2010a, USDA-ERS 2011a).

It is important to note that the current NOP regulations do not specify an acceptable threshold level for the 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 Fouce 2006, USDA-AMS 2014). However, certain markets or contracts may have defined thresholds which growers need to attain (Non-GMO-Project 2010).

4.2.3.2 Preferred Alternative: Organic Corn Production

GE corn lines are already in use by farmers. MON 87419 corn should not present any new and different issues and impacts for organic and other specialty corn producers and consumers.

Organic producers employ a variety of measures to manage identity and preserve the integrity of organic production systems (NCAT 2003). The trend in the cultivation of GE corn, non-GE, and organic corn varieties, and the corresponding production systems to maintain varietal integrity, are likely to remain the same as the No Action Alternative.

According to the petition, agronomic trials conducted in a variety of locations in the U.S. demonstrated that MON 87419 corn is not significantly different in agronomic, phenotypic, environmental, and compositional characteristics from its nontransgenic counterpart (Monsanto 2015a). No differences were observed in pollen diameter, weight, and viability. Therefore, MON 87419 corn is expected to present no greater risk of cross-pollination than that of existing corn cultivars. The practices currently employed to preserve and maintain purity of organic production systems would not require changes to accommodate the production of MON 87419 corn.

Historically, organic corn production represents a small percentage (approximately, 0.2 percent) of total U.S. corn acreage (USDA-ERS 2011c). Organic production likely would remain small regardless of whether MON 87419 corn or other new varieties of GE or non-GE corn varieties, become available for commercial corn production. Accordingly, a determination of nonregulated status of MON 87419 corn is not expected to have a significant impact on organic corn production.

4.3 Physical Environment

4.3.1 Soil Quality

4.3.1.1 No Action Alternative: Soil Quality

Under the No Action Alternative, MON 87419 corn would continue to be regulated by USDA. The usage of currently available commercially cultivated corn varieties (both GE and non-GE varieties) is expected to remain the same under the No Action Alternative, as well as land acreage and agronomic practices.

An important aspect of corn production for farmers across the U.S., as discussed throughout this EA, is weed management. While acreage for corn production is not expected to increase, more diverse weed management strategies potentially including more aggressive tillage practices that can affect soil quality may be needed to address the increasing emergence of glyphosate-resistant weeds (Owen and Zelaya 2005c, Harker and O'Donovan 2013, Fernandez-Cornejo and Osteen 2015). The weed management strategies employed by an individual producer would be dependent upon several factors, such as the types of resistant weeds in the given cropping system and economic considerations.

The development of herbicide-resistant weeds is likely to increase in some areas of the U.S. (Livingston, Fernandez-Cornejo et al. 2015). Under the No Action Alternative glyphosate resistant (GR) weeds are expected to continue to be a concern in all corn-growing regions and would require modifications of crop management practices to address these resistant weeds (Owen 2011). These changes may include diversifying application of herbicides with different modes of action, and making adjustments to crop rotation and tillage practices, utilizing integrated weed management strategies (Weirich, Shaw et al. 2011, Harker and O'Donovan 2013, Garrison, Miller et al. 2014, Fernandez-Cornejo and Osteen 2015).

Integrated weed management practices can sustain or improve soil quality through careful management of fertilizers and pesticides; use of cover crops to increase plant diversity and limit the time soil is exposed to wind and rain; crop rotations; and varying tillage practices (USDA-NRCS 2006b). However, if herbicide-resistant weeds become problematic enough where other strategies are not effective, growers will likely have to consider mechanical weed control strategies which may, in turn, potentially impact soil quality (NCGA 2007b, Givens, Shaw et al. 2009a, Sharma and Abrol 2012). For example, growers with glyphosate resistant Kochia in Kansas have become increasingly reliant on tillage to control the weed (Lenz, 2014), and this practice has detrimental effects on soil quality. Similarly, herbicide use may increase in some areas to control herbicide-resistant weeds in different corn production systems (Owen and Zelaya 2005c, Behrens, Mutlu et al. 2007, Vencill, Nichols et al. 2012). In Monsanto's third party

analysis of regional patterns of corn tillage, most areas of the country may show no trends towards reduced conservation tillage during the period in which herbicide resistant weeds were increasing 2007-2013, but the trend in Southeast US corn production was that conventional tillage either was increasing or at least unchanging, while no-till methods, were declining; otherwise, there were no corn production areas where conventional tillage was increasing (Monsanto 2015a).

The total acreage that could be impacted by an increase in tillage would be based on the extent of resistant weeds that occur in corn production systems, and the weed management strategies used by various growers. The particular mix of weed management tactics selected by an individual producer is dependent upon many factors, including the local ecology, the problem weed type, and agronomic management practices required to maximize crop yield. Currently, most corn growing states have between 7 to 26 different species of weeds that are herbicide resistant (Heap 2015).

The herbicides dicamba and glufosinate-ammonium, which are used currently in commercial corn production, are degraded by soil microorganisms, with rates related to environmental conditions (US-EPA 2013b, Zhang, Wang et al. 2014, NPIC N.D.).

Glufosinate is rapidly degraded by soil microbiota to carbon dioxide and natural phosphorus compounds (TOXNET 2015b). The aerobic half-life in soil is typically 3 to 11 days, the anaerobic half-life is 5 to 10 days, and the field dissipation half-life is around 6 to 20 days (average of 13 days) (TOXNET 2015b).

Aerobic degradation of dicamba by soil microbes is the main process by which the herbicide is degraded in the environment, with the formation of 3,6-dichlorosalicylic acid and ultimately carbon dioxide (TOXNET 2015a). The persistence of dicamba in agricultural soils is highly variable and depends on factors such as application rates, moisture content, temperature, pH, and soil type. Typical field dissipation half-lives can vary from 4 to 50 days under aerobic conditions, with 18 days being an approximate median half-life (TOXNET 2015a).

The effects of dicamba on beneficial soil microorganisms have only been studied infrequently, and there is little indication that dicamba has significant adverse effects on soil biota (Martens and Bremner 1993, Tu 1994, USFS 2007). Glufosinate applications may impact soil microbe communities, although the research reports vary (see, e.g., (Bartsch and Tebbe 1989, Gyamfi, Pfeifer et al. 2002, Lupwayi, Harker et al. 2004, Wibawa, Mohamad et al. 2010). For example, Gyamfi et al. (2002) suggest that some of the observed microbial population shifts may be caused by the increase of herbicide-degrading soil microbes following application, because of an increase in populations of microbes that use glufosinate as a source of nitrogen (Bartsch and Tebbe 1989). Other research suggests that glufosinate beneficially inhibits the activity of crop pathogens such as bacterial blight (Pline 1999) and grapevine downy mildew (Kortekamp 2011). Detrimental effects of glufosinate have also been observed. Glutamine synthetase activity in fungi or fungal like organisms can be inhibited, similar to the inhibition of glutamine synthetase in plants (Kortekamp 2011). This effect would only transiently affect populations of soil fungi.
4.3.1.2 Preferred Alternative: Soil Quality

A determination of nonregulated status of MON 87419 corn, soil quality in U.S. corn fields is unlikely to be substantially affected where MON 87419 corn is cultivated. Because MON 87419 corn is compositionally, agronomically and phenotypically equivalent to commercially cultivated corn, and the environmental interactions of MON 87419 are same as or similar to conventional corn (Monsanto 2015a), soil microbial populations and associated biochemical processes in soil are not expected to change with the introduction of MON 87419 corn.

No changes to agronomic practices typically applied in the cultivation of corn, including both commercially available GE corn and conventional varieties, are required for MON 87419 corn. Consequently, crop management practices for MON 87419 corn would be similar to, or the same as, those for other crop production systems using stacked-trait corn varieties.

As discussed above weed management is an important facet of corn production for farmers across the U.S. MON 87419 corn would provide growers with alternatives to currently available GE HR corn varieties, which will increase weed-management options available to growers. These additional options for weed control and flexibility could provide more diverse strategies for growers to control HR weeds (Behrens, Mutlu et al. 2007, Harker and O'Donovan 2013, Garrison, Miller et al. 2014, Livingston, Fernandez-Cornejo et al. 2015).

MON 87419 corn would likely replace other commercially available glyphosate-resistant corn cultivars, because glyphosate resistance will likely be introgressed into this variety via conventional crossing (Monsanto 2015a). Stacked corn varieties reached 76 percent of corn plantings in 2014, and this trend is expected to continue as part of expansion of integrated weed management strategies in U.S. corn production systems (Brookes 2014, CropLife-International 2015, USDA-ERS 2015a). The area and acreage of corn production is not expected to change (Westcott and Hansen 2015) and any potential for impacts on soil quality following a determination of nonregulated status of MON 87419 corn is not likely to change, either.

Weed management practices needed for the production of MON 87419 corn would differ little from those used for other stacked trait GE corn cultivars, apart from the fact that weed management practices under the Preferred Alternative would include the application of glufosinate and dicamba; both herbicides are currently used in corn production systems across the U.S., but the amount of dicamba used per acre may change as noted below.

Dicamba and glufosinate are currently registered and labeled for use as preplant and postemergence herbicides in corn production. Glufosinate is currently labeled for preplant applications on conventional and herbicide-tolerant corn hybrids and for post-emergence applications on glufosinate-tolerant hybrids. Glufosinate use with MON 87419 will not change from currently permitted uses in corn production. Use of these herbicides is regulated by EPA under FIFRA. The EPA will decide to issue a permit for the any new use of dicamba on MON 87419 corn. USDA considers the potential cumulative impacts on soil, in conjunction with EPA's decision, in Chapter 5.

4.3.2 Water Resources

4.3.2.1 No Action Alternative: Water Resources

Under the No Action Alternative current acreage for corn production and agronomic practices, including irrigation, tillage, nutrient management, and use of glufosinate and dicamba on corn crops, would not be expected to significantly change. Consequently, no substantial changes to water quality or use beyond current trends, and normal variation, associated with U.S. corn production would be expected under the No Action Alternative.

Corn is expected to continue to be a major crop in the U.S., with U.S. planted acres to remain steady through 2024/25 at around 88 million acres (Westcott and Hansen 2015). Current agronomic practices associated with corn production that have potential to impact water quality or quantity such as tillage, agricultural inputs, and irrigation, would be expected to remain fairly constant. However, over time, climate change impacts are expected to alter both water supplies and water demands across and within regions. Warming temperatures, changing precipitation patterns, and reduced snowpack are expected to significantly reduce late spring/summer stream flows (flows that historically were available for reservoir storage to meet peak irrigation water demands) and groundwater recharge across much of the West. In addition, higher temperatures are expected to increase crop-water demands in coming years via reduced crop evapotranspiration (ET) efficiency (Schaible and Aillery 2012). Historically, around 7 to 11 percent of corn acreage has been irrigated in the U.S., and this trend would be expected to continue (Schaible and Aillery 2012, NCGA 2014).

Although it is possible that some growers may increase tillage of corn to deal with GR weeds such as Palmer amaranth, there are several reasons why this may not happen. As T. Legleiter notes (Weed scientist, Purdue University) a better solution for no-till growers to preserve benefits of no-till production is to plant several years of continuous corn, because there are multiple POST herbicides available to corn that cannot be used on soybean (Dobberstein 2013). Soybean growers are more likely to resort to tillage to control Palmer amaranth, but even this should be seen as a one-time tactic (J. Norsworthy in (Morrison 2014)).

Fertilizer and pesticide use in corn production has, and will have, the potential to adversely impact water quality. In 2010, fertilizer (primarily nitrogen) was applied to 97 percent of corn acres, and herbicides applied to 98 percent of planted corn, with glyphosate being the most commonly applied herbicide (USDA-NASS 2011). Dicamba use for corn production has increased over the last several years from approximately 1.5 million pounds in 2008, to approximately 1.9 million pounds in 2012 (US-EPA 2015g). Conversely, glufosinate use decreased, from approximately 1.2 million pounds in 2008, to 0.6 million pounds in 2012 (US-EPA 2015g). As discussed under Section 2.2.2, Water Quality, various National and regional efforts are underway to reduce NPS contaminants in agricultural run-off, and run-off itself. These efforts, and others, are expected to continue to mitigate potential impacts of agriculture on water quality (US-EPA 2008e, US-EPA 2015a, US-EPA 20151, USDA-NRCS 2015b, USDA-NRCS 2015c, USDA-NRCS 2015a, USDA 2015b).

4.3.2.2 Preferred Alternative: Water Resources

Determination of nonregulated status for MON 87419 corn would make available to farmers another stacked variety of corn to manage weeds. According to Monsanto, glyphosate tolerance might be introgressed into MON 87419 using classical breeding strategies (Monsanto 2015a). It is therefore expected that dicamba, glufosinate, and glyphosate herbicides will be employed in an integrated weed management program to maximize yield and crop production efficacy.

As discussed in Section 2.1.1, Acreage and Area of Corn Production, herbicide-tolerant corn comprises around 73 percent of all planted corn acreage in the U.S., the majority of which are glyphosate resistant varieties. Because of the compositional similarity of MON 87419 corn to other GE and non-GE varieties (Monsanto 2015a), no significant changes to irrigation, agronomic practices, or total acreage would be expected to occur as a result of approval of the petition, other than use restrictions in application of dicamba to this variety (which will be determined by EPA).

As described under the No Action Alternative, fertilizer and pesticide use, including dicamba and glufosinate on MON 87419 corn, would have the potential to adversely impact water quality. The potential impacts of pesticides on water quality are well understood, and, as discussed above under the No Action Alternative, various National and regional efforts are underway to reduce NPS contaminants in agricultural run-off, and run-off itself. These efforts to mitigate potential impacts of agriculture on water quality would be expected to continue; however, much of the success of these efforts depends on grower practices, adoption of resources conservation measures, in tandem with local weather patterns and soil types.

To the extent that cultivation of MON 87419 corn allows the grower to adopt or expand conservation tillage practices, water quality improvement associated with these practices would be expected to follow. There is evidence that suggests adoption of herbicide-tolerant crops can minimize environmental impacts through reduced herbicide use and increased use of conservation tillage practices. Herbicide resistant crops generally make weed control more effective, and may provide an incentive of lower cost of production to growers (NRC 2010, Fernandez-Cornejo, Hallahan et al. 2012)

Assuming authorization of dicamba use on MON 87419 by the EPA, the anticipated use patterns for dicamba resistant corn will likely vary across U.S. corn growing regions. Usage will be adjusted according to the species of problematic weeds present in given areas, and local environmental conditions. The use of dicamba and glufosinate on MON 87419 corn will be regulated by EPA under FIFRA. The EPA determines the use requirements for these herbicides, which are intended to be protective of water quality and human health. As part of assessing the risk of the exposure of aquatic organisms and the environment to a pesticide, EPA estimates concentrations of pesticides in aquatic environments. The EPA also, as part of the Food Quality Protection Act (FQPA) of 1996, estimates pesticide concentrations in drinking water when it establishes maximum pesticide residues on food (tolerance limits). For both drinking water and aquatic exposure assessments, and for water quality assessments, EPA typically relies on field monitoring data as well as mathematical models to generate exposure estimates.

In light of the above factors, the potential impacts of the Preferred Alternative on water resources, both beneficial and adverse, would be the same as or similar to the No Action Alternative. The Preferred Alternative may lead to adoption of new herbicide-tolerance in a corn variety, MON 87419, and would provide growers with another option to help respond to presence of glyphosate or other herbicide resistant weeds (Behrens, Mutlu et al. 2007, Vencill, Nichols et al. 2012, Brookes 2014, Garrison, Miller et al. 2014, CropLife-International 2015). However, after USDA has determined that a plant is no longer regulated under the provisions of the Plant Protection Act (PPA) or the regulations of 7 CFR Part 340, the USDA does not maintain control over where the crop is grown, or the agronomic practices growers may choose in crop production.

The USDA considers the potential cumulative impacts on water resources in its decision to deregulate MON 87419 corn, in tandem with EPA's pesticide use decision, in Chapter 5.

4.3.3 Air Quality

4.3.3.1 No Action Alternative: Air Quality

Potential impacts to air quality associated with corn cultivation are not expected to be significantly affected by regulation of MON 87419. Air quality would continue to be affected, along current trends, by agronomic practices associated with corn production such as tillage practices, pesticide applications (i.e., drift and diffusion), crop residue burning, use of equipment burning fossil fuels, and nitrous oxide emissions from the use of nitrogen fertilizer.

Tillage not only is associated with increased emissions due to burning of fossil fuels but also results in the release of particulate matter into the air (Madden, Southard et al. 2009). By generating fewer suspended particulates (dust), reduced tillage also potentially contributes to lower rates of soil wind erosion, thus benefitting air quality (Towery and Werblow 2010). Although this impact is variable and is affected by factors such as soil moisture and specific tillage regime employed, this observation demonstrates the role of conservation tillage in reducing particulate matter. Reduced tillage also minimizes burning of fossil fuels and the production of airborne particulates, both of which are major aspects of agricultural practices that affect air quality.

Prescribed burning is a land treatment, used under controlled conditions, to accomplish resource management objectives. Open combustion produces particles of widely ranging size, depending to some extent on the rate of energy release of the fire (US-EPA 2011a). The extent to which agricultural and other prescribed burning may occur is regulated by individual State Implementation Plans to achieve compliance with the National Ambient Air Quality Standards.

Volatilization of fertilizers, herbicides, and pesticides from soil and plant surfaces also introduces these chemicals to the air. The USDA Agricultural Research Service (ARS) is conducting a long-term study to identify factors that affect pesticide levels in the Chesapeake Bay Region airshed (USDA-ARS 2011). This study has determined volatilization is highly dependent on exposure of disturbed unconsolidated soils, and variability in measured compound levels is correlated with temperature and wind conditions. Another ARS study of volatilization of certain herbicides after application to fields has found moisture in dew and soils in higher temperature regimes significantly increases volatilization rates (USDA-ARS 2011).

Pesticide and herbicide spraying may impact air quality through both drift and diffusion. Pesticides are typically applied to crops by ground spray equipment or aircraft. Small, lightweight droplets are produced by equipment nozzles; many droplets are small enough to remain suspended in air for long periods allowing them to be moved by air currents until they adhere to a surface or drop to the ground. The amount of drift varies widely and is influenced by a range of factors, including weather conditions, topography, the crop or area being sprayed, application equipment and methods, and practices followed by the applicator.

In some areas of the South, multi-herbicide-resistant Palmer amaranth has forced growers to include or intensify tillage (Price, Balkcom et al. 2011), which can indirectly affect air quality as particulate matter can increase with more aggressive tillage practices. More aggressive tillage practices can also use more fossil fuels than conservation tillage methods. The benefits of no-till or conservation tillage may be reduced in areas where growers employ more aggressive tillage to control the increasing resistance of weeds to herbicides.

