Pioneer Hi-Bred International, Inc. Petition (11-244-01p) for Determination of Nonregulated Status of Insect-Resistant and Herbicide-Tolerant Pioneer 4114 Maize: Event DP-004114-3

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Agency Contact
Cindy Eck
USDA, APHIS, BRS
4700 River Road, Unit 91
Riverdale, MD 20737-1237
Phone: (301) 734-0667
Fax: (301) 734-8910
Cynthia.A.Eck@aphis.usda.gov

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ACRONYMS AND ABBREVIATIONS

ae	Acid equivalent
AIA	advanced informed agreement
AMS	Agricultural Market Share *or* Ammonium sulfate
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* protein
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council of Environmental Quality
CFR	Code of Federal Regulations (United States)
CH_4	methane
CO	carbon monoxide
CO_2	carbon dioxide
COC	Crop oil concentrate
CRP	Conservation Reserve Program
Cry Protein	The crystalline protein and active ingredient in the plant incorporated protectants derived from *Bacillus thuringiensis*
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
g/L	grams per liter
GE	genetically engineered
GHG	greenhouse gas
GMO	genetically modified organism
HFCS	High fructose corn syrup
IPCC	Intergovernmental Panel on Climate Change
IPM	Integrated pest management
IRM	Insect Resistance Management
ISHRW	International Survey of Herbicide Resistant Weeds
ISPM	International Standard for Phytosanitary Measure
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
NRCS	National Resources Conservation Service
NOP	National organic program
NPS	Non-point source
OECD	Organization for Economic Cooperation and Development

ACRONYMS AND ABBREVIATIONS

PAT	phosphinothricin-acetyl-transferase, an enzyme
pat	The gene derived from *Streptomyces viridochromogenes* which encodes the PAT enzyme
PIP	Plant incorporated protectant
ppm	Parts per million
PPRA	Plant Pest Risk Assessment
PRA	pest risk analysis
RNA	ribonucleic acid
RSPM	Regional Standards 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	United States Code
USFWS	U.S. Fish and Wildlife Service
VEC	Value enhanced corn
WPS	Worker Protection Standard for Agricultural Pesticides

1 PURPOSE AND NEED

1.1 BACKGROUND

On September 1, 2011, Pioneer Hi-Bred International, Inc. of Johnston, Iowa (recently renamed DuPont Pioneer, and referenced hereafter as Pioneer) petitioned (#11-244-01p) the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) for a determination of nonregulated status of Pioneer 4114 corn (Maize) event DP-004114-3 (Pioneer, 2011b). Pioneer 4114 corn (Maize) event DP-004114-3 is referenced hereafter as Pioneer 4114 Maize. Pioneer 4114 Maize provides insect resistance to certain lepidopteran and coleopteran pests (e.g., European corn borer and corn rootworm, respectively) from the accumulation of three Cry proteins. Additionally, Pioneer 4114 Maize exhibits tolerance to the glufosinate herbicide from the incorporation of the phosphinothricin-acetyl-transferase (PAT) protein (Pioneer, 2011b). Pioneer 4114 Maize is currently regulated under 7 Code of Federal Regulations (CFR) Part 340. Interstate movements and field trials of Pioneer 4114 Maize have been conducted under permits issued or notifications acknowledged by USDA-APHIS since 2006. These field trials were conducted in diverse growing regions within the United States, including Arkansas, California, Colorado, Delaware, Georgia, Hawaii, Iowa, Illinois, Indiana, Kansas, Michigan, Minnesota, Missouri, Nebraska, Oklahoma, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, and Wisconsin. Data resulting from these field trials are described in the Pioneer 4114 Maize petition (Pioneer, 2011b) and analyzed for plant pest risk in the USDA-APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2012c).

Pioneer's petition stated that USDA-APHIS should not regulate Pioneer 4114 Maize because it does not present a plant pest risk. In the event of a determination of nonregulated status, the nonregulated status would include Pioneer 4114 Maize, any progeny derived from crosses between Pioneer 4114 Maize and conventional corn, and crosses of Pioneer 4114 Maize with other biotechnology-derived corn that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000.

1.2 PURPOSE OF PRODUCT

Pioneer 4114 Maize is a genetically engineered (GE) insect-resistant and herbicide-tolerant corn product. Insect resistance in Pioneer 4114 Maize is derived from the accumulation of the insecticidal crystalline proteins[1], Cry1F, Cry34Ab1, and Cry 35Ab1 (Pioneer, 2011b). Additionally, tolerance to the glufosinate herbicide in Pioneer 4114 Maize is conferred through activity of the PAT protein (Pioneer, 2011b). The Cry1F, Cry34Ab1 and Cry 35Ab1 proteins are derived from the common soil bacterium, *Bacillus thuringiensis* (Bt); the PAT protein is derived from a common soil bacteria, *Streptomyces viridochromogenes* (Pioneer, 2011b).

The Cry1F protein in Pioneer 4114 Maize is derived from Bt, subsp. *aizawai* (USDA-APHIS, 2012c). Cry1F is effective in controlling lepidopteran larvae such as European corn borer (*Ostrinia nubilalis*), a major maize pest (Pioneer, 2011b). The Cry34Ab1 and Cry35Ab1 proteins

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[1] Also known as Cry proteins or Bt proteins, after *Bacillus thuringiensis*.

are derived from Bt strain PS149B1 (USDA-APHIS, 2012c). Together, Cry34Ab1 and Cry35Ab1 comprise an active binary insecticidal crystal protein that confers resistance to coleopteran corn rootworm pests, including western corn rootworm (*Diabrotica virgifera virgifera*), also a major maize pest (Pioneer, 2011b).

In addition to the Cry1F, Cry34Ab1, and Cry35Ab1 proteins, Pioneer 4114 Maize also contains the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides. The PAT protein acts to convert glufosinate ammonium into its inactive form, thus rendering the plant tolerant to glufosinate ammonium (Pioneer, 2011b).

In Pioneer 4114 Maize, the genes for the Cry1F, Cry34Ab1, Cry35Ab1, and PAT proteins are contained on a single transformation construct and have been integrated at a single locus in the genome. This is in contrast to the commercially-available 1507 x 59122 Maize variety where the insertions for the events are located at two unlinked loci[2] (Pioneer, 2011b; USDA-APHIS, 2012c). Pioneer 4114 Maize is functionally equivalent to 1507 x 59122 Maize (Pioneer, 2011b; USDA-APHIS, 2012c); Pioneer 4114 Maize is a corn variety that will provide similar insect resistance/herbicide tolerance to that of 1507 x 59122 Maize and function as an alternative to the breeding stack combination of the two previously approved events, 1507 Maize and 59122 Maize.

Pioneer 4114 Maize is not intended to be a stand-alone commercial product, but will be combined with other approved events using conventional breeding to create stacked and pyramided[3] products with multiple modes of action for control of insect pests and corn weeds. As a single event with all genes located at a single locus, Pioneer 4114 Maize will be bred more efficiently into new product offerings for growers that are customized to their local insect protection and agronomic needs.

1.3 COORDINATED FRAMEWORK REVIEW AND REGULATORY REVIEW

Since 1986, the United States government has regulated GE organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (EOP-OSTP, 1986; US-FDA, 1992). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products and explains how Federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the

[2] In contrast to a single locus insertion, insertion in two loci means that genes have been inserted in two separate locations within a genome. For example, in 1507 x 59122 Maize, the gene encoding Cry1F is located in one location in the genome; whereas the gene encoding Cry34Ab1/Cry35Ab1 is located in another location in the genome.

[3] Stacked products contain two or more genes targeting multiple pests; whereas pyramided products contain two or more genes targeting a single species.

characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

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

USDA-APHIS

USDA-APHIS regulations at 7 CFR Part 340, which were promulgated pursuant to authority granted by the Plant Protection Act of 2000, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act of 2000 or to the regulatory requirements of 7 CFR Part 340 when USDA-APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and also is considered a plant pest. A GE organism also is regulated under Part 340 when USDA-APHIS has reason to believe that the GE organism may be a plant pest or USDA-APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act of 2000 or the regulations at 7 CFR 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 when USDA-APHIS determines that it is unlikely to pose a plant pest risk.

US-EPA

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

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

EPA also sets tolerances for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). US-EPA is required, before establishing pesticide tolerance, to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the FQPA. US-FDA enforces the pesticide tolerances set by US-EPA.

US-FDA

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

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

On December 23, 2011, Pioneer submitted materials in support of a voluntary consultation to the US-FDA for the Pioneer 4114 Maize (US-FDA Docket Number BNF 136). US-FDA is evaluating the submission, and as of October 1, 2012, has not completed the consultation.

1.4 PURPOSE AND NEED FOR USDA-APHIS ACTION

Under the authority of the plant pest provisions of the Plant Protection Act of 2000 and 7 CFR Part 340, USDA-APHIS has issued regulations for the safe development and use of GE organisms. Any party can petition USDA-APHIS to seek a determination of nonregulated status for a GE organism that is regulated under 7 CFR 340. As required by 7 CFR 340.6, USDA-APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as Pioneer 4114 Maize. When a petition for nonregulated status is submitted, USDA-APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 when USDA-APHIS determines that it is unlikely to pose a plant pest risk.

USDA-APHIS must respond to a Pioneer petition for determination of nonregulated status of Pioneer 4114 Maize. USDA-APHIS has prepared this Environmental Assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality's (CEQ) National Environmental Policy Act of 1969 and subsequent amendments (NEPA) regulations and the USDA and USDA-APHIS NEPA implementing regulations and procedures (40 CFR Parts 1500-1508, 7 CFR Part 1b, and 7 CFR Part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[4] that may result from a determination of nonregulated status for Pioneer 4114 Maize.

1.5 PUBLIC INVOLVEMENT

USDA-APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. USDA-APHIS does this through a notice published in the *Federal Register*. When USDA-APHIS considered the petition complete, it prepared its PPRA and EA, and the three documents are being made available for public comment for 60 days through a notice in the *Federal Register*. Although USDA-APHIS' review of the Pioneer 4114 Maize is following a previously established approach, it is also important to acknowledge that USDA-APHIS recently has implemented a change to the public involvement process for select future deregulation decisions (as of March 6, 2012, (USDA-APHIS, 2012a)). The issues raised by this product are relatively straightforward and no new issues are raised. The issues discussed in this EA are those noted in section 1.6 for resources and also include those of agricultural production of corn using various production methods and the environmental and food and feed safety of GE plants. These were addressed to analyze the potential environmental impacts of Pioneer 4114 Maize.

This EA, the petition submitted by Pioneer, and USDA-APHIS's PPRA will be available for public comment for a period of 60 days (7 CFR § 340.6(d)(2)). Comments received by the end of the 60-day period will be analyzed and used to inform USDA-APHIS' determination decision of the regulated status of Pioneer 4114 Maize and to assist USDA-APHIS in determining whether

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

an Environmental Impact Statement (EIS) is required prior to the determination decision of the regulated status of this maize variety.

1.6 ISSUES CONSIDERED

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

Agricultural Production Considerations:

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

Environmental Considerations

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

Public Health Considerations

- Human Health
- Worker Safety

Livestock Health Considerations

- Animal Feed/Livestock Health

Socioeconomic Considerations

- Domestic Economic Environment
- Trade Economic Environment

Cumulative Impacts

Threatened and Endangered Species

Other United States Regulatory Approvals and Compliance with Other Laws

2 AFFECTED ENVIRONMENT

The Affected Environment Section provides an overview of the biology and use of corn[5] (Subsection 2.1 – Corn Background Information), followed by a discussion of the current condition of those aspects of the human environment potentially affected by a determination of nonregulated status of Pioneer 4114 Maize (Subsections 2.2 – 2.7). For this draft EA, those aspects of the human environment are: agricultural production of corn (Subsection 2.2); the physical environment (Subsection 2.3); biological resources (Subsection 2.4); public health (Subsection 2.5); animal feed (Subsection 2.6); and socioeconomics (Subsection 2.7). Note that alternatives, environmental consequences, cumulative impacts, threatened and endangered species, and consideration of executive orders (EOs), standards, and treaties relating to environmental impacts are not presented in Section 2, but in Sections 3, 4, 5, 6, and 7, respectively.

Important to the description of the Affected Environment and the analysis of Environmental Consequences in this draft EA, Pioneer 4114 Maize notably contains traits from two GE maize varieties that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. The Cry1F protein and its associated genetic elements in Pioneer 4114 Maize are identical to those in DAS-01507-1 Maize (hereafter referred to as 1507 Maize), which had a determination of nonregulated status by USDA, and was registered by the EPA and was reviewed by the US-FDA in 2001 (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2001; USDA-APHIS, 2001). The binary Cry proteins, Cry34Ab1 and Cry35Ab1, and their associated genetic elements are identical to those in DAS-59122-7 Maize (hereafter referred to as 59122 Maize), which had a determination of nonregulated status by USDA in 2005, was registered by US-EPA in 2005, and was reviewed by US-FDA in 2004 (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2004; USDA-APHIS, 2005). Both 1507 and 59122 Maize contain the PAT protein, which itself has had USDA nonregulated status since 1995 and has been commercially cultivated in the United States since 1996 (USDA-APHIS, 1995).

The regulatory history of 1507 and 59122 Maize bears repeating here because commercial corn hybrids based on these varieties, including a conventional hybrid breeding stack of the two lines, 1507 x 59122 Maize, are now licensed broadly across the seed industry (Pioneer, 2011b). The 1507 x 59122 breeding stack combination was reviewed and registered by US-EPA in 2005 (US-EPA, 2010f). Similarly, in 2005 the European Food and Safety Authority (EFSA) approved the marketing of 1507 maize for import, feed and industrial processing and cultivation (EFSA, 2005); in 2007 approved 59122 for import, feed and industrial processing (EFSA, 2007); and since 2009, has reviewed and approved at least four commercial hybrids based on the 1507 x 59122 hybrid stacks for food and feed uses, import and processing (EFSA, 2009a, 2010). In each case, EFSA concluded that the hybrid products were unlikely to have any adverse effects on human or animal health or on the environment (EFSA, 2009a, 2010).

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[5] *Zea mays*, corn, and maize refer to the same domesticated plant species and will be used interchangeably throughout the text.

In 2010, commercial products containing 1507 x 59122 Maize were grown on approximately 14 million acres or approximately 16% of U.S. maize acres (GfK Kynetec, 2010; Pioneer, 2011b).

Accordingly, as the events contained in Pioneer 4114 Maize are already commercially cultivated, this draft EA presents a summary of the Cry and the PAT proteins and the events in Pioneer 4114 Maize as part of the Affected Environment and in the Environmental Consequences analysis.

2.1 CORN – BACKGROUND INFORMATION

Corn (*Z. mays* subsp. *mays* L.) is a member of the Maydeae tribe of the grass family, Poaceae (OECD, 2003). Corn is a wind-pollinated, monoecious, annual grass species with imperfect flowers[6] (OECD, 2003; Wozniak, 2002). Corn has been domesticated through selection of key agronomic characters, such as a non-shattering rachis, grain yield, and resistance to pests (Wozniak, 2002). A large variety of corn types (e.g., dent, flint, flour, pop, and sweet) have been developed through standard breeding techniques (OECD, 2003; Wozniak, 2002).

Corn cultivars and landraces are both known to have two sets of chromosomes with a total number of 20 and consequently can largely crossbreed. However, some evidence for genetic incompatibility exists within the species (e.g., popcorn x dent crosses; Mexican maize landraces x Chalco teosinte) (Wozniak, 2002). The closest wild relatives of corn are various *Zea* taxa known as “teosinte” (Ellstrand et al., 2007a). More than 40 landraces of maize have been identified in Mexico, and over 250 throughout the Americas (OECD, 2003). Several of the identified subspecies are identified as teosinte, including *Z. mays* subsp. *Mexicana*; *Z. mays* subsp. *Parviglumis*; *Zea diploperennis*; and *Zea luxurians* (Ellstrand et al., 2007a; OECD, 2003). None of the teosinte subspecies are known to occur naturally north of the tropical and subtropical areas of Mexico, Guatemala, Honduras, and Nicaragua (Sanchez et al., 2011), although teosinte may be found as introduced populations in botanical gardens and as feral populations of *Zea mexicana* in Florida, Maryland, and Alabama (USDA-NRCS, 2012b), and feral populations of *Zea perennis* in South Carolina (USDA-NRCS, 2012c).

Corn has food, feed, and industrial uses (USDA-ERS, 2012c). A variety of food and industrial products are derived from corn, including starches[7], sweeteners[8], corn oil, organic acids, and alcohols[9] (CRA, 2011; Pioneer, 2011b). In 2012, approximately 45% of total U.S. corn production was dedicated to ethanol production for biofuels and 42% for animal feed (USDA-ERS, 2012c). In addition to being cultivated for ethanol and animal feed production, approximately 6% of the total corn production is harvested for silage (USDA-NASS, 2012c).

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[6] A morphological feature that limits inbreeding, where spatially separate tassels (male flowers) and silks (female flowers) are found on the same plant, (Wozniak, 2002).

[7] Starches include unmodified and modified starches, dextrin, and maltodextrin.

[8] Sweeteners include glucose, dextrose, fructose, and high-fructose corn syrup.

[9] Alcohols include beverage, industrial and fuel ethanols.

2.2 AGRICULTURAL PRODUCTION OF CORN

2.2.1 Areas and Acreage of Corn Production

Corn is an annual plant typically grown in zones of abundant rainfall and fertile soils (OECD, 2003). In U.S. temperate regions, moisture levels and number of frost-free days are ideal for corn to be grown (see, e.g., IPM, 2004, 2007). However, through selective breeding to variable conditions of humidity, sunlight, altitude, and temperature, corn is cultivated in a variety of regions in the United States (OECD, 2003).

Corn is grown in all 48 states of the continental United States, with production concentrated in the U.S. Corn Belt. The Corn Belt is loosely defined as the states of Illinois, Iowa, Indiana, the eastern portions of South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri (USDA-NASS, 2012b). Iowa and Illinois, the two top corn-producing states, typically account for slightly more than one-third of the total U.S. corn crop (USDA-NASS, 2012b).

In the 2012 production year, corn was cultivated in the United States on approximately 96 million acres, representing a 5% increase in corn acreage from 2011 (USDA-NASS, 2012b). Corn production in 2011 was estimated at 12.44 billion bushels and valued at an estimated $5.15 to $5.65 per bushel (USDA-NASS, 2012b). Corn is the most widely cultivated feed grain in the United States, accounting for approximately 96% of total value and production of feed grains (USDA-ERS, 2012c). In addition to demand as feed grain, strong demand for ethanol production has resulted in higher corn prices and corresponding incentives to growers to increase corn acreage (USDA-ERS, 2012c). In many cases, growers have increased corn acreage by adjusting corn plantings between corn, soybean, and other crops (USDA-ERS, 2012c).

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

Agronomic practices associated with corn production include several crop management systems that are available to growers. Conventional farming, as defined in this document, includes any farming system where synthetic pesticides or fertilizers may be used. This type of farming may vary between occasional use of synthetic pesticides and fertilizers to those that depend on regular inputs for successful crop production. This definition of conventional farming may also include the use of GE corn varieties that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. Organic systems exclude certain production methods, such as synthetic agricultural inputs and GE crops, and are discussed in Subsection 2.2.3 – Organic Corn Farming and Specialty Corn Systems.

Growers can choose from several different crop management practices depending upon geographic cultivation area and end-use market (see, e.g., IPM, 2004, 2007). However, common corn agronomic practices include tillage, the selection of crop rotation system, and the use of agronomic inputs. The following subsections introduce the basic cultivation requirements of corn and the agronomic practices commonly employed to produce corn in the United States.

2.2.2.1 Tillage

Prior to planting of corn seed, tillage may be used to prepare a seedbed, address soil compaction, incorporate fertilizers and herbicides, manage water movement both within and out of a production field, control weeds, and reduce the incidence of insect pests and plant disease (Christensen, 2002; Fawcett and Towery, 2002; Givens et al., 2009; Hoeft et al., 2000; NRC, 2010; Tacker et al., 2006).

Field preparation is accomplished 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 to 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 (Heatherly et al., 2009; USDA-ERS, 1997; USDA-NRCS, 2005).

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

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

Tillage can increase yields in some cropping systems and soils, and not in others. For example, if a tillage system increases moisture infiltration, production potentially increases in response. Tillage can also impact the amount of agronomic inputs needed to maintain soil fertility and moisture and the amount of agricultural chemicals needed to control insect and weed pests (Cerdeira and Duke, 2006; Hoeft et al., 2000; Olson and Sander, 1988).

According to the 2010 USDA Agricultural Resource Management Survey (USDA-ARMS), an average of 1.4 tillage operations per corn crop were conducted, leaving an average of 34% plant residue on the soil surface after planting (USDA-ERS, 2011b). The plant residue coverage of the soil after planting was approximately 65% for no-till corn production in 2005; however, no-till corn production represented only 24% of all corn acres planted in the United States (USDA-ERS, 2011b). In 2010, 62% of planted corn acreage in 19 surveyed states was dedicated to no-till or minimum till systems (USDA-NASS, 2011c).

Increases in total acres dedicated to conservation tillage have been attributed to increased use of GE crops, reducing the need for mechanical weed control. However, the change in tillage practices in corn was less dramatic than other crops such as soybean or cotton, as many growers of corn had already changed to conservation tillage systems as a means to reduce soil erosion (Fawcett and Towery, 2002; Givens et al., 2009).

Conservation tillage has been identified as a potential challenge for corn disease management. The surface residues have been identified as an inoculum source for certain plant pathogens[10] (Robertson et al., 2009). This is especially a problem for growers who cultivate corn-to-corn with minimal tillage (Robertson et al., 2009). Corn-to-corn cultivation is discussed in the following subsection, and refers to the cultivation of corn in consecutive years in the same field (Erickson and Lowenberg-DeBoer, 2005). 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).

2.2.2.2 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, control volunteers[11], and limit the potential for weeds to develop resistance to herbicides (IPM, 2004, 2007; USDA-ERS, 2005). Since 1991, 75% of corn planted acreage has been in some form of rotation in the United States (USDA-ERS, 2005). 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 (IPM, 2007). Other crops used in rotation with corn vary regionally and may include cotton, oats, canola, sugar beets, peanut, rye, barley and forage (see e.g., IPM, 2004; Peel, 1998; Pioneer, 2012).

The benefits of corn rotation with, for example, soybean are many and include (Al-Kaisi et al., 2003):

- Improved yield and profitability of one or both crops;
- Decreased need for additional nitrogen on the crop following soybean;
- Increased residue cover resulting in reduced soil erosion;
- Mitigation or disruption of disease, insect, and weed cycles;
- Reduced soil erosion;
- Increased soil organic matter;
- Improved soil tilth and soil physical properties; and
- Reduced runoff of nutrients, herbicides, and insecticides.

The high global demand for corn-produced ethanol is increasing corn prices relative to soybean prices. The increased corn demand and commodity prices encourage more corn-to-corn acreage, rather than corn-soybean rotations, which in turn contributed to overall increased U.S. corn

[10] 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).

[11] See Subsection 2.4.2.2 – Corn as a Weed or Volunteer.

acreage (Doerge, 2007). Consecutive plantings of corn require more management than corn-soybean rotations, and increases risk of disease and insect pest pressure (Erickson and Lowenberg-DeBoer, 2005; IPM, 2004; Sawyer, 2007; Stockton, 2007). Consecutive plantings of corn also have been associated with the development of resistance by western corn rootworm (*D. virgifera*) and other pests to management practices utilizing Bt (Gassmann et al., 2011). Bt-resistance is further discussed in Subsection 2.4.1.2 – Invertebrates.

2.2.2.3 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; and irrigation to ensure normal plant growth and development (Howell et al., 1998; IPM, 2007). Fertilizer and pesticide use is discussed in this subsection; irrigation is discussed in Subsection 2.3.2 – Water Resources.

Fertilization

Given the importance of nutrient availability to corn agronomic performance, fertilization is widely practiced (Ritchie et al., 2008). Soil and foliar macronutrient applications to corn primarily include nitrogen, phosphorous (phosphate), potassium (potash), calcium, and sulfur, with other micronutrient supplements such as zinc, iron, and magnesium applied as needed (Espinoza and Ross, 2006). In a 2010 survey of program states, USDA-NASS reported that nitrogen was applied to 97% of corn acreage at an average of 140 pounds per acre (lb/acre); phosphate was applied to 78% of corn acreage at an average rate of 60 lb/acre; and potash was applied to 61% of corn acreage at a rate of 79 lb/acre (USDA-NASS, 2011a). The survey found that sulfur was applied less extensively at a rate of 13 lb/acre to 15% of corn acres (USDA-NASS, 2011a).

Pesticides

Cornfields are host to a variety of insect and plant pests that reduce both the quality and quantity of grain at harvest. Due to improvements in pesticide technology, corn growers have increasingly turned to chemical control in corn production (Smith and Scott, 2006).

Pesticides may be applied pre-planting[12], pre-emergence[13], or post-emergence[14]. Pesticide application strategies are often dependent on the corn variety cultivated. Growers may choose from a large number of corn varieties produced from traditional breeding or GE systems (NCGA, 2012). Like the major commodity crops, cotton and soybean, GE varieties of corn have been adopted widely in the past decade. In 2000, approximately 25% of cultivated corn varieties were

[12] Before the crop seed has been planted, i.e. “burn-down” herbicide application.

[13] After the crop seed has been planted but before crop seed germination.

[14] After crop seed germination.

GE. This included 18% insect-resistant varieties, 6% herbicide-tolerant varieties, and 1% stacked varieties (Benbrook, 2009). By 2011, total GE corn adoption had increased to 88% of U.S. corn acreage. GE insect-resistant varieties represented 16% of this total; whereas GE herbicide-tolerant and GE stacked varieties represented 23% and 49%, respectively (NCGA, 2012; USDA-NASS, 2012b). Table 2-1 shows the current GE corn adoption rates in the United States.

Table 2-1. Percentage of herbicide-tolerant, insect-resistant, stacked trait, total GE corn, and total corn acreage planted in selects states in 2012.

State	Herbicide-tolerant (%)	Insect-resistant (Bt) (%)	Stacked* (%)	Total GE (%)	Total Corn Acreage Planted (1000 acres)
Illinois	18	14	53	85	13,000
Indiana	15	9	60	84	6,200
Iowa	15	12	64	91	14,000
Kansas	19	20	51	90	4,700
Michigan	26	8	52	86	2,600
Minnesota	22	19	47	88	8,700
Missouri	20	18	48	86	3,600
Nebraska	20	16	55	91	9,900
North Dakota	36	17	43	96	3,400
Ohio	20	13	43	76	3,900
South Dakota	23	9	62	94	6,000
Texas	21	20	44	85	1,900
Wisconsin	23	10	53	86	4,350
Total United States	21	15	52	88	96,450

* Stacked corn varieties contain at least one herbicide-tolerant trait. Source: (USDA-NASS, 2012b)

Factors influencing the adoption of insect-resistant crops include (Brookes and Barfoot, 2010):

- Reduced risk of crop loss associated with insect pests;
- Convenience associated with less time spent on crop scouting and/or applying insecticides;
- Savings in fuel use mainly from reduced number of spray applications and reduced tillage;
- Savings in the use of machinery (for spraying and possibly reduced harvesting times);
- Improved quality (e.g., lower levels of mycotoxins[15] in GE insect-resistant corn);
- Improved health and safety for farmers and farm workers from reduced handling and use of pesticides;
- Easier crop husbandry practices; and
- Facilitation of second crop cultivation.

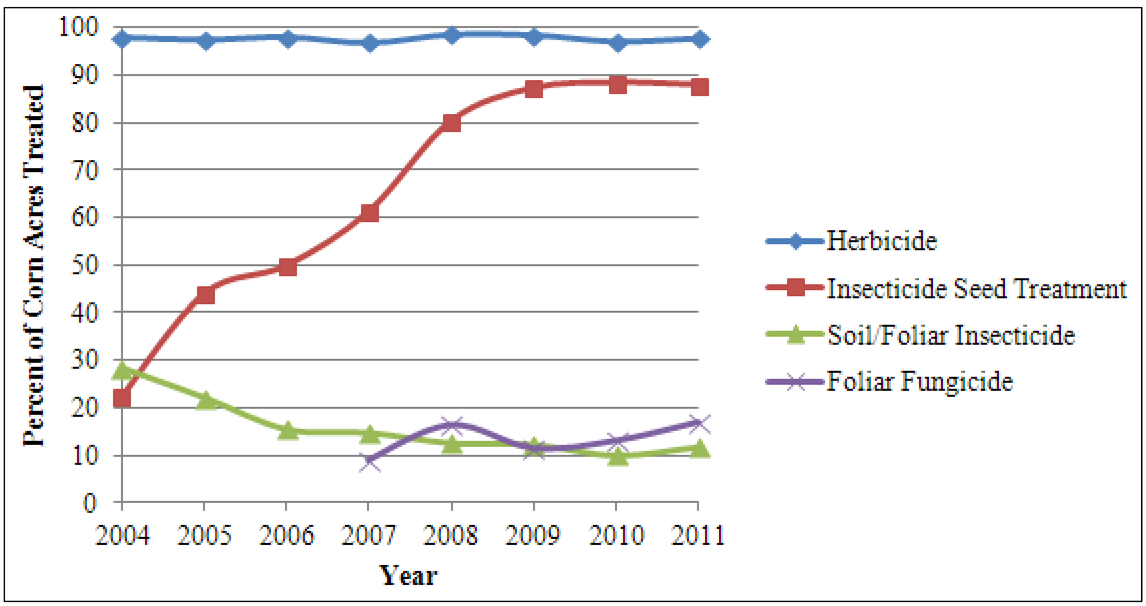
[15] Mycotoxins are compounds produced by some corn fungal pathogens that may pose a human health risk. A well-known example is aflatoxin, produced by the fungus genus *Aspergillus.* (See, e.g., http://www.ansci.cornell.edu/plants/toxicagents/aflatoxin/aflatoxin.html, accessed 10/1/12.)

Factors influencing the adoption of herbicide-tolerant crops include (Brookes and Barfoot, 2010):

- Ease of use associated with broad-spectrum, post-emergent herbicides and the increased/longer time window for spraying;
- Reduction in damage to crop arising from the application of post-emergent herbicides;
- Ability to use alternative production technologies such as no/reduced tillage practices;
- Time and fuel savings from the adoption of no/reduced till compared to equivalent conventional crop management practices;
- Ease of weed control leading to cleaner crops and reduced harvesting time and costs, and thereby improving harvest quality and premium price for quality; and
- Avoidance of potential damage from soil-incorporated residual herbicides in crops grown in subsequent seasons.

The selection of an insect-resistant and/or herbicide-tolerant variety influences a corn grower's pest management strategy. Figure 2-1 shows the percent of total corn acres treated with the major types of agricultural pesticides from 2004 – 2011. The graph suggests that herbicide use as a percent of total corn acres has remained relatively consistent, insecticide use has decreased, seed treatments have substantially increased, and foliar fungicide applications have increased to a lesser extent. Further discussion of these trends is presented in the following subsections on insecticides, herbicides, and microbial pest management.

Figure 2-1. Percent of total corn acres treated with pesticides from 2004-2011.



Source: (Pioneer, 2011b)

Pesticides - Insecticides

In 2010, approximately 12% of corn acreage was treated with insecticides, with the most abundantly applied (listed in order of total pounds applied) being chlorpyrifos for corn rootworm, earworms, and European corn borer (1% of the acreage, with total applications of approximately 478,000 pounds); tefluthrin for control of corn rootworm (3% of the acreage, with total applications of 242,000 pounds); and tebupirimphos for corn rootworm and seed corn maggot (2% of the acreage, with total applications of 195,000 pounds) (USDA-NASS, 2011a).

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 (Benbrook, 2012; Brookes and Barfoot, 2010). The Cry proteins from Bt are generally target specific (e.g., lepidoptera vs. coleoptera) (OECD, 2007). This target specificity allows a grower to select a corn variety containing a Cry protein specific to an insect pest. For example, Cry1F in 1507 Maize targets lepidopteran pests and Cry34Ab1/Cry35Ab1 in 59122 Maize to targets coleopteran pests (Pioneer, 2011b, 2012). 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 (Benbrook, 2012; Brookes and Barfoot, 2010). This provides benefits to growers and the environment from the reduction of exposure to insecticides and a corresponding reduction in costs to the grower associated with insecticide purchases and applications (US-EPA, 2010a, 2010b, 2010f).

In 2012, 52% of the total U.S. corn acreage was planted in a stacked variety containing at least one Bt trait (USDA-NASS, 2012b). The US-EPA reviews PIPs, such as the Cry proteins, pursuant to FIFRA, and publishes exemptions from tolerance pursuant to its authority under FFDCA. Since 1995, the US-EPA has registered over 35 crops expressing one or more proteins derived from Bt (US-EPA, 2011b). Table 2-2 provides a summary list of the PIPs registered by the US-EPA. The US-EPA has published full tolerance exemptions for the Cry proteins (US-EPA, 2007a)[16].

Pesticides - Herbicides

Herbicides were applied to 98% of corn acreage in 2010 (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); and acetochlor (25% of the acreage, ~28 million pounds) (USDA-NASS, 2011a, 2011b).

[16] As noted in Subsection 1.3, 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 2-2. Summary list of plant incorporated protectants (PIP) registered by the US-EPA.

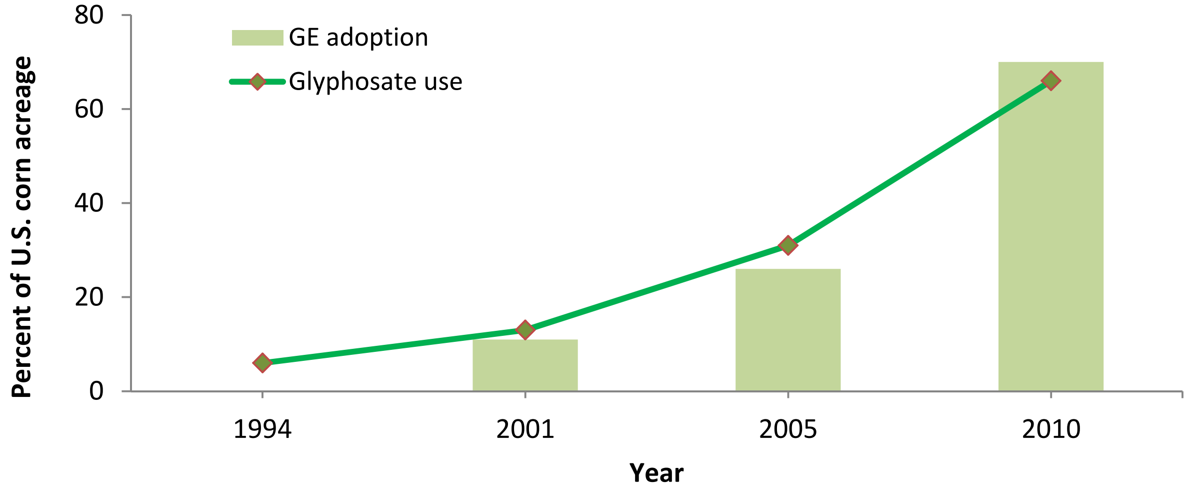
PIP Event	Crop	Registration Date
Cry 3A	Bt Potato	May, 1995
Cry 1Ab	Bt Corn	August, 1995
Cry 1Ac	Bt Cotton	October 1995
Cry 9C	Bt Corn	May, 1998
Cry 1F*	Bt Corn	May, 2001
Cry 3Bb1	Bt Corn	February 2003
Cry 34Ab1 and Cry 35Ab1*	Bt Corn	August, 2005
Cry 2Ab2	Bt Cotton	September, 2005
Vip3Aa19	Bt Cotton	June, 2006
Vip 3Aa20	Bt Corn	February 2008

Note: This table presents a summary of the US-EPA's PIP Registrations since 1995. Multiple registrations of the same PIP event are not shown. The complete US-EPA PIP Registration list can be found at http://www.epa.gov/oppbppd1/biopesticides/pips/pip_list.htm
* Represents PIPs present in Pioneer 4114 Maize, the subject of this EA.

Like insect-resistant corn varieties, the introduction of herbicide-tolerant corn varieties has substantially affected how corn is produced in the United States. The introduction of herbicide-tolerant corn varieties allowed the post-emergent application of some herbicides, simplifying a grower's weed management strategy.

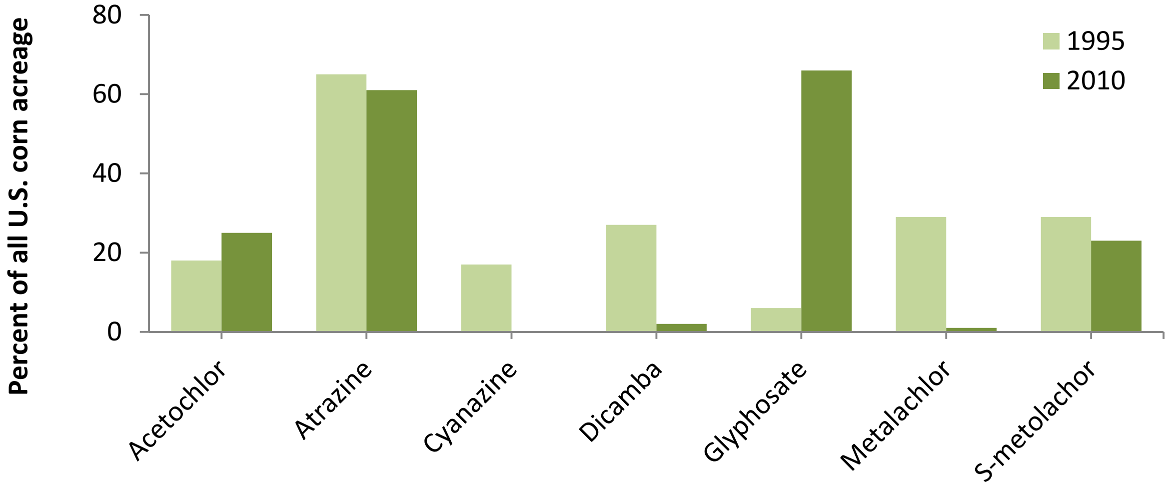
In particular, glyphosate-tolerant corn varieties have strongly influenced weed management strategies (Figure 2-2). Although glyphosate-tolerant corn has not substantially affected the percentage of corn acreage managed with herbicides, the introduction of glyphosate-tolerant corn varieties has resulted in the substitution of glyphosate for some other corn herbicides (Figure 2-3) (Brookes and Barfoot, 2012; Vencill et al., 2012).

Figure 2-2. Adoption of GE corn varieties with at least one herbicide-tolerant trait and glyphosate in U.S. corn production, 1994 – 2010.



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

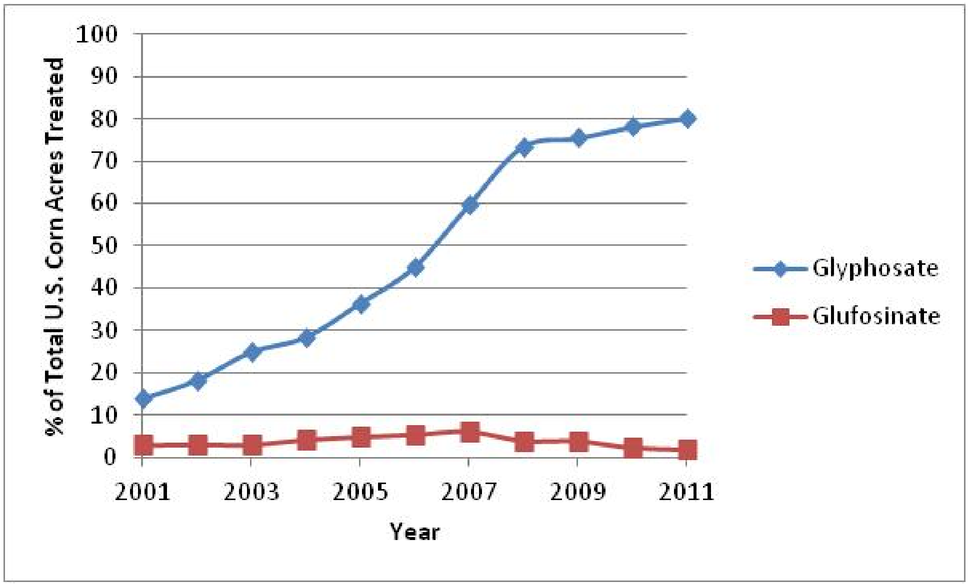
Figure 2-3. Commonly used herbicides in U.S. corn production, 1995 – 2010.



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

In addition to glyphosate-tolerant corn varieties, glufosinate-tolerant corn varieties are also cultivated in the United States. Glyphosate-tolerant and glufosinate-tolerant corn are the most common GE herbicide-tolerant corn varieties currently cultivated in the United States. Figure 2-4 illustrates the percent of U.S. corn acres treated with glyphosate or glufosinate.

Figure 2-4. Percent of U.S. corn acres treated with glyphosate or glufosinate.



Source: (Pioneer, 2011b).

Although glufosinate-tolerant corn has been available since 1996, the use of glufosinate on total corn acres has remained stable and low over the past decade, with between 2% and 6% of the total U.S. corn acreage treated with glufosinate (Pioneer, 2011b). In 2010, 515,000 lbs. of glufosinate was applied to 2% of U.S. corn acreage (USDA-NASS, 2011d). In contrast, 57,536,000 lbs. of glyphosate was applied to 66% of U.S. corn acres in 2010 (USDA-NASS, 2011d).

Growers have selected glyphosate over glufosinate based on several reasons, including (Pioneer, 2011b):

- Glufosinate has limited systemic activity compared to glyphosate;
- Higher volumes of water (and higher pressure in spray nozzles) are needed for glufosinate compared to glyphosate;
- The window of application for effective control of weeds for glufosinate is narrower than for glyphosate;
- Popularity of glyphosate-tolerant soybeans allows for growers to use glyphosate on all their GE crops in a corn/soybean operation; and
- Potentially higher relative cost of glufosinate compared to glyphosate.

Long-term trends related to herbicide use resulting from the utilization of GE technologies are the subject of much debate (Benbrook, 2009; Benbrook, 2012; Brookes and Barfoot, 2010; Brookes and Barfoot, 2012; Fernandez-Cornejo et al., 2009). Benbrook reported that the adoption of herbicide-tolerant crops has resulted in an increase in the volume of herbicides applied to crops (see, e.g., Benbrook, 2009; Benbrook, 2012). Benbrook noted that between 1996 and 2001, herbicide use declined apparently in direct response to the adoption of herbicide-tolerant crops. However, since 2001, herbicide use has increased (Benbrook, 2009; Benbrook, 2012). Benbrook suggests that the reported increases in herbicide use during the last decade reflect an increase in glyphosate applications as more glyphosate-tolerant crops are planted with an associated increase in use of other herbicides used to control glyphosate-resistant weeds (Benbrook, 2009; Benbrook, 2012). Other authors interpret the herbicide use data differently (see, Brookes and Barfoot, 2012; Brookes et al., 2012). Benbrook's analysis of trends in herbicide use is based on assumptions that may lead to overestimates of herbicide use in herbicide-tolerant crop programs, including assumptions of herbicide usage on conventional crops that may be underestimated, extrapolation of trends to years where no USDA data are available, and not accounting for the role of increased crop acreage in the estimated increases in herbicide use (Brookes et al., 2012). Further, Benbrook’s analysis fails to consider the differing environmental profiles of herbicides used, particularly the substitution of relatively environmentally benign products for those with less environmentally friendly profiles (Brookes et al., 2012). In contrast to Benbrook's findings, Brookes and Barfoot (2012) estimate that GM crop adoption in the United States reduced the use of pesticides in the United States by 246 million kg compared to what might reasonably be expected if GM crops were no longer available.

As noted above, growers have sometimes substituted glyphosate for other herbicides presenting greater environmental harm, such as metalochlor and fomesafen, both of which have US-EPA groundwater impact advisories on the label (Vencill et al., 2012). Additionally, total use (i.e., pounds of active ingredient per acre) does not reflect the environmental fate or toxicity of the herbicide. Consequently, the total use metric does not allow comparison of herbicides.

In 2011, it was estimated that glyphosate was applied to approximately 80% of U.S. corn acres (Pioneer, 2011b). However, increased selection pressure resulting from the wide-spread adoption of glyphosate-tolerant crops, along with the reductions in the use of other herbicides and weed management practices, has resulted in both weed population shifts and increasing glyphosate resistance among some weed populations (Duke and Powles; Owen, 2008). The emergence of resistance to herbicides is not exclusive to glyphosate-tolerant crops and corresponding weed species (Norsworthy et al., 2012).

Weed resistance to herbicides is a concern in agricultural production and the wide-spread adoption of herbicide-tolerant crops, especially GE-derived glyphosate-tolerant crops, has dramatically changed the approach that farmers take to avoid yield losses from weeds (Duke and Powles, 2009; Gianessi, 2008). Subsection 2.4 – Biological Resources, provides a discussion on the role of herbicide-resistant weeds in corn weed management.

To reduce development of resistant weeds, growers can continually practice weed management strategies by choosing different herbicides with alternative modes of action, including auxin growth regulators, amino acid inhibitors, chlorophyll pigment inhibitors, or lipid biosynthesis inhibitors (Ross and Childs, 2011). The practice of using herbicides with alternative modes of action could potentially diminish the populations of glyphosate-resistant weeds and reduce the likelihood of the development of new herbicide-resistant weed populations (Dill et al., 2008; Duke and Powles, 2008, 2009; Norsworthy et al., 2012; Owen, 2008; Pioneer, 2011b; Vencill et al., 2012).

Weed control methods differ depending on a number of factors including regional practices, grower resources, and crop trait; the techniques may be direct (e.g., mechanical, biological, and chemical) or indirect (e.g., cultural) (Hoeft et al., 2000). Additionally, weed management strategies need to be carefully planned to integrate appropriate technologies into an economic level of control (Shaw et al., 2011). A diverse strategy is essential to reduce selection pressure on the weed population (Powles and Preston, 2009).

Recently, the Weed Science Society of America presented a series of best management practices (BMPs) to address herbicide resistance in weeds. These recommendations are (Norsworthy et al., 2012):

- Reduce the weed seedbank through diversified programs that minimize weed seed production;
- Implement a herbicide MOA labeling system for all herbicide products and conduct an awareness campaign;
- Communicate that discovery of new, effective herbicide MOAs is rare and that the existing herbicide resource is exhaustible;
- Demonstrate the benefits and costs of proactive, diversified weed-management systems for the mitigation of HR [herbicide-resistant] weeds;
- Foster the development of incentives by government agencies and industry that conserve critical herbicide MOAs as a means to encourage adoption of best practices;

- Promote the application of full-labeled rates at the appropriate weed and crop growth stage. When tank mixtures are employed to control the range of weeds present in a field, each product should be used at the specified label rate appropriate for the weeds present.
- Identify and promote individual BMPs that fit specific farming segments with the greatest potential impact;
- Engage the public and private sectors in the promotion of BMPs, including those concerning appropriate herbicide use; and
- Direct federal, state, and industry finding to research addressing the substantial knowledge gaps in BMPs for herbicide resistance and to support cooperative extension services as vital agents in education for resistance management.

Glufosinate

The herbicide glufosinate ammonium was first registered with the US-EPA in 1993 for home, non-food and farmstead weed control uses (OSTP, 2001), and received its first crop-product registration in 2000 (US-EPA, 2008b). The US-EPA has published exemptions for tolerance for both glufosinate and the PAT protein (US-EPA, 2010d). Glufosinate is a non-selective foliar herbicide that is used for pre-plant and post-emergence control of broadleaf weeds. Glufosinate inhibits glutamine synthetase, resulting in the overproduction of ammonia in plant tissues and ultimately resulting in plant death (US-EPA, 2008b).

Glufosinate is available in several formulations, and is sold under the trade names Basta, Ignite, Rely, Liberty®, Remove, AEH, Finale, and Derringer F. A copy of a sample label for Liberty®, a Bayer formulation, is provided in Appendix B. Although the Liberty® label limits the use of that formulation to corn, soybeans, and canola tolerant to the product, glufosinate ammonium is registered for use on apples, berries, canola, corn, cotton, currants, grapes, grass grown for seed, potatoes, rice, soybeans, sugar beets, and tree nuts (US-EPA, 2008b). Registrations for non-crop areas include golf course turf, residential lawns, ornamentals, and a variety of industrial, residential, and public areas (US-EPA, 2008b). Aerial and ground spraying are allowed, with a wide range of application rates.

The mode of action is not changed by these formulations and applications, but the chemical and physical properties of each formulation influence the selection of equipment, mitigation measures adopted in the field to minimize off-target impacts, and formulation-specific safety measures. Glufosinate is not a dermal irritant or a dermal sensitizer and has been deemed a toxicity category III for acute oral, dermal, and inhalation toxicity (US-EPA, 2003). Glufosinate is highly water soluble (1,370 g/L), and has a half-life in soil ranging from 3 to 70 days, dependent upon soil type and moisture content (Clewis et al., 2008; Jariani et al., 2010).

