Monsanto Company Petition (13-290-01p) for Determination of Nonregulated Status of Corn Rootworm-Protected and Glyphosate-Tolerant MON 87411 Maize

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ACRONYMS AND ABBREVIATIONS

AIA	Advanced Informed Agreement
AMS	Agricultural Market Service
ANZFS	Australia and New Zealand Food Standards Agency
AOSCA	American Organization of Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
BMP	Best Management Practices
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
Bt	*Bacillus thuringiensis*
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council of Environmental Quality
CFR	Code of Federal Regulations (U.S.)
CH_4	methane
CO	carbon monoxide
CO_2	carbon dioxide
COC	Crop Oil Concentrate
CRP	Conservation Reserve Program
Cry Protein	The *Bt* crystalline protein and active ingredient in PIPs derived from *Bt*
CWA	Clean Water Act
DDGs	Distillers Dry Grain solubles
DNA	deoxyribonucleic acid
EA	Environmental Assessment
EFSA	European Food Safety Agency
EIS	Environmental Impact Statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
EQIP	Environmental Quality Incentives Program
ESA	Endangered Species Act of 1973
ESPP	Endangered Species Protection Program
FFDCA	Federal Food, Drug, and Cosmetic Act

ACRONYMS AND ABBREVIATIONS

FFP	Food, Feed, or Processing
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FONSI	Finding of No Significant Impact
FQPA	Food Quality Protection Act
FWS	U.S. Fish and Wildlife Service
g/L	grams per liter
GE	Genetically Engineered
GHG	greenhouse gas
GMO	Genetically Modified Organism
GR	Glyphosate Resistant
HFCS	High Fructose Corn Syrup
HR	Herbicide Resistant
IPCC	Intergovernmental Panel on Climate Change
IPM	Integrated Pest Management
IR	Insect Resistant
IRM	Insect Resistance Management
ISHRW	International Survey of Herbicide Resistant Weeds
ISPM	International Standard for Phytosanitary Measures
IPPC	International Plant Protection Convention
lb	pound
LMO	Living modified organism
LOEC	Lowest Observable Effect Concentration
MOU	Memorandum of Understanding
MSO	methylated seed oil
N_2O	nitrous oxide
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
NMFS	National Marine Fisheries Service
NOEC	No Observable Effect Concentration
NRC	National Research Council

ACRONYMS AND ABBREVIATIONS

NRCS	National Resources Conservation Service
NOP	National Organic Program
NPS	Non-point source
OECD	Organization for Economic Cooperation and Development
PAT	phosphinothricin-acetyl-transferase, an enzyme
pat	Gene from *Streptomyces viridochromogenes* that encodes the PAT enzyme
PIP	Plant-Incorporated Protectant
ppm	Parts Per Million
PPRA	Plant Pest Risk Assessment
PRA	Pest Risk Analysis
RNA	ribonucleic acid
RNAase	ribonuclease
RSPM	Regional Standard for Phytosanitary Measures
SOx	Sulfur oxides
TES	Threatened or Endangered Species
TSCA	Toxic Substances Control Act
U.S.	United States
US-FDA	U.S. Food and Drug Administration
USDA	U.S. Department of Agriculture
USDA-APHIS	U.S. Department of Agriculture-Animal and Plant Health Inspection Service
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-ARMS	U.S. Agricultural Resource Management Survey
USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USC	U.S. Code
VEC	Value Enhanced Corn
WPS	Worker Protection Standard for agricultural pesticides

1 PURPOSE AND NEED

Monsanto Company, St. Louis, Missouri (Monsanto) submitted a petition (No. 13-290-01p) to the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) on October 17, 2013. This petition requested a determination of non-regulated status for a new variety of genetically engineered (GE) [1]corn: Monsanto 87411 Maize (henceforth referred to as MON 87411 Maize).

1.1 BACKGROUND

MON 87411 Maize is an insect-resistant (IR) and herbicide-resistant (HR) cultivar of corn currently regulated by USDA-APHIS under Title 7 of the Code of Federal Regulations part 340 (7 CFR part 340). These regulations include rules for preventing the introduction of GE organisms into the United State that are plant pests.

Interstate movement and field trials of MON 87411 Maize have been conducted since 2010 under permits issued by APHIS and notifications acknowledged by the Agency. These field trials were conducted in diverse growing regions within the United States that include Arkansas, California, Colorado, Georgia, Hawaii, Iowa, Illinois, Indiana, Kansas, Louisiana, Michigan, Minnesota, Missouri, Mississippi, Nebraska, North Carolina, Ohio, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, and Wisconsin. Details about and data resulting from these field trials are described in the MON 87411 Maize petition (Monsanto, 2013d), and analyzed for plant pest risk in a preliminary Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2014b).

The petition stated that APHIS should not regulate MON 87411 Maize because it does not present a plant pest risk. If a determination of nonregulated status is made by APHIS, nonregulated status would include MON 87411 Maize, all progeny derived from crosses between it and conventional (non-GE) maize, and those between MON 87411 Maize and other GE-maize varieties no longer regulated under 7 CFR part 340 or the authority of the pest provisions of the Plant Protection Act of 2000 (PPA).

1.2 PURPOSE OF PRODUCT

MON 87411 Maize contains three GE modes-of-actions (MOAs): two for insect pest protection; one for resistance to the herbicide, glyphosate. The insect protection mechanisms are designed to control corn rootworms (CRWs). CRWs are a major pest of maize in the United States. MON 87411 Maize also contains a transgene, *cp4 epsps,* for glyphosate resistance. It was isolated from a bacterium, *Agrobacterium* sp. (Monsanto, 2013c). Expression of this glyphosate resistance trait in MON 87411 Maize allows growers to make post-emergent applications of

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

herbicide products containing glyphosate as the active ingredient (a.i.) for broad-spectrum weed control.

MON 87411 Maize also contains two transgenes to control CRW. The *Cry3Bb1* gene protects against CRW larval feeding by promoting expression of an insecticidal crystalline (Cry) protein, Cry3Bb1. The *Cry3Bb1* gene is a modified form of a gene derived from the soil bacterium *Bacillus thuringiensis* subsp. *kumamotoensis*, also known as *Bt* (Monsanto, 2013c). Crops producing Cry proteins are also known as *Bt* crops. Another transgene in MON 87411 Maize promotes expression of an interference RNA (RNAi). The RNAi expressed in MON 87411 Maize mediates a gene silencing mechanism that stops expression of a gene (*Snf7)* in western corn rootworm (WCR: *Diabrotica virgifera virgifera*) (Monsanto, 2013c). When expression of the *Snf7* gene is suppressed by RNAi in WCR, production of the DvSnf7 protein is suppressed. This results in WCR death (Bolognesi et al., 2012). This additional mechanism was developed and incorporated into MON 87411 Maize because some CRW populations, especially WCR populations, have become resistant to the insecticidal Cry protein expressed by other *Bt* corn crop crops (Tabashnik et al., 2013; US-EPA, 2013; Gassmann et al., 2014).

MON 87411 Maize also contains the *epsps* gene coding sequence from an *Agrobacterium* sp. (strain CP4) that encodes the EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) protein that confers resistance to glyphosate (Monsanto, 2013d). The CP4 EPSPS protein in MON 87411 Maize is identical to the CP4 EPSPS protein present in several other commercially available crops that are no longer regulated following USDA reviews (e.g., glyphosate resistant [GR] varieties of soybean, maize, cotton, sugar beet, canola, and alfalfa).

Monsanto has indicated that MON 87411 Maize will be sold as a stacked trait, produced using traditional breeding methods and expressing other GE maize traits that are not regulated. MON 87411 Maize could be incorporated into other proprietary GE maize varieties (Monsanto, 2013d).

1.3 COORDINATED FRAMEWORK REVIEW FOR MON 87411 MAIZE

The Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 1986; 57 FR 22984), published in 1986 by the Office of Science and Technology Policy, describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products. It outlines guidance for Federal agencies to 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 (US-FDA, 1992a). The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA-APHIS, the U.S. Environmental

Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA). A summary of each of these roles follows.

1.3.1 USDA-APHIS

USDA-APHIS regulations at 7 CFR part 340 (7 U.S. Code [U.S.C.] 7701–7772) are applicable to the introduction into the United States (i.e., importation, interstate movement, and/or release into the environment) of those GE organisms defined as plant pests. Certain products derived from GE organisms that are plant pests are also regulated.

A GE organism is classified as a regulated article as a plant pest if the recipient organism (i.e., the organism modified by inserting a GE trait) is regulated as a plant pest under 7 CFR part 340. It is also a regulated article as a plant pest, when a GE trait that is inserted into a recipient organism is derived from a donor organism that is a plant pest defined in 7 CFR part 340. If vectors, or vector agents used in the process of engineering an organism are derived from an organism that belongs to one of the taxa listed in the regulation (7 CFR 340.2) as a plant pest, the recipient organism is also considered to be a plant pest. A GE organism is also regulated under 7 CFR part 340, when USDA-APHIS has other evidence that a GE organism may be a plant pest, or the Agency does not have sufficient information to determine if GE organism is unlikely to pose a plant pest risk.

Any individual may petition the Agency for a determination that a particular GE regulated article is unlikely to pose a plant pest risk, and therefore, should not be regulated under the plant pest provisions of the PPA or the regulations at 7 CFR part 340. Approval of petitions for non-regulated status of GE organisms is contingent upon the regulation at § 340.6(c)(4): the petitioner must provide sufficient relevant information related to plant pest risk that the Agency may use to determine that the regulated article is unlikely to present a plant pest risk.

A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA, when APHIS determines that it is unlikely to pose a plant pest risk.

1.3.2 Environmental Protection Agency

The U. S. Environmental Protection Agency (EPA) is responsible for regulating the sale, distribution, and use of pesticides, including those pesticides produced by GE organisms. The latter are referred to as plant-incorporated protectants (PIPs). The EPA is authorized to regulate PIPs under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). It also regulates certain biological control organisms under the authority of the Toxic Substances Control Act (TSCA) (15 U.S.C. 53 *et seq.*). Before planting a new GE crop containing a PIP in field trials, a grower must obtain a FIFRA Section 5 experimental use permit from the EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 (regular) registration with the EPA.

Under the authority of FIFRA (7 U.S.C. 136 *et seq.*), the EPA regulates pesticides by requiring a registration that describes specific allowable patterns of use prior to sale or distribution. The EPA evaluates: ingredients in pesticide formulations; the particular sites or crops (targets) for the intended uses of pesticides (use pattern); the allowable quantity in, frequency and timing of applications, and required storage and disposal practices. Prior to registration of a new use for a new or previously registered pesticide, the EPA must determine from testing results that the pesticide will not cause unreasonable adverse effects on humans, the environment, and non-target species if it is used in accordance with instructions on a label the agency issues in conjunction with registration approval. The EPA must approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide cannot be used legally unless it is used in a manner consistent with the EPA-approved directions on the label for the pesticide. The overall intent of the label is to provide clear directions that ensure effective product performance and minimal risks to human health and the environment.

The 1988 amendments to FIFRA authorized the EPA to implement periodic registration reviews of pesticides. These are intended to ensure that allowable uses of pesticides continue to be consistent with current scientific and regulatory standards of safety that ensure no unreasonable adverse effects. In addition, all pesticides with food uses must meet the safety standard of section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). EPA must be able to conclude with "reasonable certainty" that "no harm" will come to infants, children, or other sensitive individuals exposed to pesticides. All non-occupational pesticide exposures (i.e., from food, drinking water, and home and garden use) must be considered in determining allowable levels of pesticide residues in food. The EPA must also consider the cumulative effects of pesticides and other compounds with common mechanisms of toxicity.

The Pesticide Registration Improvement Act of 2003 directed EPA to complete reviews summarized in Reregistration Eligibility Decisions (REDs) for pesticides with food uses/tolerances.

The EPA also sets tolerances (maximum residue levels [MRLs]) for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance under the FFDCA. Before establishing an MRL for a pesticide, the EPA is required to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the Food Quality Protection Act of 1996. The FDA enforces the pesticide tolerances set by the EPA.

1.3.3 Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301, *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, in the *Federal Register* on May 29, 1992 (US-FDA, 1992b). 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 food derived from bioengineered products. This voluntary consultation process provides a way for developers to receive assistance from FDA to comply with their obligations under Federal food safety laws prior to marketing.

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" (US-FDA, 2006) for establishing voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties, including bioengineered plants, intended for use as food,. Early food safety evaluations are intended to ensure that potential food safety issues related to a new protein in a new plant variety are addressed early in the development process. 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.

MON 87411 Maize is subject to the 1992 FDA policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (US-FDA, 1992d). In compliance with this policy, Monsanto initiated a consultation with the FDA on the food and feed safety and nutritional assessment summary for MON 87411 Maize. A copy of the FDA letter asserting completion of this review process is provided in Appendix A of this draft Environmental Assessment (EA).

1.4 PURPOSE AND NEED FOR APHIS ACTION

Under the authority of the plant pest provisions of the PPA and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. Any party can petition APHIS to seek a determination of nonregulated status for a GE organism that is regulated under 7 CFR part 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 87411 Maize. When a petition for nonregulated status for a GE organism is submitted to APHIS, the Agency must determine if the GE organism poses a plant pest risk. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the Agency may use to compare the plant pest risk of the regulated article to that of the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA, when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS must respond to the October 2013 petition from Monsanto requesting a determination of the regulated status of MON 87411 Maize. APHIS has prepared this draft EA to consider the potential environmental impacts of an Agency determination that MON 87411 Maize is not regulated, consistent with the Council of Environmental Quality's (CEQ) National Environmental Policy Act (NEPA) regulations and the USDA and APHIS NEPA-implementing regulations and procedures (40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372). This draft EA has been prepared to specifically evaluate impacts on the quality of the human environment[2] that may result from a determination that MON 87411 Maize is not regulated under 7 CFR part 340.

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

1.5 PUBLIC INVOLVEMENT

It is routine APHIS policy to seek public comments on petitions, preliminary PPRAs and draft EAs related to petitions seeking a determination of nonregulated status for regulated GE organisms. In conjunction with these documents, APHIS publishes two separate notices in the *Federal Register.* The first one announces the availability of the petition for public review and comment. The second notice announces the availability of the decisionmaking documents (i.e., the preliminary PPRA and the draft EA) for public review and comment. Details about these two opportunities for public involvement follow.

1.5.1 First Opportunity for Public Involvement

Once APHIS determines that a petition is complete, it is made available for public comments. This assists the Agency in identifying issues that should be considered as it develops its preliminary PPRA and draft EA, if it makes a preliminary determination that the organism that is the subject of the petition is not a plant pest. APHIS initiates this process by publishing a notice in the *Federal Register* to inform the public that the Agency will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice.

1.5.2 Second Opportunity for Public Involvement

If the preliminary PPRA prepared by APHIS indicates that the GE organism that is the subject of the petition is not a plant pest, and the draft EA does not identify significant environmental impacts if the organism is no longer regulated, the preliminary PPRA and the draft EA are made available for public review during a second comment period that is announced in a *Federal Register* notice. The Agency follows one of two approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status represents a GE organism that has substantive new issues (e.g., novel biological mechanisms) that have not been evaluated previously.

Approach 1: GE Organisms That Do Not Raise Substantive New Issues

This approach for public participation is used when APHIS decides, based on its review of the petition and its 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 draft EA, preliminary finding of no significant impact (FONSI), and preliminary PPRA, APHIS publishes a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the preliminary PPRA, draft EA, and preliminary FONSI for a 30-day public review period.

If APHIS does not receive substantive information that warrants altering the Agency’s analysis, preliminary regulatory determination or FONSI, The Agency’s preliminary regulatory determination becomes final and effective upon public notification through an announcement on the APHIS website. No further *Federal Register* notices are published to announce the Agency's final regulatory determination.

Approach 2: 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. Examples include: petitions involving a type of recipient organism that has not previously been determined by APHIS to have nonregulated status; gene modifications that involve substantive biological, cultural, or ecological issues not previously analyzed by APHIS. Substantive issues are identified by APHIS based on the Agency's review of the petition and its 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 preliminary PPRA during a 30-day comment that is announced in a *Federal Register* notice. After the close of the comment period, APHIS reviews and evaluates comments and other relevant information it receives. It then revises the preliminary PPRA as necessary, and prepares a final EA if no significant impacts from the Agency's proposed regulatory decision were identified during this second review process. Following preparation of these documents, APHIS approves or denies the petition, announcing in the *Federal Register* its regulatory determination (i.e., the regulatory status of the GE organism), the availability of the Agency's final EA, final PPRA, and NEPA decision document (either a FONSI or NOI to prepare an EIS).

Enhancements to public input are described in more detail in the *Federal Register* notice[3] published on March 6, 2012.

1.5.3 Public Involvement for Petition AHPIS Petition No. 13-290-01p

APHIS announced the availability of the petition (13-290-01; MON 87411 Maize) in a *Federal Register* notice (79 FR 13035-6)[4] on March 7, 2014. The 60-day public comment period closed on May 7, 2014. APHIS received 423 comments during the period the petition was available for public review. Comments are available for public review in the docket[5] file.

The majority of public comments APHIS received expressed a general dislike of the use of GE organisms. Most of the comments that identified specific issues related to MON 87411 Maize or GE crops in general could be categorized as expressing one or more of the following concerns:

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

[4] This notice can be accessed at: http://www.gpo.gov/fdsys/pkg/FR-2014-03-07/pdf/2014-04968.pdf

[5] This docket can be accessed at: http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0007

- Gene flow from MON 87411 Maize to non-GE crops and/or wild/weedy/feral relatives might occur

- MON 87411 Maize might have negative economic impacts on the US corn market

- Cross-pollination between MON 87411 Maize and organic corn will negatively affect sales for growers of these crops

- MON 87411 Maize will have impacts on biodiversity.

- MON 87411 Maize corn will alter agronomic practices, and specifically will increase fertilizer needs

- MON 87411 Maize plants will cause adverse health effects on humans and animals

- Consumption of food derived from MON 87411 Maize and other GE organisms is unsafe

APHIS has evaluated these issues, cited conclusions from relevant scientific studies, and provided a discussion of these issues in this draft EA where appropriate.

APHIS determined from information received during the first comment period (for petition review), and the information acquired during the preparation of the preliminary PPRA and draft NEPA documents that review of these documents will follow the review process described in Approach 2. This decision was based primarily on the fact that a corn cultivar expressing an interference RNAi trait to confer resistance to insect pests has not been evaluated previously by APHIS.

1.6 ISSUES CONSIDERED

The issues addressed in this draft EA were developed by considering the public concerns expressed in comments received on the petition during the first opportunity for public involvement (60-day review period). Issues were also identified from public comments submitted for other EAs for GE organisms, concerns described in lawsuits, and those expressed by various stakeholders.

1.6.1 Summary of Issues

Issues identified for this draft EA were organized according to the following subject/resource areas:

Agricultural Production:

- Areas and Acreage of Maize Production
- Agronomic Practices
- Organic Maize Farming and Specialty Corn Production

Environmental Resources:

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

Human Health:

- Public Health
- Worker Health and Safety

Animal Health:

- Animal Feed
- Livestock Health

Socioeconomics:

- Domestic Economic Environment
- Trade Economic Environment

Cumulative Impacts

Threatened and Endangered Species

Other U.S. Regulatory Approvals and Compliance with Other Laws

1.6.2 Response to Comments

If substantive issues are identified in the second review process (Approach 2 for this draft EA) they will be addressed and included in the final EA. Specific responses to substantive comments submitted for this draft EA may instead be addressed in an attachment to the FONSI that includes responses to comments, should the Agency determine that there is/are no significant impact(s) that would require the preparation of an EIS, and there are no comments that would require revision of this draft EA.

2 AFFECTED ENVIRONMENT

This section describes the affected environment potentially impacted by a determination of nonregulated status of MON 87411 Maize. The affected environment includes the human environment, which is defined as the natural and physical environment and the relationship of people with that environment (40 CFR 1508.14). For this draft EA, those aspects of the human environment that are considered are agricultural production of maize, the physical environment, biological resources, human health, animal feed, and socioeconomics.

2.1 AGRICULTURAL PRODUCTION OF Maize

In terms of acreage, corn ranks first among crops cultivated in the U.S. (USDA-NASS, 2013a). Maize is an annual plant typically grown in zones of abundant rainfall and fertile soils (OECD, 2003). In the United States, moisture levels and the number of frost-free days required to reach maturity influence ideal conditions for maize to be grown within temperate regions (see, e.g., IPM, , 2004; 2007). However, maize is reported to have a strong ability to adapt to extreme and variable conditions of humidity, sunlight, altitude, and temperature (OECD, 2003).

Maize planting dates range from late March in Kansas to late May in North Dakota (IPM, 2007). Recommended planting conditions include a minimum temperature of 55°F at a depth of two inches (IPM, 2007). Most of the maize produced in the United States is hybrid maize adapted to regional environmental and soil conditions. General agronomic characteristics, such as optimal planting timeframe, disease and pest pressures, length of growing period, and water requirements, vary by region (Neild and Newman, 1990; Hoeft et al., 2000a; USDA-ERS, 2000; Koenning and Wiatrak, 2012). Maize planting dates range from late March in Kansas to late May in North Dakota (IPM, 2007).

Maize has food, feed, and industrial uses (USDA-ERS, 2014c). A variety of food and industrial products are derived from maize, including starches[6], sweeteners[7], corn oil, organic acids, and alcohols[8] (CRA, 2011). In 2012, approximately 45% of total U.S. maize production was dedicated to ethanol production for biofuels and 42% for animal feed (USDA-ERS, 2013a). Maize is the most widely cultivated feed grain in the United States, accounting for approximately 96% of feed grains produced (USDA-ERS, 2014c). In addition to being cultivated for ethanol and animal grain feed, approximately 6% of the total U.S. maize production is harvested for silage (USDA-NASS, 2012e).

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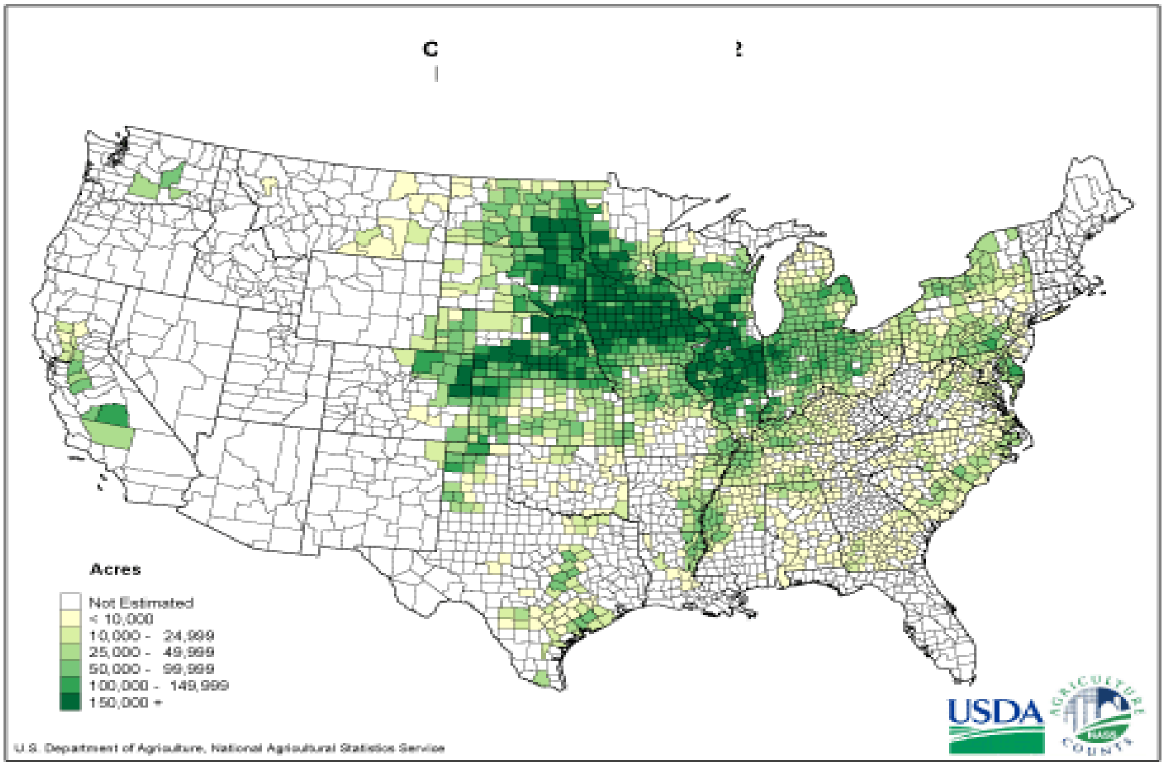
[6] Starches include unmodified and modified starches, dextrin, and maltodextrin.
[7] Sweeteners include glucose, dextrose, fructose, and high-fructose corn syrup.
[8] Alcohols include beverage, industrial and fuel ethanols.

2.1.1 Areas and Acreage of Corn Production

Maize is grown in all 48 states of the conterminous continental United States. The highest concentration of production (Figure 1) is located in the central United States.[9] (USDA-ERS, 2013a; USDA-NASS, 2013c). The two states with the most production are Iowa and Illinois. They account for slightly more than a third of the United States (USDA-ERS, 2014c).



Source: (USDA-NASS, 2013c).

Figure 1. 2012 Maize Acreage Distribution in the Conterminous United States.

Increased maize yields have resulted from improved seed varieties, fertilizers, pesticides, machinery, and production methods (e.g., conservation tillage, irrigation, crop rotation, and pest management practices) (USDA-ERS, 2014c).

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[9] The USDA Heartland region includes Illinois, Iowa, Indiana, eastern portions of South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri.

During the past two decades, corn acreage has also increased. In the period, 2006-2012, acreage of corn planted annually in the United States. increased (Figure 2) because market prices favored the planting of maize over alternative crops In addition to the demand for feed grain, strong demand for ethanol production resulted in higher maize prices, which corresponded to an incentive to growers to increase maize acreage (USDA-ERS, 2013a). The increase in acreage involved all varieties of maize and occurred throughout the corn growing areas (USDA-ERS, 2010). In many cases, farmers increased maize acreage by adjusting crop rotations between maize and soybeans, which caused soybean plantings to decrease. Other sources of land for increased maize plantings included cropland used as pasture, reduced fallow, acreage returning to production from expiring Conservation Reserve Program contracts, and shifts from other crops, such as cotton (USDA-ERS, 2014c). Figure 2 (USDA-NASS, 2014b) provides more details about U.S. maize planting and harvesting data during the period, 1993-2014[10] .

Source: (USDA-NASS, 2014b)

Figure 2. U.S. Planted and Harvested Maize Acreage between 1993-2014.

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[10] Harvested acreage for 2014 is projected.

Large-scale field testing of GE crops began in the 1980s. Commercially introduced in the United States in 1996, major GE crops were rapidly adopted. These GE crops have featured enhanced input traits, such as herbicide resistance, resistance to insects, resistance to environmental stress (e.g., drought), and value-added output traits, such as nutrient-enhanced seeds for feed. Three crops (maize, cotton, and soybeans) account for most of the U.S. GE crop acreage. Most are either HR or IR varieties.

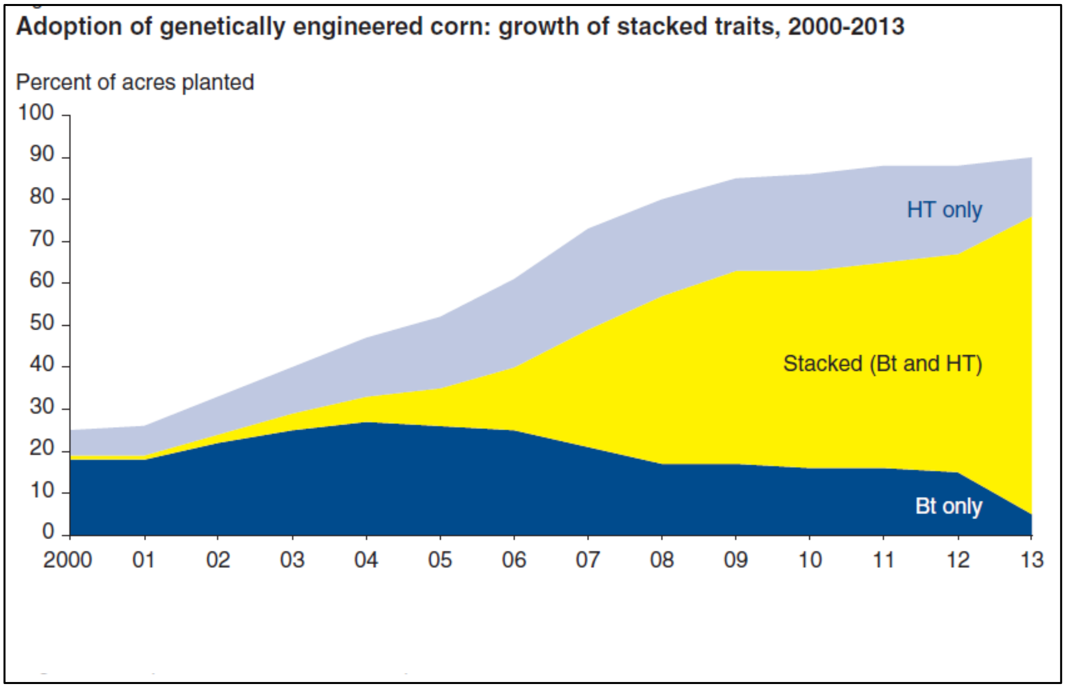
In 2000, 25% of U.S. maize production was from GE varieties. IR (18%) and HR (6%) accounted for most of this; only 1% contained both traits (USDA-ERS, 2013b). In 2002, stacked hybrids were introduced, and this led to a further increase in acreage of GE maize (Fernandez-Cornejo et al., 2014b). By 2009, GE maize acreage exceeded 70% of the total in all major maize-growing states except Ohio (67%) (Fernandez-Cornejo et al., 2014b). By 2013, 90% of the 87.6-million-acre U.S. crop was produced from GE maize. Stacked varieties with both IR and HR traits accounted for 70% of this crop. Only 14% contained just the HR trait, and 5% was IR (USDA-ERS, 2013b). Table 1 includes more details about the percentage of acres planted with GE IR, HR and stacked maize varieties for selected states in 2013. Crop varieties with three or four traits are now common. Figure 3 shows that the adoption of GE maize with stacked traits has been increasing and now accounts for more than half of GE maize seed currently purchased.

Table 1. Adoption of GE Maize Varieties in the United States in 2013.

State	Corn acreage planted (1,000 acres)	Insect-resistant (*Bt*) only (%)	Herbicide-resistant only (%)	Stacked gene varieties (%)*	All GE varieties (%)	Total acreage planted to GE varieties (1,000 acres)
Illinois	12,000	4	7	78	89	10,680
Indiana	6,000	2	10	73	85	5,100
Iowa	13,600	5	14	72	91	12,376
Kansas	4,300	7	15	69	91	3,913
Michigan	2,600	4	15	71	90	2,340
Minnesota	8,600	3	10	78	91	7,826
Missouri	3,350	5	16	71	92	3,082
Nebraska	9,950	6	13	74	93	9,254
North Dakota[2]	3,850	5	20	69	94	3,619
Ohio	3,900	6	16	63	85	3,315
South Dakota	6,200	2	12	82	96	5,952
Texas[2]	2,350	16	20	53	89	2,092
Wisconsin	4,100	3	18	63	84	3,444
Other States[1]	16,355	6	21	61	88	14,392
United States	97,155	5	14	71	90	87,440

Source: (USDA-ERS, 2013b).

1 Includes all other States in the corn estimating program
2 Estimates published individually beginning in 2005.
* Stacked maize varieties contain at least one trait for herbicide resistance.



Source: (Fernandez-Cornejo et al., 2014b).

Figure 3. GE Maize Traits Planted in the United States between 2000-2013.

IR (*Bt*) crops contain a gene from a widely prevalent soil bacterium, *Bacillus thuringiensis* (*Bt*), which produces a protein that is toxic to specific lepidopteran insects. *Bt* maize was commercially introduced to control European corn borers in 1996, CRWs in 2003, and corn earworm in 2010. *Bt* maize was planted on 19% of maize acres in 2000, 35% in 2005, and 76% in 2013 (see Figure 4 for distribution by states) (Fernandez-Cornejo et al., 2014b).

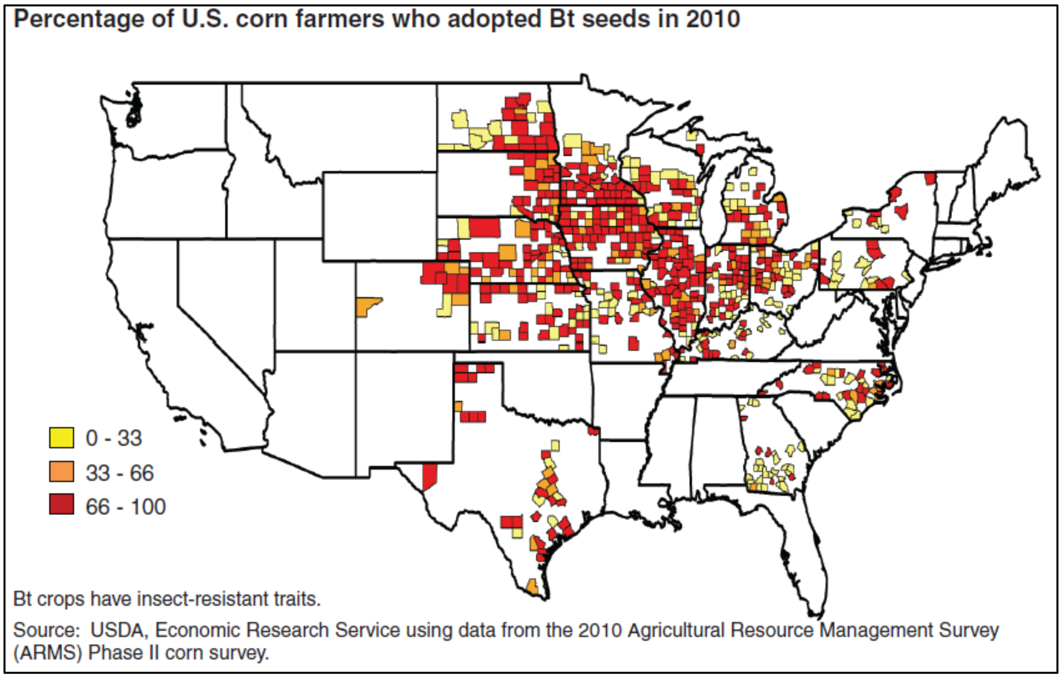
2.1.2 Agronomic Practices: Tillage, Crop Rotation, and Agronomic Inputs

Agronomic practices associated with maize production include several crop management systems. Conventional farming includes a broad scope of farming practices, including occasional or regular application synthetic fertilizers and pesticides. Conventional farming also includes the use of GE varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. Organic systems exclude certain production methods, such as synthetic agricultural inputs and GE crops. Although specific crop production practices vary according to region and end-use market, they commonly include tillage, crop rotation, agricultural inputs, and maize seed production. A summary of these follows (see, e.g., IPM, 2004; IPM, 2007).

Tillage

Prior to planting maize seed, tillage may be used to prepare a seedbed, address soil compaction, incorporate fertilizers and herbicides, manage water movement (drainage) in fields, control weeds, and reduce the incidence of insect pests and plant disease (Hoeft et al., 2000b;

Christensen, 2002; Fawcett and Towery, 2002; Tacker et al., 2006; Givens et al., 2009; NRC, 2010b).



Percentage of U.S. corn farmers who adopted Bt seeds in 2010

Bt crops have insect-resistant traits.

Source: USDA, Economic Research Service using data from the 2010 Agricultural Resource Management Survey (ARMS) Phase II corn survey.

Source: (Fernandez-Cornejo et al., 2014b).

Figure 4. **Percentage of U.S. Growers Planting GE *Bt*-Maize Varieties in 2010.**

Soil can be prepared for planting through a variety of tillage systems, with each system defined by the remaining plant residue on the field. Conventional tillage is associated with intensive plowing and less than 15% crop residue in the field. Reduced tillage is associated with 15-30% crop residue, and conservation tillage is associated with at least 30% crop residue remaining in the field (US-EPA, 2009). Conservation tillage includes no-till, reduced-till, mulch-till, eco-fallow, strip-till, ridge-till, and zero-till practices (IPM, 2007). Conservation tillage is valued as a means to enhance soil quality, preserve soil moisture, and reduce soil erosion (USDA-ERS, 1997; USDA-NRCS, 2005; Heatherly et al., 2009).

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

- Desired yields
- Soil type and moisture storage capacity
- Crop rotation pattern
- Prevalence of insect and weed pests
- Risk of soil compaction and erosion
- The need for crop residue or animal waste disposal

- Management and time constraints

In general, despite variable adoption rates before 2001, use of conservation tillage, especially no-till practices, has increased in U.S. maize production compared to conventional tillage (Horowitz et al., 2010).

Conservation tillage has been identified as a potential challenge for maize disease management. The surface residues have been identified as an inoculum source for certain plant pathogens[11] (Robertson et al., 2009). This is especially a problem for growers who rotate corn-to-corn with minimal tillage (Robertson et al., 2009). Corn-to-corn rotational production is reviewed in the following subsection. It refers to the cultivation of maize in consecutive years in the same field (Erickson and Lowenberg-DeBoer, 2005a). For each of these diseases, the disease agent overwinters in the cool and moist soil, and the pathogenic inoculum from the corn residue then infects the next year's crop (Robertson et al., 2009). Recommended disease control measures are already practiced and include cultivation of resistant hybrids, crop rotation, and more careful balancing of conservation tillage with residue management, with resistant hybrids the most economical method (Robertson et al., 2009).

Crop Rotation

Crop rotation is the successive planting of different crops on the same land in subsequent years. Crop rotation may be used to optimize soil nutrition and fertility, reduce pathogen loads, limit the potential for weeds to develop resistance to herbicides and control volunteers[12] (IPM, 2004; USDA-ERS, 2005; IPM, 2007). Diversifying crop rotation is also needed to spread weather and price risks, manage workloads and equipment resources, reduce fixed costs per unit of production, and access alternative markets (Dakota Lakes Research Farm). Financial circumstances and physical conditions dictate the different rotations chosen by a grower.

Designing the appropriate crop rotations for a field should systematically consider agronomic, environmental, economic, and engineering factors. Having less diversity than needed could eventually result in production and profitability problems. Diversifying rotations more than needed can reduce efficiency, by increasing the number of crops that must be managed, handled, and marketed. Outside influences (e.g., government subsidies, crop insurance) may discourage diversity (Dakota Lakes Research Farm).

Corn can be grown successfully in conservation tillage system if rotated with other crops, such as wheat or soybean, which may reduce some of the problems encountered with conservation tillage

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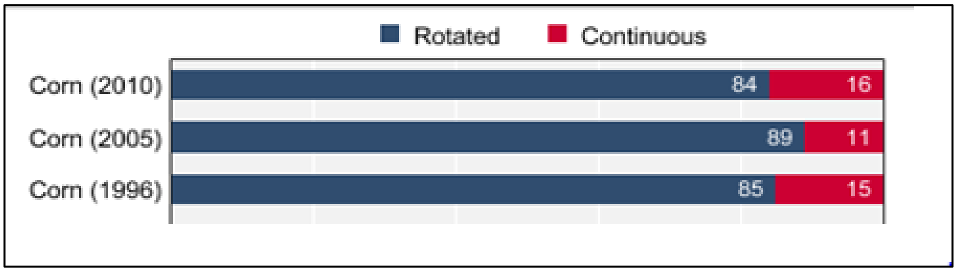
[11] Diseases identified as related to corn residues include anthracnose (caused by the fungus *Colletotrichium graminicola*), Eyespot (caused by the fungus *Kabatiella zea*), Goss's wilt (caused by the bacteria *Corynebactierum nebraskense*), Gray leaf spot (caused by the fungus *Cercospora zeae-maydis*), and Northern corn leaf blight (caused by the fungus *Helminthosporium turcicum*) Robertson et al. (2009).

[12] See Corn as a Weed or Volunteer in Section 2.

