

The Monsanto Company Petition (10-281-01) for Determination of Nonregulated Status of MON 87427 Maize

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Environmental Assessment

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Acronyms and Abbreviations

AIA	advanced informed agreement
AMS	Agricultural Marketing Service
AOSCA	American Organization of Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
BRAD	Biopesticide Registration Action Document
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
Bt	<i>Bacillus thuringiensis</i> protein
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CH₄	methane
CO	carbon monoxide
CO₂	carbon dioxide
CRP	Conservation Reserve Program
DNA	deoxyribonucleic acid
DT	drought tolerant
EA	environmental assessment
EIS	environmental impact statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
EQIP	Environmental Quality Incentives Program
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
FR	Federal Register
GDP	gross domestic product
GE	genetically engineered
GHG	greenhouse gas
GMO	genetically modified organism
IP	Identity Preservation
IPCC	Intergovernmental Panel on Climate Change
IRM	Insect Resistance Management

Acronyms and Abbreviations

ISPM	International Standard for Phytosanitary Measure
IPPC	International Plant Protection Convention
LD50	lethal dose that kills 50% of the animals being tested
MBu	million bushels
NO₂	nitrogen dioxide
N₂O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NOEL	no observable effect level
NOP	National Organic Program
NPS	Agricultural non-point source
NRC	National Research Council
PPRA	Plant Pest Risk Assessment
PPA	Plant Protection Act
PRA	pest risk analysis
RNA	ribonucleic acid
TES	threatened and endangered species
TSCA	Toxic Substances Control Act
U.S.	United States
USDA	U.S. Department of Agriculture
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USDA-NOP	U.S. Department of Agriculture-National Organic Program
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 submitted petition 10-281-01 to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in October 2010 seeking a determination of nonregulated status of maize¹ event MON 87427 that exhibits a tissue-selective glyphosate tolerant phenotype. MON 87427 corn is currently regulated under 7 CFR part 340. Interstate movements and field trials of MON 87427 corn have been conducted under notifications and permits acknowledged by APHIS since 2005. These field trials were conducted in typical corn production regions within the U.S., ranging from Arkansas to Wisconsin. Details regarding and data resulting from these field trials are described in the MON 87427 petition (Monsanto, 2010) and analyzed for plant pest risk in the APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2012).

The petition stated that APHIS should not regulate MON 87427 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 87427 corn, any progeny derived from crosses between MON 87427 and conventional corn, including crosses of MON 87427 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.

1.2 Purpose of Product

Almost all commercial corn seed in the United States is produced through hybridization. Hybrid corn seed production requires the use of two corn inbred parents, one designated as the pollen receiver (female) and another designated as the pollen donor (male). In this process, the female inbred is fertilized with pollen from the male inbred. To ensure cross pollination between female and male inbred parents and limit self-fertilization² of the female parent, female inbred plants are often detasseled³. Detasseling of the female inbred may be accomplished by hand and/or through mechanical means. In addition to representing one of the largest costs in hybrid corn seed production, detasseling of female inbred parents may also incur a yield penalty through plant injury or inefficient detasseling (Pioneer, 2009; Monsanto, 2010).

MON 87427 corn is genetically engineered (GE) to reduce the cost of producing hybrid corn seed. When used as a female inbred parent and sprayed with glyphosate during late vegetative development, MON 87427 corn is unable to produce viable pollen and self-fertilize. This phenotype precludes the need for manual/mechanical detasseling of MON 87427, decreasing the costs and yield penalties generally associated with manual/mechanical detasseling.

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

² Corn is a monoecious plant, meaning that both female and male reproductive structures are found on a single individual. The female reproductive structure is called an ear, while the male reproductive structure is called a tassel. Self-fertilization in corn occurs when pollen from one individual fertilizes an egg of that same individual.

³ Pollen control of the female inbred parent may be undertaken through removal of the tassel.

The MON 87427 phenotype is derived from tissue-specific expression⁴ of *cp4 epsps*, a gene commonly used to confer glyphosate resistance in crop plants. When MON 87427 corn is sprayed with glyphosate prior to or during male reproductive tissue development, viable pollen will not develop. However, growth and female reproductive tissue development proceeds normally in MON 87427, such that its ears remain fully receptive to pollen from another corn plant

1.3 Coordinated Framework Review and Regulatory Review

Since 1986, the United States government has regulated GE organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 1986; 57 FR 22984, 1992). 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).

USDA-APHIS

APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, 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 Plant Protection Act 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.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act or the regulations at 7 CFR 340. The petitioner is required to provide information

⁴ When *cp4 epsps* expression is under control of the *35S-hsp70* promoter in corn, as in MON 87427 corn, glyphosate tolerance only occurs in vegetative and female reproductive tissues and does not occur in male reproductive tissues.

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

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*), EPA regulates the use of pesticides, including plant-incorporated protectants, requiring registration of a pesticide for a specific use prior to distribution or sale of the pesticide for a proposed use pattern. 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, 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. 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 (FQPA) of 1996 amended FIFRA, enabling EPA to implement periodic registration review of pesticides to ensure they are meeting current scientific and regulatory standards of safety and continue to have no unreasonable adverse effects (EPA, 2011).

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). 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. FDA enforces the pesticide tolerances set by EPA.

Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, in the *Federal Register* on May 29, 1992 (57 FR 22984, 1992). Under this policy, FDA implements a voluntary consultation process

to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under Federal food safety laws prior to marketing.

More recently, in June 2006, FDA published recommendations in “Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use” (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 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 Plant Protection Act 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 87427 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 Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS must respond to an October 2010 petition from the Monsanto Company requesting a determination of the regulated status of MON 87427 corn. APHIS has prepared this Environmental Assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality’s (CEQ) National Environmental Policy Act (NEPA) regulations and the USDA and APHIS NEPA implementing regulations and procedures (40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment⁵ that may result from a determination of nonregulated status of MON 87427 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

⁵ Under NEPA regulations, the “human environment” includes “the natural and physical environment and the relationship of people with that environment” (40 CFR §1508.14).

notice published in the *Federal Register*. On March 6, 2012, APHIS published a notice⁶ in the *Federal Register* advising the public that APHIS is implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for GE organisms to allow for early public involvement in the process. As identified in this notice, APHIS will publish two separate notices in the *Federal Register* for petitions for which APHIS prepares an EA. The first notice will announce the availability of the petition, and the second notice will announce the availability of APHIS' decision making documents. As part of the new process, with each of the two notices published in the *Federal Register*, there will be an opportunity for public involvement:

1.5.1 First Opportunity for Public Involvement

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

1.5.2 Second Opportunity for Public Involvement

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

Approach 1: GE organisms that do not raise substantive new issues.

This approach for public participation is used when APHIS decides, based on the review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition, that the petition involves a GE organism that does not raise new biological, cultural, or ecological issues because of the nature of the modification or APHIS' familiarity with the recipient organism. After developing its EA, finding of no significant impact (FONSI), and PPRA, APHIS publishes a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the EA, FONSI, and PPRA for a 30-day public review period.

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

⁶ This notice can be accessed at: <http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf>

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

APHIS solicits comments on its draft EA and draft PPRA for 30 days, as announced in a *Federal Register* notice. APHIS reviews and evaluates comments and other relevant information, then revises the PPRA as necessary and prepares a final EA. Following preparation of these documents, APHIS approves or denies the petition, announcing in the *Federal Register* the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, National Environmental Policy (NEPA) decision document, and regulatory determination.

Enhancements to stakeholder input are described in more detail in the [Federal Register](#) notice⁷ published on March 6, 2012.

APHIS has determined that this EA will follow Approach 1. The issues discussed in this EA were developed by considering the public concerns, including public comments received in response to the *Federal Register* notice (77 F.R. 41364-6) announcing the availability of the petition (i.e., the first opportunity for public involvement previously described in this document), as well as issues noted in public comments submitted for other EAs of GE organisms, and concerns described in lawsuits and expressed 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 Monsanto 87427 corn.

The public comment period for MON 87427 corn petition closed on September 11, 2012. At its closing, the docket file contained a total of 102 docket records, reflecting a total of 23,698 public comments. These were screened and sorted into categories according to the subject matter addressed (e.g., air, water, soil impacts), and classified as either non-substantive or substantive. The majority of the comments were non-substantive and expressed a general dislike of the use of GE organisms or were form letters sent to all of the dockets which were open at the time that this docket was open. The form letter expressed a concern that there were too many dockets published on the same day. It also referenced other open dockets and potential effects from the use of the subjects of those petitions. These issues are outside the scope of this EA. Only 18 comments were deemed substantive ones. From the substantive comments, the issues raised included:

⁷ This notice can be accessed at: <http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf>

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- As another glyphosate resistant corn, additional use of glyphosate will increase glyphosate resistant weeds, requiring use of other herbicides, and weeds will develop resistance to these as well.
- Should not deregulate MON 87427 until the provider has obtained authorizations from key foreign markets prior to deregulation.
- More glyphosate use will increase herbicide levels in air and water sources and affect biological organisms. Herbicides such as glyphosate increase soil pathogens and lead to diseases including *Fusarium* wilt.
- Gene flow of the resistance trait from cultivated plants to wild/weedy/feral relatives may occur.
- Cultivation of this crop may reduce organic production of corn, because cross-pollination will affect sensitive markets for organic growers.
- Concerns that GE plants cause adverse health effects on humans and animals

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 Areas of Corn Production
- Agronomic/Cropping Practices
- Corn Seed Production

Environmental Considerations:

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

Human Health Considerations:

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- Consumer Health
- Worker Safety

Livestock Health Considerations:

- Animal Feed/Livestock Health

Socioeconomic Considerations:

- Domestic Economic Environment
- Organic Corn Production
- Trade Economic Environment

2 Affected environment

2.1 Agricultural Production of Corn

2.1.1 Acreage and Range of Commercial 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 United States (USDA-NASS, 2012a). From 1991 to 2011, acreage planted with corn increased from just over 76.0 million acres to about 91.9 million acres (Figure 1) Over that 20 year span, U.S. production of field corn for grain increased from approximately 7.5 billion bushels in 1991 to approximately 12.4 billion bushels in 2011, and average annual yield increased approximately 41 percent from 109 bushels per acre in 1991 to 147 bushels per acre in 2011 (USDA-NASS, 2012e).

In the United States, corn may be cultivated where there is sufficient moisture (natural or irrigated) and frost-free days to reach maturity. The geographic range of corn production in the United States has been expanded by growing the crop under irrigation and breeding programs to increase drought and cold tolerance, shorten length of growing period, and improve disease and pest resistance (Neild and Newman, 1990; Hoefl et al., 2000; Corn and Soybean Digest, 2009; Carena, 2010). U.S. corn production is primarily focused 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 1) (USDA-NASS, 2010). In general, the Corn Belt has an adequate combination of seasonal warm weather, rainfall, and favorable soil conditions for growth (Hoefl et al., 2000). While the Midwest typically experiences a minimum of 30 inches of rainfall annually, the central part of the Great Plains (~26 percent of U.S. corn production) receives an average of 20 inches, making it less optimal for corn production (Lew, 2004).

Seed Production Acreage

Although the focus of this EA is on MON 87427 which is a trait whose main importance is to hybrid seed production, seed production is dependent upon commercial corn needs. Consequently it is relevant to discuss the acreage trends in commercial corn. After an extended

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historical period of changing grower preferences dating from 1933, nearly all commercial corn production fields are planted with hybrid seed (USDA-APHIS, 2011a). Hybrid seed production may occur anywhere corn is typically cultivated, although the majority is generally produced in the Corn Belt due to ideal environmental conditions (Monsanto, 2010). Despite a general trend of increasing corn acreage, hybrid corn seed production has been fairly constant in the United States, totaling an approximate 0.5 - 1 million acres and 21 million bushels annually (Monsanto, 2010; USDA-ERS, 2012c). Over the last 35 years, the volume of hybrid maize seed planted in the U.S. has changed very little, with 20.10 million bushels (MBu) planted in 1975 and 22.55 MBu planted in 2009 (USDA-ERS, 2010). Grain yields have increased significantly over this same period (Figure 7).

Selection of a suitable growing area is a key decision for seed production. Factors such as temperature, rainfall, day length, and soil nutrient status are important because seed yields may be sensitive to unfavorable conditions during particular periods (Monsanto, 2010). For example, extremely high temperatures and dry conditions can affect the timing of silk emergence and growth, pollen shed and pollen viability resulting in poor seed formation and yield.

Climatic conditions in the U.S. Corn Belt are well suited for corn seed production and include the major Corn Belt states of Nebraska, Iowa, Illinois, and Indiana (McDonald and Copeland, 1997). Only limited quantities of corn seed are produced in the southern states due to high temperatures during pollination, inadequate rainfall during the growing season, and a higher incidence of insects and diseases (Chad Peters, Monsanto Global Operations, personal communication, 2010). Corn seed is also not produced in the most northern portions of the corn belt due to colder temperatures where the mean number of growing degree days accumulated during the season may not be sufficient for corn to reach maturity prior to frost (Hoeft et al., 2000a). Hybrid corn seed is typically harvested prior to damaging frost that can reduce seed viability (Wych, 1988).

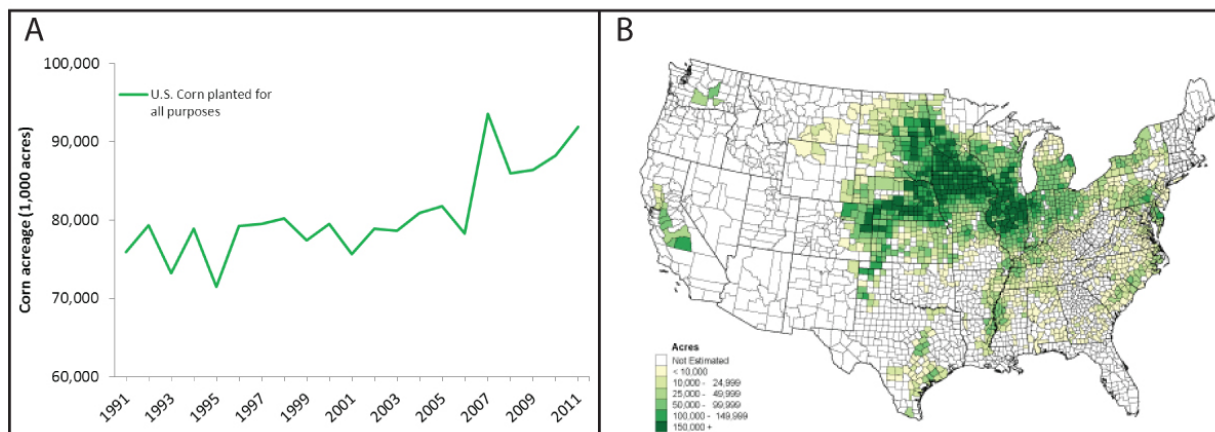


Figure 1. U.S. corn production, planted acreage.

(A) U.S. corn planted for all purposes, 1991 – 2011. Source: USDA-NASS (2012e). (B) Corn planted for all purposes, 2011. Source: USDA-NASS (2012d).

2.1.2 Agronomic Practices of Commercial Corn Production

Most of the corn produced in the United States is hybrid corn adapted to regional environmental and soil conditions. Generally, corn agronomic characteristics, such as optimal planting timeframe, disease and pest pressures, length of growing period, and water requirements, may vary by region (Neild and Newman, 1990; Hoelt et al., 2000; USDA-ERS, 2000; Koenning and Wiatrak, 2012). The majority of corn planted in the United States is GE. In 2011, GE corn varieties represented approximately 88 percent of U.S. planted acreage (USDA-ERS, 2011a). Among these planted GE corn varieties, herbicide-tolerant varieties accounted for 23 percent, insect-resistant varieties accounted for 16 percent, and stacked varieties totaled 49 percent (USDA-ERS, 2011a).

Agronomic practices associated with corn production include several crop management systems that are available to producers. Conventional farming covers a broad scope of farming practices, including farmers that may occasionally or regularly use synthetic fertilizers and pesticides. Conventional farming also includes the use of GE varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Organic systems exclude certain production methods, such as synthetic agricultural inputs and GE crops. Organic systems are further discussed in Section 2.1.4. Although specific crop production practices vary according to region and end-use market, they commonly include tillage, crop rotation, agricultural inputs, and corn seed production. The following introduces the agronomic practices commonly employed to produce corn in the United States. More detailed information may be obtained by consulting the MON 87427 petition (Monsanto, 2010) or the APHIS PPRA for MON 87427 corn (USDA-APHIS, 2012).

Tillage and Production of Commodity Corn

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 (Hoelt et al., 2000; Fawcett and Towery, 2002; Tacker et al., 2006; Givens et al., 2009; 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 (Hoelt 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) (Figure 2). 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, 2011b). 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, 2011b; USDA-ERS, 2012b).

Tillage and Production of Hybrid Seed Corn

Planting conditions for hybrid maize seed production are generally the same as for the cultivation of commercial maize. A minimum soil temperature of 50°F is recommended for planting maize to achieve good germination and stands. Delayed emergence from colder soil conditions can result in damage from microorganisms and insects. Foundation seed will generally not be among the first corn planted mainly because colder soil temperatures may result in non-uniform emergence of inbred lines and a risk of frost damage. Medium-textured, well-drained soils with high water-holding capacities are ideal for commercial maize and maize seed production (Hoefl et al., 2000a; Hoefl, et al., 2000b; a). Sandy soils are less desirable because of their low water-holding capacities, but are suitable if adequate rainfall or irrigation is available during the growing season. Fields with non-uniform soil conditions may result in variable growth and variable timing of pollination and silk emergence (Chad Peters, Monsanto Global Operations, personal communication, Monsanto Company, 2010). Conservation tillage is most commonly used in maize seed production (C. Peters, Monsanto, Global Operations, personal communication, 2010). No-till is seldom practiced in maize seed production due to poor emergence and growth of the inbred lines, plus higher incidence of insect pests and diseases. Soils tend to stay colder and wetter longer in the spring under no-till systems which are less favorable for maize production (McDonald and Copeland, 1997).). When tillage is used for weed control, growers may use rotary hoes and cultivators (Bennett, nd.)

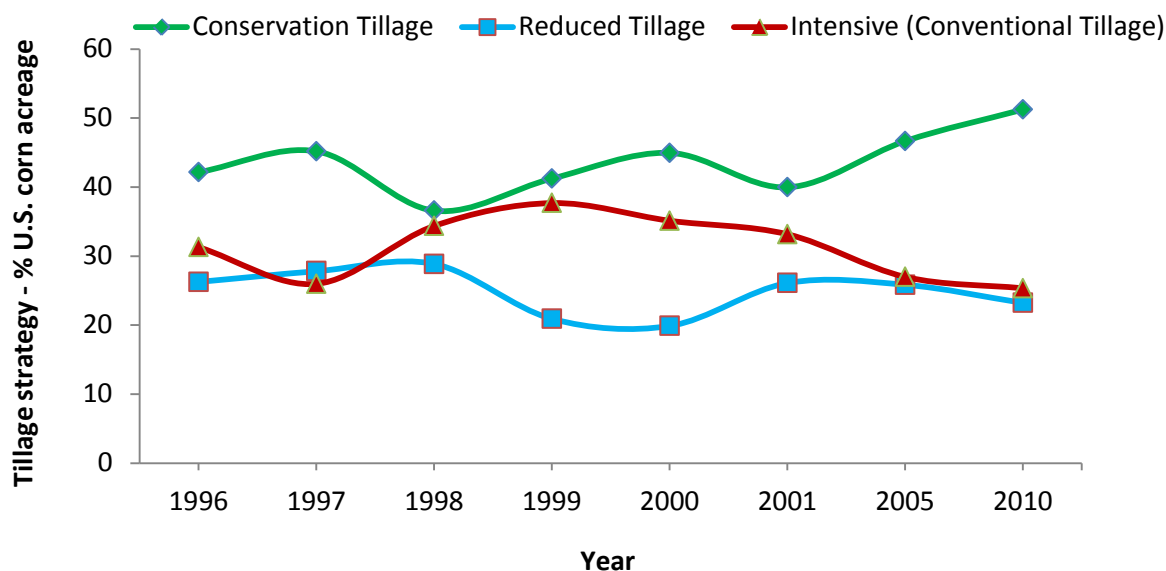


Figure 2. Adoption rates of three major tillage types in U.S. corn production, 1996 – 2010.

Sources: USDA-ERS (2012b).

Crop Rotation in Commodity Corn Production

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, and reduce weeds, insects, and disease problems (Olson and Sander, 1988). 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 United States and may include oats, peanut, soybean, wheat, rye, and forage (USDA-APHIS, 2011c). In 2010, 71 percent of corn acreage in 19 surveyed states was under some form of rotation (USDA-NASS, 2011b). 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, 2011c). 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).

Crop Rotation in Hybrid Seed Production

Since most hybrid seed is produced in the maize belt, a two-year rotation of maize/soybean is the most widely used crop rotation (Monsanto, 2010). Wheat could be added to the rotation or replace soybean in the cropping sequence, particularly in the western maize belt. Although seed producers prefer not to plant maize following maize, it is necessary in some areas (NE and MI) or situations because of the limited soybean acres or other crops available on the farm for rotation (Chad Peters, Monsanto Global Operations, personal communication, 2010). Planting maize following maize can result in a higher incidence of diseases, increase nutrient requirements and make management of volunteer maize plants more difficult and expensive.

Fertilization in Commodity Corn Production

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, 2011b). Macronutrient 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, 2011b).

Fertilization in Hybrid Seed Production

Nutrient requirements for hybrid maize seed production are generally the same as for the cultivation of commercial maize. Nutrient management programs include the addition of nitrogen, phosphorus and potassium fertilizer to optimize maize yields and profitability. Soil tests are used to measure pH and the levels of phosphorus and potassium. Soil pH affects nutrient availability and should be maintained at or above 6.0 for maximum maize yields (Hoefst et al., 2000). Supplemental nitrogen requirements for the crop year may be based on soil tests or calculated from target yields (Hoefst et al., 2000). Deficiencies in secondary nutrients (calcium, magnesium, and sulfur) or micronutrients (boron, chloride, copper, iron, manganese, molybdenum, and zinc) are uncommon but can result in yield reduction unless corrected with supplemental nutrient applications (Hoefst et al., 2000).

Other Production Practices for Hybrid Seed Corn: Density, Isolation, Parental Inbred Delay

Just as the optimum seeding rate and subsequent plant population in commercial maize is specific to each hybrid, so also for inbred lines in hybrid seed production (Chad Peters, Monsanto Global Operations, personal communication, 2010 in (Monsanto-Co., 2010)). Seeding rates for male and female parent inbreds planted in 30-inch row spacing are generally the same and are specified by seed companies (Chad Peters, Monsanto Global Operations, personal communication, 2010 (Monsanto-Co., 2010)). Male and female parent inbreds may be planted at different populations, though, with the female parent inbred population typically being higher than the male parent inbred population. There has been considerable interest in recent years in narrower row spacing in maize seed production (Chad Peters, Monsanto Global Operations, personal communication, 2010 in Monsanto, 2010). Narrowing the row spacing from 30 inches can result in better distribution and spacing of maize plants for greater light penetration and less evaporation of water from the soil, to provide higher plant populations with no yield loss (Abendroth and Elmore, 2006).

In maize hybrid seed production, the male and female parent inbreds are physically separated to control pollination within the field. The male inbred parent can be double planted to extend the pollen shedding period, so that the timing of peak pollen shedding coincides with the timing of peak silk exposure (Monsanto, 2010). Planting patterns in seed production fields include 4:1 (four rows of female parent inbred to one row of male parent inbred), 4:2, 4:1:2:1, 6:2, and solid female parent inbred with interplanted male parent inbred (Monsanto-Co., 2010)). The female parent inbred is never more than two rows from the male parent inbred in the first three patterns (Monsanto-Co., 2010). One half of the female parent inbred rows are adjacent to a male parent inbred in the 4:1 and 4:2 patterns, and two-thirds of the female parent inbred rows are adjacent to a male parent inbred in the 4:1:2:1 pattern. The 6:2 pattern has been used for production of doublecross hybrids, and for the production of single cross hybrids with male parent inbreds that shed an abundant supply of pollen. A planting pattern where every other or every fourth between-row space of a solid planted female parent inbred is interplanted with the male parent inbred fully utilizes the land area for female parent inbred production and achieves closer placement of the male and female parent inbreds (Craig (Craig, 1977)Wych (Wych, 1988)).

Hybrid maize seed production plots are isolated from neighboring maize fields to avoid inadvertent cross-pollination during the flowering stage by wind-borne pollen (Monsanto, 2010).

Physical isolation is used because temporal isolation is difficult to manage and would require the flowering time of the male and female parent inbreds to occur in synchrony, yet independently from the flowering times of other nearby maize. The isolation distance from other maize is regulated by seed certification standards, and is typically at least 660 feet from other maize (AOSCA, 2009). Planting additional male parent inbred border rows around the perimeter of the seed production plots increases desirable pollen shed from the male parent inbred during silking of the female parent inbred, and reduces the potential for contamination from external pollen sources. Other rows can be composed of varieties which shed pollen out of synchrony with the recipient female lines (Bennett, N.D.). Official seed certification regulations often allow isolation distances between seed production fields to be reduced as the number of male parent inbred border rows increases (Agrawal et al., 1998).

Various parent delay techniques can be used to synchronize the flowering of male and female parent inbreds that would otherwise occur at different times (Monsanto-Co., 2010). Split-date planting is the most common of these techniques, where the male and female parent inbreds are planted at different times, based on a combination of the number of days, growth stages, and heat units accumulated from the date when the first parent was planted (Wych, 1988). In addition, the pollen-shedding period may be extended by planting the male parent inbred at two or more dates. Plantings are timed so that peak pollen shed coincides with maximum female parent inbred silk exposure. Special techniques are also available to manipulate the flowering dates of one or both of the seed parents (Wych, 1988). These techniques can delay flowering or extend the duration of flowering by days (Monsanto-Co., 2010). The timing of flowering of the second-planted seed parent may be advanced by varying planting depth or fertilization rate. The flowering date of the first-planted parent can be delayed using techniques that involve burning off the above-ground leaves and stalk of young plants, or cutting off the tops of the plants. These techniques are rarely used to delay the female parent inbred because they typically result in reduced seed yield.

Pesticide Use in Commodity Corn Production

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 herbicides applied on U.S. corn acres (USDA-NASS, 2011b). Relative to herbicide use, fungicide and insecticide use is relatively minor (Figure 3).

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, 2011b). Also in 2010, the most commonly applied fungicides in U.S. corn were pyraclostrobin (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).

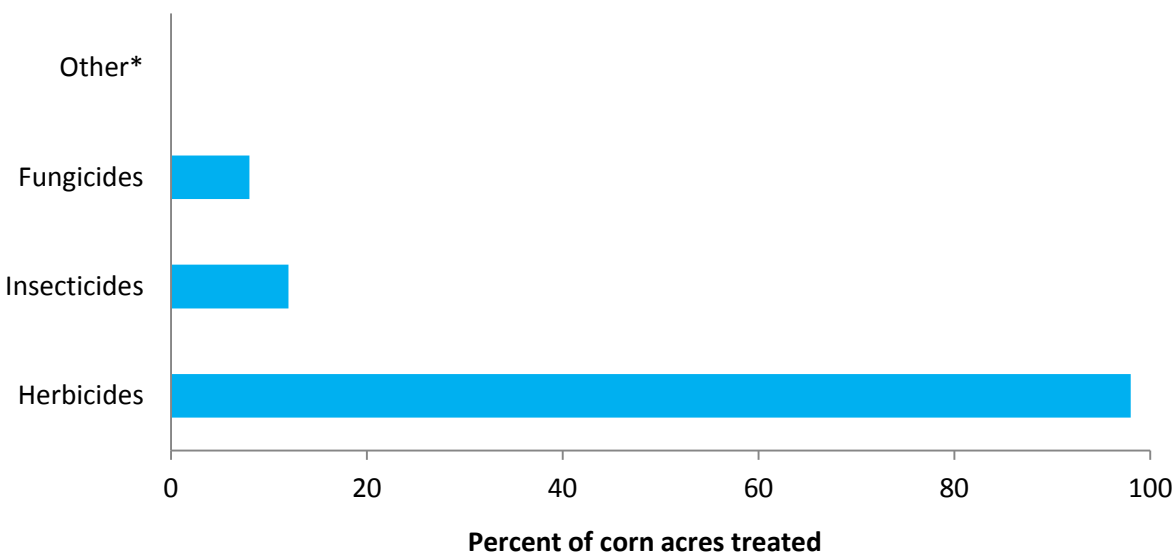


Figure 3. Percent of U.S. corn acreage treated with pesticides, 2010.

*Less than 0.5 percent. Source: USDA-NASS (2011b).

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 12 percent of acres planted to corn in 19 surveyed states (USDA-NASS, 2011b). Tefluthrin was the most commonly-applied insecticide on U.S. corn, with 242,000 lbs. used over 3 percent of corn acreage (USDA-NASS, 2012c). 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, 2012c). 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, 2012c).

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 application⁸ (USDA-NASS, 2011b). 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, 2011b). The use of glyphosate in U.S. corn production has increased since 1994, a trend associated with the increasing adoption of herbicide-tolerant [primarily glyphosate-tolerant] corn varieties (Figure 4). 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, 2011b).

⁸ As measured by total pounds of active ingredient per acre (lbs. ai/acre) applied.

