The Monsanto Company Petition (14-213-01p) for Determination of Nonregulated Status for MON 87403 Maize

OECD Unique Identifier:
MON-87403-1

Environmental Assessment

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

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)
CH_4	methane
CO	carbon monoxide
CO_2	carbon dioxide
DNA	deoxyribonucleic acid
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

Acronyms and Abbreviations

OECD	Organization for Economic Cooperation and Development
PIP	plant incorporated protectants
PPRA	Plant Pest Risk Assessment
PPA	Plant Protection Act
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

The Monsanto Company of St. Louis, MO (henceforth referred to as Monsanto) submitted petition 14-213-01 to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in September 2014 seeking a determination of nonregulated status of corn[1] event MON 87403 that has increased ear biomass at the early reproductive stage compared to conventional control corn. MON 87403 corn is currently regulated under 7 CFR part 340. Interstate movements and field trials of MON 87403 corn have been conducted under notifications and permits acknowledged by APHIS since 2007. These field trials were conducted in diverse growing regions within the U.S., including in Arkansas, California, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, Ohio, Pennsylvania, South Dakota, Tennessee, Texas, Wisconsin, and Puerto Rico. Details regarding and data resulting from these field trials are described in the MON 87403 petition (Monsanto, 2014) and analyzed for plant pest risk in the APHIS preliminary Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2014a).

The petition stated that APHIS should not regulate MON 87403 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 87403 corn, any progeny derived from crosses between MON 87403 corn and conventional corn, including crosses of MON 87403 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 87403 corn is genetically engineered (GE) to have increased ear biomass at the early reproductive stage (R1) compared to conventional control corn. Ear biomass, which is set during early reproductive stages, is considered an important determinant of reproductive success and a larger ear biomass at early reproductive stages is associated with increased grain yield at harvest.

MON 87403 corn was produced by insertion of *ATHB17* gene from *Arabidopsis thaliana* through *Agrobacterium*-mediated transformation. ATHB17 is a member of the HD-Zip family of plant transcription factors, which are proteins that bind to specific deoxyribonucleic acid (DNA) sequences and regulate gene expression (Monsanto, 2014). HD-Zip proteins have been shown to play an important role in the modulation of plant growth and development. In MON 87403 corn, maize-specific splicing of the *ATHB17* transcript results in a truncated protein, ATHB17Δ113, which is missing the first 113 N-terminal amino acids that are expressed in *Arabidopsis thaliana*. The ATHB17Δ113 protein retains the ability to bind to target DNA sequences like the full-length protein, however, ATHB17Δ113 is unable to function as a transcriptional repressor because the protein lacks a functional repression domain (Monsanto, 2014). The ATHB17Δ113 protein likely

[1] Maize and corn will be used interchangeably throughout this document.

modulates HD-Zip regulated pathways in the ear, which leads to increased ear growth at the early reproductive stage (Monsanto, 2014; Rice *et al.*, 2014). Larger ear biomass at early reproductive stages is associated with increased grain yield at harvest. Consistent with this, multiple years of field testing showed that MON 87403 corn out-yielded its comparators at a majority of locations tested (Leibman *et al.*, 2014; Monsanto, 2014).

1.3 Coordinated Framework Review and Regulatory Review

Since 1986, the United States (U.S.) government has regulated GE organisms pursuant to a 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 Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). A summary of each role follows.

<u>USDA-APHIS</u>

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. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

An individual may petition the Agency for a determination that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, should no longer be regulated under the plant pest provisions of the PPA or the regulations at 7 CFR 340. Under § 340.6(c)(4) the petitioner is required to provide information related to plant pest risk that the Agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

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, 2011).

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 87403 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 determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS must respond to a September 2014 petition from the Monsanto Company requesting a determination of the regulated status of MON 87403 corn. APHIS has prepared this Environmental Assessment (EA) to consider the potential environmental impacts of an agency determination of nonregulated status consistent with 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 impacts on the quality of the human environment[2] that may result from a determination of nonregulated status of MON 87403 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 notice[3] in the

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[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

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 approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status raises substantive new issues:

<u>Approach 1: GE organisms that do not raise substantive new issues.</u>

This approach for public participation is followed when APHIS decides, based on the review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition, that the petition involves a GE organism that raises no substantive new issues, such as gene modifications that do not raise new biological, cultural, or ecological issues due to the nature of the modification or APHIS' familiarity with the recipient organism. Under this approach, APHIS will publish a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the EA, FONSI, and PPRA for a 30-day public review period.

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

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

A second approach for public participation will be 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 will solicit comments on its draft EA and preliminary PPRA for 30 days, as announced in a *Federal Register* notice. APHIS will review and evaluate 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 will either approve or deny 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* notice[4] published on March 6, 2012.

APHIS has decided this EA will follow Approach 2. The issues discussed in this EA were developed by considering the public concerns, including public input received from the *Federal Register* notice announcing the availability of the petition (first opportunity for public involvement) (80 F.R. 2674-2675), as well as issues raised in public comments submitted for other EAs of GE organisms, concerns raised in lawsuits, as well as those issues of concern that have been raised by various stakeholders. These issues, including those regarding the agricultural production of corn using various production methods and the environmental and food/feed safety of GE plants, were addressed to analyze the potential environmental impacts of MON 87403 corn.

The public comment period for MON 87403 corn petition closed on March 23, 2015. During the comment period, APHIS received a total of 20 public comments. The majority of the comments expressed a general dislike of the use of GE organisms. The issues that were raised in the public comments that were related to the MON 87403 corn petition included:

- Concerns that gene flow from GE crops to non-GE crops and wild/weedy/feral relatives may occur
- Potential economic impacts on the US corn market.
- Concerns that cross-pollination between GE and organic corn will affect sales for growers of these crops.
- Concerns about the impacts of GE crops on biodiversity.
- Concerns that MON 87403 corn will have altered agronomic practices, specifically increased fertilizer needs.
- Concerns that GE plants cause adverse health effects on humans and animals.
- Concerns about the safety of consuming foods containing GE organisms.

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

APHIS evaluated these issues and provided citations and has included a discussion of these issues in this EA where appropriate.

1.6 Issues Considered

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

Agricultural Production Considerations:
- Acreage and Range of Corn Production
- Agronomic Practices of Commercial Corn Production
- Organic Corn Production

Environmental Considerations:
- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Microorganisms
- Biodiversity

Human Health Considerations:
- Consumer Health
- Worker Safety

Livestock Health Considerations:
- Animal Feed/Livestock Health

Socioeconomic Considerations:
- Domestic Economic Environment
- Trade Economic Environment

2 AFFECTED ENVIRONMENT

The Affected Environment Section provides a discussion of the current conditions of those aspects of the human environment potentially impacted by a determination of nonregulated status of MON 87403 corn. For the purposes of this EA, those aspects of the human environment are: corn production practices, the physical environment, biological resources, public health, animal feed, and socioeconomic issues.

2.1 Agricultural Production of Corn

2.1.1 Acreage and Range of Corn Production

Corn (*Zea mays L.*), a member of the Maydeae grass family tribe, is an annual plant cultivated under a variety of production environments (Morris and Hill, 1998). In terms of acreage, corn ranks first among crops cultivated in the U.S. (USDA-NASS, 2014a). From 1994 to 2014, acreage planted with corn increased from approximately 78.9 million acres to about 90.9 million acres (Figure 1).

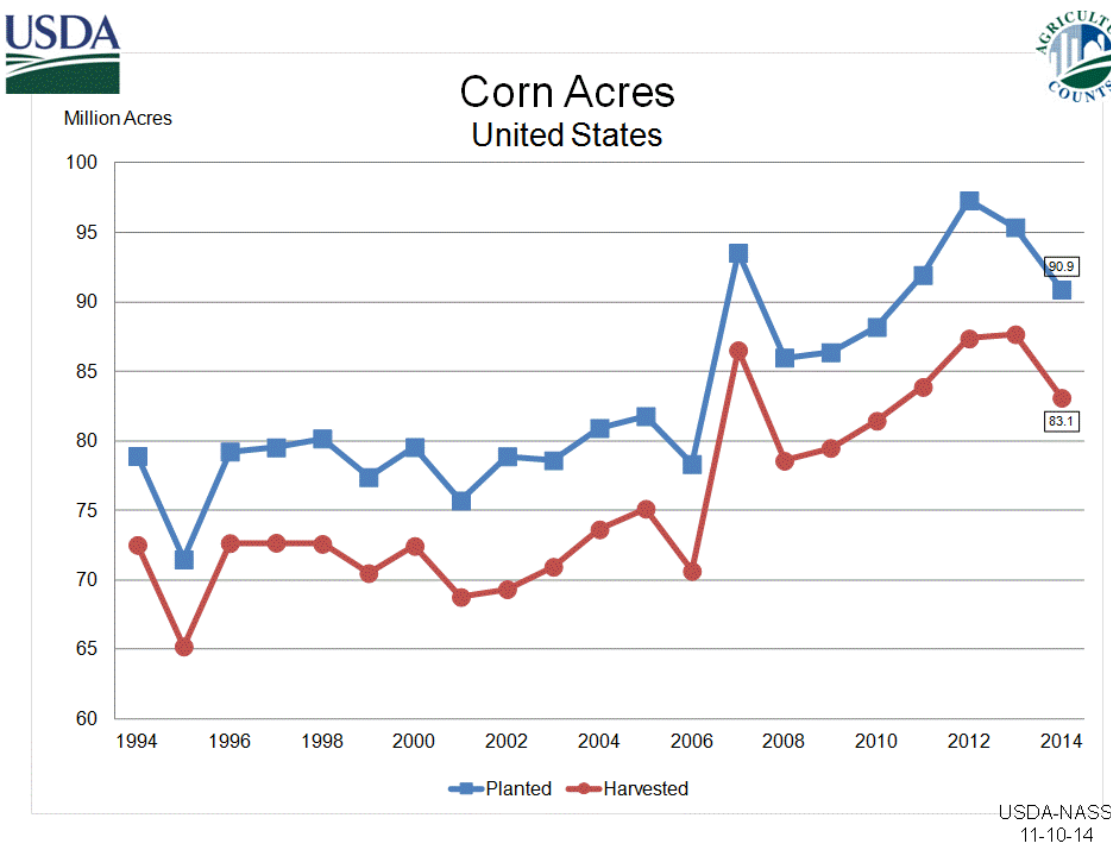

Figure 1. U.S. corn acreage by year, 1994 – 2014.
Source: (USDA-NASS, 2014b).

In the U.S., corn is generally cultivated where there is sufficient moisture (natural or irrigated) and frost-free days to reach maturity. The geographic range of corn production in the U.S. is primarily concentrated in the Corn Belt, an area that represents approximately 80 percent of annual U.S. corn production and includes Iowa, Illinois, Nebraska, and Minnesota, and parts of Indiana, South Dakota, Kansas, Ohio, Wisconsin, and Missouri (Figure 2) (USDA-NASS, 2014c). Iowa and Illinois, the two top corn-producing states, typically account for one-third of the total U.S. corn crop (USDA-NASS, 2014a).

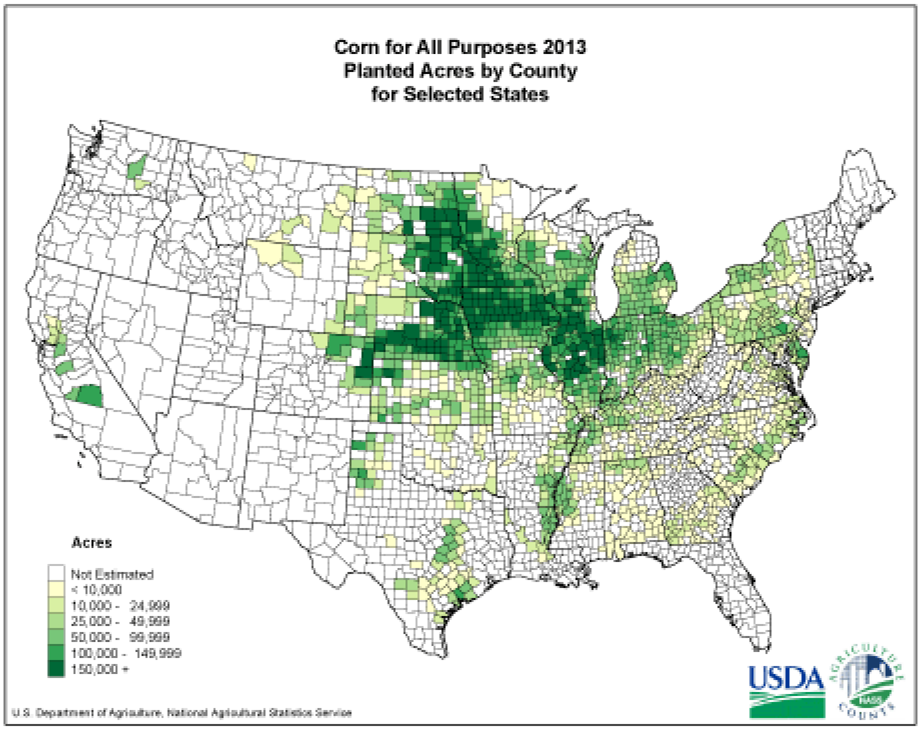

Figure 2. Corn planted acres by county.
Source: (USDA-NASS, 2014c).

Corn is the most widely cultivated feed grain in the U.S., accounting for approximately 96 percent of total value and production of feed grains (USDA-ERS, 2013a). In addition to demand as feed grain, strong demand for ethanol production has resulted in higher corn prices and corresponding incentives to growers to increase corn acreage (USDA-ERS, 2013a). In many cases, growers have increased corn acreage by adjusting corn plantings between corn, soybean, and other crops (USDA-ERS, 2013a).

In the 2014 production year, corn was cultivated in the U.S. on approximately 91.6 million acres, representing a 4 percent decrease in corn acreage from 2013 (USDA-NASS, 2014a). Over the last 20 years, U.S. production of field corn for grain increased from approximately 10 billion bushels in 1994 to approximately 14.4 billion bushels in 2014, and average annual yield increased approximately 20.1 percent from 138.6 bushels per acre in 1994 to 173.4 bushels per acre in 2014 (USDA-NASS, 2014f). As of 2014, it was estimated that approximately 13 percent of the crop was GE herbicide-resistant only, 4 percent was GE insect-resistant only, 76 percent was a stacked gene variety (likely both herbicide resistant and insect resistant), and 93 percent of the total U.S. corn crop was planted in some GE variety (USDA-NASS, 2014a).

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

Agronomic practices associated with corn production include several crop management systems that are available to producers. Conventional farming, as defined in this document, includes any farming system where synthetic pesticides or fertilizers may be used. This type of farming may vary between occasional use of synthetic pesticides and fertilizers to those that depend on regular inputs for successful crop production. 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 and are further discussed in Section 2.1.3.

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 U.S. More detailed information may be obtained by consulting the MON 87403 petition (Monsanto, 2014) or the APHIS preliminary PPRA for MON 87403 corn (USDA-APHIS, 2014a).

Tillage

Tillage may be used to prepare a seedbed, address soil compaction, incorporate fertilizers and herbicides, manage water movement both within and out of a production field, control weeds, and reduce the incidence of insect pests and plant disease (Hoeft *et al.*, 2000; Christensen, 2002; Fawcett and Towery, 2002; Tacker *et al.*, 2006; Givens *et al.*, 2009b; NRC, 2010). A variety of tillage systems accomplishes these goals. The choice to till is dependent upon a variety of factors, 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; and management and time constraints (Hoeft *et al.*, 2000).

Tillage systems are often defined by the amount of remaining in-field plant residue. Tillage may be characterized as conservation (> 30 percent plant residue), reduced (15-30 percent plant residue), or intensive (0-15 percent plant residue) (CTIC, 2008). Conservation tillage includes no-till, ridge till, or mulch till practices (CTIC, 2008). The resulting plant residues associated with conservation tillage may contribute to the preservation of soil moisture and reduction of wind and water-induced soil erosion (USDA-ERS, 1997; USDA-NRCS, 2005; Heatherly *et al.*, 2009). In general, despite variable adoption rates before 2001, use of conservation tillage, especially no-till practices, has increased in U.S. corn production at the expense of conventional tillage (Horowitz *et al.*, 2010). In 2010, the average residue remaining on the soil surface after planting corn was 34 percent and an average of 1.4 tillage operations per corn crop were conducted (USDA-ERS, 2010a). In 2010, 51 to 62 percent of planted corn acreage in 19 surveyed states was dedicated to no-till or minimum till systems (USDA-NASS, 2011; USDA-ERS, 2012).

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 *et al.*, 2009). This is especially a problem for growers who cultivate corn-to-corn with minimal tillage (Robertson *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 *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 *et al.*, 2009). Disease control measures include cultivation of resistant hybrids, crop rotation, and more careful balancing of conservation tillage with residue management (Robertson *et al.*, 2009).

Crop Rotation

Crop rotation is the successive planting of different crops on the same land in subsequent years. In order to sustain productivity of an agricultural field and/or maximize economic return, corn growers may implement various crop rotation strategies (Hoeft et al., 2000). Crop rotation may be used to optimize soil nutrition and fertility, reduce pathogen loads, control volunteers (carry over in successive years), and limit the potential for weeds to develop resistance to herbicides (Olson and Sander, 1988; IPM, 2004; 2007; USDA-ERS, 2013b). Since 1996, at least 84 percent of corn planted acreage has been in some form of rotation in the U.S. (USDA-ERS, 2013b). 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 et al., 2000; USDA-NRCS, 2010).

Crops used in rotation with corn vary regionally in the U.S. and may include alfalfa, oats, soybean, wheat, rye, and forage (Peel, 1998; IPM, 2004). In 2010, 71 percent of corn acreage in 19 surveyed states was under some form of rotation (USDA-NASS, 2011). Cropland used for corn and soybean production is nearly identical in many areas, where over 90 percent of the cropped area is planted in a two-year corn-soybean rotation (Hoeft *et al.*, 2000). Recently, there has been an increase in continuous corn rotations due to high corn commodity prices and the strong demand for corn grain (USDA-ERS, 2011b). 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).

Agronomic Inputs

Corn production typically involves the extensive use of agronomic inputs to maximize grain yield (Ritchie et al., 2008). Agronomic inputs include fertilizers to supplement available nutrients in the soil; pesticides to reduce pest plant, insect, and/or microbial populations; and water to ensure normal plant growth and development (Howell *et al.*, 1998; IPM, 2007).

Fertilization

Given the importance of nutrient availability to corn agronomic performance, fertilization is widely practiced in order to maximize corn grain yield (Hoeft *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 2010 survey of 19 corn producing states conducted by the USDA National Agricultural Statistics Service (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 140 pounds per acre (lb/Ac) (USDA-NASS, 2011). Phosphate was applied at an average rate of 60 lb/Ac to 78 percent of planted corn and potash was applied to 61 percent of planted acres at the rate of 79 lb/Ac. The survey found that sulfur was applied less extensively at a rate of 13 lb/Ac to 15 percent of acres planted to corn (USDA-NASS, 2011).

Pesticides

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 (USDA-NASS, 2011). Relative to herbicide use, fungicide and insecticide use is relatively minor (**Error! Reference source not found.**).