As of the March 2008 *Glufosinate Summary Document Registration Review*, there were insufficient data available on terrestrial plant toxicity for an ecological assessment to be completed (US-EPA, 2008b). Based on the data collected as of the 2008 review summary, however, the areas of concern are impacts to non-target plants, chronic toxicity to mammals, and the indirect impacts to terrestrial animals from potential alterations in aquatic plant communities (US-EPA, 2008b). The EPA requires additional plant toxicity and field dissipation studies to determine potential impacts of typical end-use products. Existing environmental assessments of the toxicity of glufosinate to animal species indicated a relatively low direct risk, but high risk to plants composing the animals' habitat (US-EPA, 2008b). On an acute exposure basis, glufosinate is considered practically nontoxic to birds, mammals, and insects; slightly non-toxic to freshwater fish; slightly toxic to estuarine/marine fish; moderately toxic to freshwater and estuarine/marine invertebrates; and toxic to terrestrial and aquatic plants (US-EPA, 2008b). For birds, glufosinate is practically non-toxic on an acute and subacute dietary basis; therefore, the risk potential is presumed to be low (US-EPA, 2008b).The US-EPA label for this herbicide includes use restrictions and safety measures. FIFRA requires that registered herbicides be applied in accordance with these label restrictions.

Pesticides - Fungicides

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

Historically, foliar applications of fungicides were not common, and fungal disease management was focused on selection of disease-resistant hybrids, crop rotation to break the disease cycle, and tillage to encourage decomposition of crop residues that were reservoirs for the disease (see, e.g., Purdue, 2012) The corn-to-corn rotations discussed previously in Subsection 2.2.2.2 – Crop Rotation, along with conservation tillage, has resulted in an increased disease risk in some areas (Robertson et al., 2007; Robertson and Mueller, 2007). Corn yields have been reported to increase as a result of these foliar applications of fungicides (Robertson and Mueller, 2007).

2.2.3 Organic Corn Farming and Specialty Corn Systems

2.2.3.1 Organic Corn

In the United States, only crops produced using specific methods and certified under USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (Ronald and Fouche, 2006; USDA-AMS, 2010). The NOP is administered by USDA's AMS. The USDA maintains current information on the domestic organic commodity market at: http://www.nal.usda.gov/afsic/pubs/organicstats.shtml.

Organic certification is a process-based certification, not a certification of the end product. The certification process specifies and audits the methods and procedures by which the product is produced (Ronald and Fouche, 2006). In accordance with NOP, an accredited organic certifying agent conducts an annual review of the certified operation's organic system plan and makes on-site inspections of the certified operation and its records. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards.

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

> To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or group(s)),” the product must be produced and handled without the use of:
>
> (a) Synthetic substances and ingredients,…
>
> (e) Excluded methods,…

Excluded methods are then defined at 7 CFR §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 prohibition on the use of excluded methods. In NOP organic systems, the use of GE crops is excluded (USDA-AMS, 2010).

Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (NCAT, 2003). Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2010). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2010).

The organic farming plan used as the basis for organic certification should include a description of practices used to prevent or reduce the likelihood of unwanted substances, like GE pollen or seed, at each step in the farming operation, such as planting, harvesting, storing, and transporting the crop (Krueger, 2007; Kuepper, 2002; Riddle, 2004; Roth, 2011). Organic corn production begins with certified organically grown seed (Diver et al., 2008). The adventitious presence of GE material in organic corn is a concern because corn naturally cross-pollinates (Coulter et al., 2010). Although GE pollen is frequently cited as a concern, non-organic products can be introduced accidently from impure seed; seed admixture; volunteer plants; and residual non-organic seed in the equipment, vehicles, and facilities (Coulter et al., 2010; Mallory-Smith and Sanchez-Olguin, 2011). Organic farming plans should include how the risk of GE pollen or co-mingling of seed will be monitored (Roth, 2011). Farmers using organic methods are requested to let neighboring farmers know that they are using organic production practices and request that the neighbors also help the organic farmer reduce potential contamination events (Krueger, 2007; NCAT, 2003). Delayed planting has been used successfully by some organic corn producers to control weeds and to avoid potential contamination by GE pollen from adjacent fields (Roth, 2011). The late planting allows the organic corn grower to conduct a secondary tillage pass before planting to control early emerged weeds. Moreover, the late planting results in a later silking in the corn flower thereby avoiding pollen contamination from GE fields which have been planted earlier (Roth, 2011).

Although conventional corn yields (e.g., bushels per acre) tend to be higher than organic yields, net returns (e.g., price per bushel) from organic acres continue to be greater than net returns from conventional acres, with a 16% premium received for organic growers reported in 2008 (Coulter et al., 2010; Kuepper, 2002; Roth, 2011). 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). The approximately 169,000 acres in 2011 represent a decrease from the approximately 195,000 certified organic corn acres cultivated in 2008 (USDA-NASS, 2012a).

2.2.3.2 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 led these seed producers and growers to employ a variety of techniques to ensure that their products are not pollinated by or commingled with conventional or GE crops (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 (NCAT, 2003; Wozniak, 2002). The Federal Seed Act Regulations provide additional details on Certified seed production (see 7 CFR §201, *et seq.*). Field monitoring for off-types is generally carried out by company staff and state crop improvement associations (Bradford, 2006). Seed handling standards are established by the American Organization of Seed Certifying Agencies (AOSCA) to reduce the likelihood of seed source mixing during planting, harvesting, transporting, storage, cleaning, and ginning (AOSCA, 2004). In general, the conventional management practices used for conventional seed production are sufficient to meet standards for the production of specialty crop seed (Bradford, 2006).

2.3 PHYSICAL ENVIRONMENT

2.3.1 Soil Quality

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. As discussed in Subsection 2.2.2.1, tillage is an integral part of production agriculture (Givens et al., 2009). Conservation practices, including conservation tillage, have been developed to reduce field tillage and thus reduce the corresponding soil erosion and runoff (USDA-NRCS, 2006c). By definition, conservation tillage leaves at least 30% of the soil covered by crop residue (Peet, 2001). In conservation tillage programs, the new crop is planted into the plant residue or in narrow strips of tilled soil. This is in comparison to conventional tillage where the seedbed is disrupted through plowing (to turn the soil surface over), disking (to reduce the size of soil clods created by plowing), and harrowing (to reduce the size of clods left by disking) (Peet, 2001).

As conservation tillage practices have been adopted, there is a corresponding benefit to soil. In addition to an increase in soil organic matter, total soil loss on highly erodible croplands and non-highly erodible croplands decreased from 462 million tons per year to 281 million tons per year or by 39.2% 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, and will be discussed in Subsection 2.3.2 – Water Resources.

Corn tillage strategies may directly and indirectly affect soil quality. Corn plant residues remaining in a field in a conservation tillage production system may 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; and judicious use of appropriate herbicides to control weeds remaining in the conservation tillage fields (NCGA, 2007b; Werblow, 2007).

2.3.2 Water Resources

Corn is a water sensitive crop with a relatively low tolerance for drought compared to other cultivated crops. Corn requires approximately 4,000 gallons through the growing season to produce one bushel of grain, or approximately 600,000 gallons per acre for each 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) (Farahani and Smith, 2011; Heiniger, 2000).

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 (Farahani and Smith, 2011; Heiniger, 2000). 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). However, for those corn acres that require supplemental moisture, groundwater is the major source of water for irrigation and is used on almost 90% of irrigated corn acreage in the United States (Christensen, 2002).

In addition to direct use of water, agricultural production of corn may affect water resources through erosion and runoff of nutrients and suspended sediments from farm fields, and infiltration of groundwater by supplemental nutrients and pesticides. This type of non-point source (NPS) pollution is the primary source of water quality impacts on surveyed rivers and lakes and a major contributor to groundwater contamination. Common management practices that contribute to NPS pollution include the type of crop cultivated, plowing and tillage, and the application of pesticides, herbicides, and fertilizers. The primary cause of NPS pollution, however, is increased sedimentation in surface waters following soil erosion (US-EPA, 2005). Agricultural pollutants released by soil erosion include sediments, fertilizers, and pesticides that are introduced to area lakes and streams when they are carried off of fields by rain or irrigation waters (US-EPA, 2005). Increased sediment loads to surface waters can directly affect fish, aquatic invertebrates, and other wildlife maintenance and survival. It also reduces the amount of light penetration in water which directly affects aquatic plants. Soil erosion-mediated sedimentation may also increase fertilizer runoff, thereby increasing nutrient loading and facilitating higher water turbidity, algal blooms, and oxygen depletion (US-EPA, 2005).

2.3.3 Air Quality

Agricultural production of corn may affect air quality in direct and indirect ways. Agriculture directly affects air quality through the common agricultural practices and may include smoke from agricultural burning and vehicle exhaust associated with agricultural equipment. In particular, aerial application of pesticides may cause air quality impacts from drift and diffusion; pesticides also may volatilize after application or may move with the wind as droplets or as constituents of entrained materials in wind eroded soils (Vogel et al., 2008).

Agricultural production of corn may also indirectly affect air quality through common management practices, such as the emission of greenhouse gases (GHG, i.e., carbon dioxide) from tillage or the use of nitrogen fertilizer (i.e., nitrous oxide) (Aneja et al., 2009; Hoeft et al., 2000; US-EPA, 2012b; USDA-NRCS, 2006a).

Many of the conservation plans and practices being developed by growers have an air quality focus which target reductions in air emissions from agricultural operations (USDA-NRCS, 2006a). Practices to improve air quality include conservation tillage, residue management, wind breaks, road treatments, burn management, prunings shredding, feed management, manure management, integrated pest management, chemical storage, nutrient management, fertilizer injection, chemigation and fertigation (inclusion in irrigation systems), conservation irrigation, scrubbers, and equipment calibration (USDA-NRCS, 2006a). Conservation tillage practices resulting in improved air quality include: fewer tractor passes across a field, thus decreasing dust generation and tractor emissions; and an increase in surface plant residues and untilled organic matter which physically hold the soil in place and reduce 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).

2.3.4 Climate Change

Climate change represents a statistical change in global climate conditions, including shifts in the frequency of extreme weather. Agriculture is recognized as a direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) source of GHG emissions. Agriculture, including land-use changes for farming, is responsible for an estimated 6% of all human-induced GHG in the United States (US-EPA, 2012b). Emissions of GHG released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide (CO), nitrogen oxides (N_2O), methane (CH_4), reactive organic gases, particulate matter, and sulfur oxides (SO_x) (US-EPA, 2012b). Nitrous oxides, methane and carbon dioxide are the primary GHGs resulting from agricultural activities (US-EPA, 2012b). Agricultural soil management practices, including nitrogen-based fertilizer application and cropping practices, represent the largest source of U.S. nitrous oxide emissions; croplands account for 68% of the total N_2O emissions attributable to agricultural land uses (US-EPA, 2012b). Agricultural sources of methane emissions are associated primarily with enteric emissions of gas from cattle and manure management. Carbon dioxide also is a substantial GHG associated with several agricultural practices, including certain land uses and energy consumption (US-EPA, 2012c).

The contribution of agriculture to climate change largely is dependent on the production practices employed, the region in which the commodities are grown, and the individual choices made by growers. For example, emissions of nitrous oxide, produced naturally in soils through microbial nitrification and denitrification, can be influenced dramatically by fertilization, introduction of grazing animals, cultivation of nitrogen-fixing crops and forage (e.g., alfalfa), retention of crop residues (i.e., no-till conservation), irrigation, and fallowing of land (US-EPA, 2012b). These same agricultural practices can influence the decomposition of carbon-containing organic matter sequestered in soil, resulting in conversion to carbon dioxide and subsequent loss to the atmosphere (US-EPA, 2012b). On-site emissions associated with farm machinery can be reduced by half for some crops when changing from conventional tillage to no-till systems (Nelson et al., 2009). Conversion of crop land to pasture results in increase nitrogen sequestration in soils (US-EPA, 2012b). Tillage contributes to the release of GHG because of the loss of carbon dioxide (CO_2) to the atmosphere, and the exposure and oxidation of soil organic matter (Baker et al., 2005). No-till practices generally sequester more carbon in the soil due to less soil disturbance, higher soil moisture, and increased biomass inputs from surface residues (West, N.D.). The gross carbon sequestration value used for corn, taken from the national assessment data, is 595 kg carbon/ha/yr (approximately 530 lbs/acre) (West, N.D.). Corn crops using no-till practices have the potential to sequester an additional net 288 kg carbon/ha/yr (approximately 263 lbs/acre) compared to conventional tillage (West, N.D.). The carbon footprint of corn is directly affected by its associated cultivation practices; corn cultivation has been estimated to produce higher total CO_2 emissions than wheat or soybean, and lower total emissions than cotton or rice (Nelson et al., 2009).

The US-EPA has identified regional differences in GHG emissions associated with agricultural practices on different soil types, noting that carbon emission rates differ between mineral soils and organic soils (US-EPA, 2012b). Mineral soils contain from 1 to 6% organic carbon by weight in their natural state; whereas organic soils may contain as much as 20% carbon by weight (US-EPA, 2012b). In mineral soils, up to 50% of the soil organic carbon can be released to the atmosphere on the initial conversion; however, over time, the soil establishes a new equilibrium that reflects a balance between carbon inputs from decaying plant matter and organic amendments and carbon losses from microbial decomposition (US-EPA, 2012b). Organic soils, with their depth and richness in carbon content, continue to release carbon to the atmosphere for a longer period of time (US-EPA, 2012b). The US-EPA has estimated that mineral soil-based cropland areas sequestered over 45.7 Tg CO_2 Eq[17] in 2008, as compared with carbon emissions from organic soil-based croplands of 27.7 Tg CO_2 Eq (US-EPA, 2012b). The adoption of conservation tillage, particularly in the Midwest regions with mineral soil shows the highest rates of carbon sequestration (US-EPA, 2012b).

Although agriculture may influence climate change, climate change may reciprocally affect agriculture. In response to climate change, the current range of weeds and pests of agriculture may increase (Field et al., 2007). Current agricultural practices will be required to change in response to these changes in the ranges of weeds and pests of agriculture (Field et al., 2007).

Climate change potentially may also provide a positive impact to agriculture in general. The Intergovernmental Panel on Climate Change (IPCC) predicts that potential climate change in North America may result in an increase in crop yield by 5-20% for this century (Field et al., 2007). However, this positive impact will not be observed across all growing regions. The IPCC report notes that certain regions of the United States will be impacted negatively because the available water resources may be reduced substantially. Note that the extent of climate change effects on agriculture is highly speculative. Nevertheless, North American production is expected to adapt to climate change impacts with improved cultivars and responsive farm management (Field et al., 2007).

[17] The global warming potential of greenhouse gases are measured against the reference gas CO_2, and are reported as teragrams (or million metric tons) of CO_2 Equivalent, expressed as Tg CO_2 Eq.

2.4 BIOLOGICAL RESOURCES

2.4.1 Animal Communities

2.4.1.1 Birds and Mammals

Compared to natural areas, agricultural production fields generally have reduced animal populations (Dale et al., 2010). However, corn production fields may be host to a variety of animal species, despite monoculture conditions and perpetual disturbances (e.g., planting and harvesting) associated with common agricultural practices (Palmer et al., 1992; Vercauteren and Hygnostrom, 1993). Some birds and mammals may use cornfields at various times throughout the corn production cycle for reproduction, though most birds and mammals that utilize cornfields are ground-foraging omnivores that feed on the corn grain remaining in the fields following harvest (Krapu et al., 2004; Palmer et al., 1992; Vercauteren and Hygnostrom, 1993).

The types and numbers of birds that inhabit cornfields may vary regionally and seasonally; however, the numbers are low in general, although some of the birds are considered agricultural pests. (Patterson and Best, 1996; see also: Purdue, 2010). 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; Mullen, 2011; Patterson and Best, 1996; Purdue; Southern States, 2010):

- 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*); and
- Various quail species.

Following harvest, it is common to find large flocks of Canada geese (*Branta canadensis*), Snow geese (*Chen caerulescens*), Sandhill cranes (*Grus canadensis*), and other migratory waterfowl in cornfields (Sherfy et al., 2011; Sparling and Krapu, 1994; Taft and Elphick, 2007).

Depending on the region, a variety of mammals may also forage in a cornfield. For the most part, herbivorous and omnivorous mammals feed on the ear at various stages of growth. Large- to medium-sized mammals that are common foragers of cornfields include (Beasley and Rhodes Jr., 2008; DeVault et al., 2007; Illinois, 2012; ODNR, 2001; Stewart et al., 2007):

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

The most notable of these is the white-tailed deer and raccoon. 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 effects of white-tailed deer herbivory are well documented (Vercauteren and Hygnostrom, 1993) and are considered responsible for more corn damage than any other wildlife species (Stewart et al., 2007). In addition to deer, substantial damage to corn by raccoons also has been documented (Beasley and Rhodes Jr., 2008; DeVault et al., 2007). Corn has been shown to constitute up to 65% of the diet of raccoons in some areas during the fall (MacGowan et al., 2006).

As with these larger mammals, small mammal use of cornfields for shelter and forage also varies regionally and includes (Smith, 2005; Stallman and Best, 1996; Sterner et al., 2003):

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

The deer mouse is commonly found in agricultural fields (Illinois, 2000; Stallman and Best, 1996; Sterner et al., 2003). Deer mice feed on a wide variety of plant and animal matter depending on availability, but primarily feed on seeds and insects. Deer mice have been considered beneficial in 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 reduced tillage fields (Illinois, 2000). Most crop damage by this mouse is done between planting and crop emergence (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 for its role in the consumption of weeds, the vole can be a substantial agricultural pest where abundant and when it consumes 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).

2.4.1.2 Invertebrates

As noted in Subsection 2.4.1.1 – Birds and Mammals, 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 Caribidae), 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 plants and adversely affect grain yield. These include Lepidopteran species that feed on the corn ear or stalk and Coleopteran species that feed on other corn vegetative structures. Major Lepidopteran and Coleopteran insect pests in the United States include European corn borer and western corn rootworm, respectively. The European corn borer is present in every corn growing state except Arizona, California, Idaho, Nevada, Oregon, Utah, and Washington (ISU, 2012). Western corn rootworm has been reported as active in every corn growing state, with the exceptions of California, Florida, Louisiana, Nevada, Oregon and Washington (Edwards and Kiss, 2012) In the United States, monetary losses and expenses related to European corn borer and corn rootworm exceed $1 billion/year for each pest (Gray et al., 2009; Ostlie et al., 2002). As noted in Subsection 2.2.2.3 – Agronomic Inputs, the advent of GE Bt corn targeting these major insect pests has enabled a reduction in input costs by decreasing the number and volume of broad-spectrum insecticide application in U.S. corn cultivation (Benbrook, 2012; Brookes and Barfoot, 2010).

Although Bt corn has 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). For example, Gassmann (2011) reported pockets of corn rootworm resistance to one type of Bt corn in several locations in Iowa (Gassmann et al., 2011); and the US-EPA has confirmed resistance to Cry1F to Fall armyworm in Puerto Rico (Storer et al., 2012; US-EPA, 2010b). 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 the grower's failure to adhere to the refuge strategy (see, e.g., Storer et al., 2012).

As a condition of Bt registrations by US-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 US-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 (Pioneer, 2012). 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 corn rootworms) can feed, mate and reproduce without exposure to the Bt corn and the Cry proteins, maintaining a genetic reservoir of susceptible target pests that express the dominant trait (Pioneer, 2012; US-EPA, 2010f). Future mating interactions with these susceptible insects (i.e., those that have not been exposed to Bt proteins) with 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 (Pioneer, 2012).

Despite some evidence of Bt resistance, widespread failure of control measures using Bt crops has not been observed, in part due to IRM strategies. IRM strategies generally include supplemental pesticide use and the planting of refuges (Tabashnik et al., 2008). In the case of Bt corn grown in the Corn Belt, refuge acres are typically 5% to 20% of the cornfield area, depending on the product's requirements (US-EPA, 2010f). Resistance management strategies, which are mandated by US-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.

2.4.2 Plant Communities

2.4.2.1 Surrounding Landscapes and Other Vegetation in Cornfields

Cornfields may be bordered by other field crops or by woodlands, hedgerows, rangelands, or pasture/grassland areas. These surrounding plant communities may occur naturally or they may be managed for the control of soil and wind erosion. The vegetation adjacent to a cornfield is often dependent on the geographic region where the corn is planted.

Corn generally is generally cultivated as a monoculture (Dale et al., 2010). Members of the plant community that adversely affect corn cultivation may be characterized as weeds. The types of weeds in and around a cornfield depend on the local landscape in which the corn is planted (IPM, 2004 2007; 2007; Purdue, 2011; University of California, 2009). Some of the most common weeds in cornfields located in North Central Region of the United States include (Purdue, 2012):

- Giant foxtail (*Setaria faberi*);
- Giant ragweed (*Ambrosia trifida*);
- Velvetleaf (*Abutilon theophrasti*);
- Common lambsquarters (*Chenopodium album*);
- Common ragweed (*Ambrosia artemisiifolia)*;
- Common cocklebur (*Xanthium pensylvanicum*);
- Canada thistle (*Cirsium arvense)*;
- Johnsongrass (*Sorghum halepense*);
- Fall panicum (*Panicum dichotomiflorum*); and
- Marestail (*Conyza canadensis*).

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). For example, in addition to the common weeds listed above, the Iowa State University Extension office has listed the following as “Weeds to Watch: New Weed Threats for Corn and Soybean Fields” (Iowa State University Extension, 2003):

- Cressleaf groundsel (*Senecio glabellus*);
- Purple deadnettle (*Lamium purpureum)*;
- Biennial wormwood (*Artemisia biennis*);
- Asiatic dayflower (*Commelina communis)*;
- Hophornbeam copperleaf (*Acalypha ostryfolia*);
- Burcucumber (*Sicyos angulatus*);
- Wild buckwheat (*Polygonum convolvulus*);
- Kochia (*Kochia scoparia)*;
- Waterhemp (*Amaranthus rudis)*;
- Palmer amaranth (*Amaranthus palmeri)*;
- Star-of-Bethlehem (*Ornithogalum umbellatum*);
- White campion (*Silene latifolia*);
- Wild four o' clock (*Mirabilis nyctaginea*); and
- Pokeweed (*Phytolacca americana*).

Weed control is an important aspect of corn cultivation. Weed control typically involves an integrated approach that includes timely applications of herbicide, crop rotation, weed surveillance, and weed monitoring (Farnham, 2001; Hartzler, 2008; IPM, 2004, 2007; 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 corn crops in their area and the most effective means for their control (see, e.g., IPM, 2004, 2007; University of California, 2009).

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 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 herbicide-resistant biotypes (Shaw et al., 2011; Vencill et al., 2012; Wilson et al., 2011). Ecological shifts in the weed community may result in the selection of weeds that have an inherent tolerance[18] to an herbicide MOA; whereas the development of herbicide resistance[19] in a population usually relies on the appearance and maintenance of herbicide-resistant alleles in a population (Vencill et al., 2012).

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[18] In the context of weeds, tolerance is defined by the Weed Science Society of America (WSSA) as, ‘‘the inherent ability of a species to survive and reproduce after herbicide treatment. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant.’’

[19] In the context of weeds, resistance is defined by the WSSA as, “the inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type.”

The emergence of herbicide resistance is not limited to any one herbicide or production system (Heap, 2012). However, as described in Subsection 2.2.2.3 – Agronomic Inputs, large-scale adoption of GE herbicide-tolerant corn varieties (e.g., glyphosate-tolerant corn) has resulted in changes in herbicide use patterns, culminating with the use of glyphosate as the primary means of weed control on the majority of U.S. cornfields. Tables 2-3 through 2-5 list those weedy species which have been identified as herbicide-tolerant to glyphosate, as well as glufosinate and atrazine, in at least some part of their range. These three herbicides are listed to illustrate the differences between glyphosate and atrazine, the two most commonly used corn herbicides, and glufosinate, a less commonly applied product to which some GE corn varieties (e.g., 1507, 59122, and 1507 x 59122 Maize) are tolerant. The emergence of herbicide resistance presents continued challenges to growers to understand which herbicide-resistant species are present and the best agronomic practice available to manage the herbicide-resistant weed.

Table 2-3. U.S. glyphosate-resistant (G/9) weeds through July 2012.

System	Scientific Name	Common Name	Year Identified
Weeds identified outside of Roundup Ready® Systems	*Lolium rigidum*	Rigid Ryegrass	1998
	Conyza bonariensis	Hairy Fleabane	2003
Weeds identified in Roundup Ready® Systems	*Poa annua*	Annual Bluegrass	2010
	Kochia scoparia	Kochia	2007
	Ambrosia artemisiifolia	Common Ragweed	2004
	Ambrosia trifida	Giant Ragweed	2004
	Eleusine indica	Goosegrass	2010
	Conyza Canadensis	Horseweed, Marestail	2000
	Amaranthus palmeri	Palmer Amaranth	2005
	Amaranthus rudis	Common Waterhemp	2005
	Lolium multiflorum[1]	Italian Ryegrass	2001
	Echinochloa colona	Junglerice	2008
	Sorghum halepense	Johnsongrass	2005

Source: (Heap, 2012)
As noted in Table 2-5, Italian Ryegrass resistant to both glyphosate and glufosinate has been identified in Oregon.

Table 2-4. Photosystem II inhibitor-resistant* (C/1) weeds through July 2012.

Scientific Name	Common Name	Year Identified
Abutilon theophrasti	Velvetleaf	1984
Amaranthus hybridus	Smooth Pigweed	1972
Amaranthus palmeri	Palmer Amaranth	1993
Amaranthus powellii	Powell Amaranth	1977
Amaranthus retroflexus	Redroot Pigweed	1980
Amaranthus tuberculatus (syn. rudis)	Common Waterhemp	1994
Ambrosia artemisiifolia	Common Ragweed	1976
Atriplex patula	Spreading Orach	1980
Capsella bursa-pastoris	Shepherd's-purse	1984
Chenopodium album	Lambsquarters	1973
Chenopodium strictum var. glaucophyllum	Late Flowering Goosefoot	1976
Chloris inflata	Swollen Fingergrass	1987

Scientific Name	Common Name	Year Identified
Conyza canadensis	Horseweed	1981
Datura stramonium	Jimsonweed	1992
Echinochloa crus-galli	Barnyardgrass	1978
Eleusine indica	Goosegrass	2003
Kochia scoparia	Kochia	1976
Poa annua	Annual Bluegrass	1978
Polygonum pensylvanicum	Pennsylvania Smartweed	1990
Polygonum persicaria	Ladysthumb	1980
Portulaca oleracea	Common Purslane	1991
Senecio vulgaris	Common Groundsel	1970
Setaria faberi	Giant Foxtail	1984
Setaria glauca	Yellow Foxtail (glauca)	1981
Solanum ptycanthum	Eastern Black Nightshade	2004

Source: (Heap, 2012)
*Atrazine is a photosystem II inhibitor.

Table 2-5. U.S. glutamine synthase inhibitor1 (H/10) weeds through July 2012.

Scientific Name	Common Name	Year Identified
Lolium multiflorum[2]	Italian Ryegrass	2010

Source: (Heap, 2012)
Notes:

1. Glufosinate is a glutamine synthase inhibitor
2. Italian Ryegrass also is resistant to glyphosate. In 2012, Heap notes that Italian Ryegrass was found in Oregon at 2 to 5 sites, between 51 and 100 acres, demonstrating multiple resistance.

2.4.2.2 Corn 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[20]) (USDA-NRCS, 2011a, 2012a). Furthermore, corn is grown throughout the world without any report that it is 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). However, corn seed from a previous year's crop can overwinter and germinate the following year in a field, similar to other domesticated crops. Manual or chemical measures are often applied to remove these volunteers. The plants that are not removed do not typically 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; USDA-APHIS, 2012c) (see also Bernards et al., 2010; Davis, 2009; Hager, 2009; Johnson et al., 2010; Stewart, 2011; Wilson, 2011; Wilson et al., 2010). 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 when weather late in

[20] http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/weedlist-2010doc.pdf

the season causes ears to drop or lodging to occur which places the ears on the ground where the seeds then 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 those seeds survive to the subsequent growing season, volunteer plants may develop within subsequent crops or outside of the cropped area. The potential for corn, including GE corn to establish as a volunteer has been the subject of recent research, with a particular emphasis on yield impact and management of herbicide-tolerant corn as a volunteer in subsequent crops modified for tolerance to the same herbicide (Beckett and Stoller, 1988; Beckie and Owen, 2007; Davis, 2009; Wilson, 2011; Wilson et al., 2010).

Corn volunteers are limited by the geography in which they initially are planted. Corn is an annual plant, and cannot survive temperatures below 0 °C for more than 6 to 8 hours when the growing point is above ground; however, corn seeds which are incorporated in the soil during harvest or in fall tillage may overwinter and grow the following spring (OECD, 2003; Stewart, 2011). Volunteer corn lacks vigor and competitiveness because the volunteer plant is two generations removed from the cross which produced the hybrid planted (Davis, 2009). 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 (Bernards et al., 2010; Davis, 2009; Hager, 2009; Johnson et al., 2010; Stewart, 2011; Wilson, 2011; Wilson et al., 2010). 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 in corn – soybean rotation systems (Davis, 2009), and a 2010 survey of soybean cultivation in Illinois identified a field with up to 500,000 volunteer corn plants per acre (Hager, 2010).

Volunteer corn competes with the intended crop for light, soil moisture, and nutrients (Bernards et al., 2010; Soltani et al., 2006; Wilson et al., 2010). The effect of volunteer corn on the yields of the intended crop depends on the density of the volunteer corn (Bernards et al., 2010; Davis, 2009; Jeschke and Doerge, 2010). In controlled agronomic studies, an analysis of yield impacts to soybeans from volunteer corn was evaluated at densities up to 17,800 corn plants per acre of soybean (Alms et al., 2007, 2008). In these controlled studies, volunteer corn densities ranging from zero plants per square meter up to 4.4 plants per square meter were cultivated in soybean, with corresponding soybean yield losses of up to 58% (Alms et al., 2007, 2008). Pre-harvest herbicide treatments of the volunteer corn reduced but did not eliminate the yield impacts. In experimental studies, volunteer corn in soybeans was controlled using different application rates of the herbicide Clethodim in the attempt to better quantify soybean yield loss (Alms et al., 2008). Clethodim treatments of the volunteer corn did reduce the volunteer corn density, although even after a 98% control of the volunteer corn, soybean yield still suffered a 5% reduction in yield (Alms et al., 2008).

Successful control of corn volunteers, including herbicide-tolerant varieties, is accomplished with the use of various combinations of cultivation practices and herbicides (Beckett and Stoller, 1988; Beckie and Owen, 2007; Jeschke and Doerge, 2010; Sandell et al., 2009). 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 in 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, volunteer corn which has emerged from this overwintered seed requires control with spring tillage or with an application of herbicides (Bernards et al., 2010).

Volunteer corn also can be problematic in fields where the grower elects to cultivate corn after corn. Such volunteer corn in cornfields can be controlled using inter-row cultivation and several different herbicides (Minnesota, 2009; Sandell et al., 2009). As noted with volunteer corn in soybean, growers can take advantage of alternate modes of herbicide action if the herbicide tolerance differs between the current crop and the volunteer (e.g., glufosinate in LibertyLink® Corn to control a glyphosate-tolerant variety) (Minnesota, 2009). Pre-emergent controls might include Gramoxone Inteon (paraquat) mixed with Atrazine (Monsanto, 2010; Sandell et al., 2009). When these two herbicides are used together, optimal control is observed if the applications are made before the corn reaches the 6-inch stage (Monsanto, 2010). If the volunteer corn is stacked to contain both a glyphosate- and glufosinate-tolerant trait, inter-row cultivation is the only option for post-emergent control within corn (Sandell et al., 2009).

2.4.3 Soil Microorganisms

Microorganisms in the field may mediate both negative and positive outcomes. Diseases that afflict 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 may also play an important role in the ecology of the soil (OECD, 2003). Soil microorganisms play a key and beneficial role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004; Young and Ritz, 2000). 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) (Garbeva et al., 2004; Young and Ritz, 2000). Plant roots release a large variety of compounds into the soil, creating a unique environment for microorganisms in the rhizosphere[21] (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).

2.4.4 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 crops through and including 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

[21] 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).

ecosystem, such as a cornfield, to support species that do not contribute directly to crop production but represent important components of the biological landscape. Such species include species affecting pollination (e.g., bees, butterflies) and control of insect pests; important avian (e.g., songbirds) and mammalian (e.g., small mammals) wildlife; and 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 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 and play 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).

Species diversity and abundance in corn agro-ecosystems may differ among conventional, GE, and organic production systems. 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; and 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 which increase habitat preservation and plant biodiversity (see, e.g., IPM, 2004, 2007; Palmer et al., 2011; Sharpe, 2010).

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 effect 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 (Palmer et al., 2011; Sharpe, 2010). 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, 1999; Altieri and Letourneau, 1982, 1984; 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, 1999; Altieri and Letourneau, 1982, 1984). 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, 1999; Altieri and Letourneau, 1982, 1984).

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 invertivorous 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).

2.4.5 Gene Movement

2.4.5.1 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., Diver et al., 2008; Lerner and Dana, 2001). 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).

These practices for maintaining varietal purity are also discussed in Subsection 2.2.3 – Organic Corn Farming and Specialty Corn Systems.

The possibility of gene movement from the host plant into native or feral populations of *Zea* species or wild or weedy relatives of corn has been evaluated by the US-EPA and determined to not be a concern in the continental United States (US-EPA, 2010e). 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 outcrossing in corn to these wild corn varieties.

The closest relative of *Zea* is the genus *Tripsacum* (OECD, 2003). Seventeen species of *Tripsacum* have been identified, with chromosome number varying from 2n = 36 to 2n = 108 (OECD, 2003). All of the *Tripsacum* species are perennial and are mostly found in Central America[22] (OECD, 2003). However, three species have been identified in the United States: *T. dactyloides*, Eastern gamagrass, is known to occur in the eastern half of the United States, *T. lanceolatum*, Mexican gamagrass, occurs in the southwest of the United States, and *T. floridanum*, Florida gamagrass, is native to South Florida and Cuba (OECD, 2003; Wozniak, 2002). *T. dactyloides* is the only *Tripsacum* species of widespread occurrence and agricultural importance in the United States, and commonly is grown as a forage grass (Wozniak, 2002).

Distinctions in genetic construct between related species are important to recognize, as the genetic differences directly affect the ability of cultivated corn to interbreed with wild relatives.

Tripsacum differs from corn in many respects, including chromosome number (*T. dactyloides* n = 18; *Z. mays* n = 10) (Wozniak, 2002). The three *Tripsacum* species in the United States exhibit several ploidy types. *T. floridanum* has a diploid chromosome number of 2n = 36 (Wozniak, 2002). *T. dactyloides* includes 2n = 36 forms which are native to the central and western United States, and 2n = 72 forms which extend along the Eastern seaboard and along the Gulf Coast from Florida to Texas, but which also have been found in Illinois and Kansas (Wozniak, 2002). *T. lanceolatum* has a diploid number 2n = 72 (Wozniak, 2002). The potential for pollen-directed gene flow from maize to Eastern gamagrass is remote (Wozniak, 2002). Although hybridization of *Tripsicum x Z. mays* has been accomplished in the laboratory using special techniques under highly controlled conditions, these hybrids have not been observed in the field (Wozniak, 2002). Additionally, *Tripsicum* does not represent any species considered a serious or pernicious weed in the United States or its territories (Wozniak, 2002). Any introgression of corn genes into this species as a result of cross fertilization is not expected to result in a species that is weedy or difficult to control (Wozniak, 2002). Hybrids between *Z. mays* and the teosinte subspecies *Z. mays* subsp. *mexicana* are known to occur when the two are sympatric in Mexico (CEC, 2004; Ellstrand et al., 2007a). Many species of *Tripsacum* can cross with *Zea*, or at least some accessions of each species can cross, but only with difficulty and the resulting hybrids are primarily male and female sterile (Wozniak, 2002). The rate at which crop genes enter teosinte populations may be limited by genetic barriers, phenological differences, and subsequently by the relative fitness of the hybrids (CEC, 2004; Ellstrand et al., 2007a).

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[22] For example, *Tripsacum* may be found in Central Mexico, Belize, Guatemala, El Salvador, Honduras, Nicaragua and Costa Rica.

2.4.5.2 Horizontal Gene Movement

Horizontal gene movement (i.e., horizontal gene transfer) and consequent expression of deoxyribonucleic acid (DNA) from a plant species to 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; Kaneko et al., 2002; Wood et al., 2001). 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).

2.5 PUBLIC HEALTH

2.5.1 Human Health

Since 1980, the public's consumption of corn-based products has more than doubled. Per capita consumption of corn products rose from 12.9 pounds annually per capita in 1980 to 33 pounds in 2008; and corn sweeteners increased from 35.3 pounds annually per capita to 69.2 pounds during that period (USCB, 2011). As of 2012, 88% of the corn cultivated is GE (USDA-NASS, 2012c). Human health concerns associated with the use of GE corn generally focus on human consumption of GE corn and products derived from GE corn. This subsection provides a summary of the principal human health concerns related to the consumption of GE corn. Issues related to farm workers or animal feed are presented in Subsection 2.5.2 – Worker Safety and Subsection 2.6 – Animal Feed, respectively.

Potential public health concerns from GE crops may result from two aspects of the crop: the use of pesticides on a crop and the potential changes in crop composition[23], including exposure to the introduced genes/proteins.

In general, members of the general public may be exposed to pesticides and pesticide residues through consumption of agricultural crops. Before a pesticide can be used on a food crop, US-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 US-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, 2012e). 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 tolerance (e.g., PAT) (US-EPA, 2007a). Common corn herbicides and PIPs that are currently used in U.S. corn production are listed and discussed in Subsection 2.2 – Agricultural Production of Corn. The US-FDA and the USDA monitor foods for pesticide residues and work with the US-EPA to enforce these tolerances (see USDA-AMS, 2011).

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[23] As determined by the OECD Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea mays*): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites. http://www.oecd.org/science/biosafety-biotrack/46815196.pdf. Last accessed August 27, 2012.

Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and labeled properly. GE organisms for food and feed may undergo a voluntary consultation process with the US-FDA prior to release onto the market. 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 US-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 US-FDA a summary of its scientific and regulatory assessment of the food. This process includes: 1) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; 2) an assessment of the protein's potential for digestion; and 3) an evaluation of the history of safe use of the protein in food (Hammond and Jez, 2011). US-FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Several international agencies also review food safety associated with GE-derived food items, including the EFSA and the Australia and New Zealand Food Standards Agency (ANZFS).

Additionally, foods derived from biotechnology also undergo a comprehensive safety evaluation before entering the market, including reviews under the CODEX, the European Food Safety Agency, and the World Health Organization (FAO, 2009; Hammond and Jez, 2011). Food safety reviews frequently will compare the compositional characteristics of the GE crop with non-transgenic, conventional varieties of that crop (see also Aumaitre et al., 2002; FAO, 2009). Moreover, this comparison also evaluates the composition of the modified crop under actual agronomic conditions, including various agronomic inputs (see, e.g., Pioneer Petition, 2011b). 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; Pioneer, 2011b).

Comparison of anti-nutrients represents an important element of this 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). Raffinose is a low molecular weight oligosaccharide that is non-digestible, causing flatulence from consumption (OECD, 2002). Phytic acid chelates mineral nutrients rendering them unavailable to monogastric animals (OECD, 2002; Pioneer, 2011b). Trypsin inhibitors inhibit protein digestion (Cordain, 1999).

As noted by the National Research Council (NRC), unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional hybridizing and GE (NRC, 2004). The NRC also noted in its 2004 report that no adverse human health effects attributed to GE had been documented. More recently, the NRC found that the cultivation of GE crops has resulted in improvements of pesticide application regimens (applications of fewer pesticides or using pesticides with lower environmental toxicity), and that the cultivation of herbicide-tolerant crops were advantageous because of their efficacy in pest control and concomitant economic, environmental, and presumed personal health advantages (NRC, 2010). 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, 2004; Van Deynze et al., 2004).

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 that 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, 1999; Munkvold and Hellmich, 2000). By reducing insect predation and kernel damage, the incorporation of Bt in corn has been shown to reduce contamination by the mycotoxin, fumonisin (Munkvold and Hellmich, 1999).

2.5.2 Worker Safety

Worker hazards in farming are common to all types of agricultural production, and include hazards of machinery and common agricultural management practices. A common agricultural practice, pesticide application, represents the primary exposure route to pesticides for farm workers. Pesticides, including herbicides, are used on most corn acreage in the United States (Pioneer, 2012). Changes in acreage, crops, or farming practices may affect the amounts and types of pesticides used, and thus, the risks to workers.

As discussed in Subsection 1.3 – Coordinated Framework Review and Regulatory Review, all pesticides labeled for use on crops in the United States must first be registered by the US-EPA. Among other elements, the US-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 as to the appropriate levels of personal protection required for agricultural workers to use herbicides. These may include instructions on personal protective equipment, specific handling requirements, and field reentry procedures (Bayer, 2012). When used in accordance with the label, one corn herbicide, glufosinate, been determined to not present a health risk to workers (US-EPA, 2008b).

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 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.

2.6 ANIMAL FEED

Corn comprises more than 95% of the total U.S. feed grain production (USDA-ERS, 2012d). Corn is valuable as a feed because of its composition, including key nutrients, anti-nutrients and secondary metabolites, protein content, fiber, among others (OECD, 2002). Corn grain is used for feed for beef cattle, poultry, hogs and dairy cattle, with beef cattle consuming the largest volume harvested (NCGA, 2009). 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: corn refining, corn dry millers, and distillers also are used as animal feed (CRA, 2006). 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, 2006).

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, 2006). 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, 2006). 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, 2006). The high protein content also is valued as a cattle feed to protect the cow's rumen (CRA, 2006). Corn germ meal is a residual product obtained from the corn germ after the corn oil has been extracted (CRA, 2006). 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, 2006). Corn steep liquor is a high protein product comprised of the soluble portions of the corn kernel removed during the corn steep process (CRA, 2006). Corn steep liquor is sometimes combined with other ingredients in corn gluten feed or provided as a liquid protein source (CRA, 2006). Amino acids are produced through the fermentation of corn-derived dextrose (CRA, 2006). Lysine, an essential animal amino acid, is a highly valued corn-derived amino acid for both poultry and swine (CRA, 2006). Threonine and tryptophan amino acid feed supplements also are produced from corn (CRA, 2006).

Public concern for animal feed and GE crops generally relates to two aspects of the crop: the use of a pesticide on the crop; and the potential changes in crop composition, including genes or proteins associated with the introduced trait. For pesticides and pesticide residues, US-EPA generally establishes animal feed tolerances at the same time as the tolerances for food (http://www.epa.gov/pesticides/bluebook/chapter11.html). Similar to tolerance values for food, these US-EPA tolerance values for feed are set to ensure 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 tolerance (e.g., PAT protein) (US-EPA, 2012e).

2.7 SOCIOECONOMIC

Corn is produced for food and feed commodities as well as industrial uses (USDA-ERS, 2012d). Corn is the most widely cultivated feed grain in the United States, accounting for more than 95% of total value and production of feed grains (James, 2009; USDA-ERS, 2011c, 2012d). Corn is grown in all 48 states of the continental United States, with production concentrated in the Corn

Belt. The U.S. Corn Belt is loosely defined as the states of Illinois, Iowa, Indiana, the eastern portions of South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri. Iowa and Illinois are the two top corn producing states and typically account for more than one-third of the total U.S. crop (USDA-ERS, 2012d; USDA-NASS, 2012b).

2.7.1 Domestic Economic Environment

In the 2012 production year, corn was cultivated in the United States on over 96 million acres, a 5% increase in corn acreage from 2011(USDA-NASS, 2012b). Corn production in 2011 was estimated at 12.44 billion bushels and valued at an estimated $5.15 to $5.65 per bushel. This resulted in a total value of approximately $64.1 – 70.3 billion for 2011. In 2012, production was estimated at 12.38 billion bushels (USDA-NASS, 2012c). However, because of severe drought throughout the Corn Belt, the estimates for corn production in 2012 were projected sharply lower. In August, 2012, the season average farm price for corn was projected at $7.50 to $8.90 per bushel, a 39% increase in price from the previous month and a 58% average increase over 2011 (USDA-OCE, 2012b).

The cultivation of corn for animal feed varies depending upon the demand in the livestock industry (USDA-ERS, 2012d). Direct feeding of corn to livestock has declined in response to declines in meat production since 2007 in the United States, as has the use of certain corn by-products for livestock feeds (USDA-OCE, 2012b). The production of ethanol generates several economically valuable co-products for animal feed, including distillers dried grains with solubles (DDGs) (USDA-ERS, 2012d). 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, 2011c). 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, 2011, 2012b).

Gross value of production on a typical U.S. corn farm in 2011 was approximately $837/acre (USDA-ERS, 2012b). However, this does not take into associated production costs, such as operating costs and allocated overhead costs. In general, operating costs represented 40% ($332/acre) of corn farm gross income and may include expenses related to seed purchases, agronomic inputs (e.g., fertilizers, irrigation, and pesticides), and the maintenance of farm equipment. Allocated overhead costs, on the other hand, represented approximately 34% ($284/acre) of corn farm gross income and include expenses related to labor, acquisition of farming equipment, land rental rates, taxes, and insurance premiums. In total, net profit of a typical U.S. corn farm, minus operating and overhead costs, was $221/acre in 2011 (USDA-ERS, 2012b).

The costs for GE corn seed are higher than that for non-GE seed. Growers pay a premium for GE seed, with growers in 2008 paying as much as 50% more for GE corn seed than conventional seed (NRC, 2010). This seed premium includes a technology fee for the cultivation of the seed (NRC, 2010). This seed premium also reflects the increased value offered by the seed. For example, a corn variety containing a Cry protein (e.g., 1507, 59122, or 1507 x 59122 Maize) is purchasing both the corn seed and an insecticide combined in a single product (NRC, 2010).

Despite the increased cost of GE corn seed, total farm operating costs are often offset by improved grain yield and reduced corn production costs. These production cost reductions may be a result of increased yields, reductions in average herbicide and pesticide use per field, and corresponding reductions in tillage and associated field cultivation costs (Carpenter et al., 2002). Fuels and chemicals are each estimated to comprise approximately 5% of farm production expenses (USDA-NASS, 2009). Other benefits to the grower from adoption of GE corn have included (Brookes and Barfoot, 2010; Carpenter et al., 2002):

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

Herbicide-tolerant corn has been cultivated commercially since 1997. The cultivation of this crop has reduced costs and increased profitability, with average grower profitability improved by $20/hectare to $25/hectare in most years when compared with the costs of conventional herbicide treatment used to gain the same level of control in a low/reduced till system (Brookes and Barfoot, 2010). These economic benefits are influenced by the comparative cost of the herbicides. For example, in 2007, the manufacturers of glyphosate posted a substantial increase in price, resulting in reduced average profitability of 17.60/hectare (Brookes and Barfoot, 2010).

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., Brookes and Barfoot, 2012; Fernandez-Cornejo and Caswell, 2006). Cost savings to the grower include less time spent scouting the crop for pests and savings in machinery use (Brookes and Barfoot, 2012).

The incorporation of Bt in corn has a secondary 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 United States commodity market have been estimated as high as $5 billion/year (Schmale III and Munkvold, 2012).

The emergence of glyphosate-resistant weed biotypes has been identified as an economic concern (NRC, 2010). Glyphosate resistance has been demonstrated to reduce the effectiveness and economic benefits of glyphosate-tolerant crop systems (Weirich et al., 2011). To manage these resistant weeds, growers generally increased herbicide application rates, increased the number of herbicide applications, and returned to more traditional tillage practices. Economic impacts of glyphosate-resistant 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; and tillage, labor, and management hours increase in association with the application of additional herbicides and machinery use (NRC, 2010; Weirich et al., 2011). There also is an additional cost from the reduction in yield associated with the competition of the crop and the glyphosate-resistant weeds (NRC, 2010; Weirich et al., 2011).

2.7.2 Trade Economic Environment

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

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

Identity protection is important in international trade. Some countries are sensitive to the importation of GE crops, and some have yet to approve importation of GE corn varieties (see, e.g., ICTSD, 2005). For certain key export markets, such as Canada, Japan, Mexico, Taiwan, South Korea and China, developers will prepare regulatory submissions prior to the commercial launch of the product (Pioneer, 2011b). 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 (as discussed in Subsection 2.2.3 – 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

This document analyzes the potential environmental consequences resulting from a determination of nonregulated status of Pioneer 4114 Maize. To respond favorably to a petition for nonregulated status, USDA-APHIS must determine that Pioneer 4114 Maize is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2012c), USDA-APHIS has concluded that Pioneer 4114 Maize is unlikely to pose a plant pest risk. Therefore, USDA-APHIS must determine that Pioneer 4114 Maize is no longer subject to 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000.

Two alternatives will be evaluated in this EA: 1) no action; and 2) determination of nonregulated status of Pioneer 4114 Maize. USDA-APHIS has assessed the potential for environmental impacts for each alternative in Section 4 of this EA, Environmental Consequences.

Pioneer has indicated its intention to limit the cultivation of Pioneer 4114 Maize to use as a foundation stock for developing stacked hybrids through conventional breeding techniques (Pioneer, 2011b). In this process, the herbicide or insect resistance or other trait(s) in Pioneer 4114 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 Plant Protection Act of 2000. USDA-APHIS does not have jurisdiction under the Plant Protection Act of 2000 and Part 340 to review such stacked hybrids developed using nonregulated articles and conventional hybridization techniques where there is no evidence of a plant pest risk. Accordingly, this EA focuses on the cultivation of Pioneer 4114 Maize. Issues associated with potential future stacking are presented and discussed in the cumulative impacts analyses (see Section 5 – Cumulative Impacts), where appropriate.

3.1 NO ACTION: CONTINUATION AS A REGULATED ARTICLE

Under the No Action Alternative, USDA-APHIS would deny the petition. Pioneer 4114 Maize and progeny derived from Pioneer 4114 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 Pioneer 4114 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 Pioneer 4114 Maize.