EA of MON 87427 Glyphosate Tolerant Male Sterile Corn (10-281-01)

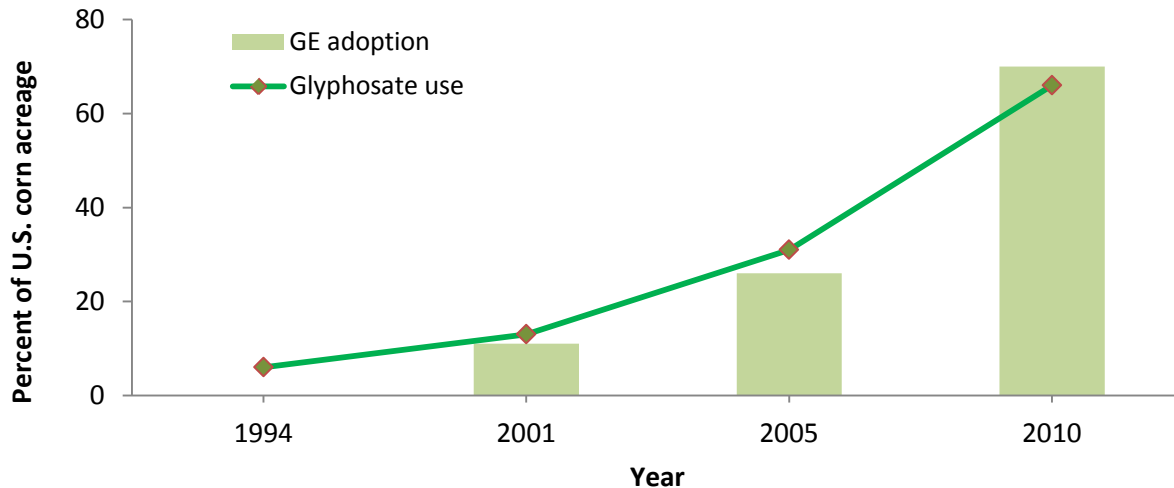


Figure 4. Adoption of GE corn varieties with at least one herbicide-tolerant trait and glyphosate in U.S. corn production, 1994 – 2010.

Source: USDA-ERS (2011a) and USDA-NASS (1996; 2002; 2006; 2011b).

Pesticide Use in Hybrid Seed Corn Production

As earlier noted, inbreds used in corn seed production are not all glyphosate resistant (usually only one of the parental crosses (Monsanto, 2010)). The simplified procedures favored by growers allowing only glyphosate for preplant as well as postemergence weed control is consequently not possible in these hybrid crosses. At least five post-emergence herbicides are labeled for use in postemergence application to seed corn including dicamba, bromoxynil, carfentazone-ethyl, primisulfuron and nicosulfuron often in specialized formulations or as premixes with other herbicides such as atrazine (Iowa-State-University, 2005). Tillage may also be used in addition or alternatively for weed control on acreage used in seed production (Bennett, nd).

2.1.3 Hybrid Corn Seed Production: Pollen Control

In contrast to other agricultural crops, nearly all commercial corn production fields are planted with hybrid seed (USDA-APHIS, 2011a). Hybrid seed production⁹ may occur anywhere corn is typically cultivated, although the majority is generally produced in the Corn Belt due to ideal environmental conditions (Monsanto, 2010). Despite a general trend of increasing corn acreage, hybrid corn seed production has been fairly constant in the United States, totaling an approximate 0.5 - 1 million acres and 21 million bushels annually (Monsanto, 2010; USDA-ERS, 2012c).

Hybridization is a fundamental principle of U.S. corn breeding and production programs, supplying the majority of seed for commercial maize grain production (Wych, 1988). Hybrid corn seed production requires the use of two corn inbred parent lines, one designated as the female inbred (pollen receiver) and the other designated as the male inbred (pollen donor). In

⁹ For the purpose of this EA, hybrid production is synonymous with single cross hybrid production.

general, female inbred and male inbred corn plants are interplanted in a corn seed production field, using a variety of time-tested measures to ensure temporal and spatial isolation (these measures are further discussed in Section 2.3). At its core, hybrid corn production utilizes heterosis¹⁰ (i.e., hybrid vigor), resulting from the crossing of a male inbred with a female inbred, to overcome general reductions in vigor related to the fixation of alleles in parental corn inbred lines (Duvick, 2001).

Pollination Control.

Some mechanism to prevent pollination of female inbred plants prior to anthesis¹¹ is necessary to limit self-fertilization, due to the monoecious nature of maize, and ensure effective cross pollination with male inbred plants (Figure 5). To ensure complete pollination of female parent inbreds by male parent inbreds to produce the desired hybrid maize seed, the type of pollen reaching the female silks must be controlled (Monsanto, 2010). Pollen control in hybrid maize seed production is critical for producing hybrid maize seed with high purity of the background genetics. The first strategy for controlling pollination is comprised in large measure by planting patterns, but additional methods are also required. A number of these methods are described below, including the two most common production methods of detasseling and cytoplasmic male sterility (Craig, 1977; Wych, 1988). Chemical hybridization agents (male gametocides) have also been developed for pollen control, but their use is severely limited due to off target effects (Loussaert, 2004).

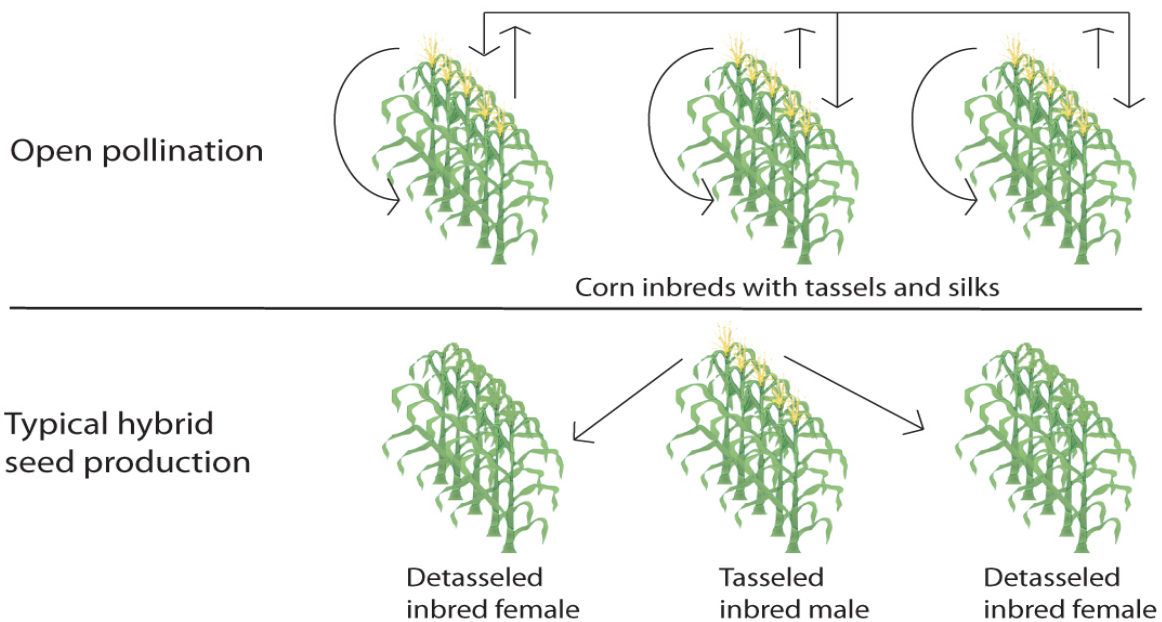


Figure 5. Pollen movement: open and hybrid

¹⁰ Heterosis is the improvement of an organism’s biological attributes through hybridization. In the case of maize hybridization, grain yield is generally the target attribute of heterosis.

¹¹ Pollen shed.

Pollen movement (arrows) compared between corn during open pollination and tasseled (inbred male) and detasseled plants (inbred female) typical of hybrid corn seed production systems. Figure is derived from BIOfortified (2010).

Detasseling. Detasseling is the most widely used method of pollen control in the production of hybrid maize seed (Monsanto-Co., 2010). Tassels are physically removed from female parent inbred maize before undergoing pollen shed or silk emergence. Removal of all of the tassels from the female parent inbred avoids self-fertilization of silks by the pollen that could have been produced from this genetic line. Instead, fertilization of the detasseled female parent inbred is achieved by pollination from a male parent inbred with different background genetics that is grown in close proximity. The window for detasseling averages 3-4 days, and occurs between tassel emergence from the leaf sheath and the initiation of pollen shedding (Hoeft et al., 2000).

Pollen shed usually occurs in corn over a 5-8 day period with the peak production on about the third day (Hoeft et al., 2000). Pollen shed is not always a continuous process, and can stop and restart depending on climatic conditions or when additional pollen has matured (Hoeft et al., 2000). As a result, the window for detasseling that averages 3-4 days prior to the initiation of pollen shed is a critical step in corn seed production that, once begun, must be performed on a regular basis, regardless of weather (Monsanto-Co., 2010). Removal of the tassel from the female parent inbred in seed production fields is accomplished by a combination of mechanical and manual detasseling methods (Wych, 1988). Mechanical detasseling methods came into widespread use in the 1970s as a way to better control rising production costs that resulted from increasing labor costs and a declining labor supply (Craig, 1977).

Mechanical detasseling machines either cut or pull the tassels from the corn in all the female parent inbred rows (Monsanto, 2010). Mechanical "cutters" use a rotating blade or knife (similar to a lawnmower) to remove the top of the maize plant and tassel. In a second step performed a few days later, mechanical "pullers" which are complementary to cutters are sent through the seed production fields. The pullers use two counter-rotating wheels or rollers to grasp and remove the tassel and upper leaves. Mechanical detasseling is delayed as long as possible before silk emergence, to permit maximum exertion of tassels and enable their removal with minimum leaf damage (Monsanto, 2010). Best results are achieved in a uniform seed field in which the tassels are well exerted ahead of pollen shedding. As conditions become less favorable, the percentage of tassels removed per pass will decrease and leaf damage will increase. Removal of the entire tassel can result in the removal of too much leaf tissue, and reduce corn seed yields by as much as 10% (McDonald and Copeland, 1997). In addition, the tassels that have been removed can become lodged in the leaf canopy and shed pollen, resulting in unwanted self-pollination (Monsanto, 2010). This complication is resolved by hand detasseling crews. Crews detassel by hand any corn that was not completely detasseled with the mechanical methods.

Although detasseling is relatively straightforward to accomplish, the production of hybrid maize seed is expensive and labor-intensive (Monsanto, 2010). It employs tens of thousands of teenage, migrant, and other agricultural workers each year to hand detassel maize in the U.S. (Monsanto, 2010). The large manual labor force is needed for only a relatively short period of time that may last from less than a week to many weeks depending upon the volume of production and the range in female parent inbred maturity dates planted within a seed production area (Monsanto, 2010). A detasseling operation is at risk from weather such as heavy rain or windstorms that can lodge or tangle the female parent inbreds just as the tassels begin to emerge,

making it difficult to walk or drive through the field. Extreme heat or drought during the onset of flowering can delay the emergence of tassels and silks. Seed fields need to be monitored and inspected closely during the detasseling period, as even a slight mistake can have considerable economic consequences. The labor force must be well trained, closely supervised, and effectively managed. This is complicated because of the reliance on temporary seasonal workers. Increasing wage rates and changing population demographics (labor supply and its distribution) are two factors that pose challenges to the industry. Liability and worker safety issues associated with employing temporary manual labor are also important considerations.

Field inspections are conducted throughout the pollination and detasseling period to measure the progress of the male pollination and female silk emergence, to ensure that female parent inbreds are not shedding pollen or self-pollinating, and to evaluate the effectiveness of the detasseling operations (Monsanto, 2010). Genetic purity of intended crosses is dependent on compliance with quality standards that certifying agencies have established when the female parent inbred has 5% receptive silks (silks emerged and turgid), which includes a limit of 1% shedding tassels in the female parent inbred at any one inspection and a total of 2% shedding tassels for three inspections at different dates, plus a limit of 0.1% male off-types at any inspection (AOSCA, 2009). Tassels are counted as shedding when more than 2 inches of the central spike and/or side branches have emerged and have shedding anthers (AOSCA, 2009). Manual and/or mechanical removal of female inbred tassels (i.e., detasseling) is used to reduce or eliminate self-fertilization on the majority of hybrid corn seed production fields (Monsanto, 2010). However, manual/mechanical detasseling requires exact timing (3-4 day time window) and is expensive, ranging between \$280 and \$350 an acre (USDA-APHIS, 2011a).

Genetic Sterility. Cytoplasmic male sterility (CMS) is a genetic method that was widely adopted in the U.S. in the 1950s and 1960s as a means to eliminate pollen from the female parent inbred without the need of manual or mechanical detasseling (Ullstrup, 1972; Craig, 1977). The genetics by which CMS functions is based on the presence of mitochondrial DNA genes that produce pollen sterility when dominant fertility restoration genes are absent in the nuclear DNA (Schnable and Wise, 1998, 1998). Pollen fertility is restored in the F1 hybrid maize seed produced from crossing this female parent inbred with a male parent inbred that possesses the dominant fertility restoration genes in its nuclear DNA. A number of CMS systems have been identified to facilitate the crossing of two inbreds, and include *S-cms*, *C-cms* and *T-cms*. With the *T-cms* system, detasseling is eliminated through the use of a female parent inbred that is completely male sterile. Unfortunately, this genotype also carries a hyper-susceptibility to *Helminthosporium maydis* race T that resulted in a virulent epidemic from southern maize leaf blight in U.S. maize in 1969-1970 (Ullstrup, 1972; Pring and Lonsdale, 1989). Continued use of this genotype was problematic because the male sterility trait was inseparable from *H. maydis* disease susceptibility (Levings and Siedow, 1992).

The C and S cytoplasm are not linked to disease susceptibility (Craig, 1977), and became important in the late 1970s as a cost-competitive and satisfactory technique for producing hybrid maize seed (Wych, 1988). Both the production of hybrid seed using CMS, and the cultivation of field maize from this hybrid maize seed are complicated. For example, C and S cytoplasm in certain genetic backgrounds result in only partial male sterility and still require some detasseling during the production of hybrid maize seed. Furthermore, the hybrid seed produced using CMS is typically blended with hybrid seed of the same genetic background that was produced without CMS, to ensure adequate pollination of the commercial maize grown from this hybrid seed.

Because of the complexity of production using CMS systems, and increased plant susceptibility to certain crop diseases CMS systems are used today in only 30% of hybrid maize seed production acres (Monsanto-Co., 2010).

Harvesting and Conditioning of Hybrid Maize Seed. Maize harvested for grain is almost entirely harvested and shelled with combines in the field. In contrast, hybrid maize seed is almost entirely harvested, and then dried, on the ear to minimize the amount of mechanical damage to the seed (Monsanto. 2010). The black layer that forms at the base of the seed at physiological maturity is an indication that maximum dry weight has been reached, and generally occurs when the seed has 30-38% moisture content (McDonald and Copeland, 1997). Freezing is a major concern to seed viability, and can be minimized by harvesting early when seed moisture content is high. This necessitates the need for artificial drying methods (McDonald and Copeland, 1997). The drying systems for maize seed are typically fan systems that force heated air through bins filled with maize seed on the ear. High-moisture seed is more sensitive to germination damage by heat than low-moisture seed, so the temperature is generally held below 95°F until 20% seed moisture content is achieved, and then the temperature can be increased to a maximum of 115°F. Seed is typically dried to a moisture content of 12-13% which is suitable for subsequent shelling and conditioning operations (McDonald and Copeland, 1997). Conditioning seed consists of three steps: 1) cleaning the seed to remove cob and kernel pieces, husks, silks, and other debris; 2) separating the seed into sizes and shapes based on width, thickness and length; and 3) treating the seed with an insecticide or fungicide or both (McDonald and Copeland, 1997).

Seed Quality. Maintaining an adequate supply of the parental inbred lines is vital to producing an adequate supply of hybrid maize seed (Monsanto, 2010). Often referred to as foundation seed, parental inbred lines are produced and maintained under strict isolation in the production field to preserve the identity and integrity of the genetics within each inbred. Quality control checks performed during the production of inbreds include visual inspections of the plants grown in isolation, and the use of molecular tools to verify the genetics of each inbred line (Hoisington, et al., 1998). Hybrid maize seed is produced in the U.S. on approximately 0.5 million acres (Jugenheimer, 1976). Over the last 35 years, the volume of hybrid maize seed planted in the U.S. has changed very little, with 20.10 million bushels (MBu) planted in 1975 and 22.55 MBu planted in 2009 (USDA-ERS, 2010a). Grain yields have increased significantly over this same period (Figure 7).

Seed certification is based on varietal lineage, as well as quality production and processing standards. Seeds produced for sale to a crop grower (certified seeds) are a limited number of generations from a verified seed stock of the specified variety (Bradford, 2006) . The U.S. Federal Seed Act of 1939 recognizes seed certification and official certifying agencies. Implementing regulations further recognize land history, field isolation, and varietal purity standards for seed. Seed certification is important to ensure the high quality of corn seed and is accomplished by a wide range of programs which include field inspections and laboratory testing (Bradford, 2006; AOSCA, n.d.-a). Various seed associations have standards to help maintain the quality of corn seed. New seed varieties are evaluated by review boards to determine if the varieties meet the eligibility requirements for certification. The Association of Official Seed Certifying Agencies (AOSCA, n.d.-b) defines the classes of seed as follows:

- *Breeder* seed is directly controlled by the plant breeder that developed the variety.

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

2.1.4 Organic Corn Production

Organic maize typically commands a market premium relative to commodity maize to offset the additional production and record-keeping costs associated with this production method. In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

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

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

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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, 2010).

The use of biotechnology such as that used to produce MON 87427 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).

Buyers recognize that when biotechnology-derived crop varieties are on the market, as with maize, a guarantee that a commodity crop is 100% “free” of biotechnology-derived material is not feasible based on the limitations of testing and sampling methodology and there are some specifications in buyer allowances that permit between 0.1 to 5% biotechnology-derived maize in organic maize (Born, 2005). International regulatory authorities have recognized that testing and sampling methodologies limit the ability to confirm that commodity or specialty maize is 100% free of biotechnology-derived material. Thus, they have set allowable tolerances for biotechnology-derived material in conventional products to support food labeling and traceability laws. These tolerances allow from 0.9% (European Union) up to 5% (Japan) of the food or food ingredients to be biotechnology-derived in products considered “conventional.” Levels above the threshold may trigger special labeling.

Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2010). The 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, 2010).

In 2008, USDA Economic Research Services (USDA-ERS) reported that 194,637 acres out of a total 93.5 million acres (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 1). 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.

Table 1: 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, 2012f).

2.2 Physical Environment

2.2.1 Soil Quality

Cultivation of corn directly impacts the qualitative and quantitative attributes of soil. For example, conventional tillage and mechanized harvesting machinery may disturb and expose the top soil surface layer, leaving the land prone to degradation. Similarly, use of detasseling 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 (CO₂) and nitrous oxide (N₂O)) (Lal and Bruce, 1999; EPA, 2010b). 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 requires a steady supply of moisture, totaling 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 United States. (Christensen, 2002). In 2007, 13.0 million U.S. corn acres were irrigated, reflecting 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 inputs, such as fertilizers or pesticides. 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 under direct grower control on a corn farm (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. Agricultural pollutants released by soil erosion include sediments, fertilizers, and pesticides that are introduced to area lakes and streams when they are carried off of fields by rain or irrigation waters (EPA, 2005).

2.2.3 Air Quality

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). Many agricultural activities affect air quality, including smoke from agricultural burning, machinery, and N₂O emissions from the use of nitrogen fertilizer (Hoefl et al., 2000; Aneja et al., 2009; EPA, 2010a). Emissions released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (EPA, 2010a). Tillage contributes to the release of GHGs because of the loss of CO₂ to the atmosphere and the exposure and oxidation of soil organic matter (Baker et al., 2005a). 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. Greenhouse gases, including CO₂, methane (CH₄), and N₂O, 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 (EPA, 2010a).

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 carbon dioxide 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 carbon dioxide and nitrous oxide may influence paradigms related to tillage strategies and global climate change (Gregorich et al., 2005). For example, increased nitrous oxide 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 nitrous oxide 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).

Global climate change may also affect agricultural crop production (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 impacts of GE crop varieties on climate change are unclear, though it is likely dependent on cropping systems, production practices, geographic distribution of activities, and individual grower decisions. APHIS will continue to monitor developments that may lead to possible changes in the typical production system likely to result from GE products brought to APHIS for a determination of nonregulated status. The potential impact of climate change on agricultural output, however, has been examined in more detail. A recent Intergovernmental Panel on Climate Change (IPCC) forecast (2007) for aggregate North American impacts on agriculture from climate change actually projects yield increases of 5 to 20 percent for this century. The IPCC report notes that certain regions of the U.S. will be more heavily impacted because water resources may be substantially reduced. While agricultural impacts on existing crops may be substantial, North American production is expected to adapt with improved cultivars and responsive farm management (IPCC, 2007).

2.3 Biological Resources

2.3.1 Animal Communities

Hybrid seed corn is produced in a subset of U.S. states, particularly central corn belt states of Nebraska, Iowa, Illinois, and Indiana (McDonald and Copeland, 1997).. As a result, an array of wildlife species (invertebrate and vertebrate species) may occupy corn fields or habitats adjacent to corn fields. Adjacent habitats may include agricultural crop land, pasture, or woodland. However, corn fields are intensely cultivated lands that provide less suitable habitat for wildlife than non-cultivated lands.

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., 2007; Iowa State University, n.d.). Other soil dwelling fauna such as earthworms and arthropods play critical roles in the aeration and turn-over of soil, processing of wastes and detritus, and nutrient cycling (USDA-NRCS, 2004; ATTR, n.d.).

A few species may directly utilize corn grain or leaves or stems for food. Bird species that have been observed in row crop fields 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*) (Best and Gionfriddo, 1991). Specific bird species can act as beneficial or detrimental members in the agro-environment. For example, red-winged blackbirds 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 nutrition. Deer (*Odocoileus virginianus*), raccoons (*Procyon lotor*), meadow voles (*Microtus pennsylvanicus*), and the thirteen-lined ground squirrel (*Ictidomys tridecemlineatus*) may all cause damage to corn fields, decreasing profitability and grain yield (Vercauteren and Hygnstrom, 1993; Neilsen, 1995; Sterner et al., 2003; Smith, 2005; Beasley and Rhodes, 2008; Koele, 2008).

2.3.2 Plant Communities

The vegetative landscape surrounding a corn field varies with region; corn fields may be surrounded by additional soybean varieties, other crops, or woodland/pasture/ grassland areas. 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). Reductions in corn agronomic performance is sometimes associated with weed competition for water, nutrients, and light. 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 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 17 herbicide MoAs (Heap, 2011). 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 6), inhabiting approximately two million acres of farmland in the U.S. (Hubbard, 2008).

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Species	States																											
	AL	AR	CA	DE	GA	IA	IL	IN	KS	KY	LA	MI	MD	MS	MN	MO	NC	ND	NE	NJ	NM	OH	OK	OR	PA	TN	VA	
<i>Conyza canadensis</i> Horseweed																						*						
<i>Amaranthus palmeri</i> Palmer Amaranth					*								*													*		
<i>Ambrosia trifida</i> Giant Ragweed															*							*						
<i>Amaranthus tuberculatus</i> (syn. <i>rudis</i>) Common Waterhemp						**	*									**												
<i>Ambrosia artemisiifolia</i> Common Ragweed																						*						
<i>Lolium multiflorum</i> Italian Ryegrass																								*				
<i>Sorghum halepense</i> Johnsongrass																												
<i>Eleusine indica</i> Goosegrass																												
<i>Kochia scoparia</i> Kochia																												

Figure 6 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 other herbicides. Source: Heap (2011).

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 United States (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), (USDA-NRCS, 2011b). Sparsely dispersed feral populations of the closely related and sexually compatible subspecies of *Z. mays* spp. *parviglumis* have also been

described in a single county of Florida (USDA, 2012) (Pioneer, 2009). Commercial corn production is not found near this location. Corn plants do not produce clonal structures nor can corn plants produce vegetative propagules. Therefore, asexual reproduction and gene flow as a result of dispersal of vegetative tissues does not occur with corn.

2.3.4 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 maize mosaic viruses (Cartwright et al., 2006).

Additionally, soil microorganisms may play a key role in dynamic biochemical soil processes (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 result limit the diversity of plants and animals (Lovett et al., 2003).

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 FFDCFA, 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). However, common farm practices, training, and specialized equipment can mitigate exposure to pesticides by farm workers (Baker et al., 2005b). For example, choosing from less toxic groups of herbicides to control corn weeds is a good common agricultural practice.

Agricultural pesticide exposure levels are regulated by EPA labels. 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 (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.

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 United States is used for livestock (KyCGA, 2011).

Similar to the regulatory control for direct consumption of corn under the FFDCFA, 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 FDA may be implemented before release of commodity products with origins from GE plants as animal feed into the market.

2.6 Socioeconomic

2.6.1 Domestic Economic Environment

The last three decades have been marked by significant transition in the development and production of seed, effectively shifting these from the public domain to large seed companies

(Fernandez-Cornejo, 2004). At the same time, the volume of hybrid corn seed planted in the U.S. has changed very little, with 20.10 million bushels (MBu) harvested in 1975 and 22.9 MBu harvested in 2009 (USDA-ERS, 2011d). The total retail value of corn seed sales in the US exceeds \$7 billion (assuming seed costs of \$85/acre for 160 Bu/acre expected yield, corn following soybean, IA (Duffy, 2012)). Grain yields have increased significantly over this same period. Seed suppliers in the US include a total of 173 independently owned companies (Monsanto, undated), and the petitioner is one of the four largest seed corn providers with multiple seed companies producing sales of seed. Additional production of U.S. seed is contracted by U.S. seed companies among South American growers as needed for flexibility and speed (Leidy, 2009; Woodall, 2012) which may reduce the need to expand acreage in the US for seed corn production.

In current hybrid corn seed production systems, detasseling of the female inbred line is an essential task to ensure genetic integrity of the seed. Detasseling has been mechanized on seed production acreage, with mechanical detasseling machines frequently used if a genetic mechanism of sterility is not employed. Mechanical detasseling must be augmented with hand labor to remove nearly all the tassels that may be left after the detasseling machines have been sent through the female inbred rows. The physical detasseling of corn involves the removal tassels from the top of thousands of tall corn plants by each detasseler daily during anthesis. Detasseling is a temporary job lasting only one to four weeks in mid-summer. The job is time sensitive because tassels need to be pulled within a day of emergence before any pollen is released. The emergence of tassels depends on the weather: hot humid weather speeds up the emergence of tassels by one or more weeks and cold wet weather slows down the emergence of tassels by one or more weeks. In consideration of the limits on available hand labor, seed producers must plant seed corn earlier or later than optimal to coincide with expected dates of detasseling (R. Wyfels, public comment APHIS-2012-0027-0048 for petition 10-281-01). Because of the short duration and physical demands of the job, the detasseling operation attracts high school students during the summer break, migrant workers and other part-time laborers (Monsanto-Co., 2010). Thousands of temporary employees are hired for detasseling each year to complete the operation on timely basis (Byrom, 2002; Pioneer, 2009; Monsanto-Co., 2010). The hybrid seed production sites where they are employed are often located in some of the major Corn Belt states of Nebraska, Iowa, Illinois, and Indiana. Finally, although mechanical detasselers reduce the need for manual (human) detasselers, they tend to reduce yields even more than manual detasseling operations (Wych, 1988).

2.6.2 Trade Economic Environment

Export value of US corn seed for planting in 2012 was \$190.3 million, likely less than 2% of the domestic market for seed (international sales: (USDA-FAS, 2013a) and domestic seed retail sales: APHIS, Section 4.6.1 Domestic Economic Environment). Total seed for planting that was exported was 42,000 metric tons or less than 0.04% of total US corn production 2013 (USDA-FAS, 2013a). World requirement for seed for planting and estimated 392.5 million acres of corn in 2010 (O'Brien, 2010) would be about 2.49 million metric tons (assuming 14# seed per acre to attain 30,000 plants/a (Duffy, 2012)). In 2004, the commercial export market for US corn seed was \$174 million (Jayasinghe et al., 2010). The primary purchasers were Italy, Mexico, Canada, France and Spain. Underdeveloped countries made only 10% of exported seed purchases, and this included India and China. By 2008, the largest purchasers of seed were Western European,

totaling almost 32 thousand metric tons, Canada with about 28 thousand mt, and South America with nearly 5 thousand mt while sales to Mexico were at 2.5 thousand mt (USDA-FAS, 2013a). By 2012 European trade had greatly declined, but Canada continued as largest importer with 24.8 thousand mt and Mexico second with 6.8 thousand mt and Pakistan third (USDA-FAS, 2013a). Besides tariffs, so also sanitary and phytosanitary regulations and technical barriers create limitations to US exports of seed. Restrictions on importation of seed further derive from regulations on planting or sale of GE varieties and these limit commercial potential in many countries.

3 Alternatives

This document analyzes the potential environmental consequences of a determination of nonregulated status of MON 87427 corn. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87427 corn is unlikely to pose a plant pest risk. APHIS has concluded through a PPRA that MON 87427 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012). Therefore, APHIS must determine that MON 87427 corn is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Two alternatives are evaluated in this EA: (1) No Action: Continuation as a Regulated Article and (2) Preferred Alternative: Determination that MON 87427 corn is No Longer a Regulated Article. 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 87427 corn and progeny derived from MON 87427 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 87427 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 87427 corn.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRA that MON 87427 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition seeking nonregulated status.

3.2 Preferred Alternative: Determination that MON 87427 Corn is No Longer a Regulated Article

Under this alternative, MON 87427 corn and progeny would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87427 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87427 corn and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition seeking nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded

that MON 87427 corn is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87427 corn is a response that is consistent with the plant pest provisions of the Plant Protection Act, 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 87427 corn and progeny derived from this event if the developer decides to commercialize MON 87427 corn.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 87427 corn. The agency evaluated these alternatives with respect to the agency's authority under the plant pest provisions of the Plant Protection Act, 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 87427 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 87427 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 87427 corn, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MON 87427 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012).

In enacting the Plant Protection Act, 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 APHIS MON 87427 PPRA (2012) and the scientific data evaluated therein, APHIS concluded that MON 87427 corn is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87427 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 87427 corn is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3.3.3 Isolation Distance between MON 87427 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 87427 from non-GE corn production. However, because APHIS has concluded that MON 87427 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of MON 87427 corn based on the location of production of non-GE corn in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' PPRA for MON 87427 corn, there are no geographic differences associated with any identifiable plant pest risks for MON 87427 corn (USDA-APHIS, 2012). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87427 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 Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. However, individuals might choose on their own to geographically isolate their non-GE corn production systems from MON 87427 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 87427 corn is available from the Association of Official Seed Certifying Agencies (AOSCA, n.d.-b) and hybrid seed growers are likely to receive detailed direction from the trait developer.