Corn diseases may also require management by some U.S. corn growers (Cartwright *et al.*, 2006). The most common corn pathogens are fungi. In 2010, fungicides were applied to 8.0 percent of acres planted to corn in 19 survey states (USDA-NASS, 2011). Also in 2010, the most commonly applied fungicides in U.S. corn were pryaclostrobin (382,000 lbs. covering 51 percent of corn acreage), propiconazole (174,000 lbs. covering 24 percent of corn acreage), and azoxystrobin (102,000 lbs. covering 14 percent of corn acres) (USDA-NASS, 2012b).

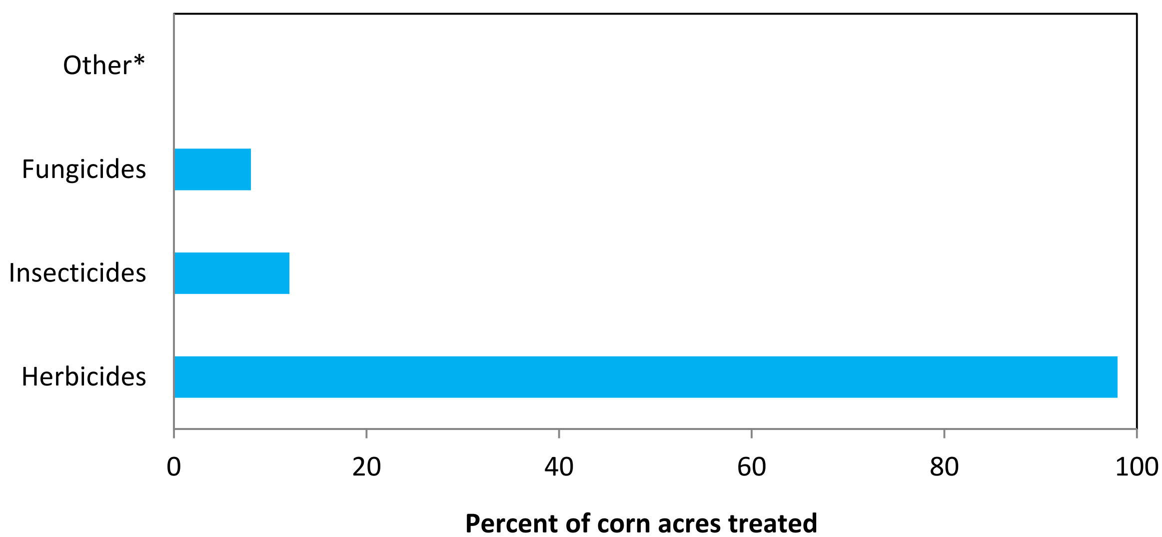

Figure 3. Percent of U.S. corn acreage treated with pesticides, 2010.
*Less than 0.5 percent. Source: (USDA-NASS, 2011).

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 *et al.*, 2000). In 2010, insecticide active ingredients were applied to approximately 12 percent of acres planted to corn in 19 surveyed states (USDA-NASS, 2011). Tefluthrin was the most commonly-applied insecticide on U.S. corn, with 242,000 lbs. used over 3 percent of corn acreage (USDA-NASS, 2012d). The next most-commonly used insecticides, each sprayed on approximately 2 percent of U.S. corn acreage, included bifenthrin (68,000 lbs.), cyfluthrin (15,000 lbs.), lambda-cyhalothrin (24,000 lbs.), and tebupirimphos (195,000 lbs.) (USDA-NASS, 2012d). Chlorpyrifos was the most abundant insecticide applied in terms of lbs. of active ingredient, though it was only applied on 1 percent of U.S. corn acreage (USDA-NASS, 2012d) (Table 1).

Table 1. Corn: total insecticide applications, 2010[1].

Insecticide	Area Applied (percent)	Applications (number)	Rate per Application (pounds per acre)	Rate per Crop Year (pounds per acre)	Total Applied (thousand pounds)
Bifenthrin	2	1	0.039	0.039	68
Chlorpyrifos	1	1	0.857	0.875	478
Cyfluthrin	2	1	0.008	0.008	15
Dimethoate	<0.5	1.1	0.481	0.513	52
Lambda-cyhalothrin	2	1	0.016	0.017	24
Permethrin	1	1	0.13	0.13	72
Propargite	<0.5	1	1.721	1.721	109
Spiromesifen	<0.5	1.2	0.194	0.224	59
Tebupirimphos	2	1	0.111	0.111	195
Tefluthrin	3	1	0.115	0.116	242
Terbufos	<0.5	1	0.722	0.722	137
Zeta-cypermethrin	<0.5	1	0.007	0.007	2

Source: (USDA-NASS, 2011).
[1]Program states surveyed – Colorado, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, New York, North Carolina, North Dakota, Ohio, Pennsylvania, South Dakota, Texas, and Wisconsin.

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). The management of weeds in corn production generally involves the application of herbicides. Individual weed species, including glyphosate-resistant species, are discussed in Section 2.3.2. In 2010, 98 percent of all U.S. corn acreage was subject to herbicide application[5] (USDA-NASS, 2011). The most commonly applied herbicide in corn was glyphosate, with approximately 58,000,000 lbs. applied over 66 percent of all planted corn acreage in 2010 (USDA-NASS, 2011). 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 (**Error! Reference source not found.**). 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 *et al.*, 2012). Other commonly applied herbicides on U.S. corn acres include atrazine (51,000,000 lbs. covering 61 percent of corn acreage) and acetochlor (28,000,000 lbs. covering 25 percent of corn acreage) (USDA-NASS, 2011) and are summarized in Table 2.

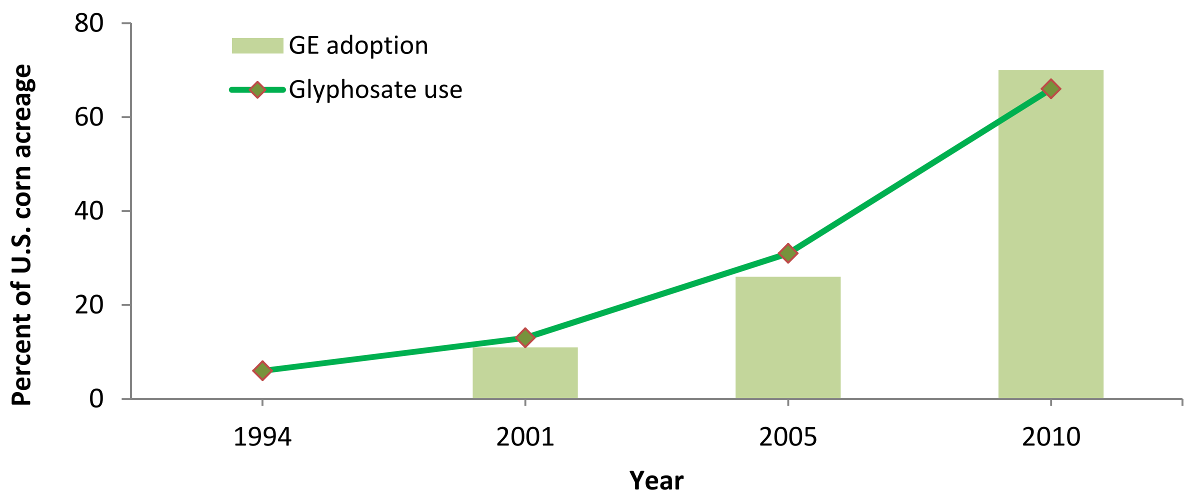

Figure 4. Adoption of GE corn varieties with at least one herbicide-resistant trait and glyphosate in U.S. corn production, 1994 – 2010.
Source: USDA-ERS (2011a) and USDA-NASS (1996; 2002; 2006; 2011).

[5] As measured by total pounds of active ingredient per acre (lbs. ai/acre) applied.

Table 2. Corn: total herbicide applications, 2010[1].

Herbicide	Area Applied (percent)	Applica-tions (number)	Rate per Applica--tion (pounds per acre)	Rate per Crop Year (pounds per acre)	Total Applied (thou-sand pounds)
2,4-D, 2-EHE	4	1.1	0.39	0.437	1,479
2,4-D, BEE	1	1.6	0.308	0.504	286
2,4-D, dimeth. salt	4	1	0.366	0.379	1,147
2,4-D, isoprop. salt	<0.5	1.3	0.069	0.086	24
Acetochlor	25	1	1.392	1.398	27,921
Acifluorfen, sodium	1	1	0.043	0.043	21
Alachlor	<0.5	1	1.225	1.232	412
Atrazine	61	1.1	0.946	1.034	51,129
Carfentrazone-ethyl	<0.5	1	0.011	0.011	4
Clopyralid	5	1	0.088	0.089	328
Dicamba	<0.5	1	0.126	0.126	23
Dicamba, digly. salt	1	1	0.194	0.194	134
Dicamba, dimet. salt	2	1.2	0.209	0.249	480
Dicamba, pot. salt	<0.5	1.7	0.246	0.145	116
Dicamba, sodium salt	3	1.1	0.088	0.097	245
Diflufenzopyr-sodium	2	1.1	0.035	0.04	79
Dimethenamid	1	1	0.986	1.02	520
Dimethenamid-P	5	1.1	0.593	0.63	2,603
Flufenacet	1	1	0.329	0.329	280
Flumetsulam	5	1	0.033	0.034	125
Foramsulfuron	<0.5	1	0.029	0.029	9
Glufosinate-Ammonium	2	1	0.296	0.298	515
Glyphosate	7	1.1	0.843	0.931	5,255
Glyphosate amm. salt	1	1.1	0.09	0.095	46
Glyphosate iso. salt	66	1.3	0.824	1.065	57,536
Glyphosate pot. salt	2	1.3	0.936	1.204	1,522
Halosulfuron	<0.5	1.1	0.017	0.019	3

Herbicide	Area Applied (percent)	Applica-tions (number)	Rate per Applica--tion (pounds per acre)	Rate per Crop Year (pounds per acre)	Total Applied (thou-sand pounds)
Isoxaflutole	7	1	0.065	0.066	399
Linuron	<0.5	1	1.356	1.356	206
MCPA, sodium slat	<0.5	1	0.427	0.427	173
Mesotrione	17	1	0.116	0.121	1,693
Metolaclor	1	1	1.234	1.276	546
Nicosulfuron	2	1	0.016	0.016	29
Paraquat	1	1.1	0.641	0.699	468
Pendimethalin	1	1	1.154	1.154	1,385
Primisulfuron	<0.5	1	0.023	0.023	5
Prosulfuron	<0.5	1	0.008	0.008	1
Rimsulfuron	4	1.1	0.014	0.015	48
S-Metolachlor	23	1.1	1.076	1.159	21,831
Saflufenacil	1	1.3	0.059	0.075	40
Simazine	2	1.1	1.038	1.169	2,196
Tembotrione	2	1	0.064	0.064	103
Thiencarbazone-methy	2	1	0.025	0.025	41
Thifensulfuron	2	1	0.007	0.007	11
Topramezone	1	1	0.014	0.014	9
Trifluralin	1	1	0.608	0.608	257

Source: (USDA-NASS, 2012c).

[1] Program states surveyed - Colorado, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, New York, North Carolina, North Dakota, Ohio, Pennsylvania, South Dakota, Texas, and Wisconsin.

2.1.3 Organic Corn Production

In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2014). 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, 2014).

The use of biotechnology such as that used to produce MON 87403 corn is an excluded method under the National Organic Program [7 C.F.R. § 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, 2014). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouce, 2006; USDA-AMS, 2014).

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 for organic growers reported in 2008 (Kuepper, 2002; Coulter *et al.*, 2010; Roth, 2011). 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 U.S. (Table 3). 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. maize production (USDA-NASS, 2012a).

Table 3: Certified organic corn acreage by state with more than 1,000 acres of certified land in 2007 and 2008.

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

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

2.2 Physical Environment

2.2.1 Soil Quality

Cultivation of corn directly impacts the qualitative and quantitative attributes of soil. In particular, soil quality of agricultural land is directly affected by tillage strategies. As discussed in Subsection 2.1.2, tillage is an integral part of production agriculture (Givens *et al.*, 2009a). Conservation practices, including conservation tillage, have been developed to reduce field tillage and thus reduce the corresponding soil erosion and runoff (USDA-NRCS, 2006c). As conservation tillage practices have been adopted, there is a corresponding benefit to soil. In addition to an increase in soil organic matter, total soil loss on highly erodible croplands and non-highly erodible croplands decreased from 462 million tons per year to 281 million tons per year or by 39.2 percent from 1982 to 2003 (USDA-NRCS, 2006b). The reduction in soil erosion is also attributed to a decrease in the number of acres of highly erodible cropland being cultivated (USDA-NRCS, 2006b). Corn tillage strategies may directly and indirectly affect soil quality.

Similarly, use of equipment and vehicles, especially when deployed in wet fields can cause soil compaction. In turn, degradation of soil structure and composition may lead to decreased water retention, a decrease in soil carbon aggregation and net positive carbon sequestration, and increased emission of radiatively-active gases that contribute to the greenhouse effect (e.g., carbon dioxide (CO_2) and nitrous oxide (N_2O)) (Lal and Bruce, 1999; US-EPA, 2010). Additionally, land that is prone to degradation is also more likely to negatively affect water resource quality and communities of organisms dependent on those water resources.

2.2.2 Water Resources

Corn cultivation may directly affect water resources through the use of local water sources or indirectly through associated management practices, including tillage and the use of agricultural inputs. Corn is a water sensitive crop with a low tolerance for drought. Corn requires approximately 4,000 gallons through the growing season to produce one bushel of grain (NCGA, 2007). This demand is met by a combination of natural rainfall, stored soil moisture from precipitation before the growing season, and supplemental irrigation during the growing season (Neild and Newman, 1990). Groundwater is the major source for irrigation, used on almost 90 percent of irrigated corn acreage in the U.S. (Christensen, 2002). In 2007, 13.0 million U.S. corn acres were irrigated, representing 15 percent of all corn acres harvested for grain (USDA, 2008).

Agricultural non-point source (NPS) pollution is the primary source of discharge pollutants to groundwater (aquifers), flowing water (permanent or intermittent streams), or semi-static water (ponds, lakes, and reservoirs) (Ramanarayanan *et al.*, 2005). NPS pollutants generally include agricultural pollutants released by soil erosion including sediments, fertilizers, and pesticides (US-EPA, 2005). Although meteorological (e.g., precipitation, temperature), morphological (e.g., land use, soil type), and environmental fate drivers affect water quality, anthropogenic practices (product use and management) are the most relevant, as this driver is generally the only one under direct grower control (Ramanarayanan *et al.*, 2005).

In particular, tillage practices often have a strong, indirect effect on water quality through the improvement of soil quality and water retention characteristics. Based on the states' water quality reports to EPA, which EPA makes available through its National Assessment Database, pesticides in general and herbicides in particular are a relatively minor contributor to impairment of surface water in the U.S., compared to sedimentation/siltation (US-EPA, 2015). Increase in sediment loads to surface waters can directly affect fish, aquatic invertebrates, and other wildlife maintenance and survival. It also reduces the amount of light penetration in water which directly affects aquatic plants. Indirectly, soil erosion-mediated sedimentation can increase fertilizer runoff, facilitating higher water turbidity, algal blooms, and oxygen depletion (US-EPA, 2005).

2.2.3 Air Quality

The Clean Air Act (CAA) requires the maintenance of National Ambient Air Quality Standards (NAAQS). The NAAQS, developed by the EPA to protect public health, establishes limits for six criteria pollutants: ozone, nitrogen dioxide, carbon monoxide (CO), sulfur dioxide, lead, and Particulate Matter (US-EPA, 2014b). The CAA requires states to achieve and maintain the NAAQS within their borders. Each state may adopt requirements stricter than those of the national standard and each is required by the EPA to develop a State Implementation Plan that contains strategies to achieve and maintain the national standard of air quality within the state. Areas that violate air quality standards are designated as non-attainment areas for the relevant pollutants, whereas areas that comply with air quality standards are designated as attainment areas (US-EPA, 2014a).

Agriculture, including land-use changes for farming, is estimated to be responsible for eight percent of all human-induced greenhouse gases (GHG) emissions in the U.S. (Massey and Ulmer, 2010; US-EPA, 2013). Many agricultural activities affect air quality, including smoke from agricultural burning, machinery, suspended soil particulates associated with tillage, pesticide drift from spraying, and N_2O emissions from the use of nitrogen fertilizer (Hoeft *et al.*, 2000; Aneja *et al.*, 2009; US-EPA, 2013). Emissions released from agricultural equipment (e.g., irrigation pumps and tractors) include CO, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (US-EPA, 2013). Tillage contributes to the release of GHGs because of the loss of CO_2 to the atmosphere and the exposure and oxidation of soil organic matter (Baker *et al.*, 2005). Pesticides may volatilize after application to soil or plant surfaces and move following wind erosion (Vogel *et al.*, 2008).

2.2.4 Climate Change

Climate change represents a statistical change in global climate conditions, including shifts in the frequency of extreme weather (Cook *et al.*, 2008; Karl *et al.*, 2008). Agriculture is recognized as a direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) source of GHG emissions. The EPA has identified CO_2, methane (CH_4), and N_2O as the most important GHGs contributing to climate change. Greenhouse gases, including CO_2, CH_4, and N_2O, function as retainers of solar radiation (Aneja *et al.*, 2009). The U.S. agricultural sector is identified as the second largest contributor to GHG emissions (US-EPA, 2013).

Agriculture may also affect dynamic soil processes through tillage and other land management practices (Smith and Conen, 2004). In general, conservation tillage strategies are associated with more stable and increased carbon sequestration due to a net reduction in CO_2 emissions (Lal and Bruce, 1999; West and Marland, 2002). Recent literature, however, suggests that the relationship between conservation tillage and increased carbon sequestration require more study, as soil depth level and seasonal sampling bias may inadvertently affect measurements (Potter *et al.*, 1998; Baker *et al.*, 2007). Additionally, the relationship between different GHG emissions, such as CO_2 and N_2O may influence paradigms related to tillage strategies and global climate change (Gregorich *et al.*, 2005). For example, increased N_2O emissions as a result of conservation tillage strategies may offset any gains achieved through increased carbon sequestration. Like the relationship between conservation tillage strategies and carbon sequestration, a broad generalization regarding the impact of tillage strategy and N_2O emissions is difficult, as numerous factors influence soil nitrification cycles, including geographic location, soil structure, moisture, and farm-level management practices (Gregorich *et al.*, 2005; Grandy *et al.*, 2006; Rochette *et al.*, 2008).

Although agriculture may influence climate change, climate change, in turn, may also affect agriculture (CCSP, 2008). These potential impacts on the agro-environment and individual crops may be direct, including changing patterns in precipitation, temperature, and duration of growing season, or may cause indirect impacts influencing weed and pest pressure (Rosenzweig *et al.*, 2001; Schmidhuber and Tubiello, 2007). The potential impact of climate change on agricultural output has been examined in some detail. A recent Intergovernmental Panel on Climate Change (IPCC) forecast (IPCC, 2007) for aggregate North American impacts on agriculture from climate change actually projects yield increases of 5 to 20 percent for this century. However, this positive impact will not be observed across all growing regions. The IPCC report notes that certain regions of the U.S. will be more heavily impacted because water resources may be substantially reduced. While agricultural impacts on existing crops may be substantial, North American production is expected to adapt with improved cultivars and responsive farm management (IPCC, 2007).