(IPM, 2007) (e.g., increased soil compaction, perennial weeds, plant diseases). Other crops used in rotation with corn vary regionally and may include cotton, oats, canola, sugar beets, peanut, rye, barley and forage (Peel, 1998; see e.g., IPM, 2004; Pioneer, 2012). Since 1991, 75% of corn planted acreage has been in some form of rotation in the United States (USDA-ERS, 2005). Corn acreage rotated to other crops still accounts for a majority of planted acreage in 2010 (see Figure 5).

More recently, the high global demand for corn-produced ethanol increased maize prices relative to soybean prices. The increased maize demand and commodity prices encouraged more corn-to-corn acreage, rather than corn-soybean rotations, which in turn contributed to overall increases in U.S. maize acreage (Doerge, 2007). During the peak demand for maize spurred by demand for maize for ethanol, many growers in the upper Midwest converted to a three year rotation schedule where consecutive years of maize were followed by soybean (Hart, 2006). The current decreased demand for maize and the increased demand for soybean may reduce the frequency of the three-year rotation of maize in favor of the two-year corn/soybean rotation.



Source: (USDA-ERS, 2013c)

Figure 5. Maize Acreage in Crop Rotation between 1996-2010.

A rotation of corn following soybeans will often yield 5-20% more than corn in continuous cultivation. Corn in rotation with a hay crop will yield as much as, or more than corn following soybeans (Penn-State-University, 1996).

The most important factors influencing lower yields from corn in continuous cultivation are nitrogen availability, corn residue accumulation, and weather (Heatherly, 2012). Growers have identified practices to compensate for the impacts of these, including management of crop residues with fall nitrogen and tillage, maintenance of adequate phosphorus, potassium and nitrogen levels in the soil, nitrogen, and high plant populations (Heatherly, 2012).

Consecutive plantings of corn usually require more management than corn-soybean rotations, because of an increased risk from disease and insect pests (IPM, 2004; Erickson and Lowenberg-DeBoer, 2005a; Sawyer, 2007; Stockton, 2007). One factor contributing to increased pest risk is the development of resistance to *Bt* by western CRW and other pests (Gassmann et al., 2011). In some locations, when corn always follows soybeans or wheat or is planted every two years, some CRW populations have adapted to these uniform rotational practices. In the Corn Belt for instance, the continuous corn-soybean rotation cycle has led to the development of two CRW variants (Beck and Beck, 2014).

Agronomic Inputs

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

Fertilizers

Fertilizers are generally defined as any material, organic or inorganic, natural or synthetic, that supply any of the chemical elements required for the plant growth (Utah State University, 2015). Because of the importance of nutrient availability to corn agronomic performance, fertilization is widely practiced (Ritchie et al., 2008). Soil and foliar macronutrient applications to corn include nitrogen, phosphorous (phosphate), potassium (potash), calcium, and sulfur. Micronutrient supplements include zinc, iron, and magnesium (Espinoza and Ross, 2006). A 2010 survey of fertilizer use in program states estimated the following application statistics for corn acreage: 97% received an average of 140 pounds/acre of nitrogen; 78% were treated with phosphate an average rate of 60 pounds/acre; 61% received potash at an average rate of 79 pounds/acre (USDA-NASS, 2011a). The survey also found that sulfur was applied less extensively at a rate of 13 pounds/acre to 15% of corn acres (USDA-NASS, 2011a).

Pesticides

Pest management is an integral part of any corn production system and is used to increase both yield and quality. Corn pests include microbes (e.g., nematodes, fungi, bacteria) and insects. Weeds also present a major production problem. Control strategies in corn production are often dependent on the variety cultivated. Fungicides, insecticides, and herbicides are the most commonly used pesticides on U.S. corn acreage (USDA-NASS, 2011c). Herbicides are required and applied much more frequently than fungicides and insecticides.

Fungicides—Foliar fungicide treatments are most commonly used on standing corn crops. Fungicide, usually combined with an insecticide, is also used to treat seeds. This practice is not universal, and varies by grower preferences and region disease distribution (Hoeft et al., 2000b; Ruhl, 2007). Some of the common fungal diseases on corn include anthracnose leaf blight (*C. graminicola*), common rust (*Puccinia sorghi*), eyespot (*K. zeae*), gray leaf spot (*C. zea-maydis*), northern corn leaf blight (*Exserohilum turcicum*), corn leaf spot (*Bipolaris zeicola*), and seed rot caused by fungi and bacteria (Hoeft et al., 2000b; Ruhl, 2007). Historically, foliar applications of fungicides were not common, and fungal disease management was focused on selection of disease-resistant hybrids, crop rotation to break the disease cycle, and tillage to encourage decomposition of crop residues that were reservoirs for the disease (see, e.g., Purdue, 2012). Continuous cultivation and conservation tillage practices have increased disease risk in some areas. Foliar fungicide applications have been reported to increase corn yields (Robertson et al., 2007; Robertson and Mueller, 2007).

Insecticides—Corn is subject to insect pests throughout its development, with several groups and types of insects capable of feeding on the seeds, roots, stalks, leaves, or ears (Hoeft et al., 2000b). In 2010, insecticide active ingredients were applied to 12% of acres planted to corn in 19 surveyed states (USDA-NASS, 2011c). Tefluthrin was the most commonly-applied insecticide on U.S. corn, with 242 thousand pounds used over 3% of corn acreage (USDA-NASS, 2012c). The next most-commonly used insecticides, each sprayed on approximately 2% of U.S. corn acreage, included bifenthrin (68 thousand pounds), cyfluthrin (15 thousand pounds), lambda-cyhalothrin (24 thousand pounds), and tebupirimphos (195 thousand pounds) (USDA-NASS, 2012c). Chlorpyrifos was the most abundant insecticide applied in terms of pounds of active ingredient, though it was only applied on 1% of U.S. corn acreage (USDA-NASS, 2012c). Bifenthrin, cyfluthin, lamda-cyhalothin and chlorpyrifos are recommended for CRW control (Bledsoe and Obermeyer, 2010).

According to (USDA-NASS, 2011a), chlorpyrifos was applied for CRWs, earworms, and European corn borer (1% of the acreage, with total applications of approximately 478,000 pounds). Tefluthrin was used for control of CRWs (3% of the acreage, with total applications of 242,000 pounds), and tebupirimphos treatments were made for CRW and seed corn maggot (2% of the acreage, with total applications of 195,000 pounds).

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

In 2013, 76% of the total U.S. corn acreage was planted in a stacked variety containing at least one *Bt* trait (USDA-NASS, 2014). The EPA reviews PIPs, such as the Cry proteins, pursuant to FIFRA, and publishes tolerances or exemptions from a tolerance pursuant to its authority under FFDCA. Since 1995, the EPA has registered over 39 crops expressing one or more proteins (Table 2) derived from *Bt* (US-EPA, 2011b). The EPA has published tolerance exemptions for the Cry proteins (US-EPA, 2007a)[13].

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[13] Under its FFDCA authority, the EPA will publish an exemption from the requirement for a tolerance when it has completed comprehensive review of the toxicity and exposure data and completed health and animal risk assessment studies see http://www.epa.gov/opp00001/factsheets/stprf.htm#some for an overview of the EPA tolerance exemption process An exemption from tolerance for the Cry proteins means that the EPA completed its review and found a reasonable certainty of no harm under the FFDCA, as amended by the FQPA.

Table 2. GE Plant-Incorporated Protectants (PIPs) Registered* by EPA.

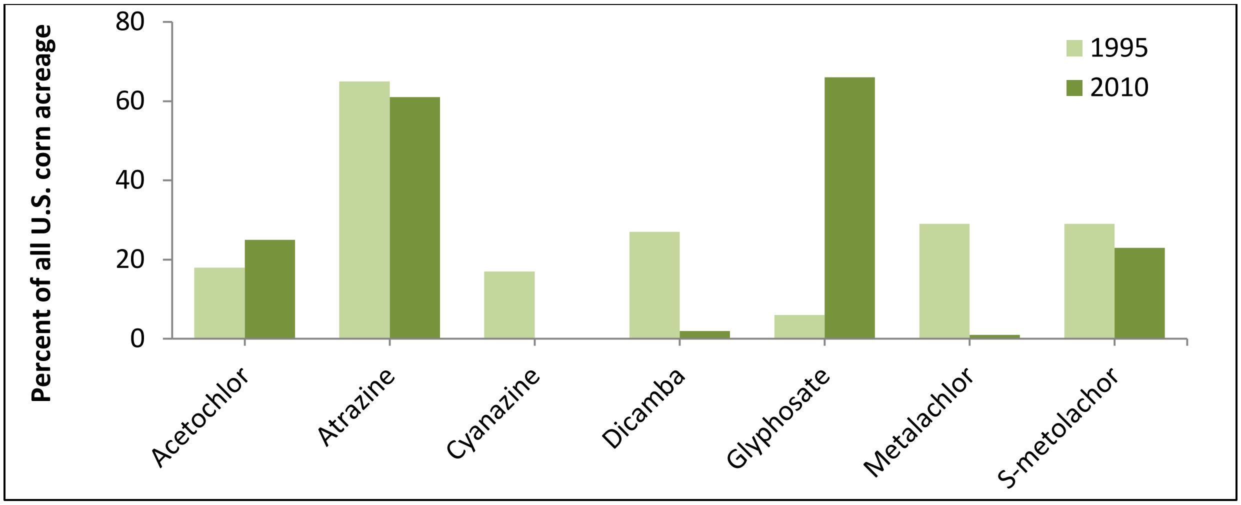
PIP Event	Crop	Registration Date
Cry3A	*Bt* Potato	May 1995
	Bt Corn	October 2006
Cry1Ab	*Bt* Corn	August 1995
	Bt Cotton	June 2008
Cry1Ac	*Bt* Cotton	October 1995
	Bt Soybean	September 2010
Cry 9C	*Bt* Corn	May 1998
Cry1F	*Bt* Corn	May 2001
	Bt Cotton	September 2004
Cry2Ab2	*Bt* Cotton	December 2002
Cry3Bb1[§]	*Bt* Corn	February 2003
Cry34Ab1	*Bt* Corn	August 2005
Cry35Ab1	*Bt* Corn	August 2005
Cry1A.105	*Bt* Corn	June 2008
Vip3Aa19	*Bt* Cotton	June 2008
Vip 3Aa20	*Bt* Corn	November 2008
Coat Protein Gene of Plum Pox Virus (CPG-PPV)	C5 HoneySweet Plum	May 2010

*Since 1995; multiple registrations of the same PIP event for the same crop are not shown. For the complete EPA registration list of PIPs go to: http://www.epa.gov/oppbppd1/biopesticides/pips/pip_list.htm

[§] PIP present in MON 87411 Maize.

Herbicides—Like IR varieties, the introduction of HR corn has substantially affected how corn is produced in the United States. HR corn allows growers to make post-emergent applications of certain herbicides. This provides growers with a simpler, more efficient and effective weed management strategy, compared to what must be used with conventional corn varieties.

In particular, GR corn varieties have had the most impact on improvement of weed management strategies. Although GR corn has not substantially affected the percentage of corn acreage managed with herbicides, the introduction of GR corn has resulted in replacing other herbicides registered for use on corn with glyphosate (Figure 6) (Brookes and Barfoot, 2012; Vencill et al., 2012).



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

Figure 6. Use Pattern, 1995-2010, for Some Herbicides Commonly Applied to U.S. Corn.

Nearly all (98%) of corn acreage is treated with herbicides (USDA-NASS, 2011a). A 2010 survey of corn growers showed the following three herbicides as the most commonly applied: glyphosate (66% of the acreage; ~57 million pounds); atrazine (61% of the acreage; ~51 million pounds applied); acetochlor (25% of the acreage; ~28 million pounds) (USDA-NASS, 2011b; 2011a). Growers have sometimes substituted glyphosate for other herbicides (e.g., metalochlor and fomesafen) that have EPA groundwater impact advisories on the label (Vencill et al., 2012).

In 2011, it was estimated that glyphosate was applied to approximately 80% of U.S. corn acreage (Monsanto, 2013d). However, increased selection pressure resulting from the wide-spread adoption of GR crops, and reductions in the use of other herbicides and weed management practices, has resulted in both weed population shifts and increasing GR among some weed populations (Owen, 2008b; Duke and Powles). However, the emergence of resistance is not confined exclusively to weeds associated with GR crops (Norsworthy et al., 2012b).

Weed resistance to herbicides is a concern in agricultural production and the widespread adoption of HR crops, especially GE-derived GR crops, has substantially shifted the approaches available to farmers to avoid yield losses from weeds (Gianessi, 2008; Duke and Powles, 2009).

To reduce development of resistant weeds, growers can continually practice weed management strategies by alternating different herbicides (Ross and Childs, 2011) with different MOAs (e.g., auxin growth regulators, amino acid inhibitors, chlorophyll pigment inhibitors, or lipid biosynthesis inhibitors). The practice tends to diminish the populations of GR weeds and reduce the likelihood of the development of new HR weed populations (Dill et al., 2008b; Duke and Powles, 2008; Owen, 2008b; Duke and Powles, 2009; Norsworthy et al., 2012b; Vencill et al., 2012; Monsanto, 2013d).

2.1.3 Organic Corn Farming and Specialty Corn Systems

In the United States, only crops produced using methods certified under USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) can be marketed and labeled as "organic" (Ronald and Fouche, 2006; USDA-AMS, 2010). The USDA maintains information on the domestic organic commodity market.

Organic Corn

Organic certification is a process-based program. The certification process specifies and audits the methods and procedures by which the product is produced (Ronald and Fouche, 2006). In accordance with NOP, an accredited organic certifying agent conducts an annual review of each certified organic system. An on-site inspection of field practices and administrative review of records is conducted. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards.

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

> To be sold or labeled as "100% 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 §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, require organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. There is no specific size of a buffer zone between organic crops and nonorganic crops (MOSES, 2009). Organic production operations also must develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the exclusion of prohibited methods. In NOP organic systems, the use of GE crops is excluded (USDA-AMS, 2010).

Common practices organic growers use to exclude GE products include planting only organic seed, staggering plantings, so flowering and pollination does not coincide with that of GE crops in neighboring fields. It also includes maintaining adequate buffers (distances) between organic and GE crops to eliminate or minimize the potential for cross-pollination (NCAT, 2003). Although the NOP 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 NOP 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. Evidence of the presence of products of methods excluded by the NOP Standards does not negate the status of an organic product. If a certified program has not used such methods, and has implemented reasonable measures detailed in the approved organic system plan to avoid contact with excluded methods and products, the status of the organic status is not compromised (Ronald and Fouche, 2006; USDA-AMS, 2010).

Although organic corn yields (i.e., bushels per acre) tend to be less than that for conventional or GE production, the profit per acre of organic corn is greater because of the 16% premium organic growers receive for their products (Kuepper, 2002; Coulter et al., 2010; Roth, 2011). Certified organic corn acreage is very small compared to conventional and GE corn acreage. The most recently available data show approximately 234,000 acres of certified organic seed corn planted in 2011, which represented approximately 0.25% of the 92 million acres of corn planted for grain in 2011 (USDA-NASS, 2012a).

Specialty Corn

Thomison and Geyer (2011) estimated that approximately 5% of the total U.S. corn acreage, or approximately 4 million acres, was devoted to specialty corn varieties. Specialty corn varieties have been developed and marketed as Value Enhanced Corn (VEC) (USDA-FAS, 2004). Varieties cultivated as specialty corn included high oil, white, waxy, blue corn, hard endosperm/food grade, high-amylose, high lysine, high oleic oil, low phytate, nutritionally enhanced, high extractable starch, high total fermentable (for ethanol), popcorn, pharmaceutical and industrial corns, and organic (Thomison and Geyer, 2011). The leading specialty corn states include Illinois, Iowa, Nebraska, and Indiana (Thomison and Geyer, 2011).

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

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

2.2 PHYSICAL ENVIRONMENT

Components of the physical environment affected by corn production in the United States include soil, water, air and climate.

2.2.1 Soil Quality

Soils are an essential component of the global ecosystem and important to the hydrosphere and atmosphere for its function. Soils have dynamic properties that can vary seasonally and their parameters, such as temperature, pH, soluble salts and organic matter, change over extended periods (McCauley et al., 2009).

Factors such as soil texture and organic matter levels have direct impact on nutrient availability, permeability, soil erosion and flooding capacity (McCauley et al., 2009). In 1993, the FAO included soil quality in the five criteria critical for sustainable land management (Smyth and Dumanski, 1993).

Soil quality on managed lands may be directly affected by the agricultural practices on that land (USDA-NRCS, 2006c). In particular, soil quality of agricultural land is directly affected by tillage strategies. Conservation tillage relies on methods that leave at least 30% of crop residue on the surface and result in less soil disruption than conventional tillage regimes (Peet, 2001). In conservation tillage programs, the new crop is planted into the plant residue or in narrow strips of tilled soil. In comparison, conventional tillage disrupts the entire seedbed by plowing to turn the soil surface over, and harrowing to reduce the size of soil clods.

Reducing tillage benefits soil quality in several ways, but there are associated management concerns. Under no-till practices, soil compaction may become a problem because tillage is useful for breaking up compacted areas (USDA-NRCS, 1996). Reducing tillage may also enhance conditions for development of economically significant pest populations that are managed more efficiently with conventional tillage (NRC, 2010a). Another consideration is soil type because not all soils, such as wet and heavy clay soils in northern latitudes, are suitable for no-till practices.

In general, there has been a corresponding overall improvement in the quality of U.S. agricultural soils, after the introduction of conservation tillage practices. For example, in addition to an increase in soil organic matter, total soil loss on highly erodible and non-highly erodible croplands decreased from 462 million tons per year to 281 million tons per year or by 39% from 1982 to 2003 (USDA-NRCS, 2006b). The reduction in soil erosion is also attributed to a decrease in the number of acres of highly erodible cropland being cultivated (USDA-NRCS, 2006b). This decrease in soil erosion carries a corresponding benefit in water resources.

Corn tillage strategies can directly and indirectly affect soil quality. Corn plant residues remaining in a field in a conservation tillage production system tend to impede cultivation equipment and cause cool, wet soils (Werblow, 2007). Cool, wet soils can delay germination and cause yield losses up to 10% (Neilsen, 2010). These concerns can each be addressed through a number of corn cultivation techniques, including: corn varieties developed to thrive in cool, wet soils; seed treatments for insect and disease control; selection of appropriate equipment to manage high-residue conditions; judicious use of appropriate herbicides to control weeds remaining in the conservation tillage fields (NCGA, 2007b; Werblow, 2007).

2.2.2 Water Resources

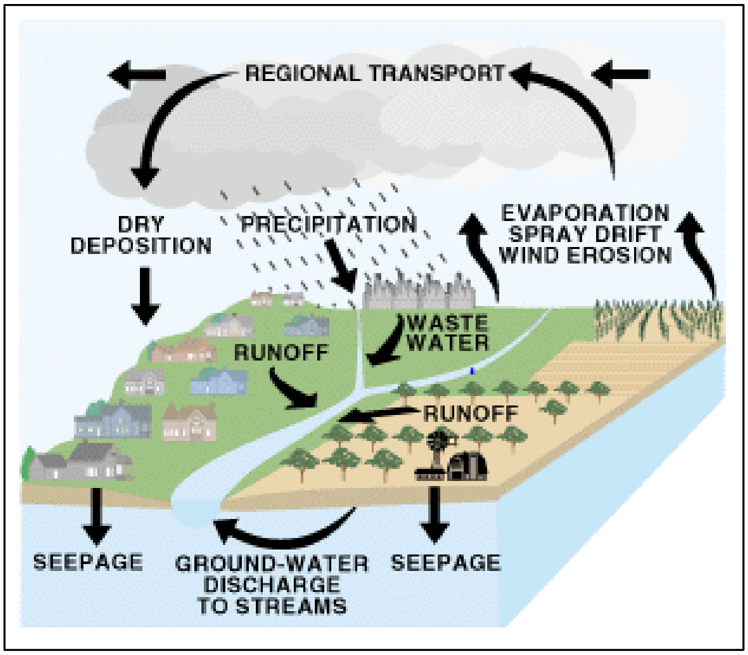
In 2005, about 77% of water used in the United States came from surface-water sources; the other 23% from groundwater. About 67% of fresh groundwater withdrawals in 2005 were for irrigation, and 18% were for public supply. More than half of fresh groundwater withdrawals in the United States in 2005 occurred in six States: California, Texas, Nebraska, Arkansas, Idaho and Florida. Most of the fresh groundwater withdrawals were for irrigation. In Florida, 52% of all fresh groundwater withdrawals were for public supply, and 34% were for irrigation. Most U.S. irrigated acreage (74%) and most of the withdrawals (85%) were in the 17 conterminous Western States. According to the World Bank, annual freshwater withdrawals in 2011 were measured at approximately 478 billion cubic feet, with withdrawals from agriculture measured as 40.2 % of total freshwater withdrawal in the United States (USGS, 2014).

Water Quality

Surface runoff from rain, snowmelt, or irrigation water can affect surface water quality by depositing sediment, minerals, or contaminants into water bodies. Meteorological factors, such as rainfall intensity and duration, and physical factors, such as vegetation, soil type, and topography, influence the extent of surface runoff. Unlike a point source, which is a “discernible, confined and discrete conveyance,” nonpoint source (NPS) pollution comes from many diffuse sources. Rainfall or snowmelt moving over the ground, also known as runoff, picks up and carries away natural and human-made pollutants, creating NPS pollution. The pollutants may eventually be transported by runoff into lakes, rivers, wetlands, coastal waters, and groundwater (USGS, 2014).

Groundwater is the water that flows underground and is stored in natural geologic formations called aquifers. It sustains ecosystems by releasing a constant supply of water into wetlands and contributes a sizeable amount of flow to permanent streams and rivers. Based on 2005 data, the largest use of groundwater in the United States is irrigation, representing approximately 67% of all the groundwater pumped each day (McCray, 2009). In the United States, approximately 47% of the population depends on groundwater for its drinking water supply.

Unlike a point source, nonpoint source (NPS) pollution comes from many diffuse sources. Rainfall or snowmelt runoff, accumulates and transports natural and human-made pollutants, creating NPS pollution (Figure 7). The pollutants may eventually be deposited in lakes, rivers, wetlands, coastal waters, and groundwater.



Source: http://water.usgs.gov/nawqa/pnsp/pubs/fs97039//sw1.html

Figure 7. Pollutant Transport in the Hydrologic Cycle.

The primary cause of NPS pollution is increased sedimentation in surface waters following soil erosion by surface runoff. Increases in sediment loads to surface waters can directly affect fish, aquatic invertebrates, and other wildlife. It also reduces the amount of light penetration in water, which directly affects aquatic plants. Indirectly, sedimentation resulting from soil erosion can increase fertilizer runoff, producing higher water turbidity, algal blooms, and oxygen depletion (US-EPA, 2005).

Agricultural NPS pollution is the leading source of impacts on surveyed rivers and lakes. It is and the third largest source of impairment to estuaries. It is also a major cause of impairment to groundwater and wetlands (USDA-EPA, 2011). Sources of agricultural NPS pollution include animal wastes, fertilizers, and pesticides. Production methods that contribute to NPS pollution include the type of crop cultivated, plowing and tillage, and the application of pesticides and fertilizers.

Use of pesticides for field crop production may introduce chemicals into surface water from airborne drift and runoff from treated fields and cleaning pesticide application equipment. They may also be absorbed on to soil particulates and deposited in sediment from soil erosion. All of these processes can serve as a mechanism of conveyance that introduces chemicals into groundwater by filtration through soil on land and sediments in surface water bodies.

To assess pesticide risks from exposure to aquatic organisms and the environment, EPA estimates concentrations of pesticides in natural water bodies, such as lakes or ponds. As part of the FQPA, EPA also estimates pesticide risks to drinking water and food for human consumption, and establishes maximum allowable residue levels. EPA typically does so using field monitoring data and mathematical models (US-EPA, 2014a).

Implementation of BMP to slow soil erosion and filter pollutants from surface runoff, such as vegetated strips, control of spray drift, and adherence to label restrictions governing safe application and equipment cleanup, minimize the potential for pesticide impacts to surface and groundwater. EPA label restrictions may require procedures to minimize impacts (e.g., prohibition of applications within 48 hours of forecasted rain events).

Irrigation

Corn is a water sensitive crop with a relatively low tolerance for drought compared to most other major cultivated crops. One bushel of corn production requires approximately 4,000 gallons of water, or approximately 600,000 gallons per acre during a growing season (NCGA, 2007a). Corn stress response and its respective water demand is variable over the growing season with the greatest water demand occurring during the silk production stage in mid-season (Farahani and Smith, 2011). During this stage, the water requirement is estimated at approximately two inches of water per week (or 0.3 inches per day) (Heiniger, 2000; Farahani and Smith, 2011).

Corn water demand is met by a combination of natural rainfall, stored soil moisture from precipitation before the growing season, and sometimes supplemental irrigation during the growing season (Heiniger, 2000; Farahani and Smith, 2011). The vast majority of corn acreage does not require supplemental irrigation (USDA-NASS, 2009). In 2010, approximately 11 million U.S. corn acres were irrigated, representing approximately 9% of the total corn acreage (NCGA, 2009). Groundwater serves as the source for almost 90% of irrigated corn acreage in the United States (Christensen, 2002).

2.2.3 Air Quality

Agricultural production of corn may affect air quality in direct and indirect ways. Primary sources of emissions associated with crop production include exhaust from motorized equipment, such as tractors and irrigation equipment; suspended soil particulates from tillage and wind-induced erosion; smoke from burning of fields; drift from sprayed herbicides and pesticides; nitrous oxide emissions from the use of nitrogen fertilizer (Hoeft et al., 2000b; USDA-NRCS, 2006a; Aneja et al., 2009; US-EPA, 2011a).

The Clean Air Act (CAA) and its amendments identify air pollutants that may reduce air quality and impact human health and the environment. The most important pollutants regulated by EPA and states (or local regulatory agencies) are identified under the National Ambient Air Quality Standards (NAAQS) referred to as “criteria pollutants.” The CAA requires the maintenance of NAAQS and establishes health-based limits for them: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and inhalable particulates (i.e., coarse particulate matter greater than 2.5 micrometers (µm) and less than 10 µm in diameter [PM_{10}] and fine particles less than 2.5 µm in diameter [$PM_{2.5}$])[14].

The main criteria pollutants associated with agricultural activities are PM and ozone precursors (pollutants that lead to the formation of ozone) (USDA-NRCS, 2011a). Ground-level ozone is not usually directly emitted, but formed in the atmosphere as a result of chemical reactions of other compounds. As a result, ozone precursors such as VOCs and NO_x are regulated.

Varying sizes of PM emissions, including $PM_{2.5}$, arise from direct releases of dust from roads, harvesting, or tillage, as well as smoke from combustion processes. PM may also be formed by atmospheric chemical reactions of PM precursor pollutants, such as ammonia (NH_3), oxides of nitrogen (NO_x), VOCs, and sulfur dioxide (SO_2). Sources of PM precursor gases include engines, fertilizer application, and animal operations (USDA-NRCS, 2012c). In agriculture, VOCs can be formed as a result of decomposition of biological materials, including manure and feed, combustion from farm equipment, burning of biological materials, or pesticide application. NO_x is also formed as a result of the breakdown or decomposition process, primarily from nitrification/denitrification, and fuel combustion and burning (USDA-NRCS, 2012b). Farming is a minor contributor compared to non-agricultural sources in regions where PM and ozone NAAQS have not been attained (USDA-NRCS, 2011a; 2012b).

Fertilizers, herbicides, and pesticides applied to soil and plant surfaces may also introduce chemicals into the air that drift and affect all living species, including humans. Drift is defined by EPA as “the movement of pesticide through air at the time of application or soon thereafter, to any site other than that intended for application” (US-EPA, 2000b). Pesticides are typically applied to crops by mechanical means: ground sprayers or aircraft. Small, lightweight droplets are produced by specially designed nozzles on spray equipment. Most are aerosols (i.e., droplets that are small enough to remain suspended in air for long periods) that are moved by air currents until they adhere to a surface or deposit on the ground. The smallest droplets are those that volatilize and disperse according to the physical process of diffusion, as a gas in the atmosphere (FOCUS, 2008). Volatilization occurs when pesticide surface residues change from a solid or liquid to a gas or vapor after application. Once airborne, volatilized pesticides may be carried long distances from the treatment location by air currents.

USDA-NRCS has approved conservation systems and activities aimed at targeting air emissions from agricultural sources in areas where these activities are impacting air quality. These

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[14] Particulate matter is made up of a number of different compounds, including acids (such as nitrates and sulfates), organic chemicals, metals, soil or dust particles, and allergens (pollen or mold spores).

According to the EPA, particulates with diameters less than 10 µm have the greatest potential to impact human health, as these small particles can get deep into the lungs, with some even entering the bloodstream. Larger particulates do not present as serious health concerns, but may irritate the eyes, nose and throat US-EPA (2003)

Particulate deposition may adversely affect ecosystems by causing nuisance dusting, changing pH balance, damaging plants or by adding additional nitrogen to the environment (USDA-NRCS (2012c) practices may be implemented to achieve reasonably available control measures (RACMs) and best available control measures (BACMs) of control (USDA-NRCS, 2012a). Other conservation practices, as required by USDA to qualify for crop insurance and beneficial Federal loans and programs (USDA-ERS, 2009), effectively reduce crop production impacts on air quality through the employment of windbreaks, shelterbelts, reduced tillage, and cover crops that promote soil protection on highly erodible lands.

Practices to improve air quality include conservation tillage, residue management, wind breaks, road treatments, burn management, shredding of prunings, feed management, manure management, integrated pest management, chemical storage, nutrient management, fertilizer injection, chemigation and fertigation (i.e., inclusion of chemicals in irrigation), conservation irrigation, scrubbers, and equipment calibration (USDA-NRCS, 2006a).

Conservation tillage improves air quality by reducing the use of mechanized equipment on fields. This reduces dust and exhaust emissions. It also increases surface plant residue and organic matter that promotes soil retention by increasing resistance to wind erosion (Baker et al., 2005; USDA-NRCS, 2006a). The USDA has estimated that the adoption of conservation management plans in the San Joaquin Valley of California had reduced air emissions by 34 tons daily, or more than 20% of the total emissions attributed to agricultural practices after a year of implementation (Baker et al., 2005; USDA-NRCS, 2006a).

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). EPA has identified carbon dioxide (CO_2), methane (CH_4), and nitrous oxide (N_2O) as the most important greenhouse gases (GHGs). During the 20-year period, 1990-2009, GHG emissions attributable to agriculture increased by 8.7%. By 2009, 7% of the total U.S. GHG emissions were produced from agricultural sources (US-EPA, 2011c).

Most of the GHGs from agriculture and natural resources consist of carbon dioxide, methane and nitrous oxide. Emissions of GHGs released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, methane (CH_4), reactive organic gases, particulate matter, and oxides of sulfur (US-EPA, 2011a). Soil management practices, including nitrogen-based fertilizer application and cropping practices, represent the largest source of U.S. N_2O emissions from agriculture (US-EPA, 2011a). Agricultural sources of methane are associated primarily with manure management and enteric emissions from cattle. Carbon dioxide is also a significant GHG associated with several other agricultural practices, including land use and energy consumption (US-EPA, 2011a).

Factors influencing the magnitude of GHGs produced by agriculture are complex. Some of the most important include production practices used by growers, the crop grown, and the locality where it’s grown. For example, emissions of nitrous oxide, produced naturally in soils through microbial nitrification and denitrification can be modified significantly by fertilization, grazing animals, cultivation of nitrogen-fixing crops (e.g., alfalfa), retention of crop residues (i.e., no-till conservation), irrigation, and fallowing of land (US-EPA, 2012a). These same agricultural practices can influence the decomposition of carbon-containing organic matter sequestered in soil, resulting in conversion to CO_2 that is released into the atmosphere (US-EPA, 2012a).

Emissions associated with farm machinery can be reduced by half for some crops by changing from conventional tillage to no-till (Nelson et al., 2009). Conversion of crop land to pasture increases nitrogen sequestration in soils (US-EPA, 2012a). Tillage releases CO_2 to the atmosphere by exposing organic matter to the air, where it is oxidized (Baker et al., 2005). No-till practices tend to sequester more carbon in the soil by reducing soil disturbance, maintaining higher soil moisture, and increasing biomass inputs from crop residue on the (West, 2000). The gross carbon sequestration value used for corn, taken from the national assessment data, is 595 kg carbon/hectare/year approximately 530 pounds per acre (West, 2000). Corn crops using no-till practices have the potential to sequester an additional 288 kg carbon/hectare/year (approximately 263 pounds/acre) compared to conventional tillage (West, 2000). The amount sequestered by corn production is directly affected by its cultivation practices. Corn cultivation is estimated to produce higher total CO_2 emissions than wheat or soybean, and lower total emissions than cotton and rice (Nelson et al., 2009).

The EPA has identified regional differences in GHG emissions associated with agricultural practices on different soil types. For example, carbon emission rates differ between mineral soils and organic soils (US-EPA, 2012a). Mineral soils contain from 1-6% organic carbon by weight in their natural state. Organic soils may contain as much as 20% carbon by weight (US-EPA, 2012a). Mineral soils can release up to 50% of the soil organic carbon to the atmosphere upon initial conversion. However, over time, the soil establishes a new equilibrium that reflects a balance between carbon inputs from decaying plant matter and other organic sources, and carbon losses from microbial decomposition (US-EPA, 2012a). Organic soils release carbon to the atmosphere for a longer period of time than mineral soils (US-EPA, 2012a). The EPA has estimated that mineral soil-based cropland soils sequester more CO_2 compared with carbon emissions from organic soil-based croplands (US-EPA, 2012a). The adoption of conservation tillage, particularly in the Midwest regions with mineral soil shows the highest rates of carbon sequestration (US-EPA, 2012a).

Climate change may also affect agriculture. Climate change may increase the range of weeds and pests that impact agricultural production (Field et al., 2007). Current agricultural practices will have to adapt to these changes in the ranges of weeds and pests of agriculture (Field et al., 2007).

2.3 BIOLOGICAL RESOURCES

Biological resources include animal, plant and microbiological organisms, and their assemblages that form living community structures in the environment.

2.3.1 Animal Communities

Animal communities include wildlife species and their habitats. Wildlife refers to both native and introduced species of mammals, birds, amphibians, reptiles, invertebrates, and fish and shellfish. Wildlife may feed on corn, and utilize the field and surrounding habitat as harborage.

Mammals and birds may seasonally consume corn, and invertebrates can feed on the plant during the entire growing season.

Birds and Mammals

Compared to natural areas, agricultural production fields have reduced animal populations (Dale et al., 2010). Nevertheless, despite the frequent disturbances of maintaining a monoculture, corn fields support a variety of animal species, (Palmer et al., 1992; Vercauteren and Hygnostrom, 1993). Some birds and mammals use cornfields for harborage and reproduction. Most are ground-foraging omnivores that feed on the corn grain remaining in the fields following harvest (Palmer et al., 1992; Vercauteren and Hygnostrom, 1993; Krapu et al., 2004a).

Most of the birds that utilize cornfields are ground foraging omnivores that feed on corn seed, sprouting corn, and the corn remaining in the fields following harvest. Bird species commonly observed foraging on corn include (Dolbeer, 1990; Patterson and Best, 1996; Purdue; Southern States Co-Op, 2010; Mullen, 2011):

- Red-winged blackbird (*Agelaius phoeniceus*)
- Grackle (*Quiscalus quiscula)*
- Horned lark (*Eremophila alpestris*)
- Brown-headed cowbird (*Molothrus ater*)
- Vesper sparrow (*Pooecetes gramineus*)
- Ring-necked pheasant (*Phasianus colchicus*)
- Wild turkey (*Meleagris gallopavo)*
- American crow (*Corvus brachyrhynchos*)
- Various quail species.

Following harvest, Canada geese (*Branta canadensis*), snow geese (*Chen caerulescens*), sandhill cranes (*Grus canadensis*), and other migratory waterfowl in frequently visit cornfields (Sparling and Krapu, 1994; Taft and Elphick, 2007; Sherfy et al., 2011).

Depending on the region, a variety of mammals may also forage in cornfields. Most are herbivorous and omnivorous mammals. The most common include (ODNR, 2001; DeVault et al., 2007; Stewart et al., 2007; Beasley and Rhodes Jr., 2008; University of Illinois, 2012):

- White-tailed deer (*Odocoileus virginianus*)
- Raccoon (*Procyon lotor*)
- Feral pigs (*Sus scrofa*)
- Woodchuck (*Marmota monax*)

White-tailed deer often inhabit woodlots adjacent to cornfields and frequent these fields for both food and cover throughout the latter half of the corn growing season (Vercauteren and Hygnostrom, 1993). The impacts of white-tailed deer are well-documented (Vercauteren and Hygnostrom, 1993). Deer cause more losses to corn production than any other wildlife species (Stewart et al., 2007). Significant losses from feeding by racoons have also been documented

(DeVault et al., 2007; Beasley and Rhodes Jr., 2008). Mature corn has been shown to constitute up to 65% of the diet of raccoons in some areas prior to harvest (MacGowan et al., 2006).

Small mammal use of cornfields for shelter and forage also varies regionally and includes (Stallman and Best, 1996; Sterner et al., 2003; Smith, 2005):

- Deer mouse (*Peromyscus maniculatus*)
- House mouse (*Mus musculus*)
- Meadow vole (*Microtus pennsylvanicus*)
- Thirteen-lined ground squirrel (*Spermophilus tridecemlineatus*)

The deer mouse is commonly found in agricultural fields (Stallman and Best, 1996; University of Illinois, 2000; Sterner et al., 2003). Deer mice feed on a wide variety of plant and animal matter depending on availability, but primarily feed on seeds and insects. Deer mice have been considered beneficial in agro-ecosystems because they consume both weed and insect pests (Smith, 2005).

The house mouse is primarily a seed and grain feeder, commonly found in the weedy edges of fields (University of Illinois, 2000). Most crop damage by house mouse damage occurs between planting and crop emergence (University of Illinois, 2000).

The meadow vole feeds primarily on fresh grass, sedges, and herbs, and also on seeds and grains of field crops. Although the meadow vole may be considered beneficial because it consumes weeds, it can be a substantial agricultural pest. Where abundant, it can consume corn seeds in the field. The vole is often associated with the field edges where cover is found off the field as well as where limited tillage agriculture and strip crops are found (Smith, 2005). The lined ground squirrel feeds primarily on seeds of weeds and available crops, such as corn and wheat. This species has the potential to damage agricultural crops, although like the meadow vole, it also can be considered beneficial when eating pest insects, such as grasshoppers and cutworms (Smith, 2005).

Invertebrates

Common agricultural practices, particularly monoculture cultivation, may reduce diversity in managed fields. This net reduction in species is not limited to birds and mammals; invertebrates are also affected (Landis et al., 2005). In spite of this, the invertebrate community in cornfields represents a diverse assemblage of feeding strategies (Stevenson et al., 2002). Numerous insects and related arthropods may perform valuable functions: they pollinate plants, contribute to the decay and processing of organic matter, reduce weed populations, and cycle soil nutrients. Arthropods may also feed upon insects and mites that are considered to be pests (Ruiz et al., 2008). Some of these beneficial predatory species include the convergent lady beetle (*Hippodamia convergens*), carabid beetles (Family Carabidae), parasitoids (e.g., *Macrocentrus cingulum*), and the predatory mite (*Phytoseiulus persimilis*) (Shelton, 2011).

The most agronomically-relevant invertebrates in corn production fields are those arthropods that feed on corn and adversely affect yield. These include lepidopteran species that feed on the corn ear or stalk and coleopteran species that feed on other corn vegetative structures. Two of the most important insect pests of corn in the United States include the European corn borer and WCR. The European corn borer is present in every corn growing state except Arizona, California, Idaho, Nevada, Oregon, Utah, and Washington (ISU, 2012). WCR has been reported as active in every corn growing state except California, Florida, Louisiana, Nevada, Oregon and Washington (Edwards and Kiss, 2012). Annual U.S. losses related to European corn borer and CRW exceed $1 billion/year for each pest (Ostlie et al., 2002; Gray et al., 2009). Other important insect pests of corn include wireworms, black cutworms, fall armyworms, earworms and grasshoppers (O'Day et al., 1998).