3.3.4 Requirements of Testing for MON 87427 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 87427 corn does not pose a plant pest risk (USDA-APHIS, 2012), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for MON 87427 corn would not meet APHIS’ purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.4 Comparison of Alternatives

Table 2 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 2. 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, 2012)
Management Practices		
Acreage and Areas of Corn Production	Yearly fluctuation but no or small net increase of acreage and no new regions of corn planted	Unchanged from No Action Alternative
Agronomic Practices	Seed production practices will continue to depend on mechanical and hand detasseling	Unchanged from No Action Alternative except for use of glyphosate to sterilize male tissue and prevent pollination. May see some reductions in use of mechanical and hand detasseling
Pesticide Use	Herbicide use patterns on GE and non-GE corn will continue with present rates	Glyphosate use in seed corn production may increase slightly
Corn Seed Production	Fluctuates yearly somewhat; foreign seed production is used to respond to specific needs	Unchanged

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Organic Corn Production	Yearly production not affected by conventional corn production	Unchanged
Environment		
Land Use	Seed corn acreage generally may range from 0.5 to one million acres	MON 87427 corn is not expected to have any effect on land use
Water Resources	Herbicides in water fluctuate with weather, climate and usage	MON 87427 corn is not expected to have any effect on water
Soil	Glyphosate in soil has a short half-life. Conservation tillage may be increasing slightly	MON 87427 corn is not expected to increase tillage or substantially change glyphosate use
Air Quality	Air quality (particulates) affected by tillage and weather	MON 87427 corn is not expected to have any effect on air quality
Climate Change	Climate changes affected by land use, tillage and greenhouse gases	MON 87427 corn is not expected to change land use, tillage practices or greenhouse gases
Animals and Plants		
Animals	Vertebrates interact infrequently with corn agriculture; impacts on invertebrates from corn production similar to impacts from any other agricultural production	MON 87427 corn and glyphosate is not expected to have any effect on vertebrate animals or most invertebrate animals. Unchanged from the No Action Alternative
Plants	Natural vegetation highly reduced near farms; herbicide resistant weeds increasing	Unchanged from no action alternative
Gene Movement	No gene flow to wild plants; gene flow to other corn controlled by grower needs. Horizontal gene flow not observed	MON 87427 corn used in seed production will allow pollination to be more directed, but not expected to have any effect on vertical or horizontal gene flow
Soil Microorganisms	Microorganisms affected by tillage, agronomic activity and pesticides	Unchanged from no action alternative
Biological Diversity	Contemporary agriculture already impacts biological	Unchanged from no action alternative

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	diversity	
Consumer and Animal Health		
Risk to Consumer Health	EPA rates glyphosate impacts from glyphosate resistant corn as having no reasonable certainty of harm	MON 87427 corn does not have any adverse human health effects. Unchanged from No Action
Risk to Animal Feed	Corn is a major feed protein for animal nutrition; quality is unchanging and adequate to animal needs	MON 87427 will be used for seed, but no effects expected on animal nutrition
Socioeconomic		
Domestic and Economic Environment	Corn seed with various traits has a competitive market in the US, with four major seed suppliers, and over a hundred smaller ones	MON 87427 would be deployed in inbreds for hybrid corn production, replacing mechanical and cytoplasmic sterility in the domestic seed corn production business; some gradual decline expected in summer temporary worker hiring
Trade Economic Environment	Corn export levels decreased by 23% from 2010 to 2012 in the US	MON 87427 corn not likely to change corn production
Other Regulatory Approvals	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted
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. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON 87427 corn are described in detail throughout this section. Certain aspects of this product and its cultivation would be no different between the alternatives; those instances are described below.

A cumulative effects analysis is also included for each resource area in Section 5. A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Examples include breeding MON 87427 corn with other events no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. If there are no direct or indirect impacts identified for a resource area, then there can be no cumulative impacts.

4.1 Scope of Analysis

Under the No Action Alternative, Mon 87427 corn will remain subject to the regulatory requirements of 7 CFR part 340 (Section 3.1); additionally, under the Preferred Alternative, MON 87427 corn will no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (Section 3.2).

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON 87427 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.

Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential impacts. Certain aspects of this product and its cultivation may be no different between the alternatives; those are described below.

Although the Preferred Alternative would allow for new plantings of MON 87427 corn to occur anywhere in the United States, APHIS will primarily focus the environmental analysis to those areas where hybrid corn seed is produced. To determine these, APHIS relied on information from Monsanto and the scientific literature.

Assumptions. MON 87427 utilizes a specific promoter and intron combination (e35S-hsp70) to drive CP4 EPSPS protein expression in vegetative and female reproductive tissues, conferring tolerance to glyphosate in the leaves, stalk, and root tissues and tissues that develop into seed or grain and silks (Monsanto, 2010). This specific promoter and intron combination also results in limited or no production of CP4 EPSPS protein in two key male reproductive

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tissues: pollen microspores which develop into pollen grains, and tapetum cells that supply nutrients to the pollen. Thus, in MON 87427, male reproductive tissues critical for male gametophyte development are not resistant to glyphosate (Monsanto, 2010). This allows glyphosate-treated MON 87427 containing inbred lines to serve as a female parent in the production of hybrid seed. Two glyphosate applications beginning just prior and/or during tassel development stages (approximate maize vegetative growth stages ranging from V8 to V13) will produce a male sterile phenotype through tissue-selective glyphosate tolerance, and will eliminate or greatly reduce the need for detasseling which is currently used in the production of hybrid maize seed.

4.2 Agricultural Production of Corn

4.2.1 Acreage and Range of Commercial Corn Production

No Action Alternative: Acreage and Range of Corn Production

Under the no action alternative MON 87427 would remain a regulated article and would not be available to seed producers. Under the no action alternative maize hybrid corn seed growers would continue to produce seed using hand and mechanical detasseling methods. As direct and associated labor costs continue to increase, (Section VIII.C.) hybrid seed production costs are also likely to increase. Because hybrid corn seed production is dependent upon commercial corn demand, it is relevant to discuss the acreage trends in commercial corn.

Existing trends related to the acreage and range of corn is expected to continue under the No Action Alternative. U.S. hybrid seed production in support of a mostly domestic market is found on about 0.5-1 million acres annually (Monsanto, 2010). The acreage is found principally in the Midwestern States of the Corn Belt (Monsanto, 2010). U.S. commercial corn production has generally increased in the past 20 years, from just over 76 million acres in 1991 to about 92 million acres in 2011 (USDA-NASS, 2012e). USDA-ERS (2012d) projects corn acreage to peak at 94 million acres in 2012 and then recede to 92 million acres by 2021. With regard to geographic range, corn is expected to continue being commercially cultivated in 49 U.S. states, with the majority of production centered in the Midwestern Corn Belt.

Dictating this general increase in U.S. corn acreage are external market forces across many commercial sectors. Increasing demand and favorable net returns for corn products are likely to sustain the market for U.S. corn grain (USDA-ERS, 2012d). In response to these market forces, U.S. farmers are planting additional corn acreage primarily at the expense of other agricultural crop commodities (e.g., wheat, soybean, and hay) (USDA-ERS, 2011c). Additionally, government policies have and will continue enabling U.S. farmers to meet corn production targets by providing economic incentive to retain arable land in agricultural production. For example, as stipulated in the Food, Conservation, and Energy Act (2008), a net reduction in Conservation Reserve Program (CRP) land enrollment from 39.2 to 32 million acres and increased funding for Working Land Conservation Programs (e.g., The Environmental Quality Incentives Program [EQIP]) represented two Federal policy tools to increase the amount of arable land for agricultural production while also encouraging farmer adoption of environmentally-friendly practices to maintain agricultural productivity.

External market forces leading to a growing demand for U.S. corn, reactive government policy designed to increase domestic production of agricultural crop commodities while maintaining the productivity of arable land, and responsive farmer land-use decisions to meet corn grain production targets by primarily implementing acreage shifts away from other agricultural commodities reflect current economic conditions and trends. These current economic conditions and trends are likely to continue under the No Action Alternative.

Preferred Alternative: Acreage and Range of Corn Production

A determination of nonregulated status of MON 87427 corn under the Preferred Alternative is unlikely to substantially impact projected trends in U.S. corn acreage (USDA-ERS, 2011c) nor

are existing trends likely to greatly change demand for hybrid seed production and for MON 87427. As previously discussed, both external market forces (i.e., increasing demand for U.S. corn products) and government policies (e.g., reduction in CRP land enrollment or increased funding for EQIP) strongly affect domestic levels of corn production. MON 87427 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. Second, MON 87427 corn is unlikely to substantially increase U.S. corn acreage and production because it is a product meant to facilitate hybrid seed production and not general corn production. While U.S. corn production has increased in the past 20 years, hybrid corn seed production has remained relatively stable at 0.5 – 1 million acres (Pioneer, 2009; Monsanto, 2010). Hybrid corn seed production is a small proportion of general corn production, with yearly fluctuations in general corn acreage and production sometimes exceeding that of hybrid corn seed production (Figure 6). Due to the external market forces that ultimately affect U.S. corn acreage and the small proportion of acreage dedicated to hybrid corn seed production relative to general corn production, U.S. corn acreage is unlikely to substantially increase beyond projected values under the Preferred Alternative.

Like many domesticated crop plants, corn is not likely to persist and spread outside the agricultural environment (USDA-APHIS, 2012). In the United States, the range of corn cultivation is generally limited by moisture and frost-free days to reach maturity. Field study of MON 87427 corn indicates that the agronomic performance of it and conventional corn is not substantially different (Monsanto, 2010; USDA-APHIS, 2012). Accordingly, the range of cultivation for MON 87427 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 87427 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 87427 corn will be derived from existing corn acreage or acreage previously used for agricultural crop commodities (USDA-ERS, 2011c; USDA-ERS, 2012d).

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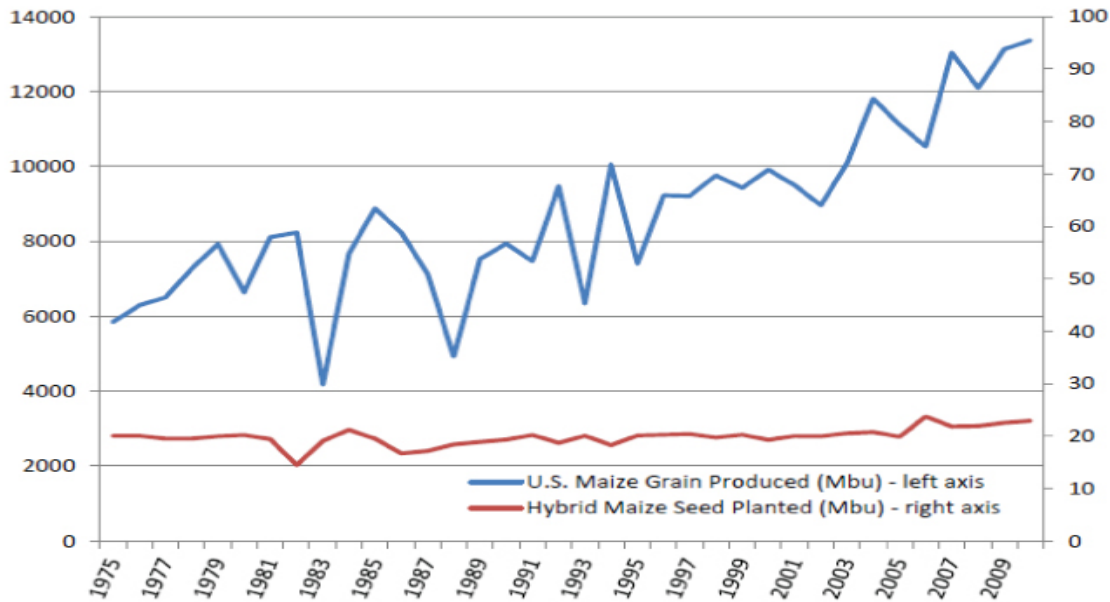


Figure 7. Hybrid corn seed planted and corn grain produced in the United States, 1975-2009
Sources: Monsanto (2010) from USDA-ERS (2010a).

4.2.2 Agronomic Practices of Commercial Corn Production

Corn (*Zea mays* L.) is the largest crop cultivated in the United States, in terms of planted acreage and net value (USDA-NASS, 2010). U.S. corn is typically produced as a hybrid, due to positive gains associated with heterosis (Wych, 1988; Duvick, 2001). In contrast to open-pollination, hybrid seed production in corn maintains heterosis and genetic uniformity (Duvick, 2001). Accordingly, corn growers in the United States generally purchase new hybrid seed at the start of each growing season to ensure optimal grain yield (Wych, 1988; USDA-APHIS, 2011b). Hybrid corn seed production, while generally similar to that of commercial corn production, does differ in some practices, including tillage, herbicides, details of planting and practices necessary for pollen control.

No Action Alternative: Tillage

Under the No Action Alternative, U.S. hybrid seed corn growers are likely to continue using conservation tillage practices which is the current practice of the majority of these producers. No-till practices are highly uncommon in corn seed production, however, which distinguishes this crop from those of commercial corn practices. Similarly, U.S. commodity corn growers will continue to use conservation, , or conventional tillage to prepare the soil for planting prior to planting hybrid corn seed. However, recent data from USDA-ERS and the USDA Agricultural Resource Management Survey (ARMS) indicates that conservation tillage, and in particular no-till activities (Figure 8), have generally increased in U.S. commodity corn production (Horowitz et al., 2010; NRC, 2010).

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). Although herbicide use is common in hybrid seed production, they do not include the glyphosate or glufosinate that can be used in crops with resistance to these herbicides.

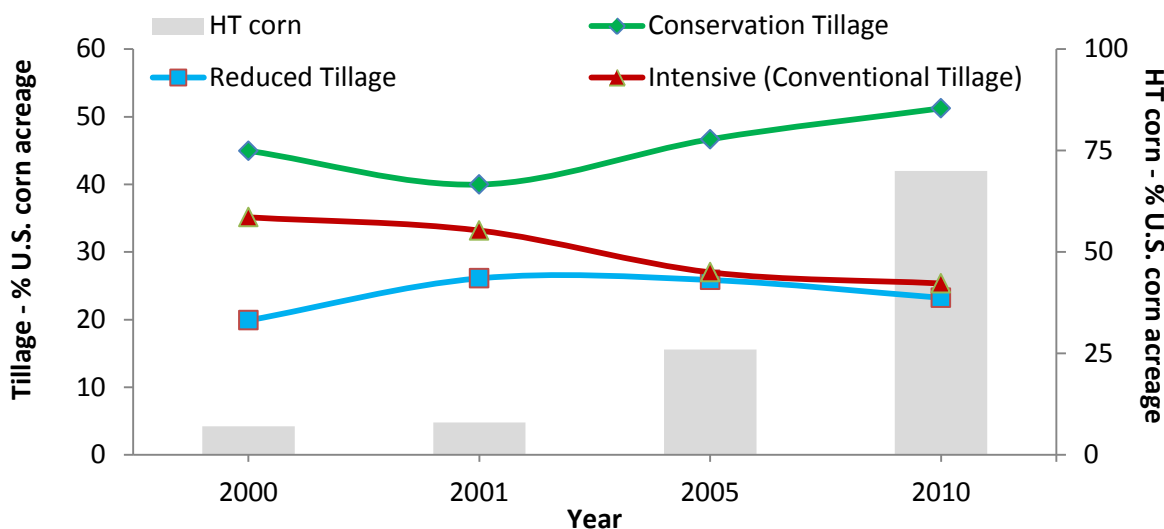


Figure 8. Tillage trends and adoption of herbicide-resistant (HT) corn in the U.S., 2000 – 2010. HT corn varieties were increasingly adopted following regulatory approval of glyphosate-resistant corn in 2004. Sources: USDA-ERS (2011a; 2012b) and CERA (2010).

Preferred Alternative: Tillage

Under the Preferred Alternative, a determination of nonregulated status is unlikely to substantially affect tillage trends in U.S. hybrid corn production. The predominant practice in hybrid corn production is already to primarily use herbicides for weed control, although not over the top application of glyphosate. Consequently, existing practice in seed production is already compatible with conservation tillage practices. MON 87427 corn, like many other commercially-available herbicide-resistant corn varieties, is resistant to glyphosate application. Glyphosate-resistant corn varieties, similar to MON 87427, have been shown to positively affect rates of conservation tillage adoption in U.S. corn production (Givens et al., 2009; Horowitz et al., 2010). Although MON 87427 is another glyphosate-resistant variety, the needs of the hybrid corn production industry require different parameters; one of these is that inbreds will require additional tillage compared to commercial varieties which themselves are successfully produced under no-till conditions. Conservation tillage in hybrid seed production will continue to be practiced, but no-till will likely not be common. MON 87427 is primarily intended for hybrid corn seed production and as previously described; hybrid seed corn represents a small proportion of U.S. commodity corn acreage. Yearly fluctuations in acres of commercial corn production is often greater than the total amount of hybrid seed corn production itself (Section 4.2.1). Thus,

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any possible effect on tillage by MON 87427 would be minor, due to the relatively small scale of hybrid corn seed production. However, no factors would encourage change in tillage practices if MON 87427 corn has nonregulated status.

No Action Alternative: Fertilization and Crop Rotation

Under the No Action Alternative, existing trends in US hybrid seed corn production related to fertilization and crop rotation are expected to continue, which are the same as those for commodity corn production. Fertilization is an important management consideration for maximizing corn grain yield (Hoefl et al., 2000). In 2010, nitrogen and phosphate were applied to 97 and 78 percent of U.S. corn acreage, respectively (USDA-NASS, 2011b). Additionally, in order to maintain productivity of an agricultural field and maximize economic return, U.S. corn growers may rotate their crops with a variety of other crops, including oats, peanut, soybean, wheat, and rye (USDA-APHIS, 2011c). In 2010, 71 percent of corn acreage in 19 surveyed states was under some form of rotation (USDA-NASS, 2011b). 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 (Hoefl 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, 2011c).

Preferred Alternative: Fertilization and Crop Rotation

Similar to the No Action Alternative, a determination of nonregulated status for MON 87427 corn is unlikely to substantially change fertilization patterns in U.S. hybrid corn seed production. Standard agricultural practices related to corn production are required for the cultivation of MON 87427 corn (Monsanto, 2010), thus suggesting that it does not require different nutrient supplementation than conventional commodity corn.

Additionally, similar to the No Action Alternative, a determination of nonregulated status for MON 87427 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). Hybrid seed is mainly grown by contract growers, many of whom are most likely already growing conventional corn. Seed production acreage would likely be one part of the rotation for the commodity corn and other crops that they also grow. MON 87427 corn exhibits similar agronomic performance to conventional corn (Monsanto, 2010; USDA-APHIS, 2012), suggesting that 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, 2011c; USDA-ERS, 2012d). For example, continuous corn cultivation has increased following increased demand and high corn prices (USDA-ERS, 2011c). Rotation crops preceding seed production are likely the same as those used by growers of conventional crops, including commonly soybean, wheat, minor crops and corn (Monsanto, 2010). A corn on corn rotation where desired by growers requires extra effort be given to eliminating volunteer corn. To avoid pollination from the unwanted corn, an investment must be made to use pre-plant or in-crop cultivation, or herbicides such as sethoxydim or quizalofop on the volunteers (Monsanto, 2010). Use of MON 87427 will not affect rotations for corn.

No Action Alternative: Pesticide Use

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. commodity corn growers has strongly decreased some pesticide use patterns. However, the inbreds used in hybrid seed production may not have traits to provide protection against insects such as Bts that provide resistance to European corn borer, other grain and leaf infesting insects, and corn rootworms, and pesticides would be employed more frequently on these fields in the absence of genetic means of protection.

Insecticides are used to control above and below ground pests, and protect against insect damage to stands, the growing plants, and the female parent inbred ears. Seed companies practice integrated pest management principles and evaluate seed fields to determine if and when insecticide application is justified (Monsanto, 2010). Fungicides are also an important component of hybrid maize seed production and are used to protect susceptible parent lines from damaging fungal diseases. Although genetic resistance to disease is preferred, chemical protection is often needed when resistance is not adequate in the parent line. Spray applications effectively reduce damage from foliar disease in susceptible inbred lines, and seed treatments are widely used to prevent seed and seedling diseases (Smith and White, 1988). Under the No Action Alternative, fungicide and insecticide use¹² in U.S. corn production fields will likely continue as it is currently practiced. In general, fungicide use has increased since 1995, primarily due to the increasing use of fungicides in corn seed coatings (Figure 9)). Use of fungicides, however, is substantially less than that of other pesticides (e.g., insecticides or herbicides) (USDA-NASS, 2011b). In 2010, approximately 744,000 lbs. of fungicides were applied to 8 percent of U.S. corn acres (USDA-NASS, 2011b; USDA-NASS, 2012b). Additionally, insecticide use will likely continue as it is currently practiced on U.S. corn fields. Insecticide use to control insect pests has decreased since 2003 (Benbrook, 2009; Fernandez-Cornejo et al., 2009; NRC, 2010), a trend generally related to the increasing adoption of GE insect-resistant 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. In 2010, this trend culminated in 1.6 million pounds (lbs.) of insecticides sprayed on 12 percent of U.S. corn acreage (USDA-NASS, 2011d; USDA-NASS, 2012c).

¹² Pesticide use is defined here as total pounds (lbs.) of active ingredient (a.i.) applied over corn.

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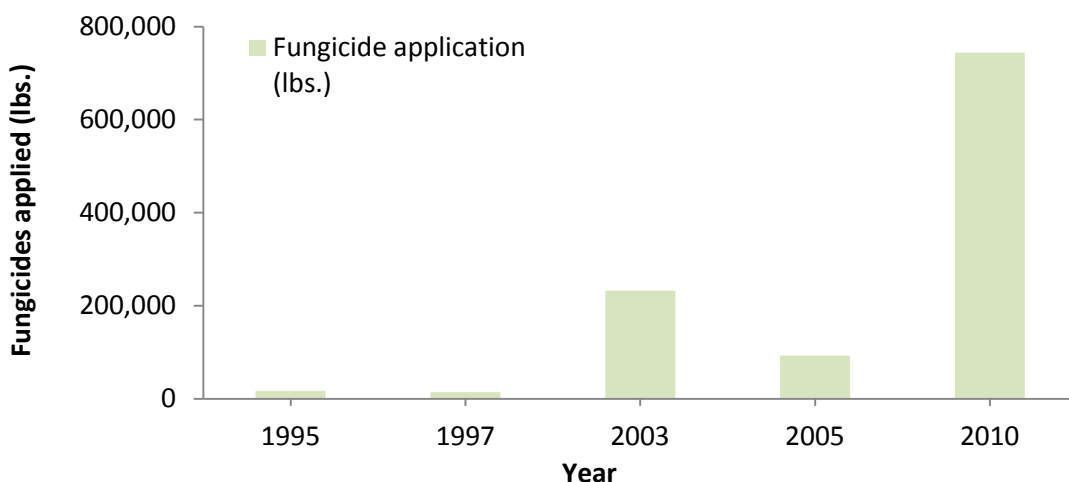


Figure 9. Total application of fungicides in U.S. corn production, 1995 – 2010.
Source: USDA-NASS (2012b).

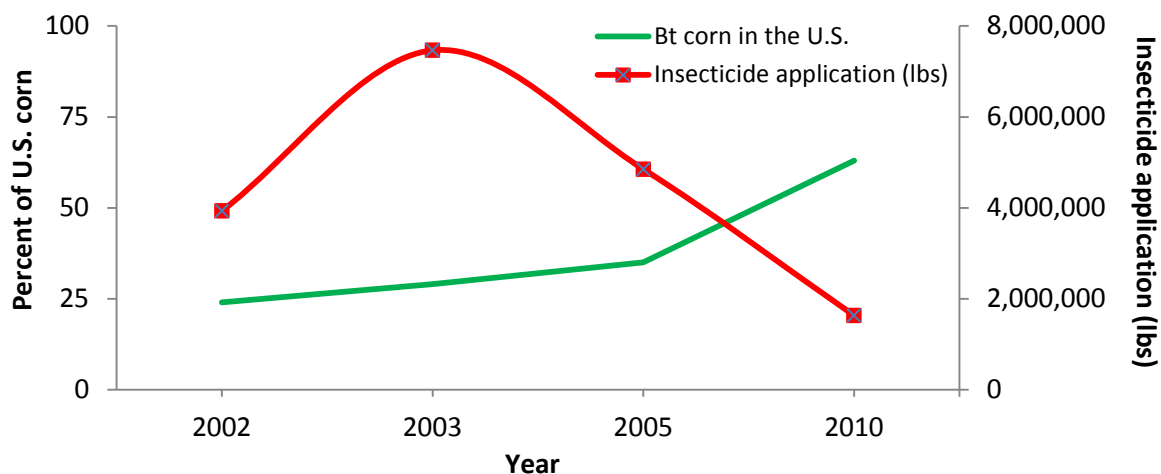


Figure 10. Trends in the use of insecticides and Bt corn in the US
Total application of insecticides (lbs. active ingredient, red line) and percent of U.S. corn acreage cultivated with genetically engineered Bt corn varieties (green line), 2002 - 2010. Sources: USDA-NASS (2012c) and USDA-ERS (2011a).

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, 2011b). Under the No Action Alternative, herbicide use trends are likely to continue as currently practiced on U.S. corn fields. U.S. corn growers will continue to have access to broad-spectrum herbicides and GE herbicide-resistant corn varieties no longer subject to the regulatory requirements of 7 CFR part 340 or the plant

pest provisions of the Plant Protection Act. While herbicide use trends and its relationship with glyphosate-resistant corn varieties are subject debate (Fernandez-Cornejo et al., 2003; Benbrook, 2009; Fernandez-Cornejo et al., 2009), it is clear that a general substitution effect has occurred in U.S. corn production in the years following the introduction of herbicide-resistant corn varieties (NRC, 2010). With the exception of acetochlor, glyphosate use has generally increased at the expense of other common corn herbicides between 1995 and 2010 (Fernandez-Cornejo et al., 2009; NRC, 2010) (Figure 11). This statement, however, should not be misinterpreted to mean that total herbicide use has decreased in U.S. corn production; rather, total herbicide use has increased since 1995 due to increasing adoption of glyphosate and decreasing use of non-glyphosate herbicides (NRC, 2010; USDA-NASS, 2011c). It is prudent to note that total herbicide use is not an effective metric to measure environmental impact, as this does not effectively permit the environmental comparison of different herbicides across time or across management strategies (Fernandez-Cornejo et al., 2009).

The increasing frequency of glyphosate-resistant weeds in some corn production fields may decrease the efficacy of glyphosate for control of weeds. In spite of this, some U.S. farmers are hesitant to stop using glyphosate through familiarity and satisfaction with the glyphosate-resistant crop system. For example, a survey of 400 corn, cotton, and soybean growers found that a majority would not restrict their use of glyphosate-resistant crops [or glyphosate] when facing increased weed pressure from glyphosate-resistant weed populations (Scott and VanGessel, 2007).

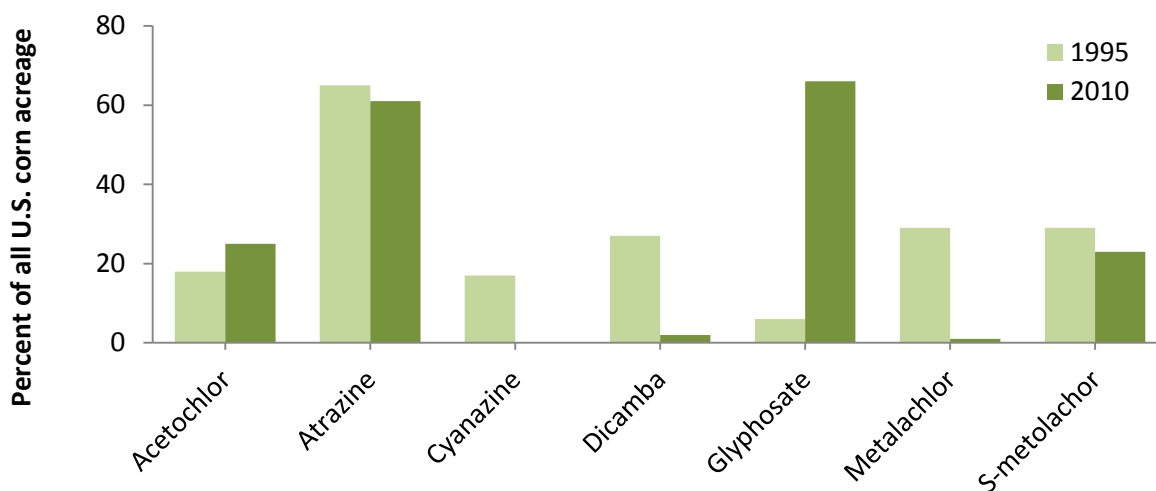


Figure 11. Commonly used herbicides in U.S. corn production, 1995 – 2010

Source: USDA-NASS (1996; 2002; 2006; 2010).

U.S. farmers, however, are beginning to understand that a diversification of selection pressure in their weed management strategies may be necessary to manage and slow glyphosate-resistant weed development (Johnson et al., 2009; NRC, 2010; Owen et al., 2011). One general farm-level response to glyphosate-resistant weeds has been to increase the rate/frequency of glyphosate application and incorporate the use of different herbicidal chemistries (NRC, 2010). A possible consequence of this action may be an increase in total herbicide use in U.S. corn production (NRC, 2010; Owen, 2010). However, total herbicide use may not be an effective

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metric to measure environmental impact, as this does not effectively permit the environmental comparison of different herbicides across time or across management strategies (Fernandez-Cornejo et al., 2009).

Preferred Alternative: Pesticide Use

Control insects, and diseases within the hybrid maize seed production field is an integral and necessary part of seed production (Wych, 1988). Seed growers rely heavily on herbicides for effective weed control, since inbred maize lines do not compete effectively with weeds. General trends related to corn pest management in hybrid seed corn production are unlikely to change under the Preferred Alternative. The inbred parental lines carrying MON 87427 may not possess resistance to disease or insects (i.e., Bt protein), and thus fungicide and insecticide applications trends will continue as they would under the No Action Alternative. Additionally, MON 87427 corn does not show increased susceptibility to microbial or insect pests, suggesting that management practices would not differ between it and commodity corn, including pesticide use or conventional breeding selection for disease resistance (Monsanto, 2010; USDA-APHIS, 2012). Environmental observations in field studies have demonstrated no apparent impact on arthropods of maize. Therefore, no changes to current insect management practices are anticipated from the introduction of MON 87427, including pesticide use, conventional breeding selection for resistance, or when used in conjunction with biotechnology-derived traits.