2.3 Biological Resources

2.3.1 Animal Communities

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. As such, the types and numbers of animal species found in cornfields are less diverse by comparison. Cornfields, however, have been shown to provide both food and cover for wildlife, including a variety of birds as well as large and small mammals (Vercauteren and Hygnstrom, 1993; Palmer *et al.*, 2011). Some birds and mammals use cornfields at various times throughout the corn production cycle for feeding and reproduction, but most of the birds and mammals that use cornfields are ground-foraging omnivores that feed on the corn remaining in the fields following harvest (Vercauteren and Hygnstrom, 1993; Krapu *et al.*, 2004; Palmer *et al.*, 2011).

The types and numbers of birds that inhabit cornfields vary regionally and seasonally but for the most part the numbers are low (Patterson and Best, 1996). Most of the birds that utilize cornfields are ground foraging omnivores that feed on corn seed, sprouting corn, and the corn remaining in the fields following harvest. Bird species commonly observed foraging on corn include, among others, blackbirds (e.g., red-winged blackbirds (*Agelaius phoeniceus*)), horned larks (*Eremophila alpestris*), brown-headed cowbirds (*Molothrus ater*), and vesper sparrows (*Pooecetes gramineus*), ring-necked pheasant (*Phasianus colchicus*), wild turkey (*Meleagris gallopavo),* American crow (*Corvus brachyrhynchos*), and various grouse and quail species (Dolbeer, 1990; Best and Gionfriddo, 1991; Patterson and Best, 1996; Mullen, 2011). Following harvest, it is also common to find large flocks of Canada geese (*Branta canadensis*), Snow geese (*Chen caerulescens*), Sandhill cranes (*Grus canadensis*), and other migratory waterfowl foraging in cornfields (Sparling and Krapu, 1994; Taft and Elphick, 2007; Sherfy *et al.*, 2011). Waste corn is a nutrient-rich source for fat synthesis prior to migration many waterfowl species (Krapu *et al.*, 2004). Specific bird species can act as beneficial or detrimental members in the agro-environment. For example, red-winged blackbird are often initially attracted to corn fields to feed on insect pests, but then also feed on the corn. Studies have shown that red-winged blackbirds can destroy more than 360,000 tons of field corn and substantial amounts of sweet corn annually (Dolbeer, 1990).

A variety of mammals may also be attracted to corn fields for forage at various stages of production. White-tailed deer (*Odocoileus virginianus*), raccoons (*Procyon lotor*), feral pigs (*Sus scrofa*), and woodchuck (*Marmota monax*) all cause damage to corn fields, decreasing profitability and grain yield (Vercauteren and Hygnstrom, 1993; Neilsen, 1995; Beasley and Rhodes, 2008; Koele, 2008). The most notable of these is the white-tailed deer which often inhabit woodlots adjacent to cornfields and frequent these fields for both food and cover especially in mid-summer (Vercauteren and Hygnstrom, 1993). White-tailed deer are considered responsible for more corn damage than any other wildlife species (Stewart *et al.*, 2007a). In addition to deer, significant damage to corn by raccoons also has been documented (DeVault *et al.*, 2007; Beasley and Rhodes, 2008). 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).

As with these larger mammals, small mammal use of cornfields for shelter and forage also varies regionally and includes deer mouse (*Peromyscus maniculatus*), meadow voles (*Microtus pennsylvanicus)*, house mouse (*Mus musculus*), and the thirteen-lined ground squirrel (*Ictidomys tridecemlineatus)* which may cause damage to corn fields (Stallman and Best, 1996; Sterner *et al.*, 2003; Smith, 2005).

Throughout the U.S., the deer mouse is the most common small mammal in almost any agricultural field (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. Deer mice have 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 for its role in the consumption of weeds, this vole can be a significant agricultural pest where abundant when it consumes seeds in the field (Smith, 2005). The 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, although it also can be considered beneficial when eating pest insects, such as grasshoppers and cutworms (Smith, 2005).

Invertebrates, such as corn earworm (*Helicoverpa zea*), European corn borer (*Ostrinia nubilalis*), fall armyworm (*Spodoptera frugiperda*), and the corn rootworm (*Diabrotica* spp.) are important insect pests in corn. Many insects are also considered beneficial (Hoeft *et al.*, 2000). Insects such as the lady beetle (Coccinellidae), big-eyed bug (Lygaeidae), ground beetle (Carabidae), lacewing (Chrysopidae), damsel bug (Nabidae), insidious flower bug/minute pirate bug (Anthocoridae), assassin bug (Triatominae), spined soldier bug (Pentatomidae), and parasitoid wasps (e.g., Braconidae, Ichneumonidae), as well as a multitude of spiders (Order: Araneae) may benefit corn production by preying on plant pests (Stewart *et al.*, 2007b; 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; ATTRA, n.d.).

2.3.2 Plant Communities

The vegetative landscape surrounding a corn field varies with region; corn fields may be surrounded by other field crops, or by woodlands, hedgerows, rangelands, pasture, and grassland areas. These plant communities may occur naturally or they may be managed for the control of soil and wind erosion.

Corn is generally cultivated as a monoculture. Members of the plant community that adversely affect corn cultivation may be characterized as weeds. Weeds are perceived to be the most substantial pest problem in corn production, negatively affecting yield through competition for light, nutrients, and moisture (Aref and Pike, 1998). Common corn field weeds include giant foxtail (*Setaria faberi*), giant ragweed (*Ambrosia trifida*), velvetleaf (*Abutilon theophrasti*), common cocklebur (*Xanthium strumarium*), Canada thistle *(Cirsium arvense),* common lambsquarters *(Chenopodium album),* and Johnsongrass *(Sorghum halepense*) (Childs, 2011).

Weed control is an important aspect of corn cultivation. Weed control typically involves an integrated approach that includes timely applications of herbicide, crop rotation, weed surveillance, and weed monitoring (Farnham, 2001; IPM, 2004; 2007; Hartzler, 2008). Weed populations can change in response to agricultural management decisions, including decisions related to herbicide application. Weeds can develop resistance to herbicides for the following reasons: frequent exposure to a single herbicide, the spread of naturally-resistant weeds seeds, and the out-crossing of herbicide-resistant genes from plants (GE or naturally-resistant plants) to weedy relatives. The development of herbicide resistance in weeds is not unique to any one country, particular herbicide, or crop variety. In the U.S., 76 weed species have developed resistance to at least 20 herbicide sites of action (Heap, 2014). Glyphosate-resistant weeds have grown increasingly problematic in U.S. corn fields. Currently, nine glyphosate-resistant weeds have been identified in U.S. corn fields (Figure 5), inhabiting approximately two million acres of farmland in the U.S. (Hubbard, 2008).

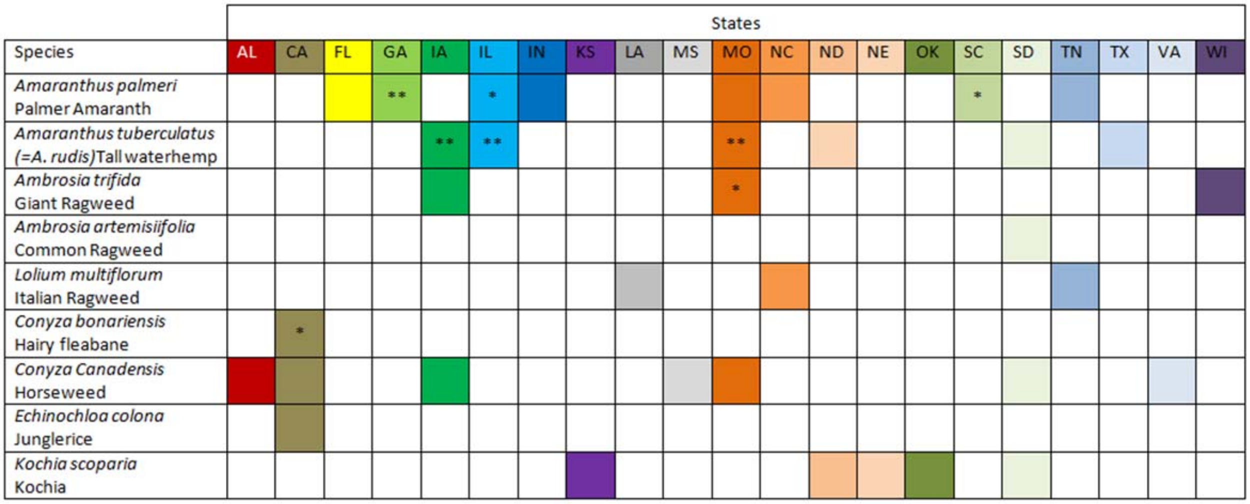

Figure 5. Glyphosate-resistant weeds in the U.S. corn fields.
Note that presence of a population is unrelated to prevalence. * indicates at least one population in that states possesses resistance to glyphosate and another herbicide. **indicates at least one population in that state possesses resistance to glyphosate and two or more other herbicides. Source: (Heap, 2014).

2.3.3 Gene Flow and Weediness

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 space, 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; or weather conditions, including temperature, wind, and humidity (Zapiola *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; or environmental conditions and events (Zapiola *et al.*, 2008).

Corn is self-compatible and wind-pollinated. Unlike other grass species in the U.S. (Wipff and Fricker, 2002; Watrud *et al.*, 2004), there are no native plant species that can be pollinated by corn pollen without human intervention (e.g., chromosome doubling or embryo rescue) (Mangelsdorf, 1974; Russell and Hallauer, 1980; Galinat, 1988). However, teosinte (wild progenitor of corn) can sometimes be found as introduced populations in botanical gardens (USDA-NRCS, 2011a; 2011b). 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. The potential for outcrossing or gene escape is defined as the ability of the gene to escape to wild corn relatives and APHIS's preliminary Plant Pest Risk Assessment determined that there is no likely route for commercial corn gene flow (USDA-APHIS, 2014a).

2.3.4 Microorganisms

Microorganisms in the field may mediate both negative and positive outcomes. Diseases that afflict corn with significant potential for economic loss include fungal corn rusts, corn leaf blights, ear smuts, ear and kernel rot fungi, and corn mosaic viruses (Cartwright *et al.*, 2006).

Additionally, soil microorganisms may play a key role in dynamic biochemical soil processes, including soil structure formation, decomposition of organic matter, toxin removal, and nutrient cycling (Garbeva *et al.*, 2004). They may also suppress soil-borne plant diseases and promote plant growth (Doran *et al.*, 1996). The main factors affecting microbial population size and diversity include soil type, plant type, and agricultural management practices (Garbeva *et al.*, 2004). Microbial diversity in the rhizosphere may be extensive and differ from the microbial community in the bulk soil (Garbeva *et al.*, 2004).

2.3.5 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). Biodiversity provides valuable genetic resources for crop improvement and also provides other functions beyond 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 degree of biodiversity in an agroecosystem depends on four primary characteristics: 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, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas. Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest limit the diversity of plants and animals (Lovett *et al.*, 2003). Biodiversity can be maintained or reintroduced into agroecosystems through the use of woodlots, fencerows, hedgerows, and wetlands. Agronomic practices that may be employed to support biodiversity include intercropping (the planting of two or more crops simultaneously to occupy the same field), agroforestry, 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.), and hedgerows and windbreaks (Altieri, 1999). Integrated pest management strategies include several practices that increase biodiversity such as retaining small, diverse natural plant refuges and minimal management of field borders.

Since biological diversity can be defined and measured in many ways, APHIS considers determining the level of biological diversity in any crop to be complex and difficult to achieve concurrence. Another complication with biodiversity studies is separating expected impacts from indirect impacts. For example, reductions of biological control organisms are seen in some Bt-expressing GE crops, but are caused by reduction of the pest host population following transgenic pesticide expression in the transformed crop plant.

2.4 Human Health

Public health concerns surrounding GE corn primarily involve the human consumption of GE corn products. Additionally, corn growers and farm workers may also be exposed to GE corn and its respective cultivation practices.

Under the FFDCA, it is the responsibility of food manufacturers to ensure that the products they market are safe and properly labeled. Food derived from GE corn must be in compliance with all applicable legal and regulatory requirements. GE organisms for food may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far, all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA.

Worker hazards in farming are common to all types of agricultural production, and include hazards of equipment and plant materials. Pesticide application represents the primary exposure route to pesticides for farm workers (USDA-NASS, 2007). The EPA pesticide registration process, however, involves the design of use restrictions that if followed have been determined to be protective of worker health.

EPA’s Worker Protection Standard (WPS) (40 CFR part 170) was published in 1992 requiring actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers (US-EPA - 40 CFR 170, 1992). The WPS offers protection to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.

Worker safety precautions and use restrictions are clearly noted on pesticide registration labels. Growers are required to use pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. These restrictions provide instructions as to the appropriate levels of personal protection required for agricultural workers to use herbicides. These may include instructions on personal protective equipment, specific handling requirements, and field reentry procedures (Monsanto, 2007). 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); therefore, it is expected that herbicide use would be consistent with the EPA-approved labels.

2.5 Animal Feed

Animal feed concerns by some for GE corn primarily involve the animal consumption of GE corn products. Approximately 55 to 60 percent of the corn produced in the U.S. is used for livestock (KyCGA, 2011). Corn comprises approximately 95 percent of the total feed grain production and use, with sorghum, barley, and oats making up the remainder (USDA-ERS, 2013a). Corn is valuable as a feed because of its composition, including key nutrients, anti-nutrients and secondary metabolites, protein content, fiber, among others (OECD, 2002). Corn grain is used for feed for beef cattle, poultry, hogs and dairy cattle, with beef cattle consuming the largest volume harvested (NCGA, 2009).

Similar to the regulatory control for direct 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 are designed to protect human health. To help ensure compliance, a voluntary consultation process with the FDA may be implemented before release of commodity products with origins from GE plants as animal feed into the market.

2.6 Socioeconomic

Corn is produced for food and feed commodities as well as industrial uses (USDA-ERS, 2013a). Corn is the most widely cultivated feed grain in the U.S., accounting for more than 95 percent of total value and production of feed grains (James, 2009; USDA-ERS, 2013a). Corn is grown in all 48 of the continental U.S. states with production concentrated in the Corn Belt.

2.6.1 Domestic Economic Environment

In the 2014 production year, corn was cultivated in the U.S. on over 91.6 million acres, a 4 percent decrease in corn acreage from 2013 (USDA-NASS, 2014a). In 2013, corn for silage was harvested on approximately 6.2 million acres, or approximately 7 percent of the total corn production area for that year (USDA-NASS, 2014a). GE herbicide-resistant corn comprised approximately 13 percent of the total corn acreage in the U.S., insect-resistant varieties comprised 4 percent of the acreage, and stacked varieties comprising 76 percent of the total corn acreage in 2014 (USDA-NASS, 2014a).

Corn production in 2012 was estimated at 10.8 billion bushels, valued at an estimated $6.89 per bushel (total value of $74.3 billion). In 2013, production was estimated at 13.9 billion bushels valued at $4.50 per bushel (total value of $62.7 billion) (USDA-NASS, 2014d; 2014e). The value of the corn crop varies over time in response to market conditions.

Corn processed for human consumption and industrial uses accounts for about one-third of domestic corn utilization (USDA-ERS, 2013a). During processing, corn is either wet or dry milled depending on the desired end products: wet millers process corn into high-fructose corn syrup, glucose and dextrose, starch, corn oil, beverage alcohol, industrial alcohol, and fuel ethanol. Dry millers process corn into flakes for cereal, corn flour, corn grits, corn meal, and brewers grits for beer production (USDA-ERS, 2013a). The cultivation of corn for animal feed varies depending upon the demand in the livestock industry (USDA-ERS, 2013a). The production of ethanol generates several economically valuable co-products for animal feed, including distillers dried grains with solubles (USDA-ERS, 2013a). Each 56 pound bushel of corn used in dry mill ethanol production generates approximately 17.4 pounds of distillers dried grains with solubles which are fed to livestock (USDA-ERS, 2013a).

Corn production has increased over time, as higher yields followed improvements in technology (seed varieties, pesticides, and machinery) and in production practices (reduced tillage, irrigation, crop rotations, and pest management systems) (USDA-ERS, 2013a). Corn acreage in the U.S. increased during the second half of the 2000s. The establishment of a bioethanol industry using corn as a feed stock has been identified as one of the key elements in the increase in acreage devoted to corn, with approximately 40 percent of the corn harvest now dedicated to corn-based biofuel production (Swoboda, 2009; Wilson, 2011; USDA-OCE, 2012b; USDA-NASS, 2014a). Corn acreage is expected to increase, as farmers convert other crops, especially soybean, to corn cultivation to support both ethanol production and export demand (USDA-ERS, 2013a). Over the past 20 years, the acreage per corn farm has increased, and the number of large corn farms (more than 500 acres) has increased, while the number of small corn farms (less than 500 acres) has declined (USDA-ERS, 2013a).

The costs for GE corn seed are higher than that for non-GE seed. Growers pay a premium for GE seed, with growers in 2008 paying as much as 50 percent more for GE corn seed than conventional seed (NRC, 2010). This seed premium includes a technology fee for the cultivation of the seed (NRC, 2010). This seed premium also reflects the increased value offered by the seed. Despite the increased cost of GE corn seed, total farm operating costs are often offset by improved grain yield and reduced corn production costs. These production cost reductions may be a result of increased yields, reductions in average herbicide and pesticide use per field, and corresponding reductions in tillage and associated field cultivation costs (Carpenter *et al.*, 2002). Fuels and chemicals are each estimated to comprise approximately 5 percent of farm production expenses (USDA-NASS, 2009). Other benefits to the grower from adoption of GE corn have included (Carpenter *et al.*, 2002; Brookes and Barfoot, 2012):

- Increased management flexibility and convenience arising from the ease of use of broad-spectrum herbicides like glyphosate;
- A decrease in "knock-back" of the crop associated with post-emergent applications of herbicides on the herbicide-resistant crop;
- Reduced harvesting costs;
- Higher quality harvested crop;
- An improvement in soil quality as growers reduce quantities of soil-applied herbicides and increase limited tillage; and
- Overall improvements in human health costs associated with use of less toxic products.

2.6.2 Trade Economic Environment

Corn is the dominant feed grain traded internationally (James, 2009; USDA-OCE, 2011; 2012b; 2012a). In 2011/2012, the U.S. produced approximately 36 percent of the total world supply of corn (USDA-OCE, 2012b). Corn is cultivated worldwide, including Argentina, South Africa, Brazil, Canada, China, and former Soviet Union States, including the Ukraine (USDA-OCE, 2012b).

As the global demand for meat increases along with the commercialization of livestock feeding, international trade in livestock feed and protein meal supplements also increases, particularly in those countries where climate and geography restrict local production of these feed materials (USDA-FAS, 2008; USDA-OCE, 2012a). Egypt, the EU, Japan, Mexico, Southeast Asia, and South Korea are net importers of corn (USDA-OCE, 2012b). Approximately 15 to 20 percent of U.S. corn production is exported, with the volume of exports projected to decrease in the next several years in the face of increased competition from lower-priced South American supplies (USDA-OCE, 2012b). China is projected to become a net importer of corn to support its expanding livestock and industrial sectors (James, 2009; USDA-OCE, 2011; 2012b; 2012a). The increase in China's imports are expected to account for one-third of the growth in world corn trade (USDA-OCE, 2012b). In addition to corn as grain, corn gluten feed is a major product in international trade in feed ingredients. Large volumes of U.S. corn gluten feed are exported to the EU (CRA, 2006).