GE *Bt* corn has had a major impact by reducing insect pest damage to corn, and limiting the need for broad-spectrum insecticide application (Brookes and Barfoot, 2010; Benbrook, 2012). Although *Bt* corn varieties have proven successful in controlling targeted insect pests since their introduction in 1996, there have been several reports of resistance by target pests in the United States, India, and South Africa (Tabashnik and Gould, 2012). Pockets of CRW resistance to one genotype of *Bt* corn has been reported in several locations in Iowa, and the EPA has confirmed fall armyworm resistance to Cry1F in Puerto Rico (US-EPA, 2010b; Gassmann et al., 2011; Storer et al., 2012). In both the Iowa and the Puerto Rico reports, these resistant populations were associated with fields where growers had cultivated consecutive years of corn expressing the same Cry protein.

The emergence of these resistant populations has been attributed to failure of growers to adhere to the refuge strategy (see, e.g., Storer et al., 2012). Refuges are used to mitigate the development of resistance to *Bt* crops. Refuges consist of non-transgenic varieties of the same crop that do not express *Bt* Cry protein(s) that are grown interspersed with the IR variety. These plants allow insects which are susceptible to the Cry protein to survive in the field and cross-breed with resistant insects. This strategy is particularly effective when insect resistance is expressed as a recessive trait (Tabashnik et al., 2013)This study also found that development of pest resistance was lowest when plants expressing multiple Cry resistance proteins were grown together, rather than concurrent deployment of plants expressing only one Cry resistance protein alongside plants with multiple resistance proteins (Tabashnik et al., 2013).

As a condition of *Bt* registrations by EPA, registrants are required to develop insect resistance management (IRM) programs to delay the development of insect resistance to Cry proteins. Examples of the limitations and conditions currently implemented for the *Bt* proteins in corn can be found in the EPA document, *Terms and Conditions for Bt Corn Registrations* (US-EPA, 2010f). As part of this program, growers of traditional *Bt*-corn products are required to plant a non-*Bt*-corn refuge (US-EPA, 2010f). Such a refuge can consist of a field or a block or strip of non-*Bt* corn (US-EPA, 2010f). Recently, the EPA also has approved an integrated refuge strategy, named "refuge in a bag", where non-*Bt* seeds are blended with the *Bt*-corn products and planted randomly within the field. Successful development and implementation of the refuge strategy requires an understanding of the genetic foundation of insect pest resistance. Incipient resistance to Cry proteins has been reported in target insect pests before being exposed to the Cry proteins (Mahon et al., 2012). This resistance trait is considered a recessive allele; susceptibility to the Cry protein is considered the dominant trait (Tabashnik and Gould, 2012). As a recessive trait, the frequency of expression of this trait is low in an unexposed population (Tabashnik and Gould, 2012). However, when the same population of target pests is exposed to the same Cry protein over several generations, the recessive resistance trait allows those individuals carrying that allele to survive and reproduce, conferring the resistance trait to their offspring as a greater percentage of the pest population (Tabashnik and Gould, 2012). The refuge strategy provides non-*Bt* corn where susceptible target insects (e.g., European corn borer and/or CRWs) can feed, mate and reproduce without exposure to the *Bt* corn and the Cry proteins. This maintains a genetic reservoir of susceptible target pests that express the dominant trait (US-EPA, 2010f; Pioneer, 2012). Future mating interactions with these susceptible insects (i.e., those that have not been exposed to *Bt* proteins) and those that have been exposed to the *Bt* proteins and survived based on the resistance allele will ensure that *Bt* resistance does not become the dominant allele in the population.

Despite some evidence of *Bt* resistance, widespread failure of control measures using *Bt* crops has not been observed (Tabashnik et al., 2008). This is partially attributable to IRM strategies. IRM strategies generally include supplemental pesticide applications in conjunction with the planting of refuges (Tabashnik et al., 2008). For *Bt* corn grown in the Corn Belt, refuges typically make up 5-20% of the cornfield area, depending on the product's requirements (US-EPA, 2010f). Resistance management strategies, which are mandated by the EPA's terms of *Bt*-corn product registrations (US-EPA, 2010f) have been developed for all *Bt*-corn products to mitigate the risk of pest resistance and to implement additional measures if resistance occurs.

Aquatic Communities

Aquatic ecosystems potentially impacted by agricultural activities include water bodies adjacent to or downstream from crop field, including impounded bodies, such as ponds, lakes, and reservoirs, and flowing waterways, such as streams or rivers. If near coastal areas, aquatic habitats affected by agricultural production may also include marine ecosystems and estuaries. Aquatic species that may be exposed to sediment from soil erosion, nutrients and pesticides from runoff, and atmospheric deposition, include freshwater and estuarine/marine fish, invertebrates and freshwater amphibians.

2.3.2 Plant Communities

Cornfields may be bordered by other field crops, woodlands, hedgerows, rangelands, pastures or grasslands. These surrounding plant communities may occur naturally or they may be managed for the control of soil and wind erosion.

Surrounding Landscapes and Other Vegetation in Cornfields

The vegetation adjacent to a cornfield is often dependent on the geographic region where the corn is planted. Weeds are plants growing in areas where their presence is undesired by humans (Baucom and Holt, 2009). Non-crop plants in corn fields are generally regarded as weeds. Ruderals, plants that colonize frequently disturbed environments, have evolved with characteristics or mechanisms that allow them to survive conditions in agricultural environments. Weedy plants typically exhibit early germination and rapid growth from seedling to sexual maturity. They have the ability to reproduce sexually and asexually, and therefore are well adapted to agricultural fields (Baucom and Holt, 2009).

The presence of weeds in corn fields is a primary detriment to productivity. Weeds are the most important pest complex in agriculture, impacting yields by competing with crops for light, nutrients, and moisture. In addition to taking valuable resources from crops, weeds can introduce weed seed or plant material into the harvested crop, thereby reducing its market value. Weeds can also harbor insects and diseases, and can interfere with harvesting equipment by clogging and causing extra wear (Loux et al., 2008).

Weeds are classified as annuals or perennials. An annual is a plant that completes its lifecycle in one year or less and reproduces only by seed. Perennials are plants that live for more than 2 years. Weeds are also classified as broadleaf (dicots) or grass (monocots). Weeds can reproduce by seeds, rhizomes (underground creeping stems), or other underground parts. Summer annuals appear in the spring or early summer and die prior to or by the first frost, producing seeds within the same growing season. These weeds grow rapidly, strongly competing with crops for resources, and can outgrow and shade slower-growing crops. These weeds tend to be the most problematic weeds in corn, as they share a similar life cycle.

Weed populations change in response to agricultural management decisions. New weeds emerge as cropping practices change and growers fail to recognize or properly identify a plant as a weed (Iowa State University Extension, 2003). Collectively, management decisions will impart selection pressures[15] on the present weed community, resulting in weed shifts on a local level (i.e., field level). These weed shifts occur regardless of what the selection pressure may be and may result in changes in weed density and/or weed diversity (Reddy and Norsworthy, 2010; Weller et al., 2010). Weed shifts are generally most dramatic when a single or small group of weeds increases in abundance at the expense of other weed populations, potentially dictating the primary management efforts of the grower. For example, with increased rates of conservation tillage, there has been a decrease in large-seeded broadleaf weeds and increases in perennial, biennial, and winter annual weed species (Green and Martin, 1996; Durgan and Gunsolus, 2003). Perennial weeds, such as quackgrass, Johnsongrass, Canada thistle, and others, have also been found to infest some corn fields. Winter perennials are particularly competitive and difficult to control, as these weeds re-grow every year from rhizomes or root systems (DAS, 2010b)

Overreliance on a single weed management strategy, for example, a single MOA herbicide application, can cause intense selection pressure on weed populations. In this context, selection pressure is the extent to which organisms possessing a particular characteristic are either

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[15] Selection pressure may be defined as any event or activity that reduces the reproductive likelihood of an individual in proportion to the rest of the population of that one individual. In agriculture, selection pressure may be imparted by any facet of management in the production of a crop, including the type of crop cultivated, strategy of pest management, or when and how a crop is planted or harvested.

eliminated or favored by environmental conditions (Vencill et al., 2012). This strong selection pressure can result in ecological shifts in the weed community or the evolution of HR biotypes (Shaw et al., 2011; Wilson et al., 2011; Vencill et al., 2012).

Weed control is an important aspect of corn cultivation. Weed control typically involves an integrated approach that includes timely herbicide applications, crop rotation, weed surveillance, and weed monitoring (Farnham, 2001; IPM, 2004; 2007; Hartzler, 2008; University of California, 2009). Data have been collected on weed population densities by species, crop yield, and crop production system economics with the intent of providing growers with insights into the sustainability and profitability of diversified weed management programs (Shaw et al., 2011). To assist growers in managing weeds, individual states, typically through their state agricultural extension service, list the prevalent weeds in crops in their area and the most effective means for their control (see, e.g., IPM, 2004; 2007; University of California, 2009).

Maize as a Weed or Volunteer

In the United States, corn is not listed as a weed (Crockett, 1977; Muenscher, 1980), nor is it present in the Federal Noxious Weed List (7 CFR part 360) (USDA-NRCS, 2011b; 2012d). Elsewhere, corn is grown without any report of it being a serious weed or that it forms persistent feral populations (Gould, 1968; OECD, 2003) because corn possesses few of the characteristics of those plants that are notably successful as weeds (Baker, 1965; Keeler, 1989). Volunteer corn lacks vigor and competitiveness because the volunteer plant is two generations removed from the hybrid planted (Davis, 2009). These plants do not result in feral populations in following years because maize is incapable of sustained reproduction outside of domestic cultivation (Gould, 1968).

Corn periodically occurs as a volunteer when corn seeds remain in the field after harvest and successfully germinates (Beckett and Stoller, 1988; Davis, 2009; Hager, 2009; see also Bernards et al., 2010; Johnson et al., 2010; Wilson et al., 2010; Stewart, 2011; Wilson, 2011; USDA-APHIS, 2012). Post-harvest seed residues in fields can be a result of harvester inefficiency, bird dispersal or seed drop, with the seed ending up beyond the field margins or remaining as residues in the field after the harvest (Davis, 2009). This can be a particular problem if late season weather causes ears to drop leaving ears on the ground with seeds that germinate the following year (Wilson et al., 2010). Volunteer corn can be present as single plants or as clumps formed when an ear drops to the ground and is partially buried (Davis, 2009; Wilson et al., 2010). When seeds survive to the next growing season, volunteer plants may develop within subsequent crops rotated with corn, or outside of the cropped area.

GE corn may be a problematic volunteer the year after harvest in field crops grown in rotation with corn, especially soybean, dry beans, sugar beets, as well as subsequent corn crops (Davis, 2009; Hager, 2009; Bernards et al., 2010; Johnson et al., 2010; Wilson et al., 2010; Stewart, 2011; Wilson, 2011). For example, the presence of volunteer corn in soybeans was identified in 12% of the soybean acreage in Illinois in a 2005 survey of soybean acreage rotated with corn (Davis, 2009).

Volunteer corn also can be problematic in fields where the grower elects to cultivate corn after corn. Such volunteer corn can be controlled using inter-row cultivation and several different herbicides (Minnesota, 2009b; Sandell et al., 2009). As noted with volunteer corn in soybean, growers can take advantage of alternate modes of herbicide action if the herbicide resistance differs between the current crop and the volunteer (e.g., glufosinate in LibertyLink® corn to control a GR variety) (Minnesota, 2009b).

Successful control of corn volunteers, including HR varieties, is accomplished with the use of various combinations of cultivation practices and herbicides (Beckett and Stoller, 1988; Beckie and Owen, 2007; Sandell et al., 2009; Jeschke and Doerge, 2010). Volunteer corn is less of a concern in no-till fields than in fall-tilled fields because of the lower probability that corn seed will survive and germinate the following growing season (Bernards et al., 2010). In no-till fields, the fallen corn is frequently predated by wildlife and also is subject to winter weather conditions (Bernards et al., 2010). In fall tillage systems, corn seed may be buried in the soil and overwinter and germinate. This overwintering volunteer corn seed requires control with spring tillage or with an application of herbicides (Bernards et al., 2010).

2.3.3 Soil Microorganisms

Microorganisms can have both positive and negative impacts. Diseases that infect corn with substantial 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).

Microorganisms have an important role in the ecology of the soil (OECD, 2003). Soil microorganisms benefit soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Young and Ritz, 2000; Garbeva et al., 2004). Microorganisms also may suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Young and Ritz, 2000; Garbeva et al., 2004). Plant roots release a large variety of compounds into the soil, creating a unique environment for microorganisms in the rhizosphere[16] (Bais et al., 2006). Microbial diversity in the rhizosphere is extensive and differs from the microbial community in the bulk soil (Garbeva et al., 2004).

2.3.4 Biological Diversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). Agricultural biodiversity has been defined to include genetic diversity of the

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[16] The rhizosphere is defined as subsoil area in the root zone of plants in which plant roots compete with the invading root systems of neighboring plants for space, water, and mineral nutrients, and interact with soil-borne microorganisms, including bacteria, fungi, and insects feeding on the organic material in the soil Walker et al. (2003).

crops by the natural biodiversity of the surrounding ecosystem (see, e.g., Carpenter, 2011). USDA-APHIS focuses its analysis of biological diversity at the ecosystem level, that aspect of the environment potentially impacted by the determination of nonregulated status of various GE crops. In this case, biodiversity refers to the ability of a highly managed ecosystem, such as a cornfield, to support species that do not contribute directly to crop production but represent important components of the biological landscape. These include pollinators (e.g., bees, butterflies), those that control insect pests, important avian species (e.g., songbirds), small mammals and some members of the plant community.

Among other benefits, natural biodiversity provides valuable genetic resources for crop improvement (Harlan, 1975), and also provides other functions beyond food, fiber, fuel, and income. These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of the local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 2000). Beneficial insects, birds, and mammals are natural predators of many crop pests that have an important role in pest management (USDA-NRCS, 2002). The loss of biodiversity results in a need for costly external inputs in order to provide these functions to the crop (Altieri, 1999; 2000).

Relative to any natural ecosystem, species abundance and richness will generally be less in intensively managed agro-ecosystems. The degree of biodiversity in an agro-ecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agro-ecosystem; 2) permanence of various crops within the system; 3) intensity of ecosystem management; 4) extent of isolation of the agro-ecosystem from natural areas of native vegetation (Altieri, 1999; USDA-NRCS, 2002). Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest limit habitat diversity resulting in a corresponding decrease in diversity of plants and animals.

Cropland management practices, including a range of practices incorporated in integrated pest management plans can be adopted that increase habitat preservation and plant biodiversity (see, e.g., IPM, 2004; 2007; Sharpe, 2010; Palmer et al., 2011).

Conservation tillage and no-till practices have a positive impact on wildlife, including the community of beneficial arthropods (Altieri, 1999; Landis et al., 2005; Towery and Werblow, 2010). These benefits derive from decreased soil erosion and improved water quality in receiving waters, retention of cover, availability of waste grain on the soil surface for feed, and increased populations of predaceous invertebrates as well as invertebrates as a food source (Landis et al., 2005; Sharpe, 2010).

Crop rotations reduce the likelihood of crop disease, insect pests, weed pests, and the need for pesticides (Randall et al., 2002). Reduced pesticide use has a direct positive impact on wildlife by reducing the direct exposure of birds, mammals, and fish to pesticides. Indirect benefits include less alteration of suitable wildlife habitat and an available food supply of insects for insectivores (Sharpe, 2010; Palmer et al., 2011). Crop rotations with legumes and small grains have been shown to provide excellent wildlife nesting cover, food, and brood-rearing habitat (Sharpe, 2010). Polycultures of plants support herbivorous insect populations because they provide a more stable and continuous availability of food and habitat for beneficial insects (Altieri and Letourneau, 1982; 1984; Altieri, 1999; Landis et al., 2005).

Field edges can be managed to promote wildlife. These borders are often the least productive areas in a farm field and in some cases, the cost of producing crop areas along field edges exceeds the value of the crop produced (Sharpe, 2010). Allowing field edges to return to non-crop vegetation does contribute to weed seeds in the field, but does not contribute to major pest problems in the crop field itself (Sharpe, 2010). Non-crop border vegetation, such as ragweed, goldenrod, asters, and forbs, may quickly develop into nesting and brood habitat for quail and a multitude of songbirds (Sharpe, 2010). Maintaining some weeds harbors and supports beneficial arthropods that suppress herbivore insect pests (Altieri and Letourneau, 1982; 1984; Altieri, 1999). Research conducted at North Carolina State University and the North Carolina Wildlife Resources Commission found that fields with bands of natural cover along ditch banks have more quail and wintering songbirds than nearby fields with closely mowed ditch banks(Sharpe, 2010). Adjacent wild vegetation provides alternate food and habitat for natural enemies to pest herbivores (Altieri and Letourneau, 1982; 1984; Altieri, 1999).

Contour-strip cropping is another management practice that can be used to promote wildlife habitat. This practice alternates strips of row crops with strips of solid stand crops (i.e., grasses, legumes, or small grains) with the strips following the contour of the land (Sharpe, 2010). The primary purpose of contour-strip cropping is to reduce soil erosion and water runoff, but the solid stand crop also provides nesting and roosting cover for wildlife (Sharpe, 2010). Grass-legume refuge strips also have been used to increase the population density of insectivorous carabid beetles in corn and soybean fields (Landis et al., 2005).

Drainage ditches, hedgerows, riparian areas, and adjacent woodlands to a cornfield also provide cover, nesting sites, and forage areas, which each contribute to enhancing wildlife populations. Ditch banks, for example, function as narrow wetlands that provide nesting sites and cover, serve as wildlife corridors, and provide areas for the wildlife to occupy when crop fields lack cover (Sharpe, 2010). Ditches have been shown to support birds, rodents, reptiles, furbearers, amphibians, fish, and aquatic organisms (Sharpe, 2010).

2.3.5 Gene Movement

Gene movement involves two components: vertical and horizontal exchange.

Vertical Gene Movement

Vertical gene movement (i.e., vertical gene flow or sexual reproduction) generally involves the movement of alleles from parents to offspring. In corn, sexual reproduction may occur between domesticated corn varieties or from corn to sexually-compatible relatives.

Vertical gene flow includes the possibility of pollen transfer between different varieties of corn. A variety of plant properties, environmental conditions, and imposed conditions can affect movement of genes between corn cultivars. For gene flow to occur between corn varieties, viable pollen must reach a receptive tassel (Lerner and Dana, 2001). This requires that flowering times must overlap, viable pollen transfer between the varieties must occur, embryo/seeds must develop, and hybrid seed must disperse and establish (see, e.g., Lerner and Dana, 2001; Diver et al., 2008). Spatial and temporal isolation can be one of the most effective barriers to gene exchange between corn crop cultivars (Mallory-Smith and Zapiola, 2008). Current practices for maintaining the purity of hybrid seed production in corn are typically successful for maintaining 99% genetic purity, though higher instances of out-crossing can occur (Ireland et al., 2006). More details about practices for maintaining varietal purity are reviewed under the topics of organic corn farming and specialty corn.

The possibility of gene movement from the host plant into native or feral corn populations, or wild or weedy relatives of corn has been evaluated by the EPA and determined to not be a concern in the continental United States (US-EPA, 2010c). The potential for outcrossing is defined as the likelihood of gene movement to wild corn relatives. This subsection provides a basis for evaluating the potential for corn to outcross with these wild varieties.

While pollen-mediated gene transfer can occur, there are no differences in the potential for gene flow and weediness from conventional or other GE varieties. Outcrossing and weediness are addressed in the preliminary PPRA and MON 87411 Maize is similar to other HR-corn varieties.

Horizontal Gene Movement

Horizontal gene movement (i.e., horizontal gene transfer) from a plant species and consequent expression in bacteria is unlikely to occur (Keese, 2008). Many bacteria (or parts thereof) that are closely associated with plants have been sequenced, including *Agrobacterium* and *Rhizobium* (Kaneko et al., 2000; Wood et al., 2001; Kaneko et al., 2002). There is no evidence that these organisms contain genes derived from plants. In cases where the review of sequence data implied that horizontal gene transfer occurred, these events were inferred to occur on an evolutionary time scale on the order of millions of years (Brown, 2003).

2.4 HUMAN HEALTH

This section provides a summary of the human health concerns for public health related to the human consumption of GE corn and for worker health and safety from potential exposure to agricultural hazards during crop production.

Human health concerns associated with a GE corn include potential impacts to public health, and worker health and safety. The public health concerns from the use of GE corn generally focus on human consumption of GE corn and corn products (corn syrup and sweeteners, starches, oil, cereal, beverage and industrial alcohol, and cosmetics and other personal hygiene) derived from GE corn. The worker health and safety concerns are mainly related to agricultural production of GE crops. USEPA regulates GE crops containing plant-incorporated protectants (PIPs), such as MON 87411 Maize. PIPs are pesticidal substances produced by plants and the genetic material necessary for the plant to produce the substance (US-EPA, 2014e). USEPA evaluates the human health risks of a pesticide associated with direct contact and dietary exposure routes during the registration process before a GM crop is registered for commercial use on the market. Concurrently, FDA evaluates the safety and nutrition of a GM crop as food under the FFDCA.

There are multiple ways in which organisms can be genetically modified through human intervention. Traditional methods include breeding or crossing an organism to elicit the expression of a desired trait, while more contemporary approaches include the use of biotechnology such as genetic engineering to produce new organisms (NRC, 2004). The 2004 National Research Council (NRC) review on GE crops indicated that unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional hybridizing and genetic engineering (NRC, 2004). The 2004 NRC report also noted that no adverse human health effects attributed to genetic engineering have been documented. Reviews on the nutritional quality of GE foods generally have generally concluded that there are no biologically meaningful nutritional differences between conventional and GE plants for food or animal feed (Aumaitre et al., 2002; Faust, 2002; Van Deynze et al., 2005). A European Union funded GMO research commission concluded at least equal assurance of the safety of GM foods compared to conventional counterparts for GM crops in the European (European Commission, 2010).

More recently, the NRC found the cultivation of GE crops resulted in changes in pesticide application practices (NRC, 2010b). For example, this included applications of fewer pesticides or using pesticides with lower environmental toxicity. Consequently, the cultivation of HR crops is advantageous because of their superior efficacy in pest control and concomitant economic, environmental, and presumed personal health advantages (NRC, 2010a).

2.4.1 Public Health

In the past 30 years, the public’s consumption of corn-based products more than doubled from 12.9 pounds annually per capita in 1980 to 33 pounds in 2009. Corn sweeteners rose from 35.3 pounds annually per capita in 1980 to 65.7 pounds in 2009 (U.S. Census Bureau, 2012). Acreage of GE corn varieties rose to 93% since the introduction of HR and IR crops in 1996 (USDA-ERS, 2014a).

The public health concerns from consumption of a GE corn and its products include the potential toxicity of the introduced genes and their products, potential expression of new antigenic proteins, potential absorption of the introduced genes in a GE plant into the human digestive system, potential for increased anti-nutrients, and/or altered levels of existing allergens (Malarkey, 2003; Dona and Arvanitoyannis, 2008). Public health effects on consumption of a GE corn are regulated under the FFDCA and food safety reviews are compared to non-GE corn varieties (both those developed for conventional use and for use in organic production systems), which are not evaluated by any regulatory agency in the United States for human food or animal feed safety prior to release into the market.

Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and labeled properly. Food and feed derived from GE organisms must be in compliance with all applicable legal and regulatory requirements. GE organisms used for food and feed purposes undergo a voluntary consultation process with the FDA prior to release into the U.S. market (US-FDA, 2001b). The FDA established this voluntary consultation process to review the safety of foods and feeds derived from GE crops for human and animal consumptions. Although a voluntary process, thus far, all applicants who have wished to commercialize a GE crop variety that would be included in the food supply have completed a consultation with the FDA. In such a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to the FDA a summary of its scientific and regulatory assessment of the food. This process includes: (1) an estimate of the concentration of any expression product in the bioengineered crop or food derived thereof; (2) the expected effect on the composition or characteristic properties of the food or feed; (3) a comparison of the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties with special emphasis on important nutrients, and toxicants that occur naturally in the food; (4) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; (5) an assessment of the protein's potential for digestion; (6) an evaluation of the history of safe use in food (US-FDA, 1997). The FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require (US-FDA, 2014).

Many international agencies also conduct food safety reviews of GE-derived food items, including the European Food Safety Agency (EFSA), Australia and New Zealand Food Standards Agency (ANZFS), Health Canada, China's National Agricultural GMO Biosafety Committee, Japan's Ministry of Health Labor and Welfare, and South Korea's Rural Development Administration.

Food safety reviews frequently will compare the compositional characteristics of the GE crop with non-transgenic, conventional varieties that crop (Aumaitre et al., 2002; FAO, 2009). This comparison also evaluates the composition of the modified crop under actual agronomic conditions, including various agronomic inputs (Monsanto, 2012a; 2012b). Composition characteristics evaluated in these comparative tests include moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and anti-nutrients (OECD, 2002; Monsanto, 2013d).

Anti-nutrients represent an important element of the food safety comparison. Anti-nutrients are naturally-occurring compounds produced by a plant which interfere with the absorption and metabolism of the consumed crop as well as other foods in the digestive tract (Cordain, 1999). Anti-nutrients in corn include raffinose, phytic acid and trypsin inhibitor (OECD, 2002). The nutritional content of corn may also be affected by corn pests and diseases. For example, mycotoxins are chemicals that are produced by fungi and are toxic or carcinogenic to animals and humans (US-EPA, 2010b). The most common mycotoxin in corn is the class of compounds called fumonisins, produced as a result of infections by the fungal genus *Fusarium* (Munkvold and Hellmich, 2000; US-EPA, 2010b). Another class of mycotoxins in corn is the aflatoxins, produced by the genus *Aspergillus* (Munkvold and Hellmich, 1999). Injury by insect pests can be an important factor in mycotoxin development in corn. Insect pests promote the growth of mycotoxin producing fungi by, creating entry wounds on the kernels and carrying fungal spores from the plant surface to damaged kernels (Munkvold and Hellmich, 2000). By reducing insect predation and kernel damage, the incorporation of *Bacillus thuringiensis* (*Bt*) in corn has been shown to reduce contamination by the mycotoxin, fumonisin (Munkvold and Hellmich, 2000).

In general, members of the general public may be exposed to pesticide residues through consumption of agricultural crops. Before a pesticide can be used on a food crop, the EPA, pursuant to the FFDCA, must establish a tolerance value establishing the maximum pesticide residue that may remain on the crop or in foods processed from that crop (21 U.S.C. §301, et seq. ; see also http://www.epa.gov/opp00001/regulating/tolerances.htm). Pesticide tolerances established by the EPA ensure safety of foods treated with pesticides and are made following risk assessments that reflect real-world consumer exposure as closely as possible (US-EPA, 2014c). These tolerances include traditional pesticides, such as herbicides, and genetic elements that may be introduced through GE processes, such as PIPs (e.g., Cry proteins) or proteins that confer herbicide resistance (e.g. EPSPS) (US-EPA, 2007b). Common corn herbicides and PIPs that are currently used in U.S. corn production are listed and reviewed in Section 2 (see Agricultural Production of Corn). The FDA and the USDA monitor foods for pesticide residues. The EPA establishes tolerances, the maximum contaminant level of a pesticide residue allowed on food for human consumption or in animal feed (USDA-AMS, 2011).

RNAi is a natural occurring ubiquitous mechanism in plants, mammals, and other eukaryotes. There is a long history of safe consumption of the RNA molecules mediating this process (Ivashuta et al., 2009). Nucleic acids are present in the cells of every living organism, including every plant and animal used for food by humans or animals, and do not raise a safety concern as a component of food. No evidence suggests that dietary consumption of nucleic acids, like RNA, is associated with toxicity or allergenicity (Petrick et al., 2013). FDA presumes the RNA material to be generally recognized as safe (GRAS) because it does not anticipate that transferred genetic material would itself be subject to regulation as a food additive (US-FDA, 1992c).

The EPA performs mammalian safety risk assessments for PIPs and biochemical products on a case by case basis. The FlavrSavr^{TM} tomato developed by “anti-sense” technology was one of the first plant products approved for human consumption in 1992 by FDA. An engineered potato expressing the gene for potato leaf roll virus replicase was registered as a PIP by EPA in 1998 (US-EPA, 2000a). Another PIP expressing a transgene delivers viral resistance in European plum was registered with the EPA in 2010 (US-EPA, 2010a).

Health effects to the general public, including children in the vicinity of the corn fields may arise from pesticide exposures via incidental ingestion, inhalation, and dermal contact. Pesticide exposures may occur from drift or accidental entry to the field during pesticide application. Adverse health effects to the general public, however, are not anticipated because of the pesticide label directions and restrictions, EPA requires agricultural workers trainings on proper pesticides uses, and restricted entry signage (agricultural worker safety is further discussed in the following section).

2.4.2 Worker Health and Safety

Agriculture is one of the most hazardous industries for U.S. workers. Farmers and, in some instances, family members who share the work and live on the premises, are at a very high risk for fatal and nonfatal physical injuries. Worker hazards in farming are common to all types of agricultural production, and include hazards associated with operation of farm machinery such as cuts, bruises, loss of fingers and limbs and common agricultural management practices, such as pesticide application. To address the high risks of injuries and illnesses experienced by agricultural workers and families, Congress directed the National Institute of Occupational Safety and Health (NIOSH) to develop an agricultural safety and health program in 1990. NIOSH supports and funds programs conducting research on agricultural injuries, as well as pesticide exposure, pulmonary disease, musculoskeletal disorders, hearing loss, and stress.

In consideration of the risk of pesticide exposure to field workers, EPA's Worker Protection Standard (WPS) (40 CFR part 170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 600,000 workplaces on farms, forests, nurseries, and greenhouse (US-EPA, 2014d). The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment (PPE), restricted entry intervals (REI) following pesticide application, decontamination supplies, and emergency medical assistance. The Occupational Safety and Health Administration (OSHA) also requires all employers to protect their employees from hazards associated with pesticides and herbicides. On February 20, 2014, the EPA announced proposed changes[17] to the agricultural WPS to increase protections from pesticide exposure for agricultural workers and their families.

The EPA is proposing to strengthen the protections provided to agricultural workers and handlers under the WPS by improving elements of the existing regulation, such as training, notification, communication materials, use of personal protective equipment, and decontamination supplies. The proposed changes to the current WPS requirements, specifically will improve training on reducing pesticide residues brought from the treated area to the home on workers' and handlers' clothing and bodies. It will also establish a minimum age for handlers and early entry workers, other than those covered by the immediate family exemption to mitigate the potential for children to be exposed to pesticides directly and indirectly. The EPA expects the revisions, once final, to prevent unreasonable adverse effects from exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations; child farmworkers and farmworker families; the general public.

FIFRA requires that all pesticides labeled for use on crops in the United States must be registered by EPA. Among other elements, the EPA pesticide registration process involves the design of use restrictions that, if followed, have been determined to be protective of worker health. Worker safety precautions and use restrictions are noted clearly on pesticide registration labels. These restrictions provide instructions about appropriate levels of personal protection required for agricultural workers to use herbicides. These may include instructions on personal protective equipment, specific handling requirements, and field reentry.

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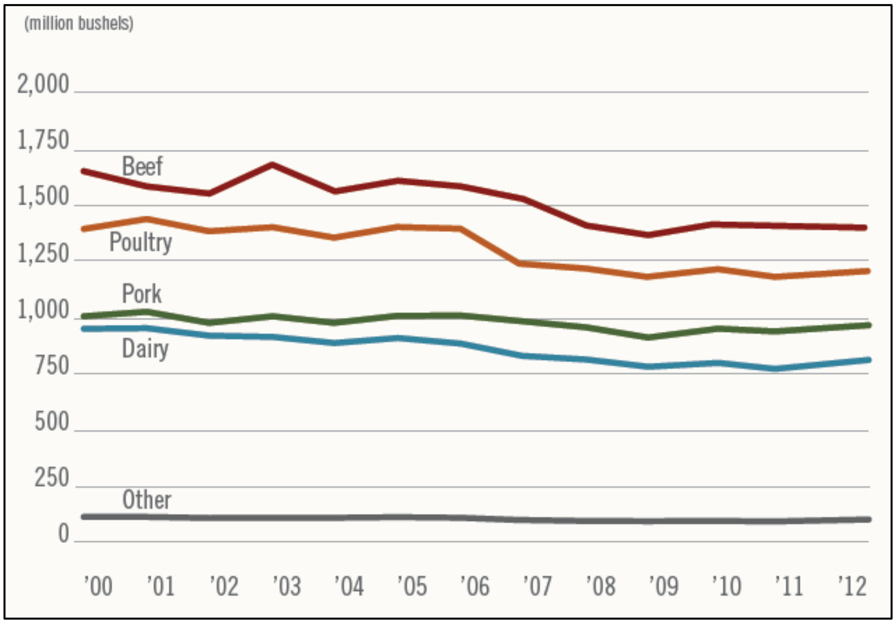
[17] For the proposed changes see: http://www.epa.gov/oppfead1/safety/workers/proposed/index.html

2.5 ANIMAL FEED

Corn comprises more than 96% of the total U.S. feed grain production (USDA-ERS, 2013a). Corn is valuable as a feed because of its composition, including key nutrients, anti-nutrients and secondary metabolites, protein content, and fiber (OECD, 2002). Corn grain is used for feed for beef cattle, poultry, hogs and dairy cattle, with beef cattle consuming the largest volume harvested (NCGA, 2009) (see Figure 8).



Source: (NCGA, 2013)

Figure 8. Livestock Consumption of Maize Feed between 2000-2012.

Animal feed derived from corn comes not only from the unprocessed grain, but also from silage, the above-ground portions of the corn plant, and stalk residues in fields that might be grazed (OECD, 2002). Processed product residuals derived from additional major corn industries (e.g., corn refining, corn dry millers, and distillers) also are used as animal feed (CRA, 2006b). Animal feed products from corn refining and wet milling include corn gluten feed, corn gluten meal, corn germ meal, corn steep liquor, and amino acids (CRA, 2006b).

In addition to direct feeding of corn grain, many corn-based animal feed products are derived from other processes involving chemical or mechanical processing. For example, corn gluten feed is the residue remaining after the extraction of starch, gluten, and germ (CRA, 2006b). Corn gluten feed is considered a medium protein product and is used widely in complete animal feeds for dairy and beef cattle, poultry, and hogs (CRA, 2006b). Corn gluten meal is a high-protein ingredient consisting of corn proteins separated in the milling process, and may contain as much as 60% protein (CRA, 2006b). The high protein content also is valued as a cattle feed to protect the cow's rumen (CRA, 2006b).

Corn germ meal is a residual product obtained from the corn germ after the corn oil has been extracted (CRA, 2006b). Corn germ meal is a small fraction of the corn kernel, and has a small market in animal feed as a carrier for liquid nutrients (CRA, 2006b).

Corn steep liquor is a high protein product comprised of the soluble portions of the corn kernel removed during the corn steep process (CRA, 2006b). Corn steep liquor is sometimes combined with other ingredients in corn gluten feed or provided as a liquid protein source (CRA, 2006b).

Amino acids are produced through the fermentation of corn-derived dextrose (CRA, 2006b). Lysine, an essential animal amino acid, is a highly valued corn-derived amino acid for both poultry and swine (CRA, 2006b). Threonine and tryptophan amino acid feed supplements also are produced from corn (CRA, 2006b).

Similar to the regulatory oversight for direct human consumption of corn under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE corn must comply with all applicable legal and regulatory requirements, which in turn protects human and animal health. To help ensure compliance, GE organisms used for feed may undergo a voluntary consultation process with FDA before being released to the market, which provides the applicant with direction regarding the need for additional data or analysis, and allows for interagency discussions regarding possible issues.

Under Section 408 of the FFDCA, the EPA regulates the levels of pesticide residues that can remain on food or food commodities from pesticide applications (US-EPA, 2010e). The EPA establishes tolerance levels[18] for feed to ensure the safety of raw or processed commodities for animal feed and may include conventional pesticides (e.g., herbicides) and genetic elements resulting from genetic engineering, such as PIPs (e.g., Cry proteins) or proteins conferring herbicide resistance (e.g., EPSPS protein) (US-EPA, 2012c). With regard to pesticides and pesticide residues, growers must adhere to the EPA label use restrictions for pesticides used to produce a corn crop before using it as forage, hay, or silage.

2.6 SOCIOECONOMIC ISSUES

Corn is produced for food and feed commodities and also has industrial uses (USDA-ERS, 2014b)

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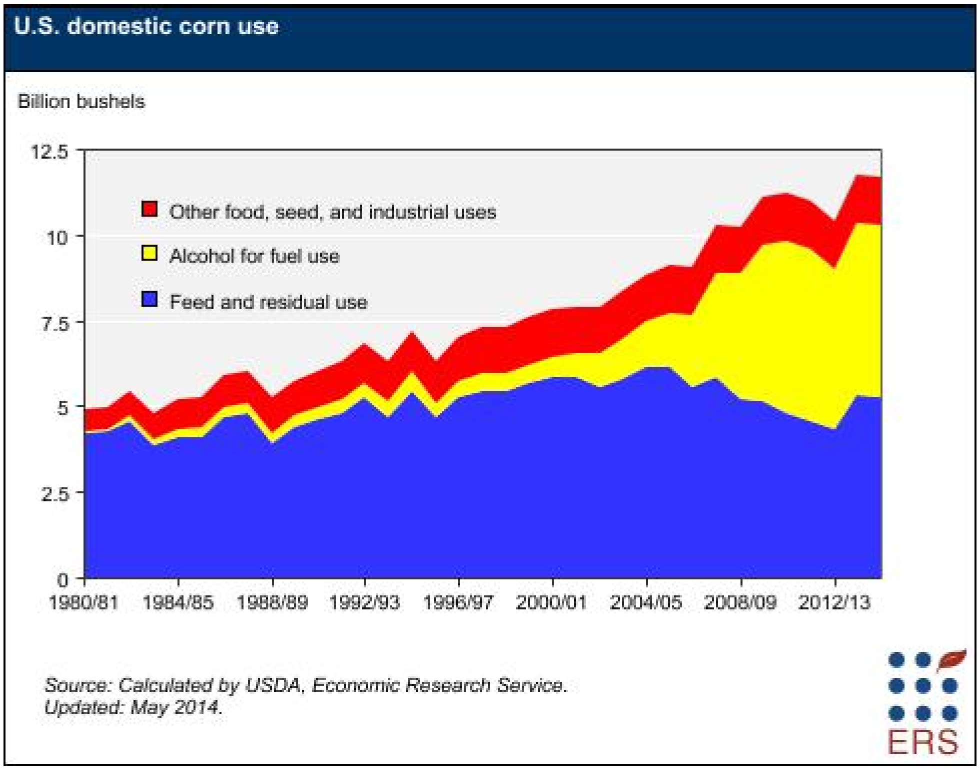
[18] The tolerance level is the maximum residue level of a pesticide that can legally be present in food or feed, and if pesticide residues are found to exceed the tolerance value, the food is considered adulterated and may be seized.

2.6.1 Domestic Economic Environment

Corn processed for human consumption and industrial uses accounts for about one-third of domestic corn utilization (USDA-ERS, 2014c). Food and industrial products derived from corn include starch, sweeteners, corn oil, beverage and industrial alcohol, and fuel ethanol (USDA-ERS, 2014c).

Corn is a major component of livestock feed and is used as the main energy ingredient in livestock feed (USDA-ERS, 2014c). Feed use, a derived demand, is closely related to the number of animals (cattle, hogs, and poultry) that are fed corn. The amount of corn used for feed also depends on crop supply and price, the amount of supplemental ingredients used in feed rations, and the supplies and prices of competing ingredients (USDA-ERS, 2014c). Figure 9 shows the domestic corn uses in the United States from 1980 through 2012. It shows that now, nearly half of U.S. production is consumed as a fuel source (USDA-ERS, 2014c).



Source: (USDA-ERS, 2014c).

Figure 9. U.S. Domestic Maize Use.