Control of weeds in inbred corn fields that are used for producing new hybrid seeds is highly important to high yields. In typical hybrid corn seed production fields, glyphosate is generally not used to control weeds because not all inbred corn lines contain a glyphosate-resistant trait. Under the Preferred Alternative, producers of hybrid corn seed will be able to use glyphosate as an herbicide to control weeds through use of MON 87427 and NK603/MON 88017 traits expressed in inbred corn lines, and in addition will make use of the tissue selective trait as intended, as an inducer of male sterility in MON 87427 corn (Monsanto, 2010).

MON 87427 provides an option for producing viable hybrid maize seed as an alternative to detasseling or the use of a CMS systems, using minimal additional agricultural inputs, i.e. late stage applications of glyphosate, (Section I.5.3.). With the introduction of MON 87427, glyphosate can be applied to hybrid maize seed production fields in early growth stage applications as part of the weed control system and applied at later vegetative growth stages (V8 through V13) to produce the male sterile phenotype through tissue-selective glyphosate tolerance in the female parent inbred line. This has not been possible before as usually only one of the inbred lines contained the trait for glyphosate tolerance.

Weed management practices in the production of hybrid maize seed using a system with MON 87427 are anticipated to be substantially the same as current hybrid maize seed production practices, with the added option of using glyphosate for early post-emergent weed control. Weed management practices in the cultivation of commercial maize with MON 87427 stacked with other already approved glyphosate-tolerant maize traits will also remain unchanged. Producers of hybrid maize seed and growers of commercial maize will be able to achieve the same high level of weed control as other biotechnology-derived herbicide tolerant maize hybrids. Additionally, because MON 87427 is agronomically and phenotypically equivalent to conventional maize as described in Section VII, it is not anticipated that MON 87427 will respond differently to commonly used herbicides, except glyphosate.

While a determination of nonregulated status of MON 87427 corn may increase total glyphosate use in U.S. corn production, this is unlikely to substantially affect the herbicide use trends already described under the No Action Alternative. Based on USDA-NASS data, glyphosate use in corn is increasing, partially related to increasing adoption of glyphosate-resistant corn varieties (USDA-NASS, 1996; 2002; 2006; 2011c). A determination of nonregulated status is unlikely to affect this existing trend, as MON 87427 corn a GE corn variety resistant to glyphosate. Additionally, while MON 87427 corn may increase total glyphosate use, this increase is unlikely to be substantial, due to the proportionally small acreage where hybrid seed corn is grown. The late stage glyphosate applications will be made only on hybrid maize seed production acres that comprise 0.6% of total maize acres in the U.S. The acreage used for hybrid seed production has been relatively constant (Monsanto, 2010), with yearly fluctuations in U.S. corn acreage (USDA-NASS, 2012a) often exceeding the annual acreage used for hybrid corn seed production.

4.2.3 Hybrid Corn Seed Production

No Action Alternative: Seed Corn Production: Pollen Control

Seed corn production differs from hybrid seed production in the details of crop spacing, isolation, treatments that affect the pollination of the crop and harvest. Hybrid maize seed producers typically must physically isolate production plots from neighboring maize seed or grain production fields to avoid cross-pollination during the flowering stage by wind-borne pollen. The isolation distance from other maize is regulated by seed certification standards, and is typically at least 660 feet from other maize.

Pollen control refers to practices that ensure complete pollination of female parent inbreds by male parent inbreds to produce hybrid maize seed. Pollen control in hybrid maize seed production is extremely critical for producing hybrid maize seed with high genetic purity. Detasseling is the most widely used method of pollen control in the production of hybrid maize seed. The detasseling period begins prior to pollen shedding when tassels have emerged from the leaf sheath. Tassels are physically removed from a female parent inbred maize line after the tassel has fully emerged and before undergoing pollen shed or silk emergence occurs. Removal of all of the tassels from the female parent inbred avoids the risk of self-fertilization of the female parent inbred. Instead, fertilization of the detasseled female parent inbreds is achieved by pollination from a genetically distinct male parent inbred line that is grown in close proximity. Pollen shed usually occurs in maize over a five to eight day period with the peak production on about the third day (Hoelt et al., 2000a). Pollen shed is not always a continuous process, and can stop and restart depending on climatic conditions or when additional pollen has matured (Hoelt et al., 2000a). As a result, the window for detasseling that averages 3-4 days prior to the initiation of pollen shed is a critical step in maize seed production that, once begun, must be performed on a regular basis, regardless of weather. Removal of the tassel from the female parent inbred in seed production fields is accomplished by a combination of mechanical and manual detasseling methods (Wych, 1988).

The pollination process must be accompanied by additional steps such as hiring of labor to begin and complete detasseling by hand to prevent pollination of inbreds by undesired pollen. Other changes include time of harvest differences of when the crop moisture content is adequate for

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seed production, and harvesting that includes gathering of complete cobs, not usually with combines that remove kernels from the cobs in the field (Monsanto, 2010).

Preferred Alternative: Hybrid Seed Corn Production.

The Monsanto Company developed MON 87427 corn to provide flexibility and reduced production costs in hybrid corn seed production. The MON 87427 trait permits the use of glyphosate to eliminate viable pollen, effectively allowing MON 87427 corn to function as a detasseled female inbred parent. This inducible male-sterile phenotype does not substantially alter other aspects of growth and development (USDA-APHIS, 2012), thus allowing MON 87427 corn to be integrated into current hybrid corn seed production practices.

Certified seed production is a carefully managed process (Section VIII.B.2) for maintaining high quality seed stocks, an essential basis for U.S. agriculture. Seed producers have learned to account for and manage pollen flow both within a seed production field and between nearby fields. For several decades the hybrid maize seed industry has created and adopted systems to maintain and preserve the purity of maize germplasm developed for commodity and specialty uses. To maintain the genetic purity of hybrid maize populations, seed production activities for each maize type are isolated from one another and from commercial grain production (Wych, 1988). Isolation is achieved through various means, but may include physical separation to prevent cross pollination, temporal isolation by planting at different times to stagger pollination times of different materials, detasseling, and the use of cytoplasmic male sterility. The goal of detasseling and CMS is to produce hybrid seed that meets the necessary purity for hybrid maize seed. Seed must meet state and federal seed standards and labeling requirements. AOSCA is dedicated to assisting companies in the production, identification, distribution and promotion of certified classes of seed. AOSCA establishes minimum standards for quality and identity. Its goal is to standardize certification regulations and procedures internationally so companies compete with one set of standards. The association cooperates with the OECD and other international organizations to develop standards, regulations, procedures, and policies to expedite movement of seed and encourage international commerce in improved seed products.

The AOSCA standards for maize seed are described in the petition, Section I.3.5 (Monsanto(Monsanto, 2010). MON 87427 meets or exceeds established seed purity standards (Feng et al., 2009). Thus, adoption of MON 87427 is not expected to have a significant impact on production of certified hybrid maize seed.

It is anticipated that hybrid seed containing MON 87427 will be produced and marketed in accordance with OECD and AOSCA standards and the U.S. Federal Seed Act, and will have no adverse impact on current hybrid seed production practices or the ability of breeders and seed producers to meet these standards.

Induced Male Sterility and MON 87427 Corn

Glyphosate is a systemic, broad-spectrum herbicide that inhibits aromatic amino acid synthesis in susceptible plants. Following glyphosate exposure, translocation of the molecule to meristematic regions occur within the plant, following a typical source/sink relationship. Regions of meristematic activity within a plant may include apical nodes, leaf primordia, and areas of reproductive development.

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The inducible male-sterile phenotype is conferred through the introduction of a specific promoter-intron combination (*35S-hsp70*) used to drive expression of the *cp4 epsps* coding sequence (Figure 12). Glyphosate tolerance is conferred by the CP4 EPSPS protein, but only in MON 87427 corn vegetative tissues (leaves, stalks, and roots) and tissues derived from the female reproductive system (seed, grain, and silks). MON 87427 corn accumulates little or no CP4 EPSPS protein in tapetum cells and pollen microspores. Following exposure to glyphosate during male reproductive system development (V8 to V13), MON 87427 pollen microspore viability is compromised through insufficient nutrient transport to the developing pollen microspore (tapetum) and death of the pollen microspore itself. The introduced regulatory element, *35S-hsp70*, is derived from the cauliflower mosaic virus (*35S*) and corn (*hsp70*). The *cp4 epsps* coding sequence is derived from *Agrobacterium* sp. strain CP4. Specific details regarding additional T-DNA components and generation of MON 87427 corn may be found in the MON 87427 petition (Monsanto, 2010) and the APHIS plant pest risk assessment (USDA-APHIS, 2012).

Application of glyphosate on MON 87427 corn during the vegetative growth phase will produce a phenotype similar to any other glyphosate-tolerant corn variety. If glyphosate is applied on MON 87427 between V8 and V13 (tassel/pollen microspore development), viable pollen production is compromised. However, growth of MON 87427 and development of its female reproductive system is not inhibited, due to the tissue specificity of the *e35S-hsp70* regulatory element driving expression of *cp4 epsps*. When the male-sterile phenotype is induced, MON 87427 performs like a detasseled female inbred in hybrid corn seed production systems, limiting self-fertilization and ensuring cross fertilization with male inbred pollen donor corn plants.

Cultivation of MON 87427 corn will widen the glyphosate application window in hybrid corn seed production systems (Monsanto, 2010). In contrast to corn containing the Roundup Ready 2[®] trait, MON 87427 corn will be able to tolerate glyphosate exposure past stage V8 (Monsanto, 2010). Additionally, when compared to typical hybrid corn seed production systems, the window of opportunity to limit self-fertilization of female inbred parents is wider (Figure 13) following the cultivation of MON 87427 corn (Monsanto, 2010). Manual or mechanical detasseling generally occurs over a three to four day window in typical hybrid corn seed production systems, while glyphosate may be used to inhibit pollen development over a 14 day period in MON 87427 corn (Monsanto, 2010).

Only specifically timed applications of glyphosate will produce the male sterile phenotype through tissue-selective glyphosate tolerance, and enable specific cross pollinations to be made in maize (Monsanto, 2010). Glyphosate is a systemic herbicide that is readily translocated in plants to areas of high meristematic activity, following a typical source to sink distribution (Franz, et al., 1997a). Early tassel growth stages start at the approximate maize vegetative growth stage V9, therefore glyphosate applications made at approximately this time allow maximum translocation of glyphosate to the male reproductive tissues, and selectively cause cell death in only those cells that are not tolerant to glyphosate (i.e. tapetum and pollen cells). Glyphosate applications made during early vegetative stages, consistent with the application timing specified in the current Roundup agricultural product label for weed control purposes, do not affect pollen production of MON 87427 because the sensitive male reproductive tissues are not actively developing at that time.

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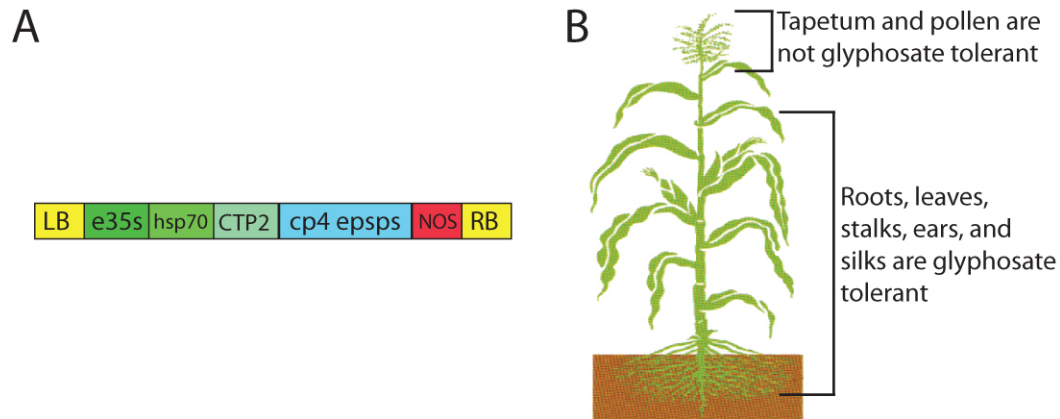


Figure 12. Genes and phenotype of MON 87427

(A) TDNA insert conferring tissue-specific glyphosate tolerance in MON 87427.

LB/RB = left/right border; *e35s* - promoter from cauliflower mosaic virus; *hsp70* - first intron from corn heat shock protein 70; CTP2 - transit peptide from *Arabidopsis thaliana*; *cp4 epsps* - codon-optimized *epsps* from *Agrobacterium* sp. strain CP4. (B) Diagram showing glyphosate tolerant tissues in MON 87427. Figure derived from The Robinson Library (2011). Source: Monsanto (2010).

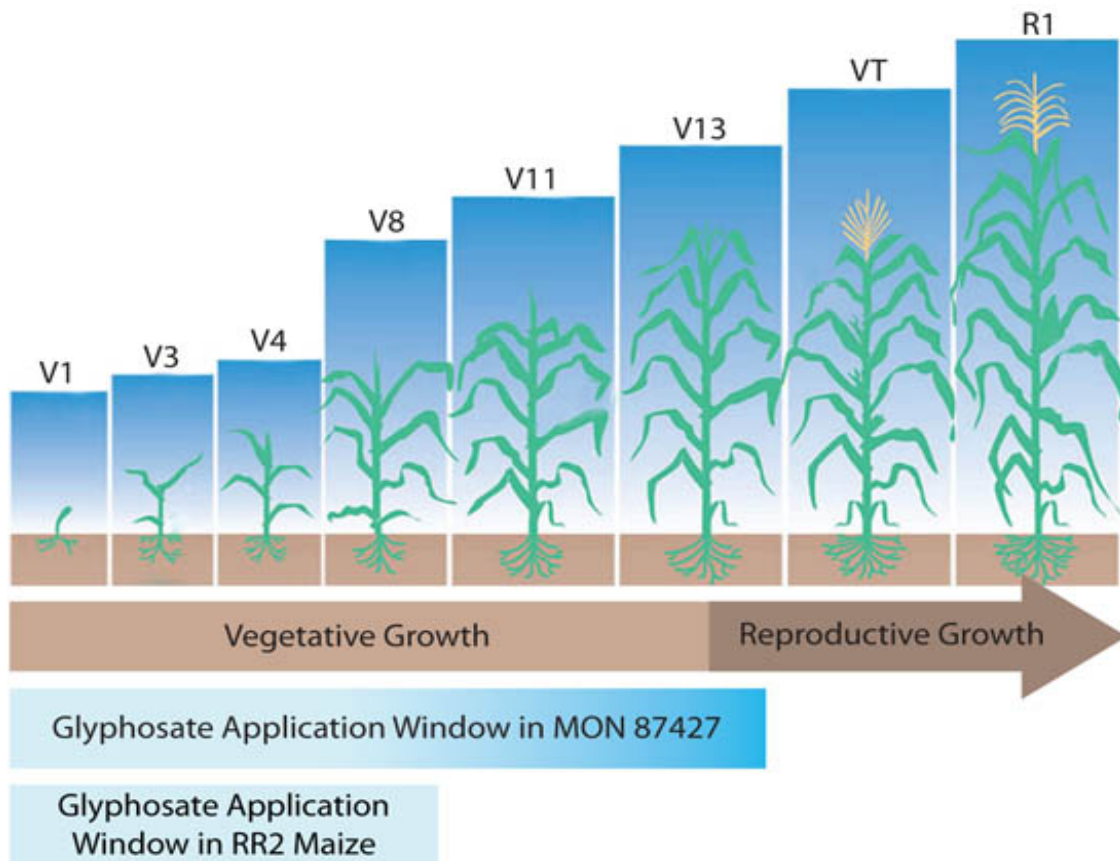


Figure 13. Comparison of glyphosate application timing between Roundup Ready 2® and MON 87427 corn. Figure derived from ISU (2012). Source: Monsanto (2010).

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Using the hybridization system made possible with MON 87427, weed management practices in the production of hybrid maize seed are anticipated to be substantially the same as current hybrid maize seed production practices, with the added option of using glyphosate for early post-emergent weed control (Monsanto, 2010). Weed management practices in the cultivation of commercial maize with MON 87427 stacked with other already approved glyphosate-tolerant maize traits will also remain unchanged (Monsanto, 2010). Producers of hybrid maize seed and growers of commercial maize will be able to achieve the same high level of weed control as other biotechnology-derived herbicide tolerant maize hybrids. Additionally, because MON 87427 is agronomically and phenotypically equivalent to conventional maize as described earlier, it is not anticipated that MON 87427 will respond differently to commonly used herbicides, except glyphosate (Monsanto, 2010).

Applications of glyphosate will be made only on production acres of hybrid maize seed and these are only 0.6% of total maize acres in the U.S. Currently registered uses of glyphosate do “not pose unreasonable risks or adverse effects to humans or the environment” as determined by the EPA (U.S. EPA, 1993). Glyphosate has been authorized by the EPA for in-season, post-emergent use in a variety of crops (U.S. EPA, 1993). Additionally, the EPA’s evaluation of glyphosate use on glyphosate-tolerant maize covers all uses in maize to a maximum amount of six pounds acid equivalent per acre (lbs a.e./acre). This rate will not be exceeded in MON 87427 even with the anticipated additional applications of glyphosate at the V8 through V13 growth stage or in hybrid seed production using this trait (Roundup PowerMAX Herbicide, 2007; 2008; Roundup WeatherMAX Herbicide, 2002; 2009).

4.2.4 Organic Corn Production

Organic production plans prepared pursuant to the National Organic Program (NOP) include practical methods to protect organically-produced crops from accidental admixture with GE materials. Genetic admixture of organic corn with GE corn varieties is a concern of some growers because corn naturally cross-pollinates (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 utilized for the cultivation of Certified seed under the AOSCA procedures. During the cultivation period, 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 (CCSP, 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 genetic admixture 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-ERS, 2011d-a; USDA-NASS, 2012f). Since its introduction in 1995, GE corn is now cultivated on over 88% of the U.S. acreage (USDA-NASS, 2012b). This concurrent growth of organic crops and GE corn is indicative of the successful adoption of these coexistence strategies. The size of the seed corn acreage compared to the current size of organic production is nearly four-fold higher. Historically, organic corn production represents a small percentage (approximately, 0.2%) of total U.S. corn acreage (USDA-ERS, 2011d-b). 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

No change in availability of inbreds or conventional (GE or non GE) corn varieties is expected. Those corn varieties that are developed for organic production are also 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, 2011a; USDA-ERS, 2011b).

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It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods 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, 2010). However, certain markets or contracts may have defined thresholds which growers need to attain (Non-GMO-Project, 2012).

Preferred Alternative: Organic Corn Production

The MON 87427 trait production in female inbreds for glyphosate resistant will not change any conditions of the corn market place or impose any new production issues that are any different from the herbicide-resistant varieties that are already in use by farmers. MON 87427 corn allowing growers to use glyphosate-dependent sterility should not present any new impacts for organic and other specialty corn producers and consumers different from those of existing varieties that require detasseling operations for seed production.

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 2008 in a variety of locations in the U.S. demonstrated that MON 87427 corn is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart (USDA-APHIS, 2012). No differences were observed in pollen diameter, weight, and viability. Therefore, MON 87427 corn is expected to present a 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 87427 corn.

Organic corn production acres are only 39% of total US seed production acres, assuming the low average estimate of corn seed acres and using the 2008 values for organic corn production (USDA-ERS, 2010b). Historically, organic corn production represents a small percentage (approximately, 0.2%) of total U.S. corn acreage (USDA-ERS, 2011b). Organic production likely would remain small regardless of whether MON 87427 corn or other new varieties of GE or non-GE corn varieties, , become available for commercial corn production.

4.3 Physical Environment

4.3.1 Water Resources

No Action Alternative: Water Resources

Production of hybrid seed corn differs somewhat from hybrid commercial corn production in some protocols that impact water resources, including plant total residues expected (inbreds are shorter than hybrids) and differences of herbicides employed, but hybrid corn seed production is likely to have no greater impacts on water resources than those of conventional production of corn. 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% of corn acreage was irrigated in the U.S in 2010(NCGA, 2011).

As discussed in Subsection 2.2.1, 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% of planted corn (USDA-NASS, 2011a). Of the treated acres, glyphosate was the most commonly applied herbicide active ingredient that year (USDA-NASS, 2011a). When used consistent with registered uses and EPA-approved labels, glyphosate presents minimal risk to surface and groundwater.

Some differences exist as earlier noted (Section 2.2.2), in the types of herbicides used on seed production acres compared to the most common conventional production acres. Herbicides can potentially be washed into water resources following heavy rainfall. Indirect impacts from herbicide use of the five herbicides earlier identified for corn seed production are not likely to present greater leaching (Gillespie et al. 2011) or transport risks (except primisulfuron with mobility to 9 inches, but limited solubility (Primisulfuron-Methyl - Herbicide Profile June, 1990. EPA Pesticide Fact Sheet) than glyphosate.

Hybrid seed producers may not have available inbreds that are all glyphosate resistant (usually only in one parental line (Monsanto, 2010), so use of postemergent glyphosate would be infrequent on acres on which seed production is currently undertaken. Weeds on seed production acres would be similar weeds on adjacent acres that the same grower uses for commercial corn production. Likewise, there is no expectation that quantities of the herbicides presently available to seed growers will be consistently used more often than the glyphosate or glufosinate used by conventional growers. If anything, growers may use quantitatively less herbicide, because post emergent application of these other herbicides can only be made for a short part of the corn development cycle. No survey exists for preferred tillage methods on corn seed production acres, although both rotary hoes and cultivators are notably used for seed production (Bennett, N.D.). Presumably commercial and seed production acres have similar tillage needs, and are dealt with similarly, since the same growers who produce seed corn also produce commercial corn, and herbicides are available for each crop.

The size and also the total mass of inbred plants used in hybrid seed production may be less than that of conventional plants. Studies indicate that multiple seasons of corn crop residue may reduce subsequent corn yield, since additional residue from continuous corn production has such an impact (Gentry et al., 2013). Thus, hybrid seed producers are likely to have less residue production than commodity corn producers, which may provide some benefit to inbreds when grown continuously and which are already sparingly productive.

Seed corn is presently grown by contractors most likely on the same acreage as that on which their commercial corn is grown, but mostly in locations where soil water holding capacity is high, and water resources are abundant. Seed companies will likely select seed corn production acres to be those on which the highest likely moisture levels can be assured (either natural or irrigation-available acres). However, since the contract growers who produce most of the seed for seed companies would be growing other corn or corn rotation crops on these same acres, there is not likely to be any difference in water use. Tillage protocols are also relevant to how much water may runoff planted fields. As described in Section 2.1.2, tillage in seed corn is predominately conservation tillage, but not no-till. The reasons for this difference from

conventional farming of corn is that the inbreds under no-till have growth and emergence problems, and are more affected by susceptibility to disease and insects (Monsanto, 2010), whose incidence may be greater under no-till. In addition, soil under no-till also remains colder and wetter during spring, thus also increasing pest susceptibility. As earlier noted, conservation tillage is the most frequent protocol in both hybrid seed and corn for grain production. As noted in section 2.1.1, conservation tillage helps minimize any impacts of maize production on water quality by reducing soil erosion is likely similar in extent in hybrid seed corn and commercial production.

As discussed in Subsection 4.2.1, Acreage and Area of Corn Production, commodity corn is expected to continue to be a major crop in the U.S., with a predicted increase in production from approximately 88 million acres of land in 2010 to between 90 and 92 million acres through 2020 (USDA-OCE, 2011a). 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. The majority of herbicide-resistant corn grown in the U.S. is glyphosate-resistant (Duke and Powles, 2009).

No expected changes to water use associated with corn production is expected for this alternative. Under the no action alternative MON 87427 would remain a regulated article and would not be available to hybrid maize seed producers. Maize hybrid seed producers would continue to produce seed using current detasseling methods with no anticipated changes in seed production acres or land use. In terms of water quality, impacts to the environment under the no action alternative would not change from the current conditions and therefore, would not result in significant impacts. As discussed above, both the approval in whole and no action alternatives would result in no significant changes to water quality.

Preferred Alternative: Water Resources

Water quality could be impacted either directly by MON 87427 via plant material impacts on water resources, or indirectly via impacts from the use of glyphosate or tillage practices associated with the planting of MON 87427. Conservation tillage, a system that leaves 30% or more of the previous crop residue covering the soil when planting another crop has been increasingly employed in commercial maize and hybrid maize seed production acres, and helps minimize any impacts of maize production on water quality by reducing soil erosion.

In terms of potential direct impacts on water quality, the CP4 EPSPS protein contained in MON 87427 is a member of the larger family of EPSPS proteins that are ubiquitous in plants and microbes in the environment (CaJacob et al., 2004). The mode of action of this family of proteins is well known (Alibhai and Stallings, 2001) and the introduced CP4 EPSPS protein itself was derived from a common soil bacterium (*Agrobacterium* sp. strain CP4). The safety of CP4 EPSPS protein present in other glyphosate-tolerant crops has been extensively evaluated (Harrison, et al., 1996), and the U.S. EPA has granted a tolerance exemption for CP4 EPSPS. A history of safe use of CP4 EPSPS is supported by the lack of any documented reports of adverse effects since the introduction of Roundup Ready crops. Therefore, it is unlikely that the presence of CP4 EPSPS protein in MON 87427 will have a significant impact on water quality.

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Under full deregulation of MON 87427 hybrid seed producers would be able to use glyphosate in seed production fields, which has not been possible previously since inbreds often did not have glyphosate resistance. MON 87427 corn's nonregulated status under the Preferred Alternative would not present any qualitatively different impacts on water resources than existing varieties of glyphosate-resistant corn and their weed management options. Just as commercial growers of particularly glyphosate resistant corn may use both glyphosate and cultivation or glyphosate in conservation tillage systems, so also growers of corn seed will doubtless use the weed management potential of glyphosate, and also cultivation when needed. As MON 87427 corn is similar in its growth and agronomic characteristics to its control cultivars and other nonregulated glyphosate-resistant maize lines (USDA-APHIS, 2012). Greater than 80% of current maize acres contain the same glyphosate tolerance trait as in MON 87427. No changes to irrigation and other agronomic practices such as fertilizer and insecticide or fungicide applications, that have the potential to affect water quality or quantity, would occur as a result of this alternative.

Current inbreds do not all carry traits for glyphosate resistance, and the herbicide is not used in hybrid production. However, the corn seed crops must be treated with other herbicides, and these would no longer be needed; thus, fewer types of herbicides would likely enter water resources, some of which are more persistent than glyphosate (such as primisulfuron); glyphosate possesses a relatively short environmental half-life and limited effects on nontarget animals. It is not likely that use of glyphosate with MON 87427 seed corn production would have a significant impact on water resources.

4.3.2 Soil Quality

No Action Alternative: Soil Quality

The no action alternative would continue the practice of pollen control by use of detasseling operations for hybrid seed production. One consequence of detasseling is that multiple passes of heavy vehicles must be made to transport the mechanical cutters along with teams of detassellers to complete the work. Typically, vehicles including a rotating blade to remove the tassels are driven through the field, and a second puller type detasseler may then follow within a few days to continue to remove tassels. Because the detasseling is not complete after the two mechanical passes, hand labor must be used to complete the process and so prevent self-pollination and resulting mixture of seed types. Each vehicular pass increases compaction of soil and may limit good root penetration (Hoeffft et al., 2000)

Both hybrid seed and commodity corn production use agronomic practices that benefit soil quality and include contouring, and use of cover crops to limit the time soil is exposed to wind and rain. Still other beneficial practices are the introduction of depleted certain soil nutrients, crop rotation, tillage for crop establishment and windbreaks which are the same or generally similar in both types of production. Agronomic practices that differ include weed control, not in general practice of herbicide use with some tillage, but in the types of herbicides used. These differences are cited in section 2.1.2 and some of the consequences of their use in soil noted in Section 4.3.1.

The production of conventional herbicide-resistant GE corn utilizes EPA-registered pesticides for insect and plant pest management, including glyphosate. In 2010, herbicides were applied to 98% of cropland planted to corn (USDA-NASS, 2011a). Pesticides (including herbicide,

insecticide, and fungicide) consist of active ingredients that control pests and inert ingredients to facilitate their application. In 2010, 66% of all active ingredients applied to corn treated with pesticides were herbicidal (USDA-NASS, 2011a), indicating their widespread use and potential to affect the environment. The amount of herbicides other than glyphosate applied to corn has declined over the last decade (NRC, 2010) (see Subsection 4.2.2, Agronomic Practices). The environmental risks of pesticide use are assessed by the EPA in the pesticide registration process and are regularly re-evaluated by the EPA to maintain their registered status under FIFRA. In this process, steps to reduce pesticide residuals and persistence in soil are included on a pesticide's label and approved by the EPA.

As discussed in Subsection 2.2.2, Soil Quality, there have been several reports of the long-term use of glyphosate immobilizing manganese and potentially reducing plant uptake or ability to use this nutrient (Eker et al., 2006; Neumann et al., 2006; Ozturk et al., 2008; Cakmak et al., 2009; Huber, 2010). Additional investigations have disclosed that with the legally permissible rate of glyphosate application, no effects are seen on either greenhouse or field micronutrients, including manganese (Duke et al. 2012). The current understanding is manganese-glyphosate interaction resulting in manganese problems appears to occur in areas where manganese deficiency already exists (Hartzler, 2010), and producers should be prepared to address it with agronomic practices designed to augment manganese (Camberato et al., 2010).

Preferred Alternative: Soil Quality

Approving a determination of nonregulated status to MON 87427 corn would not affect soil quality. Use of MON 87427 for hybrid seed production will also reduce soil compaction, as there will be no need to run heavy detasseling machinery across seed fields. Compaction from detasseling operations, especially when fields are wet and operations must be conducted to prevent pollen flow, can also increase erosion, and require more tillage in the following season. Since detasseling damages plants and reduces plant health, seed yields will be increased by using the chemical sterilization process, resulting in a potential reduction in acres needed for parent inbred seed production.

MON 87427 corn is agronomically and compositionally equivalent to other glyphosate resistant corn, and other GE and non-GE corn varieties currently in commercial production (Monsanto, 2010; USDA-APHIS, 2012). Most corn acreage is currently planted to either herbicide-resistant-only corn or herbicide-resistant corn varieties stacked with other GE traits (Duke and Powles, 2009; USDA-NASS, 2012b). 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 glyphosate-resistant corn varieties.