Identity protection is important in international trade. Some countries are sensitive to the importation of GE crops, and some have yet to approve importation of GE corn varieties (ICTSD, 2005). For certain key export markets, such as Canada, Japan, Mexico, Taiwan, South Korea and China, developers will prepare regulatory submissions prior to the commercial launch of the product (Monsanto, 2014). Specific end uses also may require identity protection throughout the export supply chain. For example, value enhanced specialty high-oil corn is an important part of the U.S. export market as a replacement for animal fats in feed rations (USDA-FAS, 2004). Identity protection in international commodity movement increases the costs, as well as the premiums paid (USDA-FAS, 2004).

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of MON 87403 corn. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87403 corn is unlikely to pose a plant pest risk. Based on its preliminary PPRA (USDA-APHIS, 2014a), APHIS has concluded that MON 87403 corn is unlikely to pose a plant pest risk. Therefore, APHIS must determine that MON 87403 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 87403 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 87403 corn and progeny derived from MON 87403 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 87403 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 87403 corn.

This alternative is not the Preferred Alternative because APHIS has concluded through a preliminary PPRA that MON 87403 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2014a). 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 87403 Corn is No Longer a Regulated Article

Under this alternative, MON 87403 corn and progeny derived from it would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87403 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2014a). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87403 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 87403 corn is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87403 corn is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to MON 87403 corn and progeny derived from this event if the developer decides to commercialize MON 87403 corn.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 87403 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 87403 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 Prohibit Any MON 87403 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 87403 corn, including denying any permits associated with field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MON 87403 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2014a).

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 preliminary PPRA (USDA-APHIS, 2014a) and the scientific data evaluated therein, APHIS concluded that MON 87403 corn is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87403 corn.

3.3.2 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that MON 87403 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2014a), it would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340to consider approval of the petition only in part.

3.3.3 Isolation Distance between MON 87403 and Non-GE Corn 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 87403 corn from non-GE corn production. However, because APHIS has concluded that MON 87403 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2014a), 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 87403 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' preliminary PPRA for MON 87403 corn, there are no geographic differences associated with any identifiable plant pest risks for MON 87403 corn (USDA-APHIS, 2014a). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87403 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 87403 corn or to use isolation distances and other management practices to minimize gene movement between corn fields. Information to assist growers in making informed management decisions for MON 87403 corn is available from the Association of Official Seed Certifying Agencies (AOSCA) (AOSCA, 2010).

3.3.4 Requirements of Testing for MON 87403 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 87403 corn does not pose a plant pest risk (USDA-APHIS, 2014a), 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 87403 corn would not meet APHIS' purpose and need to respond appropriately to the petition.

3.4 Comparison of Alternatives

Table 4 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 4. 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, 2014a)
Management Practices		
Acreage and Areas of Corn Production	Corn acreage declined 4 percent from 2013 to 91.6 million acres in 2014. Corn acreage is likely to remain steady for the foreseeable future.	Unchanged from No Action Alternative
Agronomic Practices	General cropping practices such as crop rotation, tillage, pest and disease management, and crop nutrition will remain the same as current practices for commercial corn production.	Unchanged from No Action Alternative
Organic Corn Production	Specialty crop growers employ practices and standards for production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops. Certified organic corn acreage is a small but increasing percentage of overall corn production. Organic corn production consisted of about 0.21 percent of total U.S. corn production.	Unchanged from No Action Alternative
Physical Environment		
Soil Quality	Agronomic practices such as crop type, tillage, and pest management can affect soil quality. Growers currently use best management practices to address their specific needs in producing corn.	Unchanged from No Action Alternative
Water Resources	The primary cause of agricultural non-point source pollution is	Unchanged from No Action

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as crop nutrient management, pest management, and conservation buffers help protect water quality from agricultural runoff.	Alternative
Air Quality	Agricultural activities such as burning, tilling, harvesting, spraying pesticides, and fertilizing, including the emissions from farm equipment, can directly affect air quality. Aerial application of herbicides may impact air quality from drift, diffusion, and volatilization of the chemicals, as well as motor vehicle emissions from airplanes or helicopters.	Unchanged from No Action Alternative
Climate Change	Agriculture-related activities are recognized as both direct sources of GHG (e.g., exhaust from motorized equipment) and indirect sources (e.g., soil disturbance from tillage, fertilizer production).	Unchanged from No Action Alternative
Biological Resources		
Animal Communities	Corn fields may be host to many animal and insect species. Many of these animals are typically considered pests and may be controlled by the use of integrated pest management strategies.	Unchanged from the No Action Alternative
Plant Communities	corn fields can be bordered by other agricultural fields, woodlands, or pasture and grasslands. The most agronomically important	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	members of a surrounding plant community are those that behave as weeds. Corn growers use production practices to manage weeds in and around fields.	
Gene Flow and Weediness	Cultivated corn varieties can cross pollinate. Growers use various production practices to limit undesired cross pollination.	Unchanged from No Action Alternative
Microorganisms	Microorganisms are affected by tillage, agronomic activity and pesticides.	Unchanged from No Action Alternative
Biodiversity	The biological diversity in corn fields is highly managed and may be lower than in surrounding habitats.	Unchanged from No Action Alternative
Human and Animal Health		
Risk to Human Health	Corn has a known history of safe consumption and use. The EPA's WPS; (40 CFR part 170.1, *Scope and Purpose*) requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.	Unchanged from No Action Alternative. A comprehensive assessment of MON 87403 corn demonstrated that the proteins in MON 87403 corn are nontoxic to mammals and unlikely to be a food allergen and that MON 87403 corn is compositionally equivalent to commercially available corn varieties. Agricultural production of MON 87403 corn does not require any changes to the agronomic practices currently used for conventional corn. Therefore, worker safety issues associated with the agricultural production of MON 87403 corn would remain the same as those under the No Action Alternative
Risk to Animal Feed	Corn is a major feed protein for animal nutrition. It is the responsibility of food and feed	Unchanged from No Action Alternative. A compositional analysis concluded that MON

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	manufacturers to ensure that the products they market are safe and labeled properly.	87403 corn is compositionally equivalent to conventional corn varieties.
Socioeconomic		
Domestic Economic Environment	Corn is the primary U.S. crop. The majority of corn (61.7 percent) is grown for animal feed. Corn production in 2013 had an estimated value of $62.7 billion. Crop values vary over time in response to market conditions.	Unchanged from No Action Alternative. Corn will continue to be the primary crop produced in the U.S. Adopters of MON 87403 corn may realize some financial benefits as a result of the potential increased yield opportunity.
Trade Economic Environment	In 2013, the U.S. exported approximately $9.3 billion in corn products. The U.S. produced approximately 36% of the work corn supply. The U.S. is the leading exporter of corn. U.S. corn and corn products will continue to play a role in global corn production, and the U.S. will continue to be a supplier in the international market.	The trade economic impacts associated with a determination of nonregulated status of MON 87403 corn are anticipated to be similar to the No Action Alternative because Monsanto does not intend to globally launch MON 87403 corn until the proper regulatory approvals have been obtained.
Other Regulatory Approvals		
U.S.	Monsanto indicated that they submitted a safety and nutritional assessment of food and feed derived from MON 87403 corn to FDA in October 2014 (Monsanto, 2015). FDA is presently evaluating the submission.	Monsanto indicated that they submitted a safety and nutritional assessment of food and feed derived from MON 87403 corn to FDA in October 2014 (Monsanto, 2015). FDA is presently evaluating the submission.
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

4 ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, the No Action Alternative and the Preferred Alternative, of a determination of nonregulated status of MON 87403 corn. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON 87403 corn are described in detail throughout this section. A cumulative impact analysis is presented for each potentially affected environmental concern. Certain aspects of MON 87403 corn and its cultivation would be no different between the two alternatives as described below.

4.1 Scope of Analysis

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON 87403 corn are described in detail throughout this section. An impact would be any change, positive or negative, from the existing (baseline) conditions of the affected environment (described for each resource area in Section 2.0). Impacts may be categorized as direct, indirect, or cumulative. A direct impact is an effect that results solely from a proposed action without intermediate steps or processes. Examples include soil disturbance, air emissions, and water use. An indirect impact may be an effect that is related to but removed from a proposed action by an intermediate step or process. Examples include surface water quality changes resulting from soil erosion due to increased tillage, and worker safety impacts resulting from an increase in herbicide use.

A cumulative impacts analysis is also included for each environmental issue. A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Examples include breeding MON 87403 corn with other deregulated events. If there are no direct or indirect impacts identified for a resource area, then there are no cumulative impacts. Cumulative impacts are discussed in Section 5.

Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential impacts. Certain aspects of this product and its cultivation will not differ between the alternatives.

Although the preferred alternative would allow for new plantings of MON 87403 corn to occur anywhere in the U.S., 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.

Monsanto's studies demonstrate that agronomic characteristics and cultivation practices required for MON 87403 corn are essentially indistinguishable from practices used to grow other corn varieties (Leibman *et al.*, 2014; Monsanto, 2014; USDA-APHIS, 2014a). BMPs currently employed for corn production are not expected to change if MON 87403 corn is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the PPA. Accordingly, the potential impacts on agricultural production of MON 87403 corn resulting from management practices associated with the No Action and Preferred Alternative are the same.

4.2.1 Acreage and Range of Corn Production

No Action Alternative: Acreage and Range 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, 2014a). 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 *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, 2014a). 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).

Preferred Alternative: Acreage and Range of Corn Production

A determination of nonregulated status of MON 87403 corn under the Preferred Alternative is unlikely to substantially impact projected trends in U.S. corn acreage (USDA-ERS, 2011b) relative to the No Action Alternative. Monsanto studies have demonstrated that with the exception of the increased ear biomass trait, MON 87403 corn is phenotypically and agronomically equivalent to other commercially cultivated corn (Leibman *et al.*, 2014; Monsanto, 2014). There are no changes in agronomic characteristics in MON 87403 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, 2014a). As previously discussed, both external market forces (i.e., increasing 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 87403 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.

Like many domesticated crop plants, corn is not likely to persist and spread outside the agricultural environment (USDA-APHIS, 2014a). In the U.S., the range of corn cultivation is generally limited by moisture and frost-free days to reach maturity. Field study of MON 87403 corn indicates that the agronomic performance of it and conventional corn is not substantially different (Monsanto, 2014; USDA-APHIS, 2014a). Accordingly, the range of cultivation for MON 87403 corn is similar to conventional corn, as neither its introduced trait nor agronomic performance suggests an increased capacity to grow on land not already managed for agricultural production. Under the Preferred Alternative, MON 87403 corn is likely to be cultivated on managed land, thus limiting its range to that of currently available corn varieties and ensure that land planted to MON 87403 corn will be derived from existing corn acreage or acreage previously used for agricultural crop commodities (USDA-ERS, 2011b; USDA-OCE, 2012a).

The Preferred Alternative, a determination of nonregulated status of MON 87403 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

Corn is the largest crop cultivated in the U.S., in terms of planted acreage and net value (USDA-NASS, 2014f). As discussed in Subsection 2.1.2 – Agronomic Practices, corn cultivation requires substantial management considerations regarding tillage, rotation, and agronomic inputs. Decisions concerning corn agronomic practices are dependent on grower want and need, and ultimately reflective of external factors including geography, weed and disease pressure, economics of management of yield, and production system (rotation) flexibility (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2008). Choice of management practice often dictates marketability of a corn product, with certain agricultural consumer sectors stipulating requirements and restrictions regarding corn production methods.

<u>No Action Alternative: Tillage</u>

Under the No Action Alternative, U.S. corn growers are likely to continue using conservation tillage practices as currently practiced. Prior to planting corn, U.S. growers may use conservation, reduced, or conventional tillage to prepare the soil for planting. Recent data from USDA-ERS and the USDA Agricultural Resource Management Survey (ARMS) indicates that conservation tillage, has slightly increased in U.S. corn production at the expense of conventional tillage activities between 1998 and 2010 (Figure 6). During this time period, no-till activities in U.S. corn production increased by 4 percent (4.3 million corn acres); however, this adoption of no-till practices was likely caused by shifts from growers already using conservation tillage and not conventional tillage practices (NRC, 2010).

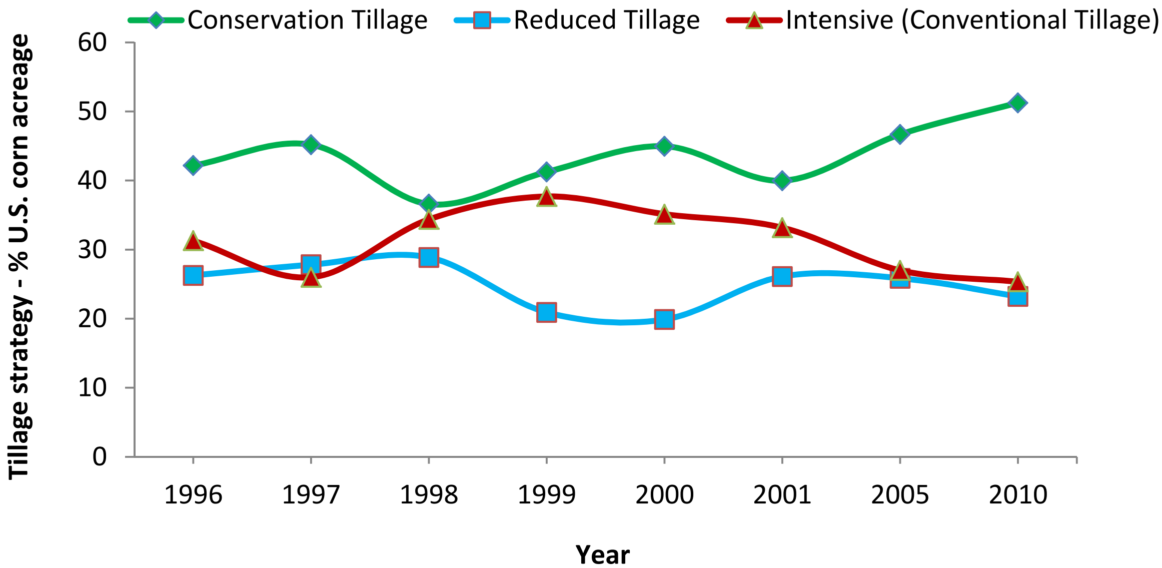

Figure 6. Adoption rates of three major tillage types in U.S. corn production, 1996 – 2010. Sources: (USDA-ERS, 2012).

Conservation tillage is generally associated with broad-spectrum herbicide use, because this tillage facilitates efficient weed control using herbicides prior to planting a crop (Mask *et al.*, 1994; Uri, 1999). In recent years, herbicide-resistant crops have further enabled broad spectrum herbicide use for pre- and post-planting weed control. Though the causality between herbicide-resistant crop adoption and conservation tillage may be debated (Fernandez-Cornejo *et al.*, 2003; Mensah, 2007), more recent empirical evidence suggests a direct relationship, where overall adoption of herbicide-resistant crops have encouraged increasing overall adoption of conservation tillage practices (NRC, 2010). This relationship, however, appears to be weaker in corn than other commodity crops, such as cotton or soybean (NRC, 2010).

Preferred Alternative: Tillage

Under the Preferred Alternative, a determination of nonregulated status is unlikely to substantially affect tillage trends in U.S. corn production. MON 87403 corn is essentially indistinguishable from other currently cultivated corn varieties in terms of agronomic characteristics and cultivation practices (Monsanto, 2014; USDA-APHIS, 2014a). Therefore, MON 87403 corn is unlikely to have any substantial impact on tillage practices in corn. Tillage practices are unlikely to be substantially different under the Preferred Alternative compared to the No Action Alternative.

No Action Alternative: Crop Rotation

Under the No Action Alternative, rotation strategies for corn are likely to continue as practiced today, with market demand and available technology strongly influencing corn rotation practices. In 2010, 71 percent of corn acreage in 19 surveyed states was under some form of rotation (USDA-NASS, 2011). Cropland used for corn and soybean production is nearly identical in many areas, where over 90 percent of the cropped area is planted in a two-year corn-soybean rotation (Hoeft *et al.*, 2000). Recently, there has been an increase in continuous corn rotations given the profitability of corn production and the strong demand for corn grain (USDA-ERS, 2011b). This trend is not specific to a single GE corn variety (USDA-ERS, 2011b) and is expected to continue as normally practiced under the No Action Alternative.

Preferred Alternative: Crop Rotation

Similar to the No Action Alternative, a determination of nonregulated status for MON 87403 corn is unlikely to substantially change current patterns of rotation in U.S. corn production. Crop rotation is primarily used to maintain productivity of the soil and to mitigate reduce pest pressure in an agricultural field (Olson and Sander, 1988). MON 87403 corn is essentially indistinguishable from other currently cultivated corn varieties in terms of agronomic characteristics and cultivation practices (Monsanto, 2014; USDA-APHIS, 2014a), suggesting that it would benefit from current corn rotational strategies. The decision to practice crop rotation, however, is a farm-level decision dependent on factors unrelated to the specific corn variety cultivated, such as corn commodity market prices (USDA-ERS, 2011b; USDA-OCE, 2012a). For example, continuous corn cultivation has increased following increased demand and high corn prices (USDA-ERS, 2011b). Use of MON 87403 corn will not affect rotations for corn.

No Action Alternative: Agronomic inputs

Under the No Action Alternative, current practices related to agronomic inputs in U.S. corn production and grower application of inputs are likely to continue as currently practiced and described in Section 2.1.2 – Agronomic Inputs.

Fertilization is an important management consideration for maximizing corn grain yield (Hoeft *et al.*, 2000). In 2010, nitrogen and phosphate were applied to 97 and 78 percent of U.S. corn acreage, respectively (USDA-NASS, 2011). Corn will continue to receive fertilizer inputs (Ritchie *et al.*, 2008). Practices related to fertilization are likely to continue as practiced today.

Corn production fields may contain a variety of pests, including fungi, insects, and weeds. Management of these pests to maintain grain yield and quality is an integral part of corn production that may be approached with a variety of strategies. The adoption of insect-resistant and herbicide-resistant GE corn varieties by U.S. corn growers has strongly decreased some pesticide use patterns.

In general, fungicide use has increased since 1995, primarily due to the increasing use of fungicides in corn seed coatings (Figure 7). Use of fungicides, however, is substantially less than that of other pesticides (e.g., insecticides or herbicides) (USDA-NASS, 2011). In 2010, approximately 744,000 pounds of fungicides were applied to 8 percent of U.S. corn acres (USDA-NASS, 2011). The application of fungicides for seed treatment is expected to continue to increase as more fungicide treatments are brought to the market (Hoeft *et al.*, 2000; Ruhl, 2007). Under the No Action Alternative, fungicide use in U.S. corn fields will likely continue as it is currently practiced.