4.3.3.2 Preferred Alternative: Air Quality

Under the Preferred Alternative grower agronomic practices would not be significantly affected, nor would the associated potential impacts on air quality. To the extent that cultivation of MON 87419 corn allows the grower to adopt or expand conservation tillage practices, air quality improvements associated with these practices would be expected to follow. Evidence suggests that the adoption of HT crops has facilitated the use of conservation tillage systems, largely because HT seeds tends to make weed control more effective, and less costly (Fernandez-Cornejo, Hallahan et al. 2012). Conservation tillage, to include no-till practices, contributes lower volumes of soil PM into the atmosphere, and reduces equipment emissions due to decreased usage of internal combustion engines, as compared to conventional tillage practices.

The commercial use of dicamba and glufosinate would be expected to increase, relative to the adoption of the MON 87419 corn. As described above, glufosinate is labeled for use on corn, and dicamba use will be determined by EPA in a forthcoming decision. Use of these herbicides and potential environmental impacts through drift and volatilization, would not be expected to be significantly different under the Preferred Alternative. Considering the above factors, determination of nonregulated status for MON 87419 corn would have no more potential for adverse impacts on air quality than the No Action Alternative.

The USDA considers the potential impacts on water resources as a cumulative impact of EPA's decision to permit any new use of dicamba, in Chapter 5.

4.3.4 Climate Change

4.3.4.1 No Action Alternative: Climate Change

The decision to deny the petition would not alter agricultural practices and GHG emissions associated with corn production. Consequently, potential impacts on climate change would

remain unchanged, as would the potential impacts of climate change on corn production. The primary GHGs emitted by corn producing operations have been and are likely to remain N₂O, CO₂, and PM. Corn crop production primarily affects climate-changing emissions through: (1) fossil fuel burning equipment producing CO₂; and, (2) cropping production practices including fertilizer application, and residue burn management, and tillage producing N₂O and PM.

Some of the changes in climate can be favorable to corn production, others are not. The general increase in the expansion of weeds and pests into new ranges in response to changes in climate is expected to continue, requiring adaptive responses among farmers to mitigate the potentially adverse impacts of new weeds and pests on crop yields and production costs (Backlund, Janetos et al. 2008, IPCC 2014). Severe weather events, such as floods, droughts, and extreme heat – all predicted to become more frequent and intense, can present substantial challenges to corn growers, and impact retail prices. For instance, the 2012 drought destroyed or damaged portions of the major field crops in the Midwest, particularly field corn and soybeans, which led to increases in the farm prices of corn (USDA-ERS 2013b).

Climate change may have a positive impact on agriculture in general. The Intergovernmental Panel on Climate Change (IPCC) predicts that potential climate change in North America may result in an increase in crop yield by 5-20 percent during the current century (Field, Mortsch et al. 2007a). However, the extent of positive effects on agriculture from climate change is speculative and will not be observed in all growing regions. The IPCC report indicates for example that certain regions of the U.S. will be impacted negatively by a significant decline in available water resources. Nevertheless, overall, North American production is expected to adapt to climate change impacts with improved cultivars and responsive farm management practices (Field, Mortsch et al. 2007a).

The impacts of climate change, both favorable and adverse, are, albeit it arguably, becoming apparent in Corn Belt states. Greater precipitation during the growing season in Iowa has been associated with increased yields; however, excessive precipitation early in the growing season has also adversely affected crop productivity. Consequently, farmers have planted corn earlier to take advantage of the longer growing season, and installed more subsurface tiles to expedite draining of excess soil water (Rogovska and Cruse 2011). Increased soil erosion rates as result heavy rain events have required many farmers to adopt additional conservation practices to improve soil and water quality (Kucharik 2008, Rogovska and Cruse 2011).

Increases in the range and diversity of herbicide-resistant weeds, discussed above, may require increased tillage for control. This could potentially release CO_2 sequestered in upper soil layers; however, the particular weed management methods employed by individual farmers would be dependent on many factors unique to the individual farm, including local ecology, the particular problem weed type(s), and on-farm economics (e.g., no-till, conventional tillage, conservation tillage). Consequently, there is significant uncertainty associated with this consideration.

It can be reasonably assumed that as the trending effects of a warming climate continue to manifest in U.S. corn growing regions, growers will continue to adapt agronomic practices to maintain yield and net returns in production of corn. However, fundamentally, climate extremes, not climate averages, more frequently control the productivity and yield of corn crops, and

extreme events, when they occur, will likely present unforeseen challenges to growers, as well as markets for corn and corn products.

4.3.4.2 Preferred Alternative: Climate Change

As described previously, MON 87419 corn is similar to other GE and non-GE corn cultivars in terms of growth habit, agronomic properties, composition, and environmental interactions (Monsanto 2015a). Consequently, the agronomic practices required to cultivate MON 87419 corn would be not be significantly different than those currently used to produce other herbicide-tolerant corn cultivars. The range of U.S. corn production is not likely to expand or diminish as a consequence of approval of the petition, through 2024/25 (Westcott and Hansen 2015). As such, no changes to corn production or agricultural practices that could significantly affect GHG emissions would be expected for a determination of nonregulated status for MON 87419 corn.

As discussed under the No Action Alternative above, more aggressive weed management strategies, which could potentially affect GHG emissions, may be needed in some areas to address an increasing emergence of glyphosate-resistant weeds. To the extent that cultivation of MON 87419 corn, a stacked-trait crop, allows a grower to continue conservation tillage practices for weed control (Franzluebbers 2005, Fernandez-Cornejo, Hallahan et al. 2012), there will be no trend towards increased N₂O and PM emissions. Under some conditions, the adoption of conservation tillage can also increase soil carbon sequestration potential on certain croplands (US-EPA 2011b). Conservation tillage practices will also reduce the use of fossil fuel and with that the associated emissions from equipment normally used in tilling, relative to conventional tillage practices.

Because MON 87419 corn is similar to other GE and conventional corn varieties, and nonregulated status would not significantly alter agronomic practices in corn production, increases in GHG emissions associated with production of MON 87419 corn would not be expected. Climate change impacts on the production of MON 87419 corn would be expected to be the same as under the No Action Alternative.

4.4 Biological Resources

4.4.1 Animal Communities

4.4.1.1 No Action Alternative: Animal Communities

Under the No Action Alternative, conventional and GE corn production will continue as currently practiced while MON 87419 corn remains a regulated article. Cultivation of other GE and non-GE corn varieties will continue, following the trends as noted in Section 2.1.2. Potential impacts of GE and non-GE corn production practices on non-target terrestrial (insect, bird, and mammal) and aquatic (fish, benthic invertebrate, and herptile) species would be unchanged.

The widespread use of conservation tillage and no-till practices associated with the use of herbicides for weed control especially in association with the planting varieties (Dill et al., 2008; Givens et al., 2009) has benefitted wildlife through improved water quality, availability of waste grain, retention of cover in fields, and increased populations of invertebrates (Brady, 2007;

Sharpe, 2010). Conservation tillage practices that leave greater amounts of crop residue serve to increase the diversity and density of birds and mammals (USDA-NRCS, 1999a). Increased residue also provides habitat for insects and other arthropods, consequently increasing this food source for insect predators. Insects are important during the spring and summer brood rearing season for many upland game birds and other birds because they provide a protein-rich diet to fast-growing young, as well as a nutrient-rich diet for migratory birds (USDA-NRCS, 2003).

Corn production practices can affect terrestrial and aquatic species directly or indirectly. Practices such as tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment can result in run-off, increased soil turbidity, decreased soluble oxygen or habitat destruction. The continued emergence of GR weeds will likely require modifications of crop management practices to address these weeds. Herbicide use may increase to meet the need for additional integrated weed management tactics to mitigate herbicide-resistant weeds in different cropping systems (Culpepper, 2008; Owen & Zelaya, 2005; Owen, 2008). Some of these adjustments may impact the adoption of conservation tillage practices.

Under the No Action Alternative, if tillage rates continue to increase as a means of weed suppression, increased soil erosion and indirect adverse impacts on wildlife are expected. Likewise if chemical inputs change, differences in impacts on wildlife may potentially occur. If cover cropping becomes more commonplace, this practice is expected to have beneficial impacts on wildlife by providing habitat and food. More diverse weed management tactics that can affect animal communities may be needed to address the increasing emergence of glyphosate-resistant and other herbicide-resistant weeds, potentially including more aggressive tillage practices (Beckie 2006, Owen, Young et al. 2011). As discussed above, more intensive tillage can reduce wildlife habitat and contribute to increased sedimentation and pollutants in runoff to nearby surface waters, affecting water quality that could impact wildlife. The particular mix of weed management tactics selected by an individual producer would be dependent upon many factors, including the agroecological setting, the problem weed type, and agronomic and socioeconomic factors important to farmers (Beckie 2006). As these management practices may have both beneficial and adverse effects on biological resources, their impacts on biological resources under the No Action Alternative are unknown.

Invertebrate communities in cornfields represent a diverse assemblage of feeding strategies including predators, crop-feeders, saprophages, parasites, and polyphages (Stevenson et al., 2002). Numerous insects and related arthropods perform valuable functions; they pollinate plants, contribute to the decay and processing of organic matter, reduce weed seed populations through predation, cycle soil nutrients, and attack other insects and mites that are considered to be pests. Although many arthropods in agricultural settings are considered pests, such as the European corn borer (*Ostrinia nubilalis*) and the corn rootworm (*Diabrotica* spp.) (Willson & Eisley, 2001), there are many beneficial arthropods which are natural enemies of both weeds and insect pests (Landis et al., 2005). Some of these beneficial species include the convergent lady beetle (*Hippodamia convergens*), carabid beetles, the caterpillar parasitoids (e.g., *Meteorus communis* and *Glyptapanteles militaris*), and the predatory mite (*Phytoseiulus persimilis*) (Shelton, 2011). Earthworms, termites, ants, beetles, and millipedes contribute to the decay of organic matter and the cycling of soil nutrients (Ruiz et al., 2008). Some high-profile or representative invertebrate species, such as honey bees, earthworms, and butterflies, are

generally studied more thoroughly than others. Insects and other invertebrates can be beneficial to corn production, providing services such as nutrient cycling and preying on plant pests. Insect injury can impact yield, plant maturity, and seed quality.

Common agricultural practices are designed to simplify the agricultural landscape, with the result that beneficial arthropods may be adversely affected (Landis et al., 2005). Intensively cultivated lands, such as those used in corn production, provide less suitable habitat for wildlife use than that found in fallow fields or adjacent natural areas. Consequently, the types and numbers of animal species found in cornfields are less diverse by comparison.

Aquatic ecosystems potentially impacted by agricultural activities include water bodies adjacent to or downstream from crop field, including impounded bodies, such as ponds, lakes, and reservoirs, and flowing waterways, such as streams or rivers. If near coastal areas, aquatic habitats affected by agricultural production may also include marine ecosystems and estuaries. Aquatic species that may be exposed to sediment from soil erosion and, nutrients and pesticides from runoff and atmospheric deposition include freshwater and estuarine/marine fish and invertebrates, and freshwater amphibians. Although some ecological research has shown that farming practices can be detrimental to stream health (Genito et al., 2002), recently some research suggests that agricultural lands may support diverse and compositionally different aquatic invertebrate communities when compared to nearby urbanized areas (Lenat & Crawford, 1994; Stepenuck et al., 2002; Wang et al., 2000).

Under the No Action Alternative, conventional corn production would continue while MON 87419 corn remains a regulated article. Potential impacts to animal communities associated with corn cultivation are not expected to change in the No Action Alternative.

4.4.1.2 Preferred Alternative: Animal Communities

Under the Preferred Alternative, the direct and indirect effects of approving these three petitions would be similar to the effects on animals under the No Action Alternative. Animals would continue to feed on corn in the field. MON 87419 corn is compositionally similar to other commercially available corn varieties. As discussed in Environmental Consequences, Animal Feed section, the PAT proteins and those expressed by other herbicide resistance genes are found in commercial varieties of corn, cotton, and soybeans. Organisms that feed on these crops are exposed to these proteins in previously deregulated varieties with no documented adverse effects. Under the Preferred Alternative, potential impacts to animal communities are not anticipated to be substantially different compared to the No Action Alternative.

Impacts to animal communities could potentially arise from changes in any agronomic inputs associated with the crop modification or with constitutive changes in the crop itself. As described in Section 4.2, Monsanto has presented the results of field trials which demonstrate that MON 87419 corn is agronomically and compositionally equivalent to other corn varieties currently in commercial production and does not require any changes to agronomic practices such as cultivation, crop rotation, irrigation, tillage, or agricultural inputs when compared with conventional corn (Monsanto 2015a). Land use and agricultural production of corn under the Preferred Alternative is likely to continue as currently practiced. Consequently, any impact to

animal communities as a result of corn production practices under the Preferred Alternative is likely to be similar to the No Action Alternative.

As described in the No Action Alternative, animals can also be impacted indirectly by agricultural practices, such as tillage. Adopting the Preferred Alternative will not result in any changes in agricultural practices. Growers will continue to use herbicides and cultural practices to manage weeds. Increases in tillage to control weeds can increase soil erosion and the indirect impacts on wildlife. An additional trait for herbicide control of weeds that could help avoid additional tillage may thus be beneficial to animal resources. The availability of additional herbicide resistance traits in corn may also allow use of additional herbicides needed for flexible approaches to management of all weeds in a typical weed complex found on farms. Agricultural production of corn and soybean would use EPA-registered pesticides, including glyphosate, glufosinate, and dicamba, for weed management. The environmental risks of pesticide use on wildlife and wildlife habitat are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. Under the Preferred Alternative, potential impacts to animal communities are not anticipated to be substantially different compared to the No Action Alternative. Potential impacts to animal communities may arise from any changes to agronomic inputs associated with the crop modification and direct exposure to the GE crop and its products; MON 87419 will not require any changes to current corn production methods.

Based on the above, the impacts of determining nonregulated status for MON 87419 corn to animal communities would be similar to those of the No Action Alternative.

4.4.2 Plant Communities

4.4.2.1 No Action Alternative: Plant Communities

Corn is grown in a wide range of locations and environments. Surrounding plant communities vary dependent upon geographic location as noted in Section 2.3.2 Plant Communities, and include other crops, those found in borders, hedgerows, windbreaks, pastures, or other adjacent natural vegetation. Growers control weeds within fields using a range of practices and products to reduce interference with optimal crop growth and development. When growers are cognizant of the presence of resistant weeds, they may also take steps to reduce the evolution of herbicide resistant weeds and avert future more serious problems (Norsworthy, Ward et al. 2012). As discussed in Section 2.3.2, Plant Communities, several weed species resistant to herbicides used with herbicide resistant crops have been identified, particularly to glyphosate; however, far more species are resistant to other herbicides that are not associated with a specifically modified resistant crop (Heap 2014).

As discussed in Subsection 2.3.2, Plant Communities, there are no species sexually compatible with corn within the continental U.S., its territories, or possessions; therefore, APHIS has concluded there is no significant risk of gene flow between cultivated corn and its weedy relatives that may impact plant communities (USDA-APHIS 2015a).

Under the No Action Alternative, conventional corn production would continue while MON 87419 corn remains a regulated article. Potential impacts to plant communities associated with corn production are not expected to change in the No Action Alternative.

Dicamba is currently used to control weeds in corn production systems that have not been genetically modified for resistance to dicamba. In addition to corn, dicamba is approved for use (Appendix A) in asparagus, cotton, grass seed production, pasture and rangeland grasses, small cereals including barley, oats, rye, and wheat, sorghum, soybean, and sugarcane. GE glufosinate-ammonium resistant corn, canola, cotton, soybean, and sugar beet have been granted nonregulated status (USDA-APHIS 2015b). As cited in Monsanto data (Table 15), approximately 13.9 percent of U.S. corn fields were sprayed with dicamba, and 1.2 percent of corn fields were sprayed with glufosinate-ammonium (Monsanto 2015a).

4.4.2.2 Preferred Alternative: Plant Communities

Land use allocation and agricultural production of corn under the Preferred Alternative is likely to continue as currently practiced. Consequently, any potential impact to other vegetation in corn and the landscapes surrounding cornfields from approving a determination of nonregulated status to MON 87419 corn is not expected to differ from the No Action Alternative.

MON 87419 corn is not expected to impact plant communities adjacent to or within agroecosystems differently from currently available corn cultivars. MON 87419 corn has been shown to be compositionally, agronomically, and phenotypically equivalent to commercially cultivated corn (Monsanto 2015a). Within corn fields, growers control directly competing weeds and also weeds that may be pest and disease reservoirs using various chemical, mechanical and cultural control methods. MON 87419 corn allows growers use glufosinate pre- and post-emergence to control weeds. The use of glufosinate will remain the same for this product as for other glufosinate resistant corn varieties. Should EPA grant a permit for new dicamba use for MON 87419 corn, Monsanto's petition requests EPA to increase the maximum rate of dicamba use in corn for preemergence and postemergence applications to 2.0 lbs. a.e. dicamba per acre per year from 1.5 lbs. (Monsanto 2015a).

Potential impacts related to gene flow and weed resistance to dicamba and glufosinate were discussed in Section 2.3.2, Plant Communities. Two weed species have been identified which are resistant to dicamba, most significantly dicamba resistant ragweed in Nebraska, which is a significant corn producing region (Heap 2015). Dicamba-resistant ragweed was also identified in North Dakota, Colorado and Kansas, which also produce corn (NCGA 2014, Heap 2015). Dicamba resistant prickly lettuce and ragweed have also been identified in Washington and Montana, respectively, which are not significant corn producing states (NCGA 2014, Heap 2015). Glufosinate resistant Italian ryegrass has been identified in Oregon, which does not produce significant amounts of corn (NCGA 2014, Heap 2015). In terms of herbicide resistant weeds, dicamba and glufosinate resistant weeds account for a very small portion of the herbicide resistant weeds that have been identified. Additionally, given that MON 87419 corn combines resistance to multiple modes of herbicide action, and will likely be subsequently bred by Monsanto to have resistance to additional herbicides, the evolution of herbicide resistance will be

less likely when multiple herbicides are applied for corn production (Norsworthy, Ward et al. 2012).

Corn generally does not survive until the following spring in those regions where freezing temperatures are reached in the winter; however, corn seeds which are incorporated in the soil during either harvest or fall tillage may overwinter and grow the following spring (Stewart 2011). Volunteer corn which has emerged from this overwintered seed requires control with tillage or with an application of different herbicides. Numerous choices for control of herbicide resistant corn are available and unwanted MON 87419 corn can be easily eliminated (Stahl, Potter et al. 2013).

4.4.3 Microorganisms

4.4.3.1 No Action Alternative: Microorganisms

Under the No Action Alternative, increases in tillage may occur and have an adverse impact on the microbial community, as noted in the Environmental Consequences section.