Since it is expected to replace non glyphosate-resistant inbreds, the nonregulated status of MON 87427 corn would not affect weed management practices or their effects on soil quality as practiced on the majority of corn acres planted to glyphosate resistant varieties. As discussed above, more diverse weed management tactics potentially including more aggressive tillage practices that can affect soil quality may be needed to address the increasing emergence of glyphosate-resistant weeds (Beckie, 2006; Owen et al., 2011). As described under the No Action Alternative, the weed management tactics selected by an individual producer would be dependent upon many factors (Beckie, 2006). Weed management practices needed for the

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production of MON 87427 corn would be no different than those used in other commercially available glyphosate-resistant corn cultivars.

As discussed above, the impact of glyphosate on manganese availability for uptake by crops after its application is an issue that may be addressed with common practices used to augment deficient soil nutrients. MON 87427 corn is agronomically similar to other GE and non-GE corn varieties and the same methods used to address manganese deficiency in current corn production would also be used with MON 87427 corn; therefore, impacts to soil quality under the Preferred Alternative would be the same as the No Action Alternative.

4.3.3 Air Quality

No Action: Air Quality

The process required for detasseling corn inbreds which are used for seed production does add indirectly to greenhouse gases not produced by conventional commodity corn agriculture. Typically, vehicles equipped with a rotating blade to remove corn tassels are driven through the field, and a second puller type detasseler may then follow within a few days to continue to remove tassels. Because the detasseling is not complete after the two mechanical passes, hand labor must be used to complete the process and so prevent self-pollination and resulting mixture of seed types. The vehicles contribute to greenhouse gases as they are driven through the field multiple times.

Preferred Alternative: Air Quality

Seed production using inbreds expressing MON 87427 will result in reduced fossil fuel use and in soil compaction, because there will be no need to run heavy detasseling machinery across seed fields. Instead, either an aerial glyphosate delivery or a herbicide sprayer will deliver the glyphosate to produce sterile female parents. Using a glyphosate based system to produce male sterility will result in fewer engine emissions from the frequent use of vehicles for the necessary detasseling operations in seed production. Since detasseling damages plants and reduces plant health, seed yields will be increased by using the chemical sterilization process, which could potentially result in at least potential reduction in acres needed for hybrid seed production. The reduction in needed seed production acreage and the unneeded trips by detasseling operations could lead to modest declines in overall greenhouse gas emissions.

Using a glyphosate based system to produce male sterility will result in fewer engine emissions from the frequent use of vehicles for the necessary detasseling operations in seed production. Changes to agronomic practices that are sources of emissions or positively contribute to air quality will result from different equipment used, and less vehicular traffic in the field following a decision that MON 87427 corn is nonregulated.

4.3.4 Climate Change

No Action Alternative: Climate Change

The major sources of GHG emissions associated with crop production are soil N₂O emissions, soil CO₂ and CH₄ fluxes, and CO₂ emissions associated with agricultural inputs and farm

equipment operation (US-EPA, 2012). Agricultural practices that produce CO₂ emissions include liming and the application of urea fertilization (i.e., nitrogen) to agricultural soils, and CH₄ produced by enteric fermentation and animal manure management. Agricultural soil management activities including fertilizer application and cropping practices are the largest source of N₂O emissions in the U.S. (US-EPA, 2012). Corn crop production primarily affects climate-changing emissions through: (1) fossil fuel burning equipment used for production and nitrogen fertilization producing CO₂; and, (2) cropping production practices including residue management and tillage (see Subsection 2.2.4, Climate Change, for detailed discussion). 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 SOC and protecting the soil from erosive forces that would release SOC 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% of planted corn acres in 2010 were produced under conservation tillage practices ranging from no-till to reduced till (USDA-ERS, 2011b). Recent increases in the incidence of herbicide-resistant weeds, including glyphosate, may require increased tillage to effect 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 SOC 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, 2011a). Nitrogen in the form of urea is commonly applied to cornfields and contributes CO₂ 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).

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 (E. Takle, Iowa State University, USDA Climate Change Seminar, Pers. Comm. 2012 (Krapfl, 2012). As climate change begins to be manifest in additional US corn growing regions, growers will continue to make accommodations to maintain production and yield.

Preferred Alternative: Climate Change

Because corn line MON 87427 is similar to other GE and non-GE corn cultivars in terms of its growth habit, agronomic properties, disease susceptibility, and composition (USDA-APHIS, 2012), several of the agronomic practices required to cultivate corn with the MON 87427 trait would be no different than those used to produce these other herbicide-resistant corn cultivars. However the process required for detasseling corn inbreds which are used for hybrid seed production does produce additional greenhouse gases not produced by commercial commodity agriculture. Typically, vehicles bearing equipment to remove the tassels are driven through the field, first a cutter with rotating blades and a second puller type detasseler may then follow within a few days to continue to remove tassels. Because the detasseling is not complete after the two mechanical passes, hand labor must be used to complete the process and so prevent self-pollination and resulting mixture of seed types. The vehicles contribute greenhouse gases as these are driven through the fields. A possible decline in GHG emissions would be expected from determining nonregulated status for MON 87427. To the extent that the cultivation of a corn variety expressing resistance to glyphosate allows a grower to not decrease conservation tillage, the potential impacts associated with the Preferred Alternative would be the same as those under the No Action Alternative.

The MON 87427 cp4 epsps gene conveyed to corn inbreds for hybrid seed production is similar to the same cp4 epsps in commercially available glyphosate-resistant corn varieties. The majority of planted corn in the U.S. is herbicide resistant (73% in 2012) primarily consisting of glyphosate-resistant cultivars (Duke and Powles, 2009; USDA-NASS, 2012b). Conferring nonregulated status to corn line MON 87427 would not likely change the development of glyphosate-resistant weeds, since it is most likely to be planted on acreage typically planted to glyphosate-resistant commercial corn; thus, no change to GHG emissions would occur from use of fossil fuels, release of SOC, or carbon sequestration in plant residue and soils compared to these other varieties under the Preferred Alternative. As discussed under the No Action Alternative above, more diverse weed management tactics, potentially those including more aggressive tillage practices that can affect GHG emissions, may be needed in the long term to address the increasing emergence of glyphosate-resistant weeds (Beckie, 2006; Owen et al., 2011). Since corn line MON 87427 is expected to be grown with mostly similar management practices used on other glyphosate-resistant cultivars, its nonregulated status would not alter weed management practices and their effects on GHGs contributing to climate change; therefore, the potential impacts to climate change under the Preferred Alternative would be similar to the No Action Alternative.

When comparing seed production practices under the No Action Alternative, use of inbreds expressing MON 87427 for seed production processes will reduce fossil fuel use and soil compaction, as there will be no need to run heavy detasseling machinery across seed fields. Instead, either an aerial glyphosate delivery or a herbicide sprayer will deliver the glyphosate to produce sterile female parents. The reduction in exhaust gas emitting equipment could lead to a modest decline in overall greenhouse gas emissions under the Preferred Alternative.

4.4 Biological Resources

4.4.1 Animal Communities

No Action Alternative: Animal Communities

Under the No Action Alternative, hybrid seed corn production will continue as currently practiced while MON 87427 corn remains a regulated article. Seed production practices resemble commodity corn production in most details, but with some differences, none likely to impact animal communities. The acreage of hybrid corn seed production is about 0.6% of that of conventional corn. Cultivation of other glyphosate-resistant GE corn varieties along with non-GE corn will also 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 2.1.2, Acreage and Area of Corn Production, hybrid seed corn was produced on about 0.5 million acres, acreage relatively unchanging with conventional corn produced on over 96 million acres in 2011, an increase of approximately 4.5 million acres over 2011 (USDA-NASS, 2012b). Corn is expected to continue to be a major crop in the U.S. through 2020 (USDA-OCE, 2011a). 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).

Glyphosate-resistant corn varieties have been approved as nonregulated since 1997 (USDA-APHIS FR Notice, 2012), and the majority of corn cultivated today is herbicide resistant (USDA-ERS, 2011a), primarily glyphosate-resistant (Duke and Powles, 2009). All glyphosate-resistant corn varieties currently available on the market have been evaluated for their food and feed safety impacts by the FDA. The EPSPS protein that confers glyphosate resistance in MON 87427 corn is derived from the soil inhabiting species, *Agrobacterium spp.* strain CP4, which is a protein also expressed in a large number of other nonregulated glyphosate tolerant corn and soybean lines (Monsanto, 2010). This EPSPS has been earlier evaluated by the FDA, who found no safety concerns from its consumption as animal feed (US-FDA, 2000). Consumption of nonregulated glyphosate-resistant corn presents minimal risk to animal communities. A final food consultation with the FDA for MON 87427 corn was submitted by Monsanto on 15 December, 2010 and completed 23 March, 2012 (BNF-00126).

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, 2011a) 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, 2011a). As discussed in Subsection 2.1.2, Agronomic Practices, there are several glyphosate formulations (US-EPA,

2009f) that differ in the timing and amount of application to field corn. The environmental risks of glyphosate herbicides are assessed by the EPA in the pesticide registration process. The glyphosate RED was last accomplished in 1993, and the herbicide is currently undergoing registration review scheduled for the final decision in 2015 (US-EPA, 2009e). As discussed in Subsection 2.3.1, Animal Communities, the registered uses for glyphosate pose minimal risk to animals, but spray drift may adversely impact non-target plants that provide habitat. The EPA is evaluating new regulations for labeling and BMPs to control drift (US-EPA, 2009d). When used consistent with the EPA-registered uses and labels, glyphosate application in corn presents minimal risk to animal communities. In 2010, 66% of all active ingredients applied to corn treated with pesticides were herbicidal (USDA-NASS, 2011a).

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).

Preferred Alternative: Animal Communities

As part of the assessment for the proposed action, APHIS has evaluated the potential effects of each alternative on a wide array of wildlife species and their habitats occurring in the U.S. Under the Preferred Alternative, a determination of nonregulated status would be extended to MON 87427 corn, and it would be available as both a weed management option for hybrid seed farmers as well as a technology to sterilize male tissues in female inbreds. As stated above, the majority of corn planted in the U.S. today is herbicide and glyphosate resistant (Duke and Powles, 2009; USDA-ERS, 2011a). MON 87427 corn is similar in its growth and agronomic characteristics to other nonregulated glyphosate-resistant corn lines (Monsanto-Co., 2010; USDA-APHIS, 2012); hence, no changes to agronomic practices such as cultivation, crop rotation, irrigation, tillage, or agricultural inputs with potential impacts to wildlife and their habitat would likely occur under this alternative.

As discussed in Subsection 2.5, Animal Feed, a final food consultation with the FDA for MON 87427 corn was submitted by Monsanto on 15 December, 2010 and completed 23 March, 2012 (BNF-0000126). As discussed in the No Action Alternative, the food safety of the EPSPS protein conveying glyphosate resistance was previously established by an FDA evaluation. In accordance with FDA (US-FDA, 2011) guidance, since the EPSPS has previously been evaluated by the FDA in an earlier food safety evaluation, no new evaluation is required for MON 87427 corn commercial distribution. Because the composition of MON 87427 corn is similar to other nonregulated glyphosate-resistant corn lines (Monsanto-Co., 2010), with no expected hazards associated with its consumption, the risk of MON 87427 corn affecting wildlife species is also unlikely, regardless of exposure.

Commercial use of glyphosate is not expected to change if MON 87427 corn is approved as nonregulated. Based upon information provided by Monsanto (Monsanto, 2010), MON 87427

corn is similar in its growth characteristics to other nonregulated glyphosate-resistant corn. No overall increases in glyphosate above those already possible for registered uses of glyphosate products on commodity corn would be required to cultivate MON 87427 corn. Consequently, there would be no difference in the potential of MON 87427 corn cultivation to impact wildlife or habitat from that of other nonregulated glyphosate-resistant corn varieties. As discussed above, the EPA is currently evaluating new regulations for labeling and BMPs to control drift (US-EPA, 2009d). When used consistent with the EPA-registered uses and labels, glyphosate application in MON 87427 corn fields presents minimal risk to animal communities.

Approving MON 87427 corn as nonregulated would not change the development of glyphosate-resistant weeds or the methods used for their control that may impact animal communities, such as increased tillage. As discussed above, MON 87427 corn would replace other herbicides labeled for use on seed production corn. The label for this product and use of glyphosate for weed management is similar to that currently used on the majority of the 73% of corn acres planted with herbicide-resistant cultivars (USDA-NASS, 2012b).

Based on the above, the impacts of determining nonregulated status for MON 87427 corn to animal communities would be similar to those of the No Action Alternative.

4.4.2 Plant Communities

No Action Alternative: Plant Communities

Hybrid seed 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, 2012). Hybrid seed production locations are concentrated in the Midwestern states of the corn belt, as noted in Section 2.1.1, and would be found in locations with either abundant water or where irrigation is available. 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. The majority of U.S. corn acres are planted with GE herbicide-resistant corn cultivars, and genetically engineered traits do not change the adaptation to the various agronomic environments in which corn hybrids can be produced.

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

Weeds are the most important 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 hybrid corn production are likely the same as those encountered in commercial corn production, since seed corn and commercial corn are likely both rotated on the same acreage. These weeds 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% of planted corn acreage, and on that acreage, the most frequently applied herbicide is glyphosate (USDA-NASS, 2011a).

Herbicide resistance occurs when a plant survives the application of an herbicide and reproduces, passing on its resistance to new generations. Herbicide-resistant weeds can become agronomically important as they out-compete crops and require additional resources to affect control. As discussed in Subsection 2.3.2, Plant Communities, weed species resistant to glyphosate are becoming agronomically more important in crop production. For example, glyphosate-resistant Palmer pigweed (amaranth) is a major economic problem in the Southeast U.S. while glyphosate-resistant waterhemp is an economically important weed in Midwestern states (Culpepper et al., 2006; Owen, 2008). In response, producers are diversifying weed management tactics in corn production to include alternating crops resistant to different herbicide modes of action grown in a field, alternating the herbicide modes of action used, practicing more crop rotation, and increasing tillage to effect control of herbicide-resistant weeds (Owen et al., 2011). Weeds are developing resistance to multiple herbicides, but are also controlled with adjustments to standard practices, so as to include crop rotation and tillage (Owen et al., 2011) when overreliance on herbicides obviates such changes.

As discussed above in Subsection 4.3.2, Soil Quality, more diverse weed management tactics, potentially including more aggressive tillage practices that can affect soil erosion, may be needed to address the increasing emergence of glyphosate-resistant weeds (Beckie, 2006; Owen et al., 2011). Increased tillage could result in more soil erosion that could consequently increase sedimentation and residual pollutant loading of nearby waters. New herbicide protocols for managing resistant weeds are available and would likely be preferred by growers, since herbicide focused strategies have captured the preponderance of the corn production market. The particular mix of weed management tactics selected by an individual producer, however, are dependent upon many factors such as the agroecological setting, the problem weed type, and agronomic and socioeconomic factors important to farmers (Beckie, 2006).

For risks of weed resistance to glyphosate, USDA in its various units is funding programs aimed at understanding weed resistance development, and managing crops to avoid resistance. At the Agricultural Research Service, this includes research programs whose goal is providing “recommendations for appropriate rotation frequencies of both crops and herbicides to stymie evolution of weed resistance and shifts to naturally tolerant weed species, and cause a general reduction in weed populations” as described in the Action Plan for 2008-2013 of the National Program 304, Crop Protection and Quarantine (USDA-ARS, 2010). The USDA, National Institute of Food and Agriculture (NIFA) recognizes the need for a broad collaboration of federal, state, academic and industry endeavors to provide responses to these and other risks to which agriculture may be exposed and provides competitive grant awards, such as those of Westra and Chisolm (2012) and Davis and Tranel (2012) to support research directed toward weed resistance. USDA presently devotes substantial funds to support research, teaching and

outreach programs (especially through the support of USDA-Extension staff and programs in individual States) for herbicide resistance management, and awarded to agricultural researchers and growers. Additionally, farmer organizations such as the National Corn Growers Association offer online training to their members for averting development of weed resistance (<http://ncga.adayana.com/>). The Weed Science Society of America has produced a five-module training course for certified crop protection specialists and others titled “Current Status of Herbicide Resistance in Weeds” which is also available online (<http://www.pentonag.com/wssa.wrm>). Seed technology developers such as Monsanto offer courses for certified pesticide applicators, such as “Weed Resistance Management (WRM) in Agronomic Row Crops & Trees, Nuts & Vines” (<http://www.pentonag.com/CA/AZWRM>). Finally, state extension services also provide documents online that supply information and management tactics for prevention of herbicide resistance, such as that from University of Minnesota (Gunsolus, 2008).

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, (USDA-APHIS, 2012) has concluded there is no significant risk of gene flow between cultivated corn and its weedy relatives that may impact plant communities.

Volunteer herbicide-resistant corn pose an additional management challenge when they appear in subsequent crops with the same herbicide resistance and can be extensive and problematic (see Subsection 2.3.2, Plant Communities). These volunteers arise from spilled corn from the previous cropping season. Corn rootworm may infest corn volunteers arising in a glyphosate-resistant soybean crop (Marquardt et al., 2012). These volunteers may become another source of rootworm infestations for successive corn plantings. Existing agronomic practices, however, are effective in the management of such volunteer corn.

Glyphosate-resistant volunteer corn may be controlled by the application of corn-active herbicides (e.g., ACCase and ALS inhibitors), mechanical means, and rotation of crops with resistance to different herbicide modes of action (Beckie and Owen, 2007; Zollinger et al., 2011). The incidence of glyphosate-resistant volunteer corn in cornfields where corn was not planted the year before could be the result of pollen-mediated gene flow. These volunteers can be controlled by maintaining adequate spatial or temporal isolation distances between corn crops. See Subsection 2.3.3, Gene Flow and Weediness, for a description of pollen-mediated gene flow in corn.

The application of an herbicide in corn production has the potential to impact non-target plant communities through spray drift, volatilization (evaporation), its adsorption to soils incorporated in runoff, leaching, and cleaning and disposal of the equipment used to dispense it. The EPA is currently evaluating new regulations for pesticide drift labeling and the identification of BMPs to control such drift (US-EPA, 2009d), as well as identifying scientific issues surrounding field volatility of conventional pesticides (EPA, 2010a). Glyphosate is currently under review by EPA for continued registration of the herbicide, with a reregistration decision expected in 2015 (US-EPA, 2009e).

Glyphosate is toxic to most terrestrial and aquatic plants, inducing plant death. The herbicide has low leaching potential, low vapor pressure, and low volatility from soils (US-EPA, 1993a; Senseman, 2007) and these properties show low potential for damage from volatility. In its 1993 glyphosate reregistration decision, the EPA required additional studies concerning vegetative

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vigor, droplet size spectrum, and a drift field evaluation that did not affect the reregistration eligibility of the herbicide (US-EPA, 1993a). The potential effects of glyphosate spray drift are minimized when growers follow EPA-approved labels that provide detailed measures to manage spray drift; these measures include applying only during optimal wind conditions and temperature inversions and at appropriate humidity, adjusting spray droplet size and sprayer boom heights and including drift reduction additives, and judicious use of aerial spraying from aircraft (Monsanto, 2010b).

In summary, under the No Action Alternative, natural selection, and the selection pressure exerted through the use of herbicides and other agronomic practices, impact plants communities by either inducing plant death, selecting for weedy characteristics, inducing shifts in the composition of the plant community, through gene flow to other related plants, and in some cases, contributing to the development of herbicide-resistant weeds. Plant species (i.e., weeds) that typically inhabit GE and non-GE corn production systems will continue to be managed through the use of mechanical and chemical control methods, as currently practiced. Multiple herbicides, including the herbicide glyphosate, will continue to be used on corn.

Preferred Alternative: Plant Communities

Corn line MON 87427 could potentially have different impacts to plant communities adjacent to or within agroecosystems that would be different from currently available glyphosate-resistant corn cultivars, mainly because the time of application of glyphosate for male sterility is different from that of commercial corn. The post emergent application of glyphosate must be completed by vegetative stage 8 for Roundup Ready crops, but when glyphosate is used to prevent development of male tissue and pollen with the MON 87427 trait, the application can continue from vegetative stage 8 up to stage 13. According to the average development stages and summarized timing of corn development, the difference between stage 8 and 13 could be about one month (Odell's-World, 2010). The end of glyphosate treatment for conventional corn would be about 50 days following emergence. It is likely that most plants within range of the glyphosate treatment would have been emerged earlier than the corn and by the approximate end of application window, would be as old (two months) or older than the MON 87427 corn. Typical of glyphosate application, larger and older plants are less or may not be sensitive to glyphosate (Hartzler et al., 2006) (Gauvrit and Chauvel, 2010). Since any non target plants likely to receive glyphosate would be less sensitive later than earlier, it is not clear that the additional window of application would impact such plants. As discussed in Subsection 4.2.2, Agronomic Practices, the agronomic and phenotypic characteristics of MON 87427 have been evaluated in field trials (Monsanto, 2010) and determined by APHIS to be similar to its comparator corn cultivars (USDA-APHIS, 2012). MON 87427 would, therefore, be cultivated similarly to other glyphosate-resistant corn, and have impacts to plant communities similar to those described under the No Action Alternative when glyphosate was used for weed management.

A determination that MON 87427 is nonregulated would not be expected to increase the development of glyphosate-resistant weeds. The planting of this crop will likely only replace similar commodity corn grown on the same farm. MON 87427 is basically similar to other glyphosate-resistant corn cultivars and the allowable application of rate of glyphosate to corn is the same as that for these commodity cultivars.

Deterring development of glyphosate resistant weeds is a topic frequently addressed to growers by University extension staff, seed developers, and corn producers associations, among many others. State specific advice, as for example, in Iowa, has identified existing methods that would be highly relevant to corn growers (Owen et al., 2011). Owen (2011) has noted that simplicity and convenience of depending solely on glyphosate “has run its course” and that diversity in weed management strategies (integrated weed management) is needed. He calls for (1) use of herbicide tank mixes, with specific knowledge of existing weed resistances on the farm (2) redundant herbicides for control of key weeds (3) multiple herbicides at each application (4) inclusion of mechanical and cultural strategies. Specific weeds of high concern for resistance development such as horseweed (*Conyza canadensis*) have been shown to be effectively controlled by combinations of herbicides, such as mesotrione and atrazine and other combinations (Armel et al., 2009). Likewise, combinations of these can be used for control of Palmer amaranth, common waterhemp, and giant ragweed (see review in Owen (2011e). Similarly, multistate successes with two or three herbicides pre-emergence have been demonstrated for giant ragweed, common lambsquarters, and giant foxtail, which build on use of atrazine (Louex et al, 2011). While atrazine is already widely used (see Section 2.1) and weed resistance to atrazine is known in Corn Belt states (Heap, 2011), some state weed extension staff continue to see a place for its use in corn production (Owen et al., 2011). The extent of weed resistance in Iowa is yet comparatively small, with state-wide estimate of about 1% of acres infested with glyphosate resistant weeds (Hartzler, 2010) (out of 14 million acres of corn planted in Iowa in 2012 (USDA-NASS, 2012b). However, some estimates place row crop glyphosate resistant water hemp as being found on 20% of Iowa acres (Corn-and-Soybean-Digest, 2013). Corn growers are aware that overuse of glyphosate as principle herbicide results in weed resistance (multistate survey from 2005: (Givens et al., 2011), and alternative strategies are both available and being publicized by a variety of expert resources (as noted in sections 2.3.2 and 4.4.2).

As discussed above, corn has no sexually compatible relatives in the U.S. likely to be in the vicinity of commercial corn cultivation, and there is little risk of its cultivation contributing to weediness that may impact plant communities; further, APHIS has determined that there are no phenotypic differences between MON 87427 and control lines that would contribute to enhanced weediness (USDA-APHIS, 2012). Herbicide-resistant corn such as MON 87427 has the potential to impact other crops in the same fields or adjacent fields in later seasons as volunteers. As MON 87427 is similar to other nonregulated corn cultivars, its volunteers would be controlled by common agronomic practices as discussed under the No Action Alternative.

Based on these findings, the potential impact to other vegetation in corn and the landscapes surrounding cornfields from approving a determination of nonregulated status to MON 87427 is not expected to differ from the No Action Alternative.

4.4.3 Gene Flow and Weediness

No Action Alternative: Gene Flow and Weediness

Hybrid seed production is focused on highly restricting gene flow, except for that occurring in the planned crosses. Pollen control methods begin with distance isolation, requiring at least

enough as that specified by prevailing state and AOSCA standards. The standards for isolation distance may be augmented or partly replaced by sufficient border rows of standard hybrid corn varieties, again to prevent unwanted gene movement. The need to precisely restrict pollen movement to female parental inbreds additionally requires either genetic sterilization methods, such as cytoplasmic male sterility methods, directed chemical (gametocyte) sprays or mechanical and hand detasseling. At each site of seed production, vigorous efforts are made to prevent genetic dilution of the inbred stocks, the hybrid crosses, or mechanical mixing of seed of unknown or uncertain parentage, since quality control is highly necessary for maintaining the reputation of the seed developer.

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 2020 (USDA-OCE, 2011a). 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 (2010) has concluded that there is not a risk of gene movement between corn and its wild or weedy maize relatives.

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 Subsections 2.1.3, Organic Corn Production, and 2.1.4, Specialty 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 (see Subsection 2.3.2, Plant Communities).

Gene transfer between microorganisms is common (Keese, 2008; McDaniel et al., 2010). Yet, biodegradation of plant materials tilled into soils generally results in fragmentation of DNA strands into small pieces (Lerat et al., 2007; Levy-Booth et al., 2009; Hart et al., 2009b), which would be unlikely to present an intact cp4 epsps gene. Cleaves (2011) have evaluated the ability of shorter DNA strands to adsorb to soil aggregates, potentially affecting their persistence in soil; however, these were unlikely to convey functional genes. Although unlikely, if a microorganism incorporated an intact epsps gene (found in many glyphosate resistant lines), it might transfer the gene to other microorganisms, resulting in a greater presence of the gene in the environment. As described in Subsection 2.3.3, Gene Flow and Weediness, gene transfers between plants and microorganisms are thought to occur on an evolutionary timescale, reflecting the conclusion of long term selection against accreting new genes especially those that conveyed either no advantage or a metabolic “drag”. Nevertheless, even if transfer occurred, the epsps genes have

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previously been approved for release under 7 CFR part 340 and the plant pest provisions of the Plant Protection Act since 1994 (USDA-APHIS FR Notice, 2012) in several herbicide-resistant crops because no impact on the environment can be determined. However, an incremental increase in gene transfer among microorganisms under the No Action Alternative is unlikely.

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) (see Subsection 2.3.3, Gene Flow and Weediness). 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

As a component of a system to control pollen flow, the trait expressed in MON 87427 corn will efficiently limit the movement of genes to only the desired corn plants. In response to treatment with glyphosate, the female parental inbred will become male sterile, preventing the self-pollination of the silk and of selfed seed. Instead, the growers will position the male parental inbreds to effectively become the only pollen source likely to fertilize the desired female parental inbred. Border rows may be chosen not only to provide space and substrate for catching non desired pollen, but have been selected and planted because they will shed pollen at a time different from the expected time of receptivity of the female inbred that will complete the cross and make the expected hybrid seed. The MON 87427 trait will provide increased effectiveness in attaining preferred genetic identity and complete uniformity in hybrid seed production and for economic production of hybrid seed. Control of gene flow will be modestly enhanced by the attainment of nonregulated status for MON 87427 corn.

4.4.4 Microorganisms

No Action Alternative: Microorganisms

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.

GE plants potentially impact soil microbes either (1) directly from the transfer of introduced genetic material, (2) by exposure to expressed proteins through root exudation and crop residue incorporated into soil, or (3) changes in agronomic practices used to produce crops. Indirect impacts may arise from (1) effects of the glyphosate or (2) changes in the amount and composition of residue from crops.

Exuded proteins

The potential for intact CP4 EPSPS protein conveying glyphosate resistance to remain functional in soils is unlikely, because similar EPSPS proteins degrade once released from cells, decaying in soils (Australian Government, 2006). If some molecules did persist in soils, there is no reason to anticipate toxicity of the CP4 EPSPS protein to soil microbes. Root exudates have been found to promote certain microbial populations, such as soybeans in symbiotic relationship with nitrogen-fixing bacteria, and other free-living microbes that have co-evolved with plants that supply nutrients to and obtain food from their plant hosts (USDA-NRCS, 2004; Bais et al., 2006). Glyphosate-resistant crops such as corn could potentially impact the soil microbial community even when not treated with the herbicide, if for example, there were properties of the plant, say novel susceptibility to disease, that were associated with the genetic transformation (Kremer and Means, 2009). However, the first author later noted that the inorganic mineral content of soils where the research was accomplished (reported in Kremer and Means, 2009 and earlier) was “highly variable” and that this soil condition could “contribute[s] to non-target effects,” (Zobiolo et al., 2012) possibly including effects apparently deriving from the RR soybean cultivar. In an earlier survey of studies of the impact of GE plants on soil microbial communities, including many with herbicide tolerance, no significant non-target effects were observed Kowalchuk (Kowalchuk et al., 2003). However, if the transformation was engineered to produce a specific chemical, then this chemical could be expected to produce an effect on soil bacteria (Kowalchuk et al., 2003). Presently, there is no evidence that corn exudates have impacts on soil microorganisms.

Changes in agronomic practices

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 glyphosate-resistant corn (and other herbicide-resistant crops) 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).

Indirect effects of glyphosate

The primary agents degrading glyphosate in soil and water are microorganisms feeding on the herbicide (Senseman, 2007). As discussed in Subsection 2.3.4, Microorganisms, investigations into the toxicity of glyphosate to microorganisms have produced varied results. Earliest studies investigating the impact of glyphosate on soil microorganisms did not detect adverse effects under field use conditions, such as on specific, limited functional properties of soil bacteria, such as nitrification, or specific species of soil bacteria; others found minor effects that could not be separated from changes in habitat, and still others reported effects at or near normal glyphosate use rates, but in most cases, the effects were minor and temporary (Giesy et al., 2000). In more recent experiments, glyphosate was applied to two different soil types, and glyphosate stimulated

bacterial biomass up to 25 fold and utilization of all carbon substrates by culturable bacteria increased substantially (Ratcliff et al., 2006). As summarized by Hart (2009a) while some studies have found effects of glyphosate or the glyphosate resistant crop, many more have shown only minor, transient effects. In the case of glyphosate resistant corn, neither crop effect nor glyphosate effects resulted in changes to the rhizosphere, denitrifying bacteria, or fungi (Hart et al., 2009). Later work showed that glyphosate could directly decrease rhizosphere populations of three types of soil bacteria around roots of glyphosate resistant soybean (Zobiolo et al., 2011). Glyphosate applied to soils may reduce soil microbial diversity (Barriuso and Mellado, 2012) but less than that of acetochlor (a common, corn herbicide) applied pre-emergence; in three year observations and with different soil types glyphosate did not impact microbial phyla diversity (Barriuso et al., 2011). Other authors show that bacterial biomass can be reduced 7 days after treatment in soybean rhizosphere, in soil previously unexposed to glyphosate, but that biodiversity does not change in response to glyphosate (Lane et al., 2012). The inconsistent results of these observations suggest that any effects of glyphosate may not be easily distinguished from multiple other influences, including soil, cultivar type, growth stage of the plant, and experimental details Hart, (Hart et al., 2009; Farago and Faragova, 2010).