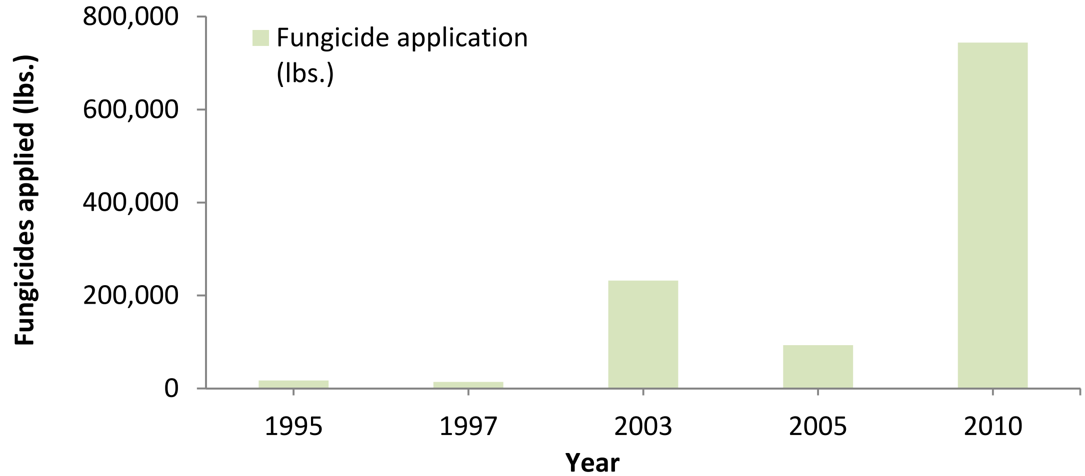

Figure 7. Total application of fungicides in U.S. corn production, 1995 – 2010.
Source: (USDA-NASS, 2012b).

Insecticides are used to control above and below ground pests, and protect against insect damage to stands, the growing plants, and the ears. Insecticide use to control insect pests has decreased since 2003, a trend generally related to the increasing adoption of GE insect-resistant corn varieties (Figure 8) (Benbrook, 2009; Fernandez-Cornejo *et al.*, 2009; NRC, 2010). In 2010, this trend culminated in 1.6 million pounds of insecticides sprayed on 12 percent of U.S. corn acreage (USDA-NASS, 2010b; 2012d). Insecticide use will likely continue as it is currently practiced on U.S. corn fields.

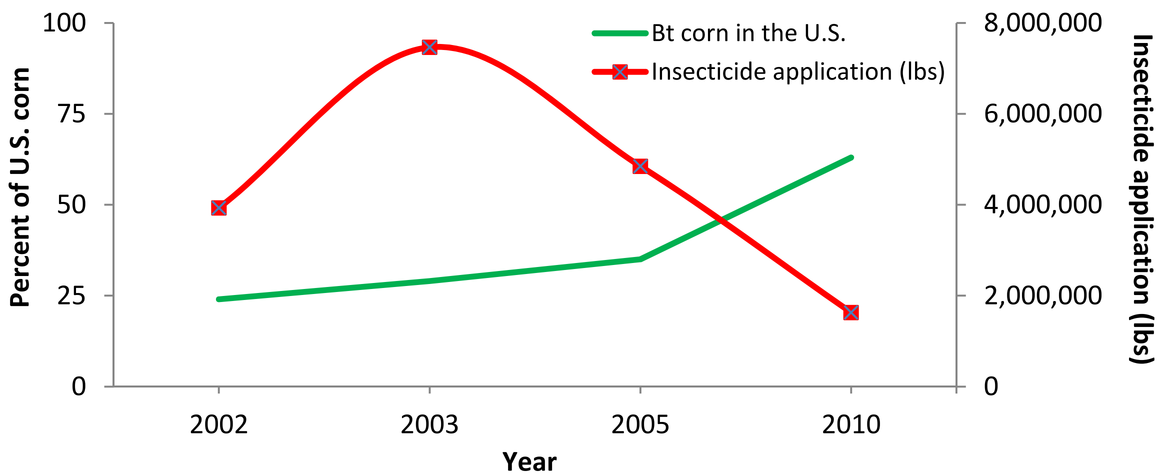

Figure 8. Trends in the use of insecticides and Bt corn in the U.S.
Total application of insecticides (lbs. active ingredient, red line) and percent of U.S. corn acreage cultivated with genetically engineered Bt corn varieties (green line), 2002 - 2010. Sources: (USDA-ERS, 2011a; USDA-NASS, 2012d).

Weeds are the most problematic pests of corn fields. At present, herbicide application is the primary method of controlling weeds in corn fields. In 2010, herbicidal active ingredients were applied to 98 percent of all U.S. corn acreage, representing nearly two-thirds of all pesticide active ingredients applied on corn (USDA-NASS, 2011). Under the No Action Alternative, herbicide use trends are likely to continue as currently practiced on U.S. corn fields.

Preferred Alternative: Agronomic Inputs

Under the Preferred Alternative, agronomic inputs associated with U.S. corn production are likely to continue as described in the analysis of the No Action Alternative.

To test performance, Monsanto compared five lines expressing the ATHB17Δ113 protein to their non-transgenic counterparts over a two year period at multiple corn growing locations using consistent agronomic inputs for all transgenic and non-transgenic comparators (Leibman *et al.*, 2014). Results demonstrated that ATHB17Δ113 expressing varieties were higher yielding than near isogenic lines 62% of the time over a two year period (Leibman *et al.*, 2014). Given the inputs were consistent for all plants included in these performance trials, the lines expressing the ATHB17Δ113 protein as well as their near isogenic lines, suggests that MON 87403 corn would require similar levels of fertilization as conventional corn varieties and benefit from the use of fungicides and pesticides. Additionally, MON 87403 corn does not show increased susceptibility to microbial or insect pests, suggesting that management practices would not differ between it and other corn varieties, including pesticide use (Monsanto, 2014; USDA-APHIS, 2014a). Weed management practices in the production of MON 87403 corn are anticipated to be substantially the same as current corn production practices (Monsanto, 2014). MON 87403 corn is essentially indistinguishable from other currently cultivated corn varieties in terms of agronomic characteristics, cultivation practices, and disease susceptibility (Monsanto, 2014; USDA-APHIS, 2014a). Under the Preferred Alternative, MON 87403 corn is unlikely to substantially affect trends related to fertilization, fungicide use, and pesticide use compared to the No Action Alternative.

4.2.3 Organic Corn Production

Organic production plans prepared pursuant to the NOP include practical methods to protect organically-produced crops from accidental admixture with GE materials. The natural cross-pollination of GE corn with organic corn is a concern of some growers (Coulter *et al.*, 2010; Moncada and Sheaffer, 2010). Typically, organic growers use more than one method to prevent unwanted pollen or other material from entering their fields including: 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 communications between neighboring (NCAT, 2003; Watrud *et al.*, 2004; Baier, 2008). These practices follow the same system used for the cultivation of certified seed under the AOSCA procedures. During the growing season, cross-pollination is managed by recognizing corn pollen dispersal patterns and maintaining adequate distances between fields (Thomison, 2009; Mallory-Smith and Sanchez-Olguin, 2010). A minimum isolation distance of 250 feet between varieties is recommended; whereas, 700 feet is preferred for complete isolation (Diver *et al.*, 2008).

APHIS 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), reasonably can be assumed to be using practices on their farm to protect their crop from unwanted substances, and thus maintain their price premium. APHIS will assume that growers of organic corn are already using, or have the ability to use, these common practices as APHIS's baseline for the analysis of the alternatives.

Organic corn acreage has increased over time concurrent with the increase in GE corn cultivation. Since 1995, organic corn acreage has increased from approximately 32,000 acres to over 194,000 acres in 2008 although these acres have declined to 135,000 in 2011 (USDA-NASS, 2012a; USDA-ERS, 2013a). Since its introduction in 1995, GE corn is now cultivated on over 90 percent of the U.S. acreage (USDA-NASS, 2014a). This concurrent growth of organic crops and GE corn is indicative of the successful adoption of these coexistence strategies. Historically, organic corn production represents a small percentage (approximately, 0.2 percent) of total U.S. corn acreage (USDA-ERS, 2011c). The percentage of corn acreage dedicated to organic corn is not anticipated to change under either the No Action or the Preferred Alternative.

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; 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).

Preferred Alternative: Organic Corn Production

GE corn lines are already in use by farmers. MON 87403 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 2012 in a variety of locations in the U.S. demonstrated that MON 87403 corn is not significantly different in agronomic, phenotypic, environmental, and compositional characteristics from its nontransgenic counterpart (Monsanto, 2014; USDA-APHIS, 2014a). No differences were observed in pollen diameter, weight, and viability. Therefore, MON 87403 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 87403 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 87403 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 87403 corn is not expected to have a significant impact on organic corn production.

4.3 Physical Environment

4.3.1 Soil Quality

No Action Alternative: Soil Quality

Under the No Action Alternative, MON 87403 corn would continue to be regulated by APHIS and current land acreage and agronomic practices associated with corn production would be expected to continue. Agronomic practices associated with GE and non-GE corn production including contouring, use of cover crops, tillage, agronomic inputs, and crop rotation are expected to continue as currently practiced.

Current availability and usage of commercially cultivated (both GE and non-GE) corn are expected to remain the same under the No Action Alternative. Impacts on soil quality are not expected to change.

Preferred Alternative: Soil Quality

A determination of nonregulated status of MON 87403 corn would not affect soil quality. MON 87403 corn is agronomically and compositionally equivalent to other corn varieties currently in commercial production (Monsanto, 2014; USDA-APHIS, 2014a). Agronomic practices such as tillage and the application of agricultural chemicals that could impact soil quality or its community structure and function would not change from those currently used for production of other nonregulated GE corn varieties. Based on these considerations, APHIS has concluded there would be no changes in the direct or indirect impacts on soil quality from the Preferred Alternative.

4.3.2 Water Resources

No Action Alternative: Water Resources

Under the No Action Alternative, current land acreage and agronomic practices, including irrigation, tillage, and nutrient management associated with corn production would not be expected to change. Growers would continue to cultivate GE corn varieties already on the market and continue the agronomic practices and inputs associated with those varieties. Irrigation from surface and subsurface sources can reduce water quantity and impact water quality by the used water acquiring increased sediment, nutrients, and chemicals adsorbed to soil that is subsequently leached to groundwater, or returned to surface water. Recent estimates indicate only about 11.0 percent of corn acreage was irrigated in the U.S in 2010 (NCGA, 2011). No expected changes to water use associated with corn production is expected for this alternative.

As discussed in Subsection 4.2.1, Acreage and Area of Corn Production, corn is expected to continue to be a major crop in the U.S., with a predicted increase in production from approximately 94 million acres of land in 2012 to between 89 and 92 million acres through 2021 (USDA-OCE, 2012a). Current agronomic practices associated with corn production that have potential to impact water quality or quantity include tillage, agricultural inputs such as fertilizer and pesticide use, and irrigation.

As discussed in Subsection 2.2.2, Water Resources, fertilizer and pesticide use has the potential to impact water quality. In 2010, fertilizer (primarily nitrogen) was applied to the majority of commercial corn acres, and herbicides applied to 98 percent of planted corn (USDA-NASS, 2011). Of the treated acres, glyphosate was the most commonly applied herbicide active ingredient that year (USDA-NASS, 2011). When used consistent with registered uses and EPA-approved labels, glyphosate presents minimal risk to surface and groundwater.

Under the No Action Alternative, water resources associated with corn production would not be expected to change. Current availability and usage of commercially cultivated (both GE and non-GE) corn are expected to remain the same under the No Action Alternative. Existing water use and water quality conditions would be expected to continue.

Preferred Alternative: Water Resources

Under the Preferred Alternative, no substantial impact to water resources is anticipated from a determination of nonregulated status of MON 87403 corn.

As discussed in Section 4.2 – Agricultural Production of Corn, MON 87403 corn would not change cultivation practices for corn production, nor would it be expected to affect the total acres and range of U.S. corn production areas. MON 87403 corn has been shown to be compositionally, agronomically and phenotypically equivalent to commercially cultivated corn (Leibman *et al.*, 2014; Monsanto, 2014). No changes to irrigation and other agronomic practices such as fertilizer and pesticide applications, that have the potential to affect water quality or quantity, are expected to occur as a result of this alternative. Based on these considerations, APHIS has concluded that the potential impacts to water resources are expected to be similar under the Preferred Alternative as under the No Action Alternative.

4.3.3 Air Quality

No Action: Air Quality

Under the No Action Alternative, current impacts to air quality associated with land acreage and cultivation practices associated with corn production are not likely to be affected. All agricultural practices have the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from agricultural burning, tillage, heavy equipment emissions, pesticide drift from spraying, and indirect emissions from CO_2 and N_2O emissions from the use of nitrogen fertilizer and degradation of organic materials (USDA-NRCS, 2006a; Aneja *et al.*, 2009; US-EPA, 2013).

Air quality will continue to be affected by current agronomic practices associated with conventional methods of corn production such as tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment.

Preferred Alternative: Air Quality

Under the Preferred Alternative, a determination of nonregulated status of MON 87403 corn is unlikely to substantially impact air quality compared to the No Action Alternative.

Agricultural practices that may affect air quality are not expected to change substantially with the introduction of MON 87403 corn. MON 87403 corn has been shown to be compositionally, agronomically and phenotypically equivalent to commercially cultivated corn (Monsanto, 2014), and is not likely to change land acreage or any cultivation practices for corn production. No changes to agronomic practices that are sources of emissions or positively contribute to air quality such as the amount, type and timing of tillage, equipment use, irrigation, and the application of fertilizers or pesticides would result from a determination of nonregulated status of MON 87403 corn. The potential impacts to air quality under the Preferred Alternative are, therefore, similar to the No Action Alternative.

4.3.4 Climate Change

No Action Alternative: Climate Change

Current agronomic practices associated with conventional corn production and current GE corn varieties which contribute to GHG emissions, including tillage, cultivation, irrigation, pesticide application, fertilizer applications, and use of agriculture equipment, are not expected to change under the No Action Alternative. Land acreage and cultivation practices associated with corn production would not be affected. To the extent that the adoption and cultivation of GE corn varieties allows the grower to implement conservation practices, GHG emissions are expected to continue to be reduced commensurate with the air quality improvements anticipated from adoption of conservation tillage practices.

Agriculture, including land-use changes associated with farming, is responsible for an estimated 6.9 percent of all human-induced GHG emissions in the U.S. (US-EPA, 2013). The major sources of GHG emissions associated with crop production are soil N_2O emissions, soil CO_2 and CH_4 fluxes, and CO_2 emissions associated with agricultural inputs and farm equipment operation (US-EPA, 2013). Agricultural practices that produce CO_2 emissions include liming and the application of urea fertilization (i.e., nitrogen) to agricultural soils, and CH_4 produced by enteric fermentation and animal manure management. Agricultural soil management activities including fertilizer application and cropping practices are the largest source of N_2O emissions in the U.S. (US-EPA, 2013). As discussed in Section 2.2.4, Climate Change, corn production primarily affects climate-changing emissions through: (1) fossil fuel burning equipment used for production and nitrogen fertilization producing CO_2; and, (2) cropping production practices including residue management and tillage. The adoption of herbicide-resistant crops and the attendant increase in conservation tillage has been identified as providing climate change benefits. Conservation tillage practices increase crop residue on the surface, promoting the production of soil organic carbon and protecting the soil from erosive forces that would release soil organic carbon back to the air. These practices also reduce the use of emissions-producing equipment normally used in tilling. The USDA has estimated approximately 74.5 percent of planted corn acres in 2010 were produced under conservation tillage practices ranging from no-till to reduced till (USDA-ERS, 2010a). Recent increases in the incidence of herbicide-resistant weeds may require increased tillage for effective weed control (Beckie, 2006; Owen *et al.*, 2011), although new herbicide use protocols exist and would likely be preferred by growers over changes in tillage. Tillage increases could potentially release more soil organic carbon 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 its agroecological setting, the particular problem weed type, and on-farm economics (Beckie, 2006).

Nitrogen is also the most-used fertilizer in U.S. corn production (USDA-NASS, 2011). Nitrogen in the form of urea is commonly applied to cornfields and contributes CO_2 emissions from the urea volatilization which also produces ammonia. Recommended BMPs to reduce volatilization include incorporating urea with equipment, accompanied with irrigation or rainfall; topdressing urea when temperatures and soil moisture levels are low; and avoiding topdressing urea in higher risk conditions, except if there is an opportunity to incorporate the urea within a few days of application (Jones *et al.*, 2007).

Climate change is already affecting U.S. water resources, agriculture, land resources, and biodiversity, and will continue to do so (CCSP, 2008). Impacts of climate change are apparent in Corn Belt states at the present time. For example, in Iowa precipitation totals are significantly increasing and summers have increasing incidents of heavy precipitation (Iowa-General-Assembly, 2011). Consequently, farmers are installing increasing amounts of drain tile to respond to increased flooding of fields (Iowa-General-Assembly, 2011). With increased drain tiling, greater nitrate-nitrogen losses are incurred (David *et al.*, 2010; Iowa-General-Assembly, 2011). Weeds have increased and more pesticides are used which accompanies reduced herbicide efficacy (Iowa-General-Assembly, 2011). Delayed planting and increased replanting attend increased heavy precipitation (Iowa-General-Assembly, 2011). Because the growing season has increased, growers have begun to use corn maturity groups suitable for lower latitudes, which may increase the yield (Krapfl, 2012). As climate change begins to be manifest in additional U.S. corn growing regions, growers will continue to make accommodations to maintain production and yield.

<u>Preferred Alternative: Climate Change</u>

Because corn line MON 87403 is similar to other GE and non-GE corn cultivars in terms of its growth habit, agronomic properties, disease susceptibility, and composition (USDA-APHIS, 2014a), the agronomic practices required to cultivate MON 87403 corn would be no different than those used to produce these other corn cultivars. Therefore, no changes to agricultural practices that could affect GHG emissions would be expected from a determination of nonregulated status for MON 87403 corn. Collectively, because the range, area, and agronomic practices of corn are unlikely to change following a determination of nonregulated status of MON 87403 corn, the potential impacts to climate change are also unlikely to change under the Preferred Alternative.

4.4 Biological Resources

4.4.1 Animal Communities

<u>No Action Alternative: Animal Communities</u>

Under the No Action Alternative, conventional and GE corn production will continue as currently practiced while MON 87403 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.

Corn production potentially impacts animal communities through the conversion of wildlife habitat to agricultural purposes. As discussed in Subsection 2.1.1, Acreage and Area of Corn Production, corn was produced on approximately 91.6 million acres in 2014, an decrease of approximately 4 percent from 2013 (USDA-NASS, 2014a). Corn is expected to continue to be a major crop in the U.S. through 2021 (USDA-OCE, 2012a). A wide array of wildlife occupy or use habitats that are within or adjacent to cornfields (see Subsection 2.3.1, Animal Communities). While cornfields are less suitable for wildlife than adjacent pasture, fallow fields, windbreaks, or shelterbelts, those in conservation tillage management provide greater benefit for wildlife than those in more intensive tillage. Under this tillage regime, greater diversity in plant species would occur and so provide more habitat and potential food sources, soil would be less disturbed, and potentially sediment and agricultural pollutant loading of nearby surface waters would be reduced, improving water quality (Brady, 2007; Sharp, 2010).