This alternative is not the Preferred Alternative because USDA-APHIS has concluded through a PPRA that Pioneer 4114 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2012c). 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 PIONEER 4114 MAIZE IS NO LONGER A REGULATED ARTICLE

Under this alternative, Pioneer 4114 Maize and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR Part 340. Pioneer 4114 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2012c). Permits issued or notifications acknowledged by

USDA-APHIS would no longer be required for introductions of Pioneer 4114 Maize and progeny derived from this event.

This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR Part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act of 2000. Because the agency has concluded that Pioneer 4114 Maize is unlikely to pose a plant pest risk, a determination of nonregulated status of Pioneer 4114 Maize is a response that is consistent with the plant pest provisions of the Plant Protection Act of 2000, the regulations codified in 7 CFR Part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to Pioneer 4114 Maize and progeny derived from this event if the developer decides to commercialize Pioneer 4114 Maize for use in breeding programs. In addition, growers and other parties that are involved in production, handling, processing, or consumption of corn would continue to be able to use the current corn products developed by conventional breeding as well as the GE corn variety. By granting nonregulated status to Pioneer 4114 Maize, the purpose and need to allow the safe development and use of GE organisms is met.

3.3 ALTERNATIVES CONSIDERED BUT REJECTED FROM FURTHER CONSIDERATION

USDA-APHIS assembled a comprehensive list of alternatives that might be considered for Pioneer 4114 Maize. USDA-APHIS evaluated these alternatives in light of the agency's authority under the plant pest provisions of the Plant Protection Act of 2000, 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 Pioneer 4114 Maize. Based on this evaluation, USDA-APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

3.3.1 Prohibit Any Pioneer 4114 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 Pioneer 4114 Maize, including denying any permits associated with the field testing. USDA-APHIS determined that this alternative is not appropriate given that Pioneer 4114 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2012c).

In enacting the Plant Protection Act of 2000, Congress found that—

> [D]ecisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science…§402(4) (codified at 7 U.S.C. §7701(4)).

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with EO 13563, to guide the development and implementation of policies for oversight of emerging technologies (such as GE) at the agency level. In accordance with this memorandum, agencies should adhere to EO 13563 and, consistent with that EO, the following principle, among others, to the extent permitted by law, when regulating emerging technologies:

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

Based on its PPRA (USDA-APHIS, 2012c) and the scientific data evaluated therein, USDA-APHIS concluded that Pioneer 4114 Maize is not likely to present a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of Pioneer 4114 Maize.

3.3.2 Approve the Petition In Part

The regulations at 7 CFR 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 concluded that Pioneer 4114 Maize is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act of 2000 for considering approval of the petition only in part.

3.3.3 Isolation Distance between Pioneer 4114 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 Pioneer 4114 Maize from conventional or specialty corn production. However, because USDA-APHIS has concluded that Pioneer 4114 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2012c), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act of 2000 and regulations in Part 340.

USDA-APHIS also considered geographically restricting the production of Pioneer 4114 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 USDA-APHIS' PPRA for Pioneer 4114 Maize, there are no geographic differences associated with any identifiable plant pest risks for Pioneer 4114 Maize (USDA-APHIS, 2012c). Moreover, in 2010, commercial products containing the 1507 x 59122 Maize were grown on approximately 14 million acres, or approximately 16% of the U.S. maize acres (GfK Kynetec, 2010; Pioneer, 2011b). Hybrid varieties based on this cross present the same herbicide tolerance and insect resistance traits as Pioneer 4114 Maize. USDA-APHIS has no regulatory authority over the cultivation of the varieties based on this hybrid. Accordingly, this alternative was rejected and not analyzed in detail. USDA-APHIS has concluded that Pioneer 4114 Maize does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area (USDA-APHIS, 2012c). Therefore, such an alternative would not be consistent with USDA-APHIS' statutory authority under the plant pest provisions of the Plant Protection Act of 2000 and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet USDA-APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in Part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act of 2000. Nevertheless, USDA-APHIS is not expecting substantial effects. However, individuals might choose on their own to geographically isolate their non-GE corn productions systems from corn incorporating the Pioneer 4114 Maize event 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 Pioneer 4114 Maize is available from Association of Official Seed Certifying Agencies (AOSCA, 2004).

3.3.4 Requirement of Testing for Pioneer 4114 Maize

During the comment periods for other petitions for granting 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. Additionally, because Pioneer 4114 Maize does not pose a plant pest risk (USDA-APHIS, 2012c), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act of 2000, the regulations at Part 340, and the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for Pioneer 4114 Maize would not meet USDA-APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.4 COMPARISON OF ALTERNATIVES

Table 3-1 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this EA. The impact assessment is presented in Section 5 of this EA.

Table 3-1. Summary of potential impacts and consequences of alternatives.

Attribute/Measure	**Alternative A: No Action**	**Alternative B: Deregulation in Whole**
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2012c)
Management Practices		
Areas and Acreage of Corn Production	Unchanged	Unchanged
Agronomic Practices	Unchanged	Unchanged
Organic Farming	Unchanged	Unchanged
Specialty Corn Production	Unchanged	Unchanged
Environment		
Soil Quality	Unchanged	Unchanged
Water Resources	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged

Attribute/Measure	Alternative A: No Action	Alternative B: Deregulation in Whole
Climate Change	Unchanged	Unchanged
Animal Communities	Unchanged	Unchanged
Plant Communities	Unchanged	Unchanged
Soil Microorganisms	Unchanged	Unchanged
Biological Diversity	Unchanged	Unchanged
Gene Movement	Unchanged	Unchanged
Public Health		
Human Health	Unchanged	Unchanged
Worker Safety	Unchanged	Unchanged
Animal Feed	Unchanged	Unchanged
Socioeconomic		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Other Regulatory Approvals		
United States Agencies	FDA completed consultations, US-EPA tolerance exemptions and seed increase registrations granted	FDA consultation pending, US-EPA tolerance exemptions and seed increase registrations granted
Compliance with Other Laws		
CAA, CWA, EOs	Fully compliant	Fully compliant

Notes:

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 not deemed substantial.

4 ENVIRONMENTAL CONSEQUENCES

4.1 SCOPE OF THE ENVIRONMENTAL ANALYSIS

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking No Action (i.e., leaving current restrictions in place) and the Preferred Alternative (i.e., unconfined cultivation of Pioneer 4114 Maize). Potential environmental impacts from the No Action Alternative and the Preferred Alternative for Pioneer 4114 Maize are described in detail throughout this section. A cumulative impacts analysis for each environmental issue is presented in Section 5 – Cumulative Impacts. Certain aspects of this product and its cultivation would be no different between the alternatives; those instances are described below.

For the analysis of Environmental Consequences in this draft EA, we note that Pioneer 4114 Maize contains traits from two GE maize varieties that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. The Cry1F protein and its associated genetic elements in Pioneer 4114 Maize are identical to those in DAS-01507-1 Maize (hereafter referred to as 1507 Maize), which had a determination of nonregulated status by USDA, was registered by the EPA, and was reviewed by the US-FDA in 2001 (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2001; USDA-APHIS, 2001). The binary Cry proteins, Cry34Ab1 and Cry35Ab1, and their associated genetic elements are identical to those in DAS-59122-7 Maize (hereafter referred to as 59122 Maize), which was reviewed by US-FDA in 2004, had a determination of nonregulated status by USDA in 2005, and was registered by US-EPA in 2005 (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2004; USDA-APHIS, 2005). Both 1507 and 59122 Maize contain the PAT protein, which itself has had nonregulated status since 1995 and has been commercially available in the United States since 1996 (USDA-APHIS, 1995).

The regulatory history of 1507 and 59122 Maize bears repeating here because commercial corn representing hybrids based on these varieties, including a conventional hybrid breeding stack of the two lines, 1507 x 59122, are now licensed broadly across the seed industry (Pioneer, 2011b). The 1507 x 59122 breeding stack combination was reviewed and registered by US-EPA in 2005 (US-EPA, 2010f). Similarly, and as noted in Subsection 2.1, in 2005 the EFSA approved the marketing of 1507 maize for import, feed and industrial processing and cultivation (EFSA, 2005), in 2007 approved 59122 for import, feed and industrial processing (EFSA, 2007), and since 2009, has reviewed and approved at least four commercial hybrids based on the 1507 x 59122 hybrid stacks for food and feed uses, import and processing, in each case concluding and that the hybrid products were unlikely to have any adverse effects on human or animal health or on the environment (see, EFSA, 2009a; EFSA, 2009b, 2010, 2011). In 2010, commercial products containing 1507 x 59122 Maize were grown on approximately 14 million acres or approximately 16% of U.S. maize acres (GfK Kynetec, 2010; Pioneer, 2011b).

Accordingly, as the events contained in Pioneer 4114 Maize are already commercially cultivated, this draft EA presents a summary of the Cry proteins and the PAT proteins and the events in Pioneer 4114 Maize within the Affected Environment section and an analysis within the Environmental Consequences section. For the discussion of environmental consequences, the following principal areas of potential environmental concern are addressed:

- Agricultural Production of Corn (Subsection 4.2);
- Physical Environment (Subsection 4.3);
- Biological Resources (Subsection 4.4);
- Public Health (Subsection 4.5);
- Animal Feed (Subsection 4.6); and
- Socioeconomic (Subsection 4.7).

Although the Preferred Alternative would allow for the cultivation of Pioneer 4114 Maize to occur anywhere in the United States for breeding stock, USDA-APHIS is limiting the environmental analysis to those areas that currently support corn production, as identified by the USDA-NASS 2007 Census of Agriculture (USDA-NASS, 2009).

The potential environmental consequences of the No Action and Preferred Alternative are analyzed under the assumption that farmers who produce conventional corn, Pioneer 4114 Maize, or corn using organic methods are using reasonable, commonly accepted best BMP specific to their agricultural corn production.

4.2 AGRICULTURAL PRODUCTION OF CORN

BMPs are commonly accepted, practical ways to grow corn. These management practices consider crop-specific planting dates, seeding rates, and harvest times, among others. Over the years, corn production has resulted in well-established management practices that are available through local Cooperative Extension Service offices and their respective websites. The National Information System for the Regional Integrated Pest Management (IPM) Centers publishes crop profiles for major crops on a state-by-state basis. These crop profiles provide production guidance for local growers, including recommended practices for specific pest control. Crop profiles for many of the corn production states can be reviewed at www.ipmcenters.org/cropprofiles/index.cfm[24].

Pioneer's studies demonstrate that agronomic characteristics and cultivation practices required for Pioneer 4114 Maize are essentially indistinguishable from practices used to grow other corn varieties, including other GE varieties, such as 1507, 59122, and 1507 x 59122 Maize (Pioneer, 2011b; USDA-APHIS, 2012c). None of the BMPs currently employed for corn production is expected to change if Pioneer 4114 Maize is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. Accordingly, the potential impacts on agricultural production of Pioneer 4114 Maize resulting from management practices associated with the No Action and Preferred Alternative are the same, as discussed below in Subsections 4.2.1 – Areas and Acreage of Corn Production; 4.2.2 – Agronomic Practices; and 4.2.3 – Organic Corn Farming and Specialty Corn Production.

[24] Last accessed October, 2012.

4.2.1 Areas and Acreage of Corn Production

GE and non-GE corn varieties are continually under development. In 2012, corn was cultivated on over 96 million acres (USDA-NASS, 2012b). Approximately 88% of U.S. corn acreage is planted with GE corn (USDA-NASS, 2012b).

4.2.1.1 No Action: Areas and Acreage of Corn Production

Under the No Action Alternative, existing trends related to area and acreage of corn is expected to continue. Corn is expected to continue being commercially cultivated in 48 U.S. States, with the majority of production centered in the Midwestern Corn Belt (USDA-NASS, 2012b).

As discussed in Subsection 4.1 – Scope of the Environmental Analysis, Pioneer 4114 Maize contains traits from GE corn varieties that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. These corn varieties are 1507, 59122, and 1507 x 59122 Maize (Pioneer, 2011b; US-EPA, 2010f). All three corn products are now licensed broadly across the seed industry (Pioneer, 2011b), covering approximately 16% of U.S. maize acres (GfK Kynetec, 2010; Pioneer, 2011b). The current cultivation of these existing corn varieties, especially 1507 x 59122 Maize, strongly suggests that traits contained in Pioneer 4114 Maize (e.g., Cry1F, Cry34Ab1, Cry35Ab1, and PAT) will maintain a continued presence in the U.S. corn market under the No Action Alternative.

With regard to acreage, conventional corn production will likely continue to gradually increase, based on current acreage trends (USDA-OCE, 2012a). Dictating this general increase in U.S. corn acreage are external market forces across many commercial sectors. Increasing demand and favorable net returns for corn products are likely to sustain the market for U.S. corn grain (USDA-OCE, 2012a). As discussed in Subsection 2.2 – Agricultural Production of Corn, this trend towards increased corn cultivation is not a result of cultivation of new farm land, but is instead a consequence of the grower's substitution of corn for other crops to take advantage of current crop pricing (USDA-ERS, 2011d). For example, the establishment of a bioethanol industry using corn as a feed stock is one of the key elements in the increase in acreage devoted to corn, with approximately 45% of the corn harvest dedicated to corn-based biofuel production (USDA-ERS, 2012c). Since 2006, many U.S. cotton farmers have converted to corn and soybean because of favorable prices, and not because of access to a new corn variety (USDA-ERS, 2009, 2011d).

Additionally, government policies have and will continue enabling U.S. farmers to meet corn production targets by providing economic incentive to retain arable land in agricultural production. For example, two Federal policy tools were enacted to increase the amount of arable land for agricultural production while also encouraging farmer adoption of environmentally-friendly practices to maintain agricultural productivity (USDA-ERS, 2011d). First, the Food, Conservation, and Energy Act (2008) required a net reduction in Conservation Reserve Program (CRP) land enrollment from 39.2 to 32 million acres. Second the Act increased funding for Working Land Conservation Programs (e.g., The Environmental Quality Incentives Program [EQIP]),.

4.2.1.2 Preferred Alternative: Areas and Acreage of Corn Production

The Preferred Alternative is not expected to extend the area of U.S. corn production or cause an increase in overall corn acreage, relative to the No Action Alternative. As discussed in Subsection 4.2.1.1 – No Action, Pioneer 4114 Maize already contains traits that are contained in currently-cultivated corn varieties. This is important to note, as Pioneer 4114 Maize is essentially a functional equivalent of 1507 x 59122 Maize. Accordingly, the potential impacts of the Preferred Alternative are likely to be similar to the No Action Alternative.

Pioneer's studies and USDA-APHIS analyses demonstrate that agronomic characteristics and cultivation practices required for Pioneer 4114 Maize are essentially indistinguishable from other corn varieties, including 1507, 59122, and 1507 x 59122 Maize (Pioneer, 2011b; USDA-APHIS, 2012c). Accordingly, Pioneer 4114 Maize might be expected to replace other varieties of corn currently cultivated, such as 1507 x 59122 Maize, that represent approximately 16% of the U.S. corn market (Pioneer, 2011b). Under the Preferred Alternative, there are no changes in agronomic characteristics in Pioneer 4114 Maize that would result in an a change in the area where corn is cultivated in the United States or an increase in acreage relative to the No Action Alternative (USDA-APHIS, 2012c). As noted in the No Action Alternative analysis in Subsection 4.2.1.1, the trend in increase in corn acreage is a function of market conditions driving growers to substitute corn for other crops. This trend is not specific to a single GE corn variety and is currently ongoing (USDA-ERS, 2011d). Consequently, this trend is not expected to be impacted by a determination of nonregulated status of Pioneer 4114 Maize.

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

As discussed in Subsection 2.2.2 – Agronomic Practices, corn cultivation requires substantial management considerations regarding tillage, rotation, and agronomic inputs. Decisions concerning corn agronomic practices are dependent on grower want and need, and ultimately reflective of external factors including geography, weed and disease pressure, economics of management of yield, and production system (rotation) flexibility (Farnham, 2001; Heiniger, 2000; University of Arkansas, 2008). Choice of management practice often dictates marketability of a corn product, with certain agricultural consumer sectors stipulating requirements and restrictions regarding corn production methods.

4.2.2.1 No Action: Agronomic Practices: Tillage, Crop Rotation, and Agronomic Inputs

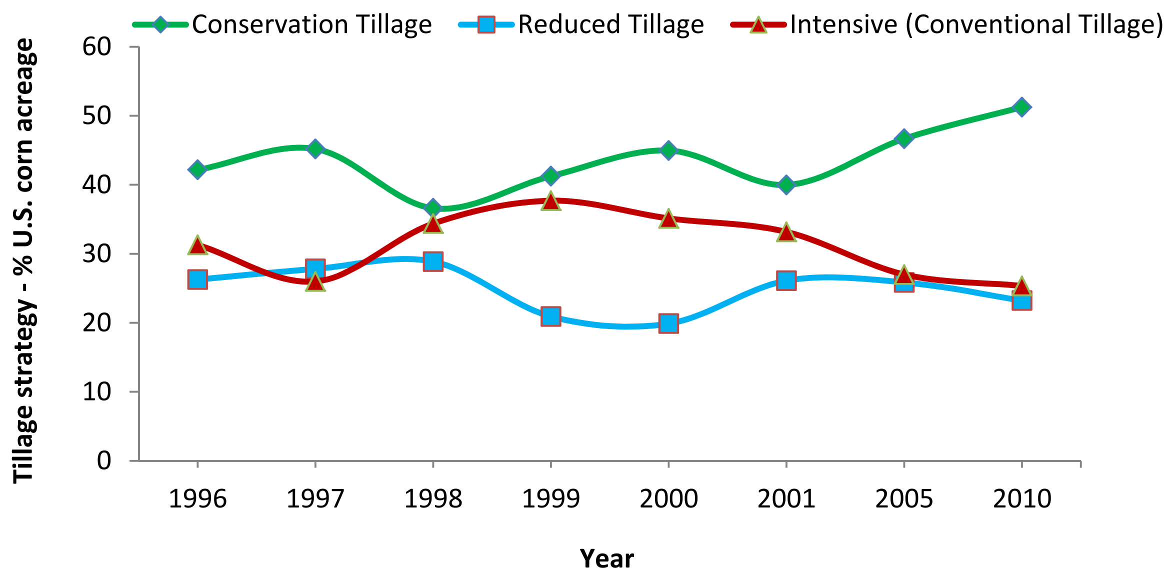
<u>No Action: Tillage and Crop Rotation</u>

Under the No Action Alternative, trends related to tillage and crop rotation are likely to continue as currently practiced, as described in Subsection 2.2.2.1 – Tillage and Subsection 2.2.2.2 – Crop Rotation.

Prior to planting corn, U.S. growers may use conventional, reduced, or conservation tillage to prepare the soil for planting. Recent data from USDA-ERS and the USDA Agricultural Resource Management Survey (ARMS) indicate that conservation tillage has slightly increased in U.S. corn production at the expense of conventional tillage activities between 1998 and 2010 (Figure 4-1). During this time period, no-till activities in U.S. corn production increased by 4% (4.3

million corn acres); however, this adoption of no-till practices was likely caused by shifts from growers already using conservation tillage and not conventional tillage practices (NRC, 2010).

Figure 4-1. Adoption rates of three major tillage types in U.S. corn production, 1996 – 2010.



Source: USDA-ERS (2012a).

In contrast to other U.S. commodity crop production systems, trends of conservation tillage adoption in U.S. corn production are not directly attributable to the adoption of GE herbicide-tolerant corn varieties (NRC, 2010). This relatively weak relationship between conservation tillage and herbicide-tolerant corn adoption may be attributed to historical and current corn cultivation practices. Prior to the introduction of herbicide-tolerant corn varieties, some U.S. corn growers were already using conservation tillage practices in their cultivation practices. A large portion of U.S. corn is grown in the Midwestern Corn Belt (USDA-NASS, 2012b). Due to soil erosion concerns in this region, concerted conservation efforts were encouraged in this area, resulting in substantial increases in reduced-till and no-till corn acreage before herbicide-tolerant corn varieties were commercially available (Givens et al., 2009). Relative to cotton or soybean, adoption of conservation tillage in corn was higher prior to the development of herbicide-tolerant varieties; consequently, the opportunity for adoption in corn was lower when herbicide-tolerant varieties were first commercialized (Givens et al., 2009).

As discussed in Subsection 2.2.2.1 – Tillage, plant residues in conservation tillage has been identified as a potential challenge for corn 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, with resistant hybrids the most economical method (Robertson et al., 2009).

Under the No Action Alternative, rotation strategies for corn are likely to continue as practiced today, with market demand and available technology strongly influencing corn rotation practices. In 2010, 71% of corn acreage in 19 surveyed states was under some form of rotation (USDA-

NASS, 2011c). As noted in the No Action analysis in Subsection 4.2.1.1, the trend in increase in corn acreage is a function of market conditions driving growers to substitute corn for other crops, including the decision to adopt corn-to-corn production. This trend is not specific to a single GE corn variety (USDA-ERS, 2011d) and is expected to continue as normally practiced under the No Action Alternative.

No Action: Agronomic Inputs

Under the No Action Alternative, current practices related to agronomic inputs in U.S. corn production are likely to continue as currently practiced. Grower application of inputs, as presented in Subsection 2.2.2.3 – Agronomic Inputs, is likely to continue as it is at present.

As a consequence of farm-level decisions discussed in Subsection 2.2.2.3 – Agronomic Inputs, 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 (Farnham, 2001; Heiniger, 2000; University of Arkansas, 2008). Practices related to fertilizer, insecticide, and herbicide application described in Subsection 2.2.2.3 – Agronomic Inputs is likely to continue as it is practiced today. Corn will continue to receive fertilizer inputs (Ritchie et al., 2008). The trends noted in Figure 2-1 and presented in Subsection 2.2.2.3 – Agronomic Inputs are likely to continue. Herbicide use as a percent of total corn acres is expected to remain relatively consistent, insecticide use is anticipated to decline as more insect-resistant varieties are cultivated, and foliar fungicide applications may continue to increase (Pioneer, 2011b). Additionally, also noted in Subsection 2.2.2.3 – Agronomic Inputs, the application of fungicides for seed treatment is expected to continue to increase as more fungicide treatments are brought to the market (see, e.g., Hoeft et al., 2000; Ruhl, 2007).

Insecticide use in U.S. corn production has steadily decreased as growers adopted the use of GE insect-resistant corn varieties (Benbrook, 2012; Brookes and Barfoot, 2010; Brookes et al., 2012). Under the No Action Alternative, Pioneer 4114 Maize will remain a regulated article. However, as noted in Subsection 2.2.2.3 – Agronomic Inputs and Subsection 4.1 – Scope of the Environmental Analysis, U.S. corn growers already have access to the insect-resistant traits in Pioneer 4114 Maize. This includes access to the Cry1F protein in 1507 Maize to manage European corn borer and Cry34Ab1/Cry35Ab1 in 59122 Maize to manage corn root worm. This also includes access to a combination of the Cry1F and Cry34Ab1/Cry35Ab1 traits in 1507 x 59122 Maize. Table 4-1 provides a complete summary of the US-EPA registrations for GE insect-resistant varieties containing Cry proteins found 1507 and 59122 Maize. In 2010, approximately 16% of the commercial U.S. corn acreage was planted with a 1507 x 59122 hybrid (Pioneer, 2011b).

Similar to insecticide use in corn production, herbicide use has been profoundly affected by the adoption of GE herbicide-tolerant corn varieties. As discussed in Subsection 2.2.2.3 – Agronomic Inputs, the wide adoption of glyphosate-tolerant corn varieties has resulted in glyphosate being applied to approximately 80% of U.S. corn acres (Pioneer, 2011b). In addition to glyphosate tolerance, corn varieties have also been genetically engineered to exhibit tolerance to glufosinate. Glufosinate use on corn in the United States has been relatively steady and low, accounting for between 2% and 6% of total U.S. corn acreage in the past decade (Pioneer, 2011b). As discussed in Subsection 4.1 – Scope of the Environmental Analysis, GE corn varieties that are tolerant to glufosinate include 1507, 59122, and 1507 x 59122 Maize. Other GE glufosinate-tolerant corn varieties are listed in Table 4-1. Additionally, other glufosinate-tolerant crops are used in U.S. agriculture; the use of glufosinate is not a new one. These varieties are listed in Table 4-2.

Table 4-1. US-EPA registrations[1] for commercial corn products containing 1507 and/or 59122 Maize.

Bt Event(s)	Product Name	Company	EPA Reg. Number	Initial Date of Registration	Expressed Trait Functions
1507	Herculex I	Pioneer Hi-Bred	29964-3	May 18,2001	Lepidopteran resistance, tolerance to glufosinate ammonium
1507	Herculex I	Mycogen Seeds (c/o Dow Agrosciences LLC)	68467-2	May 18,2001	Lepidopteran resistance, tolerance to glufosinate ammonium
59122	Herculex Rootworm	Pioneer Hi-Bred	29964-4	Aug. 31,2005	Coleopteran resistance, tolerance to glufosinate ammonium
59122	Herculex Rootworm	Mycogen Seeds (c/o Dow Agrosciences LLC)	68467-5	Aug. 31,2005	Coleopteran resistance, tolerance to glufosinate ammonium
1507 x 59122	Herculex XTRA	Mycogen Seeds (c/o Dow Agrosciences LLC)	68467-6	Oct. 27,2005	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium
1507 x 59122	Herculex XTRA	Pioneer Hi-Bred	29964-5	Oct. 27,2005	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium
MON89034[2] x 1507 x MON88017[3] x 59 122	Genuity® SmartStax®	Monsanto Company	524-581	July 20, 2009	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium; added lepidopteran resistance from Cry1A.105 and Cry2Ab2 and coleopteran resistance from Cry3Bb1
MON89034[2] x 1507 x MON88017[3] x 59 122	Genuity® SmartStax®	Mycogen Seeds (c/o Dow Agrosciences LLC)	68467-7	July 20, 2009	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium; added lepidopteran resistance from Cry1A.105 and Cry2Ab2 and coleopteran resistance from Cry3Bb1
1507 x MON810[4]	Optimum Intrasect	Pioneer Hi-Bred	29964-7	Feb. 24,2010	Lepidopteran resistance, tolerance to glufosinate ammonium; added Lepidopteran resistance from Cry1Ab
1507 xMON810 x 59122	Optimum lntrasect Extreme	Pioneer Hi-Bred	29964-8	Feb. 24,2010	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium; added Lepidopteran resistance from Cry1Ab
90% 1507 x 59122 + 10% 1507	Optimum AcreMax 1	Pioneer Hi-Bred	29964-6	April 30, 2010	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium
90% 59122 + 10% non-Bt	Optimum AcreMaxRW	Pioneer Hi-Bred	29964-10	April 30, 2010	Coleopteran resistance, tolerance to glufosinate ammonium and refuge
Bt11 x MIR162[5] x 1507	Agrisure Viptera 3220	Syngenta Seed Inc.	67979-15	March 29, 2011	Lepidopteran resistance, tolerance to glufosinate ammonium; added lepidopteran resistance from Vip3Aa20
95% MON89034 x 1507 x MON88017 x 59122 + 5% non-Bt	Genuity® SmartStax® RIB Complete	Monsanto Company	524-595	April 8, 2011	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium and glyphosate; added lepidopteran resistance from Cry1A.105 and Cry2Ab2 and coleopteran resistance from Cry3Bb1 and a refuge.
95% MON89034 x 1507 x MON88017 x 59122 + 5% non-Bt	Genuity® SmartStax® RIB Complete	Mycogen Seeds (c/o Dow Agrosciences LLC)	68467-16	April 8, 2011	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium and glyphosate; added lepidopteran resistance from Cry1A.105 and Cry2Ab2 and coleopteran resistance from Cry3Bb1 and a refuge.

Table 4-1. US-EPA Registrations[1] for Commercial Corn Products Containing 1507 and/or 59122 Maize. Continued.

Bt Event(s)	Product Name	Company	EPA Reg. Number	Initial Date of Registration	Expressed Trait Functions
Bt11[6] x 1507 x MIR604[7] x 59122	Agrisure 3 122	Syngenta Seed Inc.	67979-17	June 10,2011	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium; added lepidopteran resistance from Cry1Ab and coleopteran resistance from Cry3A.
90% 1507 x MON810 x 59122 + 10% non-Bt	Optimum AcreMax Xtra	Pioneer Hi-Bred	29964-11	Aug. 26, 2011	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium; added lepidopteran resistance from Cry1Ab and a 10%refuge.
95% 1507 x MON810 + 5% non-Bt	Optimum AcreMax	Pioneer Hi-Bred	29964-12	Aug. 26, 2011	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium; added lepidopteran resistance from Cry1Ab and a 5% refuge
1507 x MIR604	Optimum Trisect	Pioneer Hi-Bred	29964-13	Sept. 30, 2011	Lepidopteran resistance, tolerance to glufosinate ammonium; added coleopteran resistance from Cry3A.
1507 x 59122 x MON810 x MIR604 + 5% non-Bt	Optimum AcreMax Xtreme	Pioneer Hi-Bred	29964-16	March 7, 2012	Lepidopteran and Coleopteran resistance, tolerance to glufosinate ammonium; added lepidopteran resistance from Cry1Ab and coleopteran resistance from Cry3A and a 5% refuge.

Notes:

1. EPA registrations are focused on the Bt-based PIPs (the Cry proteins) presented in 1507 and 59122 Maize. US-EPA has no regulatory authority over the herbicide tolerance expressed by the various maize varieties. To the extent that information was available, the herbicide tolerance expressed by the respective maize products is provided.
2. MON89034 expresses the Cry1A.105 and Cry2Ab2 proteins, conferring resistance to certain lepidopterans.
3. MON88017 expresses the Cry3Bb1 protein, conferring resistance to certain coleopterans.
4. MON810 expresses the Cry1Ab protein, conferring resistance to certain lepidopterans.
5. MIR162 expresses the Vip3Aa20 protein, extracted from Bt, conferring resistance to certain lepidopterans.
6. Bt11 expresses the Cry1Ab protein, conferring resistance to certain lepidopterans.
7. MIR604 expresses the Cry3A protein, conferring resistance to certain coleopterans.

Table 4-2. USDA-APHIS nonregulated products expressing the PAT protein conferring tolerance to DL-Phosphinothricin, the ammonium salt of glufosinate, also known as glufosinate ammonium.

Year of Nonregulation	APHIS Product Identification Number	Petitioner	Crop	Traits
1995	94-357-01p	Agrevo	Corn	Phosphinothricin-tolerant
1996	95-145-01p	DeKalb	Corn	Phosphinothricin-tolerant
1996	96-068-01p	Agrevo	Soybean	Phosphinothricin-tolerant
1998	97-205-01p	Agrevo	Rapeseed	Phosphinothricin-tolerant
1998	97-265-01p	Agrevo	Corn	Phosphinothricin-tolerant, Lepidopteran-resistant
1998	97-336-01p	Agrevo	Sugar beet	Phosphinothricin-tolerant
1998	97-342-01p	Pioneer	Corn	Male sterile and Phosphinothricin-tolerant
1998	98-014-01p	Agrevo	Soybean	Phosphinothricin-tolerant (note relation to 96-068-01p petition)
1998	98-238-01p	Agrevo	Soybean	Phosphinothricin-tolerant
1999	98-278-01p	Agrevo	Rapeseed	Phosphinothricin-tolerant and pollination control
1999	98-329-01p	Agrevo	Rice	Phosphinothricin-tolerant
1999	98-349-01p	Agrevo	Corn	Male sterile and Phosphinothricin-tolerant
2001	00-136-01p	Mycogen c/o Dow and Pioneer	Corn	Lepidopteran-resistant and Phosphinothricin-tolerant (1507 Maize)
2002	01-206-02p	Aventis	Rapeseed	Phosphinothricin-tolerant
2002	01-206-01p	Aventis	Rapeseed	Phosphinothricin-tolerant and pollination control
2003	02-042-01p	Aventis	Cotton	Phosphinothricin-tolerant
2004	03-181-01p	Dow	Corn	Lepidopteran-resistant and Phosphinothricin-tolerant
2005	03-353-01p	Dow	Corn	Coleopteran-resistant and Phosphinothricin-tolerant (59122 Maize)
2006	06-234-01p	Bayer	Rice	Phosphinothricin-tolerant
2011	08-340-01p	Bayer	Cotton	Phosphinothricin (glufosinate)-tolerant and Lepidopteran-resistant

Note: The information presented in this table was extracted from the USDA-APHIS BRS Table of Petitions for Nonregulated Status Granted or Pending as of November 12, 2012, found at http://www.aphis.usda.gov/biotechnology/not_reg.html

Under the No Action Alternative, growers will likely continue to experience the continued emergence of Bt-resistant insect pests and glyphosate-resistant weeds. These trends require modifications of crop management practices to address these challenges, including the use of alternative herbicides for weed control (Norsworthy et al., 2012), alternative insect control strategies (including alternative PIPs), mechanical cultivation practices, and strict adherence to crop refugia requirements (Benbrook, 2009; Gassmann et al., 2011).

4.2.2.2 Preferred Alternative: Agronomic Practices: Tillage, Crop Rotation, and Agronomic Inputs

Preferred Alternative: Tillage and Crop Rotation

Under the Preferred Alternative, current trends and practices related to tillage and crop rotation in U.S. corn production are unlikely to be substantially different than that which is occurring under the No Action Alternative in Subsection 4.2.2.1 – Agronomic Practices.

As discussed in Subsection 4.2.2.1 – No Action: Agronomic Practices, the adoption of GE herbicide-tolerant corn varieties did not strongly affect trends related to the adoption of conservation tillage practices in U.S. corn production. As an herbicide-tolerant (i.e., glufosinate-tolerant) corn variety that is intended to replace cultivation on some acres of a very similar herbicide-tolerant corn variety (e.g., 1507 x 59122 Maize), Pioneer 4114 Maize is unlikely to substantially affect tillage practices in corn. Consequently, patterns of tillage are unlikely to be substantially different under the Preferred Alternative compared to the No Action Alternative.

Pioneer 4114 Maize is essentially indistinguishable from other currently cultivated corn varieties in terms of agronomic characteristics and cultivation practices (Pioneer, 2011b; USDA-APHIS, 2012c). This includes 1507 x 59122 Maize, a currently-available corn variety that is functionally equivalent to Pioneer 4114 Maize. This strongly suggests that Pioneer 4114 Maize would likely benefit from the crop rotation strategies discussed in Subsection 2.2.2.2 – Crop Rotation. However, as discussed in Subsection 4.2.2.1 – No Action: Agronomic Practices, growers may currently adopt crop rotation strategies based upon market and field conditions. A determination of nonregulated status of Pioneer 4114 Maize is unlikely to change these market conditions, as market demand for corn is dependent on product end use and not any one GE corn variety. Accordingly, crop rotation in corn is unlikely to be substantially different under the Preferred Alternative compared to the No Action Alterative.

Preferred Alternative: Agronomic Inputs

Under the Preferred Alternative, agronomic inputs associated with U.S. corn production is likely to continue as described in the analysis of the No Action Alternative in Subsection 4.2.2.1 – Agronomic Practices.

Pioneer 4114 Maize is essentially indistinguishable from other currently cultivated corn varieties in terms of agronomic characteristics, cultivation practices, and disease susceptibility (Pioneer, 2011b; USDA-APHIS, 2012c). This suggests that Pioneer 4114 Maize would require similar levels of fertilization as conventional corn varieties and benefit from the use of fungicides. Under the Preferred Alternative, Pioneer 4114 Maize is unlikely to substantially affect trends related to fertilization and fungicide use compared to the No Action Alternative.

Under the Preferred Alternative, Pioneer 4114 Maize will provide growers access to insect-resistant and herbicide-tolerant traits that are already available to U.S. corn growers. As noted in Subsection 2.2.2.3 – Agronomic Inputs and Subsection 4.1 – Scope of the Environmental Analysis, this includes the Cry1F protein in 1507 Maize to manage European corn borer and

Cry34Ab1/Cry35Ab1 in 59122 Maize to manage corn root worm. This also includes access to a combination of the Cry1F and Cry34Ab1/Cry35Ab1 traits in 1507 x 59122 Maize. Additionally, U.S. corn growers will continue having access to glufosinate-tolerant corn varieties. Glufosinate-tolerant corn varieties also include 1507, 59122, and 1507 x 59122 Maize.

A determination of nonregulated status of Pioneer 4114 Maize would provide growers with continued access to corn breeding stock product expressing multiple Cry proteins offering resistance to lepidopteran and coleopteran pests. In 2010, commercial corn products containing 1507 x 59122 Maize were grown on approximately 14 million acres, or approximately 16% of the U.S. corn acres (GfK Kynetec, 2010; Pioneer, 2011b). As Pioneer 4114 contains the same insect-resistant traits as 1507 x 59122 Maize, is virtually indistinguishable from 1507 x 59122 Maize, and is intended to replace 1507 x 59122 Maize on some U.S. corn acres, trends related to insecticide use would likely continue as currently practiced under No Action Alternative. This includes, as described in Subsection 2.2.2.3 – Agronomic Inputs and Subsection 4.2.2.1 – No Action, a decrease in the volume of insecticides (Brookes and Barfoot, 2012; Brookes et al., 2012).

A determination of nonregulated status is unlikely to substantially affect glufosinate use in U.S. corn production. As described in Subsection 2.2.2.3 – Agronomic Inputs and Subsection 4.2.2.1 – No Action, glufosinate is already used on corn. There are no proposed label changes for glufosinate use associated with the cultivation of Pioneer 4114 Maize (Pioneer, 2011b), meaning that glufosinate use patterns will remain the same as currently-available glufosinate-tolerant corn varieties. Additionally, because Pioneer 4114 Maize is functionally equivalent to 1507 x 59122 Maize, it can be reasonable expected that Pioneer 4114 Maize will replace some 1507 x 59122 Maize acreage. USDA-APHIS assumes that all glufosinate use would be in accordance with the label application requirements established by the US-EPA. For these reasons, glufosinate use trends under the Preferred Alternative are not expected to be substantially different than glufosinate use trends under the No Action Alternative.

Trends related to the development of and the management of Bt-resistant insect pests and glyphosate-resistant weed populations are not anticipated to be substantially different for the Preferred and No Action Alternatives. Pioneer 4114 Maize is functionally equivalent to 1507 x 59122 Maize, a GE corn variety already cultivated in the United States, and is thus intended to replace some 1507 x 59122 Maize acreage. Pioneer 4114 Maize will likely require similar refuge requirements and cultivation practices as 1507 x 59122 Maize. Accordingly, Bt-resistant insect pests and glyphosate-resistant weed populations may continue to develop, as described in 4.2.2.1 – No Action. However, strategies to manage resistant insect and weed pests are likely to be as applicable to Pioneer 4114 Maize as the currently-cultivated 1507 x 59122 Maize. Thus, the trends related to the evolution of and the management of Bt-resistant insect pests and glyphosate-resistant weed populations are not anticipated to be substantially different between the Preferred and No Action Alternatives.

A determination of nonregulated status of Pioneer 4114 Maize would continue providing growers with another corn hybrid exhibiting tolerance to glufosinate ammonium, offering another option for managing glyphosate-resistant weeds — a potentially valuable trait in those corn cultivation areas where herbicide-resistant weeds have emerged. This could allow for improved corn grain yields when grown in the vicinity of glyphosate-resistant weeds. This practice of using herbicides with alternative modes of action is expected to potentially diminish the populations of glyphosate-resistant weeds (Dill et al., 2008; Duke and Powles, 2008, 2009; Owen, 2008). Applications of herbicides with mixed modes of action also are expected to prolong the development of new herbicide-resistant weed populations (Duke and Powles, 2009; Owen, 2008).

4.2.3 Organic Corn Farming and Specialty Corn Production

4.2.3.1 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 with organic corn is a concern for some, knowing that corn naturally cross-pollinates (Coulter et al., 2010), though 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 border or barrier rows to intercept pollen; changing planting schedules to ensure flowering at different times; and maintaining formal communications between neighboring farms (Baier, 2008; NCAT, 2003; 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 (Mallory-Smith and Sanchez-Olguin, 2011; Thomison, 2009). A minimum isolation distance of 250 feet between varieties is recommended; whereas, 700 feet is preferred for complete isolation (Diver et al., 2008).

USDA-APHIS recognizes that producers of non-GE corn, particularly producers who sell their products to markets sensitive to GE traits (e.g., organic or some export markets), reasonably can be assumed to be using practices on their farm to protect their crop from unwanted substances and thus maintain their price premium. USDA-APHIS will assume that growers of organic corn are already using, or have the ability to use, these common practices as USDA-APHIS's baseline for the analysis of the alternatives.

<u>No Action: Organic Farming</u>

In 2011, certified organic corn production was approximately 169,000 acres, representing a decrease from approximately 194,000 acres in 2008 (USDA-NASS, 2012a). This decrease occurred in the presence of GE and non-GE corn varieties.

Organic corn production is occurring in the presence of conventional corn production using GE and non-GE corn varieties. As discussed in Subsection 4.1 – Scope of the Environmental Analysis, some of these currently-cultivated corn varieties include 1507, 59122, and 1507 x 59122 Maize. Under the No Action Alternative, it is likely that organic corn farming will continue in the presence of these GE corn varieties.

Organic producers employ a variety of measures to manage identity and preserve the integrity of organic production systems (NCAT, 2003). Historically, organic corn production represented a small percentage (approximately, 0.2%) of total U.S. corn acreage (USDA-ERS, 2011f). The percentage of corn acreage dedicated to organic corn is not anticipated to change under either the No Action Alternative. Current availability of seed for conventional (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. The grower strategies employed to support this are not expected to change and likely will remain the same under the No Action Alternative. Planting and production of GE, non-GE, and organic corn will continue to fluctuate with market demands, as it has over the last 10 years, and these markets are likely to continue to fluctuate under the No Action Alternative (USDA-ERS, 2011e, 2011g, 2012c).

<u>Preferred Alternative: Organic Farming</u>

Organic corn production is unlikely to be affected by a determination of nonregulated status for Pioneer 4114 Maize. As discussed in Subsection 4.1 – Scope of the Environmental Analysis, corn varieties containing the Cry and PAT proteins in Pioneer 4114 Maize are already cultivated in the United States (e.g., 1507, 59122, and 1507 x 59122 Maize). In 2010, commercial corn products containing 1507 x 59122 Maize were grown on approximately 16% of U.S. maize acres (GfK Kynetec, 2010; Pioneer, 2011b). Pioneer 4114 Maize may be expected to replace some 1507 x 59122 Maize acreage, as the corn varieties are functionally equivalent. Additionally, agronomic trials conducted in a variety of locations in the United States demonstrated that Pioneer 4114 Maize is not substantially different in plant growth, yield, and reproductive capacity from conventional corn, including 1507 x 59122 Maize (USDA-APHIS, 2012c). No differences were observed in pollen diameter, weight, and viability. Therefore, Pioneer 4114 Maize is expected to present a no greater risk of cross-pollination than that of existing corn cultivars, including 1507 x 59122 Maize. The practices currently employed to preserve and maintain purity of organic production systems would not be required to change to accommodate the production of Pioneer 4114 Maize.

Accordingly, the determination of nonregulated status of Pioneer 4114 Maize is not expected to have a substantial impact on organic corn production, as it likely that Pioneer 4114 Maize will simply replace some of 1507 x 59122 Maize that is already cultivated.

4.2.3.2 Specialty Corn Production

<u>No Action: Specialty Systems</u>

Specialty corn production is occurring in the presence of convention corn production using GE and non-GE corn varieties. As discussed in Subsection 4.1 – Scope of the Environmental Analysis, some of these currently-cultivated corn varieties include 1507, 59122, and 1507 x 59122 Maize. Under the No Action Alternative, it is likely that specialty corn production will continue in the presence of these GE corn varieties.

Specialty crop growers employ practices and standards for seed production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops (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 (Bradford, 2006; NCAT, 2003; Roth, 2011; Thomison, 2009; Wozniak, 2002). 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).

Current availability of seed for specialty corn varieties are expected to remain the same under the No Action Alternative. The supply chain practices described in Subsection 2.2.3.2 – Specialty Corn which growers employ to preserve and maintain identity (e.g., isolation distances, planting of border and barrier rows, field monitoring, and seed handling standards and practices from planting, harvesting transporting, storage and cleaning are note expected to change (see, e.g., AOSCA, 2004; Bradford, 2006; Wozniak, 2002).

Preferred Alternative: Specialty Systems

As noted in the discussion of Seed Production and Organic Corn Production, no changes in the production or cultivation of specialty corn are required to accommodate Pioneer 4114 Maize, as Pioneer 4114 Maize is similar to conventional corn, including the already-cultivated 1507 x 59122 Maize variety. According to the petition, agronomic trials conducted in a variety of locations in the United States demonstrated that Pioneer 4114 Maize is not substantially different in plant growth, yield, and reproductive capacity from its conventional corn (Pioneer, 2011b; USDA-APHIS, 2012c). No differences were observed in pollen diameter, weight, and viability. Therefore, Pioneer 4114 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 Pioneer 4114 Maize. A determination of nonregulated status of Pioneer 4114 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. Impacts would be similar to the No Action Alternative.

Specialty system farmers, or other farmers who choose to plant non-GE corn varieties or sell non-GE corn seed, are unlikely to be impacted by the expected cultivation of Pioneer 4114 Maize. Transgenic corn lines including those that contain herbicide-tolerant and insect-resistant traits are already in use by farmers. Pioneer 4114 Maize should not present any new and different issues and impacts for specialty corn producers and consumers.

4.3 PHYSICAL ENVIRONMENT

4.3.1 Soil Quality

This subsection discusses the potential consequences of the No Action and the Preferred Alternative on soil quality. Conservation tillage historically has not been the major tillage system in corn production. In 1996, over 60% of the corn acreage was either conventional (30%) or reduced tillage (32%), with the balance split between mulch and no-till systems (Christensen, 2002). As noted in Subsection 2.2.2.1 – Tillage, minimal tillage in corn was being adopted prior to the introduction of GE herbicide-tolerant varieties (Givens et al., 2009).

The soil environment in and around crop fields is complex and rich in microorganisms, including bacteria and fungi. Potential impacts microorganisms are discussed in Subsection 4.4.3 – Soil Microorganisms.

4.3.1.1 No Action: Soil Quality

Under the No Action Alternative, soil quality will remain the same as the present. Current agronomic practices associated with corn production including tillage, cultivation, applications of pesticides and fertilizer, and the use of agricultural equipment are not expected to change under the No Action Alternative. As discussed in Subsections 2.2 - Agronomic Practices and 2.3.1 – Soil Quality, current cultivation practices reduce insecticide use, and substitute glufosinate for more toxic herbicides, providing potential indirect soil quality benefits (Brookes et al., 2012; Towery and Werblow, 2010). Risks are reduced associated with environmental spills or misapplications of chemical herbicides and insecticides to the soil, as well as reductions in the frequency with which these products may be applied. As corn tolerant to glufosinate and containing the Cry proteins within Pioneer 4114 Maize are already on the market (e.g., 1507, 59122, and 1507 x 59122 Maize), these indirect benefits to soil quality do not change under the No Action Alternative.

As noted above in Section 4.2.2 – Agronomic Practices, glufosinate is already used on the LibertyLink® corn varieties, such as 1507 x 59122 Maize. In 2010, glufosinate was applied on approximately 2% of U.S. corn acreage. Glufosinate ammonium is weakly adsorbed to and is highly mobile in soil, undergoes rapid microbial degradation in soil, and has a short soil residual half-life of between 12 and 70 days (CERA, 2002; Senseman, 2007; US-EPA, 2008b). Glufosinate has high leaching potential in soil; however, it degrades rapidly and, therefore, is typically found no deeper than 15 centimeters (approximately 6 inches) in soil (Senseman, 2007). 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 soil (US-EPA, 2008b). Information on the direct impacts of glufosinate to soil microorganisms is presented in Subsection 4.4.3 – Soil Microorganisms.

As noted in Subsection 4.1 – Scope of the Environmental Analysis, the PAT and Cry proteins are currently cultivated, resulting in widespread dispersal of these proteins in U.S. cornfields. The *pat* gene was originally isolated from *S. viridochromogenes;* the *Bt* genes encoding for the Cry proteins were originally isolated from Bt (Pioneer, 2011b). Both *S. viridochromogenes* and *B. thuringiensis* are naturally occurring soil bacteria and are not pathogenic (Hérouet et al., 2005; US-EPA, 1998).

GE corn varieties containing Cry proteins, including 1507 x 59122 Maize, are already cultivated in the United States. The Bt source for the Cry proteins is ubiquitous in soils (US-EPA, 1998). Bt toxins (e.g., Cry1F, Cry34Ab1, and Cry35Ab1) 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, 2010a, 2010b). Field deposition of Cry proteins is associated with plant material (i.e., pollen, crop residue) or plant root exudates (e.g., carbohydrates and amino acids) (US-EPA, 2010a, 2010b). This plant material typically stimulates microbial activity and reproduction. The US-EPA has determined that the Cry proteins are degraded rapidly by soil microflora upon elution from the soil (US-EPA, 2010a, 2010b).

The US-EPA notes that many of the early experiments establishing Cry protein persistence in soil were based on bulk soil, rather than soils representing field conditions (US-EPA, 2010a, 2010b). These bulk soil experiments did not represent the realistic field conditions, including degradation pathways in soil (US-EPA, 2010a, 2010b). The US-EPA expects that degradation rates under field conditions may be higher than bulk soil experiments would suggest (US-EPA, 2010a, 2010b). Additionally, although the US-EPA found that the Cry proteins showed little degradation in soils with low pH (pH 5), the US-EPA also noted that corn does not grow well below pH 5.6; therefore, under most production conditions, corn would not be grown on soils that would inhibit the rate of degradation (US-EPA, 2010a, 2010b). The potential impacts of inadvertent exposure of non-target organisms to the residual Cry proteins in soil are discussed in Subsection 4.4.3 – Soil Microorganisms.