Although mostly anecdotal evidence suggest that use of glyphosate and some glyphosate resistant crops may increase frequency, virulence or susceptibility to certain plant diseases (as reviewed in Johal and Huber (2009) substantiation is lacking. APHIS has previously examined in detail the potential impacts of glyphosate to microorganisms in the cultivation of glyphosate-resistant alfalfa and sugar beets on soil with previously cultivated glyphosate resistant crops (USDA-APHIS, 2010; USDA-APHIS, 2011a). Based on extensive review of the literature, these EISs conclude glyphosate application might favor development of detrimental microbial species (or harm some beneficial microbes); however, to date, there is no conclusive evidence linking applications of glyphosate to changes in soil microbial communities that have adverse effects on plants grown in those soils.

Corn cultivation, including the production of glyphosate-resistant corn and its potential impacts to soil microorganisms, is expected to continue under the No Action Alternative. The majority of corn grown in the U.S. is herbicide resistant, and glyphosate is the most frequently applied herbicide to corn (USDA-ERS, 2011b; USDA-NASS, 2011a). Farmers have access to non-glyphosate-resistant corn varieties, and manage their crops by implementing practices to control pests and weeds, including the use of glyphosate.

Preferred Alternative: Microorganisms

A determination of nonregulated status to MON 87427 is not expected to result in any new impacts to microbial communities. MON 87427 expresses the same EPSPS protein that is found in a large percentage of both current and recent corn and soybean varieties (Monsanto, 2010; USDA-APHIS, 2012). The EPSPS sequence inserted into MON 87427 is functionally the same as that associated with the native EPSPS-encoding gene in corn and derives from a common soil borne plant pathogen, *Agrobacterium* spp. (USDA-APHIS, 2012). As such, nothing new or unique would be introduced into the environment or soil that may impact the microbial community under the Preferred Alternative.

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MON 87427 has been determined to be agronomically and compositionally similar to other nonregulated glyphosate-resistant corn varieties (USDA-APHIS, 2012). It is not expected to change the acreage or area of glyphosate-resistant corn production that potentially would expand the use of glyphosate herbicide with potential impacts to soil microorganisms. MON 87427 is another glyphosate-resistant corn that will be used in production of hybrid seed, and thus will see limited adoption for this small acreage activity. Approximately 73% of corn cultivated in the U.S. today is herbicide-resistant and the majority of herbicide-resistant corn is glyphosate-resistant, (Duke and Powles, 2009; USDA-NASS, 2012b). Because MON 87427 is agronomically similar to other glyphosate-resistant and conventional corn, its cultivation would not change the agronomic practices needed for its cultivation, such as amount and rate of glyphosate application. Since the use of glyphosate for corn production is not expected to change under the Preferred Alternative, there would be no potential impacts to microorganisms compared to those of the No Action Alternative.

4.4.5 Biodiversity

No Action Alternative: Biodiversity

All the plants, animals, and microorganisms interacting in an ecosystem contribute to biodiversity (Wilson, 1988) that provides valuable life functions. In agriculture, biodiversity contributes to critical functions such as pollination, genetic introgression, biological control, nutrient recycling, and other processes the loss of which requires costly management (Altieri, 1999). Concerns regarding the potential impacts to biodiversity associated with the introduction of GE crops (and crops in general) include the loss of diversity, which can occur at the crop, farm, or landscape scale (Visser, 1998; Carpenter et al., 2002; Ammann, 2005) see Subsection 2.3.5, Biodiversity).

At the crop scale, research suggests that developing GE crops has introduced novel genes that have not decreased crop diversity because of widespread use of the traits in multiple breeding programs; the technology effectively enables the introduction of novel genes in crops (Carpenter et al., 2002; Ammann, 2005). Additionally, the concern for the loss of genetic variability has led to the establishment of an extensive network of genebanks (van de Wouw et al., 2010), including an active collection of more than 14,000 accessions of corn at the ARS North Central Regional Plant Introduction Station at Iowa State University, Ames, Iowa (USDA-ARS, 2005). These collections are shared with researchers worldwide, which helps ensure a continuous reservoir of genetic diversity for future crop development. Under this alternative, growers have access to existing nonregulated herbicide-resistant and other GE corn varieties, as well as other non-GE corn varieties, while MON 87427 corn would remain a regulated article.

At the farm scale, agronomic practices that can impact biodiversity include cropping practices (e.g., strip or contour cropping, crop rotation), soil conservation practices that maintain grass strips, windbreaks and shelterbelts and the like, tillage, and the application of agrochemicals. The rotation of crops and strip contour cropping provide varied habitat that can benefit biodiversity. Recently, there has been an increase in corn-to-corn rotation given the profitability of corn production (USDA-ERS, 2011b). As discussed in Subsection 2.1.2., Agronomic Practices, continuous corn production must be highly managed to maintain productivity, which

can be less beneficial to biodiversity; however, the practice does accumulate more crop residue that benefits some species. The establishment of soil conserving grass and other vegetative borders stabilize soil that maintains additional wildlife habitat, and improves the quality of existing habitat (such as surface water quality) that contributes to biodiversity. Allowing unproductive field edges to become managed wildlife habitat promotes diversity in both plants and animal species (Sharp, 2010).

Herbicides are used to control plants in areas where humans do not want them. As described in Subsection 2.1.2, Agronomic Practices, weeds compete with crops for light and nutrients, reducing yields. Glyphosate effectively kills grass and broadleaf plants when applied at the recommended rates. At the farm scale, herbicide use in agricultural fields may impact biodiversity by decreasing weed quantities or causing a shift in weed species present in the field, which may affect those insects, birds, and mammals that use these weeds. The quantity and type of herbicide use associated with herbicide-resistant corn crops, however, is dependent on many variables, including cropping systems, type and abundance of weeds, production practices, and individual grower decisions. See Subsection 2.1.2, Agronomic Practices, for a detailed discussion of pesticide use in corn production. The effects of glyphosate on plants and animals are presented in the following discussion of landscape-scale biodiversity.

Use of herbicide-resistant crops such as corn has been linked to increased rates of conservation tillage in U.S. crop production (Givens et al., 2009). This promotes biodiversity by allowing the establishment of other plants between crop rows and the accumulation of more plant residue that creates more soil organic matter, food, and cover for wildlife. In a review of literature that assessed the impacts of GE crops on biodiversity, (Carpenter et al., 2002) found that, for the most part, impacts to biodiversity have been positive due to increased yields, decreased usage of insecticides, use of more environmentally friendly herbicides, and facilitation of conservation tillage. In 2010, 62% of planted corn acreage in 19 surveyed states was dedicated to no-till or minimum till systems (USDA-NASS, 2011a). As described in Subsection 2.3.2, Plant Communities, the increasing incidence of herbicide-resistant weeds is also causing farmers to turn to more diversified weed management strategies, including increased tillage that potentially reduces biodiversity.

Crop production in general impacts biodiversity at the landscape scale by potentially converting natural lands that have greater animal and plant species diversity to more monocultural landscapes. Corn is the largest crop grown in the U.S. in terms of acreage planted and geographic area of production with over 96 million planted acres in 2012 (USDA-NASS, 2012b). USDA projections to 2020 indicate the acreage devoted to corn production in the U.S. will remain relatively stable at this level (USDA-OCE, 2011a).

Area-wide herbicide application may negatively impact species that are dependent on the targeted weeds, reducing diversity. As stated above, the majority of corn cultivated in the U.S. is treated with herbicides and glyphosate is the most-applied herbicide to corn (USDA-NASS, 2011a). Potential impacts to landscape-scale diversity can be related to the effects of herbicides on non-target animal and plant species. Assessments of the toxicity of glyphosate to animal species indicate a minimal risk to animals, but it is toxic to targeted plants and may affect non-targeted plants and animals through spray drift, volatilization (i.e., evaporation) and runoff. Inadvertent exposure may cause adverse effects to plants composing animal habitats that could lead to a decrease in biodiversity. As discussed in Subsection 2.3.1, Animal Communities,

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glyphosate was found by the EPA to be no more than slightly toxic to birds, moderately toxic to practically nontoxic to fish, and practically nontoxic to aquatic invertebrates and honeybees (US-EPA, 1993). The EPA is currently evaluating additional labeling requirements concerning BMPs for controlling pesticide spray drift (see Subsection 2.3.2, Plant Communities). While herbicide use potentially affects biodiversity, the application of pesticides in accordance with registered uses and label instructions, and careful management of chemical spray drift, minimizes the potential impacts from their use.

In 2009, the EPA initiated reregistration of glyphosate and has identified additional data needs. Part of the risk assessment will include an acute avian oral toxicity study for passerine species. Additionally, some inert ingredients used as surfactants are more toxic than glyphosate to aquatic organisms, and will also be evaluated for acute toxicity to estuarine and marine mollusk, invertebrates, and fish (US-EPA, 2009f).

Preferred Alternative: Biodiversity

Under the Preferred Alternative, MON 87427 corn would be determined a nonregulated variety, providing hybrid seed growers a variety trait that can both extend the use of glyphosate for weed control into inbred lines of corn needed in hybrid seed production, and also establish a new technology to provide male sterility in inbred varieties. MON 87427 corn is functionally the same other GE and non-GE corn with regard to agronomic characteristics, growth, reproductive habit, utilization of resources, and production practices (Monsanto, 2010; Stebbins and Plume, 2011; USDA-APHIS, 2012). Determining MON 87427 corn to have nonregulated status is unlikely to have any direct effects on non-target organisms associated with exposure to its gene products and the modified EPSPS protein expressed by the cultivar. The genetic material in and proteins produced by MON 87427 are closely similar to those of the nonregulated corn varieties in commercial production (USDA-APHIS, 2012). Approval of nonregulated status for MON 87427 would, therefore, have no impact on biodiversity at the crop-, farm- or landscape- scales.

Because hybrid seed production acreage has remained relatively static for decades, MON 87427 corn would likely replace certain non-glyphosate resistant inbred corn lines without expanding the acreage or area of hybrid corn seed production that could impact farm- and landscape-scale biodiversity. This acreage comprises about 0.5 million acres. Among the much larger acreage of commercial corn planted in the U.S. in 2012, approximately 73% was already glyphosate-resistant (Duke and Powles, 2009; USDA-NASS, 2012b). Based on its similarity to other corn as described above, determining nonregulated status of MON 87427 corn would not result in changes to agronomic practices such as crop rotation, soil conservation, tillage, weed management, or pesticide use that potentially impact farm- or landscape-scale biodiversity.

Based on the above information, APHIS has concluded that a determination of nonregulated status to MON 87427 corn under the Preferred Alternative would not have impacts to crop-, farm-, or landscape-scale biodiversity that differ from other currently available glyphosate-resistant corn cultivars. In conclusion, the impacts to biodiversity under this alternative would be similar to the No Action Alternative.

4.5 Human Health

No Action Alternative: Public Health

Under the No Action Alternative, the production of hybrid seed would continue with little or no use of glyphosate, especially none for post emergence weed management, since many of the inbreds do not have genes for glyphosate resistance. Because of permits required for growing of the crop, APHIS would expect little cultivation of MON 87427 corn under the No Action Alternative. Agricultural workers that are currently engaged in detasseling would likely have little exposure to glyphosate, since most of the hybrid seed production fields do not use glyphosate, and inbreds do not all contain the glyphosate resistance trait. These workers are exposed to other herbicides registered for hybrid seed production.

The environmental risks of pesticide use are assessed by the EPA in the pesticide registration process and a pesticide is regularly reevaluated by the EPA to maintain its registered status under FIFRA. The human health effects from exposure to glyphosate have been evaluated by the EPA. The 1993 glyphosate RED presents the data used by the EPA for chemical reregistration (US-EPA, 1993). As previously discussed in Subsection 2.4.1, Human Health, the review for reregistration began in July 2009; the EPA is currently conducting a comprehensive human health assessment for all uses of glyphosate and its salts (US-EPA, 2009f). The glyphosate RED presents the EPA's analysis of the toxicity, carcinogenicity, and developmental toxicity of this herbicide. Glyphosate is classified as having low toxicity via the oral, dermal, and inhalation routes and is not classified as a carcinogen or teratogen (US-EPA, 2009f), (US-EPA, 2009b). Moreover, neurotoxicity has not been reported in any acute, subchronic, chronic, developmental, or reproductive studies, although additional studies will occur as part of the current review process (US-EPA, 2009b). Based on additional toxicity tests, the EPA determined the main glyphosate metabolite AMPA does not require regulation (US-EPA, 2009b).

Preferred Alternative: Public Health

Field laborers working with MON 87427 corn would be potentially exposed to chemicals that include the CP4 EPSPS protein and to glyphosate, since MON 87427 corn is a tissue-selective glyphosate resistant GE variety of corn that facilitates the production of viable hybrid maize seed (Monsanto, 2010).

Worker Health. Workers most likely to be affected by a nonregulated status of MON 87427 would be the temporary workers who would be hired to mechanically and hand detassel corn in midsummer to support hybrid seed production. Many of these workers would no longer be needed since MON 87427 would be using glyphosate application between vegetative stage 8 and 13 to sterilize male tissue, and thus prevent pollination. These workers may previously have been exposed to residues of other herbicides than glyphosate, since the inbreds which they detasseled did not receive glyphosate treatment. Instead, field workers who were retained would apply glyphosate for weed management at similar times to the herbicide applied on commercial corn production, as well as that applied in the sterilization process at later times than the times used on glyphosate resistant commercial corn. However, the total glyphosate used for MON 87427 crops would be the same as that currently approved for commercial corn, so the exposure at a later time would not result in a different total exposure compared to those who work on the

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commercial glyphosate resistant corn. Glyphosate may also be used preplant, and this would be about 4 weeks or more after emergence on average before beginning use of glyphosate for control of the pollination process and then no later than about 6 weeks on average after emergence for a second application.

Agricultural workers that will routinely handle glyphosate (mixers, loaders, and applicators) may be exposed during and after use. Due to glyphosate's low acute toxicity and lack of carcinogenicity and other toxicological concerns, occupational exposure data is not required for reregistration (US-EPA, 1993a); however, the glyphosate RED does classify some end-use glyphosate products as eye and skin irritants and recommends PPE be worn by mixers, loaders, and applicators (US-EPA, 1993). Additionally, due to the potential for skin and eye irritation, the EPA has set the restricted entry interval for glyphosate to 12 hours after products have been applied. Due to the expected short-term dermal and inhalation exposures of occupational handlers and growers, no endpoints were identified by the HED, and as such, no occupational handler or occupational post-application assessments are required for reregistration (US-EPA, 2009b). Current EPA-approved labels for glyphosate include precautions and measures to protect human health. When used consistent with the label, pesticides present minimal risk to human health and safety.

Under the Preferred Alternative, pesticide tolerance levels for glyphosate on field corn would not change. Tolerances are the limits on the amount of pesticide that may remain on or in foods marketed in the U.S. established for every pesticide based on its potential risks to human health. In 2010, Monsanto submitted information to the Environmental Protection Agency (EPA) requesting herbicide label changes to reflect the new use patterns of glyphosate that this product would require (Monsanto 2010), in order to increase tolerance levels for glyphosate. Monsanto was granted an increase in the tolerance for glyphosate on this corn variety, increasing it for field and forage to 13 ppm from 6ppm (On May 11, 2011, EPA published its approval of this request (EPA 76 FR pp. 27268-27271, May 11, 2011)). This increased tolerance was still considerably lower however than the 300 ppm allowed for nongrass animal feed (400 ppm) and forage (300 ppm) for beef and dairy cattle.

It has been suggested that the importance producers place on worker safety, perceived increased simplicity and flexibility of farm management, and decreased risk in production can be partially attributed to the high rate of adoption of GE crops (USDA-NRCS, 2004). Producers and farm workers experience reduced exposure to potentially harmful pesticides compared to before the adoption of GE crops and are also able to spend less time applying pesticides with greater flexibility in determining when pesticides are applied. There are no data indicating that workers exposed to herbicide-resistant corn (raw or byproducts), such as that which might occur during production, transportation, and milling, have experienced adverse reactions. While a small portion of the population does suffer from corn allergies, the EPSPS protein that confers glyphosate resistance in MON 87427 corn has been determined not to be an allergen (see Subsection 2.4.1, Human Health).

The environmental risks of pesticide use are assessed by the EPA in the pesticide registration process and a pesticide is regularly reevaluated by the EPA to maintain its registered status under FIFRA. The human health effects from exposure to glyphosate have been evaluated by the EPA. The 1993 glyphosate RED presents the data used by the EPA for chemical reregistration (US-EPA, 1993). As previously discussed in Subsection 2.4.1, Human Health, the review for

reregistration began in July 2009; the EPA is currently conducting a comprehensive human health assessment for all uses of glyphosate and its salts (US-EPA, 2009f). The glyphosate RED presents the EPA's analysis of the toxicity, carcinogenicity, and developmental toxicity of this herbicide. Glyphosate is classified as having low toxicity via the oral, dermal, and inhalation routes and is not classified as a carcinogen or teratogen (US-EPA, 2009f), (US-EPA, 2009b). Moreover, neurotoxicity has not been reported in any acute, subchronic, chronic, developmental, or reproductive studies, although additional studies will occur as part of the current review process (US-EPA, 2009b). Based on additional toxicity tests, the EPA determined the main glyphosate metabolite AMPA does not require regulation (US-EPA, 2009b).

Consumer Health. Glyphosate resistance in MON 87427 was conferred using a sequence of DNA derived from the soil borne crown gall pathogen, *Agrobacterium spp. strain CP4*. MON 87427 produces the same 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein that is produced in commercial Roundup Ready® crop products, via the incorporation of a *cp4 epsps* coding sequence. CP4 EPSPS confers tolerance to the herbicide glyphosate. Tissue-selective expression of CP4 EPSPS protein in MON 87427 enables an extension of the use of glyphosate resistant maize as a tool in hybrid maize seed production (Monsanto, 2010).

As discussed above, studies have found that the EPSPS protein expressed in glyphosate-resistant crops is compositionally similar to, and is as safe and nutritional as, the same non-GE crops (Ridley et al., 2002; Batista et al., 2005; Monsanto, 2010). APHIS considers the FDA regulatory assessment in making its determination of the potential impacts of removing a new agricultural product from regulated status. As discussed in Subsection 2.4., Public Health, Monsanto had earlier completed a consultation with the FDA by submitting a food and feed evaluation of the CP4 epsps protein in NK603 corn, the same as the one expressed in MON 87427 corn and FDA concluded that there were no safety issues to address under its regulatory authority (BNF-0071: Agency Response Letter) and that they had no further questions (US-FDA, 1998b; US-FDA, 2000). Because MON 87427 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 initiated the consultation process with FDA for the commercial distribution of event MON 87427. A food and feed safety consultation on MON 87427 was completed by the FDA on March, 23, 2012, and FDA concluded the product was not materially different in composition or any other relevant parameter from other corn varieties now grown, marketed, and consumed in the U.S. (BNF-00126). From the final biotechnology consultation with the FDA, potential impacts to food safety from production of MON 87427 corn under the Preferred Alternative would be similar to those of other glyphosate-resistant corn cultivars as described for the No Action Alternative.

As discussed in Subsection 2.1.1, Acreage and Area of Corn Production, 88% of corn grown in the U.S. in 2012 was GE (USDA-NASS, 2012b). The majority of GE herbicide-resistant corn grown in the U.S. is glyphosate resistant (Duke and Powles, 2009). 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). Previous studies of the EPSPS protein, which confers glyphosate resistance, found that the EPSPS protein expressed through genetic engineering poses no potential for toxicity or allergenicity (Harrison et al., 1996; Ridley et al., 2002; Batista et al., 2005; Hoff et al., 2007; Herouet-Guicheney et al., 2009). Some people are

allergic to corn, but corn is not included in the FALCPA as one of the most common food allergens (see Subsection 2.4.1, Human Health). An additional concern with GE food crops is the potential for increased levels of anti-nutrients (Dona and Arvanitoyannis, 2009). As discussed in Subsection 2.4.1, Human Health, there are several naturally occurring anti-nutrients found in corn, including phytic acid, DIMBOA, raffinose, and low levels of trypsin and chymotrypsin inhibitors (OECD, 2002). In Monsanto's study of these anti-nutrients, raffinose, phytic acid and trypsin inhibitors were not significantly different from non-transgenic controls or reference hybrids (Monsanto, 2010). In Monsanto's study of 51 nutrients and anti-nutrients in MON 87427 corn, a few were significantly different from the non-transgenic control, but all were found to be within the ranges expected of commercial corn (Monsanto, 2010). Similarly, in a study of the CP4 EPSPS protein conferring glyphosate resistance in other corn hybrids, Ridley (2002) (Ridley et al., 2002) found the genetic modification to confer glyphosate resistance did not significantly change any of the 51 biologically and nutritionally important components evaluated.

Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. The food safety evaluation of the EPSPS protein imparting glyphosate resistance was completed by the FDA on the MON 87427 corn variety (BNF No. 000126) on March 23, 2012. No food safety issues were found by the FDA in previous consultations regarding the EPSPS protein in corn or any other GE corn cultivars (See the FDA website Final Biotechnology Consultations <http://www.fda.gov/Food/Biotechnology/Submissions/ucm225108.htm>).

Potential risks to occupational handlers and growers during glyphosate application to MON 87427 corn would be the same as those of workers in glyphosate resistant GE corn, and different from those who worked in fields of non-herbicide resistant inbreds and were exposed to different herbicides other than glyphosate. Moreover, as discussed above, the application rate of glyphosate would not likely change although the registered use of glyphosate proposed under the Preferred Alternative increases the allowable stage of corn at which glyphosate may be applied. There would be no increased risk to workers' health or safety from exposure to MON 87427 corn or byproducts during typical agricultural-related activities. Fewer workers would be exposed to any possible chemical or mechanical hazards, since MON 87427 would decrease the needs for numbers of workers. FDA has no questions about consumer safety for MON 87427. Potential risks to farm workers from the use of glyphosate would be similar to the No Action Alternative. APHIS has concluded there would be no expected negative effects to human health or worker safety under the Preferred Alternative.

4.6 Animal Feed

No Action Alternative: Animal Feed

Hybrid seed resulting from planned inbred crosses is used primarily for sale as seed for planting, and by breeders to supply specific traits needed by commercial growers. Any seed that derives from inbreds (such as male pollen donor plants) that does not have the genetic background or trait stack of desired commercial seed may also be used for animal feed, as may any hybrid seed that was produced beyond the capacity of the seed producer to sell as grower seed. As described

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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, (NCGA, 2011; USDA-ERS, 2011a). Corn comprises over 95% of the total feed grain produced in the U.S. (USDA-ERS, 2011b). In 2012, corn was grown on over 96 million acres (USDA-NASS, 2012b) and measurably produced in all states but Alaska (USDA-NASS, 2009). As discussed in Subsection 2.5, Animal Feed, 45% of the corn consumed in the U.S. in 2010 was used for animal feed (Fig. 6 and (Schnepf, 2011)). In 2012, 73% of the corn produced in the U.S. was genetically engineered to be resistant to herbicides, consisting primarily of glyphosate-resistant cultivars (Duke and Powles, 2009); (USDA-NASS, 2012b). 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, 2011a). Under the No Action Alternative, corn forage, silage, grain, and refined corn feed products from currently cultivated GE herbicide-resistant and conventional corn varieties are utilized by livestock producers.

It is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled and feed derived from GE corn must comply with all applicable legal and regulatory requirements, which in turn protect human health (see Subsection 2.5, Animal Feed). All applicants who wish to commercialize a GE variety that will be included in the food supply complete a consultation with the FDA to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and submits a summary of its scientific and regulatory assessment of the food to FDA (US-FDA, 2012). The FDA evaluates the submission and responds to the developer by letter.

As previously noted, because MON 87427 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 initiated a consultation process with FDA for the commercial distribution of event MON 87427 corn. Monsanto submitted a safety and nutritional assessment of food and feed derived from MON 87427 corn to the FDA on December 15, 2010 (BNF-000137). FDA completed the evaluation and found that foods and feeds derived from MON 87427 are as safe as conventional corn varieties on March 23, 2012 (BNF-00126). A biotechnology consultation for a similar EPSPS protein was completed by the FDA on the GA21 corn variety (BNF No. 000051) on February 10, 1998 (US-FDA, 1998a). No food safety issues were found by the FDA in their review of Monsanto's safety and nutritional assessment of GA21 corn and the modified EPSPS protein (see the FDA website Final Biotechnology Consultations <http://www.fda.gov/Food/Biotechnology/Submissions/ucm225108.htm>).

This herbicide currently has established tolerances for residues, including established residue concentrations for glyphosate in field corn for forage, grain, and stover. The EPA establishes tolerances to regulate the amount of pesticide residues that can remain on food or feed commodities as the result of pesticide applications (see, e.g., <http://www.epa.gov/pesticides/bluebook/chapter11.html>). The tolerance level is the maximum residue level of a pesticide that can legally be present in food or feed, and if pesticide residues are found to exceed the tolerance value, the food is considered adulterated and may be seized.

Agricultural production of existing commercially available glyphosate-resistant corn varieties uses EPA-registered pesticides, including glyphosate. The interval between post emergence corn application of glyphosate and when the grain may be subsequently harvested is seven days

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(Monsanto, 2010b). The interval between post-harvest application of glyphosate and when the corn vegetation may be used as feed varies with product labels, for example the Roundup Power Max® interval is seven days (Monsanto, 2010b) while the Glyphosate 41 Plus ® interval for any stage is 50 days (CropSmart, 2009). Tolerances are the limits on the amount of pesticide that may remain on or in foods marketed in the U.S. that are established for every pesticide based on its potential risks to human health. The maximum tolerance level for glyphosate in field corn is 5.0 ppm for grain and is 6.0 ppm for forage (40 CFR §180.364).

Preferred Alternative: Animal Feed

MON 87427 expresses a trait to be used in production of hybrid seed, for incorporation into inbreds. Hybrid seed resulting from planned crosses of inbreds will be used exclusively for sale as seed with specific traits. Seed from inbreds used in the hybrid cross such as male pollen donor plants, or excess quantities of the planned hybrid seed may potentially enter the commodity stream for animal feed as decided by the seed producer. Hybrid seed deriving from the production process will also contain the cp4 epsps gene. 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 87427 corn. Also, as described in Subsection 4.2.2, Agronomic Practices, the cultural requirements and 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 87427 corn are similar to other commercially available glyphosate-resistant corn. 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, 2011a). Because herbicide-resistant corn is the majority of corn produced in the U.S. today, and most of that is glyphosate resistant (USDA-ERS, 2011a), MON 87427 corn would likely replace other glyphosate-resistant cultivars without impacting the supply of corn for animal feed.

Monsanto has submitted compositional and nutritional characteristics of MON 87427 corn grain and forage to APHIS (Monsanto, 2010). Samples of MON 87427 corn and its comparators that were sprayed with glyphosate were collected from six different field trial locations (four for grain samples and two for forage samples) and analyzed for comparable nutritional components in accordance with Organisation for Economic Co-operation and Development (OECD) guidelines (OECD, 2002). Tested parameters include proximates (protein, fat, carbohydrates, fiber, ash, calcium phosphorus and moisture), minerals, amino acids, fatty acids, vitamins, isoflavones, and antinutrients and secondary metabolites (i.e., ferulic acid, phytic acid, trypsin inhibitor, raffinose, inositol, and ρ -coumaric acid) (Monsanto, 2010). MON 87427 corn is similar in compositional and nutritional characteristics to other varieties of GE and non-GE corn (Monsanto, 2010; USDA-APHIS, 2012).

A biotechnology consultation of the EPSPS protein that confers glyphosate resistance in the MON 87427 corn variety has been completed (See Subsection 4.5, Public Health). Monsanto submitted a safety and nutritional assessment of food and feed derived from MON 87427 corn to the FDA in March 2012 in support of the consultation process with the FDA for the commercial distribution of MON 87427 corn (Monsanto, 2010). Pending results of the final biotechnology

consultation with the FDA, potential impacts to the safety of MON 87427 corn under the Preferred Alternative would be similar to those of the No Action Alternative.

As discussed above, label restrictions for glyphosate's application to corn prohibits harvesting the grain prior to seven days after application and the interval for harvesting or feeding the vegetation is dependent on the individual glyphosate product label. As discussed in Subsection 4.2.2, Agronomic Practices, the registered uses of glyphosate on MON 87427 corn or other corn would not change as a result of the Preferred Alternative, nor would herbicide label restrictions for feeding corn after treatment. Similarly, no change to the EPA-established tolerances of glyphosate in treated corn intended for forage or grain harvested for animal feed that could impact animal health would be required if the request for nonregulated status of MON 87427 corn is decided.

Based on the analysis of field and laboratory data and scientific literature provided by Monsanto (2010), as well as safety data available on other glyphosate-resistant corn in commercial production, APHIS has concluded that approving a determination of nonregulated status to MON 87427 corn would not adversely impact the safety of animal feed and animal health. Overall, impacts of the Preferred Alternative would be to the same as the No Action Alternative.

4.7 Socioeconomic Impacts

4.7.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Environment

Under the No Action Alternative, MON 87427 corn would continue to be a regulated article under 7 CFR part 340 and the Plant Protection Act, cultivated only in limited test fields. The petitioner and other hybrid seed producers involved in production of corn for seed would not have access to MON 87427 corn, but continue to have access to existing inbreds that do not have herbicide resistance and do not have improved technology to make the male sterilization process more efficient. Growers would continue to rely on mechanical detasseling of the female inbreds used in hybridization, with subsequent needs for hand detasseling crews to complete the process. Recruitment of hand detasselers for temporary mid-summer employment would continue for seed producers and growers.