Current corn agronomic practices potentially impacting animal communities include application of agricultural inputs, such as fertilizer, herbicides, and pesticides. Both fertilizer and pesticides are applied to the majority of corn acres in the U.S. (USDA-NASS, 2011) and potentially impact non-target wildlife from ingestion or spray drift. Glyphosate is the primary herbicide applied to herbicide-treated corn acreage in the U.S. (USDA-NASS, 2011). When used consistent with the EPA-registered uses and labels, glyphosate and other herbicide application in corn presents minimal risk to animal communities. In 2010, 66 percent of all active ingredients applied to corn treated with pesticides were herbicidal (USDA-NASS, 2011).

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 *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).

Under the No Action Alternative, conventional corn production would continue while MON 87403 corn remains a regulated article. Potential impacts to animal communities associated with corn cultivation are not expected to change in the No Action Alternative.

<u>Preferred Alternative: Animal Communities</u>

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 arise from any changes in agronomic inputs associated with the crop modification and direct exposure to the GE crop and its products.

As described in Section 4.2, Monsanto has presented the results of field trials which demonstrate that MON 87403 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, 2014). 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.

MON 87403 corn has been shown to be compositionally, agronomically and phenotypically equivalent to commercially cultivated corn with the exception of the increased ear biomass trait (Monsanto, 2014). The ATHB17Δ113 protein shares sequence identity and structural similarity with proteins present in plants currently consumed, establishing that humans and animals are exposed to this class of proteins and that no adverse effects have been attributed to this class of proteins (Monsanto, 2014). Expression of the ATHB17Δ113 protein in maize grain is below the limit of detection and is extremely low in other tissues tested, therefore exposure to ATHB17Δ113 protein is negligible (Monsanto, 2014). Additionally, compositional analysis of MON 87403 corn has shown no statistically significant differences between MON 87403 corn and conventional corn (Monsanto, 2014). Monsanto indicated that they submitted a safety and nutritional assessment of food and feed derived from MON 87403 corn to FDA in October 2014 (Monsanto, 2015). FDA is presently evaluating the submission.

Based on the above, the impacts of determining nonregulated status for MON 87403 corn to animal communities would be similar to those of the No Action Alternative.

4.4.2 Plant Communities

<u>No Action Alternative: Plant Communities</u>

Corn can be grown in a wide number of environments, dependent upon appropriate soil profiles, and locations where weather is not limiting (Iowa-State-University, 2002). Plants communities are varied and adapted to local climate and soil, as well as the frequency of natural or human-induced disturbance (Smith and Smith, 2003). Non-crop vegetation in cornfields is limited by farmers' cultivation and weed control practices. Plants communities adjacent to cornfields commonly include other crops, borders, hedgerows, windbreaks, pastures, and other natural vegetation.

Agricultural practices affect plant communities by exerting selection pressures that influence the type and composition of plants present in a community. Plant communities within agroecosystems are generally less diverse than the plant communities that border crop fields. The plant communities that inhabit crop production fields are represented by plants (including weeds) that are able to adapt and thrive in an environment that is directed specifically to the production of crops, such as corn. In crop production systems, the plant community is controlled using a number of tactics to maximize the production of food, fiber, and fuel; however, herbicides are the most common and accepted tactic to manage plant communities within agroecosystems (Gianessi and Reigner, 2007).

Weeds are the most important pest in agriculture, competing for light, nutrients, and water and can significantly affect yields (Gibson *et al.*, 2005; Baucom and Holt, 2009).Weeds commonly encountered in corn production include water hemp, giant ragweed, common lambsquarters, and others as described in Subsection 2.3.2, Plant Communities. Agronomic practices common in corn production, such as tillage and herbicide use, impart selection pressures on the weed community that can result in shifts in the relative importance of specific weeds (Owen, 2008). In aggressive tillage systems, weed diversity tends to decline and annual grasses and broadleaf plants are the dominant weeds; whereas, in no-till fields, greater diversity of annual and perennial weed species may occur (Baucom and Holt, 2009). The most common weed management tactic in U.S. corn production is to use herbicides. Recent estimates indicate herbicides are applied to 98 percent of planted corn acreage, and on that acreage, the most frequently applied herbicide is glyphosate (USDA-NASS, 2011).

As discussed in Subsection 2.3.3, Gene Flow and Weediness, there are no extant populations of sexually compatible species related to *Z. mays* 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, 2014a).

Under the No Action Alternative, conventional corn production would continue while MON 87403 corn remains a regulated article. Potential impacts to plant communities associated with corn production are not expected to change in the No Action Alternative.

Preferred Alternative: Plant Communities

Corn line MON 87403 would have no impacts to plant communities adjacent to or within agroecosystems that would be different from currently available corn cultivars. MON 87403 corn has been shown to be compositionally, agronomically and phenotypically equivalent to commercially cultivated corn (Monsanto, 2014). Growers are already managing corn to control for competing plant life and surrounding areas that could provide pest and disease reservoirs using treatments and controls. There would be no change in herbicide use or patterns. Potential impacts related to gene flow and weediness are discussed below in Section 4.4.3.

Land use 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 87403 corn is not expected to differ from the No Action Alternative.

4.4.3 Gene Flow and Weediness

No Action Alternative: Gene Flow and Weediness

Under the No Action Alternative, MON 87403 corn would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) corn are expected to remain the same under the No Action Alternative.

As described in Subsection 2.1.2, Agronomic Practices, corn is the largest crop grown in the U.S. in terms of value (USGC, 2010), acreage planted, and geographic area of production, and is predicted to remain an important crop in USDA projections to 2021 (USDA-OCE, 2012a). Gene flow may occur through dispersal of vegetative tissues, pollen, or seed. Asexual reproduction and gene flow as a result of dispersal of vegetative tissues does not occur with corn. Corn is self-compatible and primarily pollinated by wind or gravity, with minimal contribution from insect pollination (McGregor, 1976; Thomison, 2009), and is propagated by seed. There are no extant populations of sexually compatible species related to domesticated *Z. mays* within the continental U.S., its territories, or possessions; therefore, APHIS has concluded that there is not a risk of gene movement between corn and its wild or weedy corn relatives (USDA-APHIS, 2014a).

The reproductive morphology of corn encourages cross-pollination between corn plants and there is no evidence (genetic or biological barriers) to indicate that gene flow is restricted between genetically modified, conventional, and organic corn. Spatial and temporal isolation can be the most effective barriers to gene exchange between corn crop cultivars. Requirements and methods to ensure seed and crop purity are discussed in more detail in Subsection 2.1.3, Organic Corn Production.

Corn does not possess the characteristics for efficient seed-mediated gene flow. Through thousands of years of selective breeding by humans, corn has been extensively modified to depend on human cultivation for survival (Doebley, 2004). As a result of its domestication, corn is not able to survive in the wild and also has several traits that greatly reduce its ability to disperse via seeds (OECD, 2003). Corn seed dispersed after harvest may survive in fields and develop into volunteer plants, but such volunteers are controlled with common agronomic practices.

Horizontal gene flow or gene flow to unrelated species in any currently cultivated corn is unlikely, and its potential occurrence in any crop is discussed more theoretically than practically. It has never been documented under realistic conditions (Stewart, 2008). The horizontal transfer of entire transgenes, including portions of the DNA that code for the production of specific proteins, has never been shown to occur in nature (Stewart, 2008), and the risk of its occurrence in corn cultivation is considered low.

Preferred Alternative: Gene Flow and Weediness

Gene flow could be affected by changes in pollen or flower characteristics, or timing of flowering. The results from the phenotypic and agronomic evaluations support a conclusion that MON 87403 corn, compared to its conventional control variety, did not exhibit any changes in reproductive characteristics that would increase likelihood of gene flow, such as fecundity, seed dispersal, increased persistence, pollen viability, or differences in general pollen or flower morphology (Monsanto, 2014; USDA-APHIS, 2014a). Thus, under the Preferred Alternative, the likelihood of gene flow from MON 87403 corn to other corn varieties is not substantially different than between current corn varieties.

Weediness potential could be affected if seed dormancy and germination characteristics change. Monsanto has presented data from field trials showing seed dormancy and germination characterization indicating that MON 87403 corn had no changes in the dormancy or germination characteristics that could be indicative of increased plant weediness or pest potential compared to the conventional corn control (Monsanto, 2014). These findings support the conclusion that MON 87403 corn is no more likely to be a weed compared to conventional corn (USDA-APHIS, 2014a).

4.4.4 Microorganisms

No Action Alternative: Microorganisms

The soil microbial community is an integral ecosystem component that may provide and sustain critical ecological processes. Soil microorganisms are important in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva *et al.*, 2004). They may also suppress soil-borne plant diseases and promote plant growth (Doran *et al.*, 1996). As described in Subsection 2.3.4, Microorganisms, the main factors affecting microbial population size and diversity include soil and plant type, and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva *et al.*, 2004). Plant roots, including those of corn, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere.

Management practices used in corn production can affect soil microorganisms by altering microbial populations and activity through modification of the soil environment. An agronomic practice may be beneficial for one microorganism but detrimental to another. As presented in Subsection 2.3.4, Microorganisms, crop rotation, irrigation, tillage, and agricultural chemicals such as fertilizers and pesticides affect microbial community structure and functions such as nutrient cycling, disease promotion or suppression, and presence in soil. As discussed in Subsection 2.1.2, Agronomic Practices, the adoption of herbicide-resistant corn has enabled the use of conservation tillage, creating less soil disturbance and retaining more crop residue which has been found to increase soil microbe population diversity (Locke *et al.*, 2008).

Under the No Action Alternative, MON 87403 corn would continue to be regulated by APHIS. As discussed in Subsection 4.2.2 – Agronomic Practices, corn production practices are expected to remain as currently practiced. Growers will continue to have access to commercially cultivated (both GE and non-GE) corn. Impacts to microorganisms are not likely to change under the No Action Alternative.

Preferred Alternative: Microorganisms

A determination of nonregulated status of MON 87403 corn is not expected to result in any new impacts to microbial communities. MON 87403 corn is agronomically and compositionally equivalent to other corn varieties currently in commercial production and does not require any changes to agronomic practices (Monsanto, 2014). No adverse effects on soil microorganisms are associated with MON 87403 corn or its cultivation.

Because the agronomic practices of corn are unlikely to change following a determination of nonregulated status of MON 87403 corn, the impacts of corn production on microorganisms are likely to be the same as the No Action Alternative.

4.4.5 Biodiversity

No Action Alternative: Biodiversity

Biological diversity, or the variation in species or life forms in an area, is highly managed in agricultural systems. Farmers typically plant crops that are genetically adapted to grow well in a specific area of cultivation and have been bred for a specific market. In conventional agriculture, farmers want to encourage high yields from their crop, and will intensively manage plant and animal communities through chemical and cultural controls to protect the crop from damage. Therefore, the biological diversity in agricultural systems (the agro-ecosystem) is highly managed and may be lower than in the surrounding habitats.

Under the No Action Alternative, MON 87403 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 would continue unchanged. Animal and plant species that typically inhabit corn fields will continue to be affected by currently utilized management plans and systems, which include the use of mechanical, cultural, and chemical control methods. The consequences of current agronomic practices associated with corn production, both traditional and GE varieties, on the biodiversity of plant and animal communities is unlikely to be altered.

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

Preferred Alternative: Biodiversity

Monsanto has presented results of agronomic field trials comparing MON 87403 corn to conventional corn varieties. The results show that except for the increased ear biomass trait, MON 87403 corn is phenotypically and agronomically the same as commercially cultivated corn. Therefore, MON 87403 corn would not be expected to change agronomic practices and therefore would not impact biodiversity any differently than other commercially available corn.

As noted in Subsection 4.4.1 – Animal Communities, Monsanto has presented compositional data comparing the phenotypic, morphological and compositional characteristics of MON 87403 corn with other varieties, including bioinformatics analysis of allergenicity, toxicity, nutrients and anti-nutrients, and amino acid homology, among others (Monsanto, 2014). MON 87403 corn is compositionally equivalent to that of conventional corn.

Based on the above information, APHIS has determined that approval of a petition for nonregulated status of MON 87403 corn will have the same impact on biodiversity as the No Action Alternative.

4.5 Human Health

No Action Alternative: Human Health

Under the No Action Alternative, MON 87403 corn would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) corn are expected to remain the same under the No Action Alternative. Human exposure to corn products does not change from the current status. This exposure includes exposure to incorporated genes and expressed proteins in different corn varieties as well as exposure to pesticides used on corn. Management practices, and the associated human health effects, are not likely to change under the No Action Alternative.

As discussed in Section 2.4 – Human Health, agriculture, including corn farming, is a relatively high-hazard industry, with machinery-related injuries being the primary hazard. A common agricultural practice, pesticide application, represents the primary exposure route to pesticides for farm workers. Pesticides are applied to 98 percent of corn acreage in the U.S. (USDA-NASS, 2011). Growers will continue to choose agronomic practices 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). Worker safety is taken into consideration by EPA in the pesticide registration process and reregistration process. When use is consistent with the label, pesticides present minimal risk to the worker. No changes to current worker safety are anticipated under the No Action Alternative.

Human exposure to corn crops and products, and the agronomic inputs associated with their production, are not expected to change from the current condition under the No Action Alternative.

Preferred Alternative: Human Health

Under the Preferred Alternative, potential impacts to human health are not anticipated to be substantially different than under the No Action Alternative. As discussed in Subsection 2.1.1, Acreage and Area of Corn Production, 93 percent of corn grown in the U.S. in 2014 was GE (USDA-NASS, 2014a). Human health concerns associated with GE crops include the potential toxicity of the introduced genes and their products, the expression of new antigenic proteins, and/or altered levels of existing allergens (Malarkey, 2003; Dona and Arvanitoyannis, 2009).

Monsanto's studies demonstrated that MON 87403 corn grain and forage is compositionally equivalent to commercially cultivated corn varieties (Monsanto, 2014). Grain samples were analyzed for levels of nutrients including proximates, carbohydrates by calculation, fiber, amino acids, fatty acids, minerals, and vitamins. The anti-nutrients analyzed in grain included phytic acid and raffinose. Secondary metabolites analyzed in grain included furfural, ferulic acid, and p-coumaric acid. Forage samples were analyzed for levels of proximates, carbohydrates by calculation, fiber, and minerals (Monsanto, 2014). None of the components showed a significant difference between MON 87403 corn and the conventional control (Monsanto, 2014).

Bioinformatics analyses were performed to assess the potential for allergenicity, toxicity, or biological activity of ATHB17Δ113. The analysis demonstrated that ATHB17Δ113 protein does not share amino acid sequence similarity with known allergens, gliadins, glutenins, or protein toxins which could have adverse effects to human or animal health (Monsanto, 2014).

Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Because MON 87403 corn is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced through genetic engineering, Monsanto indicated that they submitted a safety and nutritional assessment of food and feed derived from MON 87403 corn to FDA in October 2014 (Monsanto, 2015). FDA is presently evaluating the submission.

Under the Preferred Alternative, cultivation practices and corresponding worker exposures to agronomic inputs are unlikely to change. Monsanto demonstrated in its petition that MON 87403 corn is phenotypically and agronomically the same as commercially cultivated corn (Monsanto, 2014). Accordingly, the health and safety protocols currently employed by farm workers in corn production do not require changes to accommodate the cultivation of MON 87403 corn.

Based on these findings, APHIS has determined that approval of a petition for nonregulated status of MON 87403 corn will have the same impact on human health as the No Action Alternative.

4.6 Animal Feed

No Action Alternative: Animal Feed

As described in Subsection 2.5, Animal Feed, most of the corn produced in the U.S. is for animal feed that is consumed primarily by cattle, poultry, and swine, (51 FR 23302, 1986). Corn comprises over 95 percent of the total feed grain produced in the U.S. (USDA-ERS, 2013a). In 2014, corn was grown on approximately 91.6 million acres (USDA-NASS, 2014a) and measurably produced in all states but Alaska (USDA-NASS, 2014e). As discussed in Subsection

2.5, Animal Feed, approximately 55 to 60 percent of the corn produced in the U.S. is used for livestock (KyCGA, 2011). In 2014, 93 percent of the corn produced in the U.S. was genetically engineered (USDA-NASS, 2014a). The amount of corn that is used for feed is dependent on a number of factors such as the number of animals that are fed corn, its supply and price, the amount of supplemental ingredients added, and the supply and price of competing ingredients (USDA-ERS, 2013a). Under the No Action Alternative, corn forage, silage, grain, and refined corn feed products from currently cultivated GE and conventional corn varieties are utilized by livestock producers.

Preferred Alternative: Animal Feed

As described in Subsection 4.2.1, Acreage and Area of Corn Production, no change to the area or acreage of corn production is expected to occur as the result of approving a determination of nonregulated status to MON 87403 corn. Also, as described in Subsection 4.2.2, Agronomic Practices, the agronomic practices for corn production that could impact the supply of corn-based animal feed would not change under this alternative because agronomic and growth characteristics of MON 87403 corn are similar to other commercially available corn varieties. As described for the No Action Alternative, the amount of corn that is used for feed is dependent on several factors, including price, supply, and the number of animals that are fed corn (USDA-ERS, 2013a).

Under FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from MON 87403 corn must be in compliance with all applicable legal and regulatory requirements. GE organisms for feed may undergo a voluntary consultation process with the FDA prior to release onto the market. As previously noted, because MON 87403 corn is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced through genetic engineering, Monsanto indicated that they submitted a safety and nutritional assessment of food and feed derived from MON 87403 corn to FDA in October 2014 (Monsanto, 2015). FDA is presently evaluating the submission.

Compositional analysis revealed no substantial differences between MON 87403 corn grain and forage and conventional corn varieties (Monsanto, 2014). Grain samples were analyzed for levels of nutrients including proximates, carbohydrates by calculation, fiber, amino acids, fatty acids, minerals, and vitamins. The anti-nutrients analyzed in grain included phytic acid and raffinose. Secondary metabolites analyzed in grain included furfural, ferulic acid, and p-coumaric acid. Forage samples were analyzed for levels of proximates, carbohydrates by calculation, fiber, and minerals (Monsanto, 2014). None of the components showed a significant difference between MON 87403 corn and the conventional control (Monsanto, 2014). Consequently, the quality of animal feed derived from MON 87403 corn is unlikely to be substantially different than animal feed produced from current corn varieties.

Based on these findings, approval of a petition for nonregulated status of MON 87403 corn will have the same impact on animal feed as the No Action alternative.

4.7 Socioeconomic Impacts

4.7.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Environment

Corn is the largest U.S. crop, both in terms of acreage and value, exceeding $62.7 billion in 2013 (USDA-NASS, 2014e), and it is expected corn would retain current planted acreage levels at least until 2021 (USDA-OCE, 2012a). Almost all of the U.S. corn supply (91.8 percent in 2013/14) comes from new annual domestic production (USDA-ERS, 2014b). In the 2013/14 marketing year, more than half (61.7 percent) of domestic corn usage was for feed, while approximately 39.3 percent of domestic use was for the production of ethanol (USDA-ERS, 2014b). Total operating costs in 2013 for U.S. corn production were $355.98 per planted acre (USDA-ERS, 2014a). Corn is widely produced in the U.S. (see Subsection 2.1.1, Acreage and Area of Corn Production, Figure 2). The most productive and profitable regions are the Heartland and Southern Seaboard (USDA-ERS, 2014a). As discussed in Subsections 2.1.3, Organic Corn Production, and 2.6.1, Domestic Economic Environment, organic corn production is a small portion (approximately 0.2 percent) of the U.S. corn market (USDA-ERS, 2011c). The value of corn produced for grain or seed from organic-certified farms in the U.S. in 2008 was nearly $111.5 million (USDA-NASS, 2010a).