Changes in agricultural practices and inputs and natural variations in season, weather, plant development stage, geographic location, soil type, and plant species or cultivar can all impact the microbial community (Kowalchuk et al., 2003; US-EPA, 2009c). Indirect impacts may result from changes in the composition of root exudates, plant litter, or agricultural practices (Kowalchuk et al., 2003; US-EPA, 2009c). Several investigations into the possible impacts of GE plants on soil communities of microbes found that either minor or no detectable effects on distinctive microbial traits of constituent non-target microorganisms (Hart, 2006; Kowalchuk et al., 2003; US-EPA, 2009b).

4.4.3.2 Preferred Alternative

The potential effects on soil quality of choosing the Preferred Alternative are no different than the effects under the No Action Alternative. Soil microorganisms are affected by agricultural management practices, as described in the No Action analysis on soil microorganisms (Section 4.1.8). One factor that drives a grower's selection of agricultural practices is weed management. Another is the trend toward increased herbicide use to control HR weeds in different cropping systems (Owen and Zelaya 2005a, Culpepper 2008, Owen 2008, Heap 2014) and they will be similar under the No Action and the Preferred Alternative. Dicamba and glufosinate can be degraded by soil bacteria (Dumitru, Jiang et al. 2009) and as with other herbicides, soil bacteria can be affected by herbicides sometimes by changes in biodiversity of soil bacteria (Jacobsen and Hjelmsø 2014). Also note the previous discussion of microorganisms in Section 4.3 Physical Environment (4.3.1 Soil Quality). Because herbicides and crop production generally can impact soils, but not necessarily with long term consequences (Jacobsen and Hjelmsø 2014), the No Action and Preferred Alternatives will likely be similar in quality and quantity of impacts to microorganisms.

4.4.4 Biodiversity

4.4.4.1 No Action Alternative: Biodiversity

Biological diversity, or the variation in species or life forms and their communities in an area, is highly managed in agricultural systems through chemical and non-chemical methods to maximize output. Biological diversity in agricultural systems (the agro-ecosystem) are lower than in the surrounding habitats because minimizing competition improves crop productivity. To maximize crop yield and profit potential, varieties that are well-adapted to a particular local environment are grown to satisfy a specific market demand. While preserving biodiversity may not profit a grower, growers do recognize that they are custodians of their agro-environment and that such a goal is coincident with the larger interest of sustainable farming (SARE 2012); these issues may be subsumed under what may be termed the "whole-farm approach." Sustainability goals of growers are meant to preserve environmental, economic and social resources for future generations, and are actively supported by a variety of US government and federally supported programs (US-EPA 2012a, USDA-NAL 2015).

Under the No Action Alternative, MON 87419 corn would continue to be a regulated article. Growers and other parties who are involved in production, handling, processing, or consumption of corn would continue to have access to conventional corn varieties, including GE corn varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. Agronomic practices associated with conventional corn production (both GE and non-GE) such as cultivation, irrigation, pesticide application, fertilizer applications and agriculture equipment are expected to continue unchanged. Animal and plant species that typically inhabit or are associated with corn fields will continue to be affected by commonly used management plans and systems, which include the use of mechanical, cultural, and chemical pest control methods.

Impacts to biodiversity associated with agronomic practices in cultivating corn are not expected to change under the No Action Alternative.

4.4.4.2 Preferred Alternative: Biodiversity

Through comparative field trial studies, Monsanto demonstrated that MON 87419 corn is phenotypically and agronomically similar to non-transgenic conventional corn varieties, with the exception of dicamba and glufosinate-ammonium tolerance traits (Monsanto 2015a). Monsanto has presented compositional data comparing the phenotypic, morphological and compositional characteristics of MON 87419 corn with other varieties, including bioinformatics analysis of allergenicity, toxicity, nutrients and anti-nutrients, and amino acid homology, among others (Monsanto 2015a) and no significant differences were demonstrated other than that of grain manganese content, but this value was still within the range of other corn varieties cataloged by ILSI-CCDB.

The quantity and type of herbicide use associated with conventional and GE crops depends on many variables, including cropping systems, type and abundance of weeds, production practices, and individual grower decisions. The intensity of tillage practices and herbicide use determines the amount and type of weed species present (Carpenter 2011b). Conservation or no-till practices

will likely remain the same or increase given the use of dicamba and glufosinate-ammonium to control weeds with this product. Therefore, use of MON 87419 corn in conjunction with reduced tillage practices may provide stability to biodiversity, especially in fields where tillage was used previously to control glyphosate resistant weeds. Dicamba and glufosinate-ammonium use may therefore decrease weed prevalence or modify the weed species complex in some regions. These changes could modify the species complex of organisms that rely on these weeds as a food source or habitat. A shift in weed species can affect insects, birds, and mammals that use these weeds. These potential impacts are not different from those found under the No Action Alternative because the same herbicides and similar production methods will be used under both.

As described in the No Action Alternative, agricultural practices can affect biodiversity in and around agricultural fields to maximize crop yield. Growers have the opportunity to choose many different practices to manage their operations. Both tillage and herbicide use patterns influence biodiversity. The use of MON 87419 corn is likely to provide stability to biodiversity, in fields where tillage is used currently to control glyphosate resistant weeds and in those relying on herbicide resistant corn; only marginal changes in weed composition after MON 87419 corn adoption are likely, with increased suppression of some problem species. However, it is important to note that many management choices apart from varietal selection and herbicide use affect farm level biodiversity, making the magnitude of any possible impact on biodiversity uncertain. Based on the above information, APHIS has determined that approval of a petition for nonregulated status of MON 87419 corn would likely have the same impact on biodiversity as the No Action Alternative.

4.5 Human Health

4.5.1 Consumer Health

4.5.1.1 No Action Alternative: Consumer Health

Under the No Action Alternative, MON 87419 corn would continue to be regulated by USDA. The production of other GE and non-GE crop varieties used in commerce would continue at same or similar quantities as presently, and consumers may continue to consume GE and non-GE corn approved for commercial use by the FDA and USDA. Denial of the petition would result in no change in consumption of GE and non-GE corn, and would have no effect on trends in pesticide usage on corn crops. Consequently, no adverse effects on human health would be expected implementing the No Action Alternative.

The EPA completed the reregistration process for dicamba and a Registration Eligibility Decision (RED) was issued in 2006. It was subsequently amended in 2008 and 2009 (US-EPA 2009b). The EPA assessed the safety of using glufosinate (as an active ingredient) to control broadleaf weeds in a 2008 risk assessment (US-EPA 2008d). EPA's human health and ecological risk assessments for the registration review of glufosinate is currently underway [Federal Register Volume 78, Number 44 (Wednesday, March 6, 2013)]. Both pesticides, when used as required by label specifications, have been determined to present negligible health risk to humans.

4.5.1.2 Preferred Alternative: Consumer Health

On May 22, 2015, Monsanto submitted a food and feed safety and nutritional assessment to the FDA to initiate a consultation on the food and feed safety and compositional analysis of MON 87419 corn. Monsanto has not yet received a completed consultation letter from the FDA.

DMO and PAT proteins

Determination of nonregulated status for MON 87419 corn would make this variety available to the commercial market where it may be used for food and feed purposes. As summarized in Section 2.4 – Human Health, the DMO and PAT proteins (both naturally occurring in the environment) expressed in MON 87419 corn have been previously reviewed and approved for commercial use by the FDA and USDA, and have a history of safe use in several commercially available soybean, canola, cotton, and corn products. Prior agency reviews of the DMO and PAT proteins, based on research from scientific literature, concluded that consumption of the PAT and DMO proteins pose negligible risk to human or animal health (US-FDA 2011, US-FDA 2013b, US-FDA 2013a, US-FDA 2013c, US-FDA 2014, USDA-APHIS 2014f, USDA-APHIS 2014g).

The safety of the PAT protein has been assessed following reviews involving various countries for more than 38 biotechnology derived products in eight different species (US-FDA 2011, US-FDA 2013b, US-FDA 2013a, US-FDA 2013c, US-FDA 2014, USDA-APHIS 2014f, USDA-APHIS 2014g). Since its first use in 1995, there have been no documented reports of adverse effects of PAT-containing crop products on human health, livestock, or the environment. The safety of DMO has also been reviewed (e.g., (FSANZ 2013, Health-CA 2015)). No potential public health risks have been identified in the assessments of DMO and PAT.

Monsanto provided the USDA and FDA with information on the identity, function, and characterization of the genes for MON 87419 corn, which contains a demethylase gene from *Stenotrophomonas maltophilia* that expresses a dicamba monooxygenase (DMO) protein to confer tolerance to dicamba herbicide, and the phosphinothricin N-acetyltransferase (pat) gene from *Streptomyces viridochromogenes* that expresses the PAT protein to confer tolerance to glufosinate herbicide (Monsanto 2015a).

On May 22, 2015, Monsanto submitted a feed safety and nutritional assessment to the FDA to initiate a consultation on the food and feed safety and compositional analysis of MON 87419 corn. Monsanto has not yet received a completed consultation letter from the FDA. The DMO and PAT proteins in MON 87419 have a history of safe use in several commercially available soybean, canola, cotton, and corn products that have been previously reviewed by the FDA and USDA, and approved for commercial use. These prior reviews of the DMO and PAT proteins have concluded that their consumption poses no risk to human and animal health (US-FDA 2011, US-FDA 2013b, US-FDA 2013a, US-FDA 2013c, US-FDA 2014). Both dicamba and glufosinate may be used on MON 87419 corn during production.

Nutritional Value

Safety assessments of GE crops use a comparative safety assessment in which the composition of the biotechnology-derived plant is compared to the appropriate conventional plant that has a history of safe use. For corn, assessments are performed using the principles outlined per process

Codex Alimentarius 2009 guidance and OECD consensus document for corn composition (FAO 2009). Compositional analysis was conducted on grain and forage of MON 87419 treated with dicamba and glufosinate and a conventional control grown at five sites in the U.S. during 2013, which confirmed the compositional equivalence of MON 87419 corn to is conventional counterparts (Monsanto 2015a). Consequently, the nutritional value of MON 87419 corn would not be significantly different than conventional corn varieties, and pose no potential public health concerns.

Pesticides

As discussed in Section 2.4 – Human Health, pesticides may pose risks to human and animal health when improperly used. Consumers of any food product grown with pesticides may become exposed to residual levels of pesticides on the food, or in processed food products. One future action considered is that EPA will approve the proposed new uses of dicamba on MON 87419 corn. The risks of pesticides to human health are assessed by the EPA through the pesticide registration and reevaluation process under FIFRA. The EPA protects consumer health by setting tolerance limits (maximum residue levels) for each pesticide that may be found on or in foods for human consumption or animal feed. Before registering and establishing a pesticide tolerance the 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. Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. The USDA enforces tolerance limits established for meat, poultry and some egg products, while the FDA enforces tolerances established for other foods.

The EPA Registration Eligibility Decision (RED) for dicamba was issued in 2006, and amended in 2008 and 2009 (US-EPA 2009b). The EPA assessed the safety of glufosinate (as an active ingredient) in a 2003, in support of registration review (US-EPA 2003). The EPA performed a second human health risk assessment for registration of glufosinate in 2012 (US-EPA 2008d, US-EPA 2008b, US-EPA 2013e). Dicamba and glufosinate currently have established tolerance limits for field corn for forage, grain, and stover. The dicamba tolerance levels established for field corn forge, grain, and stover are 3.0, 0.1, and 3.0 parts per million (ppm), respectively (40 CFR § 180.227 - Dicamba; tolerances for residues). Those for glufosinate are 4.0, 0.2, and 6.0 ppm, respectively (40 CFR §180.473 - Glufosinate ammonium; tolerances for residues 4.0, 0.2, 6.0 ppm). These tolerance limits are expected to be protective of human health. Any potential adverse health effects from exposure to pesticide residues associated with corn are also minimized by FDA residue monitoring.

Considering the historic safety of DMO and PAT, compositional equivalence of MON 87419 corn, as well as regulated use of glufosinate and dicamba intended to be protective of consumers, approval of the petition for MON 87419 corn and combination with other traits such as the nearly ubiquitous glyphosate resistance trait, is no more likely to pose a public health risk than conventional corn, or other GE corn varieties currently in commerce. Consequently, USDA finds that approval of a petition for nonregulated status of MON 87419 corn would have no more potential impacts on human health than would the No Action alternative.

4.5.2 Worker Safety

4.5.2.1 No Action Alternative: Worker Safety

Under the No Action Alternative, farm and food production workers would continue to be exposed to the same types and amounts of hazards as they currently experience in corn production and food processing. Denial of the petition would have no effect on worker safety. As described above, and in Section 2.4, current EPA-approved labels for dicamba and glufosinate include precautions and measures to protect worker health. When used consistent with the label, these pesticides present minimal risk to worker health and safety.

4.5.2.2 Preferred Alternative: Worker Safety

Under the Preferred Alternative, there will be no significant changes in agronomic or food production practices in order to produce food and feed from MON 87419 corn. Consequently, impacts to workers occurring through the various management practices that are used to grow corn would be the same as, or similar to, those under the No Action Alternative.

The most common hazards for workers are those associated with operation of machinery and vehicles, although pesticide application, as a potential route of exposure for farm workers, is also a concern. Workers engaged in production of MON 87419 corn may be exposed to insecticides, herbicides (to include dicamba and glufosinate), fungicides, or fertilizers that may pose health or safety risks, unless used in accordance with the U.S. EPA requirements in the Worker Protection Standard (WPS) (40 CFR Part 170), and FIFRA pesticide registration and label requirements (US-EPA 2015d), which serve to protect workers from the hazards of chemical exposure.

Under the Preferred Alternative management practices are expected to remain virtually the same as under the No Action Alternative. As dicamba and glufosinate are currently labelled for use in corn (US-EPA 2015j, US-EPA 2015i), the introduction of MON 87419 is not expected to have adverse impacts on current agronomic, cultivation, and management practices for corn, with the exception that dicamba usage may somewhat vary, tillage may be less frequent, and farm equipment may be used less often. The decision to approve the petition for MON 87419 corn does not in and of itself authorize use of glufosinate, or change in use of dicamba. However, these pesticides will be used with MON 87419 corn, as specified by EPA permit requirements and approved labels.

Pesticide applicators are required to use pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. Worker safety precautions and use restrictions are clearly noted on pesticide registration labels. The current labels for both dicamba and glufosinate include label use restrictions intended to protect humans, including protective equipment to be worn during mixing, loading, applications and handling, equipment specifications to control pesticide application, and reentry periods establishing a safe duration between pesticide application and exposure to the pesticide in the field (US-EPA 2015h).

Monsanto will petition EPA to increase the maximum use rate of dicamba in corn from 0.5 lbs. to 1.0 lbs. per acre (active ingredient) for pre-emergence applications and up to two applications of 0.5 lbs. of dicamba per acre (active ingredient) for post-emergence applications. The

combined maximum annual application rate of dicamba on MON 87419 would be 2.0 lbs. Dicamba per acre per year (active ingredient). EPA will determine the dicamba use requirements for MON 87419 corn. Used in accordance with the EAP approved label, it is reasonably expected that dicamba will not present a risk to human health. The proposed changes to the EPA agricultural WPS are expected to further increase protections from pesticide exposure for agricultural workers and their families (US-EPA 2015b).

4.6 Animal Feed

4.6.1.1 No Action Alternative: Animal Feed

Under the No Action Alternative, there would be no impact on animal feed. Corn forage, silage, grain, and refined corn feed products from currently cultivated GE herbicide-tolerant and conventional corn varieties would continue to be used for animal feed as a primary feed source.

As described in Section 2.5, Animal Feed, corn comprises around 95 percent of the total feed grain produced in the U.S., consumed primarily by cattle, poultry, and swine. Herbicide tolerant corn comprised around 89 percent of U.S. corn acreage in 2014 (USDA-NASS 2014a, USDA-ERS 2015b), and this trend would be expected to continue. Livestock producers in many parts of the world, including the U.S., prefer corn grain and soybean meal as a feed source in both monogastric (e.g., swine, chicken) and ruminant diets (e.g., cow, goat, sheep). Livestock consume meal from approximately 80 percent of the corn grain and silage grown in the U.S., making the livestock sector a major consumer of the GE corn crops.

4.6.1.2 Preferred Alternative: Animal Feed

Determination of nonregulated status for MON 87419 corn could make this variety available commercially, where it may be used for animal feed purposes. Similar to the regulatory requirements for human consumption of GE corn 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 corn must comply with all applicable legal and regulatory requirements, which in turn protects human health. To help ensure compliance, GE corn 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.

On May 22, 2015, Monsanto submitted a feed safety and nutritional assessment to the FDA to initiate a consultation on the food and feed safety and compositional analysis of MON 87419 corn. Monsanto has not yet received a completed consultation letter from the FDA.

Corn will continue to be used as feed due to its nutritional qualities. Because MON 87419 corn is compositionally equivalent to other commercially available corn varieties, both GE and conventional varieties (Monsanto 2015a), it may also be used as animal feed. Animals that are fed on MON 87419 corn would be exposed to the DMO and PAT proteins in this variety. Potential concerns regarding the safety of the feed are the same as those that apply to human health; the safety of consumption of the DMO and PAT proteins, and potential consumption of pesticide residues used in MON 87419 corn production, which is discussed above in Section 2.4, Human Health.

As previously described, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from MON 87419 corn must comply with the FFDCA, Food Safety Modernization Act (FSMA), and other applicable legal and regulatory requirements, for the protection of animal and human health. GE corn used for feed may undergo a voluntary consultation process with FDA before 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 feed or food supply have completed a consultation with the FDA. On May 22, 2015, Monsanto submitted a feed safety and nutritional assessment to the FDA to initiate a consultation on the food and feed safety and compositional analysis of MON 87419 corn. Monsanto has not yet received a completed consultation letter from the FDA.

Dicamba and glufosinate currently have EPA-established tolerance limits for field corn for forage, grain, and stover, as described in Section 2.4, Human Health.

Multiple generations of food animals have been consuming 70 to 90 percent of harvested GE feed for more than 15 years (Van Eenennaam 2013). Animal feed studies have been conducted with various animals, to include sheep, goats, pigs, chickens, cattle, rabbits, and fish fed different GE crop varieties. Comprehensive reviews from various authors have summarized the results of these studies (Flachowsky, Schafft et al. 2012, Bartholomaeus, Parrott et al. 2013, Deb, Sajjanar et al. 2013, Ricroch 2013, Tufarelli, Selvaggi et al. 2013, Van Eenennaam 2013, Nicolia, Manzo et al. 2014, Van Eenennaam and Young 2014). Animal feeding studies have consistently provided evidence that the performance and health of GE-fed animals were comparable to those fed non-GE feed, and no peer reviewed study has revealed any significant variation in the nutritional profile of animal products derived from GE-fed animals (Van Eenennaam 2013, Van Eenennaam and Young 2014). DNA and protein are normal components of the diets of humans and animals, derived from GE and non-GE food and feed sources. There have been no detectable or reliably quantifiable traces of GE components in milk, meat, and eggs following consumption of GE feed (Van Eenennaam 2013, Swiatkiewicz, Swiatkiewicz et al. 2014, Van Eenennaam and Young 2014).