During hybrid maize seed production, Monsanto contracts for the services of approximately 10,000 agricultural workers for roughly four weeks (or approximately 0.1% of the agricultural work force annualized) to detassel maize in a combined manual and mechanized detasseling operation (Monsanto, 2010). The Monsanto detasseling work force is comprised of 70% teenagers and 30% migrant farm workers (Patrick Geneser, Monsanto Migrant Seasonal Labor Manager, personal communication, in Monsanto, 2010). Recent publications place detasseling costs for the seed producer anywhere from USD \$130 per acre using a combination of mechanical and manual detasseling, to USD \$200 per acre with manual detasseling (Koettler, 2007). Another estimate represents costs as between \$280 and \$350 per acre (APHIS, 2011).

Certain economic and environmental issues are important when hybrid corn seed producers are contracted by seed companies to grow corn. The first is that the inbred corn used to produce the seed are low yielding corn varieties, so that compensation must be guaranteed above that accruing from commercial corn production (Monsanto, 2010). The minimum compensation for

contracted growers is likely to be equivalent to the returns that would be expected from growing conventional corn, and based on the average yields in the area and the commodity corn price (Monsanto, 2010). For example, the local average yield might be 170 bushels with a commodity price of \$4.00 per acre making the minimum standard \$680 per acre (Monsanto, 2010). Thus, pay premiums and minimums are typical parts of the standard contract (Monsanto, 2010). Seed companies also require the contract growers to meet exacting planting, growing and harvesting standards, and schedules, and this imposes additional human impacts.

Adverse environmental consequences of growing hybrid seed corn can also be sustained by growers. Contract inclusions may require that the farmers accept the large ruts that are left by detasseling machines used in muddy conditions (Monsanto, 2010). These ruts destroy soil structure, increase tillage requirements, increase erosion, result in major yield reduction in the corn crop and possibly in the crop the following year as well, and result in damage to harvesting and tillage machinery (Daum, 1996; Kok et al., 1996; UK AgNews, 2009; Roegge, 2010; South Dakota AgConnection, 2010).

Most corn planted in the U.S. today is stacked GE varieties with both herbicide and insect resistance (USDA-ERS, 2011c). The widespread adoption of herbicide-resistant corn has been attributed to the cost savings for production, among other non-monetary benefits as described in Subsection 2.1.2, Agronomic Practices (Duke and Powles, 2009; NRC, 2010; Green and Owen, 2011). Of the herbicide-resistant corn varieties on the market today, growers may choose from glyphosate, glufosinate, glyphosate stacked with imidazolinone resistance traits (USDA-APHIS, 2012).

GE technology is patented and GE seeds are proprietary in the U.S. (NRC, 2010). The costs for GE seed are higher than that for conventional seed, as GE seed includes technology fees (NRC, 2010). The higher seed costs, however, may be offset by other premiums offered by companies, such as discounts for herbicides to use on the resistant crop, and reductions in crop insurance (NRC, 2010). As discussed in Subsection 2.6.1, Domestic Economic Environment, estimates of the economic benefits of herbicide-resistant crops to farmers are limited (NRC, 2010), and studies that have been conducted have had mixed results. Overall, these studies indicate in the early years of the adoption, GE cultivars exerted downward pressure on crop prices while the earnings of adopting farmers increased, and barriers to market access for GE crops reduced grower income (NRC, 2010).

With the increase in stacking of traits and multiple offerings for commercial growers comes a corresponding increase in combinations of seed traits which need to be produced. Each trait, deriving from different inbreds, requires a large amount of effort to track the development of pollen producing tassels on male pollen donors, correlate them with potentially interfering weather developments, and coordinate with crews of mechanical detassellers and needed crews of hand detassellers. Technology to simplify and make the process more economical have been developed since corn hybrids became the standard seed corn for industry (Bennett, nd).

Farmers have recently broadened weed management to treat herbicide-resistant weeds which may be impacting yields, leading to more variety in herbicide application and increased tillage, potentially incurring higher production costs. Weirich (2009), however, investigated the economic effects of alternative glyphosate weed resistance management programs, finding that although they increased cost substantially, higher yields offset these costs such that no statistically significant decrease in net returns occurred. Their study suggests growers may be

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able to effectively respond to glyphosate resistance using weed BMPs without substantially affecting their returns.

As indicated in Subsection 2.1.1, Acreage and Area of Corn Production, the trend over the last several years in the U.S. has been to stack herbicide resistance with primarily insect-resistant traits. Developers have recently sought approvals for corn varieties that have multiple herbicide and insect resistance, as well as other value added traits ((USDA-APHIS, 2012). Herbicide-resistant-only corn has consistently comprised approximately 22 to 23% of planted corn in the U.S. since 2007 (USDA-ERS, 2011c). Only two companies hold the licenses for the majority of herbicide-resistant corn in the U.S.: Monsanto patented glyphosate-resistant corn technology and offers varieties in their Roundup Ready® corn lines, and Bayer CropScience licenses glufosinate-resistant corn in their LibertyLink® corn lines. Glufosinate-resistant corn has been commercially available even longer than glyphosate-resistant corn, but has not been as successful, thought to be due to the higher cost of glufosinate and its more restrictive application timings to smaller plants to increase its efficacy (Owen, 1999a; Green and Owen, 2011).

Growers have perceived a lack of competition in the U.S. herbicide- and insect-resistant seed corn market based on substantial increases in the price of GE seed in the last several years (Neuman, 2010). This observation may correlate with the ongoing concentration of the U.S. seed market since passage of the Plant Variety Protection Act in the 1970s established proprietary rights for certain plant varieties (Fernandez-Cornejo, 2004). In 2011, corn seed comprised approximately 25% of total per acre operating costs for farmers (USDA-ERS, 2012c). Industry has responded that the quality of seed offered has improved, and new GE traits have been added that lower costs associated with improved insect and weed control, among other production costs (Neuman, 2010). If the MON 87427 corn was not determined as nonregulated, growers would have one less technology that may provide a means to reduce costs of seed production.

Preferred Alternative: Domestic Economic Environment

Availability of MON 87427 corn could potentially impact agronomic inputs and associated on-farm costs as well as the U.S. domestic corn market. Under the Preferred Alternative, MON 87427 corn would be extended nonregulated status. One expected consequence of the MON 87427 trait is that the complexities of detasseling inbreds for hybrid seed corn would be simplified. The step of detasseling would be eliminated by timed application of glyphosate to sterilize male tissues and prevent pollen shed and self-pollination of female inbreds. The specified timing of glyphosate application would be broader than that required for mechanical and hand detasseling operations and the replacement of technology involved would be much more limited. Thus, the need for a large number of temporary workers who need annual recruiting, training, organizing, retaining and compensating would no longer be a critical necessity for the hybrid seed producer. Another indirect impact is that the temporary workers who have previously been hired for this agricultural task would in large part no longer be needed.

The transition by seed producers from mechanical and hand detasseling to fully using the Monsanto Roundup Hybridization System may occur over an extended period. When producing an elite inbred line from a non-elite line, four generations of backcrossing and up to three generations of selfing would be needed to insure homogeneity and purity of the inbred (Groth, 2013). Then a cross is made to produce the hybrid seed, for a total of eight generations. In

tropical locations up to three generations can be produced annually, which would be two and one half to four years, and additional years if produced at temperate locations. The timeframe of any seasonal job losses would likely be a gradual one as the developers adapt their inbred line to the new technology. When introduction of MON 87427 is finally complete, Monsanto estimates that its detasseling work force of 10,000 will decline to approximately 500 to 1,000 seasonal workers for four weeks (representing a decline from 0.1% to approximately 0.01% of the agricultural work force annualized), which is a small percentage of the total agricultural workers in the U.S. (USBLS, 2010). Given the large number of agricultural workers, relative stability of the forecasts for these, the number of jobs (800,000) are plentiful for those who wish to find employment in this sector, particularly for crop, greenhouse and nursery farm workers. Many of those jobs are seasonal, because of the relatively large numbers of workers who leave these jobs for other occupations (USBLS, 2010).

The practices for the production of hybrid maize seed with MON 87427 are essentially unchanged with regard to current practices for hybrid maize seed production, with the exception of the reduction in the use of mechanical detasseling and the use of glyphosate sprays during the corn vegetative stages ranging from V8-V13 needed to produce the male sterile phenotype in inbred female plants. As a result, production of seed corn with MON 87427 will reduce the number of seasonal workers recruited by seed producers to an unknown extent; this would include high school students and other classes of workers. It is reasonable to assume that such losses would have a potential negative impact until another source of income might be secured to replace these temporary jobs but the impact is not likely to be a significant one, and the decline of these temporary seasonal jobs would be gradual as the producer began to incorporate the MON 87427 trait into greater numbers of inbreds.

4.7.2 Trade Economic Environment

No Action Alternative: Trade Economic Environment

Under the No Action Alternative, MON 87427 corn would continue to be a regulated article. Farmers, processors, and consumers in the U.S. would not have access to MON 87427 corn, but do have access to existing nonregulated herbicide-resistant 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 2011/2012 marketing year (August to September), the U.S. exported approximately 37% of the world's corn while Japan, Mexico, and South Korea were the major importers (USDA-FAS, 2008). In 2011, corn exports were worth approximately \$13.7 billion (USDA-ERS, 2012d). 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-ERS, 2011g); (USDA-OCE, 2011a). 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% (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, 2008), countries with increasing GE herbicide- and insect-resistant corn production acreage (Brookes and Barfoot, 2010).

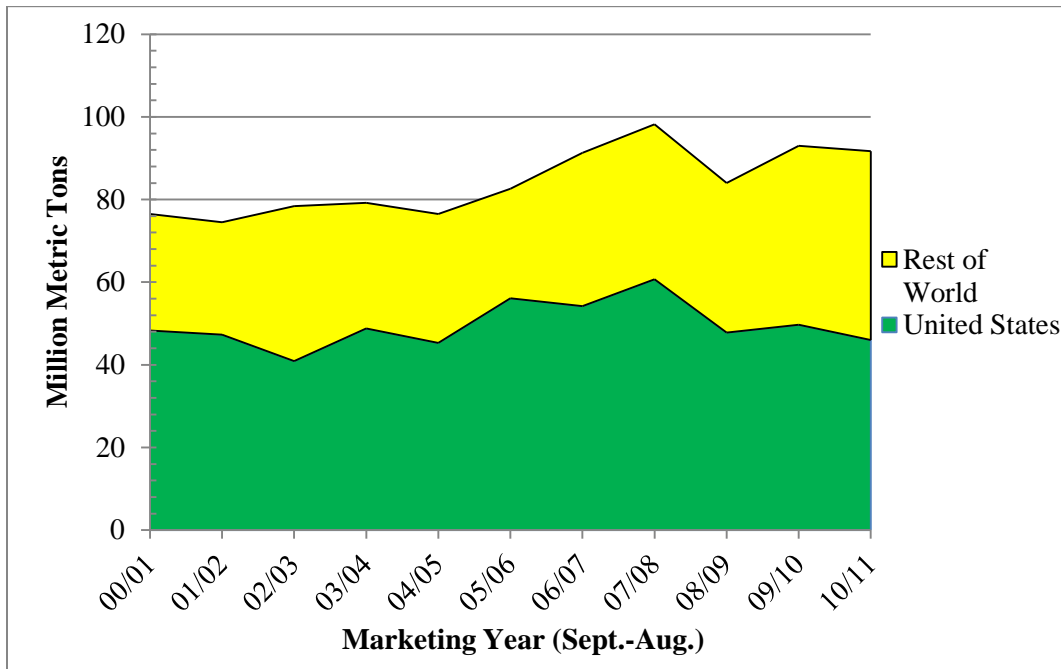


Figure 14. US and world corn exports for marketing years 2000/2001 to 2010/2011.

Source: (USDA-FAS, 2004; USDA-FAS, 2005; USDA-FAS, 2006; USDA-FAS, 2007; USDA-FAS, 2008a; USDA-FAS, 2009; USDA-FAS, 2010a; USDA-FAS, 2011a)

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 13). Note that the US percentage of corn exports in relation to overall world exports declined at the end of the last decade.

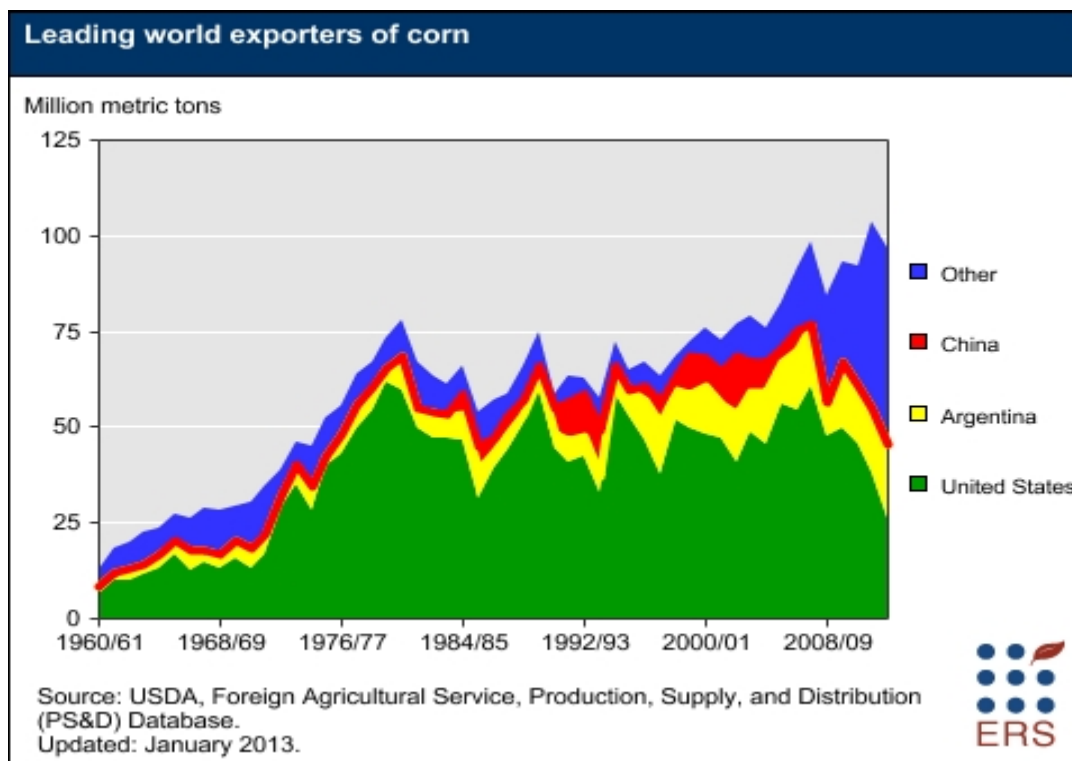


Figure 15. US and major exporters of corn for marketing years 1960/1961-2011/2012.

Source: (Capehart, 2013).

Note the increase in exports of corn in countries other than the top three, and the decline in US exports in most recent years.

Farmers in the U.S. and abroad have begun to utilize BMPs to control glyphosate or other herbicide-resistant weeds, but these BMPs have not necessarily increased costs (Weirich et al., 2011) such that the competitiveness of U.S. corn and trade economic environment would be affected. Increasing herbicide weed resistance is also occurring in other countries producing herbicide-resistant crops, including U.S. corn export competitors (for example, Argentina and Brazil (Heap, 2011) that would likely incur increases in production cost to mitigate the incidence of glyphosate-resistant weeds, similar to the U.S. experience.

As of publication of this EA, Monsanto is likely to submit applications for regulatory approval to export MON 87427 to Canada, the EU and to Japan for cultivation and use as food and feed. Canada is not a major corn export competitor of the U.S.; in the 2011/2012 market year, Canadian corn exports equalled only about 4.3% of the U.S. corn exports that year (USDA-FAS, 2013b).

Preferred Alternative: Trade Economic Environment

Under the Preferred Alternative, MON 87427 would be determined nonregulated and available to U.S. growers. Availability of MON 87427 could potentially impact the corn seed, feed, and food trade. MON 87427 is compositionally and agronomically similar to its comparators and other nonregulated glyphosate-resistant corn (Monsanto, 2010; USDA-APHIS, 2012). As such,

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it is not expected to affect the seed, feed, or food trade any differently than other nonregulated glyphosate-resistant corn varieties (see Subsections 4.7.1, Domestic Economic Environment). Although this variety is a glyphosate-resistant corn cultivar, MON 87427 it is not expected to replace any other glyphosate resistant corn, since the purpose of the developer is to deploy the trait within inbred corn varieties that are used in hybrid seed production. Approval of the request to determine nonregulated status to MON 87427 would, therefore, not likely increase the U.S. supply of corn that may affect trade. As discussed above, other countries are increasing their production of herbicide-resistant corn, including glyphosate-resistant cultivars, and are becoming significant export competitors to U.S. corn trade. Although this trait will have specific usefulness to the US hybrid seed production industry, and to international field sites where developers might increase seed (e.g., South America) it will also be present as an additional trait in commercial grain sold on the world market. As noted above, Monsanto plans to submit applications to Canada for import clearance of MON 87427(Monsanto, 2010); however, Canada is not a major U.S. corn export competitor.

As discussed in Subsection 4.4.2, Plant Communities, the cultivation of MON 87427 would not change the development of glyphosate-resistant weeds nor affect the BMPs to control glyphosate-resistant weeds any differently than other nonregulated glyphosate-resistant corn. These BMPs would not necessarily increase costs such that the competitiveness of U.S. corn and trade economic environment would be affected, as the increased costs may be offset by increased yields (Weirich et al., 2011).

As discussed under the No Action Alternative, global corn export markets respond to many factors, including consumer perception of GE crops and derived products. As a glyphosate-resistant corn cultivar, the availability of MON 87427 for hybrid seed production 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.

5 CUMULATIVE IMPACTS

A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. For example, the potential effects associated with 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 tolerance, and pest resistance, would be considered a cumulative impact.

5.1 Assumptions Used for Cumulative Impacts Analysis

Cumulative effects have been analyzed for each environmental issue assessed in Section 4, Environmental Consequences. In this EA, the cumulative effects 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 considered the potential for Maize Line MON 87427 to extend the range of corn production and affect the conversion of land to agricultural purposes. Monsanto’s studies demonstrate Maize Line MON 87427 is similar to conventional maize and other GE and non-GE corn in its growth habit, agronomic properties, disease susceptibility, and composition, with the exception of the tissue-selective glyphosate tolerance character (Monsanto, 2010; USDA-ERS, 2012a). As such, its agricultural requirements would be no different than those of other corn or no different from what growers provide in the specific areas in which corn is currently cultivated. As presented in Subsection 2.1.1, Acreage and Area of Corn Production, the majority of corn cultivated in the U.S. is herbicide-resistant, most of which is glyphosate-resistant (Duke and Powles, 2009; USDA-ERS, 2011a). Nonregulated Maize Line MON 87427 is glyphosate resistant for weed control purposes and would replace inbreds which do not have glyphosate resistance used for seed production (Monsanto, 2010). Although some of these inbreds and lines used for parental lines are resistant, but some of these not resistant, Monsanto has not been using glyphosate for weed control in seed production fields (Monsanto, 2010). If future seed production technology incorporating glyphosate resistance continues to have the same inputs as would continuous corn or as current rotation crops on lands now in production agriculture, APHIS does not expect any cultivation of new, natural lands would be undertaken by developers. Land use changes associated with approving a determination of nonregulated status to Maize Line MON 87427 are not expected to be any different than those associated with the cultivation of other

corn cultivars used in seed or commercial corn production. Accordingly, although the preferred alternative would allow for new plantings of Maize Line MON 87427 to occur anywhere in the U.S., APHIS will focus the analysis of cumulative impacts to the areas in the U.S. that currently support corn production for seed.

Potential reasonably foreseeable cumulative effects are analyzed under the assumption that seed producers who produce conventional corn have used in the past and would continue to use reasonable, commonly accepted BMPs for their chosen system and selected varieties during seed corn production. APHIS recognizes, however, that not all farmers will use such BMPs. Further, the cumulative impact analysis assumes that it is not necessary to change the use pattern of glyphosate for weed control on the glyphosate-resistant MON 87427 variety. Hence, APHIS will use current glyphosate labels for current glyphosate products as the basis for its potential past, present, and reasonably foreseeable impacts from the use of and exposure to glyphosate, and these are compared to the provisional label proposed by Monsanto, and which EPA has responsibility for issuing. APHIS assumes growers of MON 87427 will adhere to the EPA-registered uses and EPA-approved labels for all pesticides applied to this crop.

As part of the cumulative impacts analysis, APHIS accepts that that Maize Line MON 87427 will become as proposed, a common trait for most future inbreds used in seed corn production (Monsanto, 2010). Field study of MON 87427 corn indicates that the agronomic performance of it and conventional corn is not substantially different (Monsanto, 2010; USDA-APHIS, 2012), and when this trait is incorporated into inbreds, these seed production lines will be more similar to the conventional corn. In these inbreds, the MON 87427 trait will be combined with many other traits, whether non GE or nonregulated GE, such as pathogen, herbicide, insect, or drought resistance using traditional breeding techniques that along with MON 87427 will no longer be regulated by APHIS. Such varieties used in seed production could provide seed producers and developers such as Monsanto with the options of herbicide tolerance for control of weeds when inbreds for seed production have incorporated the trait.

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 grown for seed in the U.S. (see Subsections 4.2.1, Acreage and Area of Corn Production). The majority of corn grown in the U.S. is GE and herbicide resistant (USDA-ERS, 2011b). Long-term projections show planted corn maintaining between approximately 90 and 92 million acres a year through 2020, about the same as the 96 million acres planted to corn in 2012 (USDA-OCE, 2011a; USDA-NASS, 2012a; USDA-OCE, 2012). APHIS expects that MON 87427 for hybrid seed production would be grown where other similar corn cultivars are grown, and in many of the same contracted locations where seed production is currently engaged 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 87427 glyphosate-resistant corn used as a trait in inbred and breeding stocks stacked with various GE and non-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 2020 (USDA-OCE, 2011a).

5.3 Cumulative Impacts: Agronomic Practices

In the preceding analysis, the potential impacts from a determination of nonregulated status to MON 87427 corn were assessed. The agronomic characteristics evaluated for MON 87427 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. 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 87427 corn is agronomically and compositionally similar to other GE and non-GE corn varieties (Monsanto, 2010; USDA-APHIS, 2012). 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; 4.3, Physical Environment; 4.4, Biological Resources; 4.5, Public Health; and 4.6, Animal Feed). The method and timing of application for herbicides to be applied to MON 87427 corn would not change from those already approved for use on other nonregulated glyphosate-resistant corn cultivars, except for applications during development of male reproductive structures. For tassel control, an over-the top glyphosate application to MON 87427 plants targets reproductive parts when the plant development is between the V8 and V13 stage (Monsanto, 2013). If RR2 plants are to be sprayed with glyphosate during these development stages (V8 and later), the applicator must use drop nozzles to avoid application to the reproductive structures of the plant, especially when the plant height is 30-48" (Monsanto, 2009). These application methods that differ slightly will be unlikely to cause different impacts on the evaluated resource areas when considered together.

The use rate for the conventional glyphosate resistant (RR2) and the MON 87427 tissue selective line to be used for hybridization are the same. For post emergence weed control using glyphosate for both Roundup Ready 2 (RR2) corn crops and MON 87427 the total rate (Roundup Powermax), is 64 ounces, with at a 32 ounce maximum application rate for RR2 crops, and the

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same for MON 87427 (Monsanto, 2009; Monsanto, 2013 - Supplemental Labeling Personal communication). In addition, the use for tassel control in MON 87427 is 11-32 ounces, with a 64 ounce total post emergence application of glyphosate inclusive of all uses. There does not appear to be a difference in allowable timing of post emergent use of glyphosate under the EPA approved label. Because the volume of herbicide for both applications of glyphosate is similar, no differences in impacts of herbicide are expected between Monsanto 87427 and conventional RR2 corn and therefore no differences in potential cumulative impacts between MON 87427 and other types of glyphosate resistant corn. Other crops also contain a glyphosate resistant trait, with which MON 87427 lines might be rotated on leased seed corn production acres, including soybean and cotton. Labels for both of these crops allow a maximum of 5.3 quarts glyphosate per acre per season, as does that for MON 87427. However, for cotton, the label allows application of 4 quarts per acre for all in-crop application compared to 64 ounces (two quarts) with soybean, RR2 corn and MON 87427; nevertheless, total yearly application per acre is the same for all four crops. Again, APHIS determines that there will be no likely cumulative impact of differences from glyphosate application rate or methodology on MON 87427 crops when considering impacts from all other conventional RR2 crops, nor when considering possible impacts of other non-glyphosate resistant crops in rotation with corn.

Glyphosate is not presently used for weed control in hybrid seed corn production (Monsanto, 2010), because many of the inbreds employed do not incorporate the glyphosate resistant trait. The deployment of MON 87427 in the hybrid seed production system will potentially allow as many acres that are currently used for seed production overall to show some increase in the use of glyphosate. While these acres will not likely be increasing in number, the proprietary acres on which Monsanto grows seed corn and the larger number of acres on which Monsanto grows seed corn on leased acres (Groth, 2013), may show a trend towards increased use of glyphosate. On these leased acres, RR2 corn (or soybean) already will most likely have been one of the rotation crops. In these cases, the soil and water in the leased lands will already have had some continuing exposure to the glyphosate herbicide, and production of acreage with some additional glyphosate exposure at standard rates will not likely present significant new impacts, especially since the year to year variation in the predominating glyphosate-resistant corn is greater than the total of all the continuing seed corn production acres.

MON 87247 corn will be grown primarily for hybrid seed production, and therefore will be expected to be planted on a small percentage of acres compared to corn destined for grain and feed production. Corn planted for purposes of hybrid seed production has historically been restricted to small amounts of land, about 0.5 million acres annually (Jugenheimer, 1976), an area that is not expected to change with the introduction of MON 87427. Over the last 35 years, the volume of hybrid maize seed planted in the U.S. has changed very little, with 20.10 million bushels (MBu) planted in 1975 and 22.9 MBu planted in 2010 (USDA-ERS, 2011b). Grain yields have increased significantly over this same period. Thus, corn acreage with the trait will

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be 0.5/88.1 or 0.57% of total US corn acres in 2010 (USDA-NASS, 2013) quite small in relation to the surrounding corn and as noted earlier, small in relation to the fluctuation of acres in corn production on a yearly basis. In addition, glyphosate has one of the least environmental impacts of all herbicides (Duke and Powles, 2008) on the agricultural and surrounding acreages; given the already high use of glyphosate in soybean and cotton acres, does not represent a substantial new burden of herbicide into the environment.

The total amount of herbicides applied as tank mixes that could be applied to MON 87427 corn would be limited by the authorized EPA-registered uses and the total application amount allowed by that label. Glyphosate and other 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 glyphosate and other herbicides and pesticides are listed in 40 CFR §180.364 and include acceptable concentrations for corn grain and forage. In addition, the safety precautions and EPA-labeled instructions for the application of pesticides would not change under the Preferred Alternative, ensuring continued human health and worker safety (see Subsection 4.5, Public Health). Again, because any possible increase in such tank mixed additional herbicides on seed corn production would remain less than the total of such corn-applied herbicides through typical year to year variation of production corn acreage, no significant environmental impact is likely.

The herbicide glyphosate has been implicated by some in reductions of plant mineral uptake or nutrition (Duke and Powles, 2009) As noted by Duke et al. (Duke et al., 2012) the work showing such reduction has almost all been done in the greenhouse on glyphosate resistant soybean. Notable also is work that shows such changes in nutrition in response to glyphosate are most different at dosage rates beyond the allowable single application label rate (Zobiolo et al., 2012) Also, although some mineral nutrition depression with glyphosate can be detected, these appear to be “within the normal ranges for these crops” (Duke et al., 2012). Finally, when field trials are performed using label rates, content of 13 minerals was not lower following either one or two applications of glyphosate in either leaves or seed (Duke et al., 2012) . In the case of glyphosate resistant corn, neither crop effect nor glyphosate effects resulted in changes to the rhizosphere, denitrifying bacteria, or fungi (Hart et al., 2009). APHIS concludes that there is no consistent evidence for an effect of glyphosate on mineral nutrition of soybean, and not likely of corn, either.

MON 87427 corn stacked with other herbicide-resistant traits would, however, narrow the options for herbicidal management of volunteer corn. In crop rotations where glyphosate resistant soybean or some other broadleaf cultivar is rotated with corn, an approved grass herbicide could be used to control volunteer corn (Sandel et al, 2011). In continuous corn cropping systems with the same herbicide resistances, control becomes more complicated and in some cases may be accomplished through other means such as tillage (Louex et al, 2011; Sandel

et al, 2011). Loux et al. (2011) recommend careful rotation planning to eliminate this potential problem. MON 87427 stacked with insect-resistant traits would be no more likely to exhibit increased weediness characteristics than other currently available glyphosate- and insect-resistant stacked transgenic corn cultivars. Similarly, stacked MON 87427 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, approving a determination of nonregulated status to MON 87427 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 87427 corn is similar to other corn varieties currently grown (Monsanto, 2010; USDA-APHIS, 2012) and the aggregate of possible impacts are not likely to be cumulative ones. Consequently, no changes to current corn cropping practices such as tillage, crop rotation, or agricultural inputs associated with the adoption of MON 87427 are expected (see Subsection 4.2.2, Agronomic Practices).

5.4 Cumulative Impacts: Organic Corn Production

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 in 2012 was GE and herbicide resistant (USDA-NASS, 2012d). Since 1994, 27 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 Plant Protection Act (USDA-APHIS, 2012) U.S. organic corn production acreage grew 83% from 32,650 acres in 1995 to 194,637 acres in 2008, and remained at about 0.2% of total U.S. corn acreage from 2005 to 2008 (USDA-ERS, 2011d-a). Availability of another GE glyphosate-resistant corn variety, such as MON 87427 under the Preferred Alternative, is not expected to impact the organic production of corn any differently than other GE varieties, based on past growing experience or from presently available traits 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 87427 under the Preferred Alternative would have the same potential impacts to water, soil, air quality, and climate change as that of nonregulated glyphosate-resistant corn varieties presently 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 87427 is agronomically similar to other glyphosate-resistant corn and other GE and non-GE corn. 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. Because of its similarity to other nonregulated glyphosate-resistant corn and the fact that most cultivated corn in the U.S. is glyphosate resistant, adoption of MON 87427 for seed production would replace inbred and other breeding lines 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.