4.3.1.2 Preferred Alternative: Soil Quality

Under the Preferred Alternative, soil quality is not anticipated to be substantially different. As noted in Subsection 4.1 – Scope of the Environmental Analysis, Pioneer 4114 Maize contains identical genetic elements as 1507 and 59122 Maize varieties and represents a corn variety that is functionally equivalent to 1507 x 59122 Maize (Pioneer, 2011b). The crop management practices for Pioneer 4114 Maize will be the same as those employed for 1507, 59122, and 1507 x 59122 Maize. No changes to agronomic practices typically applied in the cultivation of corn, including both commercially available GE corn as well as conventional varieties, are required for Pioneer 4114 Maize (Pioneer, 2011b). Pioneer’s field trial and laboratory analyses demonstrated that the agronomic performance of Pioneer 4114 Maize was functionally identical to its non-transgenic hybrids used as controls in the tests (Pioneer, 2011b; USDA-APHIS, 2012c). Cultivation of Pioneer 4114 Maize did not require increases in applications of agronomic inputs or changes in cultivation, planting, harvesting, and volunteer control (Pioneer, 2011b). The same practices employed for corn varieties under the No Action Alternative would be employed to cultivate Pioneer 4114 Maize varieties.

Pioneer 4114 Maize offers growers another varietal option to apply glufosinate ammonium to control weeds in corn, though it is worth noting that Pioneer 4114 Maize may replace cultivation of the existing 1507 x 59122 Maize variety. As noted above in the No Action discussion, as well as Subsection 4.2.2 – Agronomic Practices, glufosinate is already used on corn varieties grown in the United States, and was applied on approximately 2% of the U.S. corn acreage in 2010. Because glufosinate use is not expected to change in U.S. corn production, it is unlikely that soil quality will be substantially-affected by glufosinate use in Pioneer 4114 Maize.

Pioneer 4114 Maize is compositionally equivalent to conventional corn, including 1507, 59122, and 1507 x 59122 Maize (USDA-APHIS, 2012c). Consequently, any crop residue remaining in the field to decompose is not anticipated to present any substantial indirect effects to soil quality compared to the No Action Alternative.

The corn varieties on which Pioneer 4114 Maize is based, 1507, 59122, and 1507 x 59122 Maize, have been commercially available for many years (Pioneer, 2011b). There are no reports of impacts to soil resources associated with the commercial cultivation of these varieties. Consequently, cultivation of Pioneer 4114 Maize is not anticipated to negatively affect soil quality relative to the No Action Alternative following a determination of nonregulated status.

4.3.2 Water Resources

Corn is a water sensitive crop with a low tolerance for drought, although the stress response and yield loss depends on the stage of the corn growth (Farahani and Smith, 2011). Corn requires approximately 4,000 gallons through the growing season to produce one bushel of grain (NCGA, 2007a). The water demand is variable over the growing season. The greatest water demand occurs during the silk production stage in mid-season and is estimated at approximately two inches of water per week (or 0.3 inches per day) (Farahani and Smith, 2011; Heiniger, 2000).

As discussed in Subsections 2.3.1 and 4.3.1, conservation tillage practices, particularly no-till practices, are currently practiced on U.S. corn acres (Horowitz et al., 2010). Intensive monitoring of surface water and groundwater proximate to agricultural fields has demonstrated that conservation tillage practices can reduce runoff from agricultural lands, decreasing NPS pollution of suspended sediment, nutrients from fertilizers, and pesticides (University of Tennessee Agricultural Extension Service, 2010). Better nutrient management, including precision farming and variable rate applications, are ensuring inputs are used by the crop and are not entering ground or surface waters (US-EPA, 2005; USDA-NRCS, 2006b).

The US-EPA considers water resources, and potential contamination of water resources, when registering a pesticide under FIFRA. Precautions to protect water resources, including aquatic animals and plants, if required, are provided on the pesticide label.

4.3.2.1 No Action: 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. Among the many GE corn varieties available, U.S. growers would continue to cultivate 1507, 59122 and 1507 x 59122 hybrid varieties and continue the agronomic practices and inputs associated with those varieties. These practices and inputs would include the use of glufosinate as an herbicide as well as inclusion of the introduced Cry proteins as part of an insect pest management strategy. No expected changes to water use beyond current trends associated with corn production are expected for this alternative.

As discussed in Subsection 4.2.2 – Agronomic Practices, the herbicide glufosinate ammonium is already approved for use on corn (USDA-NASS, 2011a). As noted in Subsection 2.2 – Agricultural Production of Corn, with the commercial introduction of GE herbicide-tolerant crops, persistent residual herbicides were replaced with shorter half-life herbicides that were more environmentally benign (Fernandez-Cornejo and Caswell, 2006; Shipitalo et al., 2008; Vencill et al., 2012). Currently capturing only approximately 2% of the corn market, glufosinate is considered one of these more benign products; because of glufosinate’s shorter half-life and lower sorption potential, glufosinate losses to surface water are lower than that reported for other herbicides (Battaglin et al., 2005; Shipitalo et al., 2008).

Glufosinate has not been found to be a source of impairment for any water body designated as impaired under §303(d) of the Clean Water Act (US-EPA, 2008b). Surface water may be impacted by glufosinate residues transported by runoff, but US-EPA label restrictions minimize potential impacts to water (US-EPA, 2008b). Glufosinate may leach to groundwater under certain conditions (such as soils with high permeability and shallow groundwater), but glufosinate degrades rapidly in soil from microbial activity and is rarely found deeper than 15 centimeters (approximately 6 inches) from the soil surface (Senseman, 2007). Glufosinate is highly water soluble and stable in water; is considered to be essentially nonvolatile from soil and surface water, and adsorption to suspended solids and sediment has been observed to be low to high (HSDB, 2010; US-EPA, 2000). Biodegradation occurs in water bodies with a half-life greater than 64 days (US-EPA, 2000). The US-EPA has considered the potential impacts to water resources from the agricultural application of glufosinate ammonium, and has included label use restrictions and guidance for product handling intended to prevent impacts to water (see, e.g., Bayer, 2012). Label restrictions specific to water resources include, for example, prohibiting applications directly to water (except as allowed for rice), managing proper disposal of equipment wash water, and adopting cultivation methods (e.g., no till) to limit runoff to surface water, and not applying the herbicide when rainfall is forecasted to occur within 48 hours (Bayer, 2012). The implications of exposure to glufosinate are discussed in Subsection 4.4.1 – Animal Communities.

As discussed in Subsection 4.1 – Scope of the Environmental Analysis, the Cry proteins in Pioneer 4114 Maize are already used in U.S. corn production, appearing for example, in 1507, 59122, and 1507 x 59122 Maize. This means that the US-EPA has already considered potential impacts to surface water in its evaluation of Cry proteins as PIPs (see, e.g., US-EPA, 1998, 2010a, 2010b). The major source of Cry proteins in freshwater is corn pollen (US-EPA, 2010a, 2010b). The EPA has determined that there are no risks to aquatic organisms from exposure to Cry proteins in corn pollen and other plant tissues in aquatic environments (US-EPA, 2010a, 2010b). Cry proteins are not considered a risk to drinking water or groundwater (US-EPA, 1998). The implications of inadvertent exposure to non-target freshwater organisms are discussed in Subsection 4.4.1 – Animal Communities.

4.3.2.2 Preferred Alternative: Water Resources

Under the Preferred Alternative, no substantial impact to water resources is anticipated from a determination of nonregulated status of Pioneer 4114 Maize, as it is functionally equivalent to currently-cultivated corn varieties (e.g., 1507 x 59122 Maize).

With regard to irrigation, no differences in morphological characteristics and agronomic requirements were found between Pioneer 4114 Maize and conventional corn, including 1507, 59122, and 1507 x 59122 Maize (Pioneer, 2011b; USDA-APHIS, 2012c). This strongly suggests that Pioneer 4114 Maize does not require more moisture than conventional corn. Also, as previously discussed in Subsection 4.2.1 – Areas and Acreage of Corn Production, the use of Pioneer 4114 Maize would not increase the total acres and range of U.S. corn production areas. Because Pioneer 4114 Maize is expected to be cultivated in lieu of some corn varieties already in wide-commercial use (e.g., 1507 x 59122), 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 Pioneer 4114 Maize is unlikely to change the current use of irrigation practices in commercial corn production compared to the No Action Alternative.

As discussed in Subsection 4.2.2 – Agronomic Practices, the herbicide glufosinate ammonium is already approved for use on corn, and the proposed application rates and total maximum annual application for use on Pioneer 4114 Maize are consistent with the current rates (Pioneer, 2011b, 2012). Because Pioneer 4114 Maize is expected to be cultivated in lieu of some corn varieties already in wide-commercial use (e.g., 1507 x 59122), and use of glufosinate on Pioneer 4114 Maize is the same as these potentially replaced corn varieties, no substantial impacts to water resources from glufosinate use are anticipated under the Preferred Alternative compared to the No Action Alternative.

The corn varieties on which Pioneer 4114 Maize is based, 1507, 59122, 1507 x 59122 Maize, have been commercially available for many years. The genetic elements in Pioneer 4114 are identical to the 1507 and 59122 Maize varieties. Consequently, it is unlikely that substantial impacts to water resources will occur as a result of Cry1F, Cry34Ab1, Cry35Ab1, and PAT proteins, as there are no reports of impacts to water resources associated with the commercial cultivation of these varieties. Additionally, US-EPA has already considered potential impacts to surface water in its evaluation of Cry proteins as PIPs, as described in the No Action Alternative (see, e.g., US-EPA, 1998, 2010a, 2010b). Cry proteins are not considered a risk to drinking water or groundwater (US-EPA, 1998).

Based on these findings, the potential impacts to water resources are expected to be the same under the Preferred Alternative as under the No Action Alternative.

4.3.3 Air Quality

As discussed in Subsection 2.3.3 – Air Quality, traditional agricultural practices have the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from agricultural burning, tillage, heavy equipment emissions, pesticide drift from spraying, and indirect emissions of carbon dioxide and nitrous oxide the degradation of organic materials in the soil and from the use of nitrogen fertilizer (Aneja et al., 2009; USDA-NRCS, 2006a).

Current corn agronomic practices have the potential to reduce air emissions from several of these sources. Conservation practices, including conservation tillage practices, require fewer tractor passes across a field, thereby decreasing dust generation and tractor emissions. Surface residues and untilled organic matter physically serve to hold the soil in place, thereby decreasing airborne soils and pesticide drift in wind-eroded soils.

4.3.3.1 No Action: Air Quality

Under the No Action Alternative, current impacts to air quality associated with land acreage and cultivation practices associated with corn production, including cultivation practices related to GE corn varieties such as 1507, 59122, and 1507 x 59122 Maize, are not likely to be affected.

Adoption of GE corn varieties are expected to continue. To the extent that the adoption and cultivation of GE corn varieties allows the grower to implement soil conservation practices presented in Subsection 4.3.1 – Soil Quality, air quality improvement associated with these practices would be expected to follow. This would include both direct air quality effects, e.g., emissions from farm equipment, airborne soil erosion and pesticide drift, as well as indirect air quality effects, e.g., decreased carbon dioxide emissions associated with the use of conservation tillage (Aneja et al., 2009; Hoeft et al., 2000; US-EPA, 2012b; USDA-NRCS, 2006a). Air quality will continue to be affected by current agronomic practices associated with conventional methods of corn production such as tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment.

4.3.3.2 Preferred Alternative: Air Quality

Under the Preferred Alternative, a determination of nonregulated status of Pioneer 4114 Maize is unlikely to substantially impact air quality compared to the No Action Alternative.

Pioneer 4114 Maize is similar in agronomic performance and likely requires similar cultivation practices as currently-cultivated conventional corn varieties, including 1507, 59122, and 1507 x 59122 Maize (USDA-APHIS, 2012c). As discussed in Subsection 2.2 – Agricultural Production of Corn, Pioneer 4114 Maize production is unlikely to change land acreage or any cultivation practices for conventional, transgenic, or non-transgenic corn production. It is expected that similar agronomic practices that are currently used for commercially available corn varieties, such as 1507, 59122, and 1507 x 59122 Maize, would also be used by growers of Pioneer 4114 Maize. Agronomic practices that have the potential to impact air quality will be the same for Pioneer 4114 Maize as they are for corn products like 1507, 59122, and 1507 x 59122 Maize that are currently cultivated on U.S. cornfields.

Based on this information, USDA-APHIS concludes that the cultivation of Pioneer 4114 Maize is not expected to adversely affect air quality.

4.3.4 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, 2012b). Agriculture-related GHG emissions include CO_2, N_2O, and CH_4, produced through the combustion of fossil fuels to run farm equipment; the use of fertilizers; or the decomposition of agricultural waste products, including crop residues, animal wastes, and 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, 2012b). A comprehensive discussion of the contribution of agricultural practices to GHGs is provided in Subsection 2.3.4 – Climate Change.

Conservation tillage practices used in U.S. corn production have been identified as providing climate change benefits (see, e.g., Brenner et al., 2001). Conservation tillage, discussed above in Agronomic Practices (Subsections 2.2.2 and 4.2.2) and Soil Quality (Subsections 2.3.1 and 4.3.1), in addition to providing benefits to soil quality, also has the benefit of increasing carbon sequestration in soils. Switching 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 lb/acre) per year (Brenner et al., 2001; Paustian et al., 2000; Towery and Werblow, 2010) .

4.3.4.1 No Action: Climate Change

Under the No Action Alternative, Pioneer 4114 Maize would remain a regulated article. Accordingly, environmental releases of Pioneer 4114 Maize would continue under the USDA-APHIS notification and permitting process.

As discussed in Subsection 4.1 – Scope of the Environmental Analysis Current, corn varieties similar to Pioneer 4114 Maize would continue to be cultivated in the United States under the No Action Alternative. These currently-available corn varieties include 1507, 59122, and in particular, 1507 x 59122 Maize. Consequently, agronomic practices associated with production of 1507, 59122, 1507 x 59122 Maize, and conventional corn varieties would continue. As discussed in Subsection 2.3.4 – Climate Change, these common agronomic practices contribute to GHG emissions, including tillage, cultivation, irrigation, pesticide application, fertilizer applications, and use of agriculture equipment. Because these common agricultural practices are not expected to change under the No Action Alternative, these common agricultural practices are also not expected to change if Pioneer 4114 Maize remains a regulated article.

To the extent that U.S. corn growers are able to implement conservation practices, GHG emissions are expected to continue to be reduced commensurate with the air quality improvements anticipated from adoption of conservation tillage practices. For example, the US-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 which had encouraged growers to take marginal lands out of production (US-EPA, 2012c). To a certain extent, the US-EPA also noted that adoption of conservation tillage resulted in increases in carbon sequestration in soils on those croplands (US-EPA, 2012c). 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, 2012c). This is in contrast to the highest emission rates from organic soils 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, 2012c).

4.3.4.2 Preferred Alternative: Climate Change

Under the Preferred Alternative, a determination of nonregulated status of Pioneer 4114 Maize would not change the cultivation or agronomic practices, or agricultural land acreage associated with growing corn, and thus is expected to have the same effect on climate change as the No Action Alternative. To the extent that the cultivation of a corn variety exhibiting tolerance to glufosinate ammonium allows a grower to minimize conventional tillage and adopt conservation tillage practices, the potential impacts associated with the Preferred Alternative would be the same as those under the No Action Alternative.

As discussed in Subsection 4.2.1 – Areas and Acreage of Corn Production, the cultivation of Pioneer 4114 Maize are not expected to convert new land to corn cultivation. As discussed in Subsection 4.2.2 – Agronomic Practices, the management practices association with the cultivation of Pioneer 4114 Maize and hybrids based on that variety are anticipated to be the same as those for current cultivation of 1507, 59122 and the 1507 x 59122 Maize.

Based on these findings, there are no substantial differences between the No Action Alternative and the Preferred Alternative on climate change.

4.4 BIOLOGICAL RESOURCES

4.4.1 Animal Communities

Corn production systems in agriculture are host to a variety of animal species. A number of insect pests as well as beneficial insects feed on corn plants or prey upon other insects inhabiting cornfields. Although cornfields generally are considered poor habitat for birds and mammals in comparison with uncultivated lands, the use of cornfields by birds and mammals is not uncommon. This subsection discusses the potential consequences of the No Action and the Preferred Alternatives on animal communities associated with cornfields.

4.4.1.1 No Action: Animal Communities

<u>Mammals and Birds</u>

Under the No Action Alternative, Pioneer 4114 Maize remains a regulated article. However, the proteins contained within Pioneer 4114 Maize (i.e., Cry1F, Cry34Ab1, Cry35ab1, and PAT) will remain in the U.S. corn market, as these proteins are already contained in other cultivated GE corn varieties. This includes the cultivation of 1507 (Cry1F and PAT proteins), 59122 (Cry34Ab1, Cry35Ab1, and PAT proteins), and 1507 x 59122 (Cry1F, Cry34Ab1, Cry35Ab1, and PAT) Maize. Potential impacts of GE and non-GE corn production practices on non-target terrestrial (insect, bird, and mammal) and aquatic (fish, benthic invertebrate, and herptile) species would be unchanged.

As discussed in Subsection 2.4.1 – Animal Communities, the majority of birds and mammals use corn as food and not for shelter, due to regular agricultural disturbances (e.g., use of agricultural machinery, application of pesticides, etc.). The exposure pathway for the majority of bird and mammal species to GE corn varieties is through consumption of corn grain. Existing GE corn varieties containing the same Cry and PAT proteins at Pioneer 4114 Maize, including 1507, 59122, and 1507 x 59122 Maize, will continue to be commercially cultivated under the No Action Alternative. Consequently, birds and mammals will continue to be primarily exposed to these GE corn varieties and their respective introduced proteins through the consumption of corn grain.

The Cry proteins in 1507 and 59122 Maize are derived from Bt, subsp. *aizawai* (Cry1F) and Bt strain PS149B1 (Cry 34Ab1 and Cry35Ab1), respectively (USDA-APHIS, 2012c). The modifying PAT enzyme, encoded by the *pat* gene, is derived from *S. viridochromogenes* (Pioneer, 2011b). Both *B. thuringiensis* and *S. viridochromogenes* are naturally occurring soil bacteria and are not pathogenic. Animals are regularly exposed to these organisms and their components without adverse consequences (Hérouet et al., 2005; Pioneer, 2011b; US-EPA, 2007a, 2010a, 2010b, 2012f). US-EPA considers animal exposure in the registration of pesticides under FIFRA, including the review of Cry proteins as PIPs. When reviewing the toxicity of these Cry proteins as PIPs, the EPA considers acute oral exposure involving a pure preparation of the PIP at doses over 5,000 mg/kg bodyweight as well as chronic exposure tests using a diet where the PIP comprised 10% of the diet (US-EPA, 2010a, 2010b). The EPA has also evaluated environmental exposures based on laboratory studies to predict lowest observed effects concentrations (LOEC) and no observed effects concentrations (NOEC) (US-EPA, 2010a). In these studies, the EPA has found no overt signs of toxicity associated with anticipated exposures in 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, 2012c).

Glufosinate is already being applied to corn. As discussed in Subsection 2.2 – Agricultural Production of Corn, the use of glufosinate on corn has been steady, ranging from 2% to 6% of U.S. corn acreage (Pioneer, 2011b). The US-EPA first registered glufosinate ammonium in 2000 as a non-selective foliar herbicide for use on a wide range of crops (US-EPA, 2008a, 2008b). In 2008, the US-EPA announced that it was undertaking a registration review of this product, and has published a final work plan for this process (US-EPA, 2008a). US-EPA's assessments of the toxicity of glufosinate indicated a relatively low risk to animals (US-EPA, 2008b). On an acute exposure basis, glufosinate is considered practically nontoxic to birds, mammals, and insects; slightly toxic to freshwater fish, slightly toxic to estuarine/marine fish; moderately toxic to freshwater and estuarine/marine invertebrates; and toxic to terrestrial and aquatic plants (US-EPA, 2008b). As of the March 2008 *Glufosinate Summary Document Registration Review*, there were insufficient data available on terrestrial plant toxicity for an ecological assessment to be completed (US-EPA, 2008b). Based on the data collected as of the 2008 review summary, however, the areas of concern are impacts to non-target plants, chronic toxicity to mammals, and the indirect impacts to terrestrial animals from potential alterations in aquatic plant communities (US-EPA, 2008b). The EPA requires additional plant toxicity and field dissipation studies to determine potential impacts of typical end-use products. Existing environmental assessments of the toxicity of glufosinate to animal species indicated a relatively low direct risk, but high risk to plants composing the animals' habitat (US-EPA, 2008b). On an acute exposure basis, glufosinate is considered practically nontoxic to birds, mammals, and insects; slightly non-toxic to freshwater fish; slightly toxic to estuarine/marine fish; moderately toxic to freshwater and estuarine/marine invertebrates; and toxic to terrestrial and aquatic plants (US-EPA, 2008b). For birds, glufosinate is practically non-toxic on an acute and sub-acute dietary basis; therefore, the risk potential is presumed to be low (US-EPA, 2008b). Non-target exposure for plants typically results from runoff or drift. Although animals also can be affected from runoff and drift, ingestion is often the most important exposure pathway. As discussed above in Subsection 4.3.3 – Air Quality, the US-EPA label provides measures to control drift. Adherence to label use restrictions will ensure that the use of the herbicide will not adversely affect animals or critical habitat; labeled uses of glufosinate are approved pending the outcome of the US-EPA's ecological risk analysis (US-EPA, 2008a).

Invertebrates

Under the No Action Alternative, non-target invertebrates will continue to be exposed to GE corn varieties and their respective introduced proteins. As discussed in Subsection 4.1 – Scope of the Environmental Analysis, GE corn varieties that contain the same introduced proteins as 4114 Maize will continue to be cultivated. Additionally, glufosinate will also continue to be applied to U.S. corn acreage. Potential impacts related to non-target invertebrates will continue as it currently exists in U.S. corn production under the No Action Alternative.

The most relevant invertebrates in a cornfield are those that are pests of corn. Under the No Action Alternative, GE insect-resistant corn varieties, such as 1507, 59122, and 1507 x 59122 Maize will continue to be available to U.S. corn growers for control of major insect pests, such as European corn borer or western corn rootworm. However, the efficacy of GE insect-resistant hybrids may decrease if resistance develops in the target insect population. Yield losses and corn lodging caused by rootworm pressure have been observed in limited areas of planted Bt-expressing hybrids and have been attributed to resistance (Hodgson and Gassman, 2011).

Under the No Action Alternative and discussed in Subsection 2.4.1.2 – Invertebrates, U.S. growers cultivating Bt corn varieties are required to adopt IRM strategies to delay the development of insect resistance as a result of continued exposure to Cry proteins. One of the key strategies required by the US-EPA involves the incorporation of refuges into their IRM practices (see, e.g., US-EPA, 2010f). The US-EPA has approved refuge strategies for 1507, 59122 , and 1507 x 59122 Maize (US-EPA, 2010f). The refuge strategy is based on the concept that resistant insect pests will mate with susceptible pests from nearby refuges of host plants without Bt toxin, thus producing offspring that are susceptible to the Bt corn crop[25] (Tabashnik, 2008; Tabashnik et al., 2008). Refuge strategies can include a field or a block or strip of non-Bt corn that does not contain a Bt trait (US-EPA, 2010f). Recently, the US-EPA also has approved an integrated refuge strategy, named "refuge in a bag," where non-Bt seeds are blended with the

[25] Assuming that resistance is a recessive genetic trait.

Bt corn products and planted randomly within the field to ensure that refuge requirements are followed (Pioneer, 2012).

Insect resistance to plant-incorporated Bt proteins has been reported (see, e.g., Blake, 2012; Blanco et al., 2010; Gassmann et al., 2011; Kilman, 2011; Storer et al., 2010). Inherent resistance to certain Bt toxins has been identified in wild target insect populations in several fields in Iowa, Puerto Rico and Australia (Blake, 2012; Blanco et al., 2010; Gassmann et al., 2011; Kilman, 2011; Storer et al., 2010). The areas where insect resistance have been reported reflect a very small proportion of the total acreage cultivated in Bt corn (several fields in Iowa as compared with 67% of the 96 million acres planted in Bt corn in 2012 as noted in Table 2-1.). It is important to note that where insect resistance has been identified in Bt cornfields, the development of insect resistance appears to be the result of growers' failure to exercise appropriate management strategies to preserve and protect against insect resistance. In Puerto Rico, for example, Fall Armyworm was identified as resistant to the Cry1F protein (Blanco et al., 2010; Storer et al., 2010). The corn varieties in which resistance was identified in Puerto Rico had been cultivated in the same fields for 12 consecutive production cycles, and typical IPM measures, including varietal rotation and refuge strategies were not well implemented (Storer et al., 2010). In Puerto Rico, this continuous, overlapping production exerts substantial selection pressure towards Bt-resistant insect pests. Similarly, in the Iowa reports, insufficient planting of refuge is believed to have contributed to the development of resistance (Gassmann et al., 2011). In the absence of refuge plantings, non-resistant insects are less available to breed, increasing the likelihood of the development of resistance (Tabashnik, 2008; Tabashnik et al., 2008). In response to the emergence of insect pest resistance noted in Puerto Rico, Pioneer and Dow AgroSciences stopped selling 1507 Maize in Puerto Rico and have worked with growers to implement a more robust integrated pest management program, including chemical insecticides (US-EPA, 2010b) .

Additionally, Gassmann et al. (2011) noted that the emergence of resistant corn rootworm was likely the result of the growers' failure to adhere to the US-EPA's refuge strategies to preserve Bt effectiveness; in each of the cases of resistance, the same corn varieties had been cultivated for several consecutive years within the same fields (Gassmann et al., 2011). Gassmann found that although the corn rootworms had developed resistance to the Cry3Bb1 protein, no cross resistance was demonstrated to other Cry proteins, including Cry34Ab1/Cry35Ab1 (Gassmann et al., 2011). The lack of cross resistance suggests that creating hybrid corn varieties accumulating multiple Cry proteins is likely to preserve beneficial insect-resistant traits in corn. Additionally, other common corn production practices may help in preserving the integrity of beneficial insect-resistant traits. For example, crop rotation in corn conducted to optimize soil nutrition and fertility, may also reduce pathogen loads and control corn pests (IPM, 2004, 2007). Crop rotation practices have been described previously in Section 2.2.2.2 – Crop Rotation.

Widespread failure of control measures using Bt crops has not been observed, despite some evidence of Bt resistance, in part due to IRM strategies, including supplemental pesticide use and refuges (Tabashnik et al., 2008). In the case of Bt corn grown in the Corn Belt, refuge acres are typically 5% to 20% of the cornfield area, depending on the product's requirements (US-EPA, 2010f). Greenhouse and laboratory tests suggest that insects under intense selection pressure by Cry proteins over multiple generations may develop resistance rapidly in the absence of a refuge to sustain susceptible populations. These data in combination with the report of field resistance to a Bt product further emphasize the importance of effective refuges for resistance management (Meihls et al., 2008). Resistance management strategies, which are mandated by US-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.

Despite the need for additional attentiveness to potential impacts of Bt-resistance in insect pests, professional advice given to growers is that multiple tactics do not necessarily need to be employed simultaneously. Thus, University of Illinois Extension staff (Gray, 2011a) suggest that neither Bt-expressing corn hybrids with soil applied insecticides nor adult control the previous season before planting Bt hybrids should become standard treatments. Rather, rotation of crops, alternation of Bt-expressing corn hybrids, insecticide use on conventional non-rootworm-resistant crops, or using pyramided hybrids, and adult suppression should all be considered (Gray, 2011a). Grower decisions should be based on corn price, identification of fields with high CRW populations, trait performance at the location, and whether other soil pests are present. Long term perspectives for managing rootworm populations and other pests need to be taken, along with a fully integrated approach (Gray, 2011b).

4.4.1.2 Preferred Alternative: Animal Communities

Mammals and Birds

Under the Preferred Alternative, potential impacts to mammals and birds are not anticipated to be substantially different compared to the No Action Alternative. As discussed in Subsection 4.1 – Scope of the Environmental Analysis, Pioneer 4114 Maize is functionally equivalent to currently-cultivated corn varieties, such as 1507 x 59122 Maize.

As discussed in Subsection 4.2 – Agricultural Production of Corn, a determination of nonregulated status of Pioneer 4114 Maize is not expected to impact agronomic practices for the cultivation of corn. Pioneer anticipates Pioneer 4114 Maize might replace some of the acres currently planted with products containing 1507 x 59122 Maize, but is not expected to cause new corn acres to be planted in areas that are not already in agricultural production (Pioneer, 2012). Accordingly, mammal and bird communities not already impacted by corn cultivation are not expected to be substantially impacted by a determination of nonregulated status of Pioneer 4114 Maize compared to the No Action Alternative. In that regard, the potential exposure of animals to typical corn cultivation practices and the introduced proteins in Pioneer 4114 Maize under the Preferred Alternative is anticipated to be the same as under the No Action Alternative.

As noted in Subsection 4.1 – Scope of the Environmental Analysis, the Cry1F, Cry34Ab1/Cry35Ab1 and PAT proteins contained in Pioneer 4114 Maize have been commercially available for a number of years. As seen in Table 4-1, many different GE corn varieties containing these proteins, including the 1507 x 59122 Maize have been registered by the US-EPA. No impacts to animal communities associated with exposure to these proteins in corn have been reported (US-EPA, 2010a, 2010b). Consequently, because Pioneer 4114 Maize contains identical genetic elements as 1507, 59122, and 1507 x 59122 Maize, it is unlikely that a substantial impact would occur on the bird and mammal community following consumption of Pioneer 4114 Maize grain under the Preferred Alternative compared to the No Action Alternative.

Pioneer has evaluated the potential allergenicity and toxicity of the proteins introduced in Pioneer 4114 Maize and found no meaningful amino acid similarities with known allergens or toxins (Pioneer, 2011b). This finding was to be expected, as these proteins have been cultivated for many years, including 1507 x 59122 Maize. These exposures are no different than those under the No Action Alternative. Further discussion on the potential impacts from the consumption of Pioneer 4114 Maize is presented in Subsection 4.6 – Animal Feed.

A determination of nonregulated status of Pioneer 4114 Maize also is not expected to result in a change in the use of glufosinate on corn. GE corn varieties containing tolerance to glufosinate has been available and cultivated commercially for many years under the Liberty® trade name (see http://www.aphis.usda.gov/biotechnology/not_reg.html USDA-APHIS, 2012b). The proposed application rates for glufosinate application on Pioneer 4114 Maize are identical to those currently approved for use on corn (Pioneer, 2012). A determination of nonregulated status for Pioneer 4114 Maize is not expected to require a change in the US-EPA registration or label for this herbicide (Pioneer, 2011b). Current label application rates and associated use restrictions for herbicides are designed by the US-EPA to minimize the potential impacts of the use of glufosinate to non-target organisms. USDA-APHIS assumes that the herbicide will be used in accordance with these label restrictions. Under the Preferred Alternative, there are no differences from the No Action Alternative in the use of glufosinate associated with cultivation of Pioneer 4114 Maize.

Invertebrates

Under the Preferred Alternative, non-target invertebrates will continue to be exposed to the agronomic practices that are common in U.S. corn cultivation. In particular, non-target invertebrates will continue to be exposed to the agronomic practices that are used to produce currently-available GE corn varieties because Pioneer 4114 Maize is functionally equivalent currently available varieties, such as 1507 x 59122 Maize, and thus, requires similar growing practices.

Pioneer assessed the non-target impact of Pioneer 4114 Maize on beneficial organisms in the corn agroecosystem, including the Ladybird beetle (*H. convergens* and *Coleomegilla maculata*), the Monarch butterfly (*Danaus plexippus*), parasitic wasps (*Nasonia vitripennis*), the green lacewing (*Chrysoperla carnea*), and the honeybee (*Apis mellifera*) (Pioneer, 2012) (USDA-APHIS, 2012c). Pioneer did not report any impacts on the abundance or diversity of non-target beneficial organisms in the field (Pioneer, 2011b; USDA-APHIS, 2012c). Based on a review of this information, USDA-APHIS has found no evidence that the presence of the *Bt* and *pat* genes or the presence of the Cry and PAT proteins would have any impact on non-target invertebrates, including non-target invertebrates beneficial to agriculture under the Preferred Alternative compared to the No Action Alternative (USDA-APHIS, 2012c).

As discussed in Subsection 2.4.1.2 – Invertebrates and the No Action analysis in Subsection 4.4.1.1, growers are required by the US-EPA to incorporate refuge strategies to delay the development of insect resistance from exposure to the Cry proteins (see, e.g., US-EPA, 2010f). As noted in the No Action discussion in Subsection 4.4.1.1, the US-EPA has published such strategies for cultivating the 1507, 59122, and 1507 x 59122 hybrids. Because Pioneer 4114 contains identical Cry proteins as these currently-available insect-resistant corn varieties and is functionally equivalent to 1507 x 59122 Maize (Pioneer, 2012), these refuge strategies would not change under the Preferred Alternative. Implementation of refuge strategies would be the same as the No Action Alternative as would currently-available and practices corn cultivation strategies to reduce selection pressure for Bt-resistance in insect pests.

Based on these findings, USDA-APHIS has determined that the impacts to the invertebrate community under the Preferred Alternative are the same as those under the No Action Alternative.

4.4.2 Plant Communities

The landscape surrounding a cornfield may be bordered by a number of vegetative communities, including other crop fields, woodland, fencerows, rangelands, and/or pasture/grassland areas. These plant communities may represent natural or managed plant buffers for the control of soil and wind erosion and also may serve as habitats for a variety of transient and non-transient wildlife species.

Additionally, the surrounding plant landscape may also influence non-crop plants (i.e., weed species) that grow within a corn production field. In this context, weeds are those plants which, when growing in the field, 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. Additionally, corn grain may remain in a field and germinate the following season among corn or other crops. These corn plants are known as volunteer corn plants. This subsection discusses the potential consequences of the No Action and the Preferred Alternatives on plant communities.

4.4.2.1 No Action: Plant Communities

Under the No Action Alternative, Pioneer 4114 Maize will remain a regulated article. Plant species (i.e., weeds) that typically inhabit GE and non-GE corn production systems will continue to be managed through the use of mechanical and chemical control methods, as currently practiced. Multiple herbicides, including the herbicide glufosinate, will continue to be used on corn. Volunteer corn will continue to be controlled by the recommended ACCase inhibitors and ALS inhibitors (Hager, 2009).

<u>Surrounding Landscapes and Other Vegetation in Cornfields</u>

Under the No Action Alternative, plant communities surrounding a cornfield may be subject to off-site movement of pesticides as described in Subsections 2.3.2 – Water Resources, 2.3.3 – Air

Quality, and 2.4.2 – Plant Communities. In particular, herbicides such as glufosinate may affect non-target plants through run off/leaching and spray drift.

As noted in Subsection 4.1 – Scope of the Environmental Analysis, corn varieties exhibiting tolerance to glufosinate have been available commercially since 1996. Despite its availability, application volumes of glufosinate have remained low in comparison to glyphosate (Pioneer, 2012). Glufosinate label rates for application to tolerant corn varieties are from 28 to 34 fluid oz. per acre, not more than twice per season with a maximum annual application of 62 fluid ounces per acre, applied post-emergent, using over-the-top broadcast or drop nozzles from emergence until the corn is 24” tall or in theV-7 growth stage (Bayer, 2012).

Surface water may be impacted by glufosinate residues transported by runoff under the No Action Alternative. Glufosinate may leach to groundwater under certain conditions (such as soils with high permeability and shallow groundwater), but glufosinate degrades rapidly in soil from microbial activity and is rarely found deeper than 15 centimeters from the soil surface (Senseman, 2007). Glufosinate is highly water soluble and stable in water and adsorption to suspended solids and sediment has been observed to be low to high (HSDB, 2010; US-EPA, 2000). Biodegradation occurs in water bodies with a half-life greater than 64 days (US-EPA, 2000). Although the EPA has determined that glufosinate use presents “no acute effects on terrestrial or … aquatic plants”, EPA acknowledges potential impacts to non-target plants either from runoff (aquatic) or spray drift (terrestrial) (US-EPA, 2007b). The US-EPA has considered non-target plant communities in its environmental risk assessment of glufosinate use and has included label use restrictions and handling guidance intended to prevent impacts to mitigate potential impacts to aquatic and terrestrial plants (see, e.g., Bayer, 2012). Label restrictions specific to water resources include, for example, prohibiting applications directly to water (except as allowed for rice), managing proper disposal of equipment wash water, and adopting cultivation methods (e.g., no till) to limit runoff to surface water, and not applying the herbicide when rainfall is forecasted to occur within 48 hours (Bayer, 2012).

Spray drift, as discussed above in Subsection 4.3.3 – Air Quality, is a concern for non-target plants growing proximate to fields when herbicides are used (see, e.g., Sanvido et al., 2007). The risk of off-target glufosinate herbicide drift is recognized by the US-EPA, which has incorporated both equipment and management restrictions to address drift in the approved herbicide labels (see Bayer, 2012; US-EPA, 2007b). Contact herbicides like glufosinate can case spotting on non-target plants when spray droplets drift onto and impact leaf tissue, although total tissue death is uncommon unless the herbicide completely covers the leaf (Ruhl et al., 2008). The US-EPA label for glufosinate addresses spray drift concerns with label language on spray droplet size, wind speeds, ambient temperature, avoidance of certain sensitive plants, and specific equipment requirements regarding boom length and height above the canopy (Bayer, 2012). For example, the label requires that the applicator only use the herbicide when there is minimal “…potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitats of threatened or endangered species, non-target crops) … or in circumstances where drift to unprotected persons or to food, forage or other plantings … can occur” (Bayer, 2012). These label use conditions by the US-EPA are intended to limit the potential impacts of glufosinate spray drift, and are not expected to change under the No Action Alternative.

Under the No Action Alternative, there are numerous weeds in cornfields and they may be controlled by current practices, as noted in Subsection 2.4.2 – Plant Communities. Additionally, herbicide-resistant weed biotypes, namely glyphosate-resistant weed biotypes may continue to occur under the No Action Alternative. The emergence of herbicide resistance is not new occurrence; new weeds may emerge as cropping practices change and growers fail to recognize or properly identify a plant as a weed (Iowa State University Extension, 2003). Although herbicide resistance in weeds was recognized long before GE crops were introduced, recent changes in grower practices to take advantage of these GE crops has impacted this phenomenon (Owen et al., 2011). The introduction of glyphosate-resistant crops, including corn, resulted in growers changing historical weed management strategies, substituting glyphosate for other herbicides such as metolachlor and fomesafen and relying on a single herbicide, glyphosate, to control weeds in the field (Owen et al., 2011; Vencill et al., 2012; Weirich et al., 2011). Over-reliance on glyphosate use as a single management technique for weed control resulted in the selection of weeds resistant to that technique (Owen et al., 2011; Weirich et al., 2011). The development of herbicide-resistant weeds requires growers to diversify their weed management strategies. Some growers, faced with glyphosate-resistant weeds, have returned to tillage and other cultivation techniques to physically control these species when herbicides prove ineffective (Pioneer, 2012). Diversifying herbicide weed management strategies is an effective alternative to tillage for mitigating the evolution of weed resistance to herbicides (Wilson, 2011). An example of an additional herbicide that may be used to control glyphosate-resistant weeds is glufosinate, though other herbicides are available for use in corn.

Table 4-3 illustrates the comparative control of glyphosate-resistant and hard to control weeds based on records of glyphosate resistance, and potential glufosinate control. Diversifying herbicide weed management strategies is an effective alternative to tillage for mitigating the evolution of weed resistance to herbicides (Wilson, 2011).

Table 4-3. Comparative control of herbicide-resistant weeds. (Heap, 2012; IPM, 2007)

Weed Species	Hard to Control	Glyphosate-resistant	ALS-resistant	Glufosinate controlled
Abutilon theophrasti (Velvetleaf)	X			
Amaranthus palmeri (Palmer amaranth)[2]	X	X	X	
Amaranthus rudis (Tall or common waterhemp)	X	X	X	
Ambrosia artemisifolia (Common ragweed)	X	X	X	
Ambrosia trifida (Giant ragweed)	X	X	X	
Chenopodium album (common lambsquarters)	X		X	
Conyza canadensis (Marestail)	X	X	X	
Eleusine indica (Goosegrass)	X	X		X[4]
Ipomoea sp. (Morningglory species)	X			
Lolium multiflorum (Italian ryegrass)	X	X[3]	X	X[3]
Lolium perenne (Perennial ryegrass)	X	X	X	X
Lolium rigidum (Rigid ryegrass)	X	X	X	X
Poa annua (Annual bluegrass)	X	X		X
Sida spinosa (Prickly sida, Teaweed)	X		X	
Solanum ptycanthum (Eastern black nightshade)	X		X	
Sorghum halepense (Johnsongrass)	X	X	X	

Notes:
1. 2,4-D application rate of 560 to 1,120 g ae/hectare.
2. Requires a broader management plan.
3. Reported in Heap as exhibiting resistance to both herbicides in Oregon.
4. Resistance to glufosinate reported in malaysia (Heap, 2012)

Globally, only two weeds have been identified as resistant to glufosinate: *Lolium multiflorum* (Italian ryegrass) and *Eleusine indica* (Goosegrass), with the *Lolium* the only reported resistant weed in the United States (Heap, 2012). The *Lolium* species is a difficult to control weed in corn (see, e.g., King et al., 2012). This species also has been reported as resistant to glyphosate in certain locations, and has exhibited resistance to both herbicides in an Oregon location (Heap, 2012). Control measures are available for this weed under the No Action Alternative, including the use of other herbicides, such as gramoxone and atrazine (King et al., 2012).

Corn as a Weed or Volunteer

As discussed in Subsection 2.4.2 – Plant Communities, corn is not considered a weed in the United States (Crockett, 1977; Muenscher, 1980). Under the No Action Alternative, corn will remain non-weedy.

Corn has been identified as a volunteer when corn seeds remain in the field after harvest and successfully germinate (Beckett and Stoller, 1988; USDA-APHIS, 2012c) (see also Bernards et al., 2010; Davis, 2009; Hager, 2009; Johnson et al., 2010; Stewart, 2011; Wilson, 2011; Wilson et al., 2010).

The adoption of herbicide-tolerant crops has changed the approaches which growers can use to reduce crop losses from volunteers (Beckie and Owen, 2007). In soybean fields cultivated in rotation with corn where the volunteer corn is glyphosate- or glufosinate-tolerant, herbicides with alternate modes of action might be employed (e.g., glufosinate in LibertyLink® soybean to control a Roundup Ready® glyphosate-tolerant volunteer corn variety) (Bernards et al., 2010; Minnesota, 2009). Post-emergent grass herbicide that function as ACCase inhibitors also are recommended, including Quizalofop, fluazifop, fenoxaprop, sethoxydim, and clethodim (Bernards et al., 2010; Hager, 2009; Johnson et al., 2010). ALS inhibitors, such as the sulfonylureas, imidazolinone, and triazoloyrimidine also have been identified for potential control of glyphosate- or glufosinate-tolerant corn (see, Hager, 2009; Wisconsin, 2011). Herbicide tank mix additives are recommended to increase on-plant spray retention and absorption (see Hager and McGlamery, 1997; Johnson et al., 2010; Sandell et al., 2009). Recommended additives include crop oil concentrate (COC), methylated seed oil (MSO), and ammonium sulfate (AMS) (Hager and McGlamery, 1997; Johnson et al., 2010; Monsanto, 2010). Imazethapyr has been identified to control up to 80% of the volunteer corn when the corn is still in early growth stages (Bernards et al., 2010). The ACCase inhibiting herbicides are to be applied prior to the corn reaching the 12 to 24 inch tall stage and the ALS herbicides are effective in controlling smaller (2 to 8 inch) corn (Minnesota, 2009; Monsanto, 2010).

GE corn varieties, such as 1507, 59122, and the 1507 x 59122 Maize are currently cultivated in the United States. These GE corn varieties, like any other non-GE or GE corn variety, possess the potential to become volunteers. These GE corn varieties, like conventional corn varieties, may be controlled by mechanical cultivation as well as readily available herbicides or other graminicides (Wozniak, 2002). As discussed in Subsection 2.4.2.2 – Corn as a Weed or Volunteer, herbicides recommended for control of volunteer corn in soybeans and canola are the ACCase inhibitors and certain ALS inhibitors (Gunsolus and Porter, 2011; Gunsolus and Stachler, 2010; Hager, 2009). The ACCase inhibitors include two families of herbicides, the AOPP ACCases (e.g., the “fops,” such as Quizalofop, fenoxaprop, and diclofop) and the cyclohexanediones (e.g., the “dims,” such as clethodim and sethoxydim) (Hager, 2009). Additionally, specific herbicide strategies to control corn volunteers in rotation with various crops are developed in consultation with local agronomists. For example, Gunsolus and Stachler (2004, Updated 2010) provide an overview of the various herbicide strategies recommended in North Dakota to control weeds in glyphosate-tolerant corn cultivated in rotation with a wide range of crops, including corn, soybean, sugar beet, wheat, potato and dry bean. Under the No Action Alternative, these currently-available herbicides and strategies may control volunteer corn, such as volunteer corn derived from 1507, 59122, and 1507 x 59122 Maize.

4.4.2.2 Preferred Alternative: Plants

The potential impacts to plant communities from a determination of nonregulated status of Pioneer 4114 Maize relates to both the potential impacts of the cultivation of Pioneer 4114 Maize on other plant communities and the potential for this corn variety to become a weed or volunteer, thus interfering with other crop cultivation. These are addressed separately in the following subsections.

<u>Surrounding Landscapes and Other Vegetation in Cornfields</u>

Under the Preferred Alternative, a determination of nonregulated status of Pioneer 4114 Maize is not anticipated to substantially impact vegetation surrounding a cornfield. As discussed in Subsection 4.2 – Agricultural Production of Corn, Pioneer 4114 Maize does not require different agricultural management strategies as commercially-available corn varieties, like 1507 x 59122 Maize, and is not expected to substantially affect the surrounding vegetation relative to the No Action Alternative.

As noted in the No Action Alternative, the US-EPA has established label use restrictions to control runoff and spray drift during/following the application of glufosinate, including the application of glufosinate on 1507, 59122, and 1507 x 59122 Maize (see, e.g., Bayer, 2012). There are no changes to the application rates or label required to cultivate Pioneer 4114 Maize (Pioneer, 2011b). Accordingly, the potential impacts to non-target plants associated with off-site herbicide movement under the Preferred Alternative are the same as the No Action Alternative.

The total volume of glufosinate used on corn has remained relatively steady in recent years, with 2% to 6% of the total corn acreage treated with glufosinate between 2001 and 2011 (Pioneer, 2012). To the extent that growers may cultivate Pioneer 4114 Maize in lieu of currently-available corn hybrids with identical traits (i.e. glufosinate-tolerance and insect-resistance), such as 1507 x 59122 Maize, the total volume of is not expected to change. There are no differences in this aspect under the Preferred Alternative compared to the No Action Alternative with respect to plant communities surrounding a corn field.

The cultivation of Pioneer 4114 Maize is not expected to change weed management strategies already conducted by growers cultivating 1507, 59122, and 1507 x 59122 Maize. These practices are consistent with those currently employed under the No Action Alternative to control weeds found within cornfields as well as those practices undertaken to protect plants located outside of the cornfield. Based on these findings, the potential impacts from a determination of nonregulated status of Pioneer 4114 Maize to vegetation surrounding cornfields are not expected to differ from the No Action Alternative.

Corn as a Weed or Volunteer

Agronomic studies conducted by Pioneer compared the weediness potential of Pioneer 4114 Maize with conventional corn (Pioneer, 2011b; USDA-APHIS, 2012c). No differences were detected between Pioneer 4114 Maize and conventional corn in dormancy, germination, growth, reproduction, or interactions with pests and diseases. Similarly, none of the characteristics of Pioneer 4114 Maize confer any additional advantage as a volunteer from GE corn varieties, such as 1507 x 59122 Maize that are already commercially cultivated.

Accordingly, Pioneer 4114 Maize is not expected to be any weedier or to exhibit different volunteer traits than those described in the No Action Alternative. To the extent that Pioneer 4114 Maize does become a volunteer in other corn or rotation crops, the management controls for this variety are expected to be similar to those currently used for control of 1507 x 59122 Maize volunteers as discussed in the No Action Alternative.

The well-established and broadly used agricultural protocols to control volunteer corn associated with Pioneer 4114 Maize are consistent with the practices currently employed under the No Action Alternative. Accordingly, the strategies to control potential volunteer 1507, 59122, and

1507 x 59122 Maize are anticipated to be equally applicable to Pioneer 4114 Maize under the Preferred Alternative.

Based on these findings, there are no anticipated differences in potential impacts between the No Action and the Preferred Alternative for plant communities.

4.4.3 Soil Microorganisms

In the cultivation of corn, potential impacts to soil microorganisms can arise from the agronomic practices in cultivating corn and from exposure to the introduced gene, protein, and composition of the corn variety if it is GE.

4.4.3.1 No Action Alternative: Soil Microorganisms

Under the No Action Alternative, Pioneer 4114 Maize remains a regulated article. As discussed in Subsection 4.2.2 – Agronomic Practices, corn cultivation practices are expected to remain as currently practiced. Growers will continue to have access to existing GE corn varieties (both lepidopteran-resistant and herbicide-tolerant) as well as conventional corn varieties. Corn varieties based on 1507, 59122, and 1507 x 59122, the foundation for Pioneer 4114 Maize, will still be available to growers. Growers will continue to manage their crops, including implementing numerous management strategies to control pests and weeds. As discussed in Subsection 4.2.2 – Agronomic Practices, these current practices include the use of glufosinate for the control of certain weeds in the LibertyLink® varieties. Under the No Action Alternative, soil microorganisms will continue being exposed to GE corn varieties, their introduced proteins, and the agronomic practices currently used to cultivate these GE corn varieties.