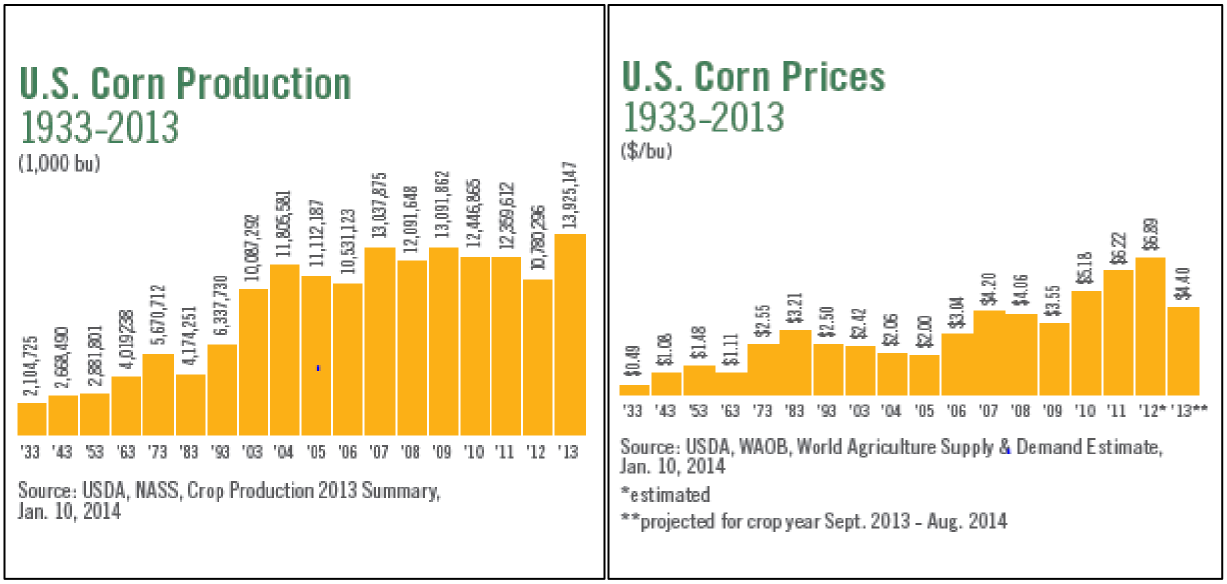
During processing, corn is either wet or dry milled depending on the desired end products: wet millers process corn into high-fructose corn syrup, glucose, dextrose, starch, corn oil, beverage alcohol, industrial alcohol, and fuel ethanol. Dry millers process corn into flakes for cereal, corn flour, corn grits, corn meal, and brewers grits for beer production (USDA-ERS, 2014c).

The production of ethanol generates several economically valuable co-products for animal feed, including distillers dried grains with solubles (DDGs) (USDA-ERS, 2012b). Each 56-pound bushel of corn used in dry mill ethanol production generates approximately 17.4 pounds of DDGs which are fed to livestock (USDA-ERS, 2014c). DDGs have been primarily used as feed for both dairy and beef cattle, but larger quantities of DDGs are being included in the feed rations of hogs and poultry (USDA-ERS, 2014c).

USDA estimated that the total U.S. corn use for the 2013/14 marketing year of approximately 13.5 billion bushels was for livestock feed, ethanol, food products, seed, and exports (USDA, 2014). The total usage estimate is higher than the 11.11 billion bushels used in 2012/13 (USDA, 2014) and the 12.5 billion bushels in 2011/12 (USDA, 2013). Feed and residual use of corn for 2013/14 was reported as 5.3 billion bushels, while food, seed and industrial uses totaled 6.3 billion bushels (USDA, 2014).

USDA estimated 2013 corn production at 13.92 billion bushels, an increase of nearly 38% from the 2012 total corn production that was slightly above 10.78 billion bushels (USDA, 2014) (Figure 10). The average yield in the United States is estimated at 158.8 bushels per acre, above the 2012 average yield of 123.4 bushels per acre. The national average corn price was estimated at $4.40 per bushel for 2013/14, which is lower compared to an estimated 12-month average farm price of $6.89 per bushel for 2012/13 (USDA, 2014) and $6.22 per bushel for 2011/12 (USDA, 2013).

U.S. corn silage production is estimated at 118 million tons in 2013, up 4% from 2012 and represents the highest production in the United States since 1981. Silage yield is estimated at 18.8 tons per acre, an increase of 3.4 tons from 2012.


U.S. Corn Production 1933-2013 (1,000 bu)

Source: USDA, NASS, Crop Production 2013 Summary, Jan. 10, 2014

U.S. Corn Prices 1933-2013 ($/bu)

Source: USDA, WAOB, World Agriculture Supply & Demand Estimate, Jan. 10, 2014

*estimated

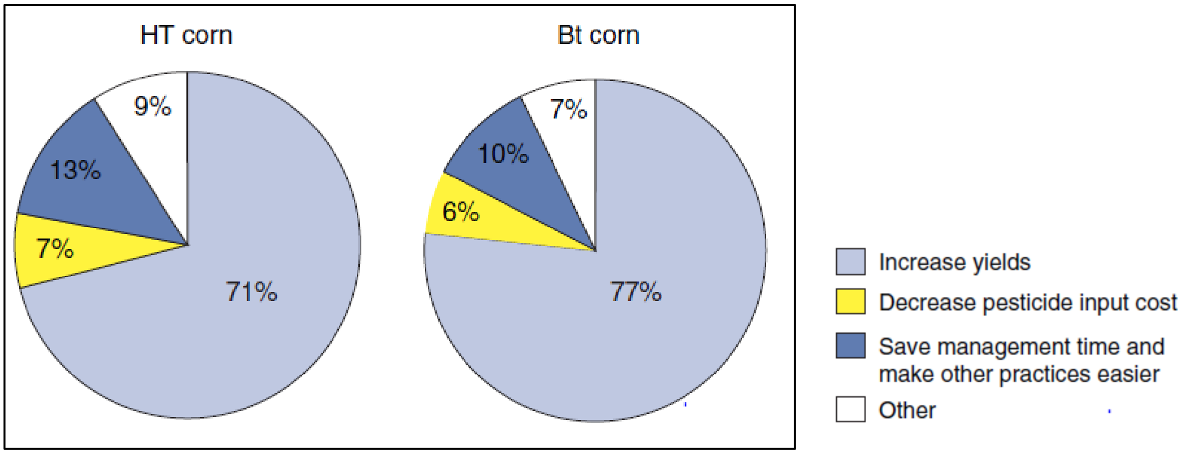
**projected for crop year Sept. 2013 - Aug. 2014

Source: (NCGA, 2014b).

Figure 10. **U.S. Maize Production and Prices between 1933-2013.**

In 2013, a total of 90% of the corn crop planted was GE or approximately 87.6 million acres. Of that number, 14% contained only HR traits, 5% was IR only, and 71% of the total crop was stacked with both GE HR and IR traits (USDA-ERS, 2013b).

The primary economic benefit of the adoption of *Bt* corn derives from the avoidance of pesticide applications and the associated increase in yield (see, e.g., Fernandez-Cornejo and Caswell, 2006; Brookes and Barfoot, 2012). According to the USDA Agricultural Resource Management Survey (ARMS), 77% of corn growers indicated they chose to grow *Bt* corn because of increased yields, while 71% selected HR corn seeds for the same reason (Figure 11). Additional reasons for adopting GE crops included: saving in management time, facilitating other production practices (such as crop rotation and conservation tillage), and reducing pesticide costs (Fernandez-Cornejo et al., 2014b).



Source: (Fernandez-Cornejo et al., 2014b).

Figure 11. Common Reasons Growers Adopt GE Maize.

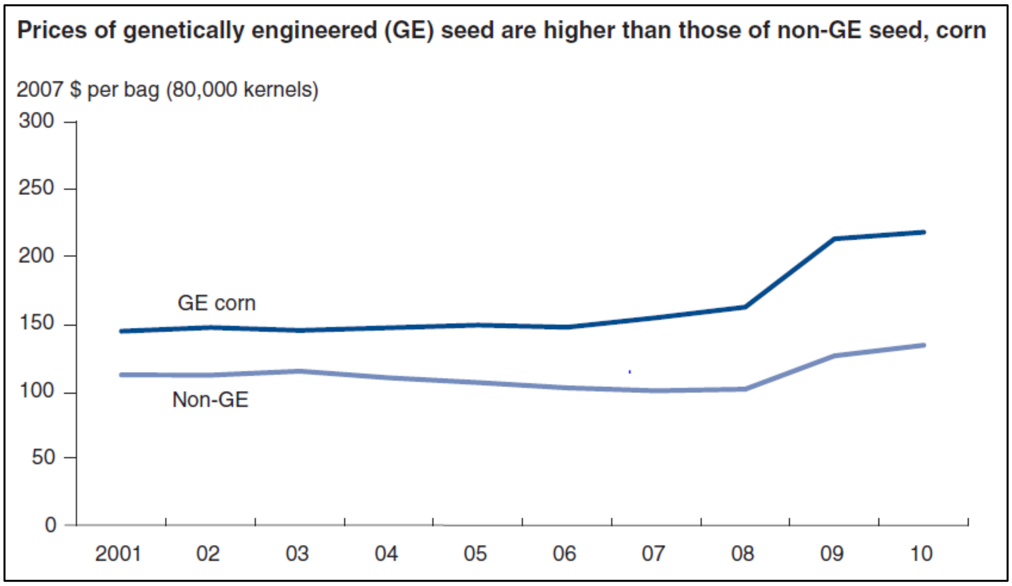
GE crops prevent yield losses by protecting the plant from certain pests, allowing the plant to approach its full yield potential. For *Bt*-corn seed, higher net returns are achieved when pest pressure is high. Because pest pressure varies from one region to another, the economic benefits of *Bt* corn varies regionally. In addition to improvements in background germplasm, *Bt* corn yields have increased over time as new insect resistance traits have been incorporated into the seeds and multiple (stacked) traits have become available (Fernandez-Cornejo and Wechsler, 2012; Fernandez-Cornejo et al., 2014b). USDA ARMS data show that the yield gain by *Bt*-corn adopters relative to conventional varieties increased from 12.5 bushels per acre in 2001 to 16 bushels in 2005 and 26 bushels in 2010 (Fernandez-Cornejo and Li, 2005; Fernandez-Cornejo et al., 2014b).

The incorporation of *Bt* in corn provides an economic benefit to growers by reducing contamination by mycotoxins. Corn that contains mycotoxins above a certain level is more likely to be rejected in the market, forcing growers to accept the lower price for non-food uses (US-EPA, 2010b). The costs of mycotoxins in the U.S. commodity market have been estimated as high as $5 billion/year (Schmale III and Munkvold, 2012).

HR weeds have become increasingly prevalent in recent years, which is likely to increase the cost of weed control. Glyphosate resistance has been demonstrated to reduce the effectiveness and economic benefits of GR-crop systems (Weirich et al., 2011). To manage these resistant weeds, growers generally have increased herbicide application rates, increased the number of herbicide applications, and returned to more traditional tillage practices. The economic impacts of GR weeds are a direct result of increased inputs: additional herbicides are required to control the resistant weeds; fuel costs increase as heavy equipment is used more frequently in the field for chemical application and tillage; tillage, labor, and management hours increase in association with the application of additional herbicides and machinery use (NRC, 2010b; Weirich et al., 2011). There is also an additional cost from the reduction in yield associated with the competition of the crop and the GR weeds (NRC, 2010b; Weirich et al., 2011).

Extension weed scientists estimate that corn growers with GR weeds may incur increased weed control costs in some severe cases of up to $35/acre compared with commonly used glyphosate-based programs, primarily due to applying herbicides with an additional mode of action (Carpenter and Gianessi, 2010). However, growers may be able to control GR weeds in corn without increasing costs, because of the availability of low-cost herbicides with efficacy against GR weeds such as waterhemp and giant ragweed in Minnesota (Carpenter and Gianessi, 2010).

The market price of seed includes the costs associated with seed development, production, marketing, and distribution (Fernandez-Cornejo, 2004; Fernandez-Cornejo et al., 2014b). The price of GE corn seeds increased by about 50% in real terms (adjusted for inflation) between 2001 and 2010 (Figure 12) (Fernandez-Cornejo et al., 2014b). In part, the increase in GE seed prices reflects increasing price premiums (which include technical fees) associated with the rising share of GE seeds with more than one trait and/or more than one mode of action for particular target pests (NRC, 2010b). Improvements in seed genetics (germplasm) also account for some of the increase in GE seed prices (NRC, 2010b). USDA-ERS analyses using 2010 ARMS data found that planting *Bt* corn is more profitable, as measured by net returns, than planting conventional seeds (Fernandez-Cornejo et al., 2014b). The high adoption rate of GE crops indicates the willingness of farmers to pay for improved seed performance and the additional pest management traits embedded in the GE seed (Fernandez-Cornejo et al., 2014b).



Source: (Fernandez-Cornejo et al., 2014b).

Figure 12. Prices of GE and Non-GE Maize Seed between 2001-2010.

2.6.2 Trade Economic Environment

Corn is the dominant feed grain traded internationally (USDA-OCE, 2011b). Corn is cultivated worldwide and during the 2013-2014 growing season, the United States was the largest producer (Figure 13). Most of the corn that is traded is used for feed. Smaller amounts are traded for industrial and food uses. Processed-corn products and byproducts, including corn meal, flour, sweeteners, and corn gluten feed, are also traded

As the global demand for meat increases, so does the commercialization of livestock feeding. In response, international trade in livestock feed and protein meal supplements also increase, particularly in those countries where climate and geography restrict local production of these feed materials (USDA-FAS, 2012; USDA-OCE, 2012a).

The United States is the largest worldwide producer and exporter of corn. Corn grain exports represent a significant source of demand for U.S. producers and make the largest net contribution to the U.S. agricultural trade balance of all the agricultural commodities, indicating the importance of corn exports to the U.S. economy. U.S. corn exports were valued at approximately 5.6 billion dollars.

In 2010/11, the United States produced 38% of the total world supply of corn (USDA-OCE, 2011b). Primary importers of corn from the United States include Japan, Mexico, Korea, Egypt, Taiwan, Syria, the EU and China (USDA-FAS, 2012). (USDA-FAS, 2012)Approximately 15-20% of the U.S. corn production is exported, with the volume of exports projected to increase over the next decade (DAS, 2010a; USDA-OCE, 2011a). Egypt, the EU, Japan, Mexico, Southeast Asia, and South Korea are net importers of corn (USDA-FAS, 2011; USDA-OCE, 2011a; 2011b). China is projected to become a net importer of corn to support its expanding livestock and industrial sectors (USDA-OCE, 2011b). The increase in China's imports is expected to account for one-third of the growth in world corn trade (USDA-OCE, 2011b).

Prices for many major crops are projected to decline in the near term as global production responds to the high prices of recent years. Nonetheless, after these initial price declines, long-term growth in global demand for agricultural products, a low-valued dollar, and continued biofuel demand, especially the United States, the EU, Brazil, and Argentina, will hold prices for corn, oilseeds, and many other crops above pre-2007 levels (USDA-OCE, 2014).

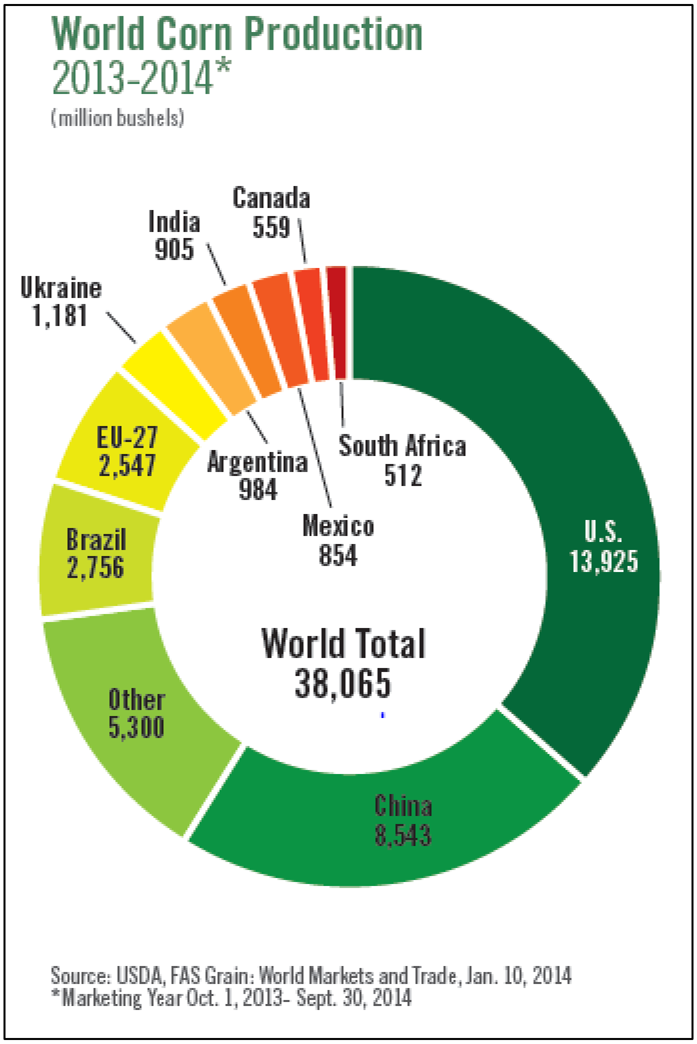


Figure 13. **World Maize Production in 2013-2014.**

Value-enhanced, specialty corn is an important part of the U.S. corn export market. High oil corn, for example, is in high export demand as a replacement for animal fats in feed rations (USDA-FAS, 2004). The challenges associated with maintaining variety identity in international commodity movement increases the costs, as well as the premiums paid, for these specialty crops (USDA-FAS, 2004). Trade in feed for livestock has been a driver of this international trade. Corn gluten feed is a major product in international trade in feed ingredients (CRA, 2006a). Large volumes of U.S. corn gluten feed are exported to the European Union (EU) (CRA, 2006a). The United States is the largest exporter of corn in the world market, exporting 48,500 tons of corn in 2010, compared to a global export market of 92,875 tons (USDA-FAS, 2011). How and where the corn and corn products will be used will be subject to global market conditions. U.S. corn exports are expected to rebound from the weather-induced production shortfalls and reduced exports of the past several years (USDA-OCE, 2014).

Identity protection is important in international trade. Some countries are sensitive to the importation of GE crops, and some have yet to approve importation of GE corn varieties (see, e.g., ICTSD, 2005). Specific end uses also may require identity protection throughout the export supply chain. For example, value-enhanced specialty high-oil corn is an important part of the U.S. export market as a replacement for animal fats in feed rations (USDA-FAS, 2004). Identity protection for organic corn farming and specialty corn systems in international commodity movement increases the costs, as well as the premiums paid (USDA-FAS, 2004).

3 ALTERNATIVES

To respond favorably to a petition for nonregulated status, USDA-APHIS must determine that MON 87411 Maize is unlikely to pose a plant pest risk. Based on its preliminary PPRA (USDA-APHIS, 2014b), USDA-APHIS has made a preliminary determination that MON 87411 Maize is unlikely to pose a plant pest risk. Before the Agency concludes that MON 87411 Maize is no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA, it must also analyze the potential environmental consequences resulting from a determination of nonregulated status of MON 87411 Maize. This is the subject of this draft EA.

Two alternatives are evaluated in this draft EA: 1) no action; 2) a determination of nonregulated status of MON 87411 Maize. These alternatives are summarized in this section. Details about how the Agency assessed the potential for environmental impacts for each alternative are reviewed in Section 4, Environmental Consequences.

Monsanto has indicated its intention to develop stacked hybrids with MON 87411 Maize through conventional breeding techniques (Monsanto, 2013d). In this process, the HR and IR traits in MON 87411 Maize would be combined with the traits from other corn crop varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. USDA-APHIS does not have authority under the PPA and 7 CFR part 340 to review such stacked hybrids developed using nonregulated articles and conventional hybridization techniques if there is no evidence of a plant pest risk. Therefore, this draft EA focuses on the cultivation of MON 87411 Maize. Relevant issues related to impacts that might be associated with stacking are reviewed in the cumulative impacts analyses of this draft EA (see Section 5).

3.1 NO ACTION: CONTINUATION AS A REGULATED ARTICLE

Under the No Action Alternative, USDA-APHIS would deny the petition. MON 87411 Maize and progeny derived from MON 87411 Maize would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by USDA-APHIS would still be required for introductions of MON 87411 Maize and measures to ensure physical and reproductive confinement would continue to be implemented. USDA-APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MON 87411 Maize.

This alternative is not the Preferred Alternative because USDA-APHIS has made a preliminary conclusion in its PPRA that MON 87411 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2014b). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

3.2 PREFERRED ALTERNATIVE: DETERMINATION THAT MON 87411 MAIZE IS NO LONGER A REGULATED ARTICLE

Under this alternative, MON 87411 Maize and progeny derived from it would no longer be regulated articles under the regulations at 7 CFR part 340 because USDA-APHIS has made a preliminary determination that MON 87411 Maize is unlikely to pose a plant pest risk (USDA-

APHIS, 2014b). Permits issued or notifications acknowledged by USDA-APHIS would no longer be required for introductions of MON 87411 Maize and progeny derived from it.

This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the Agency's authority under the plant pest provisions of the PPA. Because the Agency has made a preliminary conclusion that MON 87411 Maize is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87411 Maize is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies of the Coordinated Framework.

Under this alternative, growers may have future access to MON 87411 Maize and progeny derived from this event if the developer decides to commercialize MON 87411 Maize for use in breeding programs.

3.3 ALTERNATIVES CONSIDERED BUT REJECTED FROM FURTHER CONSIDERATION

USDA-APHIS assembled a comprehensive list of alternatives that might be considered for MON 87411 Maize. USDA-APHIS evaluated these alternatives in reference to the Agency's authority under the plant pest provisions of the PPA, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for MON 87411 Maize. Based on this evaluation, USDA-APHIS rejected several other possible alternatives. These alternatives are reviewed briefly below along with the specific reasons for rejecting each.

3.3.1 Prohibit Any MON 87411 Maize from Being Released

In response to public comments that might state a preference that no GE organisms enter the marketplace, USDA-APHIS considered prohibiting the release of MON 87411 Maize, including denying any permits associated with the field testing. USDA-APHIS determined that this alternative is not appropriate because MON 87411 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2014b).

In enacting the PPA, Congress included findings that directed (§402(4); 7 U.S. C. §7701(4)) that: "decisions affecting imports, exports, and interstate movement of products regulated under this title [i.e., the PPA] shall be based on sound science; . . . ."

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee established principles consistent with Executive Order 13563 to guide agencies in the development and implementation of policies for oversight of emerging technologies such as genetic engineering. This guidance included the following principle, among others, to the extent permitted by law:

"Decisions 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 its preliminary PPRA (USDA-APHIS, 2014b) and the scientific data evaluated therein, USDA-APHIS concluded that MON 87411 Maize is not likely to present a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87411 Maize.

3.3.2 Approve the Petition in Part

The regulations at 7 CFR part 340.6(d)(3)(i) state that USDA-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 USDA-APHIS has made a preliminary conclusion that MON 87411 Maize is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the petition only in part.

3.3.3 Isolation Distance between MON 87411 Maize and Non-GE Corn and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, USDA-APHIS considered requiring an isolation distance separating MON 87411 Maize from conventional or specialty corn production. However, because USDA-APHIS has concluded that MON 87411 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2014b), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

USDA-APHIS also considered geographically restricting the production of MON 87411 Maize based on the location of production of non-GE corn in organic production systems in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in the Agency's preliminary PPRA for MON 87411 Maize, there are no geographic differences associated with any identifiable plant pest risks for MON 87411 Maize (USDA-APHIS, 2014b). Therefore, to be consistent with this determination, this alternative was rejected and not analyzed in detail. USDA-APHIS has concluded that MON 87411 Maize does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area (USDA-APHIS, 2014b). Therefore, such an alternative would not be consistent with USDA-APHIS statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340 and the biotechnology regulatory policies described in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet the USDA-APHIS purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the Agency's authority under the plant pest provisions of the PPA. Nevertheless, USDA-APHIS is not expecting substantial impacts. However, individuals might choose on their own to geographically isolate their non-GE corn productions systems from corn incorporating the MON 87411 Maize or to use isolation distances and other management practices to minimize gene movement between cornfields. Information to assist growers in making informed management decisions for hybrid stacks based on MON 87411 Maize is available from Association of Official Seed Certifying Agencies (AOSCA, 2004).

3.3.4 Requirement of Testing for MON 87411 Maize

During comment periods for other petitions requesting a determination of nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. USDA-APHIS notes that there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Furthermore, because MON 87411 Maize does not pose a plant pest risk (USDA-APHIS, 2014b), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR part 340, and the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for MON 87411 Maize would not meet the USDA-APHIS purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.4 COMPARISON OF ALTERNATIVES

Table 3 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this draft EA. The impact assessment is presented in Section 4 of this draft EA.

Table 3. Summary 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 by regulated field trials.	Satisfied by risk assessment (USDA-APHIS, 2014b)
Management Practices		
Areas and Acreage of Corn Production:	90% of U.S. corn is GE; 70% is stacked with HR and IR traits. Market economics is the primary factor influencing U.S. corn acreage and areas of production.	Unchanged[1] from No Action Alternative
Agronomic Practices:	Crop rotation is an effective pest management method widely used in U.S. corn production. Reduced or conservation tillage practices have replaced conventional tillage on more than half of U.S. corn acreage.	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Pesticide Use:	EPA approves and labels uses of herbicides on corn and PIPs in GE corn; chemical insecticide use has declined since the introduction of IR corn varieties.	Herbicide use: Unchanged from the No Action Alternative Insecticide Use: Unchanged or Minimal[2] (Likely Reduced) Compared to No Action Alternative
Organic Farming:	An extremely small (0.25%) of corn production is certified organic; it occurs primarily in sites remote from major GE-corn-growing sites.	Unchanged from No Action Alternative
Specialty Corn including Seed Production:	The U.S. specialty corn crop is small (5%) compared to total U.S. corn production.	Unchanged from No Action Alternative
Physical Environment		
Land Use:	Current trends in acreage and areas of production are likely to continue to be driven by market conditions (i.e., increased demand for U.S. corn and corn products for animal feed, ethanol, etc.) and Federal policy.	Unchanged from No Action Alternative
Soil Quality:	Herbicide use in conjunction with HR corn has promoted conservation tillage; IR corn reduces reliance on chemical insecticide. Both tend to preserve/enhance soil quality.	Unchanged from No Action Alternative
Water Resources:	Agricultural NPS pollution sources (e.g., increased sedimentation from soil erosion; fertilizer and chemical pesticide residues) have declined as agronomic practices such as conservation tillage that mitigate runoff have been adopted for corn production.	Sediment, Fertilizer, Herbicide NPS pollution: Unchanged from No Action Alternative Insecticide Runoff: Minimal (Likely Reduced) Compared to the No Action Alternative
Air Quality:	Pollution from agricultural sources (dust from tilling; drift/diffusion/volatilization of farm chemicals; exhaust emissions from mechanized farm equipment) have declined as mitigating agronomic practices such as conservation tillage have increased in conjunction with the introduction of GE corn.	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Climate Change:	Agriculture-related activities that are sources of GHGs (e.g., exhaust from mechanized farm equipment; soil disturbance from tillage; fertilizer applications) have declined with the introduction of GE corn.	Unchanged from No Action Alternative
Biological Resources		
Animal Communities:	Currently available IR corn varieties do not impact populations of vertebrate and most invertebrate animals other than target pest species (e.g., European corn borer; CRWs). Non-target invertebrates are generally more abundant in *Bt*-corn fields than in fields of non-GE corn. EPA regulates PIPs in IR corn and herbicides applied to HR corn, and determines whether they, including the RNAi PIP that is the subject of this draft EA, pose an unacceptable risk or impact on non-target organisms.	Unchanged from No Action Alternative
Plant Communities:	Plants growing in corn fields are considered weeds. Corn fields are typically bordered by other agricultural fields, woodlands, pastures and grasslands. The most agronomically important members of surrounding plant communities are weeds. Corn growers use production practices to manage weeds in and around fields. EPA regulates herbicides applied to HR corn and PIPS, and determines whether they, including the RNAi PIP that is the subject of this draft EA, pose an unacceptable risk or impact on non-target organisms including plants.	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Soil Microorganisms:	EPA regulates herbicides applied to HR corn and PIPS in corn, and determines whether they, including the RNAi PIP that is the subject of this draft EA, pose an unacceptable risk or impact on non-target organisms including soil microorganisms.	Unchanged from No Action Alternative
Biological Diversity:	Currently available *Bt*-corn crops may increase non-target abundance compared to those treated with broad-spectrum insecticides. There is no evidence of landscape-level impacts from currently available IR HR corn varieties. EPA regulates herbicides applied to HR corn and PIPs in corn, including the RNAi PIP that is the subject of this draft EA, and determines whether they pose an unacceptable risk or impact on non-target organisms, which could adversely affect diversity.	Unchanged from No Action Alternative
Gene Movement	Cultivated corn varieties can cross pollinate. Growers and seed-corn producers use various management practices to eliminate undesired cross pollination.	Unchanged from No Action Alternative
Public Health		
Human Health:	Neither the products of the RNAi mechanism associated with subject of this draft EA, the Cry proteins of *Bt*-corn products nor the PAT protein are toxic to humans, and there are no known allergenic properties for humans.	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Worker Safety:	EPA regulates herbicides applied to HR corn. Workers that routinely handle glyphosate, may be exposed during spray operations. Because of low acute toxicity of glyphosate, and absence of evidence of carcinogenicity and other toxicological concerns, occupational exposure data is not required for reregistration. However, EPA has classified some glyphosate formulations as eye and skin irritants. When used consistent with the label, pesticides present minimal risk to the health and safety of workers.	Unchanged from No Action Alternative
Animal Feed:	Neither the products of the RNAi mechanism associated with subject of this draft EA, the Cry proteins of *Bt*-corn products nor the PAT protein are known to be toxic to any animal species fed corn products.	Unchanged from No Action Alternative
Socioeconomic Environment		
Domestic Economic Environment:	Farm income is positively impacted by currently available *Bt* and HR corn by reducing production costs or increasing revenues. Pest-resistant corn generally has a positive impact on farm income because of cost savings from reduced pesticide use.	Unchanged from No Action Alternative
Trade Economic Environment:	The primary US corn export destinations are also the largest world importers of corn and do not have major barriers for importing food or feed commodities produced from transgenic crops, including those with insect resistance traits. Nevertheless, import of each specific trait requires separate application and approval by the importing country.	Unchanged from No Action Alternative
Other Regulatory Approvals		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
U.S. Agencies:	In a letter dated October 17, 2014 (Appendix A of this draft EA), FDA confirmed completion of a consultation for a food/feed safety and nutritional assessment summary submitted to FDA in November 2013. On March 31, 2004, the EPA established a permanent exemption from the requirement of a tolerance for the PIP, *Bacillus thuringiensis* Cry3Bb1 protein, and the genetic material necessary for its production in food and feed commodities of field corn, sweet corn and popcorn (40 CFR § 180.1214).	Unchanged from No Action Alternative
Compliance with Other Laws		
CAA, CWA, EOs:	Fully compliant	Fully compliant

[1] Unchanged–the current conditions will not change as a result of the selection of this alternative;

[2] Minimal–the current conditions may change slightly as a result of the selection of this alternative, but the changes, if any, are negligible.

4 ENVIRONMENTAL CONSEQUENCES

This section includes details about how USDA-APHIS analyzed potential environmental impacts on the human environment that might result from choosing each of the two alternatives described in the previous (Alternatives) section (Table 3) of this draft EA: (1) No Action Alternative—retain unchanged the current USDA APHIS regulatory restrictions on MON 87411 Maize, (2) Preferred Alternative—determination of non-regulatory status for MON 87411 Maize, so that it is no longer subject to the regulatory requirements of 7 CFR part 340.

4.1 SCOPE OF THE ENVIRONMENTAL ANALYSIS

USDA-APHIS has determined in previous NEPA analyses that there are no significant environmental impacts associated with several GE GR corn varieties that express the CP4 EPSPS protein and GE IR corn varieties that express Cry proteins derived from *Bt* (USDA-APHIS-BRS, 2015). Both of these, the GR and the IR traits, have been combined into stacked varieties of corn that APHIS has previously analyzed and determined not to have significant impacts on the environment. Therefore, the primary focus of the analysis reported in this section is on possible environmental impacts associated with the novel GE trait in MON 87411 Maize, i.e., expression of a double-stranded interference RNA (RNAi) that augments WCR control. The potential impacts from stacking the novel RNAi trait found in MON 87411 Maize in a variety that contains the IR Cry and GR traits are analyzed in the Cumulative Impacts section of this draft EA.

Potential environmental consequences are analyzed here for the following resource attributes: agricultural production of corn, the physical environment, biological resources, human health, animal feed, and socioeconomics. The potential environmental consequences of both the No Action and Preferred Alternative are analyzed under the assumption that the geographic distribution of corn-growing regions of the United States will not change and that farmers who produce conventional corn, specialty corn, organically certified corn and/or MON 87411 Maize will use currently accepted best management practices (BMPs).

4.2 AGRICULTURAL PRODUCTION OF CORN

Recent studies demonstrate that agronomic characteristics and cultivation practices required for MON 87411 Maize are essentially indistinguishable from those used to grow other corn varieties (Monsanto, 2013d; USDA-APHIS, 2014b). None of the BMPs currently employed for corn production are expected to change if MON 87411 Maize is no longer subject to the PPA and the regulatory requirements of 7 CFR part 340. Therefore, the potential impacts on agricultural production from MON 87411 Maize resulting from management practices associated with the No Action and Preferred Alternative are expected to be similar or the same with regard to corn production acreage, agronomic practices, and production of specialty and organically certified corn. Further details about each of these topics follow.

4.2.1 No-Action Alternative: Areas and Acreage of Corn Production

Under the No Action Alternative, MON 87411 Maize could only be grown in regulated field trials. Existing trends in U.S. maize production would not be expected to change: Corn will continue to be cultivated commercially in the United States; most of it continuing to be centered in the Corn Belt (USDA-NASS, 2013b).

Each year, the USDA updates its ten-year projections of supply and utilization for major field crops. The USDA projects that in the 2022/2023 growing season, maize acreage will be 92 million acres. Although some fluctuations are likely during the 2013-2023 period, projected acreage at the end of the decade is about equal to that for 2013 (USDA, 2013). USDA expects that demand for corn will increase during that period. It also expects that this will be achieved with projected yield increases (from 147 bushels/acre in 2012 to 181 bushels/acre in 2023) rather than with an increase in U.S. corn acreage (USDA, 2013).

These USDA projections of stable corn acreage during the next 10 years represent expected conditions under the No-Action Alternative: MON 87411 Maize would continue to be regulated. Because maize is grown widely throughout the United States on land most suited for its production, the location of U.S. maize production is unlikely to change substantially. Only climate change might alter this outcome by shifting production areas in response to hotter and drier growing conditions.

According to a more recent report, USDA projects corn production to decline from 97 million acres to just under 92 million acres in 2014. A further decline to about 88.5 million acres by 2023 is anticipated (USDA-OCE, 2014). This is expected because of projected shifts by growers to soybeans, cotton, and rice. It also reflects an expected trend by growers to grow 2.8 million less acres of field crops overall (USDA-OCE, 2014).

Neither of the scenarios described in the projections cited here is likely to be influenced by a decision to choose the No Action Alternative. Under it, MON 87411 Maize would continue to be regulated by APHIS. Current availability and usage of both GE and non-GE corn would be expected to remain the same under.

4.2.2 Preferred Alternative: Areas and Acreage of Corn Production

Under the Preferred Alternative, nonregulated status of MON 87411 Maize is not expected to extend or increase the area of U.S. corn production relative to the No Action Alternative. The novel RNAi trait, DvSnf7 dsRNA, will augment currently available rootworm control strategies such as *Bt* traits, insecticides, and crop rotation. This additional mechanism for WCR control is designed to suppress rootworm populations which have developed resistance to *Bt* crops so production can be maintained in those areas (Tabashnik et al., 2013; US-EPA, 2013; Gassmann et al., 2014).

Studies demonstrate that cultivation practices for MON 87411 Maize are indistinguishable from other corn varieties (Monsanto, 2013d; USDA-APHIS, 2014b). Therefore, MON 87411 Maize is only expected to replace other corn varieties cultivated currently. Under the Preferred

Alternative, there are no changes in agronomic characteristics in MON 87411 Maize that will result in a change in the area where corn is cultivated in the United States, or an increase in corn acreage by replacing other crops grown or utilizing previously uncultivated land, compared to the No Action Alternative (USDA-APHIS, 2014b).

4.2.3 No Action Alternative: Agronomic Practices—Tillage and Crop Rotation

Under the No Action Alternative, trends related to tillage and crop rotations are likely to continue as currently practiced. Recent data from USDA-ERS and the USDA Agricultural Resource Management Survey (ARMS) indicates a slight increase in conservation tillage over conventional plowing the United States during the period 1998-2010. During this period, no-till activities in U.S. maize production increased by 4% (4.3 million acres). However, adoption of no-till practices was likely caused by shifts by growers already using conservation tillage and not conventional tillage practices (NRC, 2010b). In contrast to other U.S. commodity crop production systems, trends for conservation tillage adoption for U.S. maize are not directly attributable to the adoption of GE- HR-maize varieties (NRC, 2010b). Plant residues in conservation tillage have been identified as a potential challenge for maize disease and pest management. Recommended disease control measures are currently practiced and include cultivation of resistant hybrids, crop rotation, and more careful balancing of conservation tillage with residue management. Resistant hybrids, including GE varieties, offer the most economical options (Robertson et al., 2009).

Under the No Action Alternative, rotation strategies for maize are likely to continue as practiced today, with market demand and available technology influencing maize rotation practices. In 2010, 71% of maize acreage in 19 states surveyed was rotated with another crop (USDA-NASS, 2011c). Maize acreage is a function of market conditions that influence growers to substitute maize for other crops, including the decision to adopt continuous cultivation. This trend is not specific to a single GE maize variety (USDA-ERS, 2011a) and is expected to continue as practiced currently under the No Action Alternative.

4.2.4 Preferred Alternative: Agronomic Practices—Tillage and Crop Rotation

A determination of non-regulated status of MON 87411 Maize would provide growers with an alternative to other currently available CRW-resistant maize varieties. Cropping practices such as rotation are not likely to change as a direct or indirect result of the Preferred Alternative. Although improved CRW-resistant products could potentially reduce pressure on maize, effective control will continue to require crop rotation as a critical component of CRW IPM and efforts to limit development of resistance (Gray, 2011c; 2011d). Stacking with two or more traits effective against CRWs is likely to support better rootworm management. Current simulation models “strongly suggest that pyramided PIPs are superior to the current single trait CRW products” (US-EPA, 2009a). Despite a potential relaxation of a need for rotation in CRW control, other benefits of crop rotation (e.g., increased yield, benefits to soil, farm economics) would remain and could be more important to the grower than convenience of continuous maize production.

Current economic benefits of maize production are the most important incentive effecting changes in crop rotation practices as growers seek to maximize profits. Continuous maize is used by some growers in response to market demands and expectations of higher economic returns (Erickson and Lowenberg-DeBoer, 2005a; Malcolm et al., 2009). A determination of nonregulated status of MON 87411 Maize would not change the price of maize commodities in the United States because prices would continue to be set by market demand. A determination of nonregulated status of MON 87411 Maize would not likely affect decisions by U.S. growers related to rotation versus continuous maize cultivation as a cropping strategy because many other factors influence the choice made (Thomason et al., 2009), and it is predominantly governed by expected economic benefits (Erickson and Lowenberg-DeBoer, 2005b).

A determination of nonregulated status of MON 87411 Maize would not directly or indirectly impact tillage practices, because APHIS makes the assumption that growers have previously optimized these practices for maximizing their economic return and in consideration of relative benefits for specific soil or other physical and environmental conditions on their farm operation. Examples of the tillage decisions maize growers must consider have been summarized (Thomason et al., 2009).

4.2.5 No Action Alternative: Agronomic Inputs

Under the No Action Alternative, current practices related to agronomic inputs in U.S. maize production are likely to continue as currently practiced and described in Section 2

Corn growers will continue to choose certain pesticides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2008). Practices related to fertilizer, insecticide, and herbicide applications (described in Section 2) are likely to continue unchanged. Herbicide use is expected to remain constant and insecticide use is anticipated to decline as more IR varieties are cultivated. Fungicide use, particularly for seed treatment, is expected to continue to increase (Hoeft et al., 2000b; Ruhl, 2007).