Under the No Action Alternative, MON 87403 corn would continue to be regulated by APHIS. Farmers and other parties who are involved in production, handling, processing, or consumption of corn would not have access to MON 87403 corn and its progeny, but 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. Corn production and use would be expected to continue much as it is currently.

Impacts to the domestic economic environment associated with the cultivation of corn are not expected to change under the No Action Alternative.

Preferred Alternative: Domestic Economic Environment

A determination of nonregulated status of MON 87403 corn is not expected to adversely impact domestic commerce. The availability of MON 87403 corn would be unlikely to influence the number of acres of corn planted. Since MON 87403 corn is similar in agronomic, cultivation and management practices to other nonregulated GE and non-GE corn varieties (Monsanto, 2014), no changes to agronomic inputs or practices would be anticipated that may impact on-farm costs for corn producers or the U.S. domestic corn market.

APHIS assumes that the technology fees for MON 87403 corn seed would be consistent with those charged by developers for other GE crop varieties already in the marketplace. APHIS has no control over the establishment of these technology fees, and each grower must make an independent determination as to whether the benefits of the GE variety would offset those technology access costs.

Adopters of MON 87403 corn may realize financial benefits as a result of the potential increased yield opportunity. MON 87403 corn has been engineered to have increased ear biomass at an early reproductive phase compared to conventional control maize. Early reproductive stages in maize are a critical period of maize growth at which the maximum ear biomass is determined (Monsanto, 2014). A larger ear biomass at early reproductive stages is associated with increased grain yield at harvest (Monsanto, 2014). Consistent with this, multiple years of field testing showed that MON 87403 corn out-yielded its comparators at a majority of locations tested (Monsanto, 2014). Therefore, the Preferred Alternative has the potential for positive economic impacts for growers, compared to the No Action Alternative.

Certified organic corn cannot include GE cultivars in the U.S. (USDA-AMS, 2014). As discussed under the No Action Alternative, the organic corn market serves a smaller consumer niche for corn in the U.S. corn market. MON 87403 corn could pose comparable environmental consequences to the organic corn industry as commercially available GE corn including additional testing, and additional production and stewardship costs to avoid unintended presence of MON 87403 corn. Because MON 87403 corn is similar to other corn in its reproductive characteristics, it is expected U.S. organic producers would continue to meet organic certification requirements as outlined in Subsection 2.1.3, Organic Corn Production, by implementing standard practices to preserve the identity of their organic corn crop.

4.7.2 Trade Economic Environment

No Action Alternative: Trade Economic Environment

Under the No Action Alternative, MON 87403 corn would continue to be a regulated article. Farmers, processors, and consumers in the U.S. would not have access to MON 87403 corn, but do have access to existing nonregulated GE and non-GE corn varieties, as do the major U.S. corn export competitors.

The U.S. is the leading exporter of corn in the world market (see Subsection 2.6.2, Trade Economic Environment), while other important exporters are Argentina, Brazil, and Ukraine. In the 2013/2014 marketing year (August to September), the U.S. exported approximately 39 percent of the world's corn while the European Union, Japan, Mexico, and South Korea were the major importers (USDA-FAS, 2014). In 2013, corn exports were worth approximately $9.3 billion (USDA-ERS, 2014c). U.S. corn supply, the value of the U.S. dollar and other currencies, oil prices, U.S. and international agricultural policy, the U.S. and international biofuels sector, livestock and meat trade, prices, and population growth are all factors affecting where and how much of U.S. corn is exported (USDA-OCE, 2012b; USDA-ERS, 2013a). In addition, consumer perception of GE crop production and products derived from GE crops may present barriers to trade. Over the past decade, U.S. corn export share has eroded as exports have remained relatively stable while global exports have increased by almost 20 percent (See Subsection 2.6.2, Trade Economic Environment). U.S. share of world corn production has declined as well, even as total world production increased. This is attributed to greater domestic use of U.S. corn, smaller corn crops, and increased competition from other major corn exporters such as Argentina, Brazil, and Ukraine (USDA-FAS, 2014), countries with increasing GE herbicide- and insect-resistant corn production acreage (Brookes and Barfoot, 2010).

Market years extend from September to August. Major world exporters include Argentina, Brazil, Canada, China, EU-27, India, Paraguay, Romania, Serbia, South Africa, Thailand, Ukraine and Zambia as well as other smaller exporting countries (Figure 9). Note that the U.S. percentage of corn exports in relation to overall world exports declined at the end of the last decade. Also note the increase in exports of corn in countries other than the top three, and the decline in U.S. exports in most recent years.

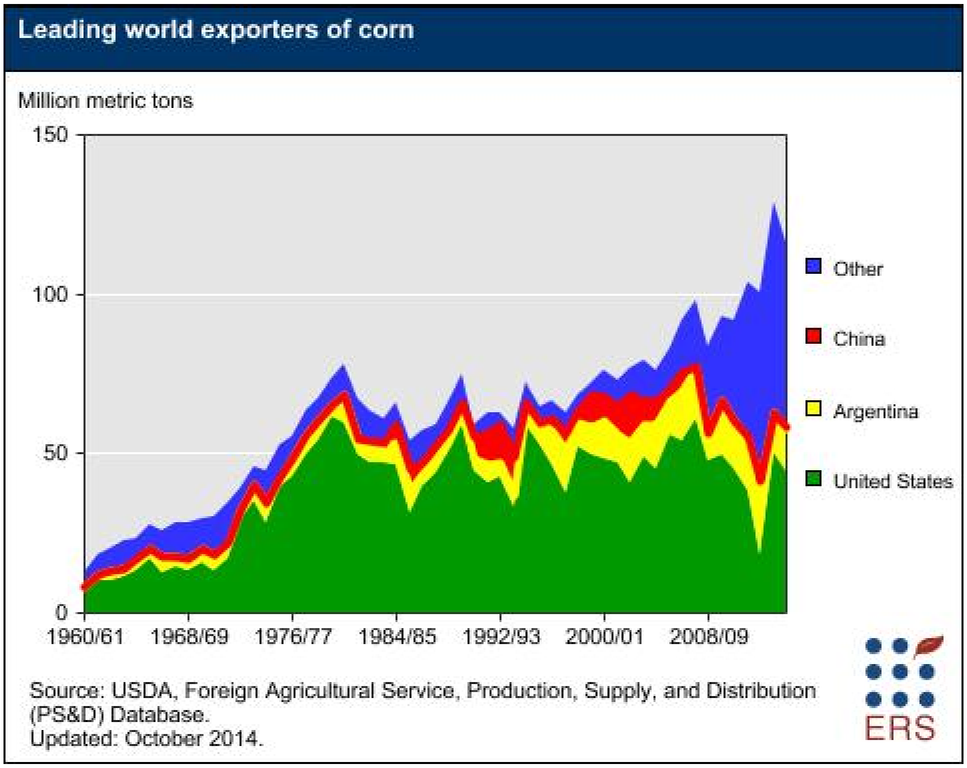

Figure 9. U.S. and major exporters of corn for marketing years 1960/1961-2011/2012.
Source: (USDA-ERS, 2013a).

Under the No Action Alternative, MON 87403 corn would continue to be regulated by APHIS. There is unlikely to be any change to the current corn market. Current availability and usage of commercially cultivated (both GE and non-GE) corn are expected to remain the same under the No Action Alternative.

Preferred Alternative: Trade Economic Environment

Under the Preferred Alternative, MON 87403 corn would be determined nonregulated and available to U.S. growers. A determination of nonregulated status of MON 87403 corn is not expected to adversely impact international corn markets. MON 87403 corn is compositionally and agronomically similar to its comparators with the exception of the increased ear biomass trait (Monsanto, 2014; USDA-APHIS, 2014a). As discussed in Subsection 4.7.1, Preferred Alternative: Domestic Economic Environment, field trials of MON 87403 corn had a higher yield than the conventional control. If the developer frequently incorporates this trait into many varieties, if adoption of the trait is high, and conditions in fields are supportive of additional corn productivity for MON 87403 corn, then there are possibilities for modest increases in overall U.S. corn production (see Subsection 4.7.1, Preferred Alternative: Domestic Economic Environment). Overall increased farm productivity, such as increased corn production, may increase U.S competitiveness in the global economy.

Adoption of MON 87403 corn would likely be gradual, dependent upon the speed of introduction of the trait by Monsanto, and upon the value growers place on a higher than average yielding corn cultivar. As discussed above in the No Action Alternative, there are several factors that influence worldwide prices for corn and how much U.S. corn is exported, including U.S. corn supply, the value of the U.S. dollar and other currencies, oil prices, U.S. and international agricultural policy, the U.S. and international biofuels sector, livestock and meat trade, prices, and population growth, as well as consumer perceptions of GE crop production and products derived from GE crops.(USDA-OCE, 2012b; USDA-ERS, 2013a). Any impact to corn market prices from the potential increased yield from the production of MON 87403 corn, would likely be difficult to assess or predict.

Approval of a petition for nonregulated status for MON 87403 corn it is not expected to affect the seed, feed, or food trade any differently than other nonregulated GE corn varieties (see Subsections 4.7.1, Domestic Economic Environment). Approval of the petition for nonregulated status for MON 87403 corn would not likely increase the U.S. supply of corn that may affect trade. To support commercial introduction of MON 87403 corn in the U.S., Monsanto intends to obtain import approvals for MON 87403 corn in all key corn import markets with a functioning regulatory system prior to commercial release of hybrids containing MON 87403 (Monsanto, 2014). Approval in these export countries is intended to mitigate global sensitivities to GE productions and work in accordance with international regulations.

As discussed under the No Action Alternative, global corn export markets respond to many factors, including consumer perception of GE crops and derived products. The availability of MON 87403 corn in the U.S. would not likely affect foreign consumer perception of GE corn products or those global forces shaping the U.S. corn trade economic environment. The potential impacts to the trade economic environment from a determination of nonregulated status of MON 87403 corn would be no different than those currently observed for other corn varieties under the No Action Alternative.

5 CUMULATIVE IMPACTS

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

5.1 Assumptions Used for Cumulative Impacts Analysis

Cumulative impacts have been analyzed for each environmental issue assessed in Section 4, Environmental Consequences. In this EA, the cumulative impacts analysis is focused on the incremental impacts of the Preferred Alternative taken in consideration with related activities including past, present, and reasonably foreseeable future actions. Certain aspects of this product and its cultivation would be no different between the alternatives; those instances are described below. In this analysis, if there are no direct or indirect impacts identified for a resource area, then APHIS assumes there can be no cumulative impacts. Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential cumulative impacts. APHIS will limit the analysis of cumulative impacts to the areas in the U.S. where corn is commercially produced.

APHIS considered the potential for MON 87403 corn to extend the range of corn production and affect the conversion of land to agricultural purposes. Monsanto's studies demonstrate that MON 87403 corn is similar in its growth habit, agronomic properties, and disease susceptibility to other commercially cultivated corn with the exception of the increased ear biomass trait (Leibman *et al.*, 2014; Monsanto, 2014). This implies that its cultural requirements would neither differ from those of other corn nor change the areas in which corn is currently cultivated. Land use changes associated with approving the petition for nonregulated status for MON 87403 corn are not expected to be any different than those associated with the cultivation of other corn varieties.

Potential reasonably foreseeable cumulative impacts are analyzed under the assumption that farmers have used in the past and would continue to use reasonable, commonly accepted BMPs for their chosen system and selected varieties during corn production. APHIS recognizes, however, that not all farmers will use such BMPs. Thus, this circumstance was also considered in the cumulative impacts analysis. APHIS assumes growers of MON 87403 corn will adhere to the EPA-registered uses and EPA-approved labels for all pesticides applied to corn.

Crop varieties that contain more than one GE trait, known as a "stacked" hybrid, are currently found in agricultural production and in the marketplace. If APHIS approves the petition for nonregulated status of MON 87403 corn, it would likely be combined with non-GE and GE corn varieties through traditional breeding techniques. Stacking of nonregulated GE crop varieties using traditional breeding techniques is common industry practice and is not regulated by APHIS. Stacking would involve combining MON 87403 corn with other corn varieties having

GE traits such as herbicide, insect, and/or drought resistance, which are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. Such stacked varieties could provide growers with several options such as insect control, and combining several herbicides with different modes of action for control of weeds. Therefore, as part of the cumulative impacts analysis, APHIS will assume that MON 87403 corn would likely be combined with commercially available herbicide and insect-resistant varieties of corn as a reasonably foreseeable future action. In the petition for determination of nonregulated status Monsanto states that MON 87403 corn will be combined with other deregulated biotechnology-derived traits through traditional breeding methods to create commercial products with increased yield opportunity as well as protection against maize pests and resistance to multiple herbicides (Monsanto, 2014).

5.2 Cumulative Impacts: Acreage and Area of Corn Production

Neither the No Action nor the Preferred Alternative are expected to directly cause a measurable change in agricultural acreage or area devoted to corn cultivation in the U.S. (see Subsections 4.2.1, Acreage and Range of Corn Production). The majority of corn grown in the U.S. is GE and herbicide resistant (USDA-NASS, 2014a). Long-term projections show planted corn maintaining between approximately 90 and 92 million acres a year through 2021, about the same as the 91.6 million acres planted to corn in 2014 (USDA-OCE, 2012a; USDA-NASS, 2014a). Because MON 87403 corn is agronomically and compositionally similar to other commercially available corn varieties (GE and non-GE), it is expected that MON 87403 corn will replace other similar varieties without expanding the acreage or area of corn production. There are no anticipated changes to the availability of GE and non-GE corn varieties on the market under either alternative. The Preferred Alternative, therefore, would have no impacts to acreage or area of corn production and corn grown for seed different than the No Action Alternative.

The potential future development and cultivation of MON 87403 corn stacked with other GE traits is not likely to change the area or acreage of corn production. Despite the availability of these cultivars, corn production acreage is expected to remain relatively stable until 2021 (USDA-OCE, 2012a).

5.3 Cumulative Impacts: Agronomic Practices

In the preceding analysis, the potential impacts from a determination of nonregulated status of MON 87403 corn were assessed. The agronomic characteristics evaluated for MON 87403 corn encompassed the entire life cycle of the corn plant and included germination, seedling emergence, growth habit, vegetative vigor, days to pollen shed, days to maturity, and yield parameters.

Monsanto compared five hybrid lines expressing the ATHB17Δ113 protein to their corresponding conventional lines at 30 corn growing locations in Iowa, Illinois, Indiana, Kansas and Ohio from 2009 – 2010 (Leibman *et al.*, 2014). For the ATHB17Δ113 lines, yield was higher than corresponding conventional lines 62% of the time (Leibman *et al.*, 2014). The inputs were consistent for all plants included in these performance trials, the lines expressing the ATHB17Δ113 protein as well as their corresponding conventional lines (Leibman *et al.*, 2014) indicating that, under consistent agronomic practices, MON 87403 corn or MON 87403 corn stacked with other nonregulated GE varieties would not alter agronomic requirements for cultivation.

The compositional analysis included the major constituents (carbohydrates, protein, fat, and ash), minerals, vitamins, amino acids, fatty acids, secondary metabolites, antinutrients, phytosterols, and nutritional impact. MON 87403 corn is agronomically and compositionally similar to other GE and non-GE corn varieties (Monsanto, 2014; USDA-APHIS, 2014a). As a result, and as determined in Section 4, Environmental Consequences, the potential impacts under the Preferred Alternative for all the resource areas analyzed would be the same as those described for the No Action Alternative.

The potential impacts under the Preferred Alternative from the use of herbicides would be the same as those under the No Action Alternative (see Subsections 4.2, Agricultural Production of Corn). The method and timing of application for herbicides to be applied to MON 87403 corn would not change from those already approved for use on other corn cultivars. The total amount of the mix of herbicides that could be applied to MON 87403 corn would be limited by the authorized EPA-registered uses and the total application amount allowed by law. Pesticides are registered by the EPA under FIFRA and are reviewed and reregistered every 15 years to assess potential toxicity and environmental impact. In order to be registered for use, a pesticide must be able to be used without unreasonable risks to people or the environment. Pesticide residue tolerances for pesticides are listed in 40 CFR §180.364 and include acceptable concentrations for corn grain and forage.

MON 87403 corn stacked with other nonregulated traits such as herbicide, insect, and/or drought resistance would be no more likely to exhibit increased weediness characteristics than other currently available GE corn cultivars. Similarly, stacked MON 87403 corn is not expected to exhibit any gene flow characteristics different from the parent transformation events (i.e., crop lines) that would pose a plant pest risk.

Under the Preferred Alternative, a determination of nonregulated status of MON 87403 corn is not expected to result in changes to current corn cropping practices. Studies conducted by Monsanto demonstrate that, in terms of agronomic characteristics and cultivation practices, MON 87403 corn is similar to other corn varieties currently grown (Monsanto, 2014; USDA-APHIS, 2014a). Consequently, no changes to current corn cropping practices such as tillage, crop rotation, or agricultural inputs associated with the adoption of MON 87403 corn alone or stacked with other nonregulated GE traits are expected (see Subsection 4.2.2, Agronomic Practices).

5.4 Cumulative Impacts: Organic Corn Production

As described in Sections 2.1.3 and 4.2.3 – Organic Corn Production, organic growers use common practices to maintain the organic status of their corn including employing adequate isolation distances between the organic fields and the fields of neighbors, planting border rows, and planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, to minimize the chance that pollen will be carried between the fields. Based upon recent trends, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share (see Subsection 4.2.3, Organic Corn Production). As described above, the majority of corn planted in 2014 was GE herbicide or insect resistant (USDA-NASS, 2014a). Since 1994, 28 GE corn events or lines have been determined by APHIS to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA (USDA-APHIS, 2014b). U.S. organic corn production acreage grew 83 percent from 32,650 acres in 1995 to 194,637 acres in 2008, and remained at about 0.2 percent of total U.S. corn acreage from 2005 to 2008 (USDA-ERS, 2011c). Availability of another GE corn variety, such as MON 87403 corn under the Preferred Alternative, is not expected to impact the organic production of corn any differently than other GE varieties grown in the past or presently under the No Action Alternative.

5.5 Cumulative Impacts: Physical Environment

As discussed in Subsection 4.3, Physical Environment, approving the petition for nonregulated status of MON 87403 corn under the Preferred Alternative would have the same potential impacts to water, soil, air quality, and climate change as that of corn varieties (GE and non-GE) currently available. Agronomic practices that have the potential to impact soil, water and air quality, and climate change such as tillage, agricultural inputs (fertilizers and pesticides), and irrigation would not change because MON 87403 corn has been determined to be agronomically similar to other GE and non-GE corn varieties (Leibman *et al.*, 2014; Monsanto, 2014). Other practices that benefit these resources, such as contouring, use of cover crops to limit the time soil is exposed to wind and rain, crop rotation, and windbreaks would also be the same between the No Action and Preferred Alternatives. Adoption of MON 87403 corn would likely replace other similar cultivars without changing the acreage or area of corn production that could impact water, soil, air quality, and climate change. No difference in impacts to these resources would occur between the Preferred and No Action Alternatives. Overall, the availability of another corn variety, such as MON 87403 corn alone or stacked with other GE traits, is not expected to impact water, soil, air quality and climate change any differently than other corn varieties (GE and non-GE) currently available. Therefore, no cumulative impacts to the physical environment would be expected.