The 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).

Although Bt occurs naturally in soil, growth of Bt corn may cause a large increase in the amount of Cry endotoxin present in agricultural systems (Blackwood and Buyer, 2004). Many studies have assessed the potential effects of Bt proteins on microbial biomass, community structure, community function, and enzymatic processes. There is little evidence that soil microorganisms or soil ecosystem level processes are negatively impacted by Bt proteins in soil or by the cultivation of GE crops (Icoz and Stotzky, 2008). Because of concerns of the potential impacts of cultivating GE crops with Bt proteins on soil communities, the decomposition rates of GE crops with Bt proteins versus non-GE crops have been studied (Icoz and Stotzky, 2008). One study specifically characterized the potential effects of cultivating Cry1F- and Cry1Ab-expressing corn on microorganism community structure (assessed by shifts in phospholipid fatty acid profiles) or function (assessed through carbon substrate utilization profiles) in three different soil types (Blackwood and Buyer, 2004). Results from this study demonstrated that, under laboratory conditions, the structure and function of microorganism communities were not affected by Cry1F or Cry1Ab proteins. This is in contrast to some other studies examining the effect of Cry proteins on soil microorganisms (US-EPA, 2010a, 2010b). However, as noted in Subsection 4.3.1.1 – No

Action: Agronomic Practices, the US-EPA notes that many of the early experiments evaluating Cry persistence in soil were based on bulk soil, rather than soils representing field conditions (US-EPA, 2010a, 2010b). These bulk soil experiments did not represent realistic field conditions, including degradation pathways in soil (US-EPA, 2010a, 2010b). The US-EPA expects that degradation rates under field conditions may be higher than bulk soil experiments would suggest (US-EPA, 2010a, 2010b). Additionally, although the US-EPA found that the Cry proteins showed little degradation in soils with low pH (pH 5), the US-EPA also noted that corn does not grow well below pH 5.6; therefore, under most production conditions, corn would not be grown on soils that would inhibit the rate of degradation (US-EPA, 2010a, 2010b).

Similarly, the Cry proteins in currently-cultivated Bt corn varieties, including 1507, 59122, and 1507 x 59122 Maize, have been examined, and were found to not have any substantial impacts on soil microorganisms (US-EPA, 2010a, 2010b; USDA-APHIS, 2001, 2005). No short-term or long-term impacts to soil invertebrate populations exposed to Bt proteins have been identified as a result of the wide-scale cultivation of Bt crops (Sanvido et al., 2007).

Corn tissue degradation has been studied as a measure of potential impacts of Bt exudates on soil microorganism function. In one laboratory study, Bt corn tissue took longer to decompose than non-Bt corn tissues (Flores et al., 2005); however, other laboratory based studies have demonstrated that there is no difference between Bt and non-Bt corn decomposition rates (Hopkins and Gregorich, 2003). Studies conducted under field conditions show the decomposition rates of Bt cotton and Bt corn did not differ from the decomposition rates of non-Bt cotton and corn (Lachnicht et al., 2004; Tarkalson et al., 2007).

Under the No Action Alternative, soil microorganisms are already exposed to the PAT protein contained in GE corn varieties no longer subject to the regulatory requirements of 340 Part 7 or the provisions of the Plant Protection Act of 2000. The PAT protein was evaluated in 1507 and 59122 Maize and is not expected to have any substantial impact on non-target organisms, including soil microorganisms (CERA, 2011; Hérouet et al., 2005; OECD, 1999; USDA-APHIS, 2001, 2005).

Under the No Action Alternative, microorganisms will continue to be exposed to glufosinate in U.S. cornfields. As discussed in Subsection 4.2.2 – Agronomic Practices, glufosinate is one of many herbicides applied on U.S. corn acres. Soil microbes rapidly degrade glufosinate to CO_2 and natural phosphorus compounds (US-EPA, 2008b). Glufosinate applications may impact soil microbe communities, although the reported research yields differing results (see, e.g., Gyamfi et al., 2002; Lupwayi et al., 2004; Wibawa et al., 2010). For example, Gyamfi et al (2002) suggest that some of these microbial population shifts may be caused by the increase of herbicide-degrading microbes following application; whereas, other research suggests that glufosinate inhibits the activity of cultivar pathogens such as bacterial blight (Pline, 1999) and grapevine downy mildew (*Plasmopara viticola*) (Kortekamp, 2010).

4.4.3.2 Preferred Alternative: Soil Microorganisms

Under the Preferred Alternative, soil microorganisms are unlikely to be substantially affected by a determination of nonregulated status of Pioneer 4114 Maize compared to the No Action

Alternative. As discussed in Subsection 4.1 – Scope of the Environmental Analysis, Pioneer 4114 Maize is functionally equivalent to 1507 x 59122 Maize. Accordingly, soil microorganisms are already exposed to the cultivation practices and introduced proteins in Pioneer 4114 Maize.

As discussed in Subsection 4.2.2 – Agronomic Practices, a determination of nonregulated status of Pioneer 4114 Maize is not expected to result in changes in corn agronomic practices. An example of this are the agronomic inputs associated with the cultivation of Pioneer 4114 Maize. Growers have the option to include glufosinate in their weed control strategies if they adopt Pioneer 4114 Maize. However, this change in weed management strategy is no different than that under the No Action Alternative, as corn varieties containing the same herbicide-tolerant and insect-resistant proteins as Pioneer 4114 Maize are already on the market (e.g., 1507, 59122, and 1507 x 59122 Maize). This means that soil microorganisms are already exposed to glufosinate and the Cry proteins in Pioneer 4114 Maize.

Soil microorganisms rapidly degrade glufosinate to CO_2 and natural phosphorous compounds (US-EPA, 2008b). USDA-APHIS does not anticipate that the use of glufosinate on Pioneer 4114 Maize will have an adverse impact on soil microorganisms. Accordingly, soil microorganisms will continue to experience typical corn agronomic practices and is not expected to be substantially impacted by agronomic practices used to cultivate Pioneer 4114 Maize.

The insect-resistant and herbicide-tolerant events contained by Pioneer 4114 Maize have been available commercially since 2006 with the development of the 1507 x 59122 variety (Pioneer, 2012). As noted in Table 4-1, a number of commercial hybrids based on this variety are currently available. Soil microorganisms are already exposed to the Cry and PAT proteins from exudates as well as decomposing plant matter. Consequently, a determination of nonregulated status of Pioneer 4114 Maize is not expected to substantially change soil microorganism exposure currently experienced under the No Action Alternative. Additionally, because soil organisms are already being exposed to the introduced proteins in Pioneer 4114 Maize, no impacts to microorganisms are anticipated from a determination of nonregulated status of Pioneer 4114 Maize.

Based on these factors, USDA-APHIS does not anticipate substantial impacts to soil microorganisms under the Preferred Alternative. As the herbicide glufosinate is registered currently for use on corn, and the traits expressed by Pioneer 4114 Maize are already commercially available, substantial differences between the No Action Alternative and the Preferred Alternative with regard to soil microorganisms are unlikely.

4.4.4 Biological Diversity

4.4.4.1 No Action: Biological Diversity

As discussed in Subsection 2.4.4 – Biological Diversity, currently commercialized GE crops have reduced the impacts of agriculture on biodiversity through current use of conservation tillage practices, reduction of insecticide use, the use of more environmentally benign herbicides, and increasing yields to alleviate pressure to convert additional land into agricultural use (Carpenter, 2011; Jasinski et al., 2003; Young and Ritz, 2000). For GE crops, like corn, insecticide applications are substantially reduced with the cultivation of Bt varieties, which has been shown to contribute to natural enemy conservation, a substantial part of biodiversity in corn cultivation (see, e.g., Romeis et al., 2006).

Under the No Action Alternative, Pioneer 4114 Maize will continue to be a regulated article. Growers and other parties who are involved in production, handling, processing, or consumption of corn would continue to have access to existing nonregulated herbicide-tolerant corn varieties, pest-resistant varieties, stacked varieties presenting both, and conventional corn varieties. These currently available varieties include 1507, 59122, and 1507 x 59122 Maize, which contains all of the traits of Pioneer 4114 Maize. The consequences of current agronomic practices associated with corn production, both traditional and GE varieties, on the biodiversity of plant and animal communities would likely not be altered.

Cultivation of GE crops engineered to accumulate insecticidal proteins or tolerate herbicide application for weed management (including 1507, 59122, and 1507 x 59122 hybrid varieties already in cultivation) may influence local biodiversity, although distinguishing direct and indirect impacts of agronomic practices is difficult (see, e.g., Marshall et al., 2002; Ponsard et al., 2002). For example, some studies have shown Bt proteins in GE crop exudates do not persist, but may degrade differently in different soil types (Carpenter, 2011). The difference in degradation appears to be primarily the result of differences in soil microbe activity, which in turn is dependent on soil type, season, crop species, crop management practices, and other environmental factors that vary with location and climate zones (Carpenter, 2011). These site-specific differences make it difficult to clearly demonstrate impacts to soil biodiversity across entire crop systems. In another example, reductions of biological control organisms are seen in some Bt crops, but are caused by reduction of the pest host population following transgenic pesticide expression in the GE crop plant (Naranjo, 2009). , as discussed in Subsections 4.4.1 – Animal Communities, 4.4.2 Plant Otherwise Communities, and 4.4.3 Soil Microorganisms, there is no evidence that exposure to the Cry and PAT proteins in currently cultivated crops impacts animals, plants or soil microorganisms;   biodiversity of an agricultural setting is constituted by the presence of these organisms.

Adoption of Bt crops has been associated with a reduction in the application of insecticides to control various insect pests (Brookes and Barfoot, 2012; Brookes et al., 2012; Carpenter, 2011) . Such a reduction in insecticide applications would bring a corresponding positive impact to biodiversity (Carpenter, 2011).

Although herbicide use potentially affects biodiversity, the application of pesticides in accordance with US-EPA registered label uses and careful management of chemical spray drift minimizes the potential biodiversity impacts from their use. The US-EPA has considered this in its registration and has established label use restrictions to minimize glufosinate drift (see Bayer, 2012). Glufosinate is deemed non-toxic to birds, mammals, and insects; slightly non-toxic to freshwater fish; moderately toxic to estuarine/marine fish; moderately toxic to freshwater and estuarine/marine invertebrates; and toxic to terrestrial and aquatic plants (US-EPA, 2008b). Glufosinate is already used in corn, including corn based on the 1507, 59122 and the 12507 x 59122 hybrid.

4.4.4.2 Preferred Alternative: Biological Diversity

Pioneer has presented results of agronomic field trials comparing Pioneer 4114 Maize conventional corn. The results suggest that there are no meaningful differences in agronomic attributes between Pioneer 4114 Maize and conventional corn (Pioneer, 2011b, 2012). Therefore, a determination of nonregulated status of Pioneer 4114 Maize is not expected to change agronomic practices. As noted in the introduction to this section, the commercial hybrid 1507 x 59122 Maize, the foundation for Pioneer 4114 Maize traits has been cultivated commercially for many years with no reports of impacts to animal or plant communities.

As discussed above in Subsection 4.2 – Agricultural Production of Corn, Subsection 4.4.1 – Animal Communities, and Subsection 4.4.2 – Plant Communities, a determination of nonregulated status of Pioneer 4114 Maize will continue the use of glufosinate in U.S. corn. Glufosinate is already labeled for use in corn, and may be applied to any of the Liberty® corn varieties. A change in label is not required to apply glufosinate to Pioneer 4114 Maize (Pioneer, 2011b). Increases in glufosinate use are unlikely, as Pioneer 4114 Maize is anticipated to replace some 1507 x 59122 Maize plants that are already cultivated as part of weed management strategy incorporating glufosinate.

Animals, plants, and microorganisms exposure to the Cry and PAT proteins in Pioneer 4114 Maize will be no different than exposure occurring under the No Action Alternative associated with cultivation of 1507, 59122 and the 1507 x 59122 Maize. Similarly, animals, plants and microorganisms associated with these fields are already exposed to glufosinate. As noted in Subsection 4.2 2 – Agricultural Production of Corn, Pioneer does not seek a change in the application or use of glufosinate for the cultivation of Pioneer 4114 Maize (Pioneer, 2011b).

Based on these findings, the potential impacts to biodiversity of plant and animal communities from the determination of nonregulated status of Pioneer 4114 Maize are similar to those from current conditions under the No Action Alternative.

4.4.5 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).

4.4.5.1 Vertical Gene Flow – Movement to Other Varieties and Corn Relatives

<u>No Action – Vertical Gene Flow</u>

Under the No Action Alternative, conventional and GE transgenic corn production will continue, including the current cultivation of 1507 59122 and 1507 x 59122 Maize. The possibility of gene movement from cultivated corn varieties into native or feral populations of *Zea* species or wild or weedy relatives of corn has been evaluated by the US-EPA and determined not to be a concern in the continental United States (US-EPA, 2010e). Vertical gene flow from currently cultivated corn varieties in the United States, including 1507, 59122, and 1507 x 59122 Maize varieties, to U.S. populations of *Zea* or *Tripsacum* species 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, make the occurrence of natural crosses in the U.S. very minor (Baltazar et al., 2005; Doebley, 1990, Doebley, 1990 #539; Ellstrand et al., 2007b; Galinat, 1988; Kermicle and Evans, 2005). If hybridization were to occur, the resulting hybrids are often sterile or have greatly reduced fertility, the hybrids are less fit, do not disseminate seed, have a reduced reproductive capacity, and none can withstand even the mildest winters (OECD, 2003; USDA-APHIS, 2012c). Additionally, hybridization between corn and *Tripsacum* is not likely in the absence of specialized hybridization techniques in controlled conditions, strongly suggesting that hybridization is unlikely in typical field conditions (Galinat, 1988; Mangelsdorf, 1974; Russell and Hallauer, 1980). Consequently, gene flow between current commercially available corn cultivars and its relatives both GE and non-GE (including those *Tripsacum* species listed in Subsection 2.4.5 – Gene Movement) is unlikely under the No Action Alternative.

Gene movement between sexually compatible corn varieties and related species is no greater for currently cultivated GE varieties, including 1507, 59122, and the 1507 x 59122 Maize than it is for other non-GE or GE cultivars (USDA-APHIS, 2012c). Many factors limit the likelihood of gene movement between corn varieties, including those noted below.

- The *pat* gene does not impart an agronomic advantage whereby a greater potential for weediness or invasiveness would result should introgression occur.

- Neither GE nor non-GE corn cultivars form self-sustaining populations outside of cultivation because of limitations in seed dispersal, germination, and seasonal requirements (US-EPA, 2010e).

- Spatial and temporal isolation can be one of the most effective barriers to gene exchange between com 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). The corn industry has 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 (see also, AOSCA, 2010).

The reproductive morphology of corn encourages cross-pollination between corn plants and there is no evidence (genetic or biological barriers) to indicate that gene flow is inherently restricted between GE and non-GE corn. Gene flow between corn varieties is most likely to occur during cultivation as well as the handling and processing of corn (Coulter et al., 2010; Mallory-Smith and Sanchez-Olguin, 2011; Thomison, 2009). Corn is a cross-pollinating crop in which most pollination results from pollen dispersed by wind and gravity (Thomison, 2009). Factors controlling pollen-mediated gene flow include the outcrossing rate of recipients, pollen loads of donors, pollen competition between donors and recipients, and local weather/climate conditions (e.g., wind, precipitation) (Lu, 2008). As discussed above in Subsection 4.2.3 – Organic Corn Farming and Specialty Corn Systems, growers concerned about cross pollination can incorporate standard management methods to control pollen drift in order to manage this form of gene flow.

Gene flow through handling and processing is problematic if product handling facilities where corn is dried, cleaned, and stored do not maintain adequate separation between varieties (Mallory-Smith and Sanchez-Olguin, 2011). Such admixtures at these facilities have been reported for varieties of GE corn and conventional corn (Mallory-Smith and Sanchez-Olguin, 2011). This form of gene flow occurs irrespective of the variety of corn being cultivated, and is not a new concern associated with the determination of nonregulated status of this variety. As discussed above in Subsection 4.2.3 – Organic Corn Farming and Specialty Corn Production, procedures for managing identity of specific varieties are already in place to minimize gene flow challenges arising from admixtures during handling.

Vertical Gene Flow – Preferred Alternative

As discussed in Subsection 4.2 – Agricultural Production of Corn, cultivation practices for Pioneer 4114 Maize are no different from those corn varieties currently cultivated under the No Action Alternative. These corn varieties include 1507, 59122, and 1507 x 59122 Maize. Pioneer has compared the morphology of Pioneer 4114 Maize with other corn varieties, including 1507 and 1507 x 59122 Maize, and has identified no biologically meaningful differences in reproductive biology (Pioneer, 2011b, 2012; USDA-APHIS, 2012c). Accordingly, as compared to the No Action Alternative, there are no new management practices or reproductive characteristics that would affect the barriers to gene flow in corn. The management practices to mitigate vertical gene flow described in the No Action Alternative would be the same as those required under the Preferred Alternative. However, as discussed in Subsection 4.4.2 – Plant Communities, in the unlikely event that the *pat* gene from Pioneer 4114 Maize should pass to progeny through cross pollination, and the PAT herbicide tolerance protein is expressed in that cross-pollinated hybrid, and that hybrid becomes a volunteer, that volunteer could still be controlled by other readily available herbicides.

Based on these findings, there are no substantial differences in Vertical Gene flow between the No Action Alternative and the Preferred Alternative following a determination of nonregulated status of Pioneer 4114 Maize.

4.4.5.2 Horizontal Gene Transfer – Movement to Unrelated Species

Horizontal Gene Transfer – No Action Alternative

As discussed in Subsection 2.4.5 – Gene Movement, there is no evidence of naturally occurring transgene movement from transgenic crops to sexually incompatible species (USDA-APHIS, 2012c). Horizontal gene transfer and consequent expression of DNA from one plant to another plant or other phyla (e.g., species of bacteria) are both unlikely to occur (Keese, 2008). This event would require physical relocation of the complete genetic material from the transgenic plant to the new location, including not only the genes which code for the production of specific proteins, but also those portions of the genome which regulate the activity of those genes (Keese, 2008). There are no known naturally occurring vectors (such as plasmids, phages, or transposable elements) that could be responsible for inter-domain gene transfer, and there is little evidence that eukaryotic cells are naturally capable of stably incorporating genes from the environment into their genome (Brown, 2003). Although viruses do move genetic material, all viruses that infect higher plants have small ribonucleic acid (RNA) or DNA genomes, usually with fewer than 20 encoded proteins (Keese, 2008). These viruses are therefore constrained as to the type and size of novel genetic material which can be acquired by horizontal gene transfer (Keese, 2008).

Two soil bacteria species commonly associated with plants, *Agrobacterium* and *Rhizobium*, have been evaluated to determine the probability of horizontal gene transfer between the bacterium and its host plants. *Agrobacterium* moves its genes from its bacterial plasmid to the plant, causing the plant to produce crown gall (abnormal outgrowth) (University of Illinois, 2010). *Rhizobium* aids in nitrogen fixation in legume nodules (Wilkinson and Elevitch, 2011). The genomes of both bacteria have been sequenced, and the sequenced genes evaluated for exogenous genes (Kaneko et al., 2000; Kaneko et al., 2002; Wood et al., 2001). Despite what would appear to be millennia of symbiotic relationships between these bacteria and their host plants, there is no evidence that these organisms contain genes derived from plants; in cases where review of sequence data implied that horizontal gene transfer occurred, these events are inferred to occur on an evolutionary time scale in the order of millions of years (Brown, 2003; Koonin et al., 2001). Transgene DNA promoters and coding sequences are optimized for plant expression, not bacterial expression. Horizontal gene transfer, resulting in the relocation of entire transgenes including the regulatory portions of the DNA (those parts of the DNA which code for the production of the specific proteins in that relocated transgene) never has been shown to occur in nature (Clarke, 2007; Stewart, 2008). Thus, even if horizontal gene transfer occurred, proteins associated with these transgenes are not likely to be produced in the new host organism.

Horizontal gene transfer may also occur within organisms of the same Kingdom. Horizontal gene transfer has been implicated in the incorporation of a specific genetic sequence in the parasitic plant purple witchweed (*Striga hermonthica*), which infests cereal fields including corn and sorghum (*Sorghum bicolor*) (Yoshida et al., 2010). Yoshida concluded that the incorporation of the specific genetic sequence (with an unknown function) occurred between sorghum and purple witchweed before speciation of purple witchweed (*S. hermonthica*) and related cowpea witchweed (*S. gesnerioides*), a parasitic plant of dicots, from their common ancestor. In other words, horizontal gene transfer between a parasitic plant and its host is an extremely rare event and like potential horizontal gene transfer events between plants and bacteria, normally occurs over very large time scales. Furthermore, *S. hermonthica* is not found in the United States and *S. asiatica* (another related parasite of cereal crops) is only present in North Carolina and South Carolina (USDA-NRCS, 2011b). The *Striga* that occurs in the United States is listed as a Federal noxious weed, and is restricted in its distribution - largely due to an USDA-APHIS containment, quarantine, and eradication program (Nickrent and Musselman, 2004, Updated 2010 available at http://www.apsnet.org/edcenter/intropp/pathogengroups/pages/parasiticplants.aspx).

Horizontal Gene Transfer – Preferred Alternative

Pioneer has evaluated the morphological and compositional characteristics of Pioneer 4114 Maize with the 1507 and 1507 x 59122 Maize, and has determined that any differences are not biologically meaningful (Pioneer, 2011b, 2012; USDA-APHIS, 2012c). The characteristics of Pioneer 4114 Maize are functionally identical to corn varieties already cultivated, including 1507 x 59122 Maize. Under the Preferred Alternative, there are no changes in Pioneer 4114 Maize that would impact the barriers to horizontal gene transfer compared to the No Action Alternative.

Based on the findings noted in the No Action Alternative, USDA-APHIS considers the horizontal gene transfer from Pioneer 4114 Maize to unrelated species to be unlikely under the Preferred Alternative, and the same as potential horizontal gene transfer from existing GE and non-GE corn varieties.

4.5 PUBLIC HEATH

4.5.1 Human Health

The assessment of potential human health effects from GE crops considers two aspects of the crop: the introduction of an herbicide when the crop contains an herbicide-tolerant trait, and potential changes in crop composition associated with newly introduced proteins. This subsection provides a summary of this analysis, with discussion of farm worker safety in Subsection 4.5.2.

As noted in Subsection 4.1 – Scope of the Environmental Analysis, the introduced proteins in Pioneer 4114 Maize, notably Cry1F, Cry34Ab1, Cry35Ab1, and PAT, have been previously reviewed, and corn varieties containing these events are already widely cultivated. Moreover, there are several previous assessments of the indirect effects associated with the exposure to glufosinate. Humans are already likely exposed to the agronomic practices related to Pioneer 4114 Maize and the introduced proteins in Pioneer 4114 Maize. Accordingly, to facilitate the review of this section, and to reduce redundancy, these impacts are discussed in the context of the No Action Alternative.

4.5.1.1 No Action: Human Health

Under the No Action Alternative, Pioneer 4114 Maize would remain a regulated article and would not be widely cultivated in the United States. However, human exposure to the agronomic practices associated with Pioneer 4114 Maize and its introduced proteins would not change. Growers already cultivate GE maize varieties that contain the Cry1F, Cry34Ab1, Cry35Ab1 and PAT proteins (e.g., 1507, 59122, and 1507 x 59122 Maize varieties), meaning that humans will continue to be exposed to those proteins. The Cry1F protein and its associated genetic elements were introduced with 1507 Maize, which had a determination of nonregulated status by USDA, registered by the EPA, and reviewed by the US-FDA in 2001 (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2001; USDA-APHIS, 2001). The binary Cry proteins, Cry34Ab1 and Cry35Ab1, and their associated genetic elements were introduced in 59122 Maize, which was reviewed by US-FDA in 2004, had a determination of nonregulated status by USDA in 2005, and registered by

US-EPA since 2005 (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2004; USDA-APHIS, 2005). Maize expressing the PAT protein has had a nonregulated status since 1995 and commercially cultivated in the United States since 1996 (USDA-APHIS, 1995).

Maize varieties based on 1507, 59122, and 1507 x 59122 Maize are anticipated to still be cultivated. As noted previously in Subsection 4.2.2 – Agronomic Practices, in 2010, approximately 16% of the commercial corn acreage was planted with a 1507 x 59122 Maize (Pioneer, 2011b). With regard to glufosinate use on corn, in 2010, approximately 2% of the total corn acreage was treated with glufosinate (USDA-NASS, 2011a). Consumers would continue to be exposed to glufosinate and its residues on those corn acres treated with that herbicide, and consumers also will be exposed to the same Cry proteins incorporated within the Pioneer 4114 Maize.

USDA-APHIS' evaluation of potential human health effects considers potential impacts associated with incidental exposure to the pesticides applied to the GE crop and an analysis of the crop composition associated with the GE agricultural crop. USDA-APHIS considers the US-EPA and the US-FDA regulatory assessments when evaluating these aspects of potential impacts to human health.

Glufosinate Use and Exposure

USDA-APHIS considers the US-EPA's registration of pesticides when evaluating the potential consequences arising from a determination of nonregulated status of a GE crop. The US-EPA considers human health effects from the use of pesticides when it evaluates the registration of pesticides. Prior to pesticide registration, including the new use of a previously-registered pesticide, US-EPA must determine that the pesticide will not cause unreasonable adverse effects on human health (and the environment, and non-target species). Frequently, the US-EPA will establish label restrictions to mitigate or alleviate any potential impact on human health and the environment. Once registered, a pesticide may not legally be used unless the use is consistent with the guidelines and application restrictions and precautions on the pesticide's label. The pesticide registration label is intended to provide appropriate use instructions so as to protect human health. US-EPA uses the standard of "no unreasonable adverse effects" in making its registration determinations. FIFRA defines this term as follows—

> UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT — The term ''unreasonable adverse effects on the environment'' means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) …(See; FIFRA, Section 2(bb), 7 U.S.C. §136(bb))

EPA's core pesticide risk assessment and regulatory processes ensure that protections are in place for all populations of non-target species potentially exposed to pesticides, including humans. This risk assessment included acute, short-term and chronic aggregate risk assessments as well as occupational and residential exposure risk assessments. The US-EPA is currently collecting and reviewing data supporting a reevaluation of the “acute and/or chronic dietary analysis” as part of its registration review of glufosinate (US-EPA, 2008a).

These assessments provide US-EPA with information needed to develop label use restrictions for the pesticide. Growers are required to use pesticides such as glufosinate ammonium consistent with the application instructions provided on the US-EPA-approved pesticide label (Bayer, 2012). These label restrictions carry the weight of law and are enforced by US-EPA and the states (FIFRA 7 USC 136j (a)(2)(G) Unlawful Acts).

As discussed in Subsection 2.2.2.3 – Agronomic Inputs, the use of glufosinate on total corn acres has remained stable and low over the past decade, with between 2% and 6% of the total U.S. corn acreage treated with glufosinate (Pioneer, 2011b). This includes application of glufosinate on GE maize varieties already containing the glufosinate-tolerant trait, such as 1507 x 59122 Maize. Additionally, as noted above, corn expressing the PAT protein and tolerant to glufosinate has been commercially available since 1996. The application of glufosinate to corn is not a new practice. Under the No Action Alternative, the application of glufosinate to corn acreage is expected to follow U.S. corn growers’ adoption of glufosinate-tolerant corn varieties, such as 1507, 59122, or 1507 x 59122 Maize.

As glufosinate is currently applied to some U.S. corn acreage, glufosinate residue may occur on some U.S. corn grains. As noted in Subsection 1.3 – Coordinated Framework Review and Regulatory Review, before allowing the use of a pesticide on food crops, the US-EPA sets a tolerance, or maximum residue limit, for the amount of pesticide residue allowed to remain on or in each treated food commodity (US-EPA, 2012f). US-EPA is required to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA. To make this finding, US-EPA considers the toxicity of the pesticide and its breakdown products, how much pesticide is applied and the frequency of application, and how much pesticide remains on the food by the time it is marketed and prepared (US-EPA, 2012f). The US-EPA has established exemptions for tolerance for glufosinate (US-EPA, 2010d). The US-EPA’s tolerance exemptions for glufosinate in corn are 6.0 parts per million (ppm) for corn stover, 4.0 ppm for corn forage, and 0.20 ppm for corn grain (US-EPA, 2010d). The establishment of these glufosinate tolerances by the US-EPA ensure safety of foods treated with glufosinate and are made following risk assessments that reflect real-world consumer exposure as closely as possible (US-EPA, 2012e).

Additionally, the processing of corn-based food products, including those derived from corn varieties treated with glufosinate, has been demonstrated to reduce pesticide residues below the level of detection, reducing the exposure levels to the general U.S. population (CRA, 2000). In 1998, the USDA evaluated pesticide residues in high-fructose corn syrup, milk, vegetables, and fruits (USDA-AMS, 1998). Corn syrup samples were collected from 40 states and analyzed for 109 pesticides; no pesticide residues were detected in any of the corn syrup samples (USDA-AMS, 1998).

Composition of Maize: Introduced Proteins

Human exposure to Cry1F, Cry34Ab1, Cry35Ab1, and PAT proteins has been reviewed by the USDA, the US-EPA and the US-FDA in the regulatory assessments, as cited in Subsection 4.1 – Scope of the Environmental Analysis. These event traits have been commercially cultivated for many years in 1507, 59122, and 1507 x 59122 Maize.

As discussed in Subsections 1.3 – Coordinated Framework Review and Regulatory Review and 2.5 Public Health, the US-EPA's role in review of GE crops includes review of any introduced Cry proteins as PIPs under their FIFRA authority, and exemptions from tolerance for residues of pesticides on and in food and animal feed under its FFDCA authority. The Cry1F protein and its associated genetic elements had a determination of nonregulated status by USDA, was registered by the EPA, and was reviewed by the US-FDA in 2001 (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2001; USDA-APHIS, 2001). The binary Cry proteins, Cry34Ab1 and Cry35Ab1, and their associated genetic elements was reviewed by US-FDA in 2004, had a determination of nonregulated status by USDA in 2005, and was registered by US-EPA in 2005 (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2004; USDA-APHIS, 2005). Maize expressing the PAT protein has had a nonregulated status since 1995 and commercially cultivated in the United States since 1996 (USDA-APHIS, 1995). The US-EPA has published exemptions from tolerance[26] for these proteins (US-EPA, 2007a). There are no reports of human health effects associated with exposure to Bt or PAT proteins, or the 1507, 59122 or 1507 x 59122 Maize.

The Cry1F, Cry34Ab1, and Cry35Abl proteins incorporated into 1507 and 59122 Maize were derived from Bt, a common bacterium, naturally occurring in soil, dust, insects, and leaves (McClintock et al., 1995; Schnepf et al., 1998; US-EPA, 1998). Bt is not a known human pathogen (US-EPA, 1998). Some strains of Bt have been shown to be opportunistic pathogens; however, this pathogenicity was not related to the Bt proteins (Hernandez et al., 1999). Bt microbial preparations containing Cry proteins have been used safely as pesticide sprays for decades, and have been deemed to pose no toxic effects to mammals (US-EPA, 1998; USDA-FS, 2004). These proteins have been present in commercial corn varieties such as 1507, 59122, and/or 1507 x 59122 Maize since 2003, 2006, and 2006, respectively (Pioneer, 2012). The incorporation of Bt proteins in corn has resulted in a decrease in the application of insecticides for the control of lepidopteran and coleopteran pests, an indirect benefit to human health (Brookes and Barfoot, 2010).

The PAT protein incorporated into 1507 and 59122 Maize is derived from *S. viridochromogenes*, a common soil bacterium (Pioneer, 2012). The PAT protein has a safe history of exposure in

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[26] As discussed in Subsection 1.3, the US-EPA, pursuant to its authority under the FFDCA, sets tolerances for the maximum residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement of tolerance, to reach a safety determination based on a finding of reasonable certainty of no harm from the potential exposure. To establish tolerance values, the US-EPA considers the toxicity of the pesticide and its breakdown products, the frequency of pesticide application and volume applied, and the amount of residue remaining in or on the food at the time it is marketed and prepared. Some pesticides are exempted from tolerance where the exemption is found to be safe. For additional details, see http://www.epa.gov/pesticides/factsheets/stprf.htm.

humans, animals, and the environment. *S. viridochromogenes* is widespread in soil and is not associated with human, animal, or plant pathogens (Hérouet et al., 2005). Related PAT proteins are found in at least six other species of common soil bacteria, none of which have been reported as toxic or allergenic to humans or animals (Hérouet et al., 2005). As noted in Subsection 2.2 – Agricultural Production of Corn, the PAT protein has been present in commercial corn, as well as other crops, since 1996.

Cry1F, Cry34Ab1, Cry35Ab1, and PAT proteins have previously been reviewed for potential allergenicity and toxicity, and have been determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and are degraded rapidly and completely in gastric fluid. (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2001, 2004; USDA-APHIS, 2001, 2005). Current human exposure to these Cry and PAT proteins has been determined to present no human health risk under the No Action Alternative.

Additionally, as discussed in Subsection 2.5 – Public Health, human food products manufactured from feed corn are subjected to a variety of mechanical and chemical processes to produce the final product, each step of which tends to disrupt protein integrity (Hammond and Jez, 2011). These processes suggest that human exposure to the Cry1F, Cry34Ab1, Cry35Ab1, and PAT proteins in corn will be limited under the No Action Alternative.

Additionally, also noted in Subsection 2.5 – Public Health, the accumulation of the Cry proteins in GE corn plants provides an additional indirect benefit to human health, in that the control of certain insect pests of corn results in a lower incidence of fungal infection and mycotoxin formation (Munkvold and Hellmich, 1999; Munkvold and Hellmich, 2000; US-EPA, 2010a, 2010b; Vincelli and Parker, 2002). These benefits already accrue from the widespread adoption of corn varieties containing these Cry proteins, including 1507 and 59122 Maize which are already in the market.

4.5.1.2 Preferred Alternative: Human Health

Under the Preferred Alternative, potential impacts to human health are not anticipated to be substantially different than under the No Action Alternative. As discussed in Subsection 4.1 – Scope of the Environmental Analysis, Pioneer 4114 Maize contains the same genetic elements as 1507, 59122, and 1507 x 59122 Maize; accordingly, Pioneer 4114 Maize is functionally equivalent to 1507 x 59122 Maize.

The human health effects of the cultivation of the Pioneer 4114 Maize are expected to be identical to those already evaluated and described for 1507, 59122, and 1507 x 59122 Maize. Public health concerns surrounding GE crops, like Pioneer 4114 Maize, are generally related to consumption of the GE crop itself. Pioneer 4114 Maize contains the Cry1F, Cry34Ab1, Cry35Ab1, and PAT proteins. Pioneer 4114 Maize also is likely to be sprayed with glufosinate if it is commercialized following a determination of nonregulated status. It is expected that glufosinate use on the Pioneer 4114 Maize would be consistent with the US-EPA-approved label.

Glufosinate Use and Exposure

As discussed in the No Action Alternative, glufosinate is already used in U.S. corn production, meaning that the general population may already be exposed to glufosinate or its residues on corn grain.

A determination of nonregulated status of Pioneer 4114 Maize is not likely to change the herbicide use patterns for glufosinate in U.S. corn production. There are no proposed label changes for glufosinate use associated with the cultivation of Pioneer 4114 Maize (Pioneer, 2011b).The per acre volume of glufosinate will not increase over currently approved label rates (Pioneer, 2011b). As discussed in Subsection 4.2.2 – Agronomic Practices, a grower adopting Pioneer 4114 Maize varieties would potentially substitute Pioneer 4114 for 1507 x 59122 Maize. Moreover, growers are highly likely to substitute glufosinate for other herbicides (Towery and Werblow, 2010). The US-EPA has determined that glufosinate does not present a human health impact when applied in accordance with label restrictions (US-EPA, 2003). As there are no changes in application rates or total applications for Pioneer 4114 Maize, pesticide residue tolerances are not expected to change.

Accordingly, a determination of nonregulated status for Pioneer 4114 Maize is not expected to substantially impact human health with respect glufosinate or its residues on corn grain, relative to the No Action Alternative.

Composition of Pioneer 4114 Maize: Expressed Proteins

The traits expressed in Pioneer 4114 Maize have been commercially cultivated for many years. The introduced Cry and PAT proteins in Pioneer 4114 Maize are identical to the Cry and PAT proteins previously reviewed by the US-EPA, US-FDA, and USDA for 1507, 59122 and 1507 x 59122 Maize varieties that are currently cultivated and presented in the No Action analysis.

The Cry1F protein and its associated genetic elements are identical to those in 1507 Maize; the binary Cry proteins, Cry34Ab1 and Cry35Ab1, and their associated genetic elements are identical to those in 59122 Maize; maize expressing the PAT protein has had a nonregulated status since 1995 and commercially cultivated in the United States since 1996 (USDA-APHIS, 1995). Pioneer has compared Pioneer 4114 with the foundation varieties, and has found no biologically meaningful differences in the accumulation of these proteins or composition of the corn plants (Pioneer, 2011b; USDA-APHIS, 2012c). Consequently, the health impacts of Pioneer 4114 Maize is unlikely to be substantially different than the health impacts of 1507, 59122, or 1507 x 59122 Maize varieties described in the No Action Alternative.

Pioneer conducted safety evaluations based on Codex Alimentarius Commission procedures to assess any potential adverse effects to humans or animals resulting from environmental releases and consumption of Pioneer 4114 Maize (FAO, 2009; Pioneer, 2011b; US-FDA, 2011). These safety studies included evaluating protein structure and function, including homology searches of the amino acid sequences with comparison to all known allergens and toxins (Pioneer, 2011b). The Cry and PAT proteins expressed in Pioneer 4114 Maize have previously been reviewed for potential allergenicity and toxicity, and have been determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and are degraded rapidly and completely in gastric fluid (Pioneer, 2011b).

Pioneer has compared the compositional characteristics of Pioneer 4114 Maize with the near isoline and reference maize hybrids (Pioneer, 2011b). 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; Pioneer, 2011b). A comprehensive comparison of Pioneer 4114 Maize with the near isoline variety showed no biologically meaningful differences for composition (Pioneer, 2011b; USDA-APHIS, 2012c).

Pioneer submitted a Voluntary Consultation to the US-FDA for this product on 22 December 2011, but as of the date of the publication of this EA, the US-FDA has not completed its review. Anticipated completion of the US-FDA consultation is late Fall 2012. As noted above, Pioneer 4114 Maize proteins have been present in commercial corn varieties such as 1507, 59122, and 1507 x 59122 Maize since 2003, 2006, and 2006, respectively (Pioneer, 2012). There are no reports of adverse effects to human health from the consumption of these corn varieties. Corn varieties based on these three lines are already in the commercial market. Additionally, the proteins in Pioneer 4114 Maize are rapidly degraded by gastric fluids, further limiting human exposure to the proteins expressed by this corn variety.

Based on these factors, including an analysis of field and laboratory data related to Pioneer 4114 Maize (Pioneer, 2011b), safety data available on other GE corn varieties, and the functional equivalence of Pioneer 4114 Maize to the currently-cultivated 1507 x 59122 maize, USDA-APHIS has concluded that a determination of nonregulated status of Pioneer 4114 Maize is unlikely to present an adverse impact on human health. Overall impacts on human health are similar to those expected for the No Action Alternative.

4.5.2 Worker Safety

EPA's 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 contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.

4.5.2.1 No Action: Worker Safety

During agricultural production of corn, agricultural workers and pesticide applicators may be exposed to a variety of US-EPA-registered pesticides. Under the No Action Alternative, agricultural workers and pesticide applicators may be exposed to the herbicide glufosinate which is labeled for use on corn. The 2003 US-EPA registration for glufosinate evaluated occupational exposures, including short-term inhalation and dermal exposure estimates (US-EPA, 2003, 2008a). In this review, the US-EPA concluded that occupational exposures were below the US-EPA's level of concern (US-EPA, 2003, 2008a).

Maize varieties based on 1507, 59122, and 1507 x 59122 Maize are anticipated to still be cultivated. As noted previously in Subsection 4.2.2 – Agronomic Practices, in 2010, approximately 16% of the commercial corn acreage was planted with a 1507 x 59122 Maize (Pioneer, 2011b). With regard to glufosinate use on corn, in 2010, approximately 2% of the total corn acreage was treated with glufosinate (USDA-NASS, 2011a). Agricultural workers would continue to be exposed to glufosinate and its residues on those corn acres treated with that herbicide.

As discussed in Subsection 4.5.1 – Human Health, US-EPA's pesticide registration labels establish use restrictions for the pesticide. Growers are required to use pesticides such as glufosinate ammonium consistent with the application instructions provided on the US-EPA-approved pesticide label (Bayer, 2012). These label restrictions carry the weight of law and are enforced by US-EPA and the states (FIFRA 7 USC 136j (a)(2)(G) Unlawful Acts).

The current label for glufosinate includes guidance and label use restrictions intended to protect agricultural workers, including protective equipment to be worn during mixing, loading, applications and handling, equipment specifications to control pesticide application, and reentry periods establishing a safe duration between pesticide application and exposure to the pesticide in the field (Bayer, 2012). Used in accordance with the label, glufosinate has been determined to not present a health risk to humans (US-EPA, 2008b). Appendix B provides a copy of a sample glufosinate label.

As discussed in Agricultural Production of Corn (Subsections 2.2 and 4.2), in 2010, 16% of the corn acreage was cultivated in 1507, 59122, or 1507 x 59122 Maize (Pioneer, 2011b). Growers cultivating these varieties are already exposed to glufosinate and the Cry and PAT proteins. In 2010, corn growers applied glufosinate to 2% of the total acreage of corn cultivated (USDA-NASS, 2011a).

4.5.2.2 Preferred Alternative: Worker Safety

Under the Preferred Alternative, no substantial impacts to worker safety are anticipated compared to the No Action Alternative. Glufosinate is currently registered for use on corn (see, e.g., Bayer, 2012), including 1507, 59122, and 1507 x 59122 Maize. Similar to the No Action Alternative, it is expected that US-EPA registered pesticides that currently are used for corn production will continue to be used by growers, including the use of glufosinate. Pioneer 4114 Maize is not expected to change the application rates of glufosinate on corn, and a label change is not required (Pioneer, 2011b). Worker exposure to glufosinate under the Preferred Alternative is not expected to be substantially different than that already experienced under the No Action Alternative, as Pioneer 4114 Maize is anticipated to be cultivated in lieu of 1507 x 59122 Maize in the United States.

Based on the above information, the potential impacts to worker safety from a determination of nonregulated status of Pioneer 4114 Maize under the Preferred Alternative are the same as those under the No Action Alternative.

4.6 ANIMAL FEED

Corn comprises approximately 95% of the total feed grain produced and used in the United States (USDA-ERS, 2011c). Animal feed derived from corn comes not only from the unprocessed grain, but also from the residuals derived from three major corn industries: corn refining, corn dry millers, and distillers (CRA, 2006). 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, 2006).

As with human health, animal consumption of GE is a concern expressed by some individuals. This includes consumption of GE corn material as feed and the consumption of any herbicide or herbicide residues that may remain on the plant material after processing for animal feed.

4.6.1 No Action: Animal Feed

Under the No Action Alternative, Pioneer 4114 Maize will remain a regulated product and will not be available as an animal feed. However, corn-based animal feed will still be available from currently cultivated corn crops, such as 1507, 59122, and 1507 x 59122 Maize. Consequently, the Cry and PAT proteins contained within 1507, 59122, and 1507 x 59122 Maize will continue to be present in U.S. corn production and thus be present in animal feed. This includes Cry1F (1507 Maize), Cry 34Ab1 and Cry35Ab1 (59122 Maize), and any hybrid containing the 1507 x 59122 cross. This means that under the No Action Alternative, the introduced proteins in Pioneer 4114 Maize may continue to be present in animal feed in the United States through the continued cultivation of 1507, 59122, and 1507 x 59122 Maize.

As discussed in Subsection 4.5 – Public Health, the US-EPA and the US-FDA have already reviewed the animal feed safety of the introduced proteins in 1507, 59122, and 1507 x 59122 Maize. These Cry and PAT proteins have previously been reviewed for potential allergenicity and toxicity, and have been determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and are degraded rapidly and completely in gastric fluid (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2001, 2004; USDA-APHIS, 2001, 2005). Under the No Action Alternative, current exposure to these Cry and PAT proteins has been determined to present no animal feed risk. Additionally, as discussed in Subsection 4.5.1.1 – Human Health, tolerances have been published for glufosinate and the introduced proteins in 1507, 59122, and 1507 x 59122 Maize (US-EPA, 2007a, 2010d).

Under the No Action Alternative, animals may continue to be exposed to 1507, 59122, and 1507 x 59122 Maize and Cry1F, Cry34Ab1, Cry 35Ab1, PAT, and glufosinate through animal feed in the United States.

4.6.2 Preferred Alternative: Animal Feed

Under the Preferred Alternative, it is unlikely that a determination of nonregulated status of Pioneer 4114 Maize will result in substantial impacts to animal feed compared to the No Action Alternative. The results of studies conducted by Pioneer confirm that there are no differences in feed safety between the Pioneer 4114 Maize and other varieties currently available under the No

Action Alternative (Pioneer, 2011b). As discussed in the analysis of the No Action Alternative, animal feed likely already contains the introduced proteins in Pioneer 4114 Maize and glufosinate or glufosinate residues. The Preferred Alternative is unlikely to be different in this regard.

As noted in Subsection 1.3 – Coordinated Framework Review and Regulatory Review, Pioneer has made a voluntary submittal to the US-FDA for this product. As of October, 2012, the US-FDA has not completed its review.

USDA-APHIS' assessment of the potential impacts of the consumption of the Cry1F, Cry34Ab1, Cry35Ab1, and PAT proteins by animals through animal feed considers the source of the gene and the expressed protein, exposure to pesticide residuals, and safety evaluations conducted by Pioneer. Our analysis is similar to that presented above in Subsection 4.5 – Public Health.

As described in Subsection 4.5 – Public Health, Pioneer has evaluated the allergenicity and toxicity of Pioneer 4114 Maize, and has compared this variety with a conventional corn isoline to assess composition. Compositional elements compared included protein, fat, acid detergent fiber, neutral detergent fiber, carbohydrates, ash, fatty acids, amino acids, vitamins and minerals, key anti-nutrients, and key secondary metabolites (Pioneer, 2011b). In these studies, compositional comparisons were made between Pioneer 4114 Maize and a near isoline control grain (Pioneer, 2011b). There were no biologically meaningful differences for any of these compositional characteristics between the Pioneer 4114 Maize and conventional corn varieties, including 1507, 59122, and 1507 x 59122 Maize (Pioneer, 2011b). Animals are already exposed to glufosinate and glufosinate residues in animal feed, particularly animal feed derived from 1507, 59122, and 1507 x 59122 Maize, as described in the No Action Alternative. Pioneer is not proposing a change in label application rates for Pioneer 4114 Maize; glufosinate will be applied in the same rates as those discussed in the No Action Alternative. Accordingly, the tolerance exemptions for glufosinate for animal feed uses will not change, and are no different than those under the No Action Alternative.

Based on the analysis of field and laboratory data and scientific literature provided by Pioneer (Pioneer, 2011b, 2012), safety data available on other GE corn (e.g.,1507, 59122 and 1507 x 59122 Maize), and the already-extant exposure of animals to Cry1F, Cry34Ab1, Cry35Ab1, and PAT proteins through animal feed, USDA-APHIS has concluded that a determination of nonregulated status of Pioneer 4114 Maize is unlikely to have an adverse impact on animal health with regard to animal feed. Overall impacts are similar to those of the No Action Alternative.

4.7 SOCIOECONOMIC

4.7.1 Domestic Economic Environment

Domestic economic impacts associated with adoption of a new GE trait are focused on the impact of that trait on the agronomic inputs and associated on-farm costs, as well as the potential market impacts.

As noted in Subsection 2.2 – Agricultural Production of Corn, insect-resistant corn and herbicide-tolerant varieties incorporating insect resistance are already widely cultivated in the United States. Additionally, as discussed in Subsection 2.7.1 – Domestic Economic Environment, the cultivation of insect-resistant Bt corn provides several collateral economic benefits. The incorporation of Bt proteins in corn has resulted in a decrease in the application of insecticides for the control of lepidopteran and coleopteran pests. Growers adopting this technology would benefit from the reduction in costs associated with the purchase, handling, application and disposal of these insecticides.

An additional economic benefit is the reduction in mycotoxin contamination that is a secondary impact from insect injury to corn kernels (Munkvold and Hellmich, 1999; Munkvold and Hellmich, 2000). Bt corn is less prone to insect injury, which, in turn, prevents the growth of fungi that produce mycotoxins (Munkvold and Hellmich, 1999; Munkvold and Hellmich, 2000; US-EPA, 2010a, 2010b; Vincelli and Parker, 2002). Reductions in fumonisin mycotoxins have a positive economic benefit to the growers as corn grain 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).

4.7.1.1 No Action: Domestic Economic Environment

Under the No Action Alternative, Pioneer 4114 Maize will continue to be a regulated article under the regulations at 7 CFR Part 340. Growers and other parties who are involved in production, handling, processing, or consumption of corn will not have access to Pioneer 4114 Maize, but will continue to have access to currently-available conventional and GE corn varieties. As noted in Subsection 4.1- Scope of the Environmental Analysis, this includes GE corn varieties that are no longer subject to the regulations are 7 CFR Part 340 and the plant pest provisions of the Plant Protection Act of 2000, such as 1507, 59122, and 1507 x 59122 Maize.