Insecticide use in U.S. maize production has steadily decreased as growers adopted GE- IR-maize varieties (Brookes and Barfoot, 2010; Benbrook, 2012; Brookes et al., 2012). Corn growers already have access to the Cry3Bb1 IR trait in MON 87411 Maize. Other IR traits (e.g., Cry34Ab1 and Cry35Ab1) are used to manage European corn borers and CRWs. Refuges will continue to be used to mitigate the development of resistance to *Bt* crops. This includes interspersing non-transgenic plants that do not express the *Bt* Cry proteins. This allows insects that are susceptible to the Cry protein to survive. This strategy has been found to be especially effective when fields are planted with crops that have multiple Cry resistance proteins (Tabashnik et al., 2013). Under the no action alternative, growers will not have access to the DvSnf7 dsRNA trait for WCR control, and will continue to rely on refuges, rotation, and other insect control strategies.

4.2.6 Preferred Alternative: Agronomic Inputs

Under the Preferred Alternative, agronomic inputs associated with U.S. corn production are likely to continue as described in the analysis of the No Action Alternative. MON 87411 Maize will require similar levels of fertilization, and pesticides with the exception of insecticides, as other GE and non-GE varieties of corn because MON 87411 Maize is essentially indistinguishable from other currently cultivated corn varieties in terms of agronomic characteristics, cultivation practices, and disease susceptibility (Monsanto, 2013d; USDA-APHIS, 2014b). The only difference is that MON 87411 Maize will provide growers with access to an additional rootworm control trait.

A determination of nonregulated status for MON 87411 Maize is unlikely to substantially affect glyphosate use in U.S. corn production because this variety will only be used to replace other GR corn varieties and there are no proposed label changes for glyphosate use associated with it (Monsanto, 2013d). Therefore, glyphosate use patterns will remain the same as described for the No-Action Alternative.

Trends related to the development and management of *Bt*-resistant insect pests and GR weed populations are not anticipated to be substantially different for the Preferred and No Action Alternatives. For example, MON 87411 Maize will likely require similar refuge requirements as other IR corn varieties. A determination of nonregulated status for MON 87411 Maize will provide growers with another corn variety that is resistant to glyphosate, and has enhanced resistance to CRWs because of improved resistance to WCR. This will reduce costs to growers from insect damage losses and the direct cost of applying chemical insecticides. The latter will also reduce environmental impacts.

4.2.7 No-Action Alternative: Organic Corn Farming

Under the No Action Alternative, MON 87411 Maize can only be grown in APHIS-regulated field trials. Existing trends in the United States are not expected to change with regard to organic corn production. It is currently occurring in regions where both GE and non-GE varieties are grown, and this would not change under the No-Action Alternative. Organic corn producers use a variety of measures to manage identity and preserve the integrity of their production systems (NCAT, 2003). Organic corn represents a small percentage (approximately 0.2%) of total U.S. corn acreage (USDA-ERS, 2011d). This is not anticipated to change under the No Action Alternative. Current availability of seed for both GE and non-GE corn varieties, and those corn varieties that are developed for organic production, is expected to remain the same under the No Action Alternative. Organic growers are already using accepted agricultural practices to reduce or limit cross pollination between corn varieties. Strategies to support this are not expected to change under the No Action Alternative. Planting and production of GE, non-GE, and organic corn will continue to fluctuate with market demands, as they have over the past 10 years, and these markets are unlikely to be impacted if the No Action Alternative were selected (USDA-ERS, 2011b; 2011c; 2013a).

4.2.8 Preferred Alternative: Organic Corn Farming

Organic production plans prepared pursuant to the NOP include practical methods to prevent co-mingling of organic and GE corn. The adventitious presence of GE corn in organic corn resulting from cross-pollination is a concern (Coulter et al., 2010). However, common agricultural practices are already used by corn growers to limit cross pollination. Typically, organic growers use more than one method to prevent unwanted material from entering their fields including: isolation of the farm; physical barriers or buffer zones between organic production and non-organic production; planting borders or barrier rows to intercept pollen; changing planting schedules, so that flowering and pollination of organic corn does not coincide with that of non-GE varieties; maintaining formal communications between neighboring farms (NCAT, 2003; Baier, 2008; Roth, 2011). These practices follow the same system used for the cultivation of certified seed under the AOSCA procedures. During the growing season, gene flow is managed by understanding corn pollen dispersal and maintaining adequate distances between fields (Thomison, 2009; Mallory-Smith and Sanchez-Olguin, 2011). A minimum isolation distance of 250 feet between varieties is recommended; whereas, 700 feet is preferred for complete isolation (Diver et al., 2008).

Organic corn production is unlikely to be affected by a determination of nonregulated status for MON 87411 Maize because the DvSnf7 dsRNA trait does not alter plant characteristics. Agronomic trials conducted in a variety of locations in the United States demonstrated that MON 87411 Maize is not substantially different in plant growth, yield, and reproductive capacity from non-GE corn. For example, no differences were observed in pollen diameter, weight, and viability between non-GE varieties and MON 87411 Maize (Monsanto, 2013d). Therefore it is not expected to present any greater risk of cross-pollination than that of existing corn cultivars, so the current practices used to preserve and maintain purity of organic production systems would not need to change if MON 87411 Maize were no longer regulated. Therefore, a determination of nonregulated status for MON 87411 Maize is not expected to have significant impacts on organic corn production, nor differ from that of the No-Action Alternative.

4.2.9 No-Action Alternative: Specialty Corn Production

Specialty corn is currently produced in the presence of both GE varieties and other non-GE corn varieties. This is unlikely to change under the No Action Alternative. Specialty crop growers employ practices and standards for seed production, cultivation, product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops (Bradford, 2006). These management practices include maintaining isolation distances to prevent pollen movement from other corn sources, planting border or barrier rows to intercept pollen, changing planting schedules to ensure flowering at different times, and employing natural barriers to pollen (Wozniak, 2002; NCAT, 2003; Bradford, 2006; Thomison, 2009; Roth, 2011). These management practices allow the grower to meet standards for the production of specialty crop seed, maintain genetic purity, and protect the genetic diversity of corn (Bradford, 2006).

4.2.10 Preferred Alternative: Specialty Corn Production

To preserve seed integrity, specialty corn production uses the same as those described for organic corn production. No changes in the production or cultivation of specialty corn are required to accommodate MON 87411 Maize, as it is similar to conventional corn, and GE-corn varieties that are no regulated. According to the petition, agronomic trials conducted in a variety of locations in the United States demonstrated that MON 87411 Maize is not substantially different in plant growth, yield, and reproductive capacity from its conventional corn (Monsanto, 2013d; USDA-APHIS, 2014b). No differences were observed in pollen diameter, weight, and viability. Therefore, MON 87411 Maize is expected to present a similar risk of cross-pollination as existing corn cultivars including other GE corn varieties. The practices currently employed to preserve and maintain purity of specialty corn production systems would not be required to change to accommodate the production of MON 87411 Maize if it were no longer regulated. Therefore, a determination of nonregulated status for MON 87411 Maize under the Preferred Alternative would not change the availability and genetic purity of seed for specialty corn varieties. Conventional management practices and procedures, as described previously for corn seed production, proper seed handling, protection of wild relatives of corn, and organic corn farming, are in place to protect and maintain the genetic diversity of corn. Corn growers have used these methods effectively to meet the standards for the production of specialty crop seed. Therefore, Selection of the Preferred Alternative would not differ in impact from that of the No Action Alternative.

4.3 PHYSICAL ENVIRONMENT

Recent studies demonstrate that agronomic characteristics and cultivation practices required for MON 87411 Maize are essentially indistinguishable from those used to grow other corn varieties (Monsanto, 2013d; USDA-APHIS, 2014b). None of the BMPs currently employed for corn production are expected to change if MON 87411 Maize is no longer subject to the PPA and the regulatory requirements of 7 CFR part 340. Therefore, if MON 87411 Maize were no longer regulated, the potential impacts on components of the physical environment (i.e., soil quality, water resources, air quality and climate change) associated with the No Action and Preferred Alternative are expected to be similar. Details about each of these topics follow.

4.3.1 No Action Alternative: Soil Quality

Current agronomic practices associated with corn production including tillage, cultivation, applications of pesticides and fertilizers, and the use of agricultural equipment are not expected to change under the No Action Alternative. Modern mechanized cultivation practices reduce insecticide use, and substitute glyphosate for more toxic herbicides, providing potential indirect soil quality benefits (Towery and Werblow, 2010; Brookes et al., 2012). This reduces risks to the soil environmental from spills or misapplications of chemical herbicides and insecticides because modern application methods following BMPs are highly precise and efficient. These practices slow soil erosion and filter pollutants from surface runoff. They include vegetated strips that control spray drift, and other pesticide label requirements that ensure safe application, and cleanup, which minimize potential pesticide impacts on soil (US-EPA, 2008).

Since many types of IR corn expressing the Cry proteins and the GR trait, either individually or combined in stacked varieties are no longer regulated and are currently planted in the United States, the practices and impacts associated with their cultivation will not change under the No Action Alternative. The *Bt* source for the Cry3Bb1 protein is ubiquitous in soils (US-EPA, 1998). *Bt* toxins may persist in soils for several months (US-EPA, 1998). However, proteins do not bio-accumulate. The biological nature of these Cry proteins makes them readily susceptible to metabolic, microbial, and abiotic degradation (US-EPA, 2010b; 2010a). Field deposition of Cry proteins is associated with plant material (i.e., pollen, crop residue) or plant root exudates such as carbohydrates and amino acids (US-EPA, 2010b; 2010a). This plant material typically stimulates microbial activity and reproduction. The EPA has determined that the Cry proteins are degraded rapidly by soil microorganism (US-EPA, 2010b; 2010a).

Some early experiments indicated that Cry proteins persist in soil. These used bulk soil samples, rather than soil representing field conditions (US-EPA, 2010b; 2010a). These bulk soil experiments did not represent the realistic field conditions that include natural degradation pathways in soil (US-EPA, 2010b; 2010a). Based on this, EPA expects that degradation rates under field conditions are higher than bulk soil experiments would suggest (US-EPA, 2010b; 2010a). EPA did find that the Cry proteins degraded slower in soils with a low pH (i.e., pH 5). However, corn does not grow well in soils below pH 5.6. Therefore, under typical production conditions, corn would not be grown on soils that would inhibit the rate of degradation (US-EPA, 2010b; 2010a).

4.3.2 Preferred Alternative: Soil Quality

Under the Preferred Alternative, soil quality is not anticipated to be impacted differently than what is expected under the No Action Alternative. No changes to agronomic practices typically applied in the cultivation of GE and non-GE corn will required if MON 87411 Maize is no longer regulated (Monsanto, 2013d). Field trials and laboratory analyses demonstrated that the agronomic performance of MON 87411 Maize was functionally equivalent to the non-transgenic control varieties (Monsanto, 2013d; USDA-APHIS, 2014b). Cultivation of MON 87411 Maize did not require changes in the management of volunteer corn or other agronomic practices such as cultivation, planting, and harvesting (Monsanto, 2013d). Practices used for corn varieties under the No Action Alternative would be the same as those for MON 87411 Maize if it were no longer regulated.

Under the Preferred Alternative, MON 87411 Maize, the nucleic acids associated with the expression of the double-stranded RNAi trait would be present in the environment. However, this is one of a class of compounds that are already constantly present in the environment. There is no evidence that that DvSnf7 dsRNA will persist or function any differently in soil than naturally occurring dsRNA. One degradation study found that DvSnf7 dsRNA was undetectable within two days of soil application (Dubelman et al., 2014). These results are described in greater detail in Cumulative Impacts: Physical Environment below.

4.3.3 No Action Alternative: Water Resources

Under the No Action Alternative, current land acreage and agronomic practices, including irrigation, tillage, and nutrient management associated with U.S. corn production would not be expected to change. U.S. growers will continue to cultivate the same corn varieties and use the same agronomic practices and inputs associated with those varieties. These include current uses of glyphosate in conjunction with both GE GR corn and non-GE varieties. They also include insect integrated pest management (IPM) practices used in conjunction with GE- IR-corn varieties that express Cry proteins.

The Cry protein in MON 87411 Maize is already used in U.S. GE IR corn production, so EPA has already evaluated potential impacts to surface water from Cry proteins as PIPs. The only major source of Cry proteins in freshwater is from corn pollen and residues of plant tissues (US-EPA, 2010b; 2010a). Cry proteins are not considered a risk to drinking water or groundwater (US-EPA, 1998).

4.3.4 Preferred Alternative: Water Resources

Under the Preferred Alternative, no substantial impacts to water resources are anticipated from a determination of nonregulated status of MON 87411 Maize, as it is functionally equivalent to currently-cultivated corn varieties. With regard to irrigation, no differences in morphological characteristics and agronomic requirements were found between MON 87411 Maize, other GE varieties, or conventional corn (Monsanto, 2013d; USDA-APHIS, 2014b). Since MON 87411 Maize would not increase the total acreage of corn or and range of regions within the United States where corn, and it is only expected to replace some corn varieties with similar moisture requirements, the consequences of the Preferred Action Alternative on water use in corn production are the same as the No Action Alternative. Therefore, a determination of nonregulated status of MON 87411 Maize is unlikely to change the current use of irrigation practices in commercial corn production compared to the No Action Alternative.

Two of the genetic elements in MON 87411 Maize express proteins, Cry3Bb1 and CP4 ESPS, have been evaluated by EPA for potential impacts to surface water described in the No Action Alternative. Cry proteins are not considered a risk to drinking water or groundwater (US-EPA, 1998). It is not anticipated the inclusion of DvSnf7 dsRNA will have any impact on water usage or water runoff because this trait will not impact tillage practices. Nucleic acid elements such as RNAi have limited stability in water because of the presence of naturally occurring enzymes that metabolize and break down RNA. Therefore, it is not anticipated that DvSnf7 RNA will persist in water, or impact water use, so no differences between the Preferred Alternative and the No Action Alternative are likely.

4.3.5 No Action Alternative: Air Quality

Agricultural practices have the potential to impact air quality. Agricultural emission sources include smoke from agricultural burning, tillage, heavy equipment emissions, pesticide spray drift, carbon dioxide and nitrous oxide emissions from the degradation of organic materials disrupted by soil tillage, and emissions from nitrogen fertilizer applications (USDA-NRCS, 2006a; Aneja et al., 2009). Modern corn agronomic practices have the potential to reduce several of these sources. For example, conservation tillage requires less plowing, which decreases dust and tractor exhaust emissions. It also allows surface residues to accumulate, which creates a physical barrier that promotes soil retention. This decreases airborne soil erosion and drift of soil-borne pesticide residues in wind-eroded soils.

Under the No Action Alternative, current impacts to air quality associated with land acreage and cultivation practices associated with corn production, including cultivation practices related to GE corn varieties are not likely to change. This includes both direct air quality impacts, e.g., emissions from farm equipment, airborne soil erosion and pesticide drift. It also includes indirect air quality impacts, such as decreased carbon dioxide emissions associated with the use of conservation tillage (Hoeft et al., 2000b; USDA-NRCS, 2006a; Aneja et al., 2009; US-EPA, 2012a).

4.3.6 Preferred Alternative: Air Quality

Under the Preferred Alternative, no differences in impacts on air quality is likely from a determination of nonregulated status for MON 87411 Maize compared to the No Action Alternative.

MON 87411 Maize has similar agronomic requirements to those of currently cultivated commercial GE and non-GE corn varieties, (USDA-APHIS, 2014b). Therefore, MON 87411 Maize production is unlikely to change land acreage or any cultivation practices for conventional, transgenic, or non-transgenic corn, so the potential to impact air quality will be the same for MON 87411 Maize. The additional novel DvSnf7 dsRNA trait would not change the agronomic inputs associated with this variety with the possible exception of reducing the need for chemical insecticides to control WCR, which has the potential to reduce impacts on air quality from spray drift and residue associated air-borne soil erosion. As mentioned above, this trait also does not require alterations to current cultivation practices that would impact air quality such as increased tillage. The DvSnf7 dsRNA trait will not impact air quality directly because it is non-volatile, nor will it indirectly as residue associated with air-borne soil erosion because it is rapidly degraded (Dubelman et al., 2014). Therefore, USDA-APHIS concludes that the cultivation of MON 87411 Maize is not expected to adversely affect air quality.

4.3.7 No Action Alternative: Climate Change

Agriculture, including land-use changes associated with farming, is responsible for an estimated 6% of all human-induced GHG emissions in the United States (US-EPA, 2012a). Agriculture-related GHG emissions include CO_2, N_2O, and CH_4, produced from combustion in mechanized farm equipment; fertilizer applications; decomposition of agricultural waste products, including crop residues, animal wastes; enteric emissions from livestock. N_2O emissions from agricultural soil management (primarily nitrogen-based fertilizer use) represent 69% of all U.S. N_2O emissions (US-EPA, 2012a).

Conservation tillage has been identified an agronomic practice that reduces GHG emissions (Brenner et al., 2001). Conservation tillage increases carbon sequestration in soils. Converting from conventional tillage to a no-till corn-soybean rotation in Iowa, for example, has been estimated to increase carbon sequestration by 550 kg/hectare (485 pounds/acre) per year (Paustian et al., 2000; Brenner et al., 2001; Towery and Werblow, 2010) .

To the extent that U.S. corn growers are able to implement conservation practices, GHG emissions are expected to continue to decline. For example, the EPA has identified a net reduction in the sequestration of carbon in soil over a 20-year time scale, which it attributes to the declining influence of the Conservation Reserve Program. The CRP encouraged growers to take marginal lands out of production (US-EPA, 2012b). To a certain extent, the EPA also noted that adoption of conservation tillage resulted in increases in carbon sequestration in soils on those croplands (US-EPA, 2012b). The highest rates of carbon sequestration in mineral soils occurred in the Midwest, which is the region with the largest area of cropland managed with conservation tillage (US-EPA, 2012b). In contrast, the highest emission rates from organic soils were noted in the southeastern coastal region, the areas around the Great Lakes, and the central and northern agricultural areas along the West Coast (US-EPA, 2012b).

Under the No Action Alternative GHG emissions associated with U.S. corn production would not change as a result of the continued regulation of MON 87411 Maize. Currently cultivated corn varieties similar to MON 87411 Maize will continue to be grown in the United States. Therefore, the common agronomic practices associated with these varieties that affect GHG emissions (e.g., tillage, cultivation, irrigation, pesticide and fertilizer applications, mechanized agriculture equipment) will not to change under the No Action Alternative, these common agricultural practices are also not expected to change if MON 87411 Maize remains a regulated article.

4.3.8 Preferred Alternative: Climate Change

Under the Preferred Alternative, a determination of nonregulated status of MON 87411 Maize will not result in an increase in U.S. corn acreage, nor will it change the cultivation or agronomic practices, or agricultural land acreage associated with growing corn because it will only replace other GR IR that have the same impacts on GHG emissions. The presence of the novel DvSnf7 dsRNA trait in MON 87411 Maize does not produce direct airborne emissions, nor does it indirectly affect agronomic practices that impact GHG emissions, so it is not anticipated to affect climate change. Based on these findings, there are no substantial differences between the No Action Alternative and the Preferred Alternative with regard to impacts on climate change.

4.4 BIOLOGICAL RESOURCES

Recent studies demonstrate that agronomic characteristics and cultivation practices required for MON 87411 Maize are essentially indistinguishable from those used to grow other corn varieties (Monsanto, 2013d; USDA-APHIS, 2014b). None of the BMPs currently used for corn production are expected to change if MON 87411 Maize is no longer subject to the PPA and the regulatory requirements of 7 CFR part 340. Therefore, if MON 87411 Maize were no longer regulated, the potential impacts on biological resources associated with the No Action and Preferred Alternative are expected to be similar or the same with regard to animal and plant communities, soil microorganisms, biological diversity, gene movement, human health, and animal health More details about each of these topics follow.

4.4.1 No Action Alternative: Animal Communities

Corn production systems support a variety of animal species. Among the most significant are insects, birds, and mammals. Insects, including some pests of corn and many beneficial species, utilize cornfields and the surrounding habitats. They feed on corn plants, prey on other insects and utilize cornfields for a multitude of harborage sites. To a lesser extent, birds, mammals and a few reptiles do likewise. All of these species may utilize aquatic habitats near cornfields, which in addition support fish.

Under the No Action Alternative, MON 87411 Maize will remain a regulated article. The genetic traits of MON 87411 Maize expressing Cry and PAT proteins that confer resistance to insect pests and glyphosate are present in many varieties of GE corn that are widely grown in the United States and are no longer regulated under 7 CFR part 340. Therefore, selection of the No-Action Alternative will not alter impacts on wildlife from corn cultivation in the United States.

Most birds and mammals that occur in corn fields feed on corn, but do not nest in or use fields for harborage during the growing season because of frequent disturbances (e.g., use of agricultural machinery, application of pesticides, etc.). The EPA considers non-target animal exposure in the registration of pesticides under FIFRA, including the review of Cry proteins as a PIP (US-EPA, 2010a; 2010b). The EPA has also evaluated environmental exposures based on laboratory studies to determine lowest observed effect concentrations (LOECs) and no observed effects concentrations (NOECs) (US-EPA, 2010a). In these studies, the EPA has found no overt indication of toxicity to wildlife associated with anticipated exposures under field conditions (US-EPA, 2010a; 2010b). USDA-APHIS has found no evidence that the presence of the *Bt* and *pat* genes or the accumulation of the Cry and PAT proteins would have any impact on animals, including animals beneficial to agriculture (USDA-APHIS, 2014b). Under the No Action Alternative, non-target invertebrates and vertebrate species will continue to be exposed to GE IR and IR corn varieties and their respective introduced proteins at the current rate. Therefore, potential impacts will continue unchanged.

4.4.2 Preferred Alternative: Animal Communities

Under the Preferred Alternative, potential impacts on wildlife are not anticipated to be substantially different compared to the No Action Alternative. Results from testing and animal models that represent organisms present in the environment, including birds, vertebrates and invertebrates, found no negative impacts (Monsanto, 2013c). These results indicated that none of the GE traits in MON 87411 Maize caused any detectable adverse effects on the representative species tested. Studies of potential allergenicity and toxicity from the three proteins introduced in MON 87411 Maize indicated no meaningful amino acid similarities with known allergens or toxins (Monsanto, 2013d).

The novel element in MON 87411 Maize is gene silencing by dsRNA in western CRW. This is a highly specific trait. Monsanto researchers tested 10 species of insects that were phylogenetically related to WCR to evaluate the specificity of DvSnf7 dsRNA (Bachman et al., 2013a). In direct feeding studies, the likelihood of off-target effects declined as divergence increased (i.e., in species less closely related to WCR) (Bachman et al., 2013a). The DvSnf7sequence itself has been tested in a variety of phylogenetically related insects by direct assays, or in organisms required by EPA for PIPs, including earthworm, honeybee, parasitic wasp, ladybird beetle, carabid beetle and the insidious flower bug. No adverse effects were observed. The EPA has authority for evaluating this and all other PIPs under FIFRA, so will make its decision regarding the available data relevant to DvSnf7 dsRNA by issuing, conditionally issuing, or denying a registration of MON 87411 Maize.

USDA-APHIS has determined that because of its high specificity, it is highly unlikely DvSnf7 dsRNA will impact individual animals or animal communities in a manner that will result in a plant pest risk, nor will it cause any other substantial impacts. The Agency determined that the high level of sequence specificity attributable to western CRW single nucleotide polymorphism is also highly unlikely to promote the development of resistance in this pest (Bachman et al., 2013b). Potential impacts resulting from an interaction between the three traits expressed by MON 87411 Maize considered in Section 5 of this draft EA (Cumulative Impacts).

Based on the information presented here and that reviewed for the No Action Alternative, USDA-APHIS has determined that impacts on individual animal and animal communities under the Preferred Alternative are substantially the same as those under the No Action Alternative.

4.4.3 No-Action Alternative: Plant Communities

The landscape surrounding a cornfield can be bordered by a number of different plant communities, including other crop fields, woodland, fencerows, rangelands, grasslands and pasture. These plant communities may represent natural or managed plant buffers for the control of soil and wind erosion, and may serve as habitats for a variety of wildlife species.

The surrounding plant landscape may influence non-crop plants that grow within a corn production fields. These are considered weeds because they compete with the crop for space, water, nutrients, and sunlight (IPM, 2004; 2007; University of California, 2009). Weed control programs are important aspects of corn cultivation. The types of weeds in and around a cornfield will vary depending on the geographic region where the corn is grown. Because sexually compatible species in typical plant communities that grow near cornfields do not share pollen with corn, transfer to such plants is not a concern. The most important potential impacts to plants near cornfields are from pesticide drift or runoff. EPA registers and labels pesticides, and enforces pesticide label specifications to ensure no unreasonable adverse impacts to non-target plants.

Under the No Action Alternative, MON 87411 Maize would continue to be regulated by APHIS. Currently available GE and non-GE corn varieties will remain unchanged, so any impacts on U.S. plant communities associated with corn cropping systems will remain the same.

4.4.4 Preferred Alternative: Plant Communities

With the exception of CRW protection mediated by RNAi gene suppression, MON 87411 Maize is not different from other GE IR GR corn varieties, and with the exception of its three GE traits, it is phenotypically and agronomically equivalent to non-GE commercial maize. No substantial differences between MON 87411 Maize and non-GE corn were observed in tests of seed germination characteristics, dormancy or pollen characteristics (Monsanto, 2013c). The novel RNA-mediated gene suppression trait is only active against CRWs, and expresses no activity in any plant species. Therefore, the Preferred Alternative is not expected to differ from the No-Action Alternative with respect to plant communities.

4.4.5 No Action Alternative: Soil Microorganisms

Soil bacterial communities are influenced by plant species and cultivars as are other environmental factors, such as soil type and agricultural practices (Icoz et al., 2008). Microorganisms that colonize the rhizosphere are affected by plant type and root exudates (Icoz et al., 2008). While *B. thuringiensis* occurs naturally in soil, growing transgenic *Bt* corn increases the amount of Cry endotoxins present in agroecosystems (Blackwood and Buyer, 2004). Most proteins, however, do not persist or accumulate in soils because they are inherently degradable in soils that have normal microbial populations (Icoz and Stotzky, 2008a). The numbers of microorganisms and the activity of some enzymes involved in the degradation of plant biomass exhibit substantial seasonal variation probably as a result of differences in the water content of soils, ambient temperatures, and plant stage growth at the time of sampling (Icoz and Stotzky, 2008a). Cry protein concentrations in the rhizosphere vary during the growth of the plant and can be affected by microbial activity, which depends in part on soil temperature and humidity (Baumgarte and Tebbe, 2005).

In general, cultivation of GE crops has not been demonstrated to present environmental risks to soil microbial populations (Vencill et al., 2012). The diversity of microbial populations may be affected by these crops, but effects reported to date have been transient and minor (Dunfield and Germida, 2004; Vencill et al., 2012). These conditions would not change under the No Action Alternative because current agronomic practices associated with currently available GE and non-GE corn would not alter the way soil microorganisms are affected in U.S. corn cropping systems.

4.4.6 Preferred Alternative: Soil Microorganisms

With the exception of CRW protection and glyphosate resistance, MON 87411 Maize is phenotypically and agronomically equivalent to non-GE commercial maize. With the exception of the DvSnf7 RNA trait, the same GR and CRW-protection (Cry) traits are currently available in other GE corn varieties that are no longer regulated. The RNA-mediated gene suppression mode of action (MOA), is the only difference from commercially available GE maize. As noted under the No Action Alternative, Cry proteins do not accumulate or persist in soils (Icoz and Stotzky, 2008b; Icoz and Stotzky, 2008a). In general, nucleic acids, including the DvSnf7 RNA produced in MON 87411 Maize, are not expected to persist in soil either (Widmer et al., 1996; Dale et al., 2001; Dale et al., 2002; Dubelman et al., 2014) as they are continually being degraded by natural processes.

With regard to DvSnf7 dsRNA in soil, DvSnf7 dsRNA from dried root and shoot corn tissue was found to degrade within two days for all samples tested, independent of the starting RNA concentration, even at orders of magnitude higher than present in corn plants expressing DvSnf7 dsRNA (Dubelman et al., 2014).

Based on these studies, APHIS concludes that DvSnf7 dsRNA will not accumulate to cause impacts on soils or soil organisms because the persistence in soils is unlikely. Therefore, impacts from the cultivation of MON 87411 Maize on soil microorganisms are not expected to differ from the No Action Alternative.

4.4.7 No-Action Alternative: Biological Diversity

GE crops have reduced the impacts of agriculture on biodiversity by facilitating conservation tillage practices, reducing chemical insecticide use, and enabling the replacement of more toxic herbicides with less toxic ones, while increasing yields, which contributes to a reduction of agricultural land use and preservation of natural habitat. (Young and Ritz, 2000; Jasinski et al., 2003; Carpenter, 2011). Insecticide applications are substantially reduced compared to non-GE varieties, where GE *Bt* corn is grown. This has been shown to promote conservation of the natural enemies complex, which is a substantial component of biodiversity in corn cultivation (Romeis et al., 2006).

These conditions will continue to prevail if MON 87411 Maize continues to be a regulated article under the No-Action Alternative. Growers and other parties who are involved in production, handling, processing, or consumption of corn would continue to have access to currently available GE HR and IR corn varieties that are no longer regulated. Consequences of current agronomic practices associated with both GE and non-GE corn production on the biodiversity of both plant and animal communities are not likely to be altered.

4.4.8 Preferred Alternative: Biological Diversity

Results of field trials comparing MON 87411 Maize with conventional corn indicate that there are no meaningful differences in agronomic attributes between MON 87411 Maize and conventional varieties (Pioneer, 2012; Monsanto, 2013d). With the exception of CRW protection and glyphosate resistance, MON 87411 Maize is phenotypically and agronomically equivalent to non-GE commercial corn. No significant differences were observed in seed germination characteristics, dormancy or in pollen characteristics (Monsanto, 2013d). The same GE GR and IR *Bt* traits in MON 87411 Maize are currently available in other GE varieties.

With reference to the GR trait in MON 87411 Maize, if no longer regulated, applications of glyphosate on it will be subject to the same label requirements as those for other Monsanto GR corn varieties that are no longer regulated. Monsanto is not seeking a change in application rates or uses of glyphosate for the cultivation of MON 87411 Maize.

The RNA-mediated gene suppression MOA for CRW control is the only unique trait associated with MON 87411 Maize. The DvSnf7dsRNA sequence has been tested in a variety of phylogenetically related insects by direct assays, as well as in those tests required by EPA for PIPs. These include earthworm, honeybee, parasitic wasp, ladybird beetle, carabid beetle and the insidious flower bug. No adverse effects were observed.

Based on the best available information, APHIS concludes that there is no difference between impacts associated with the No-Action Alternative and those of the Preferred Alternative with regard to biodiversity.

4.4.9 No-Action Alternative: Gene Movement

Vertical gene flow, or introgression, is the movement of genes to sexually compatible relatives and their subsequent expression (Ellstrand, 2003; Quist, 2010). Horizontal gene transfer is the stable movement of genes from one organism to another without reproduction or human intervention (Keese, 2008; Quist, 2010).

Under the No Action Alternative, conventional and GE transgenic corn production will continue unchanged. The possibility of gene movement from cultivated corn varieties into native or feral populations of *Zea* spp. or wild or weedy relatives of corn has been evaluated by the EPA and determined not to be a concern in the continental United States (US-EPA, 2010c). Vertical gene flow from currently cultivated corn varieties in the United States, to populations of *Zea* or *Tripsacum* spp.is not likely, with the limited exception of potential gene flow to feral populations of *Zea mays spp. parviglumis* in Florida and to a lesser extent, *Tripsacum floridanum*, also in Florida. Differences in flowering time between corn and these species, and current geographic separation of these species from the majority of U.S. corn production regions indicate these occurrences are a rarity and a minor concern (Galinat, 1988; Doebley, 1990, Doebley, 1990 #539; Baltazar et al., 2005; Kermicle and Evans, 2005; Ellstrand et al., 2007).

Gene movement between sexually compatible corn varieties and related species is no greater for currently cultivated GE varieties, and non-GE corn cultivars (USDA-APHIS, 2014b). Under the No-Action Alternative, MON 87411 Maize would continue to be regulated, and the minor occurrences of gene flow from both non-GE and GE corn varieties documented here would remain unchanged.

4.4.10 Preferred Alternative: Gene Movement

Evaluations of the morphological and compositional characteristics of MON 87411 Maize found no meaningful differences between it and cultivars of corn (Pioneer, 2012; Monsanto, 2013d; USDA-APHIS, 2014b). MON 87411 Maize is phenotypically and agronomically equivalent to non-GE commercial corn with the exception of its GR and CRW protection traits. Two of these traits are the same ones currently available in other GE corn varieties that are no longer regulated. The second MOA for CRW control, RNA-mediated gene suppression is the only trait that is not available in a GE corn cultivar. Under the Preferred Alternative, there are no changes in MON 87411 Maize that would modify barriers to gene transfer compared to the No Action Alternative.

Based on the information reported for the No Action Alternative, USDA-APHIS considers gene transfer from MON 87411 Maize extremely unlikely under the Preferred Alternative with the same possibility as that for currently available GE and non-GE corn varieties.

4.5 HUMAN HEALTH

Human health concerns associated with GE corn include potential impacts to public health, worker safety, and animal feed for livestock used for human consumption. This assessment compares how these three components of human health might be affected by exposure to MON 87411 Maize under the No-Action Alternative and the Preferred Alternative. It includes relevant information about safety issues related to exposure to the three GE traits in MON 87411 Maize. Two exposure scenarios are considered: risks associated with consumption of corn itself and products derived from it (e.g., corn syrup and sweeteners, starches, oil, cereal, beverage and industrial alcohol, cosmetics and personal hygiene products); risks associated with glyphosate applications used to treat MON 87411 Maize.

4.5.1 No-Action Alternative: Public Health

Corn in general has no human health risks except allergenicity, which has an exceedingly low incidence in the human population. MON 87411 Maize does not differ from non-GE corn varieties except for the expression of the Cry 3Bb1 protein for insect resistance, the CP4 EPSPS protein conveying resistance to glyphosate, and the DvSnf7 dsRNA that mediates enhanced resistance to CRW by gene-silencing. The Cry 3Bb1 and CP4 EPSPS proteins are also expressed in other GE varieties of corn that are not regulated and widely used for commercial production.

The Cry3Bb1 protein incorporated into MON 87411 Maize was derived from *Bt*, a common naturally occurring soil bacterium (McClintock et al., 1995; Schnepf et al., 1998; US-EPA, 1998). *Bt* is not a human pathogen (US-EPA, 1998). Cry proteins of *Bt* corn products are not toxic to humans. Tests performed for adverse mammalian effects from ingesting Cry proteins have been negative, even at extremely high doses (US-EPA, 2010d). The toxicity of insecticidal *Bt* proteins depends on binding to specific receptors present in the insect midgut. With regard to the specific Cry proteins produced in *Bt* crops, research demonstrates that this specificity limits each protein's toxic effect to certain insect species. *Bt* microbial preparations containing Cry proteins have been used safely as pesticide sprays for decades without evidence of toxic effects to mammals (US-EPA, 1998; USDA-FS, 2004). The Cry3Bb1 protein and its associated genetic elements were registered as a PIP by the EPA in 2003, and reviewed by the FDA in 2001. The EPA approved commercial use of the Cry3Bb1 as expressed in maize and established an exemption from the requirement of a tolerance for residues of the Cry3Bb1 protein under 40 CFR 180.1214, when used as a PIP (69 FR 16809-16814, March 31, 2004).

The CP4 EPSPS protein that mediates resistance to glyphosate was isolated from *Agrobacterium* sp. strain CP4, a common soil bacterium (Monsanto, 2013c). The CP4 EPSPS protein has a safe history of exposure in humans, animals, and the environment. *Agrobacterium* sp. is widespread in soil and is not associated with human, animal, or plant pathogens (Hérouet et al., 2005; Monsanto, 2013d).

Cry3Bb1 and CP4 EPSPS proteins have previously been reviewed for potential allergenicity and toxicity, and have been determined to have no amino acid sequence similar to known allergens. They also lack observed toxicity to mammals, and are degraded rapidly and completely in gastric fluid (US-EPA, 2010a; Monsanto, 2013c).

Under the No Action Alternative, MON 87411 Maize would remain a regulated article and would not be widely cultivated in the United States. Therefore, human exposure to the proteins expressed by MON 87411 Maize would not change. These proteins are however, expressed by other GE varieties that are no longer regulated and are widely grown, so human exposure to them is widespread. In general, human health is not likely to be affected as a direct or indirect result of the No Action Alternative. Other transgenic *Bt* corn varieties no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA would continue to be available and used as a source of food for human consumption. Exposure to existing transgenic and non-transgenic corn would not change under this alternative.

4.5.2 Preferred Alternative: Public Health

With the exception of CRW protection and glyphosate resistance, MON 87411 Maize is compositionally, phenotypically and agronomically equivalent to non-GE commercial corn. The CP4 EPSPS and Cry3Bb1 proteins have been previously assessed for safety (US-EPA, 1998; 2001) and are expressed by other GE corn varieties that are no longer regulated.

The second MOA for CRW control, RNA-mediated gene suppression, and associated production of DvSnf7 RNA is the only difference between MON 87411 Maize and other GE GR and IR corn varieties that are currently available commercially. The plant-produced DvSnf7 dsRNA specifically affects CRW corn pests but does not affect other organisms. There is a history of safe use of RNA-mediated gene suppression (Petrick et al., 2015). FDA has considered nucleic acids as Generally Recognized as Safe (GRAS) (US-FDA, 1992c) and U.S. EPA has given nucleic acids as expressed in PIPs an exemption from tolerance (US-EPA, 2001).

The EPA FIFRA Science Advisory Panel (SAP) performed a review on the problem formulation phase of risk assessment of pesticide products based on RNAi. The SAP reviewed the relatedness of the dsRNA targeted at pest species to human sequences, digestion of dsRNA and effect on absorption and structural effect of dsRNA on degradation (US-EPA, 2014f). The SAP's review concluded that the ingested dsRNA is extensively degraded in the mammalian digestive system due to ribonucleases (RNases) and acids, and biological barriers (US-EPA, 2014f).

The SAP also concluded that the available evidence supports that there is no significant absorption of dsRNA from the diet in mammals, and the likelihood of adverse effects on any absorbed RNAs in mammals is minimal (US-EPA, 2014f). The supporting evidence includes:

- observations of ingested dsRNA indicate rapid degradation in mammalian digestive systems
- a safe consumption history of plants containing RNA by humans and other mammals (Ivashuta et al., 2009)
- no significant mammalian uptake of dietary miRNA resulting in functional consequences (Dickinson et al., 2013; Snow et al., 2013; Witwer et al., 2013)
- RNA has a short half-life (about 5 minutes) in the blood (Christensen et al., 2013)

Additional literature reviews performed by independent parties indicate that there is limited potential for uptake activity of ingested RNA (Cottrill and Chan, 2014; Witwer and Hirschi, 2014). The results of a 28-day oral toxicity study in mice evaluating the effect of orally ingested dsRNA matching the mouse *vATPase* gene, concluded that orally ingested dsRNA does not produce adverse health effects in mammals (Petrick et al., 2015).

Available data indicate that the potential for human exposure to DvSnf7 RNA is negligible, oral toxicity of RNA to higher organisms is low, and there is an absence of plant-produced DvSnf7 RNA activity in organisms other than CRW pests (Monsanto, 2013c). Therefore, available information indicates that there are no adverse health effects on human health associated with consumption of DvSnf7 RNA in food products derived from MON 87411 Maize. RNA-mediated gene suppression in plants also has a history of safe use. FDA has deemed nucleic acids as Generally Recognized as Safe (GRAS) (US-FDA, 1992c). EPA has exempted nucleic acids with insecticidal activity expressed as PIPs from tolerance requirements (US-EPA, 2001).

Based on a review of available information from analyses of field and laboratory data for MON 87411 Maize, and relevant human health data for functionally equivalent non-GE and GE corn varieties that are no longer regulated, APHIS has concluded that a determination of non-regulated status under the Preferred Alternative would not have public health impacts different from those of the No-Action Alternative.