In summary, extensive research over the past 20 years on genetically engineered plants and foods has significantly contributed to the body of knowledge on a variety of GE cultivars, and our ability to identify and characterize possible risks associated with foods/feed derived from genetically modified crops. Reviews of current information by research scientists, public health organizations, and organizations such as the National Academy of Sciences, the Royal Society of Medicine, and World Health Organization, have concluded that consuming foods containing ingredients derived from GE crops is safe to eat and poses no more risk than consuming the same foods containing ingredients from crops modified by conventional plant improvement techniques (SOT 2003, WHO 2005, Keese 2008, NRC 2010, NSCF 2014).

The data and information presented in the petition support the conclusion that MON 87419 corn is agronomically, phenotypically, and compositionally comparable to conventional control and commercially cultivated corn, with the exception of the introduced traits (Monsanto 2015a). As described in Section 2.4 and 4.4 – Human Health, the PAT and DMO proteins pose no risk to animals that consume these proteins in current GE corn varieties, and nutritional quality is expected to be comparable to current GE and non-GE corn varieties currently available and used

as feed. When combined with other traits in current commercial releases which are unlikely to have any impact on animals and animal feed, MON 87419 is unlikely to result in any differences of impacts between the No Action and Preferred Alternatives.

4.7 Socio-Economic Impacts

4.7.1 Domestic Economic Environment

4.7.1.1 No Action Alternative: Domestic Economic Environment

Under the No Action Alternative, farmers and other parties who are involved in production, processing, and consumption of corn will have access to current nonregulated GE corn, conventional corn, and organic corn varieties.

In terms of crop value, corn is the primary U.S. crop exceeding \$52.3 billion in 2014 (USDA-NASS 2015e). USDA projects planted corn acres to remain relatively unchanging through 2024/25 at 89 million acres, with net returns to increase to \$300 /acre, as compared \$216/acre for 2015/16 (USDA 2014, Westcott and Hansen 2015). Strong demand for ethanol production has resulted in higher corn prices and has provided incentives to increase corn acreage. However, ethanol production in the U.S. is projected to remain stable over the next decade, with most production using corn as the feedstock (USDA-OCE 2015, Westcott and Hansen 2015). About 35 percent of total corn use is projected to go to ethanol production. Food and industrial use of corn (other than ethanol production) is projected to rise at a moderate pace over the next decade, averaging less than population growth, and research is expected to continue to expand the various industrial uses for corn and corn byproducts (USDA-ERS 2015b).

Denial of the petition would not result in any changes to the domestic economy relative to corn commodities. The USDA projections for domestic corn supply and demand through 2024 (USDA 2014, USDA-OCE 2015, Westcott and Hansen 2015), would not be affected under the No Action Alternative.

4.7.1.2 Preferred Alternative: Domestic Economic Environment

Under the Preferred Alternative, MON 87419 corn would be extended nonregulated status, and farmers and other parties who are involved in the production or consumption of corn would have access to this stacked trait variety. It is anticipated that MON 87419 will likely be combined with other deregulated glyphosate-tolerant corn through traditional breeding techniques (Monsanto 2015a). The in-crop use of dicamba and glufosinate herbicides, in addition to glyphosate herbicide, could potentially provide broader weed management options in corn production to control a broad spectrum of grass and broadleaf weed species.

MON 87419 corn has been determined to be similar in composition, growth habits, and cultural requirements as compared to other nonregulated corn varieties (Monsanto 2015a). As discussed above, herbicide-tolerant corn dominates U.S. corn production, either as single trait or stacked trait varieties; therefore, MON 87419 corn would likely replace or augment single trait varieties (e.g., glyphosate-resistant corn cultivars), although without impacting corn acreage or production, or affecting domestic markets (Westcott and Hansen 2015). Consequently, no

significant changes to agronomic inputs or practices would be anticipated that may impact onfarm costs for corn producers or the U.S. domestic corn market. As discussed, farmers are broadening their weed management strategies to control herbicide-resistant weeds, including glyphosate-resistant weeds, and these can increase costs of production. However, these costs can be offset by increases in yields, relative to the integrated weed management practices used, with little negative impact on net returns (Weirich et al., 2011a) (Brookes 2014, Fernandez-Cornejo and Osteen 2015).

USDA assumes that the technology fees for MON 87419 corn seed would be consistent with those charged by developers for other GE crop varieties already in the marketplace. However, the USDA has no control over the establishment of these technology fees, and each grower will make an independent determination as to whether the benefits of the MON 87419 corn variety would offset those technology access costs.

USDA recognizes that producers of non-GE corn, particularly producers who sell their products to markets sensitive to GE traits (e.g., organic or some export markets), can be concerned about GE varieties and potential impacts of contamination with GE pollen or seed. As described in Section 2.6 – Socioeconomics, strategies and guidance to prevent contamination of non-GE corn are well established and include isolation of the farm; physical barriers or buffer zones between organic production and non-organic production; planting border or barrier rows to intercept pollen; changing planting schedules to ensure flowering at different times; and formal cooperative communications between neighboring farms to ensure crop protection (Baier 2008, Roth 2011a). These practices follow the same system utilized for the cultivation of Certified seed under the Association of Official Seed Certifying Agencies (AOSCA) procedures.

Organic systems are usually certified organic according to USDA National Organic Program standards (USDA-AMS 2015b), which requires measures such as distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent to prevent genetic commingling due to pollen flow, as well as post-harvest commingling. Plans under the approved operating system enable the production operator to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods (USDA-AMS 2015b)

USDA assumes non-GE crop producers use practices on their farm to protect their crop from unwanted substances and thus maintain their price premium v, and that growers of organic corn are already using, or have the ability to use, those common practices as prescribed by AOSCA and NOP.

Based upon the above considerations, and that described in Section 2.6 - Socioeconomic Impacts, introduction of MON 87419 corn into commerce would be expected to have little to no potential impacts on the domestic economy as compared to the No Action Alternative. The availability of MON 87419 corn could have potentially minor impacts on grower choices, agronomic inputs and practices, and associated on-farm costs; however, these would not be expected to be economically detrimental to growers or consumers of corn or corn products, or

significantly impact on-farm net returns. It is considered reasonable to assume that growers would not adopt the MON 87419 corn variety if it were not economically beneficial in both short term and long term economic environments. Thus, APHIS concludes that there will be no differences of the impacts of No Action or Preferred Alternatives on the Domestic Economic Environment.

4.7.2 Trade Economic Environment

4.7.2.1 No Action Alternative: Trade Economic Environment

Under the No Action Alternative MON 87419 corn would continue to be a regulated article. Farmers, processors, and consumers would not have access to MON 87419 corn, and continue to use the existing nonregulated herbicide-tolerant and non-GE corn varieties. Denial of the petition would not be expected to result in any effects on USDA projections for international trade through 2024 (USDA 2014, USDA-OCE 2015, Westcott and Hansen 2015), as described in Section 2.6 – Socioeconomic Environment.

Over the next decade corn is expected to gain an increasing share of world coarse grain trade. Expansion of livestock production in feed-deficit countries is expected to be the principal driver of growth in coarse grain imports. Key growth markets for U.S. corn exports include China, Mexico, Africa and the Middle East, and Southeast Asian and Oceania. U.S. corn exports are expected to expand steadily over the next decade, to 63.5 million tons by 2024/25, and comprise approximately 45 percent of the share of world corn exports by 20024/25 (Westcott and Hansen 2015). Trade competition from Argentina, Brazil, and the former Soviet Union, as well as continued use of corn for ethanol production in the United States, serve to limit the U.S. world trade share to the 45 percent mark, which is below the 1970-2000 average of 71 percent.

Primary reliance on glyphosate as an herbicide has resulted in the development of GR weeds both domestically and abroad. Recent observations indicate the presence of GR-weeds on 5.6 percent of U.S. corn acres in 2010, with the Corn Belt and Northern Plains accounting for the majority of acres. However, growers reported GR weeds and declines in glyphosate effectiveness on greater percentages of both corn and soybean acres in the South than in the North (Fernandez-Cornejo and Osteen 2015). Consequently, farmers in the U.S. and abroad have begun to use integrated weed management (IWM) strategies to control glyphosate or other herbicide-resistant weeds (e.g., crop rotation, tillage, herbicide rotation, herbicide mixtures using multiple modes of action, stacked trait GE varieties). Implementing IWM strategies can increase costs, although through higher crop yields, these may not impact, and may even improve net returns (Fernandez-Cornejo and Osteen 2015, Livingston, Fernandez-Cornejo et al. 2015).

However, when a grower makes decisions about weed control strategies, economic costs and benefits of the weed management program are primary criteria for selection and implementation (Fernandez-Cornejo, Wechsler et al. 2014b, Fernandez-Cornejo and Osteen 2015, Livingston, Fernandez-Cornejo et al. 2015). Some growers can be reluctant to use other herbicides in combination with glyphosate because of concerns about increased costs in weed management. Where IWM strategies are not implemented, and resistant weeds exist, it can adversely impact the net returns of crop production. For example, it has been observed that U.S. corn and soybean producers who used glyphosate by itself received lower yields and returns than similar corn and soybean producers who used at least one other herbicide in combination with glyphosate (Fernandez-Cornejo and Osteen 2015).

Increasing weed resistance to herbicides is also occurring in other countries producing herbicidetolerant crops, including U.S. corn export competitors such as Argentina and Brazil. Similar to the U.S. experience costs of production to mitigate the incidence of GR weeds may also be incurred. Consequently, where herbicide-resistant weeds exist, and IWM strategies are not implemented, there can be associated impacts on the net returns of crops such as corn and soybean.

As of publication of this EA, Monsanto submitted an application to the Canadian Food Inspection Agency for regulatory approval of MON 87419 corn, for cultivation and use as food and feed.

4.7.2.2 Preferred Alternative: Trade Economic Environment

Under the Preferred Alternative, MON 87419 corn would be determined nonregulated and available to U.S. growers. Because MON 87419 corn is determined to be similar in composition, growth habits, and cultural requirements as compared to other nonregulated herbicide-tolerant, and non-GE corn varieties (Monsanto 2015a), it is not expected to affect the seed, feed, or food trade any differently than other nonregulated herbicide-tolerant corn varieties. As another herbicide-tolerant corn cultivar that would be available to growers, MON 87419 corn would be expected to replace other herbicide-tolerant cultivars, primarily single trait cultivars, to the extent growers find economic value in utilization of MON 87419 corn.

As discussed, farmers are broadening weed management strategies to control herbicide-resistant weeds, primarily glyphosate-resistant weeds, and these can increase costs of production. However, these costs may be offset by increases in crop yields, which can result in a gain in net returns (Weirich, Shaw et al. 2011, Brookes 2014, Fernandez-Cornejo and Osteen 2015, Livingston, Fernandez-Cornejo et al. 2015). MON 87419 will likely be combined with Roundup Ready[®] Corn 2 technology utilizing traditional breeding techniques. The combination of herbicide-tolerance traits will allow the pre-emergence and post-emergence use of dicamba, glufosinate, and glyphosate herbicides in an integrated weed management program to control a broad spectrum of grass and broadleaf weed species. With the introduction of MON 87419, growers would continue to use established herbicides and current corn production practices including crop rotation, tillage systems, and row spacing, exactly the same agronomic practices now in use. Consequently, the availability of MON 87419 corn for planting, both domestically and abroad, would not be expected to increase production costs. Competitiveness of U.S. corn and trade economic environment would not be affected, because any possible increased costs for weed management would likely be offset by increased yields (Weirich, Shaw et al. 2011, Fernandez-Cornejo and Osteen 2015, Livingston, Fernandez-Cornejo et al. 2015). Monsanto will continue to seek international acceptance of MON 87419 corn through formal applications for product approvals in key U.S. corn-importing countries, which has been its pattern for all previous products.

A determination of nonregulated status of MON 87419 corn would, therefore, not likely affect the U.S. supply of corn that may affect trade. As discussed above, other countries are increasing

their production of herbicide-tolerant corn, including glyphosate-resistant cultivars, and are becoming significant export competitors to U.S. corn trade. Because the U.S. and other countries already have access to other herbicide-resistant corn cultivars, both single and stacked-trait varieties, and MON 87419 corn presents another option for herbicide-tolerant corn varieties, its availability to U.S. producers would not be expected to impact the trade economic environment.

5 CUMULATIVE IMPACTS

This section assesses current and reasonably foreseeable future impacts if APHIS chooses the Preferred Alternative. APHIS considers the impacts of the Preferred Alternative combined with its past, present, and reasonably foreseeable future actions as well as the actions of others in this section.

Cumulative impacts are defined as the "impact on the environment, which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (federal or non-federal) or person undertakes such other actions" (40 CFR 1508.7).

Environmental consequences were assessed individually in Section 4. From those analyses, APHIS determined there are no direct or indirect impacts from the potential nonregulated status of MON 87419 corn because these varieties are not phenotypically or agronomically different from other corn cultivars.

This chapter includes a review and analysis of potential impacts associated with the Preferred Alternative (see Section 2) combined with past, present and reasonably foreseeable future actions within the affected environment (described in Section 3).

The first reasonably foreseeable future action considered is that EPA will approve the registration of the proposed new uses of dicamba on MON 87419 corn. These herbicide products are formulated with the diglycolamine (DGA) salt of dicamba which have lower volatility than the dimethylamine (DMA) or other formulations of dicamba currently in use. Presently, EPA has allowed registration of Xtendimax (EPA #524-617) dicamba for use on field trials of dicamba resistant corn (US-EPA 2014a), but not commercial use and similarly of Xtend [dicamba with DGA formulation and glyphosate premix] (US-EPA 2014b). A second reasonably foreseeable action is the expected determinations of nonregulated status for other HR crops, whose implications are noted later in this section.

This section analyzes the cumulative impacts related to changes in management practices that are likely to be associated with the adoption of MON 87419 corn. The context of the analysis is in U.S. agriculture where there are already impacts on resources in the areas where corn is grown. One possible cumulative impact is an increased selection for dicamba-resistant weeds that may occur associated with the long-term increased use of dicamba herbicide applications. Because this impact would occur only if both APHIS (determines nonregulated status) and EPA (registers new use of dicamba herbicides on dicamba-resistant crops) take the actions described here, APHIS has analyzed the potential cumulative impacts of both APHIS and EPA in combination and present the potential impacts that may include, for example, development of dicamba-resistant weeds.

Impacts on natural and biological resources are considered in the cumulative impacts analyses. Possible implications of how these impacts might affect the availability of those resources for human use and consumption are also analyzed. The initial step in this process was an analysis of the potential changes in management practices likely to occur if APHIS approves the Monsanto petition and EPA approves the uses of dicamba on MON 87419 corn. In the second phase of analysis, APHIS analyzed how changes in management practices might impact natural and biological resources. Possible impacts of an interaction with other APHIS actions (past and those currently pending) were also considered.

From the analyses in Environmental Consequences section, APHIS concluded there are no direct or indirect impacts following determination of nonregulated status of MON 87419 corn because the variety is not agronomically different from other GE corn cultivars that are no longer regulated by the Agency. The action Monsanto requested of EPA, which is approval of the use of dicamba on corn, may be subsequent to a determination of nonregulated status for MON 87419 corn by the USDA. A reasonably foreseeable action is that EPA will approve registration of formulations of XtendimaxTM (dicamba registered with EPA as M1691) and of XtendTM dicamba resistant corn.

5.1 Assumptions Used for Cumulative Impacts Analysis

For this analysis of cumulative impacts, the No Action Alternative was the baseline for comparisons. Under the No Action Alternative, MON 87419 corn would not be determined as nonregulated and could only be grown under APHIS notifications or permits. Under this scenario, APHIS assumes that the EPA would not approve Monsanto's application for the new dicamba uses on this GE variety that is the subject of the EA. Existing EPA-approved uses of dicamba would continue as at present and currently available varieties of corn would continue to be grown.

Additional dicamba resistant crops, soybean and cotton, are expected to be available to growers, and cumulative impacts of increased dicamba use on these crops and MON 87419 corn will be addressed by EPA. Peak MON 88710 cotton use, which Monsanto estimated may reach about 50 percent of cotton acres, will likely result in more frequent applications of dicamba to cotton, since the trait allows new POST emergent exposure of the target cotton crop where at present only preplant has been allowed (Appendix Table A-40) (Monsanto 2013a). For MON 87708 soybean, the new label would similarly allow for applications at later stages of plant growth than currently approved for dicamba use on soybean. At peak MON 87708 soybean use, Monsanto estimates that about 40 percent of acres will be planted with the technology. Again, more frequent application can be expected on MON 87708 soybean since post-emergent exposure is tolerated (USDA-APHIS 2014c) and Table A-2, A-3, A-5 (Monsanto 2013a). Thus, more soybean acres planted to MON 87708 soybean are likely to be sprayed with dicamba than present varieties, where it is used only as a burndown herbicide.

Additional dicamba would be used on MON 87419 corn on greater than the 10-14 percent of total planted corn acres currently determined for corn production, using Monsanto's predicted adoption rate. Monsanto estimates that at the current rate of increase of dicamba use on corn, by the time that MON 87419 is commercially available, 24% of corn will be treated with dicamba (Monsanto 2015b). Monsanto predicts that the MON 87419 trait penetration in corn seed will eventually attain to 89 percent, and that on this acreage, about 40 percent of growers will apply dicamba (Monsanto 2015b). This would result in about 36 percent of corn acres to which dicamba would be applied after about seven years (Monsanto 2015a,b). An assessment of potential environmental impacts deriving from cumulative increases in use of dicamba on these

two crops in addition to those increases likely from corn are assessed quantitatively by EPA in their Environmental Effects assessment.

Because impacts of dicamba use would occur only if both APHIS and EPA take the actions already described here, APHIS has analyzed in this section the potential cumulative impacts of its action combined with potential Xtend herbicide applications. This chapter also considers the cumulative impacts of stacking additional traits such as herbicide resistance to additional herbicides. The chapter also includes a review and analysis of the cumulative impacts of weed resistance caused by long term use of dicamba. It includes a discussion of potential cumulative impacts associated with the Preferred Alternative (see Section 2) combined with other past, present, and reasonably foreseeable future actions within the affected environment (described in Section 3). These are covered in more detail and greater breadth in the antecedent documents, the APHIS EIS for dicamba resistant soybean and corton and impacts of the similar auxinic herbicide, 2,4-D, in the EIS for 2,4-D soybean and corn, to which this document is tiered.