Growers currently select corn varieties based on a wide range of considerations, including market conditions and end use requirements. For example, as discussed in Subsection 2.7.1 – Domestic Economic Environment, 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, 2012e; 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.

Growers adopting GE corn varieties incur a cost premium to acquire the seed (NRC, 2010). 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, 2010). 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 outweigh the extra costs of the GE seed (NRC, 2010). All growers adopting GE crops would incur these fees. These costs are unaffected by the No Action Alternative.

The continued emergence of glyphosate-resistant weed biotypes has been identified as an economic concern (NRC, 2010). Glyphosate-resistant weed biotypes have been demonstrated to reduce the effectiveness and economic benefits of glyphosate-tolerant crop systems (Owen et al., 2011; Weirich et al., 2011). Current research advocates using herbicides presenting multiple modes of action to manage these weeds (see, e.g., Owen et al., 2011). Growers would select other herbicides based on the targeted weed and herbicide resistance traits of the targeted weed (Purdue, 2012). Glufosinate is one such herbicide offering another mode of action to control glyphosate-resistant weeds. As previously noted in Subsection 2.2 – Agricultural Production in Corn, in 2010, 16% of the commercial corn acreage was cultivated in 1507, 59122, or the 1507 x 59122 hybrid, each of which is tolerant to glufosinate (Pioneer, 2012).

To manage herbicide-resistant weeds, growers have increased herbicide application rates, increased the number of herbicide applications, and have returned to more traditional tillage practices (NRC, 2010; Sandell et al., 2009). The economic impacts of glyphosate-resistant weeds are a direct result of increased inputs: additional herbicides are required to control the weeds; fuel costs increase as heavy equipment is used more frequently in the field for chemical application; and tillage and labor and management hours increase in association with the application of additional herbicides and machinery use (NRC, 2010; Weirich et al., 2011). There is an additional cost from the reduction in yield associated with the competition of the crop with the weeds (NRC, 2010; Weirich et al., 2011; Wilson, 2011).

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 insecticide applications (Duke and Powles, 2009). At the same time, those growers managing herbicide-resistant weeds may incur increased costs to employ a wide range of management techniques, including increased pesticide use and increased tillage. These trends are unaffected by the No Action Alternative.

4.7.1.2 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 (Subsection 4.7.1.1).

Pioneer presented results of field trials comparing the performance and composition of Pioneer 4114 Maize with other GE and non-GE corn varieties when cultivated under different agronomic conditions and using a range of agronomic inputs (Pioneer, 2012; USDA-APHIS, 2012c). No biologically meaningful differences were observed regarding agronomic characteristics between Pioneer 4114 Maize and any of the other varieties (Pioneer, 2012). As noted in Subsection 4.1 – Scope of the Environmental Analysis, Pioneer 4114 Maize is functionally equivalent to 1507 x 59122 Maize, meaning that it contains identical genetic elements (Cry1F, Cry34Ab1, Cry35Ab1, and PAT), identical traits, and similar agronomic performance. Based on this functional equivalence and the likelihood that Pioneer 4114 Maize will replace some of the acreage planted to 1507 x 59122 Maize, a determination of nonregulated status of Pioneer 4114 Maize is not anticipated to change the area or acreage of U.S. corn production (Subsection 4.2.1) or Agronomic Practices (Subsection 4.2.2) associated with corn production, Additionally, as noted in Subsection 2.7.1 – Domestic Economic Environment and Subsection 4.7.1.1 – No Action, 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. Based on this data, the potential domestic economic impacts associated with the cultivation of Pioneer 4114 Maize are no different than those currently observed for other corn varieties under the No Action Alternative.

To the extent that the planting of hybrids based on Pioneer 4114 Maize results in a substitution of glufosinate for other herbicide applications to control glyphosate-resistant weeds, those who have reduced or eliminated these multiple herbicide applications to control glyphosate-resistant weeds might experience reduced input costs and a commensurate increase in net income. As corn hybrids based on 1507, 59122, and the 1507 x 59122 Maize are currently cultivated, there is no difference in economics in this aspect from the No-Action Alternative.

4.7.2 Trade Economic Environment

Potential impacts to the trade economic environment from a determination of nonregulated status of a new GE trait relates to the potential of that trait to impact trade of corn commodities between the United States and other countries.

4.7.2.1 No Action: Trade Economic Environment

The cropping and marketing decisions made by corn growers are unlikely to be influenced by the selection of this alternative. The acreage planted in GE corn has increased over time, and it is expected that the corn produced will continue to be planted with the currently available GE corn. In 2012, 88% of the corn cultivated in the United States was GE (USDA-NASS, 2012b). U.S. corn will continue to play a role in global corn market, based on existing trends of corn production. The United States is the largest exporter of corn in the world market, although the anticipated export in 2012 will be reduced substantially as a result of the extreme heat and dryness in the Corn Belt (USDA-OCE, 2012c, 2012d). In 2010/2011, the United States exported approximately 46.59 million metric tons of corn, against a global export market of 91.46 million metric tons (USDA-OCE, 2012c). Projections for the export market in 2011/2012 show an estimated United States export of 39.19 million metric tons, against a global export market of 108.11 million metric tons (USDA-OCE, 2012c). How and where the corn and corn products will be used will be subject to global market conditions. In 2012, over 25 countries were identified to import corn (USDA-FAS, 2012). These conditions are not expected to change under the No Action Alternative.

4.7.2.2 Preferred Alternative: Trade Economic Environment

A determination of nonregulated status of Pioneer 4114 Maize is not expected to adversely impact the trade economic environment. Products containing 4114 Maize will have the same global uses as products containing 1507 x 59122 Maize, once appropriate regulatory authorizations are obtained in key export countries for the Pioneer 4114 Maize (Pioneer, 2012). Pioneer plans to submit applications to several international agencies, including the regulatory authorities in Canada, China, Japan, Mexico, South Korea and Taiwan (Pioneer, 2011b). These regulatory authorities include United States trade partners for import clearance and production approval (USDA-FAS, 2012). As of the time of the preparation of this EA, conclusions of the other international agencies had not been published. However, Pioneer will only initiate a commercial launch of the product after obtaining all necessary authorizations in both the United States and key import countries with functioning regulatory processes (Pioneer, 2011b).

Based on these factors, the trade economic impacts associated with the determination of nonregulated status of Pioneer 4114 Maize are anticipated to be similar to the No Action Alternative.

5 CUMULATIVE IMPACTS

5.1 ASSUMPTIONS USED FOR THE CUMULATIVE IMPACTS ANALYSIS

Potential cumulative impacts regarding specific issues are analyzed and addressed within this section. The principal issue associated with the analysis of cumulative impacts pertains to Pioneer's intention to limit the cultivation of Pioneer 4114 Maize as a foundation stock for developing stacked hybrids[27] through conventional breeding techniques (Pioneer, 2011b).

In this hybridization process, the traits in Pioneer 4114 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 Plant Protection Act of 2000. USDA-APHIS does not have jurisdiction under the Plant Protection Act of 2000 and Part 340 to review such stacked hybrids developed using nonregulated articles and conventional hybridization techniques where there is no evidence of a plant pest risk. Accordingly, the body of this EA focuses on the cultivation of Pioneer 4114 Maize. This cumulative impacts analysis focuses on the incremental impacts of the Preferred Alternative taken in consideration with related activities, including past, present, and reasonably foreseeable future actions, with a focus on the implications of future stacking or pyramiding of this product with glyphosate tolerance. USDA-APHIS' rationale for limiting this review to a stacked product resulting in a hybrid combining the traits of Pioneer 4114 Maize with glyphosate tolerance is provided below.

It is important to reiterate that the four introduced proteins in Pioneer 4114 Maize, Cry1F, Cry34Ab1, Cry35Ab1, and PAT, are unique only insofar as they are integrated at a single locus[28] in the genome. The individual elements of Pioneer 4114 Maize have been commercially available for over a decade as 1507 and 59122 Maize, and more recently, hybrid stacks in which the two are combined as 1507 x 59122 Maize. Stacked products based off of the Pioneer 4114 Maize are not necessarily complete replacement products for 1507, 59122 or 1507 x 59122 hybrid varieties; some growers may only have a need for the 1507 product, for example, to control European Corn Borer (Pioneer, 2011b, 2012). In 2010, commercial products containing the 1507 x 59122 Maize were grown on approximately 14 million acres, or 16% of U.S. maize acres (GfK Kynetec, 2010; Pioneer, 2011b). Table 4-1 presents those US-EPA registrations for commercial corn products containing 1507, 59122, or 1507 x 59122 Maize events.

To narrow the issue, and provide a basis for a meaningful evaluation, this cumulative impact analysis is undertaken with the assumption that Pioneer 4114 Maize will be stacked with a GE

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[27] As previously defined in Subsection 1.2, stacked products contain two or more genes targeting multiple pests; whereas pyramided products contain two or more genes targeting a single species.

[28] As previously defined in Subsection 1.2, an insertion at a single locus in the genome means that all introduced genetic elements are integrated at a single point. This is in contrast to conventional breeding stacks where the introduced genetic elements are located in more than one point in the genome. For example, in 1507 x 59122 Maize, the gene encoding Cry1F is located in one location in the genome; whereas the gene encoding Cry34Ab1/Cry35Ab1 is located in another location in the genome

corn variety exhibiting glyphosate tolerance. This stack was selected for analysis in this Cumulative Impacts section because Pioneer has expressly stated that a conventionally produced hybrid stacking Pioneer 4114 Maize with a glyphosate-tolerant corn variety is reasonably expected and highly likely to be the first product developed using the Pioneer 4114 Maize as the foundation variety (Pioneer, 2011b, 2012). Note that the current environmental conditions and associated impacts associated with the cultivation of 1507, 59122, 1507 x 59122 hybrid varieties and Pioneer 4114 Maize have been presented previously in Subsections 2.1-2.3 and 4.1-4.3. Pioneer 4114 Maize includes three different Cry proteins, Cry1F and Cry34Ab1/Cry35Ab1 that provide robust insect resistance to both coleopteran and lepidopteran insect pests, and the creation of a hybrid pyramiding additional Cry proteins to target the same pest cohorts was not proposed by Pioneer in the petition; for these reasons, additional stacks of insect resistant traits were not assessed.

The hybrid stack considered in this cumulative impacts analysis considers the combination of the glufosinate tolerance and insect resistance from Pioneer 4114 Maize combined, using conventional breeding techniques, with glyphosate tolerance from a GE corn variety no longer subject to the regulatory requirements at 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. Corn varieties presenting tolerance to both glufosinate and glyphosate are already in the market (see, e.g., Darby, 2007; Neilsen, 2010; Wilson et al., 2010). Recent commercial hybrids presenting this stack include the following products:

- DAS/Pioneer Hi-Bred Herculex 1 Monsanto Roundup Ready® Corn, which combined 1507 with NK603;
- Syngenta Agrisure GT/CB/LL, which combined SYGGA21 and Bt11;
- DAS Pioneer Hi-Bred Herculex RW Monsanto Roundup Ready® Corn 2, which combined 59122 and NK603;
- DAS Pioneer Hi-Bred Herculex Xtra Monsanto Roundup Ready® Corn 2, which combined 1507 x 59122 and NK603; and
- Monsanto Genuity® SmartStax®, which combined Mon88017 x Mon89034 x 1507 x 59122 (Neilsen, 2010).

Glyphosate is not an approved tank mix partner with glufosinate (see, e.g., Bayer, 2012). When growers adopt a stacked hybrid and elect to use both herbicides, the herbicides are applied sequentially, in accordance with label instructions, as part of the grower's weed management strategies (see, e.g., Monsanto, 2009).

The potential impacts from the cultivation of glyphosate-tolerant crops, with a corresponding analysis of the implications of the use of glyphosate, have been thoroughly evaluated in other USDA-APHIS EAs and EISs (notably the recent EISs for glyphosate-tolerant Sugar Beet and glyphosate-tolerant alfalfa) prepared to support determination of nonregulated status decisions, beginning in 1993 with the introduction of the first glyphosate-tolerant crop product. (See: www.APHIS.USDA.gov/biotechnology/not_reg.htm.) Several of these evaluations included crops expressing tolerance to multiple herbicides. Specific crop examples include:

- Sugar Beet, 2011. Monsanto and KWS SAAT AG Glyphosate-tolerant Sugar Beet (Petition No. 03-323-01p).

- Soybean, 2011. Monsanto Improved Fatty Acid Profile Soybean (which includes glyphosate tolerance) (Petition No. 09-201-01p).
- Alfalfa, 2011. Monsanto Glyphosate-tolerant Alfalfa (Petition 04-110-01p).
- Corn, 2009. Pioneer Glyphosate and Imadazolinone-tolerant Corn (Petition 07-152-01p).
- Cotton, 2009. Bayer Crop Science Glyphosate-tolerant Cotton (Petition 06-332-01p).
- Soybean, 2008. Pioneer Glyphosate and Acetolactate Synthase-tolerant Soybean (Petition No. 06-271-01p).
- Soybean, 2007. Monsanto Glyphosate-tolerant Soybean (Petition 06-178-01p).
- Cotton, 2005. Monsanto Glyphosate-tolerant Cotton (Petition 04-086-01p).
- Rapeseed 2001. Monsanto Glyphosate-tolerant Rapeseed (Petition 01-324-01p).
- Corn, 2000. Monsanto Glyphosate-tolerant Corn (Petitions No. 97-099-01p and 00-011-01p).
- Rapeseed 1998. Monsanto Glyphosate-tolerant Rapeseed (Petition 98-216-01p).
- Sugar Beet, 1998. Novartis Seeds and Monsanto Glyphosate-tolerant Sugar Beet (Petition No. 98-173-01p).
- Corn, 1997. Monsanto Glyphosate-tolerant Corn. (Petition No. 97-099-01p).
- Corn, 1996. Monsanto Glyphosate-tolerant and European Corn Borer-resistant Corn. (Petition No. 96-317-01p).
- Cotton, 1995. Monsanto Glyphosate-tolerant Cotton (Petition 95-045-01p).
- Soybean, 1993. Monsanto Glyphosate-tolerant Soybean (petition 93-258-01p).

Glyphosate-tolerant (e.g., Roundup Ready®) corn varieties no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 have been in the market since 1996 (USDA-APHIS, 2012b). As evidenced by the above list of glyphosate-tolerant crops, the application and use of glyphosate on Roundup Ready® crops has been well-described and will not be further addressed here. Glyphosate is already used in corn in both conventional and Roundup Ready® varieties.

5.2 CUMULATIVE IMPACTS: AREAS AND ACREAGE OF CORN PRODUCTION

As discussed in Subsection 4.2.1 –Areas and Acreage of Corn Production, the traits that are the foundation for Pioneer 4114 Maize are already in widespread cultivation, and there are no characteristics of Pioneer 4114 Maize that would be expected to change the areas or range of corn cultivated. Neither the No Action Alternative nor the Preferred Alternative are expected to directly cause an increase in agricultural acreage devoted to corn production or those corn acres devoted to GE corn cultivation. The availability of Pioneer 4114 Maize as a breeding stock to create hybrid stacks would not change cultivation areas for corn production in the United States and there are no anticipated changes to the availability of GE and non-GE corn varieties on the market under either alternative.

Stacking Pioneer 4114 Maize with glyphosate-tolerant maize is not expected to influence areas and acreage of crop production. Glyphosate-tolerant corn has been commercially available since 1996 (see http://www.aphis.usda.gov/biotechnology/not_reg.html). The glyphosate-tolerant varieties are already widely cultivated, based on the percentage of corn currently treated with glyphosate (noted in Subsection 2.2 – Agronomic Inputs as 66% of the acreage, ~57 million pounds) (USDA-NASS, 2011a, 2011b). Any stack between Pioneer 4114 Maize and a GE glyphosate-tolerant corn variety would also not be expected to increase the area or range of corn cultivation in the United States. The individual GE corn parents of this stack would have been previously reviewed and found to not likely extend the area of range of U.S. corn cultivation (USDA-APHIS, 2012c), strongly suggesting that any offspring from Pioneer 4114 and glyphosate-tolerant corn would not extend area or range of corn cultivation in the United States. Additionally, as noted above in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, multiple commercial varieties stacking glufosinate and glyphosate tolerance are already in the market and are being commercially cultivated. Moreover, as discussed in Subsection 4.2 – Agricultural Production of Corn, the cultivation of a GE variety is not the determinative factor in a grower's selection of corn. Growers select corn over soybean or cotton, for example, on the basis of market demand (USDA-ERS, 2011d). Consequently, a stacked product offering tolerance to glufosinate and glyphosate is not expected to change the acreage or the range of corn production.

Because changes in the acreage and locations for corn production using Pioneer 4114 Maize as a breeding foundation stacked with glyphosate tolerance are not expected, no cumulative impacts have been identified for areas and acreage of corn production.

5.3 CUMULATIVE IMPACTS: AGRONOMIC PRACTICES: TILLAGE, CROP ROTATION, AND AGRONOMIC INPUTS

5.3.1 Tillage and Crop Rotation

As discussed in Subsection 4.2.2 – Agronomic Practices, a determination of nonregulated status of Pioneer 4114 Maize is not expected to result in changes in current corn agronomic practices, as Pioneer 4114 Maize contains identical genetic elements to and requires the same cultivation practices as currently-cultivated GE corn varieties, such as 1507 x 59122 Maize.

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 changes in tillage or crop rotation. Pioneer's studies demonstrate Pioneer 4114 Maize is essentially indistinguishable from other corn varieties used in terms of agronomic characteristics and cultivation practices, such as 1507 x 59122 Maize (Pioneer, 2011b). As noted in the introduction to this section, the GE parents of a stacked 4114/glyphosate-tolerant hybrid were previously reviewed and determined to be similar in agronomic characteristics to conventional corn varieties. Thus, any hybrid stemming from those two GE parents can be reasonably expected to be similar to conventional corn, and thus, benefit from the benefits of crop rotation. Additionally, because crop rotation strategies may be undertaken dependent on market conditions, any one hybrid stack is unlikely to affect these market conditions.

The current cultivation of glyphosate-tolerant and glufosinate-tolerant GE corn varieties suggests that growers have already adopted tillage and crop rotation practices that incorporate the two herbicides into the crop weed control program.

5.3.2 Agronomic Inputs

As discussed in Subsection 4.2.2 – Agronomic Practices, the cultivation of Pioneer 4114 Maize is unlikely to change current agronomic inputs for corn, including fertilizers, fungicides, insecticides, and herbicides because it is functionally equivalent to 1507 x 59122 Maize, a currently-available corn variety.

The cultivation of a stacked variety containing both insect-resistant and herbicide-tolerant traits is consistent with current crop cultivation practices. As note in the introduction to this section, both 4114 and any nonregulated glyphosate-tolerant variety 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 from these two GE parents will also likely be similar to conventional corn in agronomics and cultivation requirements.

The stacking of beneficial traits represents an increasing proportion of commercially-available corn varieties (see Table 2-1 in Subsection 2.2.2.3). 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 noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, there are several commercially available corn varieties that contain a combination of insect-resistant and glufosinate- and glyphosate-tolerant traits. The factors discussed in Subsection 2.2 – Agricultural Production of Corn that influence the grower's selection of insect-resistant varieties, and the consequent application or avoidance of various insecticides are not changed by the cultivation of a hybrid stack because the current trend to reduce insecticide use in reliance on the incorporated Bt proteins is expected to continue (see, Brookes and Barfoot, 2010; Brookes et al., 2012). This stacked variety would present another grower option for cultivating a Bt corn variety.

The addition of glyphosate tolerance to the Pioneer 4114 events is not expected to require a change in the refuge strategies for managing insect resistance associated with the expression of the Cry proteins. As discussed in Subsection 2.4.1.2 – Invertebrates, refuge strategies are part of an insect resistance management strategy to delay the development of insect resistance to the expressed Cry proteins. Growers planting a stacked hybrid incorporating glyphosate tolerance with the Pioneer 4114 Maize would need to ensure that their refuge strategy incorporated the appropriate herbicide-tolerant corn varieties. The Genuity® SmartStax® hybrid, listed in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis is an example of a conventional hybrid containing traits tolerant to both herbicides and presenting a convenient refuge strategy (see Monsanto, 2012). There are no cumulative impacts associated with insecticide use or refuge strategies associated with the cultivation of this hybrid. Refuge strategies are presented again in the Animal Communities analysis below.

With regard to potential changes in use of certain herbicides, as noted in Subsection 4.2.2 – Agronomic Practices, corn containing traits tolerant to glufosinate was cultivated on approximately 16% of the total corn acreage in 2010 (GfK Kynetec, 2010), but in that same time period, glufosinate was applied to only 2% of the corn acreage (USDA-NASS, 2011a). The cultivation of a corn variety exhibiting tolerance to both glufosinate and glyphosate provides the grower with the option to apply herbicides with two different modes of action to control hard-to-control weeds. As discussed in Subsections 2.2.2, Agronomic Inputs, and 2.4.2, Plant Communities, growers continually adapt weed management strategies to manage hard-to-control weeds (Norsworthy et al., 2012; Vencill et al., 2012). Weed control methods differ depending on a number of factors including regional practices, grower resources, and crop trait; the techniques may be direct (e.g., mechanical, biological, and chemical) or indirect (e.g., cultural) (Hoeft et al., 2000). Mechanical controls include a reversion to tillage, and chemical controls include the use of herbicides with alternative modes of action, such as auxin growth regulators, amino acid inhibitors, chlorophyll pigment inhibitors, or lipid biosynthesis inhibitors (Norsworthy et al., 2012; Ross and Childs, 2011; Vencill et al., 2012). The practice of using herbicides with alternative modes of action could potentially diminish the populations of glyphosate-resistant weeds and reduce the likelihood of the development of new herbicide-resistant weed populations (Dill et al., 2008; Duke and Powles, 2008, 2009; Norsworthy et al., 2012; Owen, 2008; Pioneer, 2011b; Vencill et al., 2012). These alternative weed management strategies are already widely used, and growers cultivating hybrid varieties tolerant to both glyphosate and glufosinate are already able to take advantage of this strategy. These strategies are unlikely to change after the development of a 4114/glyphosate-tolerant maize variety. The extent to which growers adopt this strategy will be contingent upon their response to the emergence of these weeds in their fields.

As discussed in Agronomic Practices (Subsections 2.2.2 and 4.2.2), the use of glufosinate on total corn acres has remained stable and low over the past decade (2-6% of total U.S. corn acres treated with glufosinate during 2001-2011) (Pioneer, 2012) To the extent that growers recognize the value in cultivating a stacked hybrid allowing the use of herbicides with multiple modes of action, the cultivation of varieties stacking Pioneer 4114 Maize with glyphosate tolerance may allow growers to substitute glufosinate or glyphosate or both for other herbicides such as atrazine and metolachlor, as well as avoid reverting to conventional tillage (Vencill et al., 2012). As noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, there are several commercial varieties containing these same tolerance traits already on the market and the development of a hybrid containing the traits of Pioneer 4114 Maize and glyphosate-tolerant are unlikely to change these current practices. On Roundup Ready® varieties, glyphosate is applied in many formulations post-emergence, in application rates ranging from 0.56 to 1.12 lb ae/acre (Loux et al., 2011). Glyphosate also is commonly used in conjunction with many other herbicides as a tank mix for both pre-plant/pre-emergence and post-emergent weed control up through the 12-leaf stage or until the corn reaches a height of 30 inches (see, e.g., Loux et al., 2011). Hybrids combining tolerance to both herbicides will provide growers with the opportunity to apply tank mixes of either glyphosate or glufosinate with other herbicides for control of mixed weeds, and may be valuable in providing alternative controls to growers managing glyphosate-resistant weeds (Pioneer, 2012). As noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, there are several other commercial hybrids currently cultivated that also are tolerant to both glyphosate and glufosinate. The application of both herbicides to a corn crop is thus not a new event.

As previously noted, long-term trends related to herbicide use resulting from the use of GE technologies are the subject of intense debate (Benbrook, 2009; Benbrook, 2012; Brookes and Barfoot, 2010; Brookes et al., 2012). For example, Benbrook has recently published an analysis of the impacts of GE crops on pesticide use in the United States (Benbrook, 2012). In this publication, he estimates that herbicide-tolerant crop technology has led to a 239 million kg increase in herbicide use in the United States between 1996 and 2011 and that Bt crops have reduced insecticide applications by 56 million kg over the same time period. Although Benbrook's conclusion regarding a reduction in insecticide related to the use of Bt crops is consistent with the findings of other analysts, his analysis of trends in herbicide use is based on assumptions that may lead to overestimates of herbicide use in herbicide-tolerant crop programs, including assumptions of herbicide usage on conventional crops that may be underestimated, extrapolation of trends to years where no USDA data are available, and not accounting for the role of increased crop acreage in the estimated increases in herbicide use. (Brookes et al., 2012). Further, Benbrook’s analysis fails to consider the differing environmental profiles of herbicides used, particularly the substitution of relatively environmentally benign products for those with less environmentally friendly profiles (Brookes and Barfoot, 2012). In contrast to Benbrook's findings, Brookes and Barfoot (2012) estimate that GM crop adoption in the United States reduced the use of pesticides in the United States by 246 million kg compared to what might reasonably be expected if GM crops were no longer available.

Growers are already cultivating stacked hybrids presenting the same traits as a 4114/glyphosate tolerant stack; to accomplish this, these growers have already adopted cultivation practices, including managing agronomic inputs for fertilizer, herbicides, pesticides and fungicides appropriate for these stacked hybrids. As discussed in this subsection, there are no changes in practices expected to accommodate such new hybrids; moreover, these new hybrids can be reasonably expected to replace cultivation of some of these existing hybrid varieties. Consequently, overall impacts to agronomic practices associated with the adoption of such stacked varieties are not expected, and no cumulative impacts have been identified for agronomic practices associated with corn production.

5.4 CUMULATIVE IMPACTS: ORGANIC CORN FARMING AND SPECIALTY CORN SYSTEMS

5.4.1 Organic Corn Farming

A determination of nonregulated status of Pioneer 4114 Maize is not expected to change the market demands for GE corn or corn produced using organic methods. A determination of nonregulated status of Pioneer 4114 Maize 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 Plant Protection Act of 2000. 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 discussed in Subsection 2.2.3 – 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). The approximately 169,000 acres in 2011 represent a decrease from the approximately 195,000 certified organic corn acres cultivated in 2008 (USDA-NASS, 2012a).

These acreage trends suggest that adding a new GE corn variety, in this case a new breeding stock stacked with glyphosate tolerance, is not related to the ability of an organic production systems to maintain their market share. As Table 4-1 illustrates, corn varieties containing the same traits as Pioneer 4114 Maize have been in commercial cultivation for over a decade. Corn varieties tolerant to glyphosate and no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 have been on the United States market since 1996 (see http://www.aphis.usda.gov/biotechnology/not_reg.html). The glyphosate-tolerant varieties are already widely cultivated, based on the percentage of corn currently treated with glyphosate (noted in Subsection 2.2 – Agronomic Inputs as 66% of the acreage, ~57 million pounds) (USDA-NASS, 2011a, 2011b).

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 from a determination of nonregulated status for Pioneer 4114 Maize.

5.4.2 Specialty Corn Production

A determination of nonregulated status of Pioneer 4114 Maize is not expected to change the market demands for GE corn or corn produced using specialty systems. A determination of nonregulated status of Pioneer 4114 Maize would add another GE corn variety to the corn market.

As discussed in Subsection 5.4.1 – Organic Corn Farming, corn varieties containing the same traits as Pioneer 4114 Maize have been in commercial cultivation for over a decade. Corn varieties tolerant to glyphosate and no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 have been on the United States market since 1996, and currently occupy a substantial part of the market. As discussed in Organic Corn Farming and Specialty Corn Systems (Subsections 2.2.3 and 4.2.3), growers already consider corn identity protection as part of their management strategies, from planting through harvest.

Based on Pioneer’s demonstration that there are no changes in agronomic characteristics and cultivation practices, and because the market share of specialty corn varieties is unlikely to change by the introduction of Pioneer 4114 Maize and hybrids based on this variety, USDA-APHIS has determined that there are no past, present, or reasonably foreseeable changes that would impact specialty corn producers and consumers.

5.5 CUMULATIVE IMPACTS: SOIL QUALITY

USDA-APHIS has not identified any cumulative impacts from the use of Pioneer 4114 Maize and its hybrids to soil quality. Pioneer has compared phenotypic, agronomic, and cultivation characteristics between Pioneer 4114 Maize and control corn hybrids. Pioneer 4114 Maize requires the same soil, fertilizer, water, and pest management practices as conventional corn, including the currently-available 1507 x 59122 Maize (Pioneer, 2011b). Additionally, Pioneer 4114 Maize also contains identical introduced genetic elements as 1507, 59122, and 1507 x 59122 Maize. Consequently, the phenotypic, agronomic, and ecological data presented by Pioneer support the conclusion by USDA-APHIS that Pioneer 4114 Maize would not result in any substantial modification in soil properties that are not already found in conventional corn production practices (Pioneer, 2011b; USDA-APHIS, 2012c).

As noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, the application and use of glyphosate on Roundup Ready® crops has been well-described in the EAs and EISs noted, and will not be further addressed here. Glyphosate is already used in corn in both conventional and Roundup Ready® varieties. The stacking of Pioneer 4114 Maize with a glyphosate-tolerant variety complements the glyphosate-tolerant crop by providing growers with the option to also apply glufosinate in those fields where glyphosate-resistant and inherently hard-to-control weeds have emerged, allowing the grower to avoid reverting to tillage (Towery and Werblow, 2010). As discussed in Subsection 5.10 – Cumulative Impacts: Plant Communities, the use of herbicides with multiple modes of action must also take into consideration the emergence of weed varieties containing traits resistant to multiple herbicides. As glyphosate-resistant weed varieties have emerged, growers have returned to increased tillage as one of the weed management practices. As discussed in Soil Quality (Subsections 2.3.1 and 4.3.1), the adoption of conservation tillage has resulted in substantial improvements to soil health (Towery and Werblow, 2010). The cultivation of a corn variety stacking multiple modes of action, in this case, tolerance to glufosinate ammonium, along with glyphosate-tolerance, provides growers with an opportunity to maintain their conservation tillage strategies. As noted in Soil Quality (Subsections 2.3.1 and 4.3.1), maintaining conservation tillage will have a positive impact on soil quality by minimizing soil erosion, increased retention of organic matter, and increased water retention, among other benefits (Peet, 2001)

The analysis of the impacts of glyphosate use on soil resources is well documented (Duke et al., 2012). Glyphosate is strongly adsorbed to soil, and once it enters the soil, it is essentially unavailable to plants because of this adsorption (Giesy et al., 2000; US-EPA, 1993). Glyphosate has been shown to rapidly dissipate from most agricultural ecosystems across a wide range of soil and climatic conditions, from 1.7 to 141.9 days, with a median soil half-life (the time it takes for half of the glyphosate to dissipate in the soil) of 14.9 days, depending on a wide range of soil chemical and physical parameters (Giesy et al., 2000). Impacts of glyphosate to soil microorganisms are discussed in Subsection 5.11 – Cumulative Impacts: Soil Microorganisms.

The potential future cultivation of a stacked variety and the associated use of glyphosate in addition to glufosinate are not expected to result in cumulative impacts to soil as corn varieties already exhibiting tolerance to glufosinate and glyphosate exist and are already cultivated in the United States.

Based on these findings, and because the amount of corn grown in the United States is unlikely to change by the introduction of Pioneer 4114 Maize, USDA-APHIS has determined that there are no cumulative impacts to soil quality.

5.6 CUMULATIVE IMPACTS: WATER RESOURCES

No cumulative impacts on water use have been identified for a determination of nonregulated status of Pioneer 4114 Maize or its hybrids. A determination of nonregulated status of Pioneer 4114 Maize or its hybrids is not expected to change the water use and irrigation practices used in commercial corn production. As discussed above in Subsection 5.2 – Areas and Acreage of Corn Production, corn acreage will not increase as a result of cultivation of a hybrid combining 4114 with a glyphosate-tolerant corn. Consequently, if corn acreage does not change as a result of this hybrid, then total water use trends by corn are unlikely to change.

Moreover, as presented in Subsection 4.3.2, Water Resources, for Pioneer 4114 Maize, and previous reviews of GE glyphosate-tolerant corn, these varieties require typical moisture levels as conventional corn. Any offspring from 4114 and glyphosate-tolerant corn will require similar moisture levels as its parents. Thus, any offspring from 4114 and glyphosate-tolerant corn is likely to require similar moisture levels as conventional corn. Accordingly, no cumulative impacts to water use or irrigation in corn are anticipated.

The potential stacking of Pioneer 4114 Maize with a glyphosate-tolerant variety provides growers with the option to apply herbicides with different modes of action, an approach proposed to mitigate the future development of herbicide-resistant weeds (Duke and Powles, 2009). Glyphosate-tolerant crops, also identified as "Roundup Ready®" have been in commercial use since 1993 when glyphosate-tolerant cotton was introduced. Glyphosate-tolerant corn was introduced in 1996 (see http://www.aphis.usda.gov/biotechnology/not_reg.html).

As noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, the application and use of glyphosate on Roundup Ready® crops has been well-described and will not be further addressed here. Glyphosate is already used in corn in both conventional and Roundup Ready® varieties.

As discussed in Subsection 2.2.2.1 – Tillage, the adoption of conservation tillage has resulted in substantial improvements to soil health, and correspondingly, water quality, in those areas where the practice has been adopted (Givens et al., 2009; Towery and Werblow, 2010; USDA-NRCS, 2006b, 2010). The cultivation of a corn variety stacking multiple modes of action, in this case, tolerance to glufosinate ammonium, along with glyphosate tolerance, provides growers with an opportunity to preserve their conservation tillage strategies by combining herbicides with multiple modes of action rather than reverting to tillage. As discussed in Physical Environment (Subsections 2.3 and 4.3), conservation tillage improves soil water retention and reduces soil erosion and nutrient runoff from the fields, each aspect of which benefits water quality (Peet, 2001). Maintaining conservation tillage will have a positive impact on water quality and a stacked corn product exhibiting Pioneer 4114 and glyphosate tolerance may provide growers an opportunity to maintain conservation tillage practices that have already been adopted.

The potential impacts of glyphosate use on water resources are well-documented in the previous EAs and EIS cited in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis. Although glyphosate is very soluble in water, it is strongly adsorbed to soils; consequently, glyphosate is unlikely to leach into groundwater or surface water runoff following application

(Giesy et al., 2000; US-EPA, 1993). Relying on toxicological data, bioaccumulation and biodegradation studies, and acute and chronic tests on fish and other aquatic organisms, US-EPA has determined that "the potential for environmental effects of glyphosate in surface water is minimal", and has further noted a half-life in water of 8.1 days in an anaerobic aquatic environment and 7 days in an aerobic aquatic environment (US-EPA, 1993).

The potential future cultivation of a stacked variety and the associated use of glyphosate in addition to glufosinate are not expected to result in cumulative impacts to water resources. The total amount of herbicide applied to hybrids based on the Pioneer 4114 Maize would be limited by application and per year rates approved by the US-EPA in the pesticide labels. As discussed in Subsection 1.3 – Coordinated Framework Review and Regulatory Review, the US-EPA's pesticide registration process under FIFRA requires that US-EPA determine, through testing, that the pesticide will not cause unreasonable adverse effects on humans, the environment and non-target species when used in accordance with the label. US-EPA's label restrictions include a prohibition against applying glyphosate to water or to areas where surface water is present, or to intertidal areas below the mean high water mark (see, e.g., Prokoz, 2010).

Based on these findings, and because the amount of corn grown in the United States is unlikely to change by the introduction of Pioneer 4114 Maize, USDA-APHIS has determined that there are no cumulative impacts to water resources.

5.7 CUMULATIVE IMPACTS: AIR QUALITY

USDA-APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with impacts of the proposed action that would have a negative impact on air quality. The consequences of the Preferred Action Alternative on commercial corn production and the resulting air quality are similar to those expected for the No Action Alternative.

The stacking of the Pioneer 4114 Maize with corn varieties containing tolerance to the herbicide glyphosate is not expected to impact air quality. Glyphosate-tolerant crops, also identified as Roundup Ready® have been determined by USDA-APHIS to have nonregulated status since 1993 when glyphosate-tolerant cotton was introduced. Glyphosate-tolerant corn was introduced in 1996 (see http://www.aphis.usda.gov/biotechnology/not_reg.html). As noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, the application and use of glyphosate on Roundup Ready® crops has been well-described in the EAs and EISs noted, and will not be further addressed here. Glyphosate is already used in corn in both conventional and Roundup Ready® varieties.

Some agricultural practices, including tillage and equipment use, can affect air quality through emissions from soil and equipment (US-EPA, 2012b). Cultivation of a stacked corn variety, containing tolerance to glyphosate and glufosinate, would enable growers to use a combination of herbicides to control glyphosate-resistant weeds instead of returning to tillage practices (Owen et al., 2011), reducing these impacts to air quality when compared with conventional tillage. As noted in Subsection 4.2 – Agricultural Production of Corn, any GE corn variety used as part of such a stack is likely to require the same cultivation requirements as conventional corn.

Accordingly, there are no differences in agricultural practices between conventional and GE corn, whether a single trait event or a stack variety, that would impact air quality.

Based on these findings, and because the amount of corn grown in the United States is unlikely to change following a determination of nonregulated status of Pioneer 4114 Maize, USDA-APHIS has determined that there are no cumulative impacts to air quality.

5.8 CUMULATIVE IMPACTS: CLIMATE CHANGE

USDA-APHIS has not identified any cumulative impacts for this issue. USDA-APHIS does not anticipate any changes in corn production practices or an expansion of corn acreage as a result of Pioneer 4114 Maize being no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000.

Some agricultural practices, including tillage and equipment use, can contribute to climate change through releasing GHG emissions from soil and equipment (US-EPA, 2012b). Cultivation of a stacked corn variety, containing traits tolerant to herbicides with different modes of action, in this case glyphosate and glufosinate, would enable growers to use a combination of herbicides to control glyphosate-resistant weeds instead of returning to conventional tillage practices (Owen et al., 2011; Towery and Werblow, 2010). As noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, corn products containing these stacked traits are already commercially cultivated. As discussed above in Agronomic Practices (Subsections 2.2.2 and 4.2.2), Soil Quality (Subsections 2.3.1 and 4.3.1), and Climate Change (Subsections 2.3.4 and 4.3.4), the adoption of herbicide-tolerant crops and conservation tillage (or the avoidance of conventional tillage) has been identified as providing climate change benefits by increasing carbon sequestration in soils.

Based on these findings, and because the amount of corn grown in the United States is unlikely to change by the introduction of Pioneer 4114 Maize, USDA-APHIS has determined that there are no cumulative impacts to climate change. The use of Pioneer 4114 Maize as a foundation stock for production of hybrid varieties containing multiple stacked traits, including glyphosate tolerance, is not expected to cause any cumulative effect on climate change.

5.9 CUMULATIVE IMPACTS: ANIMAL COMMUNITIES

USDA-APHIS has determined that there are no impacts from past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources associated with the ecosystem in which Pioneer 4114 Maize is planted.

5.9.1 Mammals and Birds

As discussed in Subsection 4.4 – Biological Resources, cultivation of Pioneer 4114 Maize, with the attendant accumulation of the Cry and PAT proteins providing insect resistance and herbicide tolerance, is unlikely to have direct toxic effects on non-target organisms exposed to the *Bt* and *pat* genes and the corresponding Cry and PAT proteins (USDA-APHIS, 2012c). Therefore, the likelihood of adverse cumulative impacts on non-target organisms and biodiversity as a consequence of direct exposure to these proteins following the introduction of Pioneer 4114 Maize is minimal.

Glyphosate commonly is used in conjunction with many other herbicides as a tank mix for both pre-plant/pre-emergence weed control up through the 12-leaf stage or until the corn reaches a height of 30 inches (see, e.g., Loux et al., 2011). As noted above, glyphosate is not currently approved as a tank mix with glufosinate (see, Bayer, 2012). USDA-APHIS expects that any applications of glyphosate with glufosinate would be consistent with the currently approved rates. USDA-APHIS expects that both herbicides would be used in accordance with proposed labels.

Stacked and pyramided crop varieties, exhibiting tolerance to multiple herbicides and different forms of insect resistance, are widespread in the industry. As noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, stacked varieties exhibiting tolerance to both glufosinate and glyphosate are already commercially cultivated. The introduction of hybrids based on Pioneer 4114 Maize have the potential to impact the rate of development of such varieties, as the availability of a foundation stock with the key genes on a single loci facilitates the inclusion of these gene traits in the development of other hybrid varieties (Pioneer, 2011b). Although the rate of development of such hybrids may be affected by the availability of Pioneer 4114 Maize, hybrids based on the 1507 x 59122 variety are already in commercial cultivation. In that regard, potential cumulative impacts from the cultivation of hybrids based on Pioneer 4114 Maize are the same as those already occurring under the No Action Alternative. Accordingly, USDA-APHIS expects that the associated cumulative impacts to animals of the availability of Pioneer 4114 Maize are negligible.

Glyphosate is already widely used in corn (USDA-NASS, 2011a, 2011b). As noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, there are already several stacked varieties commercially available that contain traits tolerant to both glufosinate and glyphosate. Glyphosate and glufosinate are already applied to corn varieties in accordance with the label restrictions; neither herbicide requires a label change to be used on a stacked hybrid variety. A hybrid based on Pioneer 4114 Maize also containing traits tolerant to glyphosate would provide growers with another corn varietal option allowing the use of herbicides with multiple modes of action consistent with current practice. With regard to potential risk to mammals and birds from glyphosate expose, the EPA has conducted an ecological risk assessment for glyphosate and determined that there are minimal effects to birds and mammals (as well as fish and invertebrates) (see, e.g.,US-EPA, 1993) There is no evidence that animal exposure to these herbicides would change from the current condition in the event of the cultivation of such a hybrid stack.

Growers generally have three options available to manage glyphosate-resistant weeds: 1) increase the frequency and magnitude of glyphosate applications within the restrictions of the US-EPA labels; 2) use other herbicides in addition to glyphosate; or 3) increase the use of tillage and other mechanical controls (Owen et al., 2011; USDA-NRCS, 2010). A hybrid incorporating glufosinate tolerance and glyphosate tolerance would achieve this goal. By combining herbicides offering alternative modes of action into their agronomic practices, the farmer can reduce the use of other herbicides which have been deployed to manage glyphosate-resistant weeds and continue to adopt conservation tillage systems. The associated adoption of conservation tillage and the reduced use of soil-applied herbicides have the potential to benefit animal communities in fields planted with Pioneer 4114 Maize (Eggert et al., 2004). The reduction in herbicide use and increase in conservation tillage both provide improved habitat for animals in and around the cornfields.

5.9.2 Invertebrates

As discussed in Subsection 5.3.2 – Agronomic Inputs, the addition of a glyphosate tolerance to the Pioneer 4114 events is not expected to require a change in the refuge strategies for managing insect resistance associated with the expression of the Cry proteins. As discussed in Subsection 2.4.1.2 – Invertebrates, refuge strategies are part of an insect resistance management strategy to delay the development of insect resistance to the expressed Cry proteins. Growers planting a stacked hybrid incorporating glyphosate tolerance with the Pioneer 4114 Maize would need to ensure that their refuge strategy incorporated the appropriate herbicide-tolerant corn varieties. The Genuity® SmartStax® hybrid, listed in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis and already on the market, is an example of a conventional hybrid containing traits tolerant to both herbicides and presenting a convenient refuge strategy (see Monsanto, 2012). Invertebrate exposure to glyphosate has been addressed in the EAs and EISs noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis. Glyphosate does not present an unreasonable risk to non-target invertebrates when used in accordance with the label use restrictions (see, e.g., US-EPA, 1993).

Based on these findings, USDA-APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to affect animals associated with the determination of nonregulated status of Pioneer 4114 Maize

5.10 CUMULATIVE IMPACTS: PLANT COMMUNITIES

5.10.1 Surrounding Landscapes and Other Vegetation in Cornfields

The potential impacts associated with exposure of plant communities to glyphosate has been addressed in previous USDA-APHIS analyses (see, http://www.aphis.usda.gov/biotechnology/not_reg.html). As discussed in Subsection 4.4.2 – Plant Communities, the cultivation of Pioneer 4114 Maize does not require different management strategies than commercially available corn varieties, including commercial varieties based on 1507 x 59122 Maize.

Spray drift is a concern for non-target susceptible plants growing proximate to fields. Similar to glufosinate, US-EPA label restrictions are already in place for glyphosate to address the potential off-site drift of glyphosate and minimize this impact (see, e.g., Bayer, 2012; Prokoz, 2010). As noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, growers are already cultivating commercial hybrids containing traits tolerant to both glufosinate and glyphosate. There is no evidence that the herbicide label restrictions or application requirements for either glufosinate or glyphosate would be any different than those currently used in the cultivation of the aforementioned conventional hybrid stacks that are already cultivated.

As discussed in the EAs and EISs referenced in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, glyphosate is a non-selective foliar herbicide, with little or no herbicidal activity in soil (Duke et al., 2012). Some literature suggests that glyphosate adversely affects mineral nutrition in glyphosate-tolerant crops, leading to increased plant disease, and that glyphosate-tolerant crops are more susceptible to plant diseases due to other mechanisms (see, e.g., Duke et al., 2012; Kremer and Means, 2009). The latest literature on this concern questions the science and the significance of the reported impacts associated with the use of glyphosate, specifically noting that yield data for crops that are predominately glyphosate-tolerant varieties does not support the contention that there are substantial mineral uptake or disease problems associated with the use of this herbicide (Duke et al., 2012).

As noted on Tables 2-3 and 2-4, Italian Ryegrass, *L. multiflorum*, identified in Oregon 2010 is the only weed identified as tolerant to both glufosinate and glyphosate (Heap, 2012). The International Survey of Herbicide Resistant Weeds (ISHRW) identifies many weeds containing traits for herbicide-resistance to multiple modes of action. Growers implementing weed control strategies incorporating herbicides expressing multiple modes of action will need to adhere closely to the Stewardship Strategy to avoid selecting for such species. For example, Barnyard grass (*Echinochloa crus-galli*) is identified as resistant to synthetic auxins in the United States; whereas in Brazil, this same species also is identified as resistant to the ALS herbicides (Heap, 2012). Kochia (*K. scoparia*) has been identified as resistant to both synthetic auxins and glyphosate in the United States (Heap, 2012). This weed, despite being identified as herbicide-resistant in 1994, is not reported to be a major crop management problem (Wright et al., 2011).

As noted in Subsection 2.4.2 – Plant Communities, the preferred method to manage hard to control weeds involves, among other strategies, use of herbicides with multiple modes of action. As noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, stacked hybrid varieties presenting the grower with options to consider herbicides with multiple modes of action, including tolerance to both glyphosate with glufosinate, are already commercially available. Growers are already using both glyphosate and glufosinate to control weeds in similar stacked corn hybrids (see, e.g., Monsanto, 2012). The hybrid stack envisioned here would present growers with another management option for addressing these hard to control weeds similar to those varieties already on the market.

Based on these findings, USDA-APHIS has not identified any cumulative impacts to surrounding landscapes or weed control associated with potential stacking with a glyphosate tolerance event.

5.10.2 Corn as a Weed or Volunteer

Pioneer has committed to preparing a Stewardship Strategy to preserve the effectiveness of the products associated with cultivation of future hybrids (Pioneer, 2012). Growers cultivating Pioneer 4114 Maize varieties would be expected to accept this stewardship plan as part of the technology agreement to purchase and cultivate the products (Pioneer, 2011a; see also Pioneer, 2011c, 2012). As discussed in Agronomic Practices (Subsections 2.2.2 and 4.2.2), an essential aspect of these stewardship strategies is growers’ adherence to US-EPA’s approved label application rates, and the use of herbicides expressing multiple modes of action (Owen et al., 2011). USDA-APHIS assumes that growers will use these herbicides in accordance with US-EPA's label restrictions, and that these label requirements are intended to minimize potential non-target impacts.

The remainder of this analysis of potential cumulative impacts to plant communities focuses on the control of volunteer corn engineered to contain herbicide-tolerant traits for herbicides with multiple modes of action. As stacked crops are developed containing multiple herbicide tolerance traits, the options for volunteer control become more limited.

Volunteer corn from a parent strain that exhibits glyphosate tolerance might be controlled in a LibertyLink® crop with the use of glufosinate (Minnesota, 2009; Reddy, 2011). Alternatively, corn volunteers containing only the Pioneer 4114 Maize traits easily could be controlled by mechanical cultivation as well as readily available herbicides, including glyphosate, or other graminicides (Wozniak, 2002), provided that the Pioneer 4114 Maize or its progeny does not carry tolerance to these other herbicides (e.g., accidental admixture or intentional or unintentional crossing of tolerant varieties). As discussed in Subsection 2.4.2.2 – Corn as a Weed or Volunteer, herbicides recommended for control of volunteer corn in soybeans are the ACCase inhibitors and certain ALS inhibitors. The ACCase inhibitors include two families of herbicides, the AOPP ACCases (e.g., the "fops," such as Quizalofop, fenoxaprop, and diclofop) and the cyclohexanediones (e.g., the "dims," such as clethodim and sethoxydim) (Hager, 2009). Pioneer 4114 Maize is sensitive to the herbicides recommended for control to 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 Pioneer 4114 Maize and glyphosate tolerance, for example, would still be controllable by the ACCase inhibitors and certain ALS Inhibitors noted above (Hager, 2009).