4.5.3 No Action Alternative Worker Health and Safety

Pesticides are used on most corn acreage in the United States. The EPA has authority for regulating pesticides, including registering permissible uses and establishing practices for their handling. EPA does the latter by implementing its Worker Protection Standard (WPS [40 CFR part 170.1]) that requires employers who handle pesticides to implement practices that minimize risks of poisonings and other injuries. The WPS requires: safety training; notification of pesticide applications; use of personal protective equipment; reentry time restrictions for sites treated with pesticides; decontamination procedures, and availability of emergency medical assistance. Under the No Action Alternative, MON 87411 Maize would remain a regulated article and would not be widely cultivated in the United States. Therefore, the agronomic requirement, including handling of pesticides used in corn cropping systems, would not change.

4.5.4 Preferred Alternative: Worker Health and Safety

Under the Preferred Alternative, workers who implement the routine agronomic management practices required for GE corn will not change because MON 87411 Maize will only replace other varieties of GE corn that have the same requirements for pesticide treatments. Similar to the No Action Alternative, it is expected that EPA registered pesticides that are currently used for corn production will continue to be used by growers. Therefore, there are no reasons to expect that the WPS for GE corn will change if MON 87411 Maize is not regulated. The EPA WPS will continue to provide the same level of protection as is currently available under the No-Action, so APHIS concludes that there is no difference between the No-Action Alternative and the Preferred Alternative with regard to worker safety.

4.5.5 No-Action Alternative: Animal Feed

Corn comprises most (about 95%) of livestock feed grain used in the United States (USDA-ERS, 2013a). This includes animal feed derived from unprocessed grain, and residual products of milling, refining and distilling corn (CRA, 2006b).

Under the No Action Alternative, MON 87411 Maize will remain a regulated product and will not be available as an animal feed. However, animal feed will continue to contain products derived from GE and non-GE corn at present levels. The EPA and the FDA have reviewed the Cry3Bb1and CP4 EPSPS proteins as additives to corn as feed for livestock. They have determined that they are not toxic to mammals because they are degraded rapidly and completely in gastric fluid (US-FDA, 2001a; USDA-APHIS, 2001; US-FDA, 2004; USDA-APHIS, 2005; US-EPA, 2010f; Monsanto, 2013d).

Under the No Action Alternative, current exposure to livestock from corn products will remain unchanged.

4.5.6 Preferred Alternative: Animal Feed

Under the Preferred Alternative, it is unlikely that a determination of nonregulated status of MON 87411 Maize will result in any changes in animal exposure to the GE components of corn in livestock feed compared to the No-Action Alternative with the exception of the DvSnf7 dsRNA trait. Regarding this novel trait, the SAP review concluded that ingested dsRNA is extensively degraded in the mammalian digestive system by ribonucleases (RNases), acids other biological barriers (US-EPA, 2014b). The SAP also concluded that the available evidence supports that there is no significant absorption of dsRNA from the diet in mammals, and the likelihood of adverse effects on any absorbed RNAs in mammals is minimal (US-EPA, 2014b). The supporting evidence includes:

- observations of ingested dsRNA indicate rapid degradation in mammalian systems
- a safe history of consumption by humans and other mammals of plants containing RNA (Ivashuta et al., 2009)
- no significant mammalian uptake of dietary miRNA resulting in functional consequences (Dickinson et al., 2013; Snow et al., 2013; Witwer et al., 2013)
- RNA has a short half-life (about 5 minutes) in the blood (Christensen et al., 2013)

Additional literature reviews performed by independent parties indicate that there is limited potential for uptake activity of ingested RNA (Cottrill and Chan, 2014; Witwer and Hirschi, 2014). The results of a 28-day oral toxicity study in mice evaluating the effect of orally ingested dsRNA matching the mouse *vATPase* gene, concluded that orally ingested dsRNA does not produce adverse health effects in mammals (Petrick et al., 2015).

Based on available evidence, APHIS concluded that under the Preferred Alternative, MON 87411 Maize will not affect livestock health any differently than under the No-Action Alternative.

4.6 SOCIOECONOMICS

Recent studies demonstrate that agronomic characteristics and cultivation practices required for MON 87411 Maize are essentially indistinguishable from those used to grow other corn varieties

(Monsanto, 2013d; USDA-APHIS, 2014b). If MON 87411 Maize is no longer subject to the PPA and the regulatory requirements of 7 CFR part 340 it will only replace other GE varieties of corn. Therefore, the potential impacts on the socioeconomic environment associated with the No Action and Preferred Alternative are expected to be similar or the same. Further details regarding possible impacts on the domestic and trade economic environment follow.

4.6.1 No Action: Domestic Economic Environment

Under the No Action Alternative, MON 87411 Maize will continue to be a regulated article under 7 CFR part 340. Growers and other parties who are involved in production, handling, processing, or consumption of corn will not have access to MON 87411 Maize, but will continue to have access to currently available conventional and GE corn varieties including those varieties containing the Cry3Bb1 and CP4 ESPS genes.

Growers currently select corn varieties based on a wide range of considerations, including market conditions and end use requirements. The current market for ethanol has influenced some growers to convert soybean or cotton acreage to corn, as well as convert from livestock feed corn varieties to corn varieties providing better ethanol production feedstock (USDA-ERS, 2012c; USDA-OCE, 2012b). The result of these corn cultivation trends includes changes in crop acreage dedicated to corn, shifts of corn varieties cultivated, and current commodity grain pricing. These trends are unaffected by the No Action Alternative.

Food and industrial use of corn (other than for ethanol production) is projected to increase, although this demand also is related to specific products (USDA-OCE, 2012b). Demand for high-fructose corn syrup (HFCS), glucose and dextrose is expected to increase, but at lower rates than previous years. Corn starch is considered an industrial product, the production of which is contingent on industrial demand (USDA-OCE, 2011b; 2012b).

Growers adopting GE corn varieties incur a cost premium to acquire the seed (NRC, 2010b). These technology fees are imposed by the product developer to cover their research and development costs, resulting in GE seeds that are traditionally more expensive than conventional seed (NRC, 2010b). Growers cultivating GE crops all pay such technology fees. The NRC suggests that the benefits associated with the adoption of GE crops, including a reduction in agronomic inputs and increases in yield offset the extra costs of the GE seed (NRC, 2010b). All growers adopting GE crops would incur these fees. These costs are unaffected by the No Action Alternative.

Under the No Action Alternative, growers will continue to benefit from the adoption and cultivation of GE crops, including the commensurate reduction in costs associated with pesticide applications (Duke and Powles, 2009). At the same time, those growers managing HR weeds may incur increased costs for a range of management techniques, including increased pesticide use and increased tillage. These trends are unaffected by the No Action Alternative.

4.6.2 Preferred Alternative: Domestic Economic Environment

Under the Preferred Alternative, trends related to the domestic economic environment are unlikely to be substantially different than what is currently occurring in the No Action Alternative because MON 87411 Maize would only replace other GE corn varieties.

The selection and cultivation of corn varieties, and the decision to cultivate corn (rather than soybeans or cotton, for example), is based on the market for the crop, and not the specific availability of a particular GE variety. Therefore, the potential domestic economic impacts associated with the cultivation of MON 87411 Maize are no different than those currently observed for other corn varieties under the No Action Alternative.

4.6.3 No Action Alternative: Trade Economic Environment

Under the No Action Alternative, MON 87411 Maize would continue to be a regulated article. Farmers, processors, and consumers in the United States would not have access to it, but would continue to have access to currently available non-GE and GE HR and IR varieties of maize that are not regulated.

The United States is the leading exporter of maize in the world market. In the 2011/2012 marketing year (August to September), the United States exported approximately 37% of the world's maize while Japan, Mexico, and South Korea were the major importers (USDA-FAS, 2013). In 2011, maize exports were worth approximately $13.7 billion (USDA-ERS, 2012a). U.S. maize 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 influencing where and how much of U.S. maize is exported (USDA-ERS, 2011b; 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, the U.S. corn export share has eroded as exports have remained relatively stable while global exports have increased by almost 20%. The U.S. share of world maize production has also declined, even as total world production increased. This is attributed to greater domestic use of U.S. maize, smaller crops, and increased competition from other major exporters such as Argentina, Brazil, and Ukraine (USDA-FAS, 2013) countries with increasing GE HR- and IR-maize production acreage (Brookes and Barfoot, 2010).

4.6.4 Preferred Alternative: Trade Economic Environment

A determination of nonregulated status of MON 87411 Maize is not expected to adversely impact the trade economic environment because corn products containing MON 4114 Maize will have the same global uses as current GE corn products. Therefore, MON 87411 Maize will be subject to the same international regulatory requirements as currently traded U.S. GE corn products. Monsanto will submit applications to U.S, importers of corn products, including the regulatory authorities of Canada, China, Japan, Mexico, South Korea and Taiwan (Monsanto, 2013d). These regulatory authorities include U.S. trade partners for import clearance and production approval (USDA-FAS, 2012).

Based on these factors, the trade economic impacts associated with the determination of nonregulated status of MON 87411 Maize are anticipated to be similar to the No Action Alternative.

5 CUMULATIVE IMPACTS

This section includes a review of the potential cumulative impacts that may result from the selection of the Preferred Alternative. The CEQ regulations define a cumulative impact as “the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.” (40 CFR part 1508, Section 1508.7, Cumulative impact).

5.1 METHODOLOGY AND ASSUMPTIONS

Based on the information provided in Section 4, which is summarized in Table 3, the Preferred Alternative would not adversely impact the physical, natural, social, or economic environment. Furthermore, as discussed throughout this section, there are no past, present or reasonably foreseeable actions that, in aggregate with the Preferred Alternative would adversely affect these resources.

5.1.1 Reasonably Foreseeable Future Actions

GE corn varieties marketed in the US today typically contain multiple GE traits, some of which have been combined by traditional breeding between different cultivars that are no longer subject to the plant pest provisions of the PPA and 7 CFR part 340. In the event that APHIS reaches a determination of non-regulated status of MON 87411 Maize, this variety could potentially be combined with non-GE and other GE maize cultivars by traditional breeding techniques, resulting in a plant variety that, for example, may be resistant to one or more herbicides and contain other insect-resistance traits that are no longer subject to the regulatory requirements of 7CFR Part 340 APHIS’s regulations at 7 CFR part 340 do not provide for Agency oversight of GE corn varieties that are no longer subject to the plant pest provisions of the PPA and 7 CFR part 340, unless it can be positively shown that such stacked varieties were to pose a likely plant pest risk. To date, none of the GE corn varieties that have been determined to no longer be regulated articles pursuant to Part 340 and the PPA and used for commercial corn production or corn breeding programs subsequently have been found to pose a plant pest risk.

There is no certainty that MON 87411 Maize will be stacked with any particular non-transgenic or GE trait (one no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA), as company plans and market demands play a significant role in those business decisions. Predicting all potential combinations of stacked varieties that could be created using commercially available non-transgenic and transgenic corn cultivars corn cultivars is speculative.

Most likely MON 87411 Maize will be sold to U.S. growers in combinations comprised of insect protection and herbicide resistance traits, just as some of the present products are stacked events with multiple *Bt* and herbicide resistance genes (Table 4). The benefits of insecticidal efficacy and product longevity of the traits will likely be enhanced by pyramiding with additional *Bt* genes (Ives et al., 2010), such as cry34/35, as they are today.

Table 4. Examples of Present Monsanto Stacking and Pyramiding.

Cultivar	Traits	Combination
Genuity SmartStax RIB Complete	Rootworm resistance traits Cry3Bb1 and Cry34Ab1, and Cry 35Ab1 with lepidopteran control	Glyphosate and Glufosinate Resistant
Genuity VT Triple PRO Complete	Rootworm resistance trait Cry3Bb1 with lepidopteran control	Glyphosate Resistant
Genuity SmartStax	Rootworm resistance traits Cry3Bb1 and Cry34Ab1, and Cry 35Ab1 with lepidopteran control	Glyphosate and Glufosinate Resistant
YieldGard VT Triple	Rootworm resistance trait Cry3Bb1 with lepidopteran control	Glyphosate Resistant
YieldGard VT Rootworm/RR2	Rootworm resistance trait Cry3Bb1	Glyphosate Resistant

(Monsanto, 2013a)

The likely offerings combined with the DvSnf7 dsRNA will include at least Cry3Bb1 and then potentially a second CRW-active protein (such as Cry34/35) that each provide control of western, northern, and Mexican CRWs. Some new potential hybrids with these traits would also be combined with lepidopteran-specific *Bt*-derived proteins that would deliver broad-spectrum control of economically important lepidopteran pests. Finally, these hybrids may ultimately express traits that confer resistance to glufosinate in addition to glyphosate as weed-control options. All the traits derived from other transgenic events in these breeding stacks are no longer subject to the plant pest provisions of the PPA and 7 CFR part 340.

5.1.2 Summary for Reasonably Foreseeable Future Actions

For purposes of cumulative impact analysis, reasonably foreseeable future actions include the potential for stacking certain already approved transgenic corn cultivars with MON 87411 Maize traits, or for creating new stacks with similar combinations of traits (Monsanto, 2013c). The analysis will consider those insect resistance and herbicide resistance traits found in the breeding stacks currently approved for sale or use in the US, as listed in Table 4. While Monsanto has other *Bt* traits under development (Lamoureux, 2012) including additional RNAi traits, the timeline for their potential introduction is uncertain and is not considered here.

5.2 CUMULATIVE EFFECTS ANALYSIS

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. Among the cumulative impacts considered are stacking of the MON 87411 Maize with additional herbicide resistance traits such as glufosinate, or 2,4-D and eventually, dicamba (Monsanto has approved cross licensing of this with DAS) and for pyramiding with additional CRW or lepidopteran resistance traits. Monsanto clearly signals that it will market MON 87411 Maize with multiple traits (Monsanto, 2013d).

5.3 CUMULATIVE IMPACTS: ACREAGE AND AREA OF CORN PRODUCTION

The stacking of beneficial traits represents an increasing proportion of commercially-available corn varieties (Table 4). Data presented by USDA-NASS suggests that corn varieties containing stacked traits are increasing in popularity, with approximately 52% of the total corn acreage in 2012 cultivated in stacked varieties (USDA-NASS, 2012b). As described elsewhere in this section (see Assumptions Used for the Cumulative Impacts Analysis), there are several commercially available corn varieties that contain a combination of IR and HR traits such as Monsanto's Genuity SmartStax. Other stacked corn varieties containing glufosinate include those from Pioneer, Dow AgroSciences and Syngenta. The factors discussed in Sections 2 and 4 regarding how decisions by growers influence the selection of IR varieties are not changed by the availability of a new hybrid stack. Growers will rely on incorporated *Bt*-protein traits expressed in hybrids and so will avoid applied CRW insecticides as part of a general trend to reduce insecticide use (Naranjo, 2009). Development of CRW resistance to *Bt* proteins in recent years has been jeopardizing that trend, however.

As discussed earlier, two of the traits that are present in Monsanto 87411 Maize, Cry 3Bb1 and glyphosate resistance are already in widespread cultivation. The new trait, that of DvSnf7 dsRNA expression, likely has a similar level of toxicity to rootworm larvae as the Cry proteins. Also the tissue site of action of DvSnf7 dsRNA (that is, on the midgut epithelium (Koči et al., 2014) is also similar to the existing CRW-active Cry proteins (Bravo et al., 2007). Consequently, no characteristics of MON 87411 Maize would be expected to change the areas or range of corn cultivation. Neither the No Action Alternative nor the Preferred Alternative are expected to directly cause an increase in agricultural acreage devoted to corn production or to those corn acres typically devoted to GE corn cultivation. The availability of MON 87411 Maize as a breeding stock to create hybrid stacks would not change cultivation areas for corn production in the United States; there are no anticipated changes to the availability of GE and non-GE corn varieties on the market under either alternative.

Stacking MON 87411 Maize with additional herbicide-resistance traits is not expected to influence total acreage of crop production. Glyphosate would likely continue to be a major component of weed management in corn production because of its flexibility in application, its efficacy against a broad spectrum of weeds, and its relatively low cost (Powles, 2008; Duke and Powles, 2009; Green and Owen, 2011). The GR varieties are already widely cultivated, based on the percentage of corn currently treated with glyphosate (USDA-NASS, 2011a; 2011b). . The individual traits of current stacks have been previously reviewed and found unlikely to extend the area or range of U.S. corn cultivation (USDA-NASS, 2012b). Having additional herbicide choices will not increase the overall yield or need for additional corn production acres. APHIS expects that different herbicide applications will only partly substitute for glyphosate applications as the newer HR corn traits are offered. Because the RNAi trait will be offered in stacks with more familiar varieties expressing currently deployed herbicide and insecticidal traits, the patterns for planting in familiar corn production areas will continue.

As previously discussed, the cultivation of MON 87411 Maize is unlikely to change current agronomic inputs for corn, including fertilizers, fungicides, insecticides, and herbicides. MON 87411 Maize is from a Corn–Belt adapted variety which has been crossed with additional commercial quality inbred genetic varieties along with other traits already determined as non-regulated.

The cultivation of a stacked variety containing both insect-resistance and herbicide-resistance traits is consistent with current crop cultivation practices. As noted in the introduction to this section, Monsanto Cry3Bb1-expressing corn and nonregulated GR and glufosinate-resistant varieties were previously reviewed and determined to be similar in agronomic characteristics and cultivation requirements as conventional corn. Because of these agronomic and cultivation similarities with conventional corn, any offspring produced using these GE parental types will also likely be similar to conventional corn in agronomics and cultivation requirements.

GE corn varieties are planted on most of U.S. corn acreage (93% in 2014). Transgenic maize planted in varieties that are only HR or IR has been declining. Corn varieties stacked with both types of traits are planted more frequently than those varieties conferring resistance to herbicides; however, this may merely reflect greater availability of the stacked varieties. Stacked products combining insect resistance and herbicide resistance (and potentially other traits) are likely to continue to be introduced and will afford growers increased convenience and protection.

MON 87411 Maize and any hybrid progeny produced from it including the Cry3Bb1 and DvSnf7 dsRNA resistance traits within stacks of other traits will not require significantly different crop production practices compared to other corn varieties that are currently available to growers. Therefore, a determination of nonregulated status of MON87411 Maize is not anticipated to have any cumulative impacts on existing corn hybrids when incorporated with the RNAi resistance trait. As a result, no cumulative impacts would be expected on production and yield, agronomic practices such as pesticide use, crop rotation, tillage, irrigation, disease management, or weed management related to US corn production or on specialty and organic crops or to raw and processed corn.

5.3.1 Insect Management

Increased planting of transgenic *Bt* corn has historically been correlated with reduced use of insecticides or non-reliance altogether on insecticides to control CRW (Fernandez-Cornejo et al., 2014a). As noted in the Environmental Consequences section for (see Agronomic Practices), the Preferred Alternative is expected to have the possible effect of reducing insecticide use that has been adopted in response to increasing resistance to some *Bt* herbicides. The past and current actions that may contribute to cumulative impacts on this resource are the pest management strategies that include conventional insecticide and herbicide use, crop rotation practices, and the introduction and increasing use of GE corn varieties. The array of transgenic corn cultivars currently available for insect pest management is listed in Table 5. The combinations of Monsanto corn hybrids with coleopteran resistance traits may potentially contribute to cumulative impacts, when they are pyramided in future varieties. This issue will be reviewed in the next sections.

Table 5. **Commercially Available Maize Combinations with Insect Control Traits.**

Product	**Event Names**	**Resistance/Tolerance Traits**
Agrisure® GT/CB/LL	*Bt*11/GA21	Lepidoptera, glyphosate, glufosinate
Agrisure Duracade E-Z Refuge 5222	*Bt*11/MIR604/DAS 59122-7/TC1507x5307xGA21	Lepidoptera, rootworm, glufosinate, glyphosate
Agrisure Viptera™ 3110	*Bt*11/MIR162/GA21	Lepidoptera, glyphosate, glufosinate
Agrisure Viptera™ 3111	MIR 162/*Bt*11/GA21/MIR 604	Lepidoptera, rootworm, glyphosate
Agrisure CB/LL/RW	*Bt*11/MIR604	Lepidoptera, rootworm, glufosinate
Agrisure 3000GT	*Bt*11/MIR604/GA21	Lepidoptera, rootworm, glyphosate, glufosinate
Agrisure Viptera 3111	*Bt*11/MIR604/MIR162/GA21	Lepidoptera, rootworm, glyphosate, glufosinate
Agrisure 3122	*Bt*11/MIR604/DAS 59122-7/TC1507	Rootworm, Lepidoptera, glyphosate, glufosinate
Syngenta GT/RW	MIR604/GA21	Rootworm, glyphosate
YieldGard Corn Borer with Roundup Ready® Corn 2 (RR2)	MON 810/NK603	Lepidoptera, glyphosate
YieldGard Rootworm/RR2	MON 863/NK603	Rootworm, glyphosate
Genuity VT Double PRO™	MON 89034/NK603	Lepidoptera, glyphosate
YieldGard Plus	MON 810/MON 863	Lepidoptera, rootworm
YieldGard Plus/RR2	MON 810/MON 863/NK603	Lepidoptera, rootworm, glyphosate
YieldGard VT Triple® and Genuity VT Triple	MON 810/MON 88017	Lepidoptera, rootworm, glyphosate
(Genuity) Smart Stax	MON 89034 /MON 88017/ TC1507/DAS-59122-7	Lepidoptera, rootworm, glyphosate, glufosinate
Genuity VT Triple PRO	MON 89034/MON 88017	Lepidoptera, rootworm, glyphosate
Herculex IRR2	TC1507/NK603	Lepidoptera, glyphosate, glufosinate
Herculex RW/RR2	DAS 59122-7/NK603	Rootworm, glyphosate, glufosinate
Herculex XTRA	TC1507/DAS 59122-7	Lepidoptera, rootworm, glufosinate
Herculex XTRARR2	TC1507/DAS 59122-7/NK603	Lepidoptera, rootworm, glyphosate, glufosinate
Optimum AcreMax 1	Seed blend of 90% TC1507/DAS-59122-7/ NK603 and 10% TC1507/NK603 refuge seed	90% Lepidoptera, rootworm, glyphosate; 10% Lepidoptera, glyphosate
Optimum AcreMax RW	Seed blend of 90% DAS-59122/NK603 and 10% NK603 refuge seed	90% rootworm, glyphosate; 10% glyphosate
Optimum Intrasect Xtra	TC1507/MON810/DAS59122-7/NC603	Lepidoptera, rootworm, glufosinate

*(NCGA, 2014a)

Insecticide Use

CRWs has evolved resistance to some of the chemical insecticides used in its control and also to crop rotation practices that have historically been used against these economically destructive pests (Van Rozen and Ester, 2010). As described in the previous section (Insect Management), use of conventional (chemical) pesticides to control CRWs has been reduced since the introduction of transgenic *Bt* corn for insect control. Augmenting of *Bt* traits with insecticide use has been common. Also, insecticide use as an alternative to use of CRW resistant hybrids is likely to continue to be reduced under the Preferred Alternative.

New concerns have arisen because single rootworm resistance traits show susceptibility to high CRW pressure. Consequently, some growers have seen a continuing need to treat corn at planting or post-planting with only insecticides and avoid reliance on *Bt* traits. Alternatively, growers have sometimes decided to use insecticides along with single *Bt* and even two-*Bt*-corn hybrids to respond to any evidence of trait resistance, as suggested by corn extension entomologists (Gray, 2011b; Ostlie, 2011b), by the Agricultural Biotechnology Stewardship Technical Committee, (ABSTC), a consortium of agricultural biotechnology companies and associations (Agricultural-Biotechnology-Stewardship-Technical-Committee, 2013) and also by the National Corn Growers of America website (National-Corn-Growers-Association, 2013). However, in some reports, insecticide use with *Bt* hybrids may not increase yield and may potentially promote CRW resistance to *Bt* varieties (Petzold-Maxwell et al., 2013).

It should be noted that effectiveness of existing *Bt* traits may be related to levels of pest insect pressure. Under high CRW pressure, *Bt*-expressing hybrids may sometimes be correlated with higher corn yields than can typically be achieved with insecticides alone while *Bt* hybrids may not provide an advantage over insecticides under low to moderate CRW pressure (Ma and Subedi, 2005; Ma et al., 2009; Tinsley et al., 2011). In conditions where there is no evidence of CRW resistance to Cry proteins, insecticides applied with varieties having one or two Cry protein traits may not increase yield or reduce root damage (Tinsley et al., 2014). As recently as 2010, the beginning of reporting of potential resistance to Cry proteins, approximately 9% of all corn growers used insecticides for CRW control (Fernandez-Cornejo et al., 2014a). Insecticides may be indicated in some situations and specific fields or chosen by other growers as insurance treatments in other fields with *Bt*-expressing hybrids.

Some state extension services have recommended that growers rotate non-*Bt* corn using conventional insecticide treatments with *Bt* corn as a best management practice (Gray, 2014; Hodgson and Gassmann, 2014). The elective choices by growers for simultaneous use of both insecticide and *Bt* hybrids to protect corn may be increasing; in Illinois extension entomologists noted an "escalation in the use of planting-time soil insecticides with *Bt* rootworm hybrids" (Gray, 2014) and that in "2013, … a sharp increase [was noted] in the use of planting-time soil insecticides with corn rootworm *Bt* hybrids. On average, nearly half the producers indicated they intend to use both a soil applied (at-planting) insecticide with their corn rootworm *Bt* hybrid this spring." Re-establishing grower confidence in a new combination of both DvSnf7 dsRNA and *Bt* -expressing hybrids could likely decrease the frequency of some growers' elections to treat *Bt* corn with supplementary insecticides. Thus, when combined with past, present, and reasonably foreseeable future actions, the cumulative impacts of choosing the Preferred Alternative may result, in some cases, the further reduction of insecticide use, and a potential increase in corn yields for some growers.

As also noted, with a mechanism of action dissimilar to *Bt* expressing hybrids, the DvSnf7 dsRNA strategy may reduce the likelihood that CRW populations will develop resistance to a dual protection system. The effectiveness of a new trait may extend the useful life of existing tools with which they are combined for CRW control. Growers will have more choices of CRW resistance traits in varieties for rotations in successive cropping seasons, which will lengthen sustainable use of these traits.

Resistance to *Bt* Proteins

A key issue related to the use of *Bt*-expressing corn hybrids for insect control is the potential for resistance to Cry proteins. The widespread use of transgenic *Bt*-corn hybrids generates selection pressures for insect resistance (Tabashnik et al., 2008). However, there is no indication that the widespread use of all IR *Bt* crops has caused any overall failure of all these hybrids, even though as earlier noted, reports have appeared from nine states of problem fields in which *Bt* corn has not performed adequately because of root damage from CRW (Penn-State-University, 2013). As earlier noted, sites of failure of *Bt*-expressing hybrids may be relatively infrequent, and are associated with growing areas where continuous corn has been a multiple-season pattern without rotation (Gassmann et al., 2011). These areas may be characterized by high populations of CRW, and thus high pressure on the *Bt* expressing hybrids (Monsanto, 2013b). Monsanto notes that performance issues reported to them comprised only about 0.2% of plantings, in 2011-2013 seasons (Monsanto, 2014b), but underreporting of CRW damage may be an issue. For example, in 2012 a survey of Iowa growers, about 25% overall reported that they had corn *Bt* trait failure; this survey included some 8,100 responses across Iowa (Hodgson et al., 2013).

Certain fields that have a history of continuous corn production and high rootworm populations have experienced *Bt* trait failures. This occurs typically when hybrids expressing one trait (e.g., Cry3Bb1) are grown (Gassmann et al., 2011; Gray, 2011a). A combination of the DvSnf7 dsRNA with multiple *Bt* traits will likely increase the effectiveness of either trait alone. The mechanism of action of the DvSnf7 dsRNA is different from that of IR *Bt* varieties. The dsRNA RNAi trait is effective for 5-6 days over all larval stages (Bolognesi et al., 2012). Cry3Bb1 has a more rapid action, targeting only the first three instars (Macron, 2013). However, both traits confer similar levels of mortality. MON 87411 Maize traits would help support the continuing efficacy of Cry proteins that have been successfully deployed, most likely by deferring development of resistance when plants with both one and two resistance traits are concurrently deployed with two trait plants of different toxicities (Zhao et al., 2005).

APHIS concludes that combinations of DvSnf7 dsRNA will add useful new value in pyramids of CRW traits because of the inherent weaknesses of existing *Bt* traits that include only low to moderate expression in roots. A high dose strategy for insect control is more optimal, but not attained in CRW *Bt* varieties. Another limiting issue for these, is that a larger number of preexisting *Bt*-resistance alleles in CRW populations have been detected than the numbers earlier anticipated (Devos et al., 2013).

Deterring Resistance to *Bt* Traits

To reduce the likelihood of developing resistance to *Bt* traits, insect resistance strategies have been successfully developed. The most important is that of the US-EPA, in which growers are required to plant nearby refuges with corn varieties lacking the *Bt* trait, or use the EPA-approved “refuge in a bag” approach in which a small percentage of non-*Bt*-expressing seeds are mixed with *Bt* seeds to allow some non-selected, susceptible rootworms to survive and contribute genes for susceptibility to the existing population (Zukoff et al., 2012; Onstad et al., 2014). Deterring resistance is also accomplished when growers adhere to preferred management practices, including rotation of corn with other crops, especially avoiding continuous corn production, and using pyramided CRW resistance traits (Hodgson and Gassmann, 2014) or rotation of CRW resistance traits (Penn-State-University, 2013).

Recent studies indicate that in fields in several states, WCR may have developed resistance to not only Cry3Bb1 but also mCry3A proteins (Gassmann et al., 2011; Gassmann et al., 2014) under high rootworm pressure. Detailed analysis of the possible genetic basis of the resistance has not been completed (Monsanto, 2011). No evidence has been provided that suggests that the control failures are affecting other CRW resistance traits such as Cry 34/35, (Ostlie, 2011a). However, lab generated resistance of CRW to eCry3A has been developed by some populations (Frank et al., 2013). Cross resistance to two Cry proteins have been shown in some populations of CRW such as between mCry3A and Cry3Bb1 (Gassmann et al., 2014).

Potential for New Traits to Contribute to Cumulative Impacts

Pyramids of two transgenic Cry protein traits with different modes of action against the target pest should also limit the potential for resistance to develop to any one trait (Tabashnik et al., 2008; Head et al., 2014). Syngenta’s MIR604 (mCry3A) rootworm-resistant cultivar may have a different mode of action than Syngenta’s eCry3.1Ab corn (Walters et al., 2010) and thus supports the potential for pyramided products to have greater ability to sustainably disrupt development of CRW resistance (Head et al., 2014). In addition, new CRW resistance traits are in development (Gassmann et al., 2011; Ostlie, 2011b)

MON 87411 Maize could provide growers with an additional trait that could be rotated with those existing in the marketplace, which includes a total of four Cry protein traits for CRW-control. These traits may be pyramided, and new corn varieties might be constructed with multiple combinations to avoid overuse of any one pair of traits in a corn-growing area. MON 87411 Maize could allow additional combinations for more effective IRM strategies. Because the DvSnf7 dsRNA operates via a unique mode of action, introduction of MON 87411 Maize into hybrid pyramids could also extend the useful life of the other commercially available CRW-protected products (i.e., the PIPs Cry3Bb1, mCry3A, Cry34Ab1/ Cry35Ab1, and eCry3.1Ab) (see also Appendix A of USDA APHIS EA for petition 10-336-01).

In present stacks, if two CRW toxic traits of an insecticidal pyramid are deployed into a field in which CRW has resistance to say, Cry3Bb1 then only the second CRW trait is effective, the cumulative advantage of two reinforcing Cry proteins is lost, leaving higher potential for resistance development. Similarly with the DvSnf7 trait, if only the new trait has efficacy in a pyramid, then the potential for resistance developing to that trait is increased, and the trait may not be sustainable in future uses. APHIS concludes that if growers are cognizant of which *Bt* traits were used in their previous plantings, and in which of their varieties trait efficacy was reduced, then growers should be able to select appropriate choices of pyramided products to rotate in subsequent growing seasons.

The DvSnf7 dsRNA trait could be the first of additional future dsRNA products for insect control. However, USDA is not aware of any similar GE PIP products (that is, incorporated into the plant genome) other than the present DvSnf7 trait to control CRW. Reports of the development of new products indicate that both Monsanto and Syngenta are interested in insecticidal RNAi spray products (Pollack, 2014), but timelines for development are uncertain. Consequently, in the absence of commercially available insecticidal RNAi products, no additive effects can be expected with MON 87411 Maize. USDA concludes that no cumulative impacts from other RNA interference products are likely at the current time, nor within the foreseeable future. In addition, no direct or indirect impacts of the DvSnf7 trait are likely, except to the anticipated CRW target insects. For any similar rootworm controlling product, such as *Bt* traits, no synergistic or additive impacts are expected either; no research has shown interactions between any of the *Bt* traits and this RNA interference sequence. APHIS considers that cumulative impacts to agronomic practices are not likely to accompany nonregulated status for this trait.

5.3.2 Weed Management

HR transgenic corn cultivars have been developed to allow use of herbicides to control weeds without harming the crop. As described for Weed Management in Section 2, HR corn has been widely adopted by growers in North America. Currently available transgenic HR corn cultivars include multiple glyphosate- HPPD- or glufosinate- (phosphinothricin) resistant cultivars (USDA-APHIS, 2011b).

Approximately 90% of the US corn crop was planted to transgenic HR varieties in 2014, including those stacked with other GE traits (USDA-NASS, 2014a). Excessive reliance on HR crops and single herbicides can promote the development of HR weeds (Johnson et al., 2009). Neglect of other strategies to suppress weeds, such as using cultural practices, employing herbicides having multiple modes of action, and practicing crop rotation are also likely contributors to weed resistance (Beckie, 2006). Failure to use established practices to prevent herbicide resistance in weeds that were common before HR crops were commercialized is also a contributor to development of weed resistance to herbicides. Weeds can potentially survive in crop production systems because of natural resistance to herbicide(s) and because they employ growth types or life cycles that help them avoid being treated, such as some winter annual weed species. For these reasons, integrated weed management strategies and broad use of many tactics need to be employed to minimize or delay development of weed resistance.

As previously described, some weeds have also developed herbicide resistance because the increased use of HR corn has encouraged some growers to use predominately one herbicide, and thus, provide only a single selective mechanism against weed genomes. As noted in the International Survey of HR Weeds (WSSA, 2014) numerous cotton infesting weeds have become resistant to ALS inhibitors and to PSII inhibitors, as well as to glyphosate. However, there are many effective corn herbicides available, at least 17 sites of action available for corn control. These include triazine-class herbicides (including atrazine) and two GE corn varieties with HR resistance. Growers have the potential to rotate herbicide use, rather than relying on a single herbicide. Additionally, two new HPPD class herbicidal corn varieties have been given non-regulated status and these may be commercially available to growers soon; 2,4-D- and dicamba-resistant corn will likewise provide new options as well.

Although development of resistance to herbicides is not unique to growers using HR crops, and can be expected in any case, education and training in best management practices to avert early resistance is an important remediation measure that is being pursued by many public and private entities. Weed resistance management training to reduce the potential for weeds to develop resistance to herbicides has been made available by the Weed Science Society of America in web-based training and other formats to growers and extension trainers and is readily accessible (Ohio-State-Extension, 2011). HR seed technology companies offer such training in online websites, and in field demonstrations for growers, discuss issues and best management practices. State extension services and university staff provide field day events, meetings and website documents to also provide the needed background and encouragement to undertake these management practices.

Herbicide Use

MON 87411 Maize has one herbicide resistance trait. However, the variety will likely also be pyramided with other transgenic corn traits such as glufosinate (as in SmartStax products; see Table 5), and potentially additional herbicides including some not yet commercialized. Weed management methods would generally follow current practice for similar traits already available in commercial hybrid seed. The likely pyramided product may include two available traits for herbicide resistance, and growers could continue using predominantly glyphosate for weed control, or glufosinate for resistant weeds, or use glyphosate and glufosinate separately and sequentially on the same crop. The two herbicides could also be used alternately in consecutive crop production years to optimally manage weed resistance. It should be noted that glufosinate-resistant corn is already available. Therefore, growers can already alternate the glufosinate-resistance trait with glyphosate resistance in rotations, so significant changes in glufosinate use in corn would not be expected.

As 2,4-D resistant and other HR corn traits become commercially available, these traits also may be stacked with MON 87411 Maize, allowing growers yet more choices for alternating herbicides yearly, or during a cropping season. The cumulative impact of these additional stacked herbicide traits will not change the production practices of corn farming, nor have adverse impacts on corn production, but could potentially alleviate development of new HR weeds, and assist in control of existing GR weeds.

As described earlier, total glyphosate application to corn doubled between 2005 and 2010 in NASS program states (USDA-NASS, 2013d) while HR corn (mostly glyphosate resistant) increased from 26 to 70% of acres in that same period (USDA-ERS, 2014d). Thus, the rates of glyphosate application actually changed only slightly in corn, which is similar to conclusions about glyphosate usage in soybean and cotton in 2007-2012 (Monsanto, 2013e). In the last two years, there has been little change in the percentage of acres planted to HR crops, and it is reasonable to conclude that there will be little further increase in glyphosate use.

A reason why glyphosate use is not expected to increase is that growers are aware of increasing weed tolerance to glyphosate, so do not use it where resistant weed populations are developing or already prevail. A 2013 proprietary poll of growers from 31 states showed that 49% of growers had detected at least one weed species in their fields that was resistant to glyphosate; 27% reported two resistant weed species (Stratus-Ag-Research, 2013). APHIS expects that growers with preference for GR maize will exchange existing varieties with MON 87411 Maize hybrid which will also express glyphosate resistance. Weeds may continue to develop resistance to herbicides, as with any crop and weed management system.

Stacking MON 87411 Maize with herbicide resistance traits is unlikely to significantly change current trends in herbicide use or to increase resistance of weeds to herbicides beyond current trends. When combined with the past, present, and reasonably foreseeable future actions, APHIS concluded that the Preferred Alternative would have a negligible cumulative impact on herbicide use or weed resistance to herbicides.

5.3.3 Volunteer Management of GR Corn

Potential cumulative impacts to the agricultural environment may include GR volunteer corn. As stacked corn varieties crops are developed containing multiple herbicide resistance traits, the options for volunteer control may become more limited.

Volunteer corn from a parent strain that exhibits glyphosate resistance might be controlled in the present season’s LibertyLink® crop with the use of glufosinate (Minnesota, 2009a; Reddy, 2011). Alternatively, pre-plant corn volunteers containing only the MON 87411 Maize traits could easily be controlled by mechanical cultivation as well as readily available herbicides, including various graminicides (Wozniak, 2002), provided that the MON 87411 Maize or its progeny does not carry resistance to these other herbicides (e.g., accidental admixture or intentional or unintentional crossing of resistant varieties). As discussed earlier, herbicides recommended for control of volunteer corn in soybeans are the ACCase inhibitors and certain ALS inhibitors (e.g., imazamox). The ACCase inhibitors include two families of herbicides, the AOPP ACCase inhibitors (e.g., the “fops,” such as Quizalofop, fenoxaprop, and diclofop) and the cyclohexanediones (e.g., the “dims,” such as clethodim and sethoxydim) (Hager, 2009). MON 87411 Maize is susceptible to the herbicides recommended for control of volunteer corn. Future control of volunteer corn will require the grower to understand the corn variety which has given rise to the volunteer plants. Volunteer corn representing a hybrid containing the traits of MON 87411 Maize and glufosinate resistance, for example, would still be controllable by the ACCase inhibitors and certain ALS inhibitors noted above (Hager, 2009).

Based on these findings, USDA-APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with impacts of the proposed action to affect plants associated with the determination of nonregulated status of MON 87411 Maize.