While the principle reason for adoption of MON 87427 would be for pollen control, EPA also allows weed control with glyphosate application that may total 64 ounces for all “ postemergence (in-crop) early-season weed control applications (provisional label, Roundup PowerMAX® Herbicide, EPA Reg. No. 524-549). If the petition for nonregulated status for MON 87427 is approved and it is crossed into inbreds qualified for hybrid production, depending on the extent of its adoption, it may contribute to sustaining or increasing conservation tillage (CT) in U.S. corn production. CT both directly and indirectly impacts water, soil, and air quality. Bennett (N.D.) notes that in some locations, seed producers were still using moldboard plows and conventional tillage; these could potentially be converted to minimal tillage when a glyphosate resistance trait were introduced that accompanies the trait for hybridization efficiency. If it is true that “the primary reason for tillage has been for weed management” (Duke and Powles, 2009), then the availability of MON 87427 may reduce the need for tillage in some locations, thus benefiting soil, water, and air quality. However, in some seed production situations, the need for conventional tillage is more likely to be that inbreds being less vigorous than hybrids yield better when conventional tillage is provided (Monsanto, 2010). However, if reduced tillage were to be a consequence of adoption of MON 87427, soil quality may be improved and soil erosion reduced. When considered with other glyphosate resistant corn and rotation crops, hybrid production with use of MON 87427 may possibly provide environmental benefits to the physical environment.

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. MON 87427 corn is both agronomically and compositionally similar to other nonregulated glyphosate-resistant corn; 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 glyphosate-resistant corn. Availability of MON 87427 corn would not more frequently lead to development of glyphosate-resistant weeds or diminish the trend to broaden weed management tactics to effect control over herbicide-resistant weeds, as it is expected to provide glyphosate resistance to inbreds for

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hybridization without expanding the acreage or area of corn production or changing the application rates of glyphosate (see Subsection 4.4.2, Plant Communities).

MON 87427 inbred corn would be incorporated with numerous other traits for production of stacked varieties of GE corn. Potential future stacking of MON 87427 corn might include development of inbreds using other currently available nonregulated corn varieties expressing resistance to other herbicides, or resistance to select insect pests by stacking with one of the biopesticidal Bt genes. APHIS regulations under 7 CFR part 340 do not provide for Agency oversight of stacked varieties combining GE varieties with previously approved nonregulated status, unless it can be positively shown that such stacked varieties are likely to pose a plant pest risk. Whether MON 87427 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. In addition, the adoption level of MON 87427 would depend on the extent producers value the traits offered by stacked versions of MON 87427 over other available stacked corn varieties.

Following a determination of nonregulated status, MON 87427 corn would likely be stacked with insect-resistant corn varieties that express the Bt endotoxin. Based on studies undertaken to assess the potential impacts of the Bt endotoxin to the monarch and other non-target butterflies, as well as factors such as the location of corn production and the characteristics of corn pollen, the EPA determined that the potential risk to non-target butterflies is low (EPA, 2002). Any insect-resistant trait that may be developed in the future and stacked along with the MON 87427 trait would be subject to APHIS, EPA, and FDA approval. The adoption of MON 87427 inbreds would be contingent on the extent breeders see value in conferring additional traits to a commercial corn cultivars or to generate inbreds that express herbicide- pathogen- and insect-resistant traits.

The purpose of this trait is to facilitate pollen flow from male inbreds to female inbreds; thus, gene flow is desired. With respect to gene flow not planned, to commercial or seed production fields, there are no differences in the potential for gene flow and weediness between the No Action and Preferred Action Alternatives. There is also no risk of gene movement between corn and its wild or weedy maize relatives (EPA, 2010a; USDA-APHIS, 2012). 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 (Doebley, 2004). As discussed in Subsection 2.3.3, Gene Flow and Weediness, MON 87427 corn is similar to other glyphosate-resistant corn varieties. The risk of gene flow and weediness of MON 87427 corn is no greater than that of other nonregulated glyphosate-resistant corn varieties.

As discussed in Section 4.2.2., Plant Communities, Maize Line HCEM485 would not likely impact the development or treatment of herbicide-resistant weeds or their associated costs in crop losses or methods to affect control. Weeds commonly encountered in commercial corn production will be similar to those arising in seed corn production and in commercial corn

production, since these may often be on common rotation acreage. Agronomic practices common in seed corn production, such as tillage and herbicide use, will be common ones found in commercial production. More use will be made of glyphosate when using MON 87427 because glyphosate resistance will be imparted in those inbreds used for hybridization. Consequently, conventional management used in the commercial production will also be employed in the inbred seed production fields. While the use of glyphosate when done without more comprehensive weed control plans can lead to development of new glyphosate resistant weeds, no additional weeds or new weed shifts will be expected in the MON 87427 fields than those already developing in the conventional corn and rotation crops grown on the same acreage under seed corn production. Just as growers have become more conscious of the need to proactively deal with weed development issues stemming from over-reliance on glyphosate in commercial corn fields (Beckie, 2011; Prince et al., 2012), the same growers who produce seed from glyphosate resistant inbreds will also likely respond similarly to the measures they took for their commercial production acres.

As discussed in 5.5 Cumulative Impacts: Physical Environment, it is possible that less use of tillage may be a consequence of adoption of MON 87427, and habitat value may be improved through increased water quality, availability of waste grain to animals, retention of cover in fields, and increased populations of invertebrates (Brady, 2007; Sharp, 2010). Introducing glyphosate resistance into the inbreds for seed production may promote or at least sustain conservation tillage rates, which subsequently would improve soil quality and reduce soil erosion, sustaining both crop and non-crop plants and greater plant diversity in fields (see Subsection 2.2.2, Soil Quality). When considered with other glyphosate resistant corn and rotation crops, hybrid production with use of MON 87427 may potentially provide benefits to the biological environment.

5.7 Cumulative Impacts: Public 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 87427 would have no toxic effect to human health or livestock (Monsanto, 2010). Monsanto has submitted data for a food safety and nutritional assessment of MON 87427 corn to FDA in December, 2010, (BNF No. 000126), and FDA completed their response letter on 13 April 2012. The decision is posted on the FDA website (<http://www.fda.gov/Food/Biotechnology/Submissions/ucm304083.htm>). A food safety evaluation of the same EPSPS protein as that used in the MON 87427 corn variety was completed by the FDA (BNF No. 51) on February 10, 1998, which found no safety concerns (FDA, 2012a; FDA, 2012b). In addition, the potential environmental impacts from the cultivation of glyphosate-resistant corn varieties have been thoroughly evaluated by APHIS (see

<http://www.aphis.usda.gov/publications/biotechnology/index.shtml>). As discussed in Subsection 4.4, Biological Resources, APHIS has determined there would be no significant risk to biological resources from the presence of the EPSPS protein that confers glyphosate resistance in MON 87427, which is identical to the protein found in nonregulated glyphosate-resistant corn cultivars in commerce today. No change in food and feed safety would occur between the Preferred and No Action alternatives.

Following a determination of nonregulated status, MON 87427 could be incorporated into inbreds and stacked with insect-resistant corn varieties that express the Bt endotoxin. In accordance with 40 CFR part 174, all the currently nonregulated insect-resistant corn varieties that contain the Bt endotoxin are exempt from the requirement of tolerance in feed commodities. In inbred corn varieties incorporating MON 87427 and stacked with insect-resistant (Bt) traits herbicide and insect resistance traits would likely be found as well with. Any insect-resistance trait that may be developed in the future and stacked along with MON 87427 for hybrid production would be subject to APHIS, EPA, and FDA approval. The adoption of stacked MON 87427 corn would be contingent on the extent seed developers see value in the traits expressed in comparison to other commercially available corn cultivars with similar herbicide- and insect-resistant traits.

Any additional GE traits for inbreds that may be incorporated with MON 87427 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 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. 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 GE traits into which MON 87427 would be incorporated for producing varieties of inbred corn have undergone, or are expected to undergo, this process to ensure their safety as food and feed products.

5.8 Cumulative Impacts: Domestic Economic Environment

As discussed above, based on its similarity to other nonregulated corn cultivars, MON 87427 corn would be deployed in inbreds used for hybridization without impacting corn acreage or production area that may affect domestic markets. Additionally, since MON 87427 corn is agronomically and compositionally similar to other commercially available corn, there would be few changes to agronomic inputs or practices following approval of the nonregulated status to MON 87427 other than using glyphosate to eliminate tassels during pollination. Although the hybrid system may reduce costs of seed production, it is not certain that the reductions would necessarily be passed to growers purchasing seed. Consequently, we do not expect that any production changes for seed producers may impact on-farm costs for corn seed purchasers whose

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seed derives from MON 87427, other purchasers of conventionally derived seed, or the domestic economic environment, including the organic corn market. As cited above, MON 87427 compared to other glyphosate resistant corn hybrids would not be likely to impact differently the development or management of herbicide-resistant weeds or their associated costs in crop losses or methods to effect control. Impacts of the Preferred Alternative on the domestic economic environment would therefore be no different than experienced under the No Action Alternative.

Corn inbreds for hybridization with single and multiple herbicide resistance or insect resistance are already widely used, since commercial seed with these traits comprised 73% of U.S. corn acreage in 2012 (see Subsection 2.1.1, Acreage and Area of Corn Production). While the adoption of herbicide-resistant-only corn has remained relatively level and the production of insect-resistant-only corn has decreased since 2007, the adoption of stacked varieties that confer resistance to herbicides and insects has steadily increased from 1% of planted corn acres in 2000 to 49% in 2011 (USDA-ERS, 2011b). MON 87427 corn would likely be used to produce new varieties stacked with insect-resistant and other traits and would have impacts similar to other such stacked corn cultivars already on the market. Agronomic practices, including inputs for production of MON 87427 inbreds stacked with insect resistance or other traits, would be no different than those needed to cultivate other corn with the same resistant properties; thus, changes to on-farm costs for corn seed producers or to the U.S. domestic corn market would be unlikely. Overall, it is not likely that any cumulative impact to the domestic economic environment would result from the addition of the MON 87427 trait to inbreds for making new stacked products or from the stacked products deriving from them, consisting of other readily-available GE traits, or non-GE traits.

5.9 Cumulative Impacts: Trade Economic Environment

Under the Preferred Alternative, it is possible MON 87427 corn would not be approved for import into other countries. Because the U.S. and other countries already have access to other glyphosate-resistant corn cultivars, and MON 87427 corn presents marketplace means to efficiently produce new hybrids, and its availability only to U.S. producers would not likely significantly impact the economic trade environment. Only 15% of domestically produced U.S. corn is dedicated to the export market (USDA-ERS, 2011g), and the extent of plantings of MON 87427 seed corn producers find value in this hybrid production system. If MON 87427 corn were not approved for import by other countries but were to 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 glyphosate-resistant corn cultivars MON 87427 corn would still be unlikely to affect the supply of U.S. corn available for export. If it were approved in the US, 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 stacked glyphosate and other traits have been brought to market. Global export markets respond to many factors and are unlikely to change with the commercial availability of this glyphosate-resistant corn cultivar such as MON 87427 corn alone, or if it had been used to produce stacked varieties with other currently available traits.

5.10 Cumulative Impacts: Domestic Socio Economic Analysis

MON 87427 will be used to facilitate the production of viable hybrid maize seed and offers an alternative to mechanical and manual detasseling methods, and to Cytoplasmic Male Sterile technology. Another trait to provide male sterility for corn hybridization is SPT by DuPont/Pioneer and was recognized by APHIS as nonregulated in 2011. The technology uses genetic means and color sorting to select the desired seed, and may be in use for hybrid production. This trait also removes the need to provide detasseling of female inbreds. Pioneer in 2011 had about 36% of the corn seed market, and Monsanto had 34%. As both of these technologies begin to be used by their developer, nearly 70% of the market will be eventually capable of avoiding manual detasseling. As discussed, for Monsanto, the transition to use of their inducible male sterility trait will require 2.5-4 years when using tropical seed production locations, and presumably, a similar number of years will be needed by Pioneer to convert their inbreds to ones carrying the genetic male sterility trait. As noted in Section 4.7.1, the impact of reduced employment for high school students, migrants and temporary workers who are employed in detasseling operations for about one month in summer is likely to be a gradual one because the process requires numerous crosses to obtain the inbreds with the traits. Historically, the amount of hand labor needed in detasseling has declined after the initiation of the hybrid seed production era, first with the introduction of mechanical detasseling in 1974 (cuts off first round of female plant tassels), then with wheel pullers (removes 40-85% of remaining female plant tassels) in the 1990s (Leidy, 2009) (Monsanto, 2010). With increasing contributions of technology, labor needs have declined and efficiencies of mechanical, genetic and chemical strategies have improved seed and agricultural production. It is reasonable to assume that such losses would have a potential negative impact until another source of income might be secured to replace these temporary detasseling jobs but the impact is not likely to be a significant one.

The cumulative impacts of MON 87427 along with the availability and development of Pioneer's SPT trait for hybrid production may also have impacts on overall efficiency of seed production that could have at least marginal impacts on acreage needed for seed production. As noted, removal of the entire tassel can result in the removal of too much leaf tissue, and reduce maize seed yields by as much as 10% (B. and O., 1997). The percentage of tassels removed per pass

will increase when a mechanical detasseling method is replaced and leaf damage will decrease. In addition, the tassels that have been removed in mechanical detasseling can become lodged in the leaf canopy and shed pollen, resulting in unwanted self-pollination. This complication is presently resolved by hand detasseling crews. Because plant damage will be reduced by the elimination of detasseling, additional productivity from plants may be possible, and a potential exists for reduction in allocated acreage for seed production.

6 Threatened and endangered species

THREATENED AND ENDANGERED SPECIES

Congress passed the Endangered Species Act (ESA) of 1973, as amended, to prevent extinctions facing many species of fish, wildlife and plants. The purpose of the 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 listed in accordance with the ESA, protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or critical habitat. To facilitate APHIS' ESA consultation process, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS's regulatory authority and effects analysis for petitions for nonregulated status, and developed a process for conducting an effects determination consistent with the Plant Protection

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Act of 2000 (Title IV of Public Law 106-224). APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

APHIS' regulatory authority over GE organisms under the Plant Protection Act 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). APHIS does not have authority to regulate the use of any herbicide, including glyphosate. After completing a PPRA, if APHIS determines that MON 87427 corn does not pose a plant pest risk, then MON 87427 corn would no longer be subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that the article is no longer regulated. As part of its EA analysis, APHIS is analyzing the potential impacts of MON 87427 corn on the environment including any potential effects to threatened and endangered species and critical habitat. As part of this process, APHIS thoroughly reviews the GE product information and data related to the organism (generally a plant species, but may also be other genetically engineered organisms). For each transgene/transgenic plant, APHIS considers the following information, data, and questions:

- A review of the biology and taxonomy of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant);
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered species (TES) of plants or a host of any TES; and

Any other information that may inform the potential for an organism to pose a plant pest risk.

Consistent with this review process, APHIS, has evaluated the potential effects that approval of a petition for nonregulated status for MON 87427 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. Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, APHIS obtained and reviewed the USFWS list of TES species (listed and proposed) for each state where corn hybrids are commercially produced from the USFWS Environmental Conservation Online System (USFWS, 2012). Prior to this review, APHIS considered the potential for MON 87427 corn to extend the range of corn production and also the potential to extend agricultural production into new natural areas. Monsanto's studies demonstrate that agronomic characteristics and cultivation practices required for MON 87427 are essentially indistinguishable from practices used to grow other corn varieties, including other

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herbicide-resistant varieties (Monsanto, 2010; USDA-APHIS, 2012). Although MON 87427 may be expected to replace other varieties of corn currently cultivated, APHIS does not expect the cultivation of MON 87427 to result in new corn acres to be planted in areas that are not already devoted to hybrid corn seed production. Accordingly, the issues discussed herein focus on the potential environmental consequences of the determination of nonregulated status of MON 87427 corn on TES species in the areas where hybrid corn seed are currently produced.

APHIS focused its TES review on the implications of exposure to the CP4 EPSPS protein in MON 87427, the interaction between TES and MON 87427 corn, including the potential for sexual compatibility and the ability to serve as a host for a TES, and the ability to affect plants and habitat by naturalizing in the environment. However, in furtherance of NEPA, APHIS also considered the potential impacts of the use of glyphosate, expected to be used on MON 87427 Corn, to non-target organisms and the natural environment.

Potential Effects of MON 87427 Corn on TES

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 87427 corn and potential to affect TES. Agronomic studies conducted by Monsanto tested the hypothesis that the weediness potential of MON 87427 corn is unchanged with respect to conventional corn used in hybrid seed production (Monsanto, 2010; USDA-APHIS, 2012). No differences were detected between MON 87427 corn and conventional corn in growth, reproduction, or interactions with pests and diseases, other than the intended effect of tissue-specific herbicide tolerance (USDA-APHIS, 2012). 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, 2012). 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 the determination of nonregulated status of MON 87427 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. Based on the agronomic field data and literature survey on corn weediness potential, MON 87427 corn is unlikely to affect threatened or endangered plants or their habitat as a troublesome or invasive weed, nor is it likely to affect critical habitat of any species (USDA-APHIS, 2012).

APHIS evaluated the potential of MON 87427 corn to cross with a listed species. As discussed above and in the analysis of Gene Movement and Weediness, APHIS has determined that there is no risk to unrelated plant species from the cultivation of MON 87427 corn. Corn is an annual, wind-pollinated crop which lacks sexually compatible wild relatives in the U.S., except for occasional botanical garden specimens (PPRA, APHIS, 2012). After reviewing the list of threatened and endangered plant species in the States where seed corn hybrids are grown, APHIS determined that MON 87427 corn would not be sexually compatible with any listed threatened or

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endangered plant species or plant proposed for listing as none of these listed plants are in the same genus nor are known to cross pollinate with species of the genus *Zea*. APHIS considered the possibility that MON 87427 corn could serve as a host plant for a threatened or endangered species. 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.

Threatened and Endangered Animal Species

Monsanto has presented information on the food and feed safety of MON 87427 corn, comparing the MON 87427 corn variety with conventional varieties currently grown. There are no toxins or allergens associated with this plant, and the CP4 EPSPS protein are present in many crop plants and have been analyzed in numerous EAs prepared for petitions for nonregulated status (Monsanto, 2010, Monsanto, 1996). Compositionally, MON 87427 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 (Need Citation) Results presented by Monsanto show that the incorporation of the cp4 epsps gene and the attendant expression of the CP4 EPSPS protein in MON 87427 corn does not result in any biologically-meaningful differences between MON 87427 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 87427 corn.

I suggest inserting a paragraph here that discussed the results of the FDA review. Here is an example from another EA:

The FDA has concluded its review of Monsanto's submittal of safety and nutritional data for MON-87427-7 corn (FDA, 2012). 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-87427-7 corn (Monsanto, 2010). 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, an acute oral toxicity feeding study in mice, and a feeding study in broiler chickens. MON-87427-7 corn protein was previously 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, 2010). At this time, the FDA considers the consultation on MON-87427-7 corn to be complete. A copy of the FDA consultation is provided in an Appendix.

Conclusion

After reviewing the possible effects of allowing the unregulated environmental release of MON 87427 corn, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. Therefore, a detailed species by species analysis of effects is not necessary. APHIS also considered the potential effect of approval of a petition for nonregulated status of MON 87427 corn on designated critical habitat

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or habitat proposed for designation, and could identify no differences from effects that would occur from the production of other corn varieties. This corn variety has been developed for use in hybrid seed production, and as such its use will be limited to areas where seed is produced. 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, or serves as a host species for, any listed species or species proposed for listing. Consumption of MON 87427 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 approval of a petition of nonregulated status for MON 87427 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.

Potential Impacts of Glyphosate Use on T&E species and Critical Habitat

To help clarify our ESA and NEPA obligations, APHIS met with USFWS officials on June 15, 2011 to discuss whether APHIS has any obligations under the ESA to analyze the impacts of herbicide use associated with all GE crops on T&E species. As a result of these joint discussions, the USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on herbicide use associated either with MON 87427 corn or other currently planted GE crops.

APHIS has no statutory authority to authorize or regulate the use of glyphosate, or any other herbicide, by corn growers. Under 7 CFR 340, APHIS only has the authority to regulate MON 87427 corn or any GE organism, if the agency believes it may pose a plant pest risk. APHIS has no regulatory jurisdiction over any other risks associated with GE organisms, including risks resulting from the use of herbicides or other pesticides on those organisms. Nevertheless, APHIS is aware that there may be potential environmental impacts resulting from the use of glyphosate on MON 87427 corn, including potential impacts on T&E species and critical habitat, based on assessments provided by the EPA and in peer reviewed scientific literature.

Under the Preferred Alternative, approval of a petition for non-regulated status for MON 87427 Corn does not change the weed management usage of glyphosate, nor the total allowable application of glyphosate, but adds an over-the-top application to corn at time when drop nozzle application would be recommended. As noted in this EA in the Section 2.2.1, the preponderance of corn grown in the US is herbicide resistant (USDA-NASS, 2012) Approval of non-regulated status for MON 87427 corn would only result in the addition of a glyphosate resistant variety to be used in hybrid seed production. Therefore, approval of a petition for non-regulated status for MON 87427 corn would mean a potential increase of 0.52% of corn acreage that would be glyphosate treated. Because the adoption by Monsanto of this trait for inbreds and potentially by other companies would be gradual, the slight increase in treated acreage would only occur over 3-8 years. Based on these considerations, APHIS has concluded that a determination of non-regulated status for MON 87427 Corn, would not result in any changes in impacts of glyphosate on T&E species or their designated critical habitats.

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General considerations relevant to the impact of glyphosate on T&E species have been reviewed by EPA, which has developed the Endangered Species Protection Program (ESPP). This program identifies pesticides that may cause adverse impacts to T&E species, and mitigation measures that address these impacts. To analyze the potential of registered pesticide uses that affect any particular species, the EPA assesses toxicity and exposure data developed for REDs (Reregistration Eligibility Decisions). A determination that there is a likelihood of a potential impact on a T&E species may result in limiting registered uses of a pesticide, other measures to mitigate any potential impact, and/or consultations with the USFWS and/or the NMFS.

Glyphosate is currently under reregistration review, which is scheduled to be complete in 2015 (US-EPA, 2009a). As part of the review, the EPA will conduct a risk assessment to support a complete endangered species determination (US-EPA, 2009b).

Assessments of the toxicity of glyphosate on animal species indicate low risk to animals, but high risk to plants. Glyphosate is moderately toxic to mammals, less than or slightly toxic to birds, and virtually non-toxic to fish, invertebrates, and honeybees (US-EPA, 1993). Impacts to T&E species and/or their habitats may result from non-target exposure from pesticide drift, runoff, volatilization, adsorption into soils, leaching, and cleaning and disposal of herbicide dispensing equipment. These impacts are mitigated by the requirements for the use of each product that appear on the EPA registration label. Since past ecological assessments indicated possible exposure risk to non-target terrestrial and aquatic plants outside treated fields, a spray drift buffer zone analysis is planned for the glyphosate reregistration review currently underway (US-EPA, 2009b). EPA will direct any mitigations necessary for users or growers to eliminate or reduce the potential of glyphosate to impact terrestrial or aquatic non-target plant species, including T&E species, by either changing the terms of the pesticide registration or establishing geographically specific pesticide use limitations. When geographically specific use limitations are necessary, they will be reflected in Endangered Species Protection Bulletins..

The surfactant polyethoxylated tallow amine (POEA) is included in some glyphosate product formulations. POEA is more toxic to aquatic organisms than glyphosate itself (US-EPA, 2009b). Therefore, EPA will identify and consider formulations containing POEA in its ecological and endangered species risk assessments. Under the new requirements of 40 CFR Part 158, studies to determine acute toxicity of POEA to estuarine and marine mollusks, invertebrates, and fish species will be accomplished for inclusion in the current registration review.

In the ecological risk assessment for the current reregistration process, the EPA has reviewed whether the approved uses of glyphosate represent a “no effect” or “may affect” impact on T&E species, their designated critical habitats (US-EPA, 2009b). The EPA has consulted with the USFWS and NMFS on the effects of glyphosate on certain T&E species and designated critical habitat (US-EPA, 2008a, b; US-EPA, 1993; US-EPA 2004a, b). Throughout the reregistration process, EPA will consult with USFWS and NMFS as necessary to meet their obligations under section 7 (a)(2) of the ESA to ensure that uses of glyphosate that are consistent with label regulations will not affect T&E species.

APHIS focused its TES review on the implications of exposure to the CP4 EPSPS protein in MON 87427, the interaction between TES and MON 87427 corn, including the potential for

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sexual compatibility and the ability to serve as a host for a TES; and potential impacts of the use of glyphosate to non-target organisms and the natural environment.

Based on the agronomic field data, literature survey on corn weediness potential, and that there are no TES sexually compatible with corn, APHIS has concluded that MON 87427 corn will have no effect on threatened or endangered plant species.

7 Consideration of executive orders, standards, and treaties relating to environmental impacts

7.1 Executive Orders with Domestic Implications

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

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

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

Available mammalian toxicity data associated with the CP4 EPSPS proteins establish the safety of MON 87427 corn and its products to humans, including minorities, low-income populations, and children who might be exposed to them through agricultural production and/or processing (61 CFR 150, 2007). No additional safety precautions would need to be taken.

Based on the information submitted by the applicant and reviewed by APHIS, MON 87427 corn is agronomically, phenotypically, and biochemically comparable to conventional corn except for the introduced and tissue-specific CP4 EPSPS protein. The information provided in the Monsanto petition indicates that the CP4 EPSPS protein is not expected to be allergenic, toxic, or pathogenic in mammals (Monsanto, 2010). Monsanto plans on initiating and completing the voluntary FDA consultation regarding MON 87427 corn before commercialization..

Human toxicity has also been evaluated by the EPA in its development of pesticide labels for glyphosate (EPA, 1993; EPA, 2009b). Pesticide labels include use precautions and restrictions intended to protect workers and their families from exposures. It is reasonable to assume that growers will adhere to these EPA herbicide use precautions and restrictions. As discussed in Subsection 4.5, Public Health, the potential use of glyphosate on MON 87427 corn would be no more than rates currently approved by the EPA and should not to have adverse impacts to human health when used in accordance with label instructions. It is expected that EPA would monitor

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the use of MON 87427 corn to determine impacts on agricultural practices, such as chemical use, as they have done previously for herbicide-resistant products.

Based on these factors, a determination of nonregulated status of MON 87427 corn is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

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

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

Corn is not listed in the U.S. as a noxious weed species by the Federal government, nor is it listed as an invasive species by major invasive plant data bases. 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, 2012) that would make it a successful invasive plant. Non-engineered corn, as well as other herbicide-resistant corn varieties, are widely grown in the U.S. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, MON 87427 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 (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Data submitted by the applicant has shown no difference in compositional and nutritional quality of MON 87427 compared with other GE corn or non-GE corn, apart from the presence of the CP4 EPSPS. MON 87427 corn not expected to be allergenic, toxic, or pathogenic in mammals. The CP4 EPSPS proteins has a history of safe consumption in the context of other food and feeds (61 CFR 150, 2007). Based on APHIS’ assessment of MON 87427, it is unlikely that a determination of nonregulated status of MON 87427 will have a negative effect on migratory bird populations.

The environmental effects associated with glyphosate have been analyzed by the EPA. Glyphosate is considered no more than slightly nontoxic to birds (EPA, 1993). Based on these factors, it is unlikely that the determination of nonregulated status of MON 87427 corn would have a negative effect on migratory bird populations.

7.2 International Implications

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

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 87427 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 87427 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, 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 PRA of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through 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.

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LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII, 2010).

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 Organization for Economic Cooperation and Development (OECD). NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures (RSPM) No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO, 2009).

APHIS also participates in the *North American Biotechnology Initiative (NABI)*, a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico, and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including Argentina, Brazil, Japan, China, and Korea.

7.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the potential changes in hybrid corn seed production associated with a determination of nonregulated status of MON 87427 corn (Section 4.2) and determined that the cultivation of MON 87427 corn would not lead to the increased production or acreage of corn in U.S. agriculture. The herbicide tolerance conferred by the genetic modification to MON 87427 corn would not result in any changes in water usage for cultivation. As discussed in Section 4.3.2 and 4.3.3, there are no expected negative impacts to water resources or air quality from potential use of glyphosate associated with MON 87427 corn production. Based on these analyses, APHIS concludes that a determination of nonregulated status of MON 87427 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 87427 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 87427 corn. The results of these field trials demonstrate that there are no differences in agronomic practices between MON 87427 and conventional corn. The common agricultural practices that would be carried out in the cultivation MON 87427 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.

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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 87427 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 87427 corn, including the use of EPA-registered pesticides.

With regard to pesticide use, a determination of nonregulated status of MON 87427 corn is likely to result in changes in the use of glyphosate on hybrid corn seed production fields. The potential changes in herbicide use are discussed in Section 4.2.2. Glyphosate is currently not generally used in hybrid corn seed production. APHIS assumes that the EPA label would provide for label use restrictions intended to mitigate potential impacts to the human environment, including potential impacts to unique geographic areas. As noted above, APHIS further assumes that the grower will closely adhere to EPA label use restrictions for all pesticides.

All pesticides distributed or sold in the U.S. are subject to registration by the EPA under authority of FIFRA. Glyphosate was first registered for use by the EPA in 1974, and has been assessed several times since then by the EPA and other Federal Agencies (EPA, 2009b). At present, glyphosate is currently undergoing registration review by the EPA; in 1993, EPA determined that all currently registered pesticide products containing glyphosate would not pose unreasonable risks or adverse effects to humans or the environment, thus permitting its eligibility for the EPA pesticide reregistration program (EPA, 2009b). A preliminary problem formulation has been conducted as part of the registration review of glyphosate by the EPA, identifying what is currently known and uncertainty regarding the ecological risk, environmental fate, endangered species, and drinking water assessment of glyphosate and its transformation products (EPA, 2009b). EPA produced an estimated timeline for the completion of the glyphosate registration review, with a final decision due in 2015 (EPA, 2009a). Submittals that are relevant to the EPA registration review of glyphosate can be submitted under the docket designation EPA-HQ-2009-0361 at the Regulations.gov website.

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 87427 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 NHPA of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

APHIS' proposed action, a determination of nonregulated status of MON 87427 corn is not expected to adversely impact cultural resources on tribal properties. Any farming activity that

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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 87427 corn.

APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the corn production regions. The cultivation of MON 87427 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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