The ISHRW has identified several instances of weeds in the United States which show resistance to ACCase inhibitors and other modes of action (Heap, 2012). Adherence to the Stewardship Strategy is expected to minimize the development of weeds containing traits with resistance to multiple herbicides (Owen et al., 2011). Although farmers may have to change their management strategies to adopt varieties stacked with the Pioneer 4114 Maize traits, these changes will not necessitate a major departure from well-established and broadly used agricultural protocols currently in use.

Based on these findings, USDA-APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to affect plants associated with the determination of nonregulated status of Pioneer 4114 Maize.

5.11 CUMULATIVE IMPACTS: SOIL MICROORGANISMS

A determination of nonregulated status of Pioneer 4114 Maize is not expected to result in changes to current corn cropping practices.

Stacked hybrids combining the traits of Pioneer 4114 Maize with nonregulated glyphosate-tolerant varieties would allow the application of glyphosate to Pioneer 4114 Maize in addition to glufosinate (Pioneer, 2012). As noted in Subsection 5.1 – Assumptions Used for the Cumulative

Impacts Analysis, the cultivation of corn hybrids presenting the traits of Pioneer 4114 Maize and glyphosate tolerance are already commercially available in the form of hybrids based on the 1507 x 59122 hybrid (Pioneer, 2012). No impacts to soil microorganisms have been reported associated with the commercial cultivation of this variety.

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 would 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 (Duke et al., 2012; USDA-FS, 2003). Glyphosate use has been identified as potentially causing increases in certain disease-causing microbes (Duke et al., 2012; Fernandez et al., 2009; Kremer, 2010). However, reported increases in infections from pathogenic soil fungi have been determined to be more closely related to reduced tillage and continuous cropping using herbicide-tolerant crops, rather than application of glyphosate (Duke et al., 2012; Fernandez et al., 2009).

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

5.12 CUMULATIVE IMPACTS: BIOLOGICAL DIVERSITY

A determination of nonregulated status for Pioneer 4114 Maize is not expected to result in changes in corn cultivation practices. Corn expressing the Cry proteins in Pioneer 4114 Maize has been cultivated commercially for many years. The commercial hybrid 1507 x 59122 Maize has been available in the market since 2006 (Pioneer, 2012). Glufosinate is approved for use on corn (Bayer, 2012); glyphosate-tolerant corn has been cultivated commercially since 1996 (see, http://www.aphis.usda.gov/biotechnology/not_reg.html). The glyphosate-tolerant varieties are already widely cultivated, based on the percentage of corn currently treated with glyphosate (noted in Subsection 2.2 – Agronomic Inputs as 66% of the acreage, ~57 million pounds) (USDA-NASS, 2011a, 2011b).

As noted in the introduction to this section, glyphosate is not an approved tank mix partner with glufosinate for weed control in corn (see, e.g., Bayer, 2012). When growers adopt a stacked hybrid and elect to use both herbicides, the herbicides are applied sequentially, in accordance with label instructions, as part of the grower’s weed management strategies (see, e.g., Monsanto, 2009). Tank mixes of glufosinate and glyphosate are in use for control of weeds in no-tillage weed control programs of certain crops. For example, glyphosate is a registered tank-mixture partner with glufosinate in the Liberty® cotton varieties (Koger et al., 2007). US-EPA’s review of pesticides takes into account potential non-target impacts. Total amounts of both herbicides applied to corn would be consistent with the label application rates. Pioneer has committed to develop an appropriate stewardship plan for corn varieties containing multiple herbicide tolerance events (Pioneer, 2012).

Based on these factors, USDA-APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to affect biodiversity.

5.13 CUMULATIVE IMPACTS: GENE MOVEMENT

5.13.1 Vertical Gene Flow

USDA-APHIS has considered the potential cumulative impacts of vertical gene flow associated with a new stacked variety. As noted in Subsection 4.4.5 – Gene Movement, the possibility of gene movement from the host plant into native or feral populations of *Zea* species or wild or weedy relatives of corn has been evaluated by the US-EPA and determined not to be a concern in the continental United States (US-EPA, 2010e).

USDA-APHIS has further considered vertical gene flow in its previous analysis in Subsection 4.2.3 – Organic Corn Farming and Specialty Corn Systems, and has determined that standard management methods are available to control pollen drift in order to manage vertical gene flow. 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 (Mallory-Smith and Sanchez-Olguin, 2011; Wozniak, 2002).

Additionally, USDA-APHIS has previously considered the factors limiting gene movement between corn varieties related to weediness. As noted in Subsection 4.4.5 – Gene Movement, neither GE nor non-GE corn cultivars form self-sustaining populations outside of cultivation because of limitations in seed dispersal, germination, and seasonal requirements (US-EPA, 2010e). As noted in the introduction to this section, there are several commercial hybrid varieties containing both glyphosate- and glufosinate-tolerant traits; the cultivation of these varieties has not been reported to require a change in practices used to reduce vertical gene movement.

There is no evidence to suggest that the stacking of the events conferring glyphosate tolerance in a Pioneer 4114 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 these findings, USDA-APHIS has not identified any cumulative impacts to vertical gene flow associated with potential stacking with a glyphosate tolerance event.

5.13.2 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 Pioneer 4114 Maize.

As discussed in Subsection 4.4.5.2 – Horizontal Gene Transfer, the movement of genes to unrelated species is highly unlikely. 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, 2012c). Horizontal gene transfer, resulting in the horizontal relocation of entire transgenes between unrelated species, including the regulatory portions of the DNA (those parts of the DNA which code for the production of the specific proteins in that relocated transgene), has been shown to occur in nature over very long timelines (Clarke, 2007; Stewart, 2008). There is no evidence to suggest that the stacking of the events conferring glyphosate tolerance in Pioneer 4114 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 tolerance event.

5.14 CUMULATIVE IMPACTS: HUMAN HEALTH

The potential human health effects from the cultivation of glyphosate-tolerant crops, with a corresponding analysis of the implications of the use of glyphosate, have been evaluated thoroughly in other EAs since the 1993 introduction of the first glyphosate-tolerant crop product. (See: http://www.aphis.usda.gov/biotechnology/not_reg.html.) Glyphosate has been widely used on corn since the first glyphosate-tolerant corn variety in 1996 was determined to be no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 (see Petition No. 96-317-01p, Monsanto's Glyphosate-tolerant and European Corn Borer-resistant Corn, at http://www.aphis.usda.gov/biotechnology/not_reg.html). The use of glyphosate herbicide does not appear to result in adverse effects on development, reproduction, or endocrine systems in humans and other mammals. Under present and expected use conditions, and when used in accordance with the US-EPA label, glyphosate does not pose a health risk to humans (US-EPA, 1993). US-EPA has established pesticide residue tolerances for glyphosate including concentration benchmarks for field corn for forage, grain, and stover (US-EPA, 1993, 2011a). Additionally, US-EPA has already considered registration issues in a stacked corn product expressing both the PAT and the EPSPS proteins in its analysis of the Genuity® SmartStax® product (see US-EPA, 2011c). As noted in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, these stacked products are already cultivated. USDA-APHIS assumes that applications of glyphosate to a stacked corn variety incorporating the Pioneer 4114 Maize traits will be conducted consistent with the label and consistent with the pesticide residue tolerances.

As discussed in Subsections 4.5.1 and 4.5.2 (Human Health and Worker Safety, respectively), Pioneer has determined that Pioneer 4114 Maize is the compositional equivalent of the conventional corn foundation varieties (e.g., 1507, 59122, and 1507 x 59122) (Pioneer, 2011b; USDA-APHIS, 2012c). Similar comparisons have been conducted by petitioners for all of the other nonregulated corn varieties with which Pioneer 4114 corn is likely to be stacked (see, e.g., APHIS PPRA and EA for the corn varieties presented on http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml). In each of these previous reviews, the US-FDA also has completed a consultation, including the most recent completed consultation for a CP4-EPSPS based glyphosate-tolerant corn presented by Stine Seed (see, e.g., US-FDA, 2012). In these consultations, the US-FDA notes that the presence of the EPSPS protein does not give rise to any food or feed concerns. Humans are already exposed to the EPSPS protein in these glyphosate-tolerant varieties. US-EPA has published an exemption from tolerance for the CP-4 EPSPS protein in all plants (US-EPA, 2007c) as well as tolerances for glyphosate residues (see US-EPA, 1980). It is highly unlikely that a conventional hybrid stack of Pioneer 4114 Maize with a glyphosate-tolerant variety would substantially change the composition of the resulting corn variety.

Based on these factors, no substantial cumulative impacts to human health related to the No Action Alternative or a determination of nonregulated status of Pioneer 4114 Maize are expected, and no cumulative impacts have been identified.

5.15 CUMULATIVE IMPACTS: WORKER SAFETY

As discussed in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, the cultivation of Pioneer 4114 Maize is limited to development as a foundation stock for the development of breeding pyramids or stacks with other herbicide-tolerant and insect-resistant corn events. As discussed in Subsection 5.2 – Cumulative Impacts: Areas and Acreage of Corn Production, cultivation of a stacked variety presenting tolerance to the two herbicides is not expected to increase the total acreage of corn production or the cultivation of other varieties of corn. Cumulative worker safety issues related to the continued use of US-EPA registered pesticides during conventional and GM corn production, including cultivation of hybrids should remain the same as the current condition.

The corn varieties with which Pioneer 4114 Maize is expected to be hybridized are already commercialized, and the herbicides and insecticidal properties associated with these products have already been evaluated and approved by USDA-APHIS, the US-FDA, and the US-EPA.

As discussed in Section 4.5 – Public Health, an indirect benefit to worker safety arises from the cultivation of Bt corn varieties, in the reductions of applications of insecticides (US-EPA, 2010a, 2010b, 2010f). As noted in Subsections 2.2.2 – Agronomic Practices, and 4.5.1 – Human Health, there has been a decline in the use of soil and foliar insecticides due, in part, to the adoption of Bt crops (Brookes et al., 2012). This trend is unlikely to change with the introduction of another corn hybrid combining the Pioneer 4114 Maize with a glyphosate-tolerant hybrid.

The potential effects from the cultivation of glyphosate-tolerant 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 glyphosate-tolerant crop product. (See: http://www.aphis.usda.gov/biotechnology/not_reg.html.) Glyphosate has been widely used on corn since the first glyphosate-tolerant corn variety in 1996 was determined to be no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 (see Petition No. 96-317-01p, Monsanto's Glyphosate-tolerant and European Corn Borer-resistant Corn, at http://www.aphis.usda.gov/biotechnology/not_reg.html). The use of glyphosate herbicide does not appear to result in adverse effects on development, reproduction, or endocrine systems in humans and other mammals (US-EPA, 1993). Under present and expected use conditions, and when used in accordance with the US-EPA label, glyphosate does not pose a health risk to humans, including workers (US-EPA, 1993).

Based on these factors, no substantial cumulative impacts to worker safety related to the No Action Alternative or a determination of nonregulated status of Pioneer 4114 Maize are expected.

5.16 CUMULATIVE IMPACTS: ANIMAL FEED

The potential animal feed and animal health effects from the cultivation of glyphosate-tolerant 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 glyphosate-tolerant crop product, and are summarized in Subsection 4.2.2 – Agronomic Practices (see: http://www.aphis.usda.gov/biotechnology/not_reg.html). 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 US-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, 2011a). USDA-APHIS assumes that applications of glyphosate to a stacked corn variety incorporating the Pioneer 4114 Maize traits will be conducted consistent with the label and consistent with the pesticide residue tolerances.

As discussed in Subsections 4.5.1 and 4.5.2 (Human Health and Worker Safety, respectively), Pioneer has determined that Pioneer 4114 Maize is the compositional equivalent of the conventional corn foundation varieties (e.g., 1507, 59122, and 1507 x 59122) (Pioneer, 2011b; USDA-APHIS, 2012c). Similar comparisons have been conducted by petitioners for all of the other nonregulated corn varieties with which Pioneer 4114 corn is likely to be stacked (see, e.g., APHIS PPRA and EA for the corn varieties presented on http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml). As noted in Subsection 5.14 – Cumulative Impacts: Human Health, in each of these previous reviews, the US-FDA also has completed a consultation, including the most recent completed consultation for a CP4-EPSPS based glyphosate-tolerant corn presented by Stine Seed (see, e.g., US-FDA, 2012). 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. US-EPA has published an exemption from tolerance for the CP-4 EPSPS protein in all plants (US-EPA, 2007c) as well as tolerances for glyphosate residues for corn and corn products used in animal feed (see US-EPA, 1980). It is highly unlikely that a conventional hybrid stack of Pioneer 4114 Maize with a glyphosate-tolerant variety 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 Pioneer 4114 Maize.

5.17 CUMULATIVE IMPACTS: DOMESTIC ECONOMIC ENVIRONMENT

Based on the information described in Subsection 4.7.1 – Domestic Economic Environment, USDA-APHIS concludes that a determination of nonregulated status of Pioneer 4114 Maize in itself will have no foreseeable adverse cumulative domestic economic effects.

As discussed in Subsection 4.2 – Agricultural Production of Corn, Pioneer intends to limit the cultivation of Pioneer 4114 Maize to use as a foundation breeding stock for developing stacked or pyramided hybrids, combining the Pioneer 4114 Maize traits with corn varieties no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. For the purposes of this cumulative impacts analysis, USDA-APHIS focuses its analysis on hybridization with a glyphosate-tolerant corn variety for the reasons described in Subsection 5.1 – Assumptions Used for Cumulative Impacts Analysis.

As discussed in Subsection 5.1 – Assumptions Used for the Cumulative Impacts Analysis, similar stacked varieties are already on the market. These varieties have the potential to improve grower management strategies for control of glyphosate-resistant weeds, and also improve grower economics. For example, a stacked hybrid combining both herbicide tolerance traits would allow a grower to apply herbicides with two different modes of action. This herbicide management strategy is anticipated to sustain the long-term viability of the glyphosate-tolerant cropping system and preserve the benefits it provides to growers, the agricultural industry, and society. The adoption of such a diverse weed management strategy, incorporating several herbicides with alternative modes of action, may cost more initially than the conventional single-herbicide approach, but these costs are offset by an increase in yields in those fields where the weed pressure has been reduced (Weirich et al., 2011). There also is an inherent reduction in grower costs associated with a reduction in frequency of herbicide applications and in the continued avoidance of tillage through careful herbicide applications.

The volume of herbicides applied to corn, and the chemical composition of those herbicides, may change as a result of such stacked varieties. As discussed in Section 2 – Affected Environment, in 2005, 31% of the corn acreage was treated with glyphosate, and glufosinate use has been less than 6% of the acreage. As discussed in Subsection 4.7.1.2 – Preferred Alternative: Domestic Economic Environment, to the extent that the planting of hybrids based on Pioneer 4114 Maize results in a substitution of glufosinate or glyphosate for other herbicide applications to manage hard to control weeds, those who have reduced or eliminated these multiple herbicide applications or avoided a reversion to tillage to control these weeds might experience reduced input costs and a commensurate increase in net income.

The cultivation of a stacked hybrid containing the traits from Pioneer 4114 Maize and tolerance to glyphosate is not likely to impact grower demands for stacked products. Corn containing herbicide-tolerant and insect-resistant traits is already cultivated on 52% of the United States acreage, with single trait corn only cultivated on 36% (21% herbicide-tolerant and 15% insect-resistant) (USDA-NASS, 2012b). Additionally, corn containing the traits from the Pioneer 4114 Maize foundation stock, 1507 and 59122, already are cultivated on over 16% of domestic corn acreage.

Based on these factors, no net negative cumulative impacts on domestic economics have been identified associated with the cultivation of Pioneer 4114 Maize. If growers adopt the stacked variety and take advantage of the weed management strategy incorporating herbicides with different modes of action to control glyphosate-resistant weeds, local farm economics may improve.

5.18 CUMULATIVE IMPACTS: TRADE ECONOMIC ENVIRONMENT

Current and historic economic evidence indicates that herbicide-tolerant corn technology has the potential to increase domestic production at lower cost. This trend of lower production costs could enhance international corn trade by making U.S. corn and corn products more competitive in the global market.

As noted in Subsection 4.7.2.2 – Preferred Alternative: Trade Economic Environment, Pioneer intends to submit applications to several international agencies prior to initiating commercial launch of the Pioneer 4114 Maize products (Pioneer, 2011b). Commercial launch of a stacked hybrid would be premised on the approval of the individual components of the hybrid, such as in Argentina, where the review focuses only on new aspects presented by the stack (Stein and Rodrigues-Cerezo, 2009), although other countries, e.g., Brazil and the EU, currently require specific approval for stacked hybrids (James, 2011; Stein and Rodrigues-Cerezo, 2009). As of 2011, 26% of the total global lands committed to agriculture were cultivated with stacked varieties (James, 2011).

As hybrids based on Pioneer 4114 Maize are expected to be brought to market quicker than the conventional hybrids based on the 1507 x 59122, there is an anticipated lower cost associated with that efficiency (Pioneer, 2011b, 2012). A reduction in costs for domestic growers associated with the more rapid introduction of hybrids based on this stable stack may make United States producers more competitive in the global market.

Based on the information described in Section 4 – Environmental Consequences, USDA-APHIS has determined that there are no past, present, or reasonable foreseeable actions that in aggregate with effects of the proposed action would negatively impact the trade economic environment.

6 THREATENED AND ENDANGERED SPECIES

6.1 USDA-APHIS' APPROACH TO EVALUATION OF POTENTIAL IMPACTS TO THREATENED AND ENDANGERED SPECIES

Congress passed the Endangered Species Act (ESA) of 1973, as amended, to prevent extinctions facing many species of fish, wildlife, and plants. The purpose of the ESA is to conserve endangered and threatened species and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the U.S. Fish and Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS); other Federal, State, and local agencies; Tribes; non-governmental organizations; and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal list of threatened and endangered wildlife and plants.

A species is added to the list when it is determined by the USFWS/NMFS to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; and
- The natural or manmade factors affecting its survival.

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

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or critical habitat. To facilitate USDA-APHIS' ESA consultation process, USDA-APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to USDA-APHIS's regulatory authority and effects analysis for petitions for nonregulated status, and developed a process for conducting an effects determination consistent with the Plant Protection Act of 2000 (Title IV of Public Law 106-224). This process is described in a decision tree document, which is presented in Appendix C. USDA-APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

USDA-APHIS' regulatory authority over GE organisms under the Plant Protection Act of 2000 is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which USDA-APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR §340.1). USDA-APHIS does not have authority to regulate the use of any herbicide, including glufosinate. After completing a PPRA, if USDA-

APHIS determines that Pioneer 4114 Maize does not pose a plant pest risk, then Pioneer 4114 Maize would no longer be subject to the plant pest provisions of the Plant Protection Act of 2000 or to the regulatory requirements of 7 CFR Part 340, and therefore, USDA-APHIS must reach a determination that the article is no longer regulated. As part of its EA analysis, USDA-APHIS is analyzing the potential effects of Pioneer 4114 Maize on the environment including any potential effects to threatened and endangered species and critical habitat. As part of this process, USDA-APHIS thoroughly reviews the genetically engineered product information and data related to the organism (generally a plant species, but also may be other genetically engineered organisms). For each transgene/transgenic plant, USDA-APHIS considers the following:

- Reviews 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;
- Location(s) of the new transgene and its products (if any) produced in the plant and their quantity;
- Reviews of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Concentrations of any known plant toxicants, if applicable;
- Sexual compatibility of the transgenic plant 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.

6.2 POTENTIAL EFFECTS OF THE CULTIVATION OF PIONEER 4114 MAIZE ON TES

In following this review process, USDA-APHIS, as described below, has evaluated the potential effects that a determination of nonregulated status of Pioneer 4114 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.

Pioneer's studies demonstrate that agronomic characteristics and cultivation practices required for Pioneer 4114 Maize are essentially indistinguishable from practices used to grow other corn varieties, including other herbicide-tolerant varieties (Pioneer, 2011b; USDA-APHIS, 2012c).

Pioneer 4114 Maize will be cultivated only as a foundation seed stock for the development of other hybrids, and hybrids based on Pioneer 4114 Maize are expected to replace other varieties of corn currently cultivated (Pioneer, 2011b, 2012). As noted in Subsection 2.2 – Agricultural Production of Corn, corn is cultivated commercially in each of the continental United States. USDA-APHIS considered the potential for Pioneer 4114 Maize to extend the range of corn production and also the potential to extend agricultural production into new natural areas. As discussed in Subsection 4.2 – Agricultural Production of Corn, USDA-APHIS has determined that Pioneer 4114 Maize and hybrids based on this variety are unlikely to extend the range of corn production. Moreover, New acreage is not expected to be developed to accommodate the cultivation of hybrids based on Pioneer 4114 Maize (Pioneer, 2011b).

Accordingly, the issues discussed herein focus on the potential environmental consequences of the determination of nonregulated status of Pioneer 4114 Maize on TES species and critical habitat in the areas where corn is grown.

Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, USDA-APHIS obtained and 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 4/15/2011 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp).

USDA-APHIS focused its TES effects analysis on the implications of exposure to the Cry and PAT proteins in corn, the interaction between TES and the Pioneer 4114 Maize plant including potential for sexual compatibility and ability to serve as a host for a TES (Subsection 6.2.1 – Potential Effects of Pioneer 4114 Maize on TES); and as part of its NEPA analysis considered the potential impacts of the use of glufosinate herbicide to non-target organisms and the natural environment (Subsection 6.2.2 – Potential Effects of the Use of Glufosinate Herbicides).

6.2.1 Potential Effects of Pioneer 4114 Maize on TES

After reviewing the list of threatened and endangered plant species in the States where corn is grown, USDA-APHIS determined that Pioneer 4114 Maize would not be sexually compatible with any listed TES 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*.

USDA-APHIS considered the possibility that Pioneer 4114 Maize could serve as a host plant for a TES species. A review of the species list reveals that there are no members of the genus *Zea* that serve as a host plant for any TES.

Pioneer has presented data evaluating the agronomic and morphological characteristics of Pioneer 4114 Maize, including compositional and nutritional characteristics, safety evaluations and toxicity tests, comparing the product to a conventional hybrid corn variety (Pioneer, 2011b). Compositional elements compared included moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and anti-nutrients (Pioneer, 2011b). Allergenicity and toxicity studies included bioinformatics analyses, digestibility and acute protein toxicity studies (Pioneer, 2011b). No statistically meaningful differences were observed when comparing Pioneer 4114 Maize with the near isoline variety (Pioneer, 2011b; USDA-APHIS, 2012c). Pioneer 4114 Maize does not appear to present any changes in agronomic inputs, morphological characteristics or composition that would affect TES.

The Cry proteins in Pioneer 4114 Maize are derived from Bt, subsp. *aizawai* (Cry1F) and Bt strain PS149B1 (Cry 34Ab1 and Cry35Ab1) (USDA-APHIS, 2012c). The modifying PAT enzyme, encoded by the *pat* gene, is derived from *S. viridochromogenes* (Pioneer, 2011b). Both *B. thuringiensis* and *S. viridochromogenes* are naturally occurring soil bacteria and are not pathogenic. Animals are regularly exposed to these organisms and their components without adverse consequences (Hérouet et al., 2005; Pioneer, 2011b; US-EPA, 2010a, 2010b, 2010c, 2012d).

As noted throughout this document, the traits associated with Pioneer 4114 Maize are nonregulated and have been cultivated commercially for many years. The Cry1F protein and its associated genetic elements are identical to those in 1507 Maize, which had a determination of nonregulated status by USDA, registered by the US-EPA, and reviewed by the US-FDA in 2001 (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2001; USDA-APHIS, 2001). The binary Cry proteins, Cry34Ab1 and Cry35Ab1, and their associated genetic elements are identical to those in 59122 Maize, which was reviewed by US-FDA in 2004, had a determination of nonregulated status by USDA in 2005, and registered by US-EPA since 2005 (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2004; USDA-APHIS, 2005). Maize expressing the PAT protein has had a nonregulated status since 1995 and cultivated commercially in the United States since 1996 (USDA-APHIS, 1995). The safety of the introduced proteins in Pioneer 4114 Maize has been evaluated previously by USDA-APHIS, the US-FDA and the US-EPA, and there is a history of safe use and exposure. There are no reports of potential impacts to TES or critical habitat associated with exposure to these proteins.

As discussed in Subsection 2.4.3 – Soil Microorganisms, there is little evidence that soil microorganisms or soil ecosystem level processes are negatively impacted by Bt proteins in soil or by the cultivation of GE crops (Icoz and Stotzky, 2008). Because of concerns of the potential impacts of cultivating GE crops with Bt proteins on soil communities, the decomposition rates of GE crops with Bt proteins versus non-GE crops have been studied (Icoz and Stotzky, 2008). Studies conducted under field conditions show the decomposition rates of Bt cotton and Bt corn did not differ from the decomposition rates of non-Bt cotton and corn (Lachnicht et al., 2004; Tarkalson et al., 2007).

Concerns have been raised regarding the potential exposure of non-target organisms to the Cry proteins. Pioneer has presented information on laboratory studies testing the potential impacts to representative species of interest and surrogate species (Pioneer, 2011b). Surrogate species are typically selected because they are amenable to the laboratory setting; are environmentally sensitive and representative of the agroecosystem; and can be used to predict potential impacts on related non-target organisms, including beneficial, threatened, or endangered species (Romeis et al., 2011). Surrogate species also are used because testing on TES is not permitted.

The insecticidal Cry1F and Cry34/35Ab1 proteins have been assessed by laboratory studies to evaluate the specificity of these proteins to target insects. In general, only insect species within a given taxonomic order and closely related families are susceptible to a given insecticidal protein (Pioneer, 2011b). Cry1F is US-EPA labeled for protection against lepidopterans (butterflies and moths) and coleopterans (beetles). Target species of Lepidoptera include the European corn borer (*O. nubilalis*), fall armyworm (*Spodoptera frugiperda*), corn earworm (*Helicoverpa zea*), western bean cut worm (*Striacosta albicosta (Smith)*), black cutworm (*Agrotis ipsilon*), lesser corn stalk borer (*Elasmopalpus lignosellus*), southwestern corn borer (*Diatraea grandiosella*), and sugarcane borer (*Diatraea saccharalis*) (US-EPA, 2010b). Cry34/35Ab1 is US-EPA labeled for protection against Coleoptera, specifically northern corn rootworm (*Diabrotica barberi*), western corn rootworm (*D. virgifera virgifera*), and Mexican corn rootworm (*D. virgifera zeae*)

(US-EPA, 2010a). Cry34/35Ab1 also has activity for southern corn rootworm (*Diabrotica undecimpunctata howardi*) as determined by use in bioassays (US-EPA, 2010a).

Pioneer has presented the results of laboratory assays in which springtail and earthworms were exposed to the Cry proteins (Pioneer, 2011b). None of the soil dwelling species tested showed substantial adverse effects from the proteins and the margins of exposure were greater than 22-fold (Pioneer, 2011b). Additionally, soil dwelling non-target organisms are unlikely to be exposed to concentrations of the Cry1F and Cry34/35Ab1 proteins in soil, as realistic environmental exposures are expected to be substantially lower based on protein degradation and lack of accumulation in soil (Pioneer, 2011b)

Pioneer also has presented the results of laboratory assays in which representatives of coleopteran and lepidopteran species, targeted insect orders, as well as representatives of other insect orders not considered targets, were exposed to purified Cry proteins (Pioneer, 2011b). The representative coleopteran species were the Ladybird beetle (*H. convergens* and *C. maculata*), the representative lepidopteran species was the Monarch butterfly (*D. plexippus*), and insects representing other orders were parasitic wasps (*N. vitripennis*), the green lacewing (*C. carnea*), and the honeybee (*A. mellifera*) (Pioneer, 2011b). In addition, a representative of a non-target invertebrate order was tested, the water flea (*Daphnia magna*) (Pioneer, 2011b). None of the tested species showed significant adverse effects from exposure to the proteins (Pioneer, 2011b).

Previous assessments of the Cry proteins in 1507 and 59122 Maize have found no impacts to TES (US-EPA, 2010a, 2010b; USDA-APHIS, 2001, 2005). As of August 2012, 62 insect species are listed on the USFWS website as TES (US-FWS, 2012). Twenty-two of these insects are Lepidoptera and 17 are Coleoptera, with the remaining representing insects of other orders. With the exception of two coleopteran species, the Salt Creek Tiger Beetle (*Cicindela nevadica lincolniana*) (US-FWS, 2010, 2011b) and the Casey's June Beetle (*Dinacoma caseyi*) (US-FWS, 2011a), all of the species of Lepidoptera and Coleoptera currently listed were added prior to the granting of nonregulated status of 1507 and 59122 Maize. Of the two newly listed species, only the Salt Creek tiger beetle, added to the TES list in 2005 (US-FWS, 2010, 2011b), is found in the Corn Belt. This beetle is found in Nebraska (Lancaster and Saunders counties), the third largest state for maize cultivation (US-FWS, 2010; USDA-NASS, 2012b). However, the beetle's critical habitat has been characterized as non-vegetated stream banks or edges that are in saline or freshwater wetlands and the beetles prefer to be within a few meters of these. In addition, the Salt Creek Beetle is a member of the Carabidae beetle family, which is unrelated to the corn rootworm family, the Chrysomelidae. Therefore, it is unlikely that the Salt Creek tiger beetle will be exposed to the Cry34/35Ab1 protein from 4114 Maize or will be impacted due to the specificity of the Cry34/35Ab1 protein to corn rootworm species.

The Casey's June beetle is found only in one area in the United States near Palm Springs, California (US-FWS, 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-FWS, 2011a). Although corn is grown in California, it is grown in counties farther north near San Francisco (USDA-NASS, 2012b). Based on preferred habitat, it is highly unlikely that these beetles will be exposed to the Cry34/35Abl protein from 4114 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 subject protein (Cry34/35Abl protein) would take place (US-EPA, 2010a) due to the lack of exposure and geographical and habitat limitations. These other coleopteran species are located in non-corn production areas and/or their habitat does not encompass agricultural areas.

For 1507 Maize, USDA considered the impact of the Cry1F protein on two lepidopteran species, the Karner blue butterfly (*Lycaeides melissa samuelis*) and Mitchell's satyr butterfly (*Neonympha mitchellii*) (USDA-APHIS, 2001). USDA concluded that both species would not be expected to be present in or close to maize fields; therefore it is unlikely there would be any impact of 1507 Maize cultivation (USDA-APHIS, 2001). For 59122 Maize, USDA considered the impact on one primary threatened and endangered coleopteran species, the American burying beetle, *Nicrophorus americanus* (USDA-APHIS, 2005). Habitats in Nebraska where these beetles have been recently found consist of grassland prairie, forest edge and scrubland. From review of preferred habitats, this beetle is unlikely to be found in active maize fields and therefore would not be exposed substantially to the Cry34/35Ab1 protein from 4114 Maize (USDA-APHIS, 2005).

For other lepidopteran- and corn rootworm-resistant maize events, US-EPA has made similar conclusions for the Karner blue butterfly and the American burying beetle and has not identified any new TES that would be impacted by cultivation (US-EPA, 2009, 2010a, 2010b). Furthermore, US-EPA examined the habitats of the other threatened and endangered insect species in the orders 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, 2010a, 2010b).

Similar to the conclusions for 1507 and 59122 Maize, it is unlikely that threatened and endangered species such as the Karner blue and Mitchell's satyr butterflies and the American burying beetle, Casey's June beetle and the Salt Creek tiger beetles would be affected by 4114 Maize cultivation. Based on the constituent elements required in their habitat, Cry protein target insect specificity, and the lack of habitat overlap with regions of maize cultivation, cultivation of Pioneer 4114 Maize will have no effect on any listed threatened and endangered insects.

USDA-APHIS also considered the potential for exposure to the PAT protein. The *pat* gene expressing the PAT protein in Pioneer 4114 Maize was derived from *S. viridochromogenes*, a gram-positive soil bacterium (Pioneer, 2011b). The PAT protein is identical to the protein found in many commercially-available crops no longer subject to the plant pest provisions of the Plant Protection Act of 2000 and 7 CFR Part 340, including 1507 and 59122 Maize (USDA-APHIS, 2001, 2005). Following a determination of nonregulated status in 1995, maize expressing the *pat* gene has been cultivated commercially in the United States since 1996 (USDA-APHIS, 1995). As with the discussion of the Cry proteins above, the PAT protein and its associated genetic elements are identical to those in 1507 Maize, which had a determination of nonregulated status by USDA, registered by the EPA, and reviewed by the US-FDA in 2001 (Pioneer, 2011b; US-EPA, 2010f; US-FDA, 2001; USDA-APHIS, 2001). The same PAT protein is present in 59122 Maize, which was reviewed by US-FDA in 2004, had a determination of nonregulated status by USDA in 2005, and registered by US-EPA since 2005 (Pioneer, 2011b; US-EPA, 2010f; US-

FDA, 2004; USDA-APHIS, 2005). The US-EPA has approved a tolerance exemption for the PAT protein and the genetic material necessary for its production in all plants (US-EPA, 2007a). No impacts to humans or animals have been identified associated with exposure to the *pat* gene or the PAT protein.

The environmental safety of the PAT proteins has been extensively reviewed in international scientific, peer-reviewed journals (Hérouet et al., 2005). The PAT protein expressed in GM crops has been consumed by humans and animals since 1995 and have exhibited no significant adverse effects. The PAT protein mode of action is specific to the breakdown of ammonia in plant tissues. Because animals lack this enzymatic pathway (Hérouet et al., 2005), and there is no mechanism to transfer this gene to unrelated plant species, USDA-APHIS limits its analysis of the implications of exposure to the PAT protein to the potential for gene movement to related TES corn species. This analysis also is relevant to considerations for the movement of the Cry proteins.

As discussed in Gene Movement (Subsections 2.4.5 and 4.4.5), the potential for gene movement between Pioneer 4114 Maize and related corn species is limited (Pioneer, 2011b). As discussed in Subsection 2.1 – Corn Background Information, there is a rare, sparsely dispersed feral population of teosinte, a relative of *Z. mays*, reported in Florida (USDA-APHIS, 2012c); however, this plant is not listed as a TES. 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, 2012c). None of the relatives of corn are Federally listed (or proposed) as endangered or threatened species (US-FWS, 2012). The US-EPA has concluded that there is no substantial risk for gene capture and expression of the Cry proteins in weedy or wild relatives of corn in the United States (US-EPA, 2010e). Accordingly, a determination of nonregulation of Pioneer 4114 Maize will not result in the movement of the PAT or Cry proteins to endangered or threatened species related to corn.

Pioneer 4114 Maize does not present a potential as a weed or the potential to displace a TES. The agronomic and morphologic characteristics data provided by Pioneer were used in the USDA-APHIS analysis of the weediness potential for Pioneer 4114 Maize, and evaluated for the potential to impact TES. Agronomic studies conducted by Pioneer tested the hypothesis that the weediness potential of Pioneer 4114 Maize is unchanged with respect to conventional corn (Pioneer, 2011b). No differences were detected between Pioneer 4114 Maize and nontransgenic near-isoline corn in growth, reproduction, or interactions with pests and diseases, other than the intended effect of herbicide tolerance (USDA-APHIS, 2012c). 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, 2012c). Based on the agronomic field data and literature survey on corn weediness potential, Pioneer 4114 Maize is unlikely to affect TES as a troublesome or invasive weed (Pioneer, 2011b; USDA-APHIS, 2012c).

In addition to evaluating Pioneer's comparisons of Pioneer 4114 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 discussed above in Animal and Plant Communities (Subsections 4.4.1 and 4.4.2, respectively) and Public Health (Subsection 4.5), Pioneer has submitted food and feed safety and nutritional assessments for Pioneer 4114 Maize to the US-FDA. Exemptions from pesticide residue tolerance already exist for the Cry and PAT proteins (US-EPA, 2007a).

After reviewing the possible effects of the nonregulation of Pioneer 4114 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 Pioneer 4114 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, 2010e).

Based on these factors, USDA-APHIS has concluded that the determination of nonregulated status of Pioneer 4114 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 concurrences of the USFWS or NMFS are not required.

6.2.2 Potential Effects of the Use of Glufosinate Herbicides

USDA-APHIS met with USFWS officials on June 15, 2011 to discuss whether USDA-APHIS has any obligations under the ESA regarding analyzing the impacts of herbicide use associated with all GE crops on TES. As a result of these joint discussions, USFWS and USDA-APHIS have agreed that it is not necessary for USDA-APHIS to perform an ESA effects analysis on herbicide use associated with GE crops currently planted because US-EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under the FIFRA. USDA-APHIS has no statutory authority to authorize or regulate the use of glufosinate, or any other herbicide, by corn growers. Under USDA-APHIS' current Part 340 regulations, USDA-APHIS only has the authority to regulate Pioneer 4114 Maize or any GE organism as long as USDA-APHIS believes it may pose a plant pest risk. For GE organisms, USDA-APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms. Nevertheless, USDA-APHIS is aware that there may be potential environmental impacts resulting from the use of glufosinate on Pioneer 4114 Maize, including potential impacts on TES and critical habitat, based on assessments provided to it by the US-EPA and as available in the peer-reviewed scientific literature.

The following materials provide an overview of the US-EPA's Endangered Species Protection Program (ESPP) and TES Evaluation Process, and a summary of the available information of potential environmental impacts resulting from glufosinate use on Pioneer 4114 Maize.

6.2.2.1 EPA Endangered Species Protection Program (ESPP)

In 1988, Congress enacted Public Law 100-478 (October 7, 1988) to in part address the relationship between ESA and US-EPA's pesticide labeling program (Section 1010), which required US-EPA to conduct a study, and report to Congress, on ways to implement US-EPA's endangered species pesticide labeling program in a manner that both complies with ESA and allows people to continue production of agricultural food and fiber. This law provided a clear sense that Congress wanted US-EPA to fulfill its obligation to conserve listed species and at the same time consider the needs of agriculture and other pesticide users (70 FR 211 2005-11-02).

In 1988 US-EPA established the ESPP to meet its obligations under the ESA. US-EPA ESPP Web site[29] describes the US-EPA assessment process for endangered species. Some of the elements of that process, reported on the Web site, are summarized below. The goal of US-EPA's ESPP is to carry out its responsibilities under the FIFRA in compliance with the ESA, without placing unnecessary burden on agriculture and other pesticide users consistent with Congress' intent. US-EPA is responsible for reviewing pesticide information and data to determine whether a pesticide product may be registered for a particular use including those uses associated with the approval of biotechnology products. As part of that determination, the Agency assesses whether listed endangered or threatened species or their designated critical habitat may be affected by use of the pesticide product. All pesticide products that US-EPA determines "may affect" a listed species or its designated critical habitat may be subject to the ESPP. If limitations on pesticide use are necessary to protect listed species in areas where a pesticide may be used, the information is relayed through Endangered Species Protection Bulletins. Bulletins identify the species of concern and the pesticide active ingredient that may affect the listed species. They also provide a description of the protection measures necessary to protect the species, and contain a county-level map showing the geographic area(s) associated with the protection measures, depending on the susceptibility of the species. Bulletins are enforceable as part of the product label (http://www.epa.gov/oppfead1/endanger/basic-info.htm; last accessed on August 23, 2012 and last updated by US-EPA on May 9, 2012).

6.2.2.2 EPA TES Evaluation Process

EPA evaluates listed species and their critical habitat concerns within the context of pesticide registration and registration review so that when a decision is made, it fully addresses issues relative to listed species protection. If a risk assessment determines that use limitations are necessary to ensure that legal use of a pesticide will not harm listed species or their critical habitat, US-EPA may either change the terms of the pesticide registration or establish geographically-specific pesticide use limitations (http://www.epa.gov/oppfead1/endanger/basic-info.htm).

EPA's review of the pesticide and its registration decision is independent of USDA-APHIS' review and regulatory decisions under 7 CFR 340. US-EPA does not require data or analyses

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[29] http://www.epa.gov/espp/

conducted by USDA-APHIS to complete its reviews. US-EPA evaluates extensive toxicity, ecological effects data, and environmental fate, transport and behavior data, most of which is required under FIFRA data requirements, to assess and determine how a pesticide will move through and break down in the environment. Risks to various taxa, e.g., birds, fish, invertebrates, plants and mammals are routinely assessed and used in US-EPA's determinations of whether a pesticide may be licensed for use in the United States.

EPA's core pesticide risk assessment and regulatory processes ensure that protections are in place for all populations of non-target species, not just threatened and endangered species. US-EPA has developed a comprehensive risk assessment process modeled after, and consistent with, US-EPA's numerous guidelines for EAs (http://www.epa.gov/oppfead1/endanger/consultation/ecorisk-overview.pdf). The result of an assessment, which may go through several refinements, is to determine whether the potential effects of a pesticide's registration to a listed species will result in either a "no effect" or "may affect" determination. US-EPA consults on determinations that "may affect" a listed species or adversely modify its critical habitat (http://www.epa.gov/oppfead1/endanger). As a result of either an assessment or consultation, US-EPA may require changes to the use conditions specified on the label of the product. When such changes are necessary only in specific geographic areas rather than nationwide to ensure protection of the listed species, US-EPA implements these changes through geographically-specific Endangered Species Protection Bulletins, otherwise, these changes are applied to the label for all uses of the pesticide.

6.2.2.3 Ecological Risks of Glufosinate

The US-EPA first registered glufosinate ammonium in 2000 as a non-selective foliar herbicide for use on a wide range of crops, including cotton (US-EPA, 2008a, 2008b). In 2008, the US-EPA announced that it was undertaking a registration review of this product, and has published a final work plan for this process (US-EPA, 2008a). Assessments of the toxicity of glufosinate on Federally-protected species conducted by US-EPA indicated a relatively low risk to animals but high risk to plants (US-EPA, 2008b). On an acute exposure basis, glufosinate is considered practically nontoxic to birds, mammals, and insects; slightly toxic to freshwater fish, slightly toxic to estuarine/marine fish; moderately toxic to freshwater and estuarine/marine invertebrates; and toxic to terrestrial and aquatic plants (US-EPA, 2008b). Non-target exposure for plants typically results from runoff or drift. Although animals also can be affected from runoff and drift, ingestion is often the most important exposure pathway.

The US-EPA's Final Work Plan for Registration Review for glufosinate (US-EPA, 2008a) states that:

> The planned ecological risk assessment [ERA] will allow the Agency to determine whether glufosinate-ammonium use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitat. If the assessment indicates that glufosinate-ammonium "may affect" a listed species or its designated critical habitat, the assessment will be refined. The refined assessment will allow the Agency to determine whether the use of glufosinate-ammonium is "likely to adversely affect" the species or critical habitat or "not likely to adversely affect" the species or critical habitat.

> When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Services), as appropriate.

Submittals to this analysis can be found at www.Regulations.gov under docket designation EPA-HQ-OPP-2008-0190.
There are legal precautions in place to reduce the possibility of exposure and adverse impacts to TES from application of glufosinate to Pioneer 4114 Maize. These precautions include the US-EPA pesticide label restrictions and best practice guidance provided by the herbicide manufacturer (see, e.g., Bayer, 2012). Adherence to these label use restrictions by the pesticide applicator will ensure that the use of the herbicide will not adversely affect TES or critical habitat. Labeled uses of glufosinate are approved pending the outcome of the US-EPA's ecological risk analysis. No changes to the US-EPA approved label applications of glufosinate are proposed for cultivation of Pioneer 4114 Maize.

EPA has imposed specific label use restrictions for glufosinate ammonium use when applied with aerial equipment including "The product should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for TES, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas)" (Bayer, 2012)

To facilitate pesticide applicators adherence to US-EPA label use restrictions for glufosinate ammonium, the label for glufosinate provides specific instructions for managing spray drift and cautions pertaining to applications around water so as to minimize potential effects to non-target organisms (Bayer, 2012). The label prohibits applications in conditions or locations where adverse impact on Federally listed endangered/threatened plants or aquatic species is likely (Bayer, 2012). Bayer also provides a technical and trade manual with additional guidance on the proper storage, handling and use of the product (Bayer, 2012).

These US-EPA label use restrictions and "best practice" guidance reduce the possibility of exposure and adverse impacts to TES from glufosinate application to Pioneer 4114 Maize varieties. US-EPA has considered potential impacts to TES as part of their registration and labeling process for glufosinate; and adherence to US-EPA label use restrictions by the pesticide applicator will ensure that the use of glufosinate will not adversely affect TES or critical habitat. As discussed previously, 1507 and 59122 Maize varieties also are tolerant to glufosinate. These varieties, and the commercial hybrid 1507 x 59122, have been cultivated commercially for many years, with approximately 16% of the corn acreage in 2011 cultivated in these varieties (Pioneer, 2012). USDA-APHIS assumes that some of the growers cultivating these varieties may have included the application of glufosinate to these acres. The US-EPA has not reported any impacts to TES from such use of glufosinate.

Pioneer has announced its intention to market Pioneer 4114 Maize in other stacked or pyramided varieties by combining this trait via conventional hybridization techniques with other nonregulated varieties (Pioneer, 2011b). The stacked variety discussed in the cumulative impacts analysis will combine the Pioneer 4114 Maize variety with a glyphosate-tolerant variety, providing the grower with the option to combine several herbicides with different modes of action for control of weeds. The implications of the use of glyphosate on TES has been addressed in numerous other USDA-APHIS EAs for products containing traits tolerant to this herbicide. A list of the glyphosate-tolerant products reviewed and granted nonregulated status by USDA-APHIS can be found at http://www.aphis.usda.gov/biotechnology/not_reg.html. The label use restrictions and best practices in place for the use of glyphosate are intended to reduce the possibility of exposure of TES to this herbicide.

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

7.1 EXECUTIVE ORDERS WITH DOMESTIC IMPLICATIONS

The following two 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 effects.

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

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

Available mammalian toxicity data associated with the Cry and PAT proteins establishes the safety of Pioneer 4114 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.

Human toxicity also has been evaluated thoroughly by the US-EPA in its development of pesticide labels for glufosinate (Bayer, 2012). 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 US-EPA herbicide use precautions and restrictions. As discussed in Subsection 4.5 – Public Health, the potential use of glufosinate on Pioneer 4114 Maize at the proposed application rates would be no more than rates currently approved by the US-EPA and should not to have adverse impacts to human health when used in accordance with label instructions. It is expected that US-EPA would monitor the use of Pioneer 4114 Maize to determine impacts on agricultural practices, such as chemical use, as they have done previously for herbicide-tolerant products.

As discussed in Subsection 4.2 – Agricultural Production of Corn the cultivation of GE corn varieties with herbicide-tolerant traits no longer subject to the regulatory requirements of 7 CFR

Part 340 or the plant pest provisions of the Plant Protection Act of 2000 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. The determination of nonregulated status of this variety provides growers with alternative herbicide options with different modes of action. As discussed in Subsections 2.1 – Corn Background Information and 4.2 – Agricultural Production of Corn, the herbicide glufosinate is already labeled for use in corn. However, capture of a certain market segment by a GE crop does not automatically result in a corresponding application of the agronomic inputs associated with the GE event. This is specifically evidenced in the case of the glufosinate-tolerant corn. Market segment data would suggest that glufosinate ammonium is already widely used in corn; in 2010, approximately 16% of the total corn acreage in the United States was planted with corn varieties tolerant to glufosinate. However, the use of glufosinate on total corn acres has remained stable and low over the past decade (2% - 6% of the total U.S. corn acres) (GfK Kynetec, 2010; Pioneer, 2011b, 2012).

The US-EPA also has considered human health in its review of the Cry proteins under the PIPs analysis under FIFRA (see US-EPA, 1998, 2010a, 2010b) and the determination of exemptions from tolerance for the PAT protein and the Cry proteins under FFDCA (see US-EPA, 2007a).

Based on these factors, the determination of nonregulated status of Pioneer 4114 Maize is not expected to have a disproportionate adverse effect on minorities, low income populations, or children.

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

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

Corn is not listed in the 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 herbicide-tolerant 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, Pioneer 4114 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, 2012c).

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 effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Data submitted by the applicant has shown no substantial difference in compositional and nutritional quality of Pioneer 4114 Maize compared with other GE corn or non-GE corn, apart from the presence of the Cry and PAT proteins. As previously discussed, the protein constituents expressed in Pioneer 4114 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 Pioneer 4114 Maize and its products.

The US-EPA has considered toxicity of glufosinate to birds in its registration review (US-EPA, 2008a). Acute and chronic risk quotients for birds were determined to slightly exceed the levels of concern; however, this finding was based on the highest tested dose (US-EPA, 2008a). In tests of acute and chronic exposure, the US-EPA found that glufosinate was practically non-toxic to birds (US-EPA, 2008a).

Based on these factors, it is unlikely that the determination of nonregulated status of Pioneer 4114 Maize will have a negative effect on migratory bird populations.

7.2 INTERNATIONAL IMPLICATIONS

EO 12114 (US-NARA, 2010), "Environmental Effects Abroad of Major Federal Actions" requires Federal officials to take into consideration any potential environmental effects outside the 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 Pioneer 4114 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 Pioneer 4114 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, United States 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 United States 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.

Pioneer has stated that regulatory submissions will be made in key United States maize export markets, including Canada, Japan, Mexico, Taiwan, South Korea and China (Pioneer, 2011b). Pioneer further notes that full commercial launch of any maize products containing Pioneer 4114

Maize will occur only after obtaining all necessary authorizations in the United States and key import countries with functioning regulatory processes (Pioneer, 2012).

7.3 COMPLIANCE WITH CLEAN WATER ACT AND CLEAN AIR ACT

This EA evaluated the potential changes in corn production due to a determination of nonregulated status of Pioneer 4114 Maize. Cultivation of Pioneer 4114 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 Pioneer 4114 Maize compared with current corn production. Also, there is no expected change in air quality associated with the cultivation of Pioneer 4114 Maize.

Based on this review, USDA-APHIS concludes that the cultivation of Pioneer 4114 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 Pioneer 4114 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.