5.1.1 Proposed New Dicamba Uses and EPA Risk Assessments

The EPA will conduct an independent assessment of direct and indirect effects associated with the use of dicamba on MON 87419. The role of EPA is described in the EIS for Monsanto's dicamba resistant cotton MON 88710 and dicamba resistant soybean MON 87708 and this EA is tiered to that assessment (USDA-APHIS 2014c). The direct effects of dicamba use are outside the scope of this EIS. APHIS decisions regarding the regulated status of the petitions for these new GE varieties will be made independently of the results of the EPA assessments. One assumption of the APHIS analysis is that EPA will establish label restrictions associated with the uses of dicamba on MON 87419 corn that will ensure safety standards for human health and the environment.

For this summary, one conclusion is that additional dicamba will be applied to two new dicambaresistant agricultural crops and additional dicamba applied to corn (on MON 87419) compared to dicamba applied to these crops at present. Increased selection for dicamba resistant weeds could be considered a potential consequence, and will be analyzed. Notably, while dicamba is already used on corn, the availability of MON 87419 corn would also modestly extend the use of dicamba on corn later into the growing season. Current usage of dicamba on corn is made on around 10-14 percent of corn acres, already an appreciable amount of treatment. While advantages may accrue to growers of dicamba resistant MON 87419 corn, certainly some weed control with dicamba may continue to be accomplished by use of dicamba on non-dicamba resistant corn; this EA assesses the potential changes for these changes in dicamba use.

EPA Mitigation of Weed Resistance in Dicamba-resistant Crops

The EPA has begun proposing new management requirements when appropriate for specific herbicides used for HR crops. These requirements arise from concerns about possible development of new resistant weeds with adoption of HR crops. If these provisions are established for MON 87419, Monsanto would be required to conduct an active stewardship program including monitoring and remediating weed resistance to dicamba. Following the recent pattern for 2,4-D resistant crops, HR crop developers would need to provide not only robust

monitoring of resistant weed populations but also reporting of locations of weed dicamba resistance to EPA, engage in grower education and in active remediation. If resistance develops, EPA can take swift action to impose additional restrictions on the manufacturer and the uses of the herbicide (US-EPA 2014d). The EPA's new requirements for weed resistance and responses are for 2,4-D resistant crops, and this herbicide has the same mode of action as dicamba, as detailed in Appendix 10 of the EIS. The complete description of these provisions is the same as that discussed in the EIS for 2,4-D Resistant Soybean and Corn, and this EA is tiered to that EIS (USDA-APHIS 2014e).

No Action Alternative: Cumulative Impact

Current Management Practices Considered in the Analysis of Cumulative Impacts

This analysis addresses the potential impacts of the Alternatives on natural and biological resources and their interrelated U.S socioeconomic impacts following APHIS' determination of nonregulated status for MON 87419 corn, MON 88701 cotton, and MON 87708 soybean. First, the agricultural environment in which US corn is produced, and the herbicides selected can change substantially for various reasons. Agronomic factors are changing such as an increase in glyphosate resistant and other herbicide resistant weeds, as well as a fluctuating climate, weather and pests. Superimposed on this is the price of commodities, which determines which economic practices can be used for corn production and those which are not economically justifiable. Rotation crops and their economics and needs also are part of this complex interaction, as are the production practices that are pursued on the acreage these crops are grown upon. Cultural and physical methods to control weeds are also a large and important part of the Agroecosystem and grower production processes for these crops.

Weed scientists recognize that "more diversity of tactics for weed management must be incorporated in crop systems" but that the potential for labor reduction and increased farm size were enabled with herbicide resistant crops. (Owen, Beckie et al. 2015) As noted by Green(2014), "synthetic herbicides are still essential for weed management, and any new synthetic herbicide with a new mode of action will help greatly to manage weeds, but growers need more alternatives." At best, some reductions in herbicide use may be possible, but alternatives are mostly based on experimental results too limited to project success under typical conditions (Petit, Munier-Jolain et al. 2015).

In this complex milieu of necessity and choice, dicamba use is already a part of common agronomic input practices, along with other herbicides, but would be further extended to be used with the dicamba resistant crop varieties. In the Environmental Consequences section, APHIS has presented these issues, and in this section of Cumulative impacts focuses on changing patterns of dicamba use, and of tillage, both important considerations in the potential for environmental impacts that might derive from planting of MON 87419 corn, MON 88701 cotton, and MON 87708 soybean.

Current Dicamba Use

The agronomic practices that are expected to be affected by nonregulated status for MON 87419 corn are those that relate to the application of dicamba. The factors that would contribute to

increased dicamba use on corn include the adoption rate by growers, the application rate and frequency and the number of acres to which dicamba would be applied on these new GE plant varieties.

In 2012, the highest use of dicamba was on corn crops, with almost 12 million acres of corn treated (Monsanto 2014). About 12 percent of corn acres received a dicamba application either alone or with another herbicide. The second crop most frequently treated with dicamba was fallow or idled cropland, with approximately 6.7 million acres treated. On spring and winter wheat, 1.8 and 3.6 million acres received dicamba applications or 14.6 percent and 8.4 percent of acres, respectively. Dicamba was used on 1.5 million cotton acres which represents 11.5 percent of the total U.S. cotton crop acreage (Monsanto 2014). Dicamba usage on additional crops is summarized in Appendix A. The prospective planting of the additional dicamba resistant crops, MON 88701 cotton and MON 87708 soybean, are also important in future usage patterns and applied quantity of dicamba. Finally, the usage of crops expressing the other auxinic class herbicide, 2,4-D, may be relevant to the potential for impacts deriving from nonregulated status for MON 87419 corn.

For a discussion of other crops on which dicamba is used and which may be impacted by the presence of dicamba resistant weeds, we tier the analysis to that presented in **Cumulative Impacts in APHIS' dicamba EIS (USDA-APHIS 2014c).** From this analysis it is clear that dicamba is used modestly in crops, from 1.4 percent of acres in soybean (mostly burndown activities) to 26 percent of sugarcane acres, with other uses such as on cotton at 11.6 percent of cotton acres.

Preferred Alternative: Cumulative Impacts

Production of MON 87419 corn would not affect natural or biological resources directly, but rather the agricultural management practices (e.g., pesticide applications) associated with cultivation of these crops and its potential impact on natural and biological resources. The interaction of cultural and mechanical practices affect agricultural and natural resources, and these include crop rotations, and sequences of crops, selections of varieties and traits and tillage practices. Pest control practices are also relevant and include patterns, numbers and specific choices of applied herbicides or other pesticidal chemicals as well as mechanical and cultural controls. These management practices all accumulate specific outcomes for crop yield, and soil, water, or air impacts. Other consequences may include development of problem or herbicide resistant weeds, or adverse effects on successive crops planted on the same land. APHIS will discuss those selected issues which will or may potentially impact these agricultural and natural resources in the context of the Cumulative Impacts section, since as noted, the EPA approval of new dicamba uses was a foreseeable event, rather than the existing status.

Use and planting of MON 87419 corn will likely follow the existing patterns, where production of corn is higher in the Corn Belt States than other states of the U.S. also with corn production.

5.2 Cumulative Impacts: Acreage and Area of Corn Production

It is likely that additional traits for resistance to herbicides besides dicamba and glufosinate will be added to future seed offerings, and this would include glyphosate resistance. This herbicide

stacking does not lead APHIS to expect that either the acreage of corn or its common production areas will be increased; the trait will be helpful to growers, but will not result in new corn acreage. An additional option for herbicide use and control of problem weeds will offer greater economy and efficacy for weed control, but not necessarily enable large-scale displacement of herbicide usages. Herbicide choices will remain a complex decision-making process for growers. No changes in corn production can be foreseen that would suggest more frequent planting of corn, nor would the economics of corn production be altered (see Environmental Consequences: Socioeconomic Resources). While increasing costs of control of resistant and problem weeds may be stabilized or reduced by MON 87419 corn, there is no indication that the new seed trait would be less expensive than other, similar herbicide-resistant corn varieties, and thus likely to promote any new development of corn production areas.

5.3 Cumulative Impacts: Agronomic Practices

For a presentation of cumulative impacts of nonregulated status of MON 87419 corn on Agronomic Practices, we tier the analysis to that presented in the Cumulative Impacts section of APHIS' dicamba EIS (USDA-APHIS 2014c).

Growers are presented with many options for weed control, but different crops offer different alternatives. Corn growers have a greater number of herbicides available to them than do soybean growers that are tolerated for post emergent weed control (Iowa-State-Extension 2015). Corn producers also employ more mechanical weed control techniques than soybean producers (Livingston, Fernandez-Cornejo et al. 2015), and both preplant tillage and post-emergent interrow cultivation may be useful for helping to limit the development of resistant weeds (Table 14). However, soybean growers are more likely to employ additional cultural methods such as more frequent crop rotation than to use mechanical control. It appears that corn is already using more tillage and cultivation than soybean, so that soybean is relatively more dependent on herbicide use for weed management (Livingston, Fernandez-Cornejo et al. 2015). Other weed controlling cultural strategies include choosing proper planting dates and seeding rates (both corn and soybean growers use these at similar frequencies as reported by growers) (Livingston, Fernandez-Cornejo et al. 2015)), providing optimal fertility, ensuring good drainage and selecting optimal crop rotations (Loux, Doohan et al. 2014).

Several important reasons determine why tillage or cultivation will not be an adequate substitute for the limited options for available herbicides that control resistant weeds. As noted by weed scientists from several states, based on experimental observations, deep tillage may optimally be used once to bury weed seeds when the field is overrun with weeds (Nufarm 2015). However, tillage multiple times can both stimulate more weeds to grow and also bring to the surface dormant weed seeds (Nufarm 2015). Thus, increased tillage is not usually recommended as a prudent tactic in response to hard to control or resistant weeds by many weed scientists (Nufarm 2015). APHIS concludes that MON 87419 will likely provide more favorable options for corn growers controlling resistant weeds, and that commercial availability may well deter growers from requiring tillage or cultivation as a fallback strategy.

Table 14. Comparison of Tillage, Cultivation and Cultural Practices on Corn and Soybean Acres					
Сгор	Tillage (for residue management) percentage of acres	Cultivation (for weed control) percentage of acres	Rotation to another crop		
Corn (2010)	74	15	69		
Soybean (2012)	59	8	82		

Data from (Livingston, Fernandez-Cornejo et al. 2015)

5.4 Cumulative Impacts: Organic Corn Production

For a presentation of cumulative impacts on Organic Corn Production, we tier the analysis to that presented in Cumulative Impacts section of APHIS' dicamba EIS (USDA-APHIS 2014c).

No cumulative impacts are expected on organic growers because these growers do not use herbicides such as dicamba for weed control. HR weeds would not be harder to control than nonresistant weeds by alternative measures such as those employed by organic growers. While additional dicamba may be used on crops, some potentially adjacent to organic or non-GE crops, drift of dicamba can potentially be reduced by 94% by the DGA formulation of dicamba to be used with MON 87419, compared to the DMA formulation (Egan and Mortensen 2012). Hence, drift with the DGA formulation is not considered an outstanding issue in regard to use with MON 87419 corn. Where there is the potential for drift of any herbicide, all growers within drift range of organic crops should be cognizant of EPA requirements that minimize the drift potential of any herbicide applied. Precautions and label requirements are prescribed by EPA, mandatory for all growers, and designed to avert potential impacts on organic and other non-GE crops. Not following label requirements is violation of the law, and state and federal agencies enforce implementation of pesticide label requirements. APHIS believes that the majority of pesticide applicators will follow EPA requirements for preventing drift and the resulting damage that may result from use of volatile formulations of dicamba on dicamba on dicamba resistant crops.

5.5 Cumulative Impacts: Physical Environment

For an analysis of impacts on the Physical Environment, we tier the analysis to that presented in Cumulative Impacts section within APHIS' dicamba EIS (USDA-APHIS 2014c), and the Cumulative Impacts of APHIS' 2,4-D resistant corn and soybean EIS (USDA-APHIS 2014e).

Potential cumulative impacts on the Physical Environment may include those deriving from the use of dicamba on MON 87419 corn along with additional stacked herbicide resistance traits expressed in seeds of this variety. After the EPA approves the proposed uses of dicamba and the Preferred Alternative is chosen by APHIS, there is an expectation that the use of dicamba will increase. This increase in dicamba use has the potential to impact natural resources. APHIS does not regulate the use of dicamba. The direct and indirect impacts which arise from this increased

use will be assessed by the EPA and would be the result of the action that the EPA is taking with respect to labeling dicamba herbicide (M1691) for use on MON 87419 corn. Any direct and indirect impacts of dicamba are outside the scope of this EIS. EPA has considered the cumulative impacts from changes in production practices that may arise from new herbicide use and of new HR weeds. APHIS expects the EPA to implement appropriate label requirements for registration of the M1691 herbicide (dicamba and glyphosate) to protect the human environment from potential adverse consequences of new dicamba use.

Development of additional weeds with glyphosate resistance or other herbicide resistance will likely continue; one response that growers may take would be to increase such tillage. Dicambaresistant crops may deter growers from returning to the conventional tillage that may have become necessary for controlling glyphosate-resistant weeds. Under the No Action The potential impacts on Soil, Water, Air Quality, resources which are directly affected by the increased use of tillage, could be modestly diminished under the Preferred Alternative.

5.6 Cumulative Impacts: Biological Resources

For an analysis of impacts on Biological Resources, we tier the present analysis to that found in the Cumulative Impacts section within APHIS' dicamba EIS (USDA-APHIS 2014c), and also to the Cumulative Impacts of APHIS' 2,4-D resistant corn and soybean EIS on Biological Resources (USDA-APHIS 2014e).

The impacts of the Preferred Alternative to animal and plants communities, microorganisms, and biodiversity would be no different than that experienced by these communities under the No Action Alternative. MON 87419 corn is agronomically and compositionally similar to other corn varieties currently in cultivation; therefore it would not require different agronomic practices or represent a risk to safety or increase the risk of weediness of corn or to other corn (USDA-APHIS 2015a). As established previously, the use of glufosinate will remain the same for this variety as that of the currently available corn varieties; allowable application rates are the same, and total use likely to be the same. Monsanto will petition EPA to increase the maximum use rate of dicamba in corn for pre-emergence and post-emergence applications to a total of 2.0 lbs. a.e. dicamba per acre per year (Monsanto 2015a). The actual application of herbicides is dictated by both individual farm needs and EPA label use restrictions, and Monsanto can only predict that typical dicamba use will be one or two applications per season of 0.5 to 1 lb. per acre. The EPA herbicide registration program when it is completed will effectively determine that there is no unreasonable environmental risk if the end user adheres to the directions and restrictions determined by EPA and displayed on the EPA registration label when applying herbicide formulations.

An increase in dicamba is expected under the Preferred Alternative, depending on grower adoption rates and specific field requirements (see Appendix A for estimates of new usage of dicamba on corn). The use of any corn herbicides other than dicamba are expected to potentially decline or remain the same, since dicamba may be more efficacious than existing herbicides. MON 87419 provides growers with a control strategy for glyphosate resistant and other problem weeds. The increased use of dicamba under the Preferred Alternative is expected to result in increased selection pressure for dicamba resistant weeds.

Potential impacts related to plant communities, including gene flow and weed resistance to dicamba and glufosinate-ammonium were discussed in Preferred Alternative: Plant Communities. Two weed species in the U.S. resistant to dicamba have been identified: only one species was identified in corn producing regions in the U.S. (NCGA 2014, Heap 2015). One weed species resistant to glufosinate was identified in a region that does not produce significant amounts of corn (NCGA 2014, Heap 2015). Existence of dicamba-resistant weed populations are useful indicators for development of future resistance, but other factors are also relevant for assessing the possibility of such resistance. Diversity of available management practices employed by growers may also be highly relevant for predicting future susceptibility (Norsworthy, Ward et al. 2012). The greater the diversity of management practices, the smaller the selection pressure for resistant weeds (Evans, Tranel et al. 2015). MON 87419 will provide corn growers with additional herbicide resistance options making the evolution of additional herbicide resistant weeds less likely than in those corn varieties expressing a trait with single mode of action such as glyphosate resistance (Owen 2008, Norsworthy, Ward et al. 2012).

There are no differences in the potential for gene flow and weediness between the No Action and Preferred Action Alternatives. APHIS's Plant Pest Risk Assessment determined that there is no likely route for gene flow into wild species of compatible plants (USDA-APHIS 2015a). Additionally, the domestication process in corn led to a crop that was adapted for human cultivation rather than free-living establishment in the wild (Doebley 2004, Purugganan and Fuller 2009). The risk of gene flow and weediness of MON 87419 is no greater than that of other nonregulated GE corn varieties.

Following a determination of nonregulated status, MON 87419 would likely be stacked with other nonregulated GE traits for herbicide, insect, or drought resistance. Because most corn varieties are sold with glyphosate resistance, it is likely that resistance to this herbicide (with an exceptionally broad spectrum of activity for control of many weeds) will also be stacked into corn seed. Any GE traits that may be stacked with MON 87419 corn have already been assessed by APHIS and determined to be nonregulated. As such, the production and use of products from these cultivars have been determined to have no significant negative impact on the biological resources analyzed in this EA. The use of another corn variety with glyphosate resistance, when these are already a very high percentage of planted corn varieties, should have no impact on corn production. The combination of additional traits along with MON 87419 corn will have no effect on gene flow.

Potential impacts that may impinge on biodiversity were discussed in the Preferred Alternative: Biodiversity. Use of dicamba and glufosinate to control herbicide resistant weeds, particularly glyphosate resistant weeds, may help stabilize conservation tillage practices which would have a positive impact on biodiversity due to decreases in run-off and erosion (Carpenter 2011a). Because most corn varieties are sold with glyphosate resistance, it is likely that this herbicide with broad spectrum activity for many weeds will be also stacked into corn seed. Herbicides do not directly promote biodiversity. However, the use of a new herbicide resistance trait in a corn variety that is stacked with additional herbicide resistance traits may lead to increased productivity and consequently, increased yield on existing agricultural land (Carpenter 2011a). APHIS concludes that the consequences of such yield increase could include a somewhat diminished demand for conversion of CRP lands or other as yet unconverted nonagricultural lands to corn production lands, and thus to increased potential for maintaining animal and plant biodiversity.

Weed Resistance and Dicamba Use

Weed resistance is not a consequence of the use of herbicide resistant crops. APHIS under the Preferred Alternative concludes that the extent and types of resistant weeds depend on how growers either employ the techniques of weed management or ignore them. Some growers may choose to rely exclusively on dicamba resistant crops and dicamba applications, and not diversify their weed control practices, leading to unsustainable dicamba use. Others are expected to rotate this chemistry by using other herbicides and rotation crops, and deter development of new herbicide resistant weeds.