5.3.4 Specialty Corn Production

A determination of nonregulated status of RNAi MON 87411 Maize will not change market demands for corn produced for specialty corn crops, some of which incorporate similar *Bt* and HR traits. A determination of nonregulated status of MON 87411 Maize will add another GE corn variety to the conventional corn market. Conventionally produced corn (including GE corn) represents the vast majority of corn in states that produce organic corn, and a determination of nonregulated status of MON 87411 Maize is not anticipated to significantly increase GE corn production in these areas. MON 87411 Maize should not present any new and different issues and impacts for specialty producers and consumers. According to the petition, agronomic trials conducted in a variety of locations in the United States demonstrated that MON 87411 Maize is not significantly different in plant growth, yield, and reproductive capacity from its non-transgenic counterpart Monsanto (Monsanto, 2013d). No differences were observed in pollen diameter, weight, and viability. Therefore, MON 87411 Maize 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 specialty production systems would not be required to change to accommodate the production of MON 87411 Maize. APHIS concludes that there will likely be no cumulative impacts to specialty corn following adoption of the MON 87411 Maize and none different from those of other varieties currently produced.

5.3.5 Organic Corn Production

A determination of nonregulated status for MON 87411 Maize is not expected to change the market demands for GE corn or corn produced using organic methods. This determination would add another GE corn variety to the conventional corn market. Based upon recent trend information, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share. Since 1994, 25 GE corn events or lines have been determined by USDA-APHIS to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. Between 2000 and 2008, the total acreage associated with the organic production of corn increased from 78,000 to approximately 195,000 acres, despite concurrent increases in conventional corn acreage (USDA-NASS, 2012a). As reviewed on Organic Corn Farming and Specialty Corn, certified organic corn acreage is a relatively small percentage of overall corn production in the United States. The most recently available data show 169,000 acres of certified organic corn production in 2011, which represented approximately 0.20% of the 92 million acres of corn planted in 2011 (USDA-NASS, 2012a). These total acres in 2011 represent a decrease from the approximately 195,000 certified organic corn acres cultivated in 2008 (USDA-NASS, 2012a).

The general upward acreage trends of both organic and conventional corn production suggest that adding a new GE corn variety, in this case a new breeding stock stacked with glyphosate resistance, is not related to the ability of organic production systems to maintain their market share. Corn varieties containing the same traits as MON 87411 Maize have been in commercial cultivation for over a decade. Corn varieties resistant to glyphosate and no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA have been on the U.S. market since 1996. The GR varieties are already widely cultivated, based on the percentage of corn currently treated with glyphosate (noted Agronomic Production as 66% of the acreage, ~57 million pounds) (USDA-NASS, 2011b; 2011a).

Based on these trends, and the corresponding production systems already in place to maintain varietal integrity, USDA-APHIS has determined that there are no cumulative impacts to organic corn production following a determination of nonregulated status for MON 87411 Maize.

5.3.6 Cumulative Impacts: Physical Environment

A determination of nonregulated status of MON 87411 Maize is not anticipated to have any direct or indirect cumulative impacts on water quality or use; on soil; on air quality; or on climate. Rather, determination would provide growers with an alternative to transgenic CRW-protected varieties than those currently available. A determination of nonregulated status of MON 87411 Maize is not expected to alter the range of corn cultivation as the new transgenic trait (rootworm resistance) does not otherwise change the plant's agronomic performance compared to non-transgenic varieties except for increasing options for rootworm control. Agronomic practices such as pesticide use, fertilizer use, crop rotation, tillage, irrigation, disease management, or weed management for MON 87411 Maize are similar to other corn varieties that are currently available for use by growers. Consequently, no new cumulative impacts on the physical environment are likely following determination of nonregulated status of MON 87411 Maize.

5.3.7 Soil

Soil is the mixture of minerals, organic matter, gases, liquids, and numerous organisms that support plant life. Soil supports four important functions: a medium for plant growth; a means of water storage, supply and purification; a modifier of the atmosphere; a habitat for organisms that modify the soil habitat.

Bacillus thuringiensis*--*Bt Cry proteins may enter the soil environment as either exudates of corn actively in cultivation (Saxena et al., 2004), or from residue of corn plants remaining after harvest. The Cry3Bb1 protein is nonregulated under USDA-APHIS regulations, and environmental impacts have been evaluated by EPA.

RNA--In RNA soil degradation studies, Monsanto found that DvSnf7 dsRNA rapidly degraded in soil, becoming undetectable via a molecular detection assay or insect bioassays within two days of soil application (Dubelman et al., 2014). Soil samples were collected from three maize growing regions representing a range of soil types: silt loam in Illinois, loamy sand in Missouri, and clay loam in North Dakota (Dubelman et al., 2014). The diversity of these soil samples was important given that RNA degradation will depend on the given environment and biological communities present where the product is grown, as well as the soil type (Lundgren and Duan, 2013). Dried root and shoot tissue of maize plants expressing DvSnf7 dsRNA (as in MON 87411 Maize), as well as purified DvSnf7 dsRNA were added to the three soil types to ensure high concentrations of RNA were present (Dubelman et al., 2014). Degradation of DvSnf7 dsRNA was found to occur within two days for all samples tested, independent of the starting RNA concentration, even at orders of magnitude higher than present in maize plants expressing DvSnf7 dsRNA (Dubelman et al., 2014). These studies meet EPA's regulatory requirements to evaluate degradation in different soil types (US-EPA, 2014f). Based on these studies, APHIS concludes that DvSnf7 dsRNA will not accumulate to cause impacts on soils or soil organisms because the persistence in soils is not likely.

5.3.8 Water.

RNA can be stable in aqueous solutions, but only under narrowly defined conditions when ambient RNases have been degraded (Advances-in-Biotechnology-Education, 2010), and the water is adequately buffered. Low water temperature has been shown to increase RNA stability in water. Under natural conditions, water typically contains suspended particulates with bacteria adsorbed on them. These bacteria release levels of RNases that are sufficient to rapidly degrade RNA (Advances-in-Biotechnology-Education, 2010). Based on results from laboratory studies, it is unlikely that RNA can persist in natural waters. Because there is no evidence of RNA persistence in the environment, any potential cumulative impacts of RNA from GE plants or any other sources are not likely. Therefore, APHIS concludes that cumulative impacts on water resources if MON 87411 is no longer regulated by the Agency.

5.3.9 Air Quality and Climate Change

RNAs are not volatile, so there is no potential direct impact on air or climate change, nor is it likely that climate change will greatly increase plant expression of RNAi. Other CRW traits, such as the *Bt* proteins, are also non-volatile, so have no air or climatic impacts.

Potential beneficial changes in air quality can accompany some of the production issues (manufacturing or farming usages) likely associated with adoption of MON 87411 Maize. Use of the CRW traits in stacked hybrids, with both existing *Bt* traits and new DvSnf7 ds RNA technology, may provide new, additive deterrence to CRW damage which may be superior to existing CRW resistance trait technologies. Given the potential, the corn grower may perceive less need for insecticide augmentation of *Bt* corn production, or for alternative use of an insecticide because of perceived inadequacy of CRW *Bt* traits expressed in hybrids. For the physical environment this likely suspension of increasing practices will have two results for air quality and climate change. The first is fewer passes delivering insecticide to CRW infested corn acres, resulting in less CO_2 produced from internal combustion engines. The second is that less insecticide will be produced. The manufacturing of these herbicides would be reduced, and such manufacturing typically consumes both nonrenewable energy and petrochemical precursors. Usage of both resources would be reduced through increasing reliance on plant produced protectants such as those expressed in MON 87411 Maize

APHIS concludes that decreased use of CRW insecticides would decrease petrochemical-based production of insecticides as well as combustion engine usage needed to apply insecticides on farms. These consequences would lessen agricultural impacts on air quality and greenhouse gas production that is driving climate change. There are no other similar actions that would add to any potential impacts occurring with the nonregulated status of this MON 87411 Maize variety that would cumulatively impact soil, water, air quality, or climate resources.

5.4 CUMULATIVE IMPACTS: BIOLOGICAL ENVIRONMENT

A determination of nonregulated status of MON 87411 Maize is not anticipated to have any direct or indirect cumulative impacts on animals, plants, soil microorganisms or biodiversity. A determination of nonregulated status of MON 87411 Maize would not substantively change the overall usage of transgenic corn products with insect resistance traits. Based on the assessments that Monsanto has performed, MON 87411 Maize is not likely to have substantively different impacts on non-target species than would other approved IR corn products with Cry proteins. Other approved genetically modified crops containing Cry proteins have been demonstrated to have no measurable adverse effects on animals or microbial populations in the soil and would continue to be used by growers. MON 87411 Maize does not possess weedy characteristics, so introgression into wild plants or non-GE corn seed production is unlikely to differ from that of other GE corn varieties.

5.4.1 Biodiversity.

The past and current actions potentially contributing to a cumulative effect on biodiversity are the introduction of additional transgenic corn varieties and their increasing use. The future actions potentially contributing to cumulative effects on biodiversity include any deriving from combination of MON 87411 Maize stacked with additional transgenic corn traits exhibiting insecticidal properties or herbicide resistance. This cumulative impacts analysis focuses on potential changes in biodiversity that may result from impacts to non-target plants and animals within the agroecosystem. Other aspects of biodiversity would not be affected.

Animal Communities

As identified in the Environmental Consequences, Monsanto completed an assessment of RNAi impacts on required animal models that represent organisms present in the environment, including birds, vertebrates and invertebrates and found none. The assessment included an evaluation of potential impacts on those animals most likely exposed from corn production. These included invertebrates, such as beneficial insects including honeybees and ladybird beetles. The trait assessed was that of RNAi but effects of *Bt* traits are also relevant to this analysis. For Cry3Bb1, as well as other Cry proteins, corn varieties expressing these traits have been available commercially, without causing environmental impacts on corn agroecosystems, for multiple years. Because the Cry3Bb1 gene will likely be combined with other *Bt* traits, USDA-APHIS considers those potential impacts next.

Several traits expressing different Cry proteins are incorporated into various *Bt* corn varieties to provide insect resistance, including resistance to lepidopteran and coleopteran pests. US-EPA conducted a comprehensive environmental assessment of the registered *Bt* PIPs in 2001 (US-EPA, 2001) IIC1 and in four other individual PIPs, such as m-Cry3A) (US-EPA, 2010d). Although other *Bt*-corn cultivars incorporating Cry proteins have been introduced in the intervening 10 years, and many of the PIPs in earlier cultivars were re-registered in 2010, the

2001 US-EPA review provides a general assessment of the risks to biodiversity associated with *Bt*-corn varieties. Summarizing then-existing published studies and US-EPA's reviews of submitted studies on potential Cry protein impacts to non-target species (vertebrates and invertebrates), US-EPA has concluded that "the weight of evidence from the reviewed data indicate that there is no hazard to non-target wildlife from the continued registration of *Bt* crops" (US-EPA, 2001) section IIC81). Minimal to undetectable adverse impacts, and in some cases beneficial impacts, to non-target insect populations were shown (US-EPA, 2001).

New coleopteran specific *Bt* traits however, could have differing activities towards non-target organisms, although activities are not routinely tested competitively with one another by the seed developers. Rather, GE trait developers individually test for impacts on representative vertebrate and invertebrate animals. Because one group of insects that could be affected by rootworm toxins are other coleopteran insects, non-target beetles such as the rove beetles (Staphylinidae) are often used to make assessments of effects on biodiversity. When three guilds of rove beetles were examined in fields with vegetative stage *Bt*-expressing plants, plots of DAS 59122-7 (rootworm toxins Cry34Ab1and Cry 35Ab1), DAS 59122-7 X Cry 1F (rootworm toxin X lepidopteran toxin), and an isogenic control, only the DAS 59122-7 plots were associated with a significantly larger activity density (increased trap catch) of predatory rove beetle larvae compared to the control or stacked hybrid plots, although only larger by 33% (Balog et al., 2011). In addition to this observation, none of the treatment plots, including isogenic controls or the insecticide treated controls contained lower activity densities than those found on *Bt*-trait plants (Balog et al., 2011). Thus, based on this information it appears that rove beetle biodiversity was not impacted by exposure to IR plants that express the *Bt* trait. Additional interactions of *Bt* varieties individually possessing no activity towards non-target insects are not likely to synergistically or cumulatively affect non-target insects either, since they likely all have similar mechanisms of toxicity to insects.

RNAi and Potential Biodiversity Impacts

An issue identified within the Environmental Consequences section is the potential that MON 87411 Maize may have impacts on non-target organisms. Two approaches might be taken to assess these potential impacts. A first approach can be use of test organisms similar to those recommended by EPA for assessing impacts of plant incorporated protectants such as Cry proteins; these organisms can be tested for possible adverse effects. Other approaches have been suggested by the EPA's Science Advisory Panel EPA. These may include:

- dose and response studies of DvSnf7 dsRNA on target organisms
- considering likely non-target organisms and making bio-informatics analyses on target gene similarities in the sequenced genomes
- evaluating impacts on various non-target organisms at different life stages (the target sequence may or may not be expressed in egg, larval, pupal or adult stages)
- studying RNAi uptake and molecular responses

- finally, conducting field tests for effects on food webs in target crops

Because most of the impacts of potential RNAi on non-target organisms are tested theoretically, EPA has not defined what would be appropriate testing strategies for environmental RNAi expressing products

Sequence Similarities from Bioinformatics Assessments and Mortality

The gene silencing efficacy of dsRNA based mortality using an RNAi mechanism on CRW larvae was demonstrated from multiple sequences deriving from genomic libraries of the CRW in diet based assays (Baum et al., 2007c). By appropriate design of the target sequence, specific insects can be targeted, or even multiple species (Whyard et al., 2009). Either full length genes mediating dsRNA sequences could cause CRW mortality, as could shorter 300-nucleotide t sequences (Baum et al., 2007c); after processing of this dsRNA, siRNA sequences of 21 nucleotides were found, which are the typical length of RNA gene silencing sequences. These dsRNAs can be expressed in corn, and cause gene silencing and mortality when ingested by rootworm (Baum et al., 2007c).

Impacts of DvSnf7 dsRNA on taxonomically related non-target insects, which would be expected to be most affected by off-target binding, may be directly assessed on insect populations. In testing DvSnf7 dsRNA, Monsanto researchers tested 10 species of insects (representing 10 families and 4 orders) that were phylogenetically related to WCR to test the specificity of the 240 nucleotide DvSnf7 dsRNA used in MON 87411 Maize (Bachman et al., 2013b). Within the family Chrysomelidae, in which WCR is classified, Monsanto's 240-nucleotide sequence diverges across insect taxa so that varying degrees of homology could be compared with mortality (Bachman et al., 2013a). Contiguous sequences of at least 21 nucleotides within the target 240 nucleotide sequence were the requirement for beetle mortality (Bachman et al., 2013b). As sequence divergence increased, the likelihood of, off-target effects at least in direct feeding assays declined. Because some species could not be fed the WCR dsRNA, Bachman et al. (2013) tested orthologs (homologous genes) of *DvSnf7* from different species for efficacy against WCR (Bachman et al., 2013b). At least three sets of identical 21-nucleotide sequences from these species and more than 90% 240 base pair similarity of host genes were minimally required to kill WCR (Bachman et al., 2013b). In two beetles in the same subfamily and tribe (Galerucinae: Luperini) as CRW and one in the tribe, Galerucini, DvSnf7 dsRNA showed some gene targeting activity in the indirect assay.

The lack of impact by direct feeding on beetles not of the same genus as *Diabrotica* in Monsanto's direct feeding studies may be ascribed to insufficient RNA specificity (number 21 nucleotide matches) but may also be explained by other means (Terenius et al., 2011; Bachman et al., 2013b). Other insects more taxonomically distant may take up or degrade RNA differently from CRW, and may show no impacts on target genes even though they have genes with similar sequence identities.

Potential Consequences of Sequence Similarities from Bioinformatics Assessments

Sequence identity of targeted genes with genes in non-target insects is possible, especially since the effective size of the RNA is around 21-22 bases in insects (Elbashir et al., 2001). While the potential for sequence matches of targeted genes in non-target organisms is important, the target organism may not be exposed because of degradation mechanisms, lack of feeding on the RNAi-producing tissue, or timing of exposure to those tissues, all of which could prevent effective dosage (as previously noted). All these could mean that sequence matches between the RNAi in a non-target organism and the endogenous RNA would not necessarily expose the organism to an actual impact. Sequence matches could be identified in some field-relevant non-target organisms, and probably could be evaluated insect-by-insect. However, these bioinformatics-based analyses may only be marginally useful to predict possible impacts of specific RNAi. APHIS concludes that only whole organism challenges would be most likely to provide accurate impact assessments.

Another important concern about the technology of RNA interference is that an siRNA may target not only specific RNAs of an organism, but that off-target effects can also be detected (Caffrey et al., 2011). Off target effects of an insect RNAi on a cytochrome P450 gene has been shown on one non-target sequence in the moth *Plutella* (Bautista et al., 2009), although the author qualifies this conclusion with a caution that high dosage of RNAi may be an issue. Indeed, *Snf7* from others of the Galerucinae subfamily family can be toxic to WCR, at high enough dosage, with as few as three 21 nucleotide sequence similarities in the genome, but apparently requiring a higher dosage of these Snf7s than the dose of WCR RNAi causing mortality to WCR or to southern CRW (Bachman et al., 2013b). Otherwise, even in these indirect assays, when no continuous sequences were found in non-target insects with 21 nucleotides identical to the introduced DvSnf7 dsRNA, no mortality could be shown.

Life Stage Exposure

A thorough investigation of impacts for some types of sequences may need to be assessed in just certain life stages, or developmental events, such as during reproduction. The DvSnf7 dsRNA chosen by Monsanto, however, is likely a functionally necessary protein used by all stages in insect development, so multiple insect developmental stage assessments may not be needed. Furthermore, the means of exposure to active dsRNA must be realistic ones, and similar in dosage and similar to the food matrices which would be found *in planta*.

Dosage studies should also take into account the possibility of multiple exposures. Test material stability may not provide continuous exposure. For instance, multiple exposures are needed in the cotton bollworm to attain persistent silencing (Asokan et al., 2013). Thus, length of exposure may also be relevant to effects on insects, and Bachman et al. (2013a) provided extended exposures (ca. 12 days) to non-target test insects, and also assessed stability of the dsRNA in test diets during the course of the assays (Bachman et al., 2013a). These measures assured diet exposures 250 times higher in concentration than the plant-based exposures. Concentration dependence of silencing effects depends on specific genes, with some genes better candidates than others for producing developmental or toxic effects on the recipients (Asokan et al., 2014). Non-target effects were mostly studied in newly emerged nymphs and larvae, which would likely be more susceptible than stages of these test insects Bachman (Bachman et al., 2013a).

Concentration Dependence of Interfering RNA

Off target effects can be modulated by providing RNAi in sufficiently low concentration that the off-target effects are essentially eliminated (Hannus et al., 2014). In Western CRW, specific quantities of injected dsRNA from designed WCR gene libraries differentially targeted larval sequences (with mortality or stunting) in a gene-specific manner (Baum et al., 2007b). While some RNAi candidates were active at 52 ng/ml (43% of 290 dsRNAs), others were active at 5.2 ng/ml (21% of 190 dsRNAs), and a few of the most active of these (20 of 26 dsRNAs), had an LC_{50} at 0.52 ng/ml (Baum et al., 2007b). From tissue analyses, the fresh weight in roots of expressed DvSnf7 dsRNA was 1-3 nanograms/gram, and 13-14 nanograms/gram in leaves. If the activity of dsRNA constructed from CRW libraries is typical of activity levels of the plurality of active dsRNA in CRW (52 nanograms/ml), it would appear that expected snf7 RNA in MON 87411 Maize tissues is expressed at similar and slightly lower levels (at its highest plant expression levels). If the plant-expressed DvSnf7 dsRNA is greatly diminished before gaining exposure to the sensitive insect cells, this would represent an even lower exposure level and may be less likely to induce off-target effects.

Target Site Dosage Differences

A number of other issues provide evidence for the likely safety of usage of this plant-delivered RNAi, as recognized by the EPA SAP conclusions (US-EPA, 2014f). RNA inhibition products can be expressed selectively in plant tissues, potentially allowing some non-target insects to be protected from exposure or have reduced exposure because of a limited site of plant presentation or expression; likewise, MON 87411 Maize expression is lower in some corn tissues than others. Corn leaves, roots and whole plant tissue expression levels are in the nanograms/gram range of DvSnf7 dsRNA by dry weight, and in many tissues, pollen, corn grain and stover, much less (Monsanto, 2013d). High degrees of RNA sequence specificity can reduce potential for non-target organism impacts, especially if as noted, the concentrations of delivered RNA are within low ranges that do not trigger the off-target effects. Clearly, many other issues may be barriers to possible impacts on non-targeted sequences and non-target organisms. RNAi that is ingested probably has its effects mostly on midgut tissue (Terenius et al., 2011),, although other tissues and some genes may be affected in some insects such as the moth *Plutella* (Bautista et al., 2009) and gene suppression occurs in additional *Diabrotica* tissues (Bolognesi et al., 2012), so some gene sequences and tissues may not be fully targeted. Effects are also related to the identity of the target gene and its function (Baum et al., 2007c), and perhaps to the stability of the specific sequence (Terenius et al., 2011). Finally, effects certainly depend on the species-specific kinetics of uptake and endosomal sorting that is an important parameter for activity (Terenius et al., 2011).

Multiple Sources of RNAi Exposure.

APHIS additionally concludes that there are no additional RNAi products that are likely to be available in the foreseeable future, and thus, potentially combine for additional exposure of animal targets in corn agroecosystems. Competition experiments involving simultaneous feeding of dsRNA to larval *Diabrotica virgifera* (WCR) show that the longer dsRNA sequences can suppress the activity of the shorter by about 50% (Miyata et al., 2014). Should other interference RNAs be made available because of new commercial products, additional impacts may not be likely following determination of nonregulated status for MON 87411 Maize because suppression levels provided by a second RNAi may not be adequate to produce gene silencing when both the new product and existing products are ingested by a non-target insect. If multiple products became commercially available, the specificity of targeted novel sequences for physiologically unrelated metabolic pathways would likely engender minor or incomplete interference between gene targets. APHIS does not foresee any cumulative non-target impacts that would derive from expression in corn of this RNAi corn combined with any other products to be offered in corn production.

Interference of Cry toxin proteins with RNAi targeted gene sequences has not been studied. However, non-target organisms exposed to corn are not susceptible to Cry toxins, and so there would be no additivity expected from *Bt*-trait exposure coupled with DvSnf7 dsRNA exposure. The action of Cry protein on gut tracts of non-target insects by incidental feeding from extensive assessments in previous studies is not likely to cause adverse impacts, so interaction or synergism of DvSnf7 dsRNA and *Bt* traits would not be expected to occur in these non-target organisms.

Pyramids of *Bt* Traits and Potential Impacts on Non-target Insects

Potential impacts of pyramiding of multiple rootworm toxins has been studied in field plots, but neither synergism nor complete additivity of two *Bt* traits were supported (Hibbard et al., 2011). Stacking of Syngenta eCry3.1Ab corn with MIR604 decreased adult rootworm emergence across all replications and environments in field test sites when compared to the single toxin-expressing hybrids. The two genes responsible for resistance in each line are apparently not acting entirely independently, since the numeric product of relative percentage survivorship for each line (eCry3.1Ab and for MIR604) should be the same as the measured survivorship in the dual toxin corn but adult emergence differed in both. Direct studies of potential synergism between DvSnf7 dsRNA and Cry3Bb1 were conducted (Monsanto, 2014a). No evidence for interaction was detected, following an approach proposed by Tabashnik in 1992 (Tabashnik, 1992). The potential impacts of further pyramiding of *Bt* traits and DvSnf7 dsRNA should not supply additional cumulative impacts to non-target organisms.

Pyramiding *Bt* traits with DvSnf7 dsRNA should, as described earlier, increase the useful lifetime of these traits before CRW resistance develops. The commercial *Bt* traits active on rootworm have a history of narrow toxicity, and do not have impacts even on related non-target coleopteran insects (see similar petitions including APHIS 10-336-01, 04-362-01, 04-125-01, 03-353-01 USDA-APHIS (USDA-APHIS, 2014a). The DvSnf7 dsRNA has been assessed for the potential to impact non-target organisms with a strategy much broader than that required by EPA for screening of PIPs. Bachman surveyed gene silencing effects of direct feeding on survival of DvSnf7 dsRNA in three families of Coleoptera (Bachman et al., 2013b). In the families, Chrysomelidae and Tenebrionidae, there was no observed mortality, and this was also observed for the Galerucinae except for effects on target species (i.e., *Diabrotica* spp. (Bachman et al., 2013b). This required specificity of the DvSnf7 dsRNA effects outside the *Diabrotica* genus will limit non-target impacts when coupled with *Bt* traits.

Although non-target effects are clearly not expected based upon single Cry toxin assessments, possible effects were sought by empirical methods to assess antagonism, potentiation, additive toxicity or synergism of exposure to multiple CRW traits (Monsanto, 2014a). These studies used Cry 3Bb1 and DvSnf7 dsRNA, but using subtoxic levels, with the strategy proposed initially by Tabashnik (Tabashnik, 1992). As noted earlier, there was no evidence of interaction between the traits. The hybrids likely to be constructed by Monsanto would potentially combine three rootworm-active traits that each provide control of western, northern, and Mexican CRWs. The stacked *Bt* traits can be chosen so that no cross-resistance between them has been demonstrated from empirical assays. Because the mechanisms of the traits are entirely different, cross-resistance would not be possible between the DvSnf7 dsRNA and the Cry3Bb1 protein. APHIS-USDA does not expect any deleterious impacts for the use of the new RNAi trait when combined with existing CRW *Bt* traits; if any, there may be diminished selection pressure on some *Bt* traits if DvSnf7 dsRNA is deployed with *Bt* traits, or if the RNAi trait is deployed in place of other *Bt* traits.

Impacts of GE *Bt*-Expressing Maize and Insecticide Use

Various chemical treatments are applied to corn seed with the rootworm specific traits; recently this nearly always includes a systemic neonicotinoid (Smith, 2005). When species richness within three coleopteran families was assessed throughout a field corn growing season, no differences were detected in fields of isoline and Cry3Bb1 varieties when *Bt*-corn seeds were also treated although total coleopteran numbers were higher in the isoline in the second year of the experiment. Similarly, when rows were conventionally treated with pyrethroids (during the silking stage), there was no significant difference in coleopteran abundance between Cry3Bb1 and pyrethroid treated field corn in the first and second years. However, in one year, coleopteran abundance in field corn in the Cry3Bb1 isoline was higher than that for pyrethroids plus Cry3Bb1 treatment in the second year (Leslie et al., 2010). Mortality deriving from exposure of coleopteran species to the neonicotinoid seed treatments had previously been demonstrated in laboratory analyses but not from exposure to Cry3Bb1. Specific impacts on certain species following neonicotinoid exposed Coleoptera were not different from those impacts found when these species were exposed to pyrethroids by field application. No end-of-growing-season impacts on coleopteran species followed from use of the Cry3Bb1 hybrid crop (Leslie et al., 2010).

Studies have also concluded that the use of *Bt* crops, rather than use of broad-spectrum insecticides, could allow larger populations of beneficial insects and non-pest herbivores to persist in planted fields (Pilson and Prendeville, 2004). Yu and colleagues (Yu et al., 2011) following a comprehensive survey of field populations of non-target organisms to *Bt*-expressing corn hybrids also concluded that *Bt* has no direct detrimental effects. The surveyed hybrids may be supportive of increased numbers of beneficial insects and consequently, improve natural control of pests by the increase of predatory insects.

US-EPA also noted that *Bt* crops have a positive impact on soil fauna and flora compared to non-selective synthetic chemical pesticides (US-EPA, 2001). Oliveira and others (Oliveira et al., 2008) have detected no changes in organisms or the soil activities surveyed between soils planted to *Bt* (Cry1Ab) crops or to their non-GE isolines. No effects on soil decomposer communities or litter decomposition rates from corn plant parts (Cry3Bb-expressing hybrid) buried in soil were detected during a 25 month analysis (Xue et al., 2011).

Impacts of Herbicides on Animal Diversity

In general, applying less toxic herbicides (e.g., glyphosate on GR crops) may be more environmentally beneficial than at least some other herbicides with non-GE crops (Pilson and Prendeville, 2004). However, site specific impacts on a species level basis are not always as clear. Birds that consume products of weeds targeted by the herbicides could potentially be impacted if for example, weed seed is significantly reduced. Granivorous birds in HR corn in farm scale trials have typically responded to the reduction (Chamberlain et al., 2007). Some relationships between herbicide use and biodiversity are difficult to determine. For example, one study suggested that reductions in populations of monarch butterfly (*Danaus plexippus*) overwintering in Mexico might be attributed in part to loss of host milkweed (*Asclepias syriaca*) plants in the Corn Belt from the extensive use of glyphosate (Brower et al., 2012). Other studies have indicated that monarch populations are very dynamic because of the high reproductive potential of this species, and no similar reduction was observed in populations studied in the US where glyphosate use on crops is frequent (Davis, 2012). Following analysis of the issues of potential non-target impacts, APHIS has determined that there are no likely past, present, or reasonably foreseeable actions that would combine or interact with impacts of the proposed action to affect non-target organisms.

Plant Communities

With a product likely pyramided to include two or three traits for herbicide resistance, growers using the MON 87411 Maize traits would continue using glyphosate for weed control because glyphosate still controls large numbers of weeds (Monsanto, 2013f). Additionally, they may use glufosinate sequentially on the same crop (if included in a stack) or alternately in consecutive crop years to optimally manage weed resistance. Used according to typical state extension designated practices, impacts on biodiversity of crop-associated plant species should be no different than that expected from impacts of any two or three individual herbicide traits. Under these practices, development of resistant weeds could decrease, which could have small benefits on plants associated with the margins of the agroecosystem with which such resistant weeds would be less likely to compete.

Historically, increased selection pressure on weeds originated from the “repeated and intensive use of herbicides with the same mechanisms of action” (Vencill et al., 2012), including expanded use of glyphosate on GR crops. Subsequent reductions in the use of other herbicides, and also changes in weed management practices (such as the reduction in tillage and decreased use of crop rotation) played a role as well. These factors have all resulted in both weed population shifts and increasing glyphosate resistance among some weed populations (Owen, 2008b; Duke and Powles, 2009). GR crops themselves do not influence weeds any more than non-transgenic crops. It is the weed control tactics chosen by growers that create selection pressure that gradually shifts these weed communities and may result in the continuing evolution of HR weeds (Owen, 2008b). Impacts of herbicide treatment on all environmental resources, including to non-target plants, are assessed by the EPA.

Selection pressure on weeds would not likely change with a recognition of nonregulated status for MON 87411 Maize because general herbicide usage on corn would only change marginally. However, selection pressure is influenced by factors other than the volume of herbicide applied. The selection pressure is strongly related to the repeated use of one or a limited number of herbicides (Durgan and Gunsolus, 2003; Duke, 2005). It is also a function of the diversity of management practices employed (Vencill et al., 2012). APHIS concludes that the greater the diversity of management practices, the lesser the selection pressure for resistant weed development; future grower choices to follow good management practices are important for controlling future selection pressures on weeds.

Predictions of market share for this product are not available, but as noted in 2012, Monsanto was estimated to be the top selling seed company selling 35% of total corn seed in the US with DuPont Pioneer second with 34% (ASTA, 2012). A high percentage of Monsanto branded traits are cross-licensed for sale in corn seeds in other seed brands as well, perhaps to two thirds of the corn seed market. Thus, if Monsanto offers *snf7* technology to other seed providers, APHIS concludes that the potential market share for *snf7* technology could comprise a large part of the corn market. It is possible that should resistance to other herbicides be made available in trait pyramids, such as 2,4-D, use could potentially increase, along with other herbicides for which crop resistance might also have been offered in the pyramids. Glufosinate at present is offered in a number of other brands. However, glyphosate use will likely not increase, since it appears to have reached market saturation already and most corn in the United States already has the GR trait.

Selection of the preferred alternative and the use by growers of MON 87411 Maize will also require participation in Monsanto Technology Stewardship Agreements (MTSA) and Technology Use Guides (TUGs). The TUGs contain best management practices and requirements for growers who use MON 87411 Maize varieties, including weed resistance management practices (Monsanto, 2013g). Practices in these guides direct grower to use an herbicide with a third mode of action in GR crops, and may contain recommendations for the most effective rates and timing of applications for glyphosate and glufosinate treatments. These practices could reduce the potential for weed communities to shift to more resistant weed species in cotton fields. The Guides also direct growers to use herbicides with overlapping and with alternative sites of action, practices which could potentially diminish the populations of GR weeds and reduce the likelihood of the development of new HR weed populations (Dill et al., 2008a; Duke and Powles, 2008; Owen, 2008a; Duke and Powles, 2009; DAS, 2010a; Norsworthy et al., 2012a). Appropriate weed management requires much more than the application of herbicides, however. To avoid decreased crop yields resulting from weed competition, growers must continually adapt previous weed management strategies and seek advice for best management of weed problems.

With the likely pyramiding of products deriving from MON 87411 Maize, including two or greater available traits for herbicide resistance, growers could continue using predominantly glyphosate for weed control, or use glufosinate sequentially on the same crop, or alternately in consecutive crop production years to optimally manage weed resistance. Used according to US-EPA designated conditions, impacts on biodiversity of plant species should be no different than that expected from impacts of the two individual herbicide traits. Under these practices, development of new resistant weeds could decrease, which could have small but not significant impacts on plants associated with the margins of the agroecosystem.

Stacking MON 87411 Maize with herbicide-resistance traits may potentially increase the incremental use rates of herbicides, such as glufosinate if it is stacked with MON 87411 Maize. Other herbicides might be displaced as well if additional herbicides are found to be more useful (for MON 87411 Maize production) than other frequently used herbicides now used in corn production. These increases could potentially contribute (but to a negligible degree) to increased weed resistance not merely because use of those herbicides may be increased, but if they are not used with best practices in mind that include diversity of herbicides and diversity of cultural practices as well. APHIS concludes that although specific management practices to minimize resistant weed development are necessary for prevention of new resistant weeds, and that these are grower choices, as noted earlier, growers are more likely to employ them as integral to their crop management practice than were growers in the earlier days of HR crops. Based on these findings, USDA-APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with impacts of the proposed action to affect plant communities.

Microorganisms

A determination of nonregulated status of MON 87411 Maize is not expected to result in changes to current corn agronomic or cropping practices. Stacked hybrids combining the traits of MON 87411 Maize with nonregulated GR varieties would allow the application of glyphosate to MON 87411 Maize in addition to other potentially stacked HR traits such as glufosinate. The cultivation of corn hybrids presenting the traits of Cry3Bb1 and glyphosate resistance in MON 87411 Maize is already commercially available in the form of numerous hybrids. No impacts to soil microorganisms have been reported associated with the commercial cultivation of these varieties.

Microorganisms produce aromatic amino acids through the shikimate pathway, similar to plants (USDA-FS, 2003). Because glyphosate inhibits this pathway, it could be expected that glyphosate may be toxic to microorganisms. However, field studies show that glyphosate has little effect on soil microorganisms and, in some cases, field studies have shown an increase in microbial activity due to the presence of glyphosate which can be metabolized for energy (USDA-FS, 2003; Duke et al., 2012). Glyphosate use has been identified as potentially causing increases in certain plant disease-causing microbes (Fernandez et al., 2009; Kremer, 2010; Duke et al., 2012). However, reported increases in infections from pathogenic soil fungi have been determined to be more closely related to reduced tillage and continuous cropping using HR crops, rather than application of glyphosate (Fernandez et al., 2009; Duke et al., 2012). APHIS is not aware of any persistent soil changes caused by applications of herbicides, or from various

Cry proteins. No impacts on soil microorganisms of isolated RNAs are known, and APHIS does not expect persistence of interference RNAs in soil.

Based on these factors, USDA-APHIS has determined that there are no past, present, or reasonably foreseeable actions that would combine or interact with impacts of the proposed action to affect soil microorganisms.

5.4.2 Biodiversity Conclusions

Stacking MON 87411 Maize with additional CRW resistance traits would potentially protect usage of other *Bt* traits from overexposure and thus avert future CRW resistance. Another effective CRW toxin may also decrease broad-spectrum insecticide use, because growers would have more confidence in a better plant-expressed technology. APHIS concludes that MON 87411 Maize may cumulatively reduce the selection pressure for rootworm resistance along with continued use and stacking of the genes in this variety with other *Bt* traits. Further, as an effective CRW trait, MON 87411 Maize may also indirectly lead to reduced adverse impacts to non-target insects no longer exposed to additional insecticides. APHIS concludes that there are no past, present or expected effects of other rootworm protection strategies that will accumulate to result in any cumulative impacts on biodiversity from the introduction of MON 87411 Maize.

5.5 CUMULATIVE IMPACTS: GENE MOVEMENT

Management methods are available to control pollen drift. These methods include having measures in place as part of seed certification and varietal protection to restrict pollen movement and gene flow between cornfields through the use of isolation distances, border and barrier rows, the staggering of planting dates, detasseling and hand pollination, and various seed handling, transportation and handling procedures (Wozniak, 2002; Mallory-Smith and Sanchez-Olguin, 2011).

5.5.1 Vertical Gene Flow

USDA-APHIS has considered vertical gene flow in its PPRA.APHIS concluded that there is no difference in the likelihood that MON 87411 Maize will increase vertical gene flow to other varieties of corn compared to existing cultivars.

No available evidence indicates that stacking the glyphosate resistance trait in a MON 87411 Maize hybrid would require changes to the standard management measures or result in a change in the viability of corn cultivars outside of cultivation. Based on the absence of such evidence, APHIS did not identify any cumulative impacts to vertical gene flow associated with potential stacking with a glyphosate resistance trait.

5.5.2 Horizontal Gene Transfer

Based on available scientific evidence, USDA-APHIS has not identified any cumulative impacts on horizontal gene movement that would occur from a determination of nonregulated status of MON 87411 Maize. USDA-APHIS has considered horizontal gene transfer for multiple corn varieties and has found no evidence of naturally occurring transgene movement from GE crops to sexually incompatible species (USDA-APHIS, 2014b). There is no evidence to suggest that the stacking of the events conferring new traits to MON 87411 Maize would alter this conclusion. Based on these findings, USDA-APHIS has not identified any cumulative impacts to horizontal gene transfer associated with potential stacking with a glyphosate resistance event.

5.6 CUMULATIVE IMPACTS: HUMAN AND ANIMAL HEALTH

There are no expected impacts on human health related to the Preferred Alternative. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with impacts of the Preferred Alternative to affect public health, worker safety or animal feed. A determination of non-regulated status of MON 87411 Maize would provide growers with an alternative to other transgenic CRW-protected varieties than those currently available.

5.6.1 Human Health

The Cry3Bb1 protein is derived from a family of Cry proteins that has a long history of safe use in food crops (US-EPA, 2001) (updated 2011). Likewise, the trait for glyphosate resistance has been used safely for extensive periods in several major crops, including other corn, soybean, and sugar beet varieties. DvSnf7 dsRNA will be processed by WCR to suppress the *Snf7* gene. While this trait has not been previously commercialized, double-stranded RNAs are commonly used by eukaryotes, including plants, for endogenous gene suppression. Exposure to double stranded RNA of humans or animals in food, feed or the environment are not considered a risk, since these RNAs are always present and are rapidly degraded by metabolic enzymes in human cells and organs. This topic is more extensively reviewed in subsequent pars of this subsection.

The level of exposure of humans to DvSnf7 dsRNA in corn grain was determined as 0.1 microgram/gram dry weight, and the range of exposure to other parts of the plant from below the limit of detection to 0.21 micrograms/gram dry weight over all plant tissues and times of collection (Monsanto, 2013c). The total exposure of humans through food intake was estimated at less than 0.4 nanogram/kilogram/day. The total value of all consumed RNA and DNA is 1-2 grams/day, which is greater by a factor of 2 billion times. Assuming other products of RNA technology may be available in future markets, those with similar overall exposures are not likely to contribute much to these totals. The threshold of toxicological concern is 1.5 milligrams/day of RNA (Kroes et al., 2005). Exposure at levels that are nearly 4 thousand times lower can therefore be considered inconsequential. The second critical consideration to this evaluation of potential human health impacts is that the ingested dsRNA is extensively degraded in the mammalian digestive system by ribonucleases and digestive acids. Biological barriers also reduce the potential from exposure (US-EPA, 2014f). These conclusions were derived by a panel convened by the US-EPA in 2014 to consider the safety to humans of these types of RNAi products.