Pioneer has presented results of agronomic field trials for Pioneer 4114 Maize. The results of these field trials demonstrate that there are no differences in agronomic practices between Pioneer 4114 Maize and non-GE hybrids. The common agricultural practices that would be carried out in the cultivation of Pioneer 4114 Maize are not expected to deviate from current practices, nor will the use of US-EPA registered pesticides. The product is expected to be deployed on agricultural land currently suitable for production of corn and replace existing varieties, and is not expected to increase the acreage of corn production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of Pioneer 4114 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 Pioneer 4114 Maize, including the use of US-EPA registered pesticides. The Applicant’s adherence to US-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 Pioneer 4114 Maize is not likely to result in changes to the use of glufosinate on corn. USDA-APHIS assumes that growers who elect to cultivate commercial varieties based on the Pioneer 4114 Maize will adhere closely to US-EPA label use restrictions for all pesticides applied to their crop.

All pesticides distributed or sold in the United States are subject to registration by the US-EPA under authority of FIFRA. Glufosinate ammonium was first registered for use by the US-EPA in

2000. Glufosinate is currently undergoing registration review by the US-EPA. The US-EPA has published documents relevant to its glufosinate registration review decision, including a Summary Document, a Preliminary Work Plan, and a Final Work Plan Registration Review. (See the docket folder for US-EPA-HQ-OPP-2008-0190 at the Regulations.gov website.) The US-EPA has completed preliminary human health and ecological effects analyses and has identified risk assessment data needs (US-EPA, 2008a). When these data are received, US-EPA intends to conduct an ecological and endangered species risk assessment and revisions to the human health dietary, residential, occupational, and aggregate risk assessments (US-EPA, 2008a). US-EPA produced an estimated timeline for the completion of the final registration review, with a final decision due in late 2013.

Based on these findings, including the assumption that US-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 Pioneer 4114 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 effects on historic properties and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

USDA-APHIS' proposed action, a determination of nonregulated status of Pioneer 4114 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 Pioneer 4114 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 effects on the character or use of historic properties. For example, there is potential for audible effects 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 effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects.

Additionally, these cultivation practices are already being conducted throughout the corn production regions. The cultivation of Pioneer 4114 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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APPENDIX A – FEDERAL REGISTER NOTICE REGARDING PUBLIC INPUT IN DEREGULATION PROCESS

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techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal Plant and Health Inspection Service

Title: Emergency Management Response System (EMRS).

OMB Control Number: 0579–0071.

Summary of Collection: The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease. Through the Foreign Animal Disease Surveillance Program, the Animal and Plant Health Inspection Service (APHIS) compiles essential epidemiological and diagnostic data that are used to define foreign animal diseases (FAD) and their risk factors. The data is compiled through the Veterinary Services Emergency Management Response System, a web-based database for reporting investigations of suspected FAD occurrences.

Need and Use of the Information: APHIS collects information such as the purpose of the diagnostician's visit to the site, the name and address of the owner/manager, the type of operation being investigated, the number of and type of animals on the premises, whether any animals have been moved to or from the premises and when this movement occurred, number of sick or dead animals, the results of physical examinations of the affected animals, the results of postmortem examinations, and the number and kinds of samples taken, and the name of the suspected disease. APHIS uses the collected information to effectively prevent FAD occurrences and protect the health of the United States.

Without the information, APHIS has no way to detect and monitor foreign animal disease outbreaks in the United States.

Description of Respondents: Business or other for-profit State, Local or Tribal Government.

Number of Respondents: 471.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 1,884.

Animal and Plant Health Inspection Service

Title: Importation of Fruits and Vegetables.

OMB Control Number: 0579–0264.

Summary of Collection: Under the Plant Protection Act (7 U.S.C. 7701–7772), the Secretary of Agriculture is authorized to regulate the importation of plants, plant products, and other articles to prevent the introduction of injurious plant pests. Regulations contained in Title 7 of the Code of Federal Regulations, Part 319 (Subpart-Fruit and Vegetables), Sections 319.56 *et seq.* implement the intent of this Act by prohibiting or restricting the importation of certain fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of fruit flies and other injurious plant pests that are new to the United States or not widely distributed within the United States. These regulations are enforced by the Plant Protection and Quarantine, a program with USDA's Animal and Plant Health Inspection Service (APHIS).

Need and Use of the Information: The use of certain information collection activities including phytosanitary certificates, fruit fly monitoring records, and cooperative agreements will be used to allow the entry of certain fruits and vegetables into the United States. Without the information all shipment would need to be inspected very thoroughly, thereby requiring considerably more time and would slow the clearance of international shipments.

Description of Respondents: Business or other for-profit; Federal Government.

Number of Respondents: 15.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 123.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2012–5326 Filed 3–5–12; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2011–0129]

Biotechnology Regulatory Services; Changes Regarding the Solicitation of Public Comment for Petitions for Determinations of Nonregulated Status for Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) is implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for genetically engineered organisms to allow for early public involvement in the process. Under the updated process, APHIS will publish two separate notices in the **Federal Register** for petitions for which APHIS prepares an environmental assessment. The first notice will announce the availability of the petition, and the second notice will announce the availability of APHIS' decisionmaking documents. This change will provide two opportunities for public involvement in the decisionmaking process.

FOR FURTHER INFORMATION CONTACT: Dr. T. Clint Nesbitt, Chief of Staff, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3917, email: *Thomas.C.Nesbitt@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraph (d) provides that, for petitions that meet the submission procedures, format, required data, and information requirements in paragraphs (b) and (c), APHIS will publish a notice in the **Federal Register** to inform the public that APHIS will accept written comments regarding the petition for a period of 60 days from the date of the notice.

As part of the USDA Customer Service Plan,[1] which seeks to improve the Agency's customer service processes, APHIS analyzed the current petition process using Lean Six Sigma business process techniques. Based on this analysis, APHIS is implementing changes to improve our process for evaluating and responding to petitions for determinations of nonregulated status. Changes include earlier publication of the notice announcing the petition's availability in the **Federal Register**, which will allow early public involvement in the process, and changes to the way we currently solicit and use public comment.[2]

Current Comment Process for Petitions for Determinations of Nonregulated Status

Once APHIS deems a petition to be complete (i.e., the petition meets all the submission procedures, format, required data, and information requirements in § 340.6(b) and (c)), APHIS, in most instances, prepares a plant pest risk assessment (PPRA) and a draft environmental assessment (EA). APHIS prepares a PPRA to assess the plant pest risk of the article and an EA, in accordance with the National Environmental Policy Act (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. After the completion of these documents, APHIS typically publishes a notice in the **Federal Register** announcing the availability of the petition, PPRA, and draft EA for public comment.

After the comment period closes, APHIS reviews all written comments received during the comment period and any other relevant information. After reviewing and evaluating the comments on the petition, draft EA, PPRA, and other data, APHIS prepares a final EA, PPRA, and NEPA decision document, which can be either a Finding of No Significant Impact (FONSI) or notice of intent (NOI) to prepare an environmental impact statement (EIS).[3]

If APHIS determines, based on the PPRA, that the regulated article is unlikely to pose a plant pest risk and a FONSI is reached, APHIS subsequently furnishes a response to the petitioner approving the petition. APHIS also publishes a notice in the **Federal Register** announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and regulatory determination. Copies of these documents are made available as indicated in the **Federal Register** notice.

Changes to the Comment Process for Petitions for Determinations of Nonregulated Status

Under our updated process, APHIS intends to decide whether a petition is complete within 3 months of its receipt. If APHIS deems that a petition is not complete, APHIS will so inform the petitioner. For petitions APHIS deems complete, APHIS will follow the process for public involvement described below.

EA Comment Process for Petitions for Determinations of Nonregulated Status

For complete petitions, APHIS will make the petition available for public comment before preparing our EA and PPRA.[4] APHIS will, therefore, publish two separate notices in the **Federal Register**—a notice announcing the availability of the petition, with an opportunity for public comment, followed by a notice announcing the availability of APHIS' EA and PPRA and an opportunity for public involvement on those documents. This will provide two separate and specific opportunities for public involvement in the decisionmaking process.

First Opportunity for Public Involvement

The first opportunity for public involvement will be a public comment period on the petition itself, once it is deemed complete by APHIS. APHIS will publish a notice in the **Federal Register** to inform the public that APHIS will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice. The comment period will provide the public with an opportunity to raise any issues regarding the petition and will be used by APHIS as a scoping opportunity to identify potential issues and impacts that APHIS would then determine should be considered in our evaluation of the petition.

Second Opportunity for Public Involvement

The second opportunity for public involvement will come with the publication of a notice of availability for APHIS' EA and PPRA in the **Federal Register**. This second notice will follow one of two approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues.

Approach 1

This approach for public participation will be used when APHIS decides, based on our review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition, that the petition involves a GE organism that raises no substantive new issues. This would include instances, for example, where APHIS decides that the petition involves gene modifications that do not raise substantive new biological, cultural, or ecological issues due to the nature of the modification or APHIS' familiarity with the recipient organism.

Under this approach, APHIS will publish a notice in the **Federal Register** announcing APHIS' preliminary regulatory determination and the availability of APHIS' EA, FONSI, and PPRA for a 30-day public review. Upon completion of the 30-day review period, APHIS will review and evaluate any information received. If APHIS determines that no substantive information has been received that

[1] For more information on the USDA Customer Service Plan, go to *http://www.usda.gov/open/Blog.nsf/dx/USDA-CSPlan.pdf/$file/USDA-CSPlan.pdf.*

[2] For information regarding APHIS' analysis and other internal process changes APHIS is making to our petition process, go to *http://www.aphis.usda.gov/biotechnology/pet_proc_imp.shtml.*

[3] If an EIS is determined to be necessary, APHIS completes the NEPA EIS process in accordance with Council on Environmental Quality regulations (40 CFR part 1500–1508) and APHIS' NEPA implementing regulations (7 CFR part 372) and prepares a record of decision prior to either approving or denying the petition.

[4] This notice describes our process for handling most petitions for determinations of nonregulated status. APHIS may decide that an EIS is necessary, either when we deem the petition to be complete or at any time during the EA process, in which case APHIS would complete the NEPA EIS process in accordance with Council on Environmental Quality regulations and APHIS' NEPA implementing regulations.

would warrant APHIS altering its preliminary regulatory determination or FONSI, substantially changing the proposed action identified in the EA, or substantially changing the analysis of impacts in the EA, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our Web site. APHIS will also furnish a response to the petitioner regarding our final regulatory determination. No further **Federal Register** notice will be published announcing the final regulatory determination.

Should APHIS determine that we have received substantive new information within 30 days of publication of the **Federal Register** notice that would warrant APHIS altering our preliminary regulatory determination or FONSI, substantially changing the proposed action identified in the EA, or substantially changing the analysis of impacts in the EA, our preliminary determination will not become effective. In this case, APHIS intends to notify the public through an announcement on our Web site of our intent to conduct additional analysis. APHIS will also inform the petitioner of our intent.

Based on the information APHIS received and our further analysis, the Agency will prepare an amended EA, a new FONSI, and/or a revised PPRA, as necessary. APHIS will then publish a notice in the **Federal Register** announcing the availability of these documents for public review and APHIS' preliminary regulatory determination. After reviewing and evaluating any additional information received within 30 days of publication of this **Federal Register** notice, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our Web site. APHIS will also furnish a response to the petitioner regarding our final regulatory determination. No further **Federal Register** notice will be published announcing the final regulatory determination.

Approach 2

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

Under this approach, APHIS will solicit written comments on a draft EA and PPRA for 30 days through the publication of a **Federal Register** notice. The draft EA and PPRA will be made available as indicated in the **Federal Register** notice. Upon completion of the 30-day comment period, APHIS will review and evaluate all written comments received during the comment period and any other relevant information. After reviewing and evaluating the comments on the draft EA and PPRA and other information, APHIS will revise the PPRA as necessary and prepare a final EA. Based on the final EA, APHIS will prepare a NEPA decision document—either a FONSI or NOI to prepare an EIS. If a FONSI is reached, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will publish a notice in the **Federal Register** announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

These changes to the public participation process are effective March 6, 2012. All petitions for determinations of nonregulated status for GE organisms received by APHIS on or after this date will be handled using the new process for handling petitions described in this notice. For petitions received before this date and currently under consideration by APHIS, our ability to transition to the new process will depend upon the current status of the petition. For those petitions where APHIS has not completed a draft EA and PPRA, APHIS will follow the new process, i.e., the complete petition will be published for a 60-day comment period followed by later public involvement regarding the EA and PPRA. For those petitions where APHIS has completed or is nearing completion of a draft EA and PPRA, APHIS will follow our previous process, i.e., the petition, draft EA, and PPRA will be made available in a single **Federal Register** notice for a 60-day comment period. APHIS will notify petitioners which process their petition will follow and will make this information available at *http://www.aphis.usda.gov/biotechnology/pet_proc_imp.shtml.*

These public participation process changes are consistent with (1) 7 CFR part 340, (2) the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*), (3) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (4) USDA regulations implementing NEPA (7 CFR part 1b), and (5) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 29th day of February 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2012–5364 Filed 3–5–12; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0005]

Notice of Availability of a Pest Risk Analysis for the Importation of Litchi, Longan, and Rambutan From the Philippines Into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: We are advising the public that we have prepared a pest risk analysis that evaluates the risks associated with the importation into the continental United States of fresh litchi, longan, and rambutan fruit from the Philippines. Based on that analysis, we believe that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh fruit of litchi, longan, and rambutan from the Philippines. We are making the pest risk analysis available to the public for review and comment.

DATES: We will consider all comments that we receive on or before May 7, 2012.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0005-0001.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2012–0005, Regulatory Analysis and Development, PPD, APHIS, Station

APPENDIX B – BAYER LIBERTY® LABEL

Bayer CropScience

Liberty® HERBICIDE

A NON-SELECTIVE HERBICIDE FOR USE ONLY ON CORN, SOYBEANS, AND CANOLA TOLERANT TO THE ACTIVE INGREDIENT IN THIS PRODUCT. BAYER CROPSCIENCE RECOMMENDS USE ONLY ON SEED DESIGNATED AS LIBERTYLINK® OR WARRANTED BY BAYER CROPSCIENCE AS BEING TOLERANT TO LIBERTY® HERBICIDE.

ACTIVE INGREDIENT: Glufosinate-ammonium* .... **18.19%** **

OTHER INGREDIENTS: **81.81%**

*CAS Number 77182-82-2, protected by U.S. Patent No 4,400,196 **TOTAL 100.00%**

**Equivalent to 1.67 pounds of active ingredient per U.S. gallon.

EPA Reg No. 264-660

EPA Est. No. 264-MI-001
EPA Est. No. 407-IA-2

KEEP OUT OF REACH OF CHILDREN

WARNING - AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

If swallowed	• Rinse mouth thoroughly with plenty of water. • Do not induce vomiting. • Get medical attention immediately.
If in Eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Get medical attention if irritation develops or persists.
If on skin or clothing	• Take off contaminated clothing. • Wash skin immediately with plenty of soap and water. • Get medical attention.
If inhaled	• Move person to fresh air. • Get medical attention if breathing difficulty develops.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or when going for treatment. Call 1-800-334-7577 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
If this product is ingested, endotracheal intubation and gastric lavage should be performed as soon as possible, followed by charcoal and sodium sulfate administration. Additionally, call 1-800-334-7577 immediately for further information.	

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if absorbed through skin. Causes moderate eye irritation. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:

Coveralls worn over short-sleeved shirt and short pants; chemical-resistant gloves such as barrier laminate, butyl rubber ≥14 mils, nitrile rubber ≥14 mils, neoprene rubber ≥14 mils, polyvinyl chloride (PVC) ≥14 mils, or Viton® ≥14 mils; chemical resistant footwear plus socks; protective eyewear. Wear a chemical resistant apron when mixing/loading and cleaning equipment.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering control statement:

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [(40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water or to areas where surface water is present, except as allowed by the Use Directions for rice on this label. Do not apply to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters.

This pesticide is toxic to vascular plants and should be used strictly in accordance with the drift and run-off precautions on this label in order to minimize off-site exposures.

Under some conditions, this product may have a potential to run-off to surface water or adjacent land. Where possible, use methods which reduce soil erosion, such as no till, limited till and contour plowing; these methods also reduce pesticide run-off. Use of vegetation filter strips along rivers, creeks, streams, wetlands, etc. or on the downhill side of fields where run-off could occur to minimize water run-off is recommended.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Do not use or store near heat or open flame. Keep the container tightly closed and dry in a cool, well-ventilated place. Storage temperature should not exceed 125°F. If storage temperature for bulk Liberty® Herbicide is below 32°F, the material should not be pumped until its temperature exceeds 32°F. Protect against direct sunlight.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL: *[1 and 2½ Gallon Containers Only]*

Empty containers should be triple rinsed (or equivalent), then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill, or by incineration; or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

[15 Gallons, 60 Gallons, 120 Gallons & Bulk Containers Only]

This is a sealed returnable container to be used only for Liberty® Herbicide. When this container is empty, it must not be opened, cleaned, or discarded. Empty containers must be returned to the original purchase location.

SEED DISPOSAL: To dispose of out-of-date or otherwise unmarketable seed from plants which have been treated with Liberty® Herbicide, broadcast and lightly incorporate seed into field soils using disc or other suitable implement. Any resulting crop may be destroyed by chemical or mechanical means. Alternatively, seed may be destroyed by deep burial, incineration or landfill disposal.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not use this product until you have read the entire label. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses; and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry-interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: coveralls worn over short-sleeved shirt and short pants; chemical-resistant gloves such as barrier laminate, butyl rubber ≥14 mils, nitrile rubber ≥14 mils, neoprene rubber ≥14 mils, polyvinyl chloride (PVC) ≥14 mils, or Viton® ≥14 mils; chemical resistant footwear plus socks; protective eyewear.

GENERAL INFORMATION

Liberty® Herbicide is a water-soluble herbicide for application as a foliar spray for the control of a broad spectrum of emerged annual and perennial grass and broadleaf weeds in corn, soybeans and canola.

Liberty® Herbicide may also be used during corn, soybean and seed production to remove corn and soybean plants that are not tolerant to glufosinate-ammonium.

IMPORTANT CROP SAFETY INFORMATION

READ BEFORE USING THIS PRODUCT

Liberty® Herbicide is for use only on corn, soybeans and canola tolerant to the active ingredient in this product. Bayer CropScience recommends use only on corn, soybeans and canola designated as LibertyLink® or warranted by Bayer CropScience as being tolerant to Liberty® Herbicide.

The basis of selectivity of Liberty® Herbicide in corn, soybeans and canola is the presence of a gene in LibertyLink® or other Bayer CropScience warranted corn, soybeans and canola varieties which results in a plant that is tolerant to the active ingredient of Liberty® Herbicide. Corn, soybeans and canola not containing this gene will not be tolerant to Liberty® Herbicide and severe injury may result.

Use of Liberty® Herbicide on corn, soybeans or canola not designated as LibertyLink® or not warranted by Bayer CropScience may result in severe crop injury and/or yield loss.

Do not allow spray to contact foliage or green tissue of desirable vegetation other than corn, soybeans and canola tolerant to the active ingredient in this product. This product may injure or kill all green vegetation contacted by the spray other than LibertyLink® corn, soybeans and canola or other corn, soybeans and canola varieties warranted by Bayer CropScience.

Bayer CropScience does not warrant the crop safety or weed control of this product if used on corn, soybean or canola varieties other than those designated as LibertyLink® or warranted by Bayer CropScience to safely withstand the application of Liberty® Herbicide.

SPRAY DRIFT

SENSITIVE AREAS: The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitats for threatened or endangered species, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas).

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.

Do not apply under circumstances where possible drift to unprotected persons or to food, forage, or other plantings that might be damaged or crops thereof rendered unfit for sale, use or consumption can occur.

INFORMATION ON DROPLET SIZE:

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions below).

Uniform, thorough spray coverage is important to achieve consistent weed control. Select nozzles and pressure that deliver **MEDIUM** spray droplets as indicated in nozzle manufacturer's catalogs and in accordance with ASAE Standard S-572. Nozzles that deliver **COARSE** spray droplets may be used to reduce spray drift provided spray volume per acre (GPA) is increased to maintain coverage of weeds.

CONTROLLING DROPLET SIZE:

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.
- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.
- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.
- Nozzle Type - Use a nozzle type that is designed for the intended application.

APPLICATION HEIGHT:

For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy.

WIND:

Drift potential is lowest between wind speeds of 2 - 10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. **NOTE:** Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

Wind speed must be measured adjacent to the application site, on the upwind side, immediately prior to application.

TEMPERATURE AND HUMIDITY:

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry. Avoid spraying during conditions of low humidity and/or high temperatures.

TEMPERATURE INVERSIONS:

Do not make applications into areas of temperature inversions. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

CLEANING INSTRUCTIONS

Before using Liberty® Herbicide, thoroughly clean bulk storage tank, refillable tank, nurse tanks, spray tank, lines, and filter, particularly if a herbicide with the potential to injure crops was previously used. Equipment should be thoroughly rinsed using a strong detergent solution.

After using Liberty® Herbicide, triple rinse the spray equipment and clean with a commercial tank cleaner before using for crops not labeled LibertyLink® or warranted by Bayer CropScience. Make sure any rinsate or foam is thoroughly removed from spray tank and boom. Rinsate may be disposed following the pesticide disposal directions on this label.

APPLICATION DIRECTIONS FOR USE ON CANOLA

To assure the optimum benefit from the use of Liberty® Herbicide, apply when weeds are in an early stage of growth, before they stress the growth of canola. Apply as described in the "Application Methods" section to get maximum weed control.

APPLICATION TIMING

Applications of Liberty® Herbicide on canola may be made from the cotyledon stage up to the early bolting stage of the canola. Slight discoloration of the canola may be visible after application. This effect is temporary and will not influence crop growth, maturity or yield. Liberty® Herbicide is a foliar-active material with no soil-residual activity. For best results, apply to emerged, young actively growing weeds. Weeds that emerge after application will not be controlled. Liberty® Herbicide will have an effect on weeds that are larger than the recommended leaf stage, however speed of activity and control may be reduced. Weed control may be reduced if application is made when heavy dew, fog, and mist/rain are present; or when weeds are under stress due to drought, cool temperatures or extended periods of cloudiness. Liberty® Herbicide is rainfast 4 hours after application, therefore, rainfall within 4 hours may necessitate retreatment.

RESTRICTIONS TO THE DIRECTIONS FOR USE ON CANOLA

1. **DO NOT** use on canola in the states of Alabama, Delaware, Georgia, Kentucky, Maryland, New Jersey, North Carolina, South Carolina, Tennessee, Virginia and West Virginia
2. **DO NOT** apply more than 68 ounces per acre of Liberty® Herbicide for weed control on the canola crop per growing season.
3. **DO NOT** apply Liberty® Herbicide within 65 days of harvesting canola.
4. **DO NOT** plant rotation crops in a field treated with Liberty® Herbicide within 120 days after the last application of this product with the exception of wheat, barley, buckwheat, millet, oats, rye, sorghum, and triticale which may be planted 70 days after the last application of this product. Corn, soybeans, canola, and sugar beets, cotton and rice tolerant to the active ingredient in Liberty® Herbicide may be planted at any time.
5. **DO NOT** graze the treated crop or cut for hay.

6. **DO NOT** add surfactants or crop oils. Anti-foams or drift control agents may be added if needed.
7. **DO NOT** apply Liberty® Herbicide if canola shows injury from prior herbicide applications or environmental stress (drought, excessive rainfall, etc.).
8. **DO NOT** apply this product through any type of irrigation system.
9. **DO NOT** tank mix Liberty® Herbicide with other pesticides including herbicides unless recommended on this label.

SPRAY ADDITIVES

Liberty® Herbicide must be applied with ammonium sulfate (AMS). Use only fine feed grade or spray grade AMS at 3 pounds per acre. Anti-foams or drift control agents may be added if needed.

MIXING INSTRUCTIONS

Liberty® Herbicide must be applied with properly calibrated and clean equipment. Liberty® Herbicide is specially formulated to mix readily in water. Prior to adding Liberty® Herbicide to the spray tank, ensure that the spray tank is thoroughly clean, particularly if a herbicide with the potential to injure crops was previously used (see *Cleaning Instructions*).

Mix Liberty Herbicide with water to make a finished spray solution as follows:

1. Fill tank to one-half full with clean water.
2. Add the appropriate amount of AMS to the spray tank.
3. If tank mixing with a grass herbicide specified on this label, add the correct amount of the grass herbicide.
4. Add the correct amount of Liberty® Herbicide.
5. Add the remaining amount of water, begin agitation, and spray out immediately.

The addition of an antifoaming agent may reduce foaming, especially when using soft water.

Ensure that all spray system lines including pipes, booms, etc. have the correct concentration of Liberty® Herbicide/water mixture before the application is started. Flush out any remaining air or water from the spray system lines before starting the crop application. Keep bypass line on or near bottom of tank to minimize foaming. Screen size in nozzles or line strainers should be no finer than 50 mesh.

If the tank mix partners recommended on this label are added, maintain good agitation at all times until contents of the tank are spayed. If the spray mixture is allowed to settle, thorough agitation is required to resuspend the mixture before spraying is resumed.

APPLICATION METHODS

Do not use flood jet nozzles, controlled droplet application equipment or air-assisted spray equipment. Uniform, thorough spray coverage is important to achieve consistent weed control.

Ground application: Refer to the *Rate Recommendation Tables for Weed Control in Canola* for proper application rates. DO NOT apply when winds are gusty, or when conditions will favor movement of spray particles off the desired spray target. To avoid drift and insure consistent weed control, apply Liberty® Herbicide with the spray boom as low as possible while maintaining a uniform spray pattern. Liberty® Herbicide should be applied broadcast in a minimum of 10 gallons of water per acre using a minimum spray pressure of 40 pounds per square inch and a maximum ground speed of 10 mph. The use of 80 degree or 110 degree flat fan nozzles is highly recommended for optimum spray coverage and canopy penetration. Application of the spray at a 45 degree angle forward will result in better spray coverage. **Under dense weed/crop canopies, a broadcast rate of 15-20 gallons of water per acre should be used so that thorough spray coverage will be obtained.** For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy.

RATE RECOMMENDATION TABLES FOR WEED CONTROL IN CANOLA

The rate of Liberty® Herbicide in fluid ounces (pints) of formulated product per acre to be used for the control of weeds at selected heights are shown in the following tables. In weed populations with mixed species, select the rate needed for all species present.

Grass Weeds Controlled with Liberty® Herbicide at 34 fl. oz./A (2.1 pt./A) Plus Ammonium Sulfate

Weed Species	Growth Stage of Weed (Leaves/Max. Height)	Comments
Barley, volunteer*	1-3 leaves (3")	A second application may be required
Foxtail, yellow	1-4 leaves (2")	Apply prior to tillering
Sandbur, field		
Oat, wild	1-4 leaves (4")	Maximum of 1 tiller; a second application may be required
Wheat, volunteer		
Corn, volunteer	1-4 leaves (6")	---
Barnyardgrass	1-5 leaves (3")	Maximum of 1 tiller
Crabgrass, large		
Crabgrass, smooth		
Millet, volunteer proso		
Millet, wild proso		
Panicum, fall		
Panicum, Texas		
Foxtail, giant	1-6 leaves (4")	Maximum of 2 tillers
Foxtail, green		
Cupgrass, woolly	1-8"	---

* Suppression only

When used in tank-mix combination with Assure® II Herbicide at 4 to 5 fl. oz. per acre, Select® 2EC Herbicide at 2 to 3 fl. oz. per acre, or Poast® Herbicide at 6 to 8 fl. oz. per acre, Liberty® Herbicide may be applied at 28 fl. oz. per acre plus ammonium sulfate to control grass weed species at the growth stage of weeds indicated in the table above. For improved control of heavy populations or larger than recommended volunteer wheat, volunteer barley, yellow foxtail, and wild oats, Liberty® Herbicide at 34 fl. oz per acre can be tank mixed with Assure® II Herbicide, or Poast® Herbicide.

Perennial Weeds Controlled with Liberty® Herbicide at 34 fl. oz./A (2.1 pt./A) Plus Ammonium Sulfate

Weed Species	Growth Stage of Weed (Leaves/Max. Height)	Comments
Quackgrass	1-4 leaves (4")	Top growth control; a second application may be required.
Sowthistle, perennial	1-6 leaves (4")	
Thistle, Canada		

Broadleaf Weeds Controlled with Liberty® Herbicide at 32 fl. oz./A (2 pt./A) Plus Ammonium Sulfate

Weed Species	Growth Stage of Weed (Leaves/Max. Height)	Comments
Buckwheat, wild	1-3 leaves	Up to 1" in height
Pigweed, redroot		Up to 2" in height
Carpetweed	1-4 leaves	Up to 2" in height
Lambsquarter, common		
Marshelder		
Ladysthumb		Up to 3" in height
Pigweed, smooth		
Pigweed, spiny		
Smartweed, Pennsylvania		
Velvetleaf		
Mustard, wild	1-5 leaves	Up to 3" in height
Buffalobur	1-6 leaves	Up to 3" in height
Chickweed, common		
Mallow, Venice		
Nightshade, eastern black		
Ragweed, giant		
Shepherd's purse		
Sowthistle, annual		
Cocklebur, common	1-8 leaves	Up to 5" in height
Ragweed, common		
Sunflower, common		
Kochia	1-2"	---
Thistle, Russian		---
Pigweed, prostrate	1-3"	---
Purslane, common		---
Waterhemp, tall		---
Wormwood, biennial		---
Pennycress, field	1-4"	---
Dandelion	1-6"	Diameter of rosette

For optimum canola yield, early weed removal and application prior to canola bolting is important. For optimum control of both early and late germinating grass and broadleaf weed species, Liberty® Herbicide may be applied sequentially at 20 fl. oz./A to 1-3 leaf grass and 1-2" broadleaf weed species followed by a second application of 20 fl. oz./A 7-10 days later.

APPLICATION DIRECTIONS FOR USE ON FIELD CORN, SILAGE CORN AND SOYBEANS

THOROUGH SPRAY COVERAGE IS VERY IMPORTANT. Visual effects and control from Liberty® Herbicide applications occur within 2 to 4 days after application under good growing conditions. Liberty® Herbicide works best when weeds are actively growing. To maximize weed control, no cultivation should occur in the period from 5 days before an application to 5 days after an application of Liberty® Herbicide.

APPLICATION TIMING

Liberty® Herbicide is a foliar-active material with little or no soil-residual activity. Best results are obtained when applications are made to actively growing weeds. Weeds that emerge after application will not be controlled. Applications of Liberty® following the use of soil-applied insecticides will not injure corn.

Applications of Liberty® Herbicide on corn may be made with over-the-top broadcast or drop nozzles from emergence until corn is 24" tall or in the V-7 stage of growth, i.e., 7 developed collars, whichever comes first. For corn 24" to 36" tall, only apply Liberty® using ground application and drop nozzles and avoid spraying into the whorl or leaf axils of the corn stalks.

Applications of Liberty® Herbicide on soybeans may be made from emergence to the bloom growth stage.

Liberty® Herbicide is rainfast 4 hours after application to most weed species. Rainfall within 4 hours may necessitate retreatment or may result in reduced weed control. Applications should be made between dawn and two hours before sunset to avoid the possibility of reduced control of lambsquarters and velvetleaf. Do not apply when wind causes drift to off-site vegetation as injury may occur. Weed control may be reduced if application is made when heavy dew, fog, and mist/rain are present or when weeds are under stress due to drought, cool temperatures, or extended periods of cloudiness.

Apply Liberty® Herbicide at rates of 28 to 34 fluid ounces per acre. Refer to the *Rate Recommendation Tables for Weed Control* for selection of the proper rate dependent upon weed species and size. A repeat application of Liberty® or a tank mix application with a residual herbicide selected from the tank mix partners listed on this label will be needed to control weeds that have not yet emerged at the time of application.

RESTRICTIONS TO THE DIRECTIONS FOR USE ON FIELD CORN, SILAGE CORN AND SOYBEANS

1. **DO NOT** apply more than two applications of Liberty® Herbicide to the corn or the soybean crop. DO NOT apply more than 62 fluid ounces of Liberty® per acre on corn or soybeans per growing season.
2. **DO NOT** apply Liberty® Herbicide within 60 days of harvesting corn forage and within 70 days of harvesting corn grain and corn fodder.
3. **DO NOT** apply Liberty® Herbicide within 70 days of harvesting soybean seed.
4. **DO NOT** plant rotation crops in a field treated with Liberty® Herbicide within 120 days after the last application of this product with the exception of wheat, barley, buckwheat, millet, oats, rye, sorghum, and triticale which may be planted 70 days after the last application of this product. Corn and soybeans may be planted at any time.
5. **DO NOT** harvest treated green soybean plants for forage and hay feed for livestock.
6. **DO NOT** use nitrogen solutions as spray carriers. A silicone-based antifoam agent may be added if needed.
7. **DO NOT** apply Liberty® Herbicide if soybeans or corn show injury from prior herbicide applications or environmental stress (drought, excessive rainfall, etc.).
8. **DO NOT** apply this product through any type of irrigation system.
9. Volunteer LibertyLink® crop plants from the previous season will not be controlled by an application of Liberty® Herbicide.

SPRAY ADDITIVES

For use on corn only, Liberty® Herbicide must be applied with ammonium sulfate (AMS). It is recommended to use only fine feed grade or spray grade AMS at 3 pounds per acre (17 lbs/100 gallons). However, the rate of AMS can be reduced to 1.5 pounds per acre (8.5 lbs/100 gallons) under hot environmental conditions to reduce potential leaf burn.

Liberty® Herbicide is formulated to provide optimum herbicidal performance. Use of additional surfactants or crop oils will not enhance weed control.

MIXING INSTRUCTIONS

Liberty® Herbicide must be applied with properly calibrated and clean equipment. Liberty® is specially formulated to mix readily in water. Prior to adding Liberty® to the spray tank, ensure that the spray tank is thoroughly clean, particularly if a herbicide with the potential to injure crops was previously used (see *Cleaning Instructions*).

Mix Liberty® Herbicide with water to make a finished spray solution as follows:

1. Fill the spray tank half full with water.
2. Start agitation.
3. Prepare a slurry of the proper amount of dry flowable/wettable powder tank mix partners in a small amount of water.
4. Add the slurry of dry materials to the spray tank.
5. Add the appropriate amount of ammonium sulfate (AMS) (for corn use only) to the spray tank.
6. Add the proper amount of liquid tank mix partners.
7. Complete filling the spray tank with water.
8. Add the proper amount of Liberty® Herbicide and continue agitation.
9. If foaming occurs, use a silicone-based antifoam agent.

Ensure that all spray system lines including pipes, booms, etc. have the correct concentration of Liberty® Herbicide/water mixture before the application is started. Flush out any remaining air or water from the spray system lines before starting the crop application. Keep bypass line on or near bottom of tank to minimize foaming. Screen size in nozzles or line strainers should be no finer than 50 mesh.

If tank mix partners recommended on this label are added, maintain good agitation at all times until contents of the tank are sprayed. If the spray mixture is allowed to settle, thorough agitation is required to resuspend the mixture before spraying is resumed.

APPLICATION METHOD

Refer to the *Rate Recommendation Tables for Weed Control* in the following section for the proper application rates. Uniform, thorough spray coverage is important to achieve consistent weed control.

Ground Application: Liberty® Herbicide should be applied broadcast in a minimum of 15 gallons of water per acre. Under dense weed/crop canopies, 20 to 40 gallons of water per acre should be used so that thorough spray coverage will be obtained.

Apply Liberty® Herbicide using 80-degree or 110-degree flat-fan nozzles. Select a spray pressure between 30 to 60 pounds per square inch (psi) measured at the nozzle which will achieve a droplet size of about 300 microns. If Turbo TeeJet® spray tips are used, a spray pressure of 60 or more pounds per square inch will be required to get thorough coverage of the weed foliage. Flood-jet nozzles, raindrop nozzles, controlled droplet application equipment, or air-assisted spray equipment do not provide adequate coverage characteristics; and therefore, are not recommended because weed control is likely to be reduced.

DO NOT apply when winds are gusty or when conditions will favor movement of spray particles off the desired spray target. To avoid drift and insure consistent weed control, apply Liberty® Herbicide with the spray boom as low as possible while maintaining a uniform spray pattern. For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy.

RATE RECOMMENDATION TABLES FOR WEED CONTROL IN CORN AND SOYBEANS

Apply Liberty® Herbicide at rates of 28 to 34 fluid ounces per acre. Rates in ounces of formulated product per acre for the control of weeds at selected heights are shown in the following tables. In weed populations with mixed species, apply at a rate needed for the species that requires the highest rate.

Grass Weeds Controlled with Liberty® Herbicide Plus Ammonium Sulfate

Weed Species	Maximum Weed Height or Diameter (Inches)		
	28 Fl. Oz./A	32[1] Fl. Oz./A	34 Fl. Oz./A
Barnyardgrass	**	3	4
Bluegrass, annual	**	3	4
Corn, volunteer	**	10[1,2]	12[1,2]
Crabgrass, large	**	3[3]	4[3]
Crabgrass, smooth	**	3[3]	4[3]
Cupgrass, woolly	4	6	8
Foxtail, bristly	3	6	8
Foxtail, giant	3	6	8
Foxtail, giant (ALS resistant)	3	6	8
Foxtail, green	3	6	8
Foxtail, robust purple	3	6	8
Foxtail, yellow	**	3[3]	4[3]
Johnsongrass, seedling	2	6	8
Millet, wild-proso	2	6	7
Millet, proso volunteer	2	6	7
Oat, wild	**	3[3]	4[3]
Panicum, fall	2	3	4
Panicum, Texas	2	4	5
Rice, red	2	4	5
Sandbur, field	**	**	3[3]
Shattercane	**	6	8
Shattercane (ALS resistant)	**	6	8
Signalgrass, broadleaf	2	4	5
Sprangletop	2	4	5
Sorghum, volunteer	**	6	7
Stinkgrass	2	4	5
Witchgrass	2	4	5

** Indicates suppression

[1] Volunteer corn arising from a previous corn crop containing a glufosinate tolerance gene will not be controlled.

[2] A timely cultivation 7 to 10 days after application and/or retreatment within 2 weeks is recommended for controlling dense clumps of volunteer corn arising from a previous corn crop that was not tolerant to glufosinate-ammonium.

[3] Yellow foxtail, field sandbur, crabgrass and wild oats must be treated prior to tiller initiation for best results.

Broadleaf Weeds Controlled with Liberty® Herbicide Plus Ammonium Sulfate

Weed Species	Maximum Weed Height or Diameter (Inches)		
	28 Fl. Oz./A	32 Fl. Oz./A	34 Fl. Oz./A
Amaranth, Palmer[1]	**	4	6
Beggarweed, Florida	**	4	6
Black medic	3	5	6
Buckwheat, wild	3	6	7
Buffalobur	3	6	7
Burcucumber	3	6	8
Carpetweed	**	4	6
Chickweed, common	3	6	7
Cocklebur, common	3	6	8
Cocklebur, common (ALS resistant)	3	6	8
Copperleaf, hophornbeam	2	4	6
Eclipta	2	4	6
Fleabane, annual	3	6	8
Galinsoga, hairy	3	6	8
Galinsoga, small flower	3	6	7
Groundcherry, cutleaf	2	4	6
Geranium, cutleaf	2	4	6
Java bean	2	4	6
Jimsonweed	3	6	8
Kochia[1]	2	4	6
Kochia (ALS resistant)1	2	4	6
Ladysthumb	3	6	8
Lambsquarters, common[1]	2	4	6
Lambsquarters, common (triazine resistant)	2	4	6
Mallow, common	**	4	6
Mallow, Venice	3	6	7
Marestail	3	6	8
Marshelder	**	4	6
Morningglory, entireleaf[1]	2	6	7
Morningglory, ivyleaf[1]	3	6	7
Morningglory, pitted[1]	2	6	7
Morningglory, smallflower[1]	2	4	6
Morningglory, tall[1]	3	6	7
Mustard, wild	3	6	7
Nightshade, eastern black	3	6	8
Nightshade, hairy	3	6	8
Pennycress	2	4	6
Pigweed, redroot[1]	2	4	6
Pigweed, redroot (ALS resistant) [1]	2	4	6
Pigweed, redroot (triazine resistant)	2	4	6

Weed Species	Maximum Weed Height or Diameter (Inches)		
	28 Fl. Oz./A	32 Fl. Oz./A	34 Fl. Oz./A
Pigweed, prostrate[1]	**	4	6
Pigweed, spiny[1]	**	4	6
Pigweed, smooth[1]	**	4	6
Pigweed, tumble[1]	**	4	6
Puncturevine	**	4	6
Ragweed, common	3	6	8
Ragweed, common (ALS resistant)	3	6	8
Ragweed, giant	3	6	8
Ragweed, giant (ALS resistant)	3	6	8
Sesbania, hemp	3	6	8
Shepherd's-Purse	3	6	8
Sicklepod	3	6	7
Sida, prickly	3	6	7
Smartweed, Pennsylvania	3	6	8
Smellmelon	2	4	6
Sowthistle, annual	3	6	7
Sunflower, common	3	6	8
Sunflower, common (ALS resistant)	3	6	8
Sunflower, volunteer	3	6	8
Thistle, Russian	**	4	6
Velvetleaf[1]	3	5	6
Waterhemp, common[1]	2	4	6
Waterhemp, common (ALS resistant)[1]	2	4	6
Waterhemp, tall[1]	2	4	6

**** indicates suppression**

1. Tank mixing with atrazine may enhance weed control of this species.

INSTRUCTIONS FOR BIENNIAL/PERENNIAL WEEDS

Liberty® Herbicide applied at 34 fluid ounces per acre will provide top-growth control or suppression of the biennial/perennial weed species shown in the following table. A second application of Liberty Herbicide at 28 fluid ounces per acre or a tank mix with other herbicides selected from those listed on this label is required for control.

***Biennial/Perennial* Weeds Suppressed or Controlled with Liberty® Herbicide Plus Ammonium Sulfate**

Alfalfa	Clover, red	Muhly, wirestem
Artichoke, Jerusalem	Dandelion	Orchardgrass
Bindweed, field	Dock, smooth	Poinsettia, wild
Bindweed, hedge	Dogbane, hemp	Pokeweed
Bluegrass, Kentucky	Goldenrod, gray	Quackgrass
Bromegrass, smooth	Johnsongrass, rhizome	Thistle, bull
Burdock	Milkweed, common	Thistle, Canada
Chickweed, Mouse-ear	Milkweed, honeyvine	Timothy
Clover, Alsike		

TANK MIX RECOMMENDATIONS FOR LIBERTY® HERBICIDE

Liberty® Herbicide (alone and with a tank mix partner listed on this label) may be applied following any corn or soybean pre-plant incorporated or preemergence herbicide applications. When using Liberty® Herbicide in tank mix combinations, carefully follow the "Direction of Use" labeling of the selected partner. Do not use a tank mix partner that has already been applied as a pre-plant incorporated or preemergence herbicide unless the "Directions of Use" labeling of that partner allows sequential applications of it to the same crop.

Corn Tank Mix Herbicide Partners for Liberty® Herbicide

To enhance weed control and/or provide residual control in corn, Liberty® Herbicide may be mixed with the following herbicides.

2,4-D	Confidence® Herbicide	NorthStar™ Herbicide
Accent® Herbicide	Confidence® Xtra 5.6L Herbicide	Permit® Herbicide
Accent® Gold™ Herbicide	Distinct™ Herbicide	Prowl® 3.3 EC Herbicide
Atrazine	Dual II Magnum™ Herbicide	Pursuit® Herbicide
Banvel® Herbicide	Exceed® Herbicide	Python® WDG Herbicide
Basagran® Herbicide	Frontier® 6.0 Herbicide	Scorpion® III Herbicide
Basis Gold® Herbicide	FulTime™ Herbicide	Shotgun® Herbicide
Beacon® Herbicide	Guardsman® Herbicide	Spirit® Herbicide
Bicep Lite II Magnum® Herbicide	Harness ® Herbicide	Sterling™ Plus
Bicep II Magnum® Herbicide	Harness® Xtra Herbicide	Stinger® Herbicide
Buctril® Herbicide	Harness® Xtra 5.6L Herbicide	Surpass® EC Herbicide
Buctril® 4EC Herbicide	Hornet® Herbicide	Surpass® 100 Herbicide
Buctril® + atrazine Herbicide	Laddok® S-12 Herbicide	Topnotch™ Herbicide
Callisto™ Herbicide	LeadOff™ Herbicide	Tough® 5 EC Herbicide
Celebrity™ Herbicide	Lightning™ Herbicide	Volley™ Herbicide
Clarity® Herbicide	Marksman® Herbicide	

Apply tank mixes of Lightning™ and Pursuit® only to corn designated as Clearfield™ tolerant and LibertyLink® or warranted by Bayer CropScience as being tolerant to Liberty® Herbicide.

Applications of 2,4-D, Banvel® Herbicide, Celebrity™ Herbicide, Clarity® Herbicide, Distinct™ Herbicide, or Marksman® Herbicide, and NorthStar™ Herbicide to corn during periods of rapid growth may result in temporary leaning or green snap. If these symptoms occur, cultivation should be delayed until after corn is growing normally to avoid breakage. Tank mixing with Prowl® 3.3 EC Herbicide may result in reduced control of barnyardgrass, fall panicum, field sandbur, yellow foxtail, and volunteer corn.

Corn Tank Mix Insecticide Partners for Liberty® Herbicide

To provide weed and insect control in corn, Liberty® Herbicide may be mixed with the following insecticides:

Ambush® Insecticide	Furadan® 4F Insecticide	Pounce® 3.2EC Insecticide
Asana® XL Insecticide	Lorsban® 4E Insecticide	Warrior™ Insecticide
Baythroid® 2 Insecticide		

Soybean Tank Mix Herbicide Partners for Liberty® Herbicide

To enhance weed control and/or provide residual control in soybeans, Liberty® Herbicide may be mixed with the following herbicides:

Basagran® Herbicide	Manifest™ B Herbicide	Reflex® Herbicide
Blazer® Herbicide	Manifest™ G Herbicide	Resource® Herbicide
Firstrate® Herbicide	Pinnacle® Herbicide	Scepter® Herbicide
Flexstar® HL Herbicide	Poast® HC Herbicide	Select® 2EC Herbicide
Frontier® 6.0 Herbicide	Poast Plus® Herbicide	Storm® Herbicide
Fusilade® DX Herbicide	Prism® Herbicide	Tornado® Herbicide
Fusion® Herbicide	Pursuit® Herbicide	Typhoon® Herbicide
Galaxy® Herbicide	Raptor™ Herbicide	

APPLICATION DIRECTIONS FOR USE IN FIELD CORN SEED AND SOYBEAN SEED PROPAGATION

Liberty® Herbicide may be applied to select out susceptible "segregates", i.e., corn and soybean plants that are not tolerant to glufosinate-ammonium during seed propagation. Inbred lines, plants not possessing glufosinate-ammonium tolerance, will be severely injured or killed if treated with this herbicide. A hooded sprayer may be used to protect corn and soybean plants from coming into contact with the herbicide application.

Rate Recommendations for Seed Production

Corn: For the selection of tolerant corn "segregates", Liberty® Herbicide may be applied at up to 34 fluid ounces per acre plus ammonium sulfate (AMS) at 3 pounds per acre when corn is in the V-3 to V-4 stage of growth, i.e., 3 to 4 developed collars. A second treatment of 28 fluid ounces per acre plus AMS at 3 pounds per acre may be applied when the corn is in the V-6 to V-7 stage of growth or up to 24" tall.

Soybeans: For the selection of tolerant soybean "segregates", Liberty® Herbicide may be applied at up to 34 fluid ounces per acre when soybean is in the third trifoliate stage. A second treatment of 28 fluid ounces per acre may be applied up to the bloom growth stage of soybean.

FALLOW FIELDS OR POST HARVEST

Liberty® Herbicide may be used as a substitute for tillage to control or suppress weeds in the grass, broadleaf and biennial/perennial weed tables in this label. Applications may be made in fallow fields, post harvest, prior to planting or emergence of any crop listed on this label.

Refer to the *Application Methods* section of this labeling for appropriate application rates to control specific weeds. Liberty® Herbicide must be applied with ammonium sulfate. Tank mixes with 2,4-D, glyphosate or atrazine are recommended with Liberty® Herbicide to enhance total weed control. When using Liberty® Herbicide in tank mix combinations, follow the precautions and directions of use of the most restrictive label.

Do not plant crops in a field treated with Liberty® Herbicide for 120 days after the last application of this product with the exception of wheat, barley, buckwheat, millet, oats, rye, sorghum, and triticale which may be planted 70 days after the last application of this product. Corn, soybeans, sugar beets and canola may be planted at any time.

FARMSTEADS

When applied as recommended, this product controls undesirable plant vegetation in noncrop areas around farmstead building foundations, shelter belts, along fences, and general nonselective farmstead weed control. Refer to the *Application Methods* section of this labeling for appropriate application rates to control specific weeds.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

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Net Contents: 1 Gallon, 2.5 Gallons, 15 Gallons, 60 Gallons, 120 Gallons & Bulk

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Bayer CropScience

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)
http://www.bayercropscienceus.com

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APPENDIX C – 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 whether a consultation with U.S. Fish and Wildlife Service 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[30] 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[31]?

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)[32].

4. Does the pest resistance[33] gene act by one of the mechanisms listed below? If the answer is YES then a consultation with U.S. Fish and Wildlife Service 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;

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:

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

[31] 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.

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

[33] 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.

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 U.S. Fish and Wildlife Service 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 EA.

________ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service 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 U.S. Fish and Wildlife Service 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.