If the modes of action of two herbicides are overlapping in targeting one weed species, weed scientists expect that weed resistance will be importantly delayed (Norsworthy, Ward et al. 2012). Dicamba used post-emergent with other herbicides (such as residual ones) will add to overlapping weed targeting. However, for areas where glyphosate resistance in weeds is already prevalent, the use of dicamba-and glyphosate-resistant crops (while applying glyphosate and dicamba together) may not be effective in delaying herbicide resistance to dicamba, although other non-glyphosate resistant weeds that were controlled by both could see delays in development of dicamba resistance. If growers with acreage having populations of glyphosate resistant weeds do not accept that the planting of dicamba-resistant crops may be inadvisable (when both glyphosate and dicamba are in the herbicide mixture) and if there is no additional herbicide targeting the glyphosate resistant problem weed, APHIS concludes that weed resistance to dicamba, if it develops, may be hastened. Consequently, if growers have glyphosate resistant weeds in their fields it is recommended that they use two or more different herbicides with different mechanisms-of-action on the resistant weed species (e.g., dicamba plus another non-glyphosate herbicide).

Bearing the above considerations in mind, only six weed species worldwide have developed resistance to dicamba and cross resistance to non-auxinic mode-of-action herbicides is infrequent (Heap 2014). In addition, herbicide resistance in all auxinic herbicides is of rather low frequency (Mithila, Hall et al. 2011) despite the fact that these auxinic herbicides have been used for five or six decades and on many crops. However, if new strategies are employed, such as over-the-top applications at two per year, APHIS recognizes that the historically slow development of auxinic herbicide resistance could potentially be altered.

Also notable is that one case of cross-resistance between a glyphosate resistant Italian ryegrass population with applied glufosinate has been detected (Avila-Garcia and Mallory-Smith 2011). While this is confined to one observation, it is also been shown to have only low-level resistance to glufosinate (2.4 fold). At present, especially when growers appear to use glufosinate relatively infrequently, and in some crops show declining usage, APHIS concludes that this cross-resistance is unlikely to present widespread potential for economic impacts.

Under the Preferred Alternative, APHIS notes that EPA will have new regulatory mechanisms in place to oversee HR crops and to deter resistant weed development. The EPA will likely require Monsanto to provide information for averting weed resistance on dicamba labels for use on

dicamba-resistant crops, as it has recently done for Dow Agrosciences' Enlist Duo (glyphosate and 2,4-D premix) to be used on 2,4-D-resistant soybean and corn. The EPA is also expected to require crop oversight by manufacturers for reporting and responding to new incidences of weed resistance. Monsanto will be required to take action to deal with such weed resistance in dicamba-resistant crops, following the pattern being established by the EPA for Dow Agrosciences for the continuing oversight of 2,4-D and Enlist crops.

Potential for Development of Weed Resistance to Other Auxinic Class Herbicides and Impacts on Resistance Development in Dicamba Corn Production

For an analysis of impacts of other auxinic class herbicides on MON 87419 corn, we tier the present analysis to that found in the Cumulative Impacts section within APHIS' dicamba EIS (USDA-APHIS 2014c), and the Cumulative Impacts of APHIS' 2,4-D resistant corn and soybean EIS (USDA-APHIS 2014e).

As noted earlier, other crops have recently been determined as nonregulated by USDA-APHIS may have impacts on MON 87419 corn; these may potentially hasten the development of herbicide-resistant weeds. These crops include GE soybean, corn and cotton with resistance to the auxinic class herbicide 2,4-D, and two GE soybean varieties with resistance to HPPD inhibitors.

Weed resistance to auxin class herbicides is relatively limited compared to other herbicide classes. Nevertheless, there has been some detection of cross resistance in weed populations to more than one class of auxinic herbicide, including a few with 2,4-D and dicamba resistance. The extent and mode of such cross resistance has not been well-investigated. However, because of the potential for cross-resistance, growers may be cautioned against planting 2,4-D-resistant and dicamba-resistant crops in successive years on the same fields. Because of the potential for cross-resistance, growers will need to use the full range of weed management tools that are available, (e.g., crop rotation, herbicide mixtures with multiple mechanisms-of-action). When used, 2,4-D and dicamba chemistry should not be applied alone; each should be tank mixed with another herbicide with a distinctly different and effective mechanism-of-action. Under the Preferred Alternative, APHIS concludes that weed cross-resistance between the new auxinic resistant crops will need to be monitored carefully. The EPA will likely require remedial actions should such resistance develop, given the previously noted precedent of EPA's conditions for 2,4-D use on 2,4-D resistant crops.

Other herbicides within the auxinic class that are used on corn include four different families. In 2013, the synthetic auxin class was only the fifth most frequently applied herbicide class, attaining to 40.5 % of acres (Table 15). Glyphosate was the most frequently applied herbicide and Photosystem II inhibitors were the second most frequently. While the potential for cross-resistance between varieties with other auxinic herbicides in the class with dicamba exists, these herbicides are often different enough in sites of action that such cross resistance does not actualize. As noted by some investigators, a biotype of Washington prickly lettuce is "cross-resistant to MCPA and dicamba, but not to aminopyralid or fluroxypyr" (Heap 2015).

Table 15. Corn Herbicide Modes of Action and Acres of Application in 2013					
Herbicide	Chemical Family	Mode-of-Action (MOA)	Percent of Corn Acres Treated	Percent of Corn Acres Treated per MOA	
Glyphosate	Glycine	EPSPS inhibitor	83.7	83.7	
Atrazine	Triazine		58.7	61.5	
Metribuzin	Triazine	PSII inhibitor	0.4		
Simazine	Triazine		2.4		
Acetochlor	Chloroacetamide		26.6	61.4	
Alachlor	Chloroacetamide	 Long-chain fatty acid inhibitor 	0.2		
Dimethenamid	Chloroacetamide		6.3		
Metolachlor	Chloracetamide		28.3		
Pyroxasulfone	Isoxazoline		0.3		
Isoxaflutole	Isoxazole		9.4	44.6	
Mesotrione	Triketone	— HPPD inhibitor	25.5		
Tembotrione	Triketone		6.7		
Topramezone	Triketone		3.0		
2,4-D	Phenoxy		14.3	40.5	
Clopyralid	Carboxylic acid	Synthetic Auxin	11.9		
Dicamba	Benzoic acid		13.9		
Fluroxpyr	Caryridine Carboxylic acid	_	0.4		
Flumetsulam	Imidazolinone	ALS inhibitor	11.5	29.4	
Halosulfuron	Sulfonylurea	ALS inhibitor	0.3		
Nicosulfuron	Sulfonylurea		1.1		
Primisulfuron	Sulfonylurea		0.2		
Prosulfuron	Sulfonylurea		0.2		
Rimsulfuron	Sulfonylurea		4.6		
Thifensulfuron	Sulfonylurea		2.7		
Table 15. Corn Herbicide Modes of Action and Acres of Application in 2013					
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Herbicide	Chemical Family	Mode-of-Action (MOA)	Percent of Corn Acres Treated	Percent of Corn Acres Treated per MOA	
Thiencarbazone	Triazolones		8.5		
Tribenuron	Sulfonylurea		0.3		
Diflufenzopyr	Semicarbazone	Auxin transport	7.9	7.9	
Fluthiacet	Thiadiazole	PPO inhibitor	0.9	6.1	
Carfentrazone	Aryl triazone		0.5		
Saflufenacil	Pyrimidinedione		4.0		
Flumioxazin	N-phenylphthalimide		0.7		
Paraquat	Bipyridylium	Photosystem-I- electron diverter	1.4	1.4	
Glufosinate	Phosphinic acid	Glutamine Synthase Inhibitor	1.2	1.2	
Pendimethalin	Dinitroanaline	Microtubule inhibitor	0.7	0.7	
Total			99		

Source: (Monsanto 2015a)

New usage of HR crops available to growers in the future will likely be preceded by recommendations from weed scientists that encourage growers to use diversified management practices that include combinations of herbicide mixtures with multiple mechanisms-of-action, cultural, physical, and biological tactics, to help reduce development of herbicide resistance in weeds (Davis, Hill et al., 2012). Analysis of weed and management data show that the increase of GR weeds is strongly reduced when three or more herbicides are used in crop production (Evans, Tranel et al. 2015), so additional choices in herbicides are relevant to the immediate suppression of weed resistance. For example, if dicamba resistant crops are available to corn, cotton, and soybean growers, rotations of such crops as MON 87419 corn (dicamba and glufosinate tolerant), MON 87708 soybean (dicamba and glyphosate tolerant), and MON 88701 cotton (dicamba and glufosinate tolerant) with HR crops utilizing non-auxinic herbicides could add flexibility in weed management choices.

Fundamentally, herbicide mixes alone are not a permanent solution to the development of weed resistance. Herbicide mixtures may delay evolution of resistance in the short-term, but cannot prevent development of weed resistance in the long-term (Evans, Tranel et al. 2015). Herbicide-resistant weed evolution is inevitable with herbicide use, particularly when there is extensive reliance on herbicides to control weeds. The reduction in discovery and commercialization of

new herbicide chemistries over the last two decades has further exacerbated issues with chemical control of weeds (Evans, Tranel et al. 2015). Diversified management practices integrating herbicide mixtures with multiple mechanisms-of-action, crop rotation, tillage, and biological controls, will be required to effectively reduce development of herbicide resistance in weeds.

Responsibility for Averting Future Weed Resistance to Dicamba

For an analysis of the grower's changing attitudes to how herbicide use should be managed and how that will affect impacts of MON 87419 corn, we tier the present analysis to that found in the Cumulative Impacts section within APHIS' EIS for dicamba resistant soybean and cotton (USDA-APHIS 2014c), and the Cumulative Impacts within APHIS' EIS for 2,4-D resistant corn and soybean (USDA-APHIS 2014e).

To avert future weed resistance, a relevant issue is confidence that growers will know and select appropriate strategies for management options. While State weed science extension agents will propose best management practices, and teach it to growers and crop consultants (Riar, Norsworthy et al. 2013), APHIS concludes that these are not adopted immediately by growers for a variety of reasons, but that management practices indeed change in response to grower perceptions of need and economic necessity, as for example kochia control in Kansas (Godar and Stahlman 2015). Best management practices will include employing a diversity of herbicides, rotation of herbicide choices, crop rotation, and others that will be mandated by new EPA labelling to deter weed resistance development. State extension agents, seed providers, herbicide suppliers and other professionals, will continue to provide advice to growers, who are becoming more likely to perceive the needs for sustainable weed management and execute needed practices. APHIS concludes that overall success in averting weed resistance will depend on these management choices that are appropriately made by individual growers.

Clearly the grower's responses to recommended practices prescribed by extension personnel and weed scientists will determine the potential impacts and benefits for RoundupReady Xtend adoption. Motivating new adopters will be an acceptance that reduced usefulness of dicamba herbicide will accompany failure to follow BMPs. Growers are likely to understand that continued benefits from the extended utility of dicamba resistance traits can only be obtained by observing the BMPS, as an Iowa state survey of corn and soybean growers showed (Arbuckle and Lasley 2013). Because growers have become more receptive to understanding causes of developing herbicide resistance (Prince, Shaw et al. 2012a, Prince, Shaw et al. 2012b, Riar, Norsworthy et al. 2013) they have also become more proactive on these issues. Under the Preferred Alternative, as under the No Action Alternative, APHIS concludes that more growers are likely to take actions that reduce the chances for weed resistance. More recent studies have shown that there is only modest additional short-term cost for applying these best practice actions, with no change in profitability (Edwards, Jordan et al. 2014). Large long-term costs for failing to apply these actions are also a possible consequence, which weed experts will continue to emphasize to growers. APHIS concludes that availability of a new herbicide resistant corn variety will not lead to prompt resistance, given grower cognizance of the cumulative effects of past misuse of glyphosate. At least a modest time course for utility of dicamba for problem weed control is likely. APHIS concludes that possible impacts on Biological Resources will not be any

greater under the Preferred Alternative than the No Action Alternative, and particularly not as a consequence of weed resistance to herbicides.

5.7 Cumulative Impacts: Public Health and Animal Feed

For an analysis of impacts on Public Health and Animal feed, we tier the analysis to that presented in Cumulative Impacts within APHIS' dicamba EIS (USDA-APHIS 2014c).

No cumulative impacts were identified on human health or livestock for either of the Alternatives. Use of dicamba on MON 87419 results in degradation of dicamba to include formaldehyde (Monsanto 2015a). The EPA does not consider formaldehyde a relevant metabolite in the demethylation of dicamba (US-EPA 1996). EPA has reviewed the potential impacts of the metabolites of the DMO protein, in the Human-Health Risk Assessment (US-EPA 2013a) and did not regard the issue of formaldehyde as needing analysis. As the petition summarizes, the product formaldehyde is a common product in plant metabolism (Hanson and Roje 2001), and one that is highly labile, quickly entering into the plant's one-carbon cycle (Monsanto 2015a). Formaldehyde production occurs as a common metabolite of various processes in the aqueous parts of plant cells, as does its further metabolism. Formaldehyde that is evolved from the plant may naturally be emitted in nanomoles/ m^2 /min per leaf, probably by most plants (Cojocariu, Kreuzwieser et al. 2004, Cojocariu, Escher et al. 2005). Formaldehyde is degraded by exposure to light (t $_{1/2}$ = 1.6-6h) or oxidation (7-70h) (Monsanto 2015a), and thus is non-persistent. The availability of formaldehyde from degradation of dicamba is likely to be at extremely low concentration because of rapid internal plant metabolism and not likely to be high enough in concentration to cause any relevant human exposure (USDA-APHIS 2015a).

The EPA considers the direct and indirect impacts from herbicide use on human health and nontarget organisms as part of their regulatory decision. No additional cumulative impacts for use of dicamba and glufosinate herbicides on health and animal feed safety have been suggested by existing EPA herbicide assessments for these and glyphosate, when these herbicides are used according to requirements stated on EPA approved labels. As noted earlier, the presence of an herbicide resistance trait in a crop does not invariably result in use of a corresponding herbicide application and no adverse health consequences from interactions of these herbicides are known to APHIS. APHIS concludes that stacking MON 87419 with multiple existing herbicide resistance traits will not have impacts on Public Health or Animal Feed.

5.8 Cumulative Impacts: Socioeconomics

For an analysis of MON 87419 impacts on Socioeconomic resources, we tier the analysis to that presented in the Cumulative Impacts section within APHIS' EIS for dicamba crops (USDA-APHIS 2014c) and to APHIS' EIS for 2,4-D crops (USDA-APHIS 2014e).

An issue raised by some observers of the agricultural industry is the potential for additional economic costs to growers should resistant weeds arise following the use of new herbicides on herbicide resistant crops. Now that dicamba resistant soybean and cotton are nonregulated varieties, they will be grown for commercial production of these crops. Along with the possible availability of MON 87419 corn, these crops may potentially provide the source of new dicamba resistant weeds. APHIS has surveyed the impacts of the dicamba resistant weeds, and has considered the possible costs of control of these weeds in corn that may subsequently arise in

soybean or cotton, and also the converse, all of which are major rotation crops for one another in many regions of the country.

Potential Impacts to Corn as a Rotation Crop when Dicamba-resistant Weeds Arise in Soybean

Since corn production follows soybean production 67% of the time (Monsanto 2013a), the possibility of dicamba-resistant weeds arising in corn following production of dicamba resistant soybean may be a relevant concern. However, a large number of herbicide alternatives are available for weed control in corn. For burndown options in no-till corn, Penn State Extension (2013) lists14 herbicides used alone or in combinations with other herbicides. Various *Amaranthus* species can be problem weeds because of multiple herbicide resistances, and in Iowa, PPO-, HPPD-, ALS- and glyphosate-resistant weeds are known (Iowa-State-University 2014). For Preplant or PRE use, seven of ten of the Iowa-listed corn herbicides have good to excellent effectiveness on *Amaranthus* species, if resistant weeds are not present. For POST use, 20 of 23 of the herbicides have good to excellent effectiveness. These numerous herbicide options that exist for corn production would be capable of controlling problem weeds such as dicamba-resistant ones in corn.

Potential Impacts to Soybean as a Rotation Crop when Dicamba-resistant Weeds Arise in Corn

The potential exists for dicamba-resistant weeds to arise in MON 87419 corn and subsequently be found as problem weeds in soybean, a major rotation crop following corn in 64% of U.S. acreage. While such weeds may develop, certain consequences of the use of dicamba in corn may indirectly benefit soybean. Some of the *Amaranthus* spp. with resistance to various herbicide classes may be more controllable in corn (which already has more herbicide choices than soybean) particularly because MON 87419 allows a new option for extended POST treatment with dicamba in corn. Thus, fewer problem weeds may be found when acreage is rotated to soybean. Otherwise, in some states such as Iowa, only herbicide group 14 and glufosinate can be used POST treatment of soybean (Iowa-State-University 2015).

APHIS has also considered that dicamba may eventually become less of an option in nondicamba resistant field corn. To avoid applying dicamba in consecutive growing seasons, growers may not apply dicamba to non-dicamba-resistant corn, reserving dicamba use only for dicamba-resistant varieties. This choice may lengthen the useful life of dicamba when used on rotation crops such as soybean and cotton. The possible decline of dicamba's utility in nondicamba corn may be outweighed by the benefits of having new control measures for resistant weeds in corn, and new herbicide chemistry for weeds in major rotation crops such as soybean and cotton that will also be dicamba resistant.

Production of minor crops in ecoregions where soybean, cotton and corn are major parts of the landscape (i.e., those crops that represent a small proportion of total crop acreage) are not likely to be impacted by the potential development of new dicamba-resistant weeds. Alternative, non-dicamba herbicides or cultivation techniques are available and not cost-prohibitive (USDA-APHIS 2014d).

5.9 Cumulative Impacts Summary

Other dicamba resistant crops, both soybean and cotton, will be planted that may potentially have impacts on corn production. First, potential impacts were considered that might arise from new resistant weeds, and then the impacts of these dicamba resistant weeds on rotation crops with subsequent need for control of these weeds. Second, the magnitude of increases in herbicide use were considered that will follow as a direct consequence of planting the forthcoming dicamba resistant crops.

Potential Impacts of Increased Dicamba and Glufosinate Herbicide Usage

Use of non-glyphosate herbicides has been steadily increasing in cotton and soybean during the period from 2008 to present (Monsanto 2014) most likely in response to the need to control increasingly detected glyphosate-resistant weeds (USDA-APHIS 2014d). Likewise, dicamba use on corn is also rising (Monsanto 2015a), not necessarily for use to control glyphosate resistant weeds, but perhaps in recognition of the general efficacy of the herbicide. Increased dicamba use may have come in response to advice from weed scientists to help growers avert the development of herbicide-resistant weeds, because multiple modes of action are one effective strategy to deal with these. It is likely that because PRE and POST applications of dicamba (including applications with glyphosate) will control certain HR weeds (Monsanto 2013a), use of MON 87419 corn will allow for replacement of other herbicides, as Monsanto predicts for soybean herbicides as well. Under the Preferred Alternative the addition of POST-applied dicamba (along with residual herbicides and glyphosate) will provide complementary parts of a coordinated herbicide use strategy for MON 87419 corn (see Appendix A).