A recent study questioned the safety of RNA sequences classified as microRNA (miRNA), which are short non-coding RNA sequences that regulate gene expression and are found in plants and animals. A 2012 study identified an abundant rice miRNA in animal sera and tissues following oral consumption (Zhang et al., 2012a). Researchers concluded that miRNA from the consumed rice was not only present, but it also regulated animal gene expression by binding animal mRNA in the liver (Zhang et al., 2012a). This hypothesis presented by Zhang et al. contradicts previous evidence that RNA consumed orally could not survive the gastrointestinal (GI) tract, as noted above. The abundance of miRNA in all plant-based food products, and the consequent history of safe use also confounds the Zhang et al. hypothesis (Ivashuta et al., 2009). Past and subsequent research studies and reviews have not found evidence that plant miRNAs regulate gene expression after oral consumption, or accumulate in animal sera or tissues (Zhou et al., 2011; Dickinson et al., 2013; Petrick et al., 2013; Snow et al., 2013; Witwer et al., 2013; Witwer and Hirschi, 2014). As a possible explanation for the Zhang et al. data, another study found references to plant miRNAs in public RNA databases for small animals and insects (Zhang et al., 2012b). This result led researchers to conclude that the presence of plant miRNA in animal or insect samples likely resulted from sequencing artifacts rather than oral consumption of plant miRNA (Zhang et al., 2012b). The changes in gene expression which were observed by Zhang et al have also been attributed to a lack of balanced diet. Other studies of animals fed a balanced diet that included rice did not observe such changes in gene expression (Zhou et al., 2011; Dickinson et al., 2013). It has been proposed that dietary factors can influence miRNA expression that then influences gene expression (Ross and Davis, 2014), but uptake of exogenous miRNA from the diet to regulate gene expression contradicts all previous evidence about RNA stability in the GI tract.

APHIS concludes that even considering the possibility that more RNAi products might be commercially available to consumers in the future, there is little likelihood that DvSnf7 dsRNA or other products expressing similar dsRNA will have impacts on humans, either alone or when combined with products from corn hybrids containing the trait for DvSnf7 dsRNA.

5.6.2 Worker Safety.

Worker safety issues related to agronomic practices and the use of pesticides during agricultural production of MON 87411 Maize would remain the same under both alternatives. Agricultural production with MON 87411 Maize does not require any change to the agronomic practices or chemicals currently used (i.e., pesticides) for conventional corn. A panel of experts convened by EPA on environmental impacts of RNAi technology noted that safety concerns for humans were nonexistent, given several mechanisms that would prevent systemic introduction into humans (US-EPA, 2014f).

5.6.3 Animal Health and Feed

The *DvSnf7* gene sequence itself has been tested in a variety of phylogenetically related insects by direct assays, as well as in those tests required by EPA for plant incorporated protectants. These include earthworm, honeybee, parasitic wasp, ladybird beetle, carabid beetle and the insidious flower bug, and no adverse effects were observed.

The potential animal feed and animal health effects from the cultivation of GR crops, with a corresponding analysis of the implications of the use of glyphosate, have been evaluated thoroughly in other USDA-APHIS EAs since the 1993 introduction of the first GR crop product

(USDA-APHIS-BRS, 2015). The use of glyphosate herbicide does not appear to result in adverse effects on development, reproduction, or endocrine systems in animals (US-EPA, 1993). In animals, most glyphosate is eliminated in feces and urine (US-EPA, 1993). Under present and expected use conditions, and when used in accordance with the EPA label, glyphosate does not pose a health risk to animals as an animal feed concern. Pesticide residue tolerances for glyphosate include concentration benchmarks for field corn for forage, grain, and stover, and cover animal feed and animal tissues (US-EPA, 1993; 2011d). USDA-APHIS assumes that applications of glyphosate to a stacked corn variety incorporating the MON 87411 Maize traits will be conducted consistent with the label and consistent with the pesticide residue tolerances.

Monsanto has determined that MON 87411 Maize is the compositional equivalent of other similar conventional corn foundation varieties. Similar comparisons have been conducted by petitioners for all of the other nonregulated corn traits with which MON 87411 Maize is likely to be stacked (USDA-APHIS-BRS, 2015). As noted in Environmental Consequences (Human Health) in each of these previous reviews, the US-FDA also has completed a consultation, including the most recently completed consultation for a CP4-EPSPS based GR corn for a Stine Seed Company product (US-EPA, 2014c). In these consultations, the US-FDA notes that the presence of the EPSPS protein does not give rise to any animal feed concerns. Animals are already exposed to the EPSPS protein in these glyphosate-tolerant varieties. The EPA has published an exemption from tolerance for the CP-4 EPSPS protein in all plants (US-EPA, 2007b)as well as tolerances for glyphosate residues for corn and corn products used in animal feed (40 CFR 180). It is highly unlikely that a conventional hybrid stack of MON 87411 Maize expressing a glyphosate-tolerant trait would substantially change the composition of the resulting corn variety. Based on these factors, no cumulative impacts to animal feed have been identified related to the determination of nonregulated status of MON 87411 Maize.

5.7 CUMULATIVE IMPACTS: DOMESTIC AND TRADE ENVIRONMENT

Based on information provided about the domestic economic environment in Section 4, USDA-APHIS concluded that a determination of nonregulated status of MON 87411 Maize will have no foreseeable adverse cumulative impacts on the domestic or trade economic environment.

5.7.1 Domestic Economic Environment.

As reviewed previously in this section (see Reasonably Foreseeable Future Actions), MON 87411 Maize will likely be used to develop stacked or pyramided hybrids, combining its traits with corn varieties no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA.

The cultivation of another variety pyramided with multiple CRW-resistance traits may provide a choice for growers that offers greater potential for corn protection, As noted, some of the *Bt* traits have been identified as ones to which some CRW populations have become resistant. Those traits need either additional augmentation with insecticides, or pyramiding with another *Bt* trait. For stacks containing a pyramid with another CRW trait that has no cross resistance with existing *Bt* traits, Monsanto DvSnf7 dsRNA may be an efficacious trait to permit sustainable use of these CRW toxins. Thus, MON 87411 Maize may be chosen preferentially over other existing single-trait and pyramided *Bt* traits. APHIS concludes that there may be displacement of these existing *Bt* varieties.

Based on these factors, APHIS has identified no net negative cumulative impacts on domestic economics have been identified as associated with the cultivation of MON 87411 Maize. If growers adopt the stacked variety and take advantage of the weed management strategy incorporating better traits to manage CRW and traits allowing herbicides with different modes of action to control GR weeds, increased farm economic returns can be maintained.

5.7.2 Trade Economic Environment

Current and historic economic evidence indicates that HR corn technology has the potential to lower production costs, and increase yield (Brookes and Barfoot, 2014). While production costs are important for US sales of corn on the international market, growers predicting increased input costs along with diminished US sales are likely to choose not to grow corn at all, knowing that other countries have considerable volumes of competing stocks of corn to sell (Peters and Dreibus). Thus, the grower choosing to plant corn potentially based on input costs may be only one factor in US export sales. While corn export sales are presently at half of historical levels, corn production has been increasingly tied to domestic policy decisions, especially those mandating renewable fuel production, rather than international sales (Brester, 2012; Peters and Dreibus).

Monsanto intends to submit applications to regulatory agencies of key international markets prior to initiating commercial launch of the MON 87411 Maize (Monsanto, 2013c). These decisions will be consistent with the Biotechnology Industry Organization Policy on Product Launch. As of 2011, 26% of the total global lands committed to agriculture were cultivated with stacked GE varieties, and international acceptance among many countries, especially those with a functioning biotech regulatory system, is common (James, 2011). USDA-APHIS has determined that there are no past, present, or reasonably foreseeable actions that in aggregation with impacts of the proposed action would negatively impact the trade economic environment.

6 THREATENED AND ENDANGERED SPECIES

The Endangered Species Act (ESA) of 1969, as amended (1973) was the first conservation law enacted by the United States that extended specific protections to invertebrates. As such, it is one of—perhaps the most—comprehensive conservation laws ever enacted by any nation. Congress enacted the ESA to prevent extinction of numerous species of fish, wildlife and plants challenged by overfishing and exploitation. The purpose of the ESA was and is to conserve endangered and threatened species and the ecosystems they are dependent on as key components of America's natural history heritage. To implement the ESA, the U.S. Fish & Wildlife Service (USFWS) cooperates with the National Marine Fisheries Service (NMFS), other U.S. government agencies (Federal, State, and local), Native American Tribes, non-governmental organizations, and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must 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
- The natural or manmade factors affecting its survival

Once an animal or plant is added to the list, protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

6.1 REQUIREMENTS FOR FEDERAL AGENCIES

Federal Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is "not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat." It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or designated critical habitat. To facilitate their ESA consultation requirements, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS' regulatory authority and effects analysis for petitions for nonregulated status and developed a process for conducting an effects determination consistent with the PPA (Title IV of Public Law 106-224). APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

APHIS met with USFWS officials on June 15, 2011, to discuss whether APHIS has any obligations under the ESA regarding analyzing the effects on TES that may occur from use of pesticides associated with GE crops. As a result of these joint discussions, USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on pesticide use associated with GE crops because EPA has both regulatory authority over the labeling of pesticides under FIFRA, and the necessary technical expertise to assess pesticide effects on the environment. APHIS has no statutory authority to authorize or regulate the use of glyphosate, or any other herbicide, by corn growers. Under APHIS' current Part 340 regulations, APHIS only has the authority to regulate MON 87411 Maize or any GE organism as long as APHIS believes they may pose a plant pest risk (7 CFR § 340.1). APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms.

After completing a plant pest risk analysis, if APHIS determines that MON 87411 Maize seeds, plants, or parts thereof do not pose a plant pest risk, then these articles would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340, and therefore, APHIS must reach a determination that these articles are no longer regulated. As part of its analysis, APHIS considered the potential effects of MON 87411 Maize on the environment including, as required by the ESA, any potential effects to threatened and endangered species and critical habitat. As part of this process, APHIS thoroughly reviews the GE product information and data related to the organism (generally a plant species, but may also be other GE organisms). For each transgene/transgenic plant, APHIS considers the following:

A review of the biology and taxonomy of the crop plant and its sexually compatible relatives;

Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;

A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;

A review of the agronomic performance of the plant, including disease and pest susceptibilities, weediness potential, and agronomic and environmental impacts;

Determination of the concentrations of known plant toxicants (if any are known in the plant);

Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered species (TES) of plants or a host of any TES; and

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

In following this review process, USDA-APHIS, as described below, has evaluated the potential effects that a determination of nonregulated status of MON 87411 Maize plants 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 EIS and production areas identified in the Affected Environment section of the EIS, APHIS reviewed the USFWS list of TES species (listed and proposed) for each state where corn is commercially produced from the USFWS Environmental Conservation Online System (ECOS; as accessed July 24, 2014 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp) (US Fish and Wildlife Service, 2014b). Prior to this review, APHIS considered the potential for MON 87411 Maize 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 87411 Maize are essentially indistinguishable from practices used to grow other corn varieties, including other HR varieties(Monsanto, 2013d). Although MON 87411 Maize may be expected to replace other varieties of corn currently cultivated, APHIS does not expect the cultivation of these to result in new corn acres to be planted in areas that are not already devoted to agriculture. Accordingly, the issues discussed herein focus on the potential environmental consequences of the determination of nonregulated status of MON 87411 Maize on TES species in the areas where corn is currently grown.

MON 87411 Maize was developed using recombinant DNA techniques. Three different genes were inserted into the plant: dsRNA transcript of *DvSnf7*, and *Cry3Bb1*, both of which confer resistance to corn rootworm, and *cp4 epsps*, which confers resistance to the herbicide glyphosate (Monsanto, 2013d). The novel proteins and RNAs resulting from recombinant DNA insertion in MON 87411 Maize are listed in Table 6.

Table 6. Novel Proteins and RNAs Associated with MON 87411 Maize.

Regulated Article	Protein/dsRNA	Phenotypic Effects
MON 87411 Maize	dsRNA transcript of *Diabrotica virgifera virgifera Snf7* gene (DvSnf7)	Resistance to CRW by suppressing the WCR *Snf7* gene in the pest
	Cry3Bb1 derived from *Bacillus thuringiensis* (subsp. *kumamotoensis*)	Resistance to CRW
	5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) derived from *Agrobacterium* sp.	Resistance to glyphosate

6.2 POTENTIAL EFFECTS OF MON 87411 MAIZE ON TES

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

For its analysis (Appendix B) of effects on TES animals, APHIS focused on the implications of exposure to the novel proteins and double stranded RNA (dsRNA) expressed in MON 87411 Maize plants as a result of the transformation, and the ability of the plants to serve as a host for a TES.

6.2.1 Threatened and Endangered Plant Species and Critical Habitat

The agronomic and morphologic characteristics data provided by Monsanto were used in the APHIS analysis of the weediness potential for MON 87411 Maize, and evaluated for the potential to impact TES and critical habitat. Agronomic studies conducted by Monsanto tested the hypothesis that the weediness potential of MON 87411 Maize is unchanged with respect to conventional corn (Monsanto, 2013d). No differences were detected between MON 87411 Maize and non-transgenic corn in growth, reproduction, or interactions with pests and diseases, other than the intended effect of insect resistance to CRW and resistance to the herbicide glyphosate (Monsanto, 2013d; USDA-APHIS, 2014b). Corn possesses few of the characteristics of successful weeds, and has been cultivated around the globe without any report that it is a serious weed or that it forms persistent feral populations (USDA-APHIS, 2014b). However, corn seed can germinate in undesired locations and would then be considered a weed, such as when corn emerges as a volunteer in a soybean rotation following a corn crop (USDA-APHIS, 2014b).

Because the expression of the EPSPS protein in corn results in greater resistance to glyphosate, this herbicide cannot be used effectively to control volunteer MON 87411 Maize. However, there are multiple options for control of volunteer corn, including the use of ACCase inhibitor herbicides (e.g., 2, 4-D, the cyclohexadione “dim” herbicides clethodim or sethoxydim); acetolactate synthesis inhibitors (ALS; e.g., imazamox, imazequin, and imazethapyr); and glufosinate (Heap, 2011; WSSA, 2011). The expression of the dsRNA transcript of *DvSnf7*, and *Cry3Bb1*, both of which confer resistance to CRW, and the EPSPS protein herbicide-resistance trait in MON 87411 Maize, is unlikely to appreciably improve seedling establishment or increase weediness potential. Based on the agronomic field data and literature survey on corn weediness potential, MON 87411 Maize is unlikely to affect TES or critical habitat as a troublesome or invasive weed (USDA-APHIS, 2014b).

APHIS evaluated the potential of MON 87411 Maize to cross with listed species. After reviewing the list of threatened and endangered plant species in the States where corn is grown, APHIS determined that MON 87411 Maize would not be sexually compatible with any listed threatened or 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* (US Fish and Wildlife Service, 2014b).

As discussed in Gene Movement (Section 4) the potential for gene movement between MON 87411 Maize and related corn species is limited. As reviewed previously in Section 4 (see Gene Movement), there is a rare, sparsely dispersed feral population of teosinte, a relative of *Z. mays*, reported in Florida (USDA-APHIS, 2014b); however, this plant is not listed as a TES(US Fish and Wildlife Service, 2014a). Moreover, where maize x teosinte hybrids have been identified in the field, they are found to exhibit low fitness and are unlikely to produce a second generation (USDA-APHIS, 2014b). None of the relatives of corn are Federally listed (or proposed) as endangered or threatened species (US Fish and Wildlife Service, 2014a). Accordingly, a determination of non-regulation of MON 87411 Maize will not result in movement of the inserted genetic material to any endangered or threatened species.

Based on agronomic field data, literature surveyed on corn weediness potential, and no sexually compatibility of TES with corn, APHIS has concluded that MON 87411 Maize will have no effect on threatened or endangered plant species or on critical habitat.

6.2.2 Threatened and Endangered Animal Species

Threatened and endangered animal species that may be exposed to the gene products from MON 87411 Maize would be those TES that inhabit corn fields and feed on MON 87411 Maize. As discussed further in Section 2 under Biological Resources, Animal Communities, cornfields are generally considered poor habitat for birds and mammals in comparison with uncultivated lands, but the use of cornfields by birds and mammals is not uncommon. Some birds and mammals use cornfields at various times throughout the corn production cycle for feeding and reproduction. Most birds and mammals that utilize cornfields are ground foraging omnivores that feed on corn seed, sprouting corn, and the corn remaining in the fields following harvest. Few if any TES are likely to use corn fields because they do not provide suitable habitat. For birds, only whooping crane (*Grus americana*), Mississippi sandhill crane (*Grus canadensis pulla*), piping plover (*Charadrius melodus*), interior least tern (*Sterna antillarum*), and Sprague’s pipit (*Anthus spragueii;* a candidate species) occasionally feed in farmed sites (US Fish and Wildlife Service, 2011b). These bird species may visit corn fields during migration (Krapu et al., 2004b; US Fish and Wildlife Service, 2011b). The whooping crane in particular spends the majority of its foraging time during migration in agricultural fields, although its diet during this time is not well understood (Canadian Wildlife Service and U.S. Fish and Wildlife Service, 2007; ICF, 2014). As discussed in detail in Section 2, Affected Environment, Biological Resources, Animal Communities, many mammals may feed on corn; especially white tailed deer, raccoons, mice, and voles. As for listed species, the Louisiana black bear (*Ursus americanus luteolus*), occurring in Louisiana, Mississippi, and Texas (US Fish and Wildlife Service, 2014c), may occasionally forage on corn among other crops such as sugarcane, winter wheat, and soybean (MSU, No Date).

APHIS considered the risks to threatened and endangered animals from consuming MON 87411 Maize. Monsanto has presented information on the food and feed safety of MON 87411 Maize variety compared with conventional varieties and evaluating the differences between varieties with and without herbicide applications (Monsanto, 2013d). Monsanto performed compositional analyses on MON 87411 Maize grain and forage, the original transformation line LH244, and 20 different commercial reference hybrids grown at eight representative agricultural sites in

2011/2012 in Argentina. The compositional analyses were done for a total of 78 components (nine in forage and 69 in grain) (Monsanto, 2013d). Of the 78 components assayed, 18 had more than 50% of observations that were below the assay limit of quantitation and were therefore excluded from statistical analysis. Of the 60 remaining components statistically assessed, 12 components (protein, histidine, tyrosine, oleic acid, neutral detergent fiber, copper, iron, manganese, zinc, niacin, vitamin B1 in grain, and ash in forage) showed a statistically significant difference between MON 87411 Maize and the original transformation line LH244. However, the mean difference was less than the natural variation found between the original transformation line LH244 and reference corn hybrid values (Monsanto, 2013d). Additionally, MON 87411 Maize mean component values were within the tolerance intervals of the reference hybrids, the values for corn observed in the literature, and/or the International Life Sciences Institute Crop Composition Database values (ILSI, 2010; Monsanto, 2013d). These results suggest that MON 87411 Maize is compositionally equivalent to its original transformation line LH244 and to other conventional corn hybrids.

The introduced genes did not significantly alter the observed insect pest infestation as observed in nine agricultural fields over two years encompassing fourteen arthropod pests and the occurrence of 16 corn diseases, resulting in no damage of MON 87411 Maize compared with its original transformation line LH244 and 22 corn reference hybrids (Monsanto, 2013d). There were no significant changes in MON 87411 Maize composition that would render MON 87411 Maize more susceptible to pests and diseases over its control or reference corn varieties (Monsanto, 2013d). The observed agronomic traits also did not reveal any significant changes that would indirectly indicate that MON 87411 Maize is or could be relatively more susceptible to pests and diseases over the original transformation isoline LH244 or reference varieties (Monsanto, 2013d). Thus MON 87411 Maize is unlikely to be more susceptible to plant pathogens and insect pests than conventional corn. For this reason, MON 87411 Maize is unlike to differ from conventional corn in its ability to harbor or transmit plant pathogens or pests and cause indirect plant pest effects on other agricultural products.

The results presented by Monsanto show that incorporation of a dsRNA transcript of the *Snf7* gene, *DvSnf7*, and the *Cry3Bb1*gene that both confer resistance to CRWs, and *cp4 epsps*, which confers resistance to the herbicide glyphosate, does not result in any biologically-meaningful differences between MON 87411 Maize and the non-transgenic hybrid.

DvSnf7 produces dsRNA that activates the RNA interference pathway, thereby suppressing endogenous genes of the CRW. Upon consumption of MON 87411 Maize by the WCR, DvSnf7 dsRNA is recognized by the pest’s RNAi machinery, resulting in the down-regulation of the targeted *DvSnf7* gene leading to WCR mortality (Bolognesi et al., 2012). The activity spectrum of DvSnf7 dsRNA has been shown to be highly specific to CRWs (*Diabrotica* spp.) (Baum et al., 2007a; Whyard, 2009; Bachman et al., 2013b; Monsanto, 2013d). Bachman et al. used bioassays to test representative insect species having close taxonomic relatedness to corn rootworm. In total 14 representative insect species from 10 Families and 4 Orders (Hemiptera, Hymenoptera, Lepidoptera, and Coleoptera) were tested. In these bioassays activity was found only in the subfamily Galerucinae in the family Chrysomelidae within the order Coleoptera. Specifically, only the western corn rootworm and the southern corn rootworm were affected. The

Colorado potato beetle, which is in another subfamily (Chyrsomelinae) of Chrysomelidae and which is known to be sensitive to ingested dsRNA, was not affected by DvSnf7 RNA.

In addition, Monsanto found no effect of DvSnf7 RNA on any of the other nontarget species tested including the following which are often considered beneficial to agriculture: the spotted ladybird beetle, ground beetle, honeybee, insidious flower bug, and earthworm. This, together with the results from the study using the 14 species described above and the sequence specific nature of RNAi support a conclusion that it is unlikely that DvSnf7 RNA will have an effect on nontarget organisms.

The Cry3Bb1 protein, is present in MON 88017 Maize that received a determination of non-regulated status by USDA-APHIS in 2005 (USDA-APHIS, 2014a). The amino acid sequence deduced from the Cry3Bb1 expression cassettes of MON 87411 Maize and MON 88017 Maize is also 99.8% identical to the deduced amino acid sequence for Cry3Bb1 protein in MON 863, a corn event that was granted non-regulated status by USDA-APHIS in 2002 (USDA-APHIS, 2014a). The use of *Bt*-expressing crops in United States has been widespread and the mode-of-action and specificity of these proteins has been studied and is well understood (Gill, 1992; Bravo, 2007).

Cry3Bb1 expressed by MON 87411 Maize has demonstrated to affect a narrow spectrum of organisms (Spencer, 2003; Höss, 2011). Also, from previous USDA-APHIS and U.S. EPA registrations, reviews were conducted concluding that Cry3Bb1 expressing corn has no impact on non-target organisms, including TES (EPA, 2005; USDA-APHIS-BRS, 2005). Numerous peer-reviewed reports have also established that the *Bt* protein Cry3Bb1 has not shown negative impacts on non-target organisms (Bhatti, 2005; Bitzer, 2005; Flores, 2005; Romeis, 2006; Ferry, 2007; Marvier, 2007; Meissle, 2009; Rauschen, 2009b; Rauschen, 2009a; Schmidt, 2009; Li, 2010; Rauschen, 2010; Cheeke, 2012; Devos, 2012; Burns, 2013).

As of August 14, 2014, 73 insect species are listed on the USFWS website as TES (US Fish and Wildlife Service, 2014a). Eighteen of these insects are Coleoptera, with the remaining representing insects of other orders. There are no listed insects in the family Chrysomelidae. With the exception of Casey's June Beetle (*Dinacoma caseyi*) (US Fish and Wildlife Service, 2014a), all of the species of Coleoptera currently listed were added prior to the determination of nonregulated status of MON 88017 corn. The Casey's June beetle is found only in one area in the United States near Palm Springs, California (US Fish and Wildlife Service, 2011a). This beetle's preferred habitat is sandy areas associated with desert scrub vegetation located on alluvial fans, much like the area it currently inhabits in Riverside County, California (US Fish and Wildlife Service, 2011a). Although corn is grown in California, it is grown in counties farther north near San Francisco (USDA-NASS, 2012d). Based on preferred habitat, it is highly unlikely that these beetles will be exposed to the Cry3Bb1 protein from MON 87411 Maize. US-EPA also concluded that a review of the preferred habitats of other coleopteran species listed as endangered by the USFWS indicated that no exposure to harmful levels of the PIP proteins would take place due to the lack of exposure and geographical and habitat limitations (US-EPA, 2010a). These other coleopteran species are located in non-corn production areas and/or their habitat does not encompass agricultural areas.

For other CRW-resistant maize varieties, US-EPA has made similar conclusions for the American burying beetle and has not identified any new TES that would be impacted by cultivation (US-EPA, 2009; 2010b; 2010a). Furthermore, US-EPA examined the habitats of the other threatened and endangered insect species in the orders Lepidoptera, Diptera, Hemiptera, Odonata and Orthoptera and found that they primarily occupy dune, meadow or prairie, or open forest habitats and are not closely associated with row crop production, often times due to the specificity of the habitat of their host plants (US-EPA, 2010b; 2010a).

Similar to the conclusions for MON 88017 Maize, MON 863 Maize, and other corn events analyzed by APHIS and EPA, based on the constituent elements required in their habitat, Cry proteins and DvSnf7 dsRNAi target insect specificity, and/or the lack of habitat overlap with regions of maize cultivation, APHIS concludes that cultivation of MON 87411 Maize will have no effect on any listed threatened and endangered insect.

In previous registrations, USDA-APHIS has approved petition requests for nonregulated status of six GR corn events (MON 802, GA21, MON 88017, 98140, VCO-Ø 1981-5, and MON 87427 (USDA-APHIS, 2014a). In each of these petitions, an analysis of the impact to non-target organisms was conducted without identifying a negative effect of the CP4 EPSPS protein (CERA, 2011).

In addition to evaluating Monsanto's comparisons of MON 87411 Maize with the non-transgenic near-isoline hybrid variety for potential differences in agronomic characteristics and morphology, USDA-APHIS also considers the US-EPA and US-FDA regulatory assessment in making its determination of the potential impacts of determination of nonregulated status of the new agricultural product. As described in Section 4 (see Animal and Plant Communities and Public Health), Monsanto has submitted food and feed safety and nutritional assessments for MON 87411 Maize to the US-FDA. FDA has completed its review (see Appendix A). EPA has granted an exemption from pesticide residue tolerance for the Cry3Bb1 protein (US-EPA, 2007a).

APHIS considered the possibility that MON 87411 Maize could serve a host plant for a threatened or endangered species (i.e., a listed insect or other organism that may use the corn plant to complete its lifecycle). A review of the species list reveals that there are none that would use corn as a host plant (US Fish and Wildlife Service, 2014b)

Therefore, based on the above analysis of similar corn events that have received a determination of non-regulated status by APHIS, the peer-reviewed literature, and the information provided in the petition, APHIS concludes that exposure to and/or consumption of MON 87411 Maize and the expressed PIPs, are likely to have no effect on any threatened or endangered animal species.

6.3 SUMMARY

After reviewing the possible effects of a determination of nonregulated status of MON 87411 Maize, USDA-APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. As a result, a detailed exposure analysis for individual species is not necessary. USDA-APHIS also considered the potential effect of the determination of nonregulated status of MON 87411 Maize on designated critical habitat or habitat proposed for designation, and could identify no differences from effects that would occur from the production of other corn varieties. Corn is not considered a particularly competitive plant species and has been selected for domestication and cultivation under conditions not normally found in natural settings (US-EPA, 2010f).

Based on these factors, USDA-APHIS has concluded that the determination of nonregulated status of MON 87411 Maize, 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 concurrence of the USFWS or the NMFS is not required.

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

7.1 EXECUTIVE ORDERS WITH DOMESTIC IMPLICATIONS

The following three EOs require consideration of the potential impacts of the Federal action to minority and low income populations and children:

- ***EO 12898 (US-NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,"*** requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental impacts.

- ***EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks,"*** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

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

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

Available mammalian toxicity data associated with the Cry and CP4 ESPS proteins establishes the safety of MON 87411 Maize and its products to humans, including minorities, low income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken.

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 described in Section 4(see Public Health), the potential use of glyphosate on MON 87411 Maize at the proposed application rates would not exceed those 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 the EPA would monitor the use of MON 87411 Maize to determine impacts on agricultural practices, such as chemical use, as they have done previously for HR products.

As described in Section 4 (see Agricultural Production of Corn) the cultivation of GE corn varieties with herbicide resistance traits are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA has been associated with a decrease and/or shift in pesticide applications for those who adopt these varieties that is either favorable or neutral with respect to environmental and human toxicity. A determination of nonregulated status of MON 87411 Maize provides growers with alternative herbicide options with different modes of action. As discussed in Sections 2 and 4 glyphosate is already labeled for use on maize.

Based on these factors, the determination of nonregulated status of MON 87411 Maize is not expected to have a disproportionate adverse impacts on minorities, low income populations, or children.

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

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

Corn is not listed in the United States as a noxious weed species by the Federal government, nor is it listed as an invasive species by major invasive plant databases. Corn does not possess characteristics such as tolerance for a variety of habitat conditions, rapid growth and reproduction, aggressive competition for resources, and the lack of natural enemies or pests. Non-engineered corn, as well as other HR corn varieties, is widely grown in the United States. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by USDA-APHIS, MON 87411 Maize plants are sufficiently similar in fitness characteristics to other corn varieties grown currently and are not expected to become weedy or invasive(USDA-APHIS, 2014b).

The following EO 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 impact 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 substantial difference in compositional and nutritional quality of MON 87411 Maize compared with other GE corn or non-GE corn, apart from the presence of the Cry and PAT proteins. As previously discussed, the Cry3Bb1 and CP4 ESPS protein constituents expressed in MON 87411 Maize have been cultivated in a wide variety of commercial corn strains since 1995. The migratory birds that forage in cornfields are unlikely to be affected adversely by ingesting MON 87411 Maize and its products.

Based on these factors, it is unlikely that the determination of nonregulated status of MON 87411 Maize will have a negative impact 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 impacts outside the United States, its territories, and possessions that result from actions being taken.

USDA-APHIS has given this EO due consideration and does not expect a substantial environmental impact outside the United States in the event of a determination of nonregulated status of MON 87411 Maize. It should be noted that all the existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new corn cultivars internationally apply equally to those covered by an USDA-APHIS determination of nonregulated status under part 340.

Any international trade of MON 87411 Maize and its products subsequent to a determination of nonregulated status for 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 Pest Risk Analysis (PRA) of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. USDA-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 United States is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol and the required documentation.

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

USDA-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 United States, 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, 2003).

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

Monsanto has stated that regulatory submissions will be made in critical U.S. maize export markets, including Canada, Japan, Mexico, Taiwan, South Korea and China (Monsanto, 2013d). Monsanto also states that full commercial release of any maize products containing MON 87411 Maize will occur only after obtaining all necessary authorizations in the United States and its major import countries with functioning regulatory processes (Monsanto, 2013d).

7.3 COMPLIANCE WITH CLEAN WATER ACT AND CLEAN AIR ACT

This draft EA evaluated the potential changes in corn production due to a determination of nonregulated status of MON 87411 Maize. Cultivation of MON 87411 Maize is not expected to lead to the increased production of corn in U.S. agriculture.

There is no expected change in water use and quality due to the cultivation of MON 87411 Maize compared with current corn production. Also, there is no expected change in air quality associated with the cultivation of MON 87411 Maize.

Based on this review, USDA-APHIS concludes that the cultivation of MON 87411 Maize would comply with the Clean Water Act and the Clean Air Act.

7.4 IMPACTS ON UNIQUE CHARACTERISTICS OF GEOGRAPHIC AREAS

A determination of nonregulated status of MON 87411 Maize 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.

Monsanto has presented results of agronomic field trials for MON 87411 Maize. The results of these field trials demonstrate that there are no differences in agronomic practices between MON 87411 Maize and non-GE hybrids. The common agricultural practices that would be carried out in the cultivation of MON 87411 Maize are not expected to deviate from current practices, nor will the use of the EPA-registered pesticides. The product is expected to be deployed on agricultural land currently suitable for production of corn and replace existing varieties, and is not expected to increase the acreage of corn production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sales, leases, or transfers of ownership of any property. This action is limited to a determination of nonregulated status of MON 87411 Maize. This action would not convert land use to non-agricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87411 Maize, including the use of the EPA-registered pesticides. The Applicant’s adherence to the EPA label use restrictions for all pesticides is expected to mitigate potential impacts to the human environment.

With regard to pesticide use, a determination of nonregulated status of MON 87411 Maize is not likely to result in changes to the use of glyphosate on corn. USDA-APHIS assumes that growers who elect to cultivate commercial varieties based on the MON 87411 Maize will adhere closely to the EPA label use restrictions for all pesticides applied to their crop.

Based on these findings, including the assumption that the EPA label use restrictions are in place to protect unique geographic areas and that those label use restrictions are adhered to, a determination of nonregulated status of MON 87411 Maize 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 (NHPA) OF 1966 AS AMENDED

The NHPA of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause impacts 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.

USDA-APHIS’ proposed action, a determination of nonregulated status of MON 87411 Maize and products based on this variety, is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

USDA-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 nonregulated status of MON 87411 Maize.

USDA-APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in impacts on the character or use of historic properties. For example, there is potential for audible impacts on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary impacts on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse impacts. Additionally, these cultivation practices are already being conducted throughout the corn production regions. The cultivation of MON 87411 Maize is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

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	▪

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APPENDIX A

FDA CONSULATATION LETTER

APPENDIX A—FDA CONSULATATION LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public
Health Service

Food and Drug Administration
College Park, MD 20740

John M. Cordts, M.S., M.B.A.
Monsanto Company
800 North Lindbergh B

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Dear Mr. Cordts,

This letter addresses Monsanto Company's (Monsanto) consultation with the Food and Drug Administration (FDA) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine) on genetically engineered corn, MON 87411. According to information Monsanto has provided, MON 87411 corn is genetically engineered to express: (1) double stranded RNA with the partial sequence of the *Snf7* transcript from the western corn rootworm;
(2) the *Bacillus thuringiensis cry3Bb1* gene to protect against corn rootworm; and (3) the *cp4 epsps* gene to confer tolerance to the herbicide glyphosate. All materials relevant to this notification have been placed in a file designated BNF 000145. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, Monsanto submitted a summary of its safety and nutritional assessment of MON 87411 corn on November 15, 2013. Monsanto submitted additional information on March 14, 2014. These communications informed FDA of the steps taken by Monsanto to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Monsanto has conducted, they have concluded: food and feed derived from MON 87411 Maize are not materially different in composition, safety, and other relevant parameters from corn-derived food and feed currently on the market; MON 87411 Maize does not have any traits or other issues that would require premarket review or approval by FDA.

The EPA regulates PIPs, which include both active and inert ingredients. MON 87411 Maize contains PIPs, which are regulated by the EPA. It is Monsanto’s responsibility to obtain all appropriate clearances, including those from EPA and the United States Department of Agriculture, before marketing food or feed derived from MON 87411 corn.

Page 2

Based on the information Monsanto has presented to FDA, we have no further questions concerning food and feed derived from MON 87411 corn at this time. However, as you are aware, it is Monsanto’s continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of the text of this letter responding to BNF 000145, as well as a copy of the text of FDA’s memorandum summarizing the information in BNF 000145, is available for public review and copying at http://www.fda.gov/bioconinventory.

- Sincerely yours,

Dennis M.
Keefe -S

Digitally signed by Dennis M. Keefe -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=130007277
3, cn=Dennis M. Keefe -S
Date:2014.10.17 15:46:13 -04'00'

  - Dennis M. Keefe, Ph.D.
  - Director
  - Office of Food Additive Safety
    Center for Food Safety
    - and Applied Nutrition

APPENDIX B

APHIS THREATENED AND ENDANGERED SPECIES DECISION TREE FOR U.S. FISH AND WILDLIFE SERVICE CONSULTATIONS

APPENDIX B—APHIS THREATENED AND ENDANGERED SPECIES DECISION TREE FOR US-FWS CONSULTATIONS

DECISION TREE ON WHETHER SECTION 7 CONSULTATION WITH FWS IS TRIGGERED FOR PETITIONS OF TRANSGENIC PLANTS

This decision tree document is based on the phenotypes (traits) that have been permitted for environmental releases under APHIS oversight (for a list of approved notifications and environmental releases, visit Information Systems for Biotechnology, at http://isb.vt.edu.) APHIS will re-evaluate and update this decision document as it receives new applications for environmental releases of new traits that are genetically engineered into plants.

BACKGROUND

For each transgene(s)/transgenic plant the following information, data, and questions will be addressed by APHIS, and the EAs on each petition will be publicly available. APHIS review will encompass:

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

FDA published a policy in 1992 on foods derived from new plant varieties, including those derived from transgenic plants (http://vm.cfsan.fda.gov/~lrd/fr92529b.html and http://vm.cfsan.fda.gov/~lrd/consulpr.html). The FDA’s policy requires that genetically engineered foods meet the same rigorous safety standards as is required of all other foods. Many of the food crops currently being developed using biotechnology do not contain substances that are substantially different from those already consumed by human and thus do not require pre-market approval. Consistent with its 1992 policy, FDA expects developers to consult with the agency on safety and regulatory questions. A list of consultations is available at http://vm.cfsan.fda.gov/~lrd/biocon.html. APHIS considers the status and conclusion of the FDA consultations in its EAs.

Below is a description of our review process to determine whether a consultation with U.S. Fish and Wildlife Service (FWS)is necessary.

If the answer to any of the questions 1-4 below is yes, APHIS will contact FWS to determine if a consultation is required:

Is the transgenic plant sexually compatible with a TE plant[19] without human intervention?

1. Are naturally occurring plant toxins (toxicants) or allelochemicals increased over the normal concentration range in parental plant species?

2. Does the transgene product or its metabolites have any significant similarities to known toxins[20]?

3. Will the new phenotype(s) imparted to the transgenic plant allow the plant to be grown or employed in new habitats (e.g., outside agro-ecosystem)[21].

4. Does the pest resistance[22] gene act by one of the mechanisms listed below? If the answer is YES then a consultation with FWS is NOT necessary.

A. The transgene acts only in one or more of the following ways:

- i. As a structural barrier to either the attachment of the pest to the host, to penetration of the host by the pest, to the spread of the pest in the host plant (e.g., the production of lignin, callose, thickened cuticles);
- ii. In the plant by inactivating or resisting toxins or other disease causing substances produced by the pest;
- iii. By creating a deficiency in the host of a component required for growth of the pest (such as with fungi and bacteria);
- iv. By initiating, enhancing, or potentiating the endogenous host hypersensitive disease resistance response found in the plant;
- v. In an indirect manner that does not result in killing or interfering with normal growth, development, or behavior of the pest;

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[19] APHIS will provide FWS a draft EA that will address the impacts, if any, of gene movement to the TES plant

[20] Via a comparison of the amino acid sequence of the transgene's protein with those found in the protein databases like PIR, Swiss-Prot and HIV amino acid data bases.

[21] Such phenotypes might include tolerance to environmental stresses such as drought, salt, frost, aluminum or heavy metals.

[22] Pest resistance would include any toxin or allelochemical that prevents, destroys, repels or mitigates a pest or effects any vertebrate or invertebrate animal, plant, or microorganism.

B. A pest derived transgene is expressed in the plant to confer resistance to that pest (such as with coat protein, replicase, and pathogen virulence genes).

For the biotechnologist:

Depending on the outcome of the decision tree, initial the appropriate decision below and incorporate its language into the EA. Retain a hard copy of this decision document in the petition's file.

________ BRS has reviewed the data in accordance with a process mutually agreed upon with the FWS to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS has reached a determination that the release following a determination of nonregulated status would have no effects on listed threatened or endangered species and consequently, a written concurrence or formal consultation with the Fish and Wildlife Service is not required for this draft EA.

________ BRS has reviewed the data in accordance with a process mutually agreed upon with the FWS to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of nonregulated status is not likely to adversely affect any listed threatened or endangered species and consequently obtained written concurrence from the Fish and Wildlife Service.

________ BRS has reviewed the data in accordance with a process mutually agreed upon with the FWS to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of non-regulated status is likely to affect adversely one or more listed threatened or endangered species and has initiated a formal consultation with the Fish and Wildlife Service.