5.6 Cumulative Impacts: Biological Resources

The impacts of the Preferred Alternative to animal and plants communities, microorganisms, and biodiversity as discussed in Subsection 4.4, Biological Resources would be no different than that experienced under the No Action Alternative. Animal communities would not be affected by direct contact or consumption of MON 87403 corn. This assessment is based on the lack of toxicity or allergenicity from the ATHB117Δ113 protein and due to its nutritional and compositional equivalence to other corn varieties (Monsanto, 2014). The compositional analysis included the major constituents (carbohydrates, protein, fat, and ash), minerals, vitamins, amino acids, fatty acids, secondary metabolites, antinutrients, phytosterols, and nutritional impact. MON 87403 corn is both agronomically and compositionally similar to other corn (Monsanto, 2014; USDA-APHIS, 2014a); thus, it would not require any different agronomic practices to cultivate, and does not represent a safety or increased weediness risk any differently than other currently available corn varieties. Cultivation of MON 87403 corn is unlikely to have a cumulative impact on soil microorganisms or biodiversity relative to the cultivation of other corn varieties (GE and non-GE). When compared to existing corn production practices cultivation of MON 87403 corn will utilize similar management practices including the use of herbicides. Application of herbicides in U.S. corn production will continue to be dictated by both individual farm need and EPA label use restrictions. As a consequence of its herbicide registration program, EPA has effectively determined that there is no unreasonable environmental risk if the end user adheres to the directions and restrictions on the EPA registration label when applying herbicide formulations.

There are no differences in the potential for gene flow and weediness between the No Action and Preferred Action Alternatives. Only limited populations of compatible relatives of domesticated corn with limited intercrossing ability are found within the U.S.; hence, there is not a significant risk of gene movement between corn and its wild or weedy maize relatives (Monsanto, 2014; USDA-APHIS, 2014a). Additionally, corn seed does not possess the characteristics for efficient seed-mediated gene flow, does not establish wild or feral populations, and is dependent on human cultivation for survival (OECD, 2003; Doebley, 2004). The risk of gene flow and weediness of MON 87403 corn is no greater than that of other nonregulated GE corn varieties.

Following a determination of nonregulated status, MON 87403 corn would likely be stacked with other nonregulated GE traits for herbicide, insect, and/or drought resistance. Whether MON 87403 corn would be stacked with any particular nonregulated GE variety is unknown, as company plans and market demands play a significant role in those business decisions. Any GE traits that may be stacked with MON 87403 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.

5.7 Cumulative Impacts: Human Health and Animal Feed

Food and feed derived from GE corn must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release onto the market to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food. As discussed in Subsections 4.5, Public Health and 4.6, Animal Feed, MON 87403 corn is expected to have no toxic effect to human health or livestock (Monsanto, 2014). Monsanto indicated that they submitted a safety and nutritional assessment of food and feed derived from MON 87403 corn to FDA in October 2014 (Monsanto, 2015). FDA is presently evaluating the submission. No change in food and feed safety is expected to occur under the Preferred Alternative.

In the preceding analysis, the potential impacts from approving the petition for nonregulated status to MON 87403 corn were assessed. The compositional analysis included the major constituents (carbohydrates, protein, fat, and ash), minerals, vitamins, amino acids, fatty acids, secondary metabolites, antinutrients, phytosterols, and nutritional impact. MON 87403 corn is agronomically and compositionally similar to other GE- and non-GE-corn varieties (Monsanto, 2014; USDA-APHIS, 2014a). As a result, the potential impacts under the Preferred Alternative for human health and animal feed are the same as those described for the No Action Alternative.

Following a determination of nonregulated status, MON 87403 corn would likely be stacked with other nonregulated GE traits for herbicide, insect, and/or drought resistance. As discussed above in Subsection 4.5 Public Health and 4.6 Animal Feed, food and feed derived from GE corn must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release onto the market. All varieties of GE corn with which MON 87403 corn would be stacked have undergone, or are expected to undergo, this process to ensure their safety as food and feed products. In addition any GE traits that may be stacked with MON 87403 corn have already been assessed by APHIS and determined to be nonregulated. As such, the production and use of products from these cultivars as food or feed have been determined on the basis of the FDA evaluation of food and feed uses to have no significant negative impact on the biological resources, human health, or animal feed analyzed in this EA.

5.8 Cumulative Impacts: Socioeconomics

As discussed above, based on its similarity to other corn cultivars, MON 87403 corn would be planted without impacting corn acreage or production area that may affect domestic markets. Additionally, since MON 87403 corn is agronomically and compositionally similar to other commercially available corn, there would be few changes to agronomic inputs or practices following a determination of nonregulated status of MON 87403 corn that may impact on-farm costs for corn producers or the domestic economic environment, including the organic corn market.

Agronomic practices, including inputs for production of MON 87403 corn stacked with other GE traits, would be no different than those needed to cultivate other commercially available corn; thus, changes to on-farm costs for corn producers or to the U.S. domestic corn market would be unlikely. While MON 87403 corn may also be stacked with other nonregulated GE traits, predicting these potential combinations would be purely speculative. Overall, it is unlikely that any cumulative impact to the domestic economic environment would result from a stacked product consisting of MON 87403 corn and other readily-available GE traits. Impacts of the Preferred Alternative on the domestic economic environment would therefore be no different than experienced under the No Action Alternative.

Under the Preferred Alternative, it is possible MON 87403 corn would not be approved for import into other countries. Because the U.S. and other countries already have access to other corn varieties (both GE and non-GE), and MON 87403 corn presents another option similar to cultivars already in the marketplace, its availability only to U.S. producers would not likely significantly impact the economic trade environment. Only 14.6 percent of domestically produced corn in the U.S. is dedicated to the export market (USDA-ERS, 2014b). If MON 87403 corn were not approved for import by other countries but would be approved as nonregulated in the U.S., it would not likely affect the supply of U.S. corn eligible for import to other countries. Likewise, if it were approved both in the U.S. and for import by other countries, based on its similarity to other corn varieties MON 87403 corn would still be unlikely to affect the supply of U.S. corn available for export. If it were approved in the U.S., but not for import by other countries, growers may find that more limited options were available for grain sales (Stebbins and Plume, 2011), but again, any significant impact on exports would be unlikely because the growers would likely hesitate to grow the crop and large quantities would not be produced.

As discussed in Subsection 2.6.2, Trade Economic Environment, U.S. corn exports have remained relatively stable over the last decade, a period in which other corn varieties with GE traits have been brought to market. Global export markets respond to many factors and are unlikely to change with the commercial availability of MON 87403 corn alone, or stacked with other currently available traits. In addition, Monsanto intends to obtain import approvals for MON 87403 corn in all key corn import markets with a functioning regulatory system prior to commercial release of hybrids containing MON 87403 (Monsanto, 2014). Approval in these export countries is intended to mitigate global sensitivities to GE productions and work in accordance with international regulations.

5.9 Cumulative Impacts Summary

In summary, the potential for impacts of MON 87403 corn would not result in any changes to the resource areas when compared to the No Action Alternative. No cumulative impacts are expected from approving the petition for nonregulated status for MON 87403 corn, when taken in consideration with related activities, including past, present, and reasonably foreseeable future actions.

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

The APHIS regulatory authority over GE organisms is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR §340.1). After completing a PPRA, if APHIS determines that MON 87403 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 87403 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 impacts;
- Determination of the concentrations of known plant toxicants (if any are known in the plant);
- Analysis to determine if the transgenic plant is sexually compatible with any TES of plants or a host of any TES; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

APHIS met with USFWS officials on June 15, 2011, to discuss and clarify whether 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 APHIS have agreed that it is not necessary for 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. APHIS has no statutory authority to authorize or regulate the use of pesticides by corn growers. Under APHIS' Part 340 regulations, APHIS only has the authority to regulate MON 87403 corn or any GE organism as long as APHIS believes they may pose a plant pest risk (7 CFR § 340.1). APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of pesticides on those organisms.

In following this review process, APHIS, as described below, has evaluated the potential effects that a determination of nonregulated status of MON 87403 corn may have, if any, on federally-listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation.

6.2 Potential Effects of MON 87403 Corn on TES

Based on the information submitted by the applicant and reviewed by APHIS, MON 87403 corn with the exception of the increased ear biomass trait, is agronomically, phenotypically, and biochemically comparable to conventional corn (Monsanto, 2014). Monsanto has presented results of agronomic field trials for MON 87403 corn. The results of these field trials demonstrate that there are no differences in agronomic practices between MON 87403 corn and conventional corn (Monsanto, 2014). The common agricultural practices that would be carried out in the cultivation of MON 87403 corn are not expected to deviate from current practices, including the use of EPA-registered pesticides. MON 87403 corn is not expected to directly cause a measurable change in agricultural acreage or area devoted to corn in the U.S. (see Subsection 4.2.1, Acreage and Area of Corn Production). Because MON 87403 corn is agronomically and compositionally similar to other commercially available corn varieties (GE and non-GE), it is expected that MON 87403 corn will replace other similar varieties without expanding the acreage or area of corn production.

Corn is cultivated in all 50 states within the U.S. Accordingly, the issues discussed herein focus on the potential environmental consequences of approval of the petition for nonregulated status of MON 87403 corn on TES species and critical habitat in the areas where corn is currently cultivated. APHIS obtained and reviewed the USFWS list of TES species (listed and proposed) for all 50 states where corn is produced from the USFWS Environmental Conservation Online System (US-FWS, 2015).

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 novel ATHB17Δ113 protein expressed in MON 87403 corn as a result of the transformation, and the ability of the plants to serve as a host for a TES.

6.2.1 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 87403 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 87403 corn is unchanged with respect to conventional corn (Monsanto, 2014). No differences were detected between MON 87403 corn and conventional corn in growth, reproduction, or interactions with pests and diseases, other than the intended effect of increased ear biomass (Monsanto, 2014; USDA-APHIS, 2014a). Potential of corn weediness is low, due to domestication syndrome traits that generally lower overall fitness outside an agricultural environment (Stewart *et al.*, 2003). 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, 2014a). 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 87403 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, 2014a).

APHIS evaluated the potential of MON 87403 corn to cross with a listed species. As discussed in Gene Movement and Weediness (Subsections 2.3.3 and 4.4.3), the potential for gene movement between MON 87403 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, 2014a), however, this plant is not listed as a TES (USFWS, 2015). 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, 2014a). None of the relatives of corn are Federally listed (or proposed) as endangered or threatened species (USFWS, 2015). Accordingly, a determination of nonregulated status of MON 87403 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 87403 corn will have no effect on threatened or endangered plant species or on critical habitat.

6.2.2 Threatened and Endangered Animal Species

Threatened and endangered animal species that may be exposed to the gene products from MON 87403 corn would be those TES that inhabit corn fields and feed on MON 87403 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 *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; ICF, 2014). 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 87403 corn. Monsanto has presented information on the food and feed safety of MON 87403 corn, comparing the MON 87403 corn variety with conventional varieties currently grown. There are no toxins or allergens associated with this plant (Monsanto, 2014). Compositionally, MON 87403 Corn was determined to be the same as conventional varieties. Compositional elements compared included moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and antinutrients (Monsanto, 2014). Results presented by Monsanto show that the ATHB17Δ113 protein in MON 87403 corn does not result in any compositional differences between MON 87403 corn and the non-transgenic hybrid. Therefore, there is no expectation that exposure to the protein or the plant will have any effect on T&E animal species that may be exposed to MON 87403 corn.

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 87403 corn (Monsanto, 2014). 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, an in vitro digestibility assay of the proteins, and an acute oral toxicity feeding study in mice. MON 87403 corn protein was determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and was degraded rapidly and completely in gastric fluid (Monsanto, 2014). Monsanto indicated that they intend to submit a safety and nutritional assessment of food and feed derived from MON 87403 corn to the FDA prior to commercial release (Monsanto, 2014).

APHIS considered the possibility that MON 87403 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.

Considering the compositional similarity between MON 87403 corn and other varieties currently grown and the lack of toxicity and allergenicity of the ATHB117Δ113 protein, APHIS has concluded that exposure and consumption of MON 87403 corn would have no effect on threatened or endangered animal species.

6.3 Summary

After reviewing the possible effects of allowing the environmental release of MON 87403 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 87403 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 87403 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 87403 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 of the USFWS or NMFS are not required.

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 impacts.
- ***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 impacts on minorities, low-income populations, or children.

Based on the information submitted by the applicant and reviewed by APHIS, MON 87403 corn is agronomically, phenotypically, and biochemically comparable to conventional corn except for the increased ear biomass trait expressed in MON 87403 corn. To establish that the new cultivar is nutritionally equivalent to the parent cultivar, detailed compositional analyses were conducted based on Organization for Economic Cooperation and Development (OECD) guidelines for corn to compare levels of key nutrients, anti-nutrients and secondary metabolites in MON 87403 corn to levels in the conventional corn control (Monsanto, 2014). Analysis found no statistically significant difference between MON 87403 corn and the conventional control. The lack of any statistically significant differences between MON 87403 corn and the conventional control demonstrated that MON 87403 corn was not a major contributor to variation in nutrient, antinutrient, or secondary metabolite component levels in corn grain or forage and confirmed the compositional equivalence of MON 87403 corn to the conventional control (Monsanto, 2014).

Acute oral toxicity studies conducted by Monsanto indicated that the ATHB17Δ113 did not cause any adverse effects in mice with no observable adverse effects level at the highest dose (1 billion times higher than conservative estimate of high end exposure through dietary consumption) (Monsanto, 2014). Since no evidence of mammalian toxicity has been reported for the ATHB17Δ113 protein and expression levels in grain are extremely low the dietary risk assessment indicates that there is no meaningful risk to human health from dietary exposure to the ATHB17Δ113 protein produced by MON 87403 corn (Monsanto, 2014). No additional safety precautions would need to be taken.

Monsanto initiated the consultation process with FDA and submitted a safety and nutritional assessment of food and feed derived from MON 87403 corn to FDA in October 2014 (Monsanto, 2015). The FDA is presently evaluating the submission.

Based on these factors, a determination of nonregulated status of MON 87403 corn is not expected to have a disproportionate adverse impact on minorities, low-income populations, or children.

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.

Consistent with EO 13175, APHIS sent a letter of notification and request for comment and consultation on the proposed action to tribes in areas where MON 87403 corn could be grown on January 28th, 2015. This letter contained information regarding the Monsanto petition and the MON 87403 corn variety. Additionally, this same notification also asked tribal leaders to contact APHIS if they believed that there were potentially significant impacts to tribal lands or resources that should be considered. APHIS will continue to consult and collaborate with tribal officials to ensure that they are well-informed and represented in policy and program decisions that may impact their agricultural interests, in accordance with EO 13175.

A determination of nonregulated status of MON 87403 corn will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on properties owned by Tribes are only conducted at the tribe's request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties.

The No Action and Preferred Alternatives were analyzed with respect to EO 12898, EO 13045, and EO 13175. Neither alternative is expected to have a disproportionate adverse impact on minorities, low-income populations, or children. Nor is any alternative expected to have potential Tribal implications.

The following executive order addresses Federal responsibilities regarding the introduction and impacts of invasive species:

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

Corn is not listed in the U.S. as a noxious weed species by the Federal government (USDA-NRCS, 2013), nor is it listed as an invasive species by major invasive plant data bases. Cultivated corn seed does not usually exhibit dormancy and requires specific environmental conditions to grow as a volunteer the following year (OECD, 2003). Any volunteers that may become established do not compete well with the planted crop and are easily managed using standard weed control practices. Corn does not possess characteristics such as the tolerance for a variety of habitat conditions, rapid growth and reproduction, aggressive competition for resources, and the lack of natural enemies or pests (USDA-APHIS, 2014a) that would make it a successful invasive plant. Based on historical experience with GE varieties and the data submitted by the applicant and reviewed by APHIS, MON 87403 corn plants are sufficiently similar in fitness characteristics to other corn varieties currently grown and are not expected to become weedy or invasive.

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 with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Migratory birds may be found in corn fields. A variety of birds including songbirds, swallows, waterfowl, game species, raptors, and migratory species are known to feed directly on corn or the insects and small mammals that are found in and around corn fields (Dolbeer, 1990; Best and Gionfriddo, 1991; Sparling and Krapu, 1994; Patterson and Best, 1996; Taft and Elphick, 2007; Mullen, 2011; Sherfy et al., 2011). Data submitted by the applicant has shown no difference in compositional and nutritional quality of MON 87403 corn compared with other GE corn or non-GE corn, apart from the increased ear biomass trait (Monsanto, 2014). As discussed in Section 4.6 Animal Feed, Monsanto indicated that they submitted a safety and nutritional assessment of food and feed derived from MON 87403 corn to FDA in October 2014 (Monsanto, 2015). FDA is presently evaluating the submission. MON 87403 corn is not expected to be allergenic, toxic, or pathogenic in mammals. Based on APHIS' assessment of MON 87403 corn, it is unlikely that a determination of nonregulated status of MON 87403 corn would have a negative impact 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 impacts 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 87403 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 87403 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, 2010). The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). In April 2004, a standard for pest risk analysis 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 (CBD, 2010). Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol and the required documentation. LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement.

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, 2014).

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 of MON 87403 corn (Section 4.2) and determined that the cultivation of MON 87403 corn would not lead to the increased production or acreage of corn production that could impact water resources or air quality an differently than currently cultivated corn varieties. The increased ear biomass conferred by the genetic modification to MON 87403 corn is not expected to result in any changes in water usage for cultivation. As discussed in Section 4.3.1 and 4.3.3, there are no expected significant negative impacts to water resources or air quality associated with MON 87403 corn production. Based on these analyses, APHIS concludes that a determination of nonregulated status of MON 87403 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 87403 corn is not expected to impact unique characteristics of geographic areas such as park lands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

Monsanto has presented results of agronomic field trials for MON 87403 corn. The results of these field trials demonstrate that there are no differences in agronomic practices between MON 87403 corn and conventional corn. The common agricultural practices that would be carried out in the cultivation MON 87403 corn are not expected to deviate substantially from current practices, including the use of EPA-registered pesticides. The product is expected to be deployed on agricultural land currently suitable for production of corn and replace existing varieties, and is not expected to increase the acreage of corn production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of MON 87403 corn. This action would not convert land use to nonagricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87403 corn, including the use of EPA-registered pesticides.

Based on these findings, including the assumption that EPA label use instructions are in place to protect unique geographic areas and that those label use instructions are adhered to, a determination of nonregulated status of MON 87403 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 impacts on historic properties and 2) if so, to evaluate the impacts 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 87403 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 87403 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 impacts 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 impacts 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 impacts. Additionally, these cultivation practices are already being conducted throughout the corn production regions. The cultivation of MON 87403 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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