<u>Corn.</u> According to Monsanto estimates, usage of dicamba on current corn varieties is increasing, attaining to nearly 13% in 2013, and based on the recent data, the expected usage will reach 24% by the time that the trait is launched (Monsanto 2015a). Based on an expected market penetration of 89% (as with current glyphosate resistance traits) and then actual usage of dicamba on 40% of the MON 87419 corn, the dicamba would be used on 36% of all corn acres. For corn production, Monsanto projects that growers will use dicamba once a year, unless herbicide resistant weeds are present, and in that case, will use dicamba twice per year (Monsanto 2015a).

<u>Soybean.</u> Currently, dicamba is used on only about 1% of soybean acres, and on average, once a season on soybean as a burndown or pre-plant herbicide. On MON 87708 soybean, Monsanto projects dicamba is likely to be used twice a year on no-till and GR weed infested fields, or once on conventional fields. While dicamba use is expected to increase if Xtend soybean is determined as nonregulated, APHIS agrees with Monsanto analyses indicating that significant PRE non-glyphosate herbicide applications will likely be eliminated, as may more than half of POST non-glyphosate applications (Monsanto 2013a, USDA-APHIS 2014d).

<u>Cotton.</u> At present, dicamba is used on about 12% of cotton acres, mainly as a pre-plant application once per season. Monsanto projects that 39% of MON 88710 cotton acreage will receive one application, about one half will receive two applications of dicamba per season and the remaining 11%, three. Overall, the projected adoption of MON 88710 cotton will be about

50% of all cotton acres. The amount of dicamba that would be used on cotton may increase 14fold, but APHIS agrees with estimates that the application of other herbicides would likely decrease on 2.6 million acres of cotton.

Glufosinate use on corn has been minor, attaining a peak use of 5% of acres in 2005, but only 1% in 2014 (USDA-NASS 2014e). Use on soybean and cotton has been increasing in recent years as a result of growers choosing to plant glufosinate-resistant varieties because of the increased prevalence of glyphosate-resistant weeds. APHIS previously concluded that total U.S. glufosinate use on soybean and cotton is expected to decrease because dicamba is a more versatile and efficacious herbicide, and use of dicamba as a POST application will likely be preferred on MON 87708 soybean and MON 88701 cotton. APHIS' concludes that the use of glufosinate on MON 87419 corn will likely be low as well, being applied in a limited number of circumstances for the same reasons.

Glyphosate use is not expected to increase, since it is used on most corn and soybean acreage already and on at least 83% of cotton, and will continue to be used because of its efficacy in controlling many weed species. APHIS concludes that pressure to increase conventional tillage because of increasing weed resistance of some species to glyphosate, especially soybean and cotton can be alleviated with use of a new herbicide chemistry. However, growers will continue to rely on the existing effectiveness of glyphosate as a key herbicide.

EPA is expected to respond to a Monsanto request to amend the use of dicamba for MON 87419 corn. EPA must act in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Endangered Species Act (ESA) in their evaluation of the proposed change to the dicamba use pattern. FIFRA requires that EPA determines that a registered pesticide "will not cause unreasonable adverse effects on human health or the environment." The analysis of any potential for cumulative impacts of dicamba and glufosinate following increased use on corn, cotton and soybean is also made by the EPA as it assesses the new and existing use patterns and total volume applied of this herbicide. USDA provides a cumulative analysis based on existing EPA assessments of the possible impact of herbicides likely to be used with MON 87419, and with the expectation that the EPA permits and labeling requirements will be adequate for protection of the environment as well as compatible with human and animal safety. APHIS concludes that impacts from the Preferred Alternative are unlikely to be greater than those of the No Action Alternative.

Potential Impacts of Newly Developing Dicamba Resistant Weeds

As analyzed in the Cumulative Impacts Socioeconomic section and in APHIS' EIS for dicamba soybean and cotton, new dicamba resistant weeds may arise in minor crops grown in areas where corn is rotated with these crops. APHIS concluded that dicamba resistant weeds can be controlled by currently available alternative herbicides usable in these minor crops, and in some cases, can alternatively be controlled with typical patterns of cultivation. For major rotation crops, such as soybean, the availability of MON 87419 corn will help control problem weeds so that they are of decreased importance and quantity when they arise in major crops including soybean and cotton. For dicamba resistant weeds in corn, there exist many possible PRE and POST herbicides that can control these if they arise in corn.

APHIS concludes that besides providing improved control of GR resistant weeds in corn, the potential for dicamba resistant weeds developing in rotation crops is not likely to present insurmountable problems for growers. APHIS concludes that the Preferred Alternative will not present greater likelihood of new herbicide resistant weeds arising in the near term that may cause economic impacts than will new resistant weeds arising after other herbicide applications under the No Action Alternative. Weeds will continue to develop resistance under all circumstances of their use, whether on herbicide resistant crops or on any other targeted environment or plant.

6 THREATENED AND ENDANGERED SPECIES

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, in accordance with the ESA, protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

6.1 Requirements for Federal Agencies

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, USDA-APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to USDA-APHIS' regulatory authority and effects analysis for petitions for nonregulated status and developed a process for conducting an effects determination consistent with the PPA (Title IV of Public Law 106-224). USDA-APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

The USDA-APHIS regulatory authority over GE organisms under the PPA is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which USDA-APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR §340.1). After completing a PPRA, if APHIS determines that MON 87419 corn 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 analyzed the potential effects of MON 87419 corn on the environment including, including any potential effects to threatened and endangered species (TES) and critical habitat. As part of this process, APHIS thoroughly reviews GE product information and data related to the organism to inform the ESA effects analysis and, if necessary, the biological assessment. For each transgene/transgenic plant the following information, data, and questions are considered by APHIS:

- A review of the biology, taxonomy, and weediness potential 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 impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant); and
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.
- Any other information that may inform the potential for an organism to pose a plant pest risk.

USDA-APHIS met with USFWS officials on June 15, 2011, to discuss and clarify whether USDA-APHIS has any obligations under the ESA regarding analyzing the effects on TES that may occur from use of pesticides associated with GE crops. As a result of these joint discussions, USFWS and USDA-APHIS have agreed that it is not necessary for USDA-APHIS to perform an ESA effects analysis on pesticide use associated with GE crops because EPA has both regulatory authority over the labeling of pesticides under FIFRA, and the necessary technical expertise to assess pesticide effects on the environment. USDA-APHIS has no statutory authority to authorize or regulate the use of pesticides by corn growers. Under USDA-APHIS' current Part 340 regulations, USDA-APHIS only has the authority to regulate MON 87419 corn or any GE organism as long as USDA-APHIS believes they may pose a plant pest risk (7 CFR § 340.1). USDA-APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of pesticides on those organisms.

6.2 Potential Effects of MON 87419 Corn on TES

Based on the information submitted by the applicant and reviewed by APHIS, MON 87419 corn with the exception of tolerance to dicamba and glufosinate-ammonium, is agronomically, phenotypically, and biochemically comparable to conventional corn (Monsanto 2015a). Monsanto has presented results of agronomic field trials for MON 87419 corn. The results of these field trials demonstrate that there are no differences in agronomic practices between MON 87419 corn and conventional corn (Monsanto 2015a). The common agricultural practices that would be carried out in the cultivation of MON 87419 corn are not expected to deviate from current practices, including the use of EPA-registered pesticides. MON 87419 corn is not

expected to directly cause a measurable change in agricultural acreage or area devoted to corn in the U.S. (see Subsection 4.1.1, Acreage and Area of Corn Production). Because MON 87419 corn is agronomically and compositionally similar to other commercially available corn varieties (GE and non-GE), it is expected that MON 87419 corn will replace other similar varieties without expanding the acreage or area of corn production. Accordingly, the issues discussed herein focus on the potential environmental consequences of approval of the petition for nonregulated status of MON 87419 corn on TES species and critical habitat in the areas where corn is currently cultivated. Corn is cultivated in all 50 states within the U.S. APHIS obtained and reviewed the USFWS list of TES species (listed and proposed) for all 50 states from the USFWS Environmental Conservation Online System (USFWS 2015a).

For its analysis on TES plants and critical habitat, APHIS focused on the agronomic differences between the regulated article and corn 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 modified dicamba monooxygenase (DMO), and phosphinothricin acetyltransferase (PAT) proteins expressed in MON 87419 corn as a result of the transformation (Monsanto 2015a), and the ability of the plants to serve as a host for a TES.

6.3 Threatened and Endangered Plant Species and Critical Habitat

The agronomic data provided by Monsanto were used in the APHIS analysis of the weediness potential for MON 87419 corn, and further evaluated for the potential to impact TES and critical habitat. Agronomic studies conducted by Monsanto tested the hypothesis that the weediness potential of MON 87419 corn is unchanged with respect to conventional corn (Monsanto 2015a). No differences were detected between MON 87419 corn and conventional corn in growth, reproduction, or interactions with pests and diseases, other than the intended effect of tolerance to glyphosate and glufosinate-ammonium (Monsanto 2015a) (USDA-APHIS 2015a). Potential of corn weediness is low, due to domestication syndrome traits that generally lower overall fitness outside an agricultural environment (USDA-APHIS 2015a). Mature corn seeds have no innate dormancy, are sensitive to cold, and in colder climates, many do not survive in freezing winter conditions, although volunteers can be an issue in many locations. Corn has been cultivated around the globe without any report that it is a serious weed or that it forms persistent feral populations (USDA-APHIS 2015a). Corn cannot survive in the majority of the country without human intervention, and it is easily controlled if volunteers appear in subsequent crops. APHIS has concluded that the determination of nonregulated status of MON 87419 corn does not present a plant pest risk, does not present a risk of weediness, and does not present an increased risk of gene flow when compared to other currently cultivated corn varieties (USDA-APHIS 2015a).

APHIS evaluated the potential of MON 87419 corn to cross with a listed species. As discussed in Plant Communities (Subsections 2.3.3 and 4.3.2), the potential for gene movement between MON 87419 corn and related corn species is limited. There is a rare, sparsely dispersed feral population of teosinte, a relative of Z. mays, reported in Florida (USDA-APHIS 2015a), however, this plant is not listed as a TES (USFWS 2015b). Moreover, where corn x teosinte

hybrids have been identified in the field, they are found to exhibit low fitness and are unlikely to produce a second generation (USDA-APHIS 2015a). None of the relatives of corn are Federally listed (or proposed) as endangered or threatened species (USFWS 2015b). Accordingly, a determination of nonregulated status of MON 87419 corn will not result in movement of the inserted genetic material to any endangered or threatened species.

Based on agronomic field data, literature surveyed on corn weediness potential, and no sexually compatibility of any TES with corn, APHIS determined that MON 87419 corn will have no effect on threatened or endangered plant species or on critical habitat.

6.4 Threatened and Endangered Animal Species

Threatened and endangered animal species that may be exposed to the gene products from MON 87419 corn would be those TES that inhabit corn fields and feed on MON 87419 corn. As discussed further in Section 2.3.1 Affected Environment, Biological Resources, Animal Communities, cornfields are generally considered poor habitat for birds and mammals in comparison with uncultivated lands, but the use of cornfields by birds and mammals is not uncommon. Some birds and mammals use cornfields at various times throughout the corn production cycle for feeding and reproduction. Most birds and mammals that utilize cornfields are ground foraging omnivores that feed on corn seed, sprouting corn, and the corn remaining in the fields following harvest. Few if any TES are likely to use corn fields because they do not provide suitable habitat. For birds, only whooping crane (Grus americana), Mississippi sandhill crane (Grus canadensis pulla), piping plover (Charadrius melodus), interior least tern (Sterna antillarum), and Sprague's pipit (Anthus spragueii; a candidate species) occasionally feed in farmed sites (USFWS 2011). These bird species may visit corn fields during migration (Krapu, Brandt et al. 2004),(USFWS 2011). The whooping crane in particular spends the majority of its foraging time during migration in agricultural fields, although its diet during this time is not well understood (Canadian Wildlife Service and U.S. Fish and Wildlife Service 2007). As discussed thoroughly in Section 2.3.1, Affected Environment, Biological Resources, Animal Communities, many mammals may feed on corn; especially white tailed deer, raccoons, mice, and voles. As for listed species, the Louisiana black bear (Ursus americanus luteolus), occurring in Louisiana, Mississippi, and Texas (US Fish and Wildlife Service 2014), may occasionally forage on corn among other crops such as sugarcane, winter wheat, and soybean (MSU No Date).

APHIS considered the risks to threatened and endangered animals from consuming MON 87419 corn. Monsanto has presented information pertaining to the food and feed safety of MON 87419 corn, comparing the MON 87419 corn variety with conventional varieties currently grown. There are no toxins or allergens associated with this plant (Monsanto 2015a). Compositionally, MON 87419 corn was determined to be similar to conventional varieties. Compositional elements compared included moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, antinutrients, and secondary metabolites (Monsanto 2015a). Of 61 components statistically assessed, there were no significant differences in 60 components. Only one component (manganese in grain) showed a significant difference (p<0.05) between MON 87419 and the conventional control, but these levels were within reference values for soybean (Monsanto 2015a). This demonstrates that the introduced

genetic material in MON 87419 corn does not result in any significant compositional differences between MON 87419 corn and the non-transgenic hybrid.

The DMO enzyme present in MON 87419 corn shares sequence identity and many catalytic and domain structural similarities with a wide variety of oxygenases found in numerous species of microorganisms widely distributed and prevalent in the environment(Chakraborty J, D Ghosal et al. 2012), and with oxygenases such as pheophorbide A oxygenase also found in plants such as rice, corn, canola and pea (Rodoni S, W Mühlecker et al. 1997), (Yang M, E Wardzala et al. 2004) that are consumed in a variety of food and feed sources which have a history of safe human consumption, establishing that plants, animals and humans are extensively exposed to these types of enzymes.

A history of safe use demonstrate that the PAT proteins present in MON 87419 corn present no risk of harm to humans or livestock that consume corn products or to wildlife potentially exposed to MON 87419 corn. PAT proteins are exempt by EPA from the requirement for food or feed tolerances in all crops (40 CFR Part 180 1997) and have a history of safe use in numerous transgenic crop varieties that have been deregulated by the USDA APHIS and reviewed through the biotechnology consultation process with the U.S. Food and Drug Administration.

Monsanto conducted safety evaluations based on Codex Alimentarius Commission procedures to assess any potential adverse effects to humans or animals resulting from environmental releases and consumption of MON 87419 corn (Monsanto 2015a). These safety studies included evaluating protein structure and function, including homology searches of the amino acid sequences with comparison to all known allergens and toxins. MON 87419 corn protein was determined to have no amino acid sequence similar to known allergens, and lacked toxic potential to mammals (Monsanto 2015a). Monsanto has initiated a consultation with the FDA for the safety and nutritional assessment of food and feed derived from MON 87419 corn (Monsanto 2015a).

APHIS considered the possibility that MON 87419 corn could serve as a host plant for a threatened or endangered species (i.e., a listed insect or other organism that may use the corn plant to complete its lifecycle). A review of the species list reveals that there are no members of the genus *Zea* that serve as a host plant for any threatened or endangered species (USFWS 2015a).

Considering the compositional similarity between MON 87419 corn and other varieties currently grown and the lack of toxicity and allergenicity of DMO and PAT proteins, APHIS has concluded that exposure and consumption of MON 87419 corn would have no effect on threatened or endangered animal species.

6.5 Summary

After reviewing the possible effects of allowing the environmental release of MON 87419 corn, 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 MON 87419 corn on designated critical habitat and habitat proposed for designation, and could identify no differences from effects that would occur

from the production of other corn varieties. Corn is not considered a particularly competitive plant species and has been selected for domestication and cultivation under conditions not normally found in natural settings. Corn is not sexually compatible with, nor serves as a host species for, any listed species or species proposed for listing. Consumption of MON 87419 corn 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 MON 87419 corn, and the corresponding environmental release of this corn variety 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

7 CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS, AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

7.1 Executive Orders Related to Domestic Issues

The following executive orders require consideration of the potential impacts of the Federal action to various segments of the population.

- Executive Order (EO) 12898 (US-NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.
- EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks," acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

The No Action and Preferred Alternatives were analyzed with respect to EO 12898 and EO 13045. Neither alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

Available mammalian toxicity data associated with the DMO and PAT proteins establish the safety of MON 87419 corn and its products to humans, including minorities, low-income populations, and children who might be exposed to them through agricultural production and/or processing. Monsanto has been conducting safety assessments on mammals, and considering whether tested levels of these proteins represent any potential difference of exposure for human and animal nutrition. No additional safety precautions would need to be taken with nonregulated MON 87419 corn.

Potential for human toxicity has also been thoroughly assessed by the EPA in its development of pesticide labels for dicamba (US-EPA 2006, US-EPA 2009b) and glufosinate (US-EPA 2008c, US-EPA 2012b, US-EPA 2013d)Pesticide labels include use precautions and restrictions intended to protect workers and their families from exposures. APHIS assumes that growers will adhere to herbicide use precautions and restrictions. As discussed in Subsection 4.5, Human Health, the potential use of dicamba on MON 87419 corn at the proposed application rates would be no more than that currently approved for other nonregulated corn varieties and glufosinate on glufosinate resistant corn varieties and found by the EPA not to have adverse impacts to human health when used in accordance with label instructions. It is expected that the EPA and ERS

would monitor the use of MON 87419 corn to determine impacts on agricultural practices, such as chemical use, as they have done previously for herbicide-resistant products.

Based on these factors, a determination of nonregulated status of MON 87419 corn is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

Currently, the EPA is proposing to revise the existing Worker Protection Standard (WPS) at 40 CFR part 170 to reduce the incidence of occupational pesticide exposure and related illness among agricultural workers (workers) and pesticide handlers (handlers) covered by the rule. EPA is proposing to strengthen the protections provided to agricultural workers and handlers under the WPS by improving elements of the existing regulation, such as training, notification, communication materials, use of personal protective equipment, and decontamination supplies. The EPA expects the revisions, once final, to prevent unreasonable adverse effects from exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations, child farmworkers, and farmworker families; and the general public. This regulation, in combination with other components of EPA's pesticide regulatory program, is intended to prevent unreasonable adverse effects of pesticides among pesticide applicators, workers, handlers, the general public, and vulnerable groups, such as minority and low-income populations.

Further, the increased cost of seed for HR crops, such as MON 87419 corn, relative to conventional seeds is not a barrier to low income producers, since net returns for HR corn compared to non-HR were in the aggregate no different (Fernandez-Cornejo, Wechsler et al. 2014a). Regardless of seed premiums charged for GE seeds, such as MON 87419 corn, growers select GE HR seeds because they are associated with certain conveniences in the production of the crop, such as simplifying herbicide practices and gaining the ability to spray herbicides at over expanded times during the developmental stages of the crop.

The following executive order requires consideration of the potential impacts of the Federal action on tribal lands.

EO 13175 (US-NARA 2010), "Consultation and Coordination with Indian Tribal Governments", pledges agency communication and collaboration with tribal officials when proposed Federal actions have potential tribal implications.

A determination of nonregulated status of MON 87419 corn is not expected to adversely impact cultural resources on tribal properties. Prior to the publication of this EA, APHIS sent a letter to tribal leaders in the continental United States on August 15, 2015. This letter contained information regarding MON 87419 corn and asked tribal leaders to contact APHIS if they believed that there were potentially significant impacts to tribal leaders regarding MON 87419 corn along with one telephone contact. Any farming activities by farmers on tribal lands are only conducted at a tribe's request; thus, tribes have control over any potential conflict with cultural resources on tribal properties. Thus, the tribes would have control over any potential conflict with cultural resources on tribal properties. The proposed action, a determination of

nonregulated status of MON 87419 corn, is not expected to adversely impact cultural resources on tribal properties. The following executive order addresses Federal responsibilities regarding the introduction and effects of invasive species:

EO 1311 (US-NARA, 2010), "Invasive Species," states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts caused by invasive species.

Field corn is not listed in the U.S. as a noxious weed species by the Federal government, nor is it listed as an invasive species by major invasive plant data bases (USDA-NRCS 2010b). As discussed in Subsection 2.3.3, Gene Flow and Weediness, cultivated corn seed does not have the ability to survive in the wild and requires human involvement for seed dispersion (OECD 2003). In addition, corn seed lacks dormancy, will not produce a persistent seed bank, and is large and heavy and not easily dispersed by wind or water (Mallory-Smith and Zapiola 2008); therefore, the chance of corn becoming invasive as a result of seed dispersion is not likely. As discussed in Subsection 2.3.3, Gene Flow and Weediness, there are some populations of closely related and sexually compatible subspecies of Z. mays within the U.S.; however, these populations are small and are limited to collections in botanical gardens, some feral populations in some southeastern states, and small forage crops in some western states. While corn and various teosinte species are culturally and biologically similar, and gene exchange between these groups has been documented, no successful weedy species has evolved and the potential for gene flow between Z. mays and sexually compatible wild relatives is not considered a significant agricultural or environmental risk (US-EPA 2010c). As such, the potential for a weedy species of corn to develop as a result of outcrossing with MON 87419 corn is considered to be highly unlikely.

Volunteer corn can become extensive in crop fields, competing with desired crops for light, moisture, and nutrients (Stahl, Potter et al. 2013) There have been reports of some volunteer glyphosate-resistant corn occurring in fields, even if glyphosate-resistant corn was not planted the previous year, thought to be a result of transgene pollen movement (Beckie and Owen 2007). While pollen mediated gene transfer can occur, as discussed in Subsection 2.3.3, Gene Flow and Weediness, gene flow decreases rapidly with separation distance. Recommended methods to control volunteer corn include using a combination of techniques such as alternating the glyphosate-resistant corn with non-GE crops, or with GE crop cultivars having resistance to herbicides with different modes of action, and then application of that herbicide post-emergence.

Preplant tillage and in-crop cultivation can be used to eliminate volunteer corn. Others can successfully use graminicides (such as fluazifop and sethoxydim) to control herbicide-resistant corn in crops not susceptible to the herbicide dicamba and glufosinate (Monsanto 2015a). See Subsection 2.3.2, Plant Communities, for a more extensive discussion on controlling volunteer corn. Non-GE corn, as well as other GE herbicide-resistant corn varieties, is widely grown in the U.S. Based on historical experience with these varieties, and the data submitted by the developer and reviewed by APHIS, MON 87419 corn plants are similar in fitness characteristics to other corn varieties currently grown; hence, they are not expected to become weedy or invasive. (USDA-APHIS 2015a)

The following executive order requires the protection of migratory bird populations:

EO 13186 (US-NARA, 2010), "Responsibilities of Federal Agencies to Protect Migratory Birds," states that federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Migratory birds may be found in cornfields as corn is a nutrient-rich food source for fat synthesis prior to migration (Krapu, Brandt et al. 2004). Several species of birds are also known to forage for insects and seeds found in and adjacent to cornfields (Best, Whitmore et al. 1990, Tremblay, Mineau et al. 2001, Puckett, Brandle et al. 2009). As discussed in Subsection 4.4.1, Animal Communities, data submitted by the developer indicates that levels of key nutrients, minerals, anti-nutrients, and secondary metabolites in MON 87419 corn were similar to the comparators (e.g., NL6169 (HCL645×LH244).. As discussed in Subsection 2.5, Animal Feed, a final food consultation with the FDA for MON 87419 corn was initiated by Monsanto on May 22, 2015, to provide food and feed safety and compositional analysis of MON 87419 corn. Monsanto has not yet received a completed consultation letter from the FDA. It will be posted on the FDA website Final Biotechnology Consultations when complete. The food safety of the DMO protein conveying dicamba resistance was assessed by the FDA in an earlier food safety evaluation (BNF No. 125). FDA has also determined that the S. viridochromogenes-derived PAT protein has a history of safe use (Biotechnology Consultation; BNF 000139) and that the PAT protein is unlikely to be toxic or allergenic. The same *pat* gene has already been introduced into several food crops. Based on APHIS' assessment of MON 87419 corn, it is unlikely that a determination of nonregulated status would have a negative effect on migratory bird populations.

The environmental effects associated with dicamba are summarized in the EPA RED for the herbicide (US-EPA 2008c)Testing indicates that ecological toxicity of dicamba is no more than slightly toxic to small birds and exceeds the agency's LOC at the highest corn label rate (US-EPA 1993). The label rate for dicamba in MON 87419 corn is the same as that currently allowed for corn treatments and likewise, the glufosinate rate for MON 87419 corn is the same as that for other glufosinate-resistant corn varieties. Based on these factors, it is unlikely that a determination of nonregulated status MON 87419 corn would have a negative effect on migratory bird populations.

7.2 Executive Orders related to International Issues

EO 12114 (US-NARA, 2010), "Environmental Effects Abroad of Major Federal Actions" requires federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken.

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of MON 87419 corn. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new corn varieties internationally apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of MON 87419 corn subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in

accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC) (IPPC 2015) The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC 2015)The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). In April 2004, a standard for pest risk analysis of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the pest risk analysis for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The Cartagena Protocol on Biosafety is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which include those modified through biotechnology. The Protocol came into force on September 11, 2003, and 160 countries are Parties to it as of December 2010 (Convention-on-Biological-Diversity 2015) Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol and the required documentation. LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement.

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the OECD. NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO 2003).

APHIS also participates in the *North American Biotechnology Initiative*, a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico, and

Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including Argentina, Brazil, Japan, China, and Korea.

7.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the potential changes in corn production associated with a determination of nonregulated status to MON 87419 corn (see Subsections 4.2.1, Acreage and Area and 4.2.2 Agronomic Practices) and determined that the cultivation of MON 87419 corn would not lead to the increase in, or expand the area of, corn production that could impact water resources or air quality any differently than currently cultivated corn varieties. The herbicide resistance conferred by the genetic modification to MON 87419 corn is not expected to result in any changes in water usage for cultivation compared to current corn production. As discussed in Subsections 4.3.1, Water Resources, and 4.3.3, Air Quality, there are no expected significant negative impacts to water resources or air quality from potential use of dicamba, or glufosinate or other pesticides associated with MON 87419 corn production. Based on these analyses, APHIS concludes that a determination of nonregulated status for MON 87419 corn would comply with the CWA and the CAA.

7.4 Impacts on Unique Characteristics of Geographic Areas

A determination of nonregulated status of MON 87419 corn is not expected to impact unique characteristics of geographic areas such as parklands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

Monsanto has presented results of agronomic field trials for MON 87419 corn that demonstrate there are no differences in agronomic practices, between MON 87419 corn and currently available glyphosate-resistant corn varieties like the hybrid NL6169 (Monsanto 2015a). The common agricultural practices that would be carried out in the cultivation of MON 87419 corn is not expected to deviate from current practices, which include the use of EPA-registered pesticides. The product is expected to be cultivated by growers on agricultural land currently suitable for production of corn, and is not anticipated to expand the cultivation of corn to new, natural areas.

The Preferred Alternative does not propose major ground disturbances or new physical destruction or damage to property, or any alterations of property, wildlife habitat, or landscapes; moreover, no prescribed sale, lease, or transfer of ownership of any property is proposed. This action is limited to a determination of nonregulated status to MON 87419 corn. This action would not convert land use to non-agricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87419 corn, including the use of EPA-registered pesticides. The Applicant's adherence to EPA label use restrictions for all pesticides is expected to mitigate potential impacts to the human environment.

With regard to pesticide use, a determination of nonregulated status to MON 87419 corn may result in changes to the use of dicamba on corn. Timing of applications of dicamba will be similar to timing of applications to non-dicamba resistant corn (Monsanto 2015a). Rates for POST applications may be increased to 1#/acre, but maximum annual allowable applications will not be changed. Current rates for use of glufosinate on glufosinate resistant corn will remain the

same for MON 87419 corn. APHIS assumes that the growers will closely adhere to EPA label use restrictions for glufosinate (and glyphosate).

Potential indirect impacts to unique geographic areas have been considered by the EPA in its evaluation of dicamba. In 2006, the EPA considered human health risk and ecological risks associated with potential exposure to dicamba in a reregistration assessment (US-EPA 2006) and amended in 2009 (US-EPA 2009b). Potential impacts to unique geographic areas have been considered by the EPA in its evaluation of glufosinate as well (US-EPA 2008a). A review of the registration for glufosinate ammonium was begun by EPA on March 26, 2008 and published in the Federal Register (73 FR 16011) with public comments accepted subsequently. The docket is available at the regulations.gov website (EPA-HQ-OPP-2008-0190-0021). Subsequent publication of the draft human health and ecological risk assessments were made available by EPA on March 7, 2013 and opened for public comment for 60 days. The Agency conducted an ecological risk assessment, which includes a screening-level listed species assessment. EPA acknowledges that further refinements to the listed species assessment will be completed in future revisions and the public comment period was a request for information on specific areas that could reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment. If Monsanto should combine the trait for glyphosate resistance with MON 87419 (as it noted was likely), the EPA previously assessed and made a decision for registering use of glyphosate. In this assessment, EPA considered the human health and ecological risks associated with potential exposure to glyphosate in multiple pathways (US-EPA 1993, US-EPA 2009a). The assessment allowed characterization of potential risks for use of glyphosate and the potential for impacts on FWS-listed critical habitats and species.

Based on these findings, including the assumption that label use restrictions are in place to protect unique geographic areas and that those label use restrictions are adhered to, a determination of nonregulated status to MON 87419 corn is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

7.5 National Historic Preservation Act of 1966 as Amended

The National Historic Preservation Act (NHPA) of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

APHIS' proposed action, a determination of nonregulated status of MON 87419 corn is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

APHIS' Preferred Alternative would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it

likely cause any loss or destruction of scientific, cultural, or historical resources. This action is limited to a determination of non-regulated status of MON 87419 corn.

APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the corn production regions. The cultivation of MON 87419 corn is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

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9 APPENDIX A. DICAMBA CURRENT USE, ESTIMATED USE ON CORN

Dicamba was approved by the U.S. Environmental Protection Agency (EPA) for agricultural uses in 1967 and again in 2006 after ecological and human effects assessments (US-EPA 2006; US-EPA 2009b). Dicamba is formulated as a stand-alone herbicide product and marketed by several companies under various trade names-including Banvel®, Clarity®, Diablo®, Rifle®, and Sterling®-that are various salt formulations of dicamba. These dicamba products can be tank mixed with one or more active ingredients depending on the treated crop. For example, Clarity® can be tank mixed with over 75 herbicide products in labeled crops. Additionally, dicamba is formulated as a registered premix product with one or more other herbicide active ingredients such as 2,4-D, atrazine, diflufenzopyr, glyphosate, halosulfuron, metsulfuron, nicosulfuron, primisulfuron, rimsulfuron, and triasulfuron. Dicamba herbicide (e.g., Clarity® - diglycolamine [DGA] salt of dicamba) is currently labeled for weed control in soybean, corn, cotton, sorghum, wheat, barley, oats, millet, pasture, rangeland, asparagus, sugarcane, turf, grass grown for seed, conservation reserve programs, and fallow croplands (Monsanto 2013).

Table A-1 provides a summary of dicamba-treated acres and the amount of dicamba acid equivalent applied for all labeled crops each year from 1990 through 2011. Dicamba -treated acreage has ranged from 17.4 to 36.3 million acres during this period. Usage of dicamba peaked during the period of 1994 through 1997 (1994 being the peak year, with 36.3 million acres treated with 9.4 million pounds of dicamba). After 1994, the use of dicamba steadily declined through 2006 to 17.4 million treated acres with 2.7 million pounds used, due to the competitive market introductions of sulfonylurea herbicides (chlorsulfuron, metsulfuron-methyl, and thifensulfuron-methyl) in wheat, new broadleaf herbicide active ingredients in corn, and glyphosate-tolerant corn. However, dicamba-treated acres have increased by as much as 4.0 million acres since 2006. Most of the increase in dicamba-treated acres has occurred in fallow, pastureland, sorghum, and cotton (Monsanto 2013).

Table A-1. Dicamba-Treated Acres and Amounts Applied to Labeled Crops and Uses in 2011								
Сгор	Total Crop Acres (1,000)	Dicamba- Treated Acres (1,000)	% U.S. Dicamba – Treated Acres ⁽¹⁾	% Crop Acres Treated with Dicamba ⁽²⁾	Dicamba (a.e.) (1,000 lbs)			
Asparagus	29	2	0.01	NA	<1			
Barley	2,460	80	0.3	3.2	6			
Corn	92,146	10,880	43.0	10.3	1,531			
Cotton	14,533	1,416	5.6	9.6	364			
Fallow	14,899	3,966	15.7	18.7	597			
Pastureland	95,532	2,009	7.9	2.0	438			
Sorghum	5,315	1,316	5.2	18.1	206			
Soybean	74,835	872	3.4	1.2	233			
Sugarcane	825	163	0.6	15.6	36			
Wheat, all	53,223	4,532	17.9	7.4	418			
All other uses	NA	65	0.3	NA	9			
Total		25,301	100		3,837			

Source: (Monsanto 2013)

NA denotes not applicable.

- (1) The percentage of the total dicamba-treated acres for all labeled crops and uses.
- (2) Percentages calculated from crop acres treated with dicamba (data not shown).

Expected Use Rates of Dicamba with MON 87419 Commercialization

Monsanto in its Environmental Report states that concurrent with the USDA review of MON 87419, Monsanto will petition EPA to change the maximum use rate of dicamba in corn. If authorized by EPA, the anticipated use patterns for dicamba on MON 87419 would likely vary slightly across U.S. corn growing regions. Conventional and conservation tillage (reduced or notill) planted acres with hard-to-control weed species and no glyphosate-resistant weeds are expected to receive a single in-crop application per season of dicamba up to 0.5 lbs. a.e. per acre. All acres with glyphosate-resistant weed species present, regardless of tillage system, may receive up to two applications of dicamba (one preplant application at up to 0.5 lbs. a.e. per acre and one in-crop application at up to 0.5 lbs. a.e. per acre). These recommendations are the highest estimate of anticipated dicamba use associated with MON 87419 combined with glyphosate-tolerant corn. However, lower dicamba application amounts are expected and, in most cases, recommended."

As cited in the Cumulative Impacts section (Section 5.1, Assumptions Used for Cumulative Impacts Analysis) of this EA, an increasing rate of usage of dicamba herbicide on MON 87419 corn is anticipated within five years of nonregulated status through the attaining of full market saturation. This increase will be superimposed onto an increasing rate of dicamba use on corn, probably reaching 24% of acres before the time of commercialization. Monsanto notes, "if MON 87419 trait penetration reaches levels similar to that of Roundup Ready® Corn 2 technologies and other herbicide tolerant traits, MON 87419 would see approximately 89% trait penetration of total corn acres. Therefore, the total high-end projection of dicamba use over the top of MON 87419 based on internal market projections estimated to reach levels of 36% in the reasonably foreseeable future [e.g., Total corn acres \times 89% trait penetration \times 40% acres treated with dicamba = 36%]." An example is provided below in Table A-2. The usage pattern for dicamba in corn for MON 87419 is likely to be dependent on not only the type of tillage, but also the presence of either or both problem weeds or those with glyphosate resistance. The possible deployment of herbicides would likely be that listed in Table A-3 below, with some of the principle conditions that growers would consider when choosing weed management practices.

Table A-2. Estimated Total Corn Acres Likely to be Treated with Dicamba on MON 87419					
	U.S. Corn Acres	% of Total U.S. Corn Acres			
Total U.S. Corn Acres ⁽¹⁾	91,691,000	100%			
MON 87419 Potential Trait Acres ⁽²⁾	81,604,990	89%			
Estimated MON 87419 acres treated with dicamba ⁽³⁾	32,641,996	36%			

Source: (Monsanto 2015)

(1) Corn acres planted in 2014 in the U.S. (USDA-NASS 2014e)

(2) Monsanto high-end estimate based on MON 87419 trait penetration reaching levels of currently existing herbicide-tolerant trait.

(3) Based on internal high-end market projections of 40% of MON 87419 acres treated with dicamba

Table A-5. Anticipated weed Management Recommendations for MON 87419 Combined with							
Glyphosate-Tolerant Corn Systems ⁽¹⁾							
	Conven	tional Tillage	Conservation Tillage (No-till or Reduced				
Application			Т	ill)			
Timing	Hard To	GR Weeds and Hard	Hard To	GR Weeds and			
Ŭ	Control	to Control Weeds	Control Weeds	Hard to Control			
	Weeds ⁽²⁾		(2)	Weeds			
	Residual	Residual	Glyphosate	Glyphosate			
Preemergence		+	+	+			
(burndown,at		Dicamba	Residual	Residual			
planting)				+			
				Dicamba			
Postemergence	Glyphosate	Glyphosate	Glyphosate	Glyphosate			
	+	+	+	+			
	Dicamba	Dicamba	Dicamba	Dicamba			

Table A-3, Anticipated Weed Management Recommendations for MON 87419 Corn Combined with

Source: (Monsanto 2015)

1. The anticipated use patterns represent a high-end estimate for potential dicamba use associated with MON 87419 combined with glyphosate-tolerant corn. Actual weed control practices by growers will vary depending on the specific weed spectrum and agronomic situation of the individual corn field, specifically dicamba use could be lower especially for the preemergence applications. MON 87419 allows glufosinate as another viable option available to growers for in-crop post-emergence applications. 2. Hard to control weeds namely, morningglory species, hemp sesbania, prickly sida, and wild buckwheat.

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