Genective Petition for Determination Of Non-regulated Status of VCO-01981-5

OECD Unique Identifier:
VCO-01981-5

Environmental Assessment

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ACRONYMS AND ABBREVIATIONS

AIA	advanced informed agreement
AOSCA	American Organization of Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
BRAD	Biopesticide Registration Action Document
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
Bt	*Bacillus thuringiensis* protein
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CH_4	methane
CO	carbon monoxide
CO_2	carbon dioxide
DNA	deoxyribonucleic acid
DT	drought tolerant
EA	environmental assessment
EIS	environmental impact statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act of 1973
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FFP	food, feed, or processing
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	Federal Register
GDP	gross domestic product
GE	genetically engineered
GHG	greenhouse gas
GMO	genetically modified organism
IP	Identity Preservation
IPCC	Intergovernmental Panel on Climate Change

ACRONYMS AND ABBREVIATIONS

IRM	Insect Resistance Management
ISPM	International Standard for Phytosanitary Measure
IPPC	International Plant Protection Convention
LD50	lethal dose that kills 50% of the animals being tested
NO_2	nitrogen dioxide
N_2O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NOEL	no observable effect level
NRC	National Research Council
PPRA	Plant Pest Risk Assessment
PPA	Plant Protection Act
PRA	pest risk analysis
RNA	ribonucleic acid
TES	threatened and endangered species
TSCA	Toxic Substances Control Act
U.S.	United States
USDA	U.S. Department of Agriculture
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USDA-NOP	U.S. Department of Agriculture-National Organic Program
USC	United States Code
WPS	Worker Protection Standard for Agricultural Pesticides

1 PURPOSE AND NEED

1.1 Background

Genective SA of Chappes, France with the Bayer Company of Research Triangle Park, North Carolina submitted a petition, APHIS Number 11-342-01, to The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in December 2011. The purpose of the petition is to support a determination of nonregulated status for VCO-01981-5 corn (henceforth referred to as VCO-01981-5 corn), which is resistant[1] to the herbicide, glyphosate. The event VCO-01981-5 corn is currently regulated under 7 CFR part 340. Interstate movements and field trials of event VCO-01981-5 have been conducted under permits issued or notifications acknowledged by APHIS since 2007. These field trials were conducted within two corn-growing areas in the U.S since 2007 in Puerto Rico and since 2008 in Iowa. Data resulting from these field trials are described in the petition (Genective, 2012) and analyzed for plant pest risk in the USDA-APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2012a)

The petition stated that APHIS should not regulate VCO-01981-5 corn because it does not present a plant pest risk. If a determination of nonregulated status is made, it would include VCO-01981-5 corn, any progeny derived from crosses between VCO-01981-5 corn and conventional corn, and crosses of VCO-01981-5 corn with other biotechnology-derived corn lines that are no longer subject to the regulatory requirements of 7 CFR part 340 promulgated under the authority of the Plant Protection Act of 2000 (PPA).

1.2 Purpose of the Product

A modified *epsps* gene, from the bacterium *Arthrobacter globiformis* was transformed into corn for resistance to glyphosate. The protein expressed by the gene, 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein, EPSPS ACE5, confers resistance to the common herbicide glyphosate and has greater enzymatic half-life than the native protein, but somewhat less than the native enzyme from corn. Genective has developed VCO-01981-5 to make available an additional variety of glyphosate resistant corn to growers and corn seed suppliers for weed

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[1] *"Resistance"* to herbicides is defined by the HRAC (Herbicide Resistance Action Committee) as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type HRAC, Guideline to the Management of Herbicide Resistance, 2013, Herbicide Resistance Action Committee, Available: http://www.hracglobal.com/Publications/ManagementofHerbicideResistance.aspx, January 22 2013. Several technologies are available that can be used to develop herbicide resistance in plants including classical breeding, tissue culture, mutagenesis and genetic engineering. *"Tolerance"* is distinguished from resistance and defined by HRAC (2013) as the inherent ability of a plant to survive and reproduce following exposure to a herbicide treatment. This implies the circumstance in which there is no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. Throughout this EA (Environmental Assessment), APHIS has used the terms "resistance" and "tolerance" consistent with the definitions of the HRAC. It should be noted however, that different terms for the same concept may be used interchangeably in some instances. In its petition to USDA APHIS Genective .referenced the subject as, "glyphosate-tolerant maize," and used the term "herbicide tolerant" throughout its documentation to describe it (Genective, 2011). This terminology can be considered synonymous with "herbicide-resistant" (HR) used in this EA.

management. EPA regulated applications of glyphosate will be the same as for other current varieties of corn being produced that have similar resistance to the herbicide.

1.3 Coordinated Framework Review and Regulatory Review

Since 1986, the United States government has regulated GE organisms pursuant to Federal regulations published in the *Federal Register* entitled The Coordinated Framework for the Regulation of Biotechnology (51 FR 23302, 1986)(henceforth referred to here as the Coordinated Framework), and the policy statement for foods derived from new plant varieties (57 FR 22984, 1992). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

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

1.3.1 USDA-APHIS

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

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

1.3.2 Environmental Protection Agency

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

Under FIFRA (7 U.S.C. 136 et seq.), EPA regulates the use of pesticides, and requires registration of all pesticide products for all specific uses prior to distribution for sale. 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; storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, EPA must determine through testing that the pesticide does not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may only be legally used in accordance with directions and restrictions on its label. The overall intent of the label is to provide clear directions for effective product performance, while minimizing risks to human health and the environment. The Food Quality Protection Act (FQPA) of 1996 amended FIFRA, enabling EPA to implement periodic registration review of pesticides to ensure they are meeting current scientific and regulatory standards of safety and continue to have no unreasonable adverse effects (US-EPA, 2011c).

EPA also sets tolerances (maximum residue levels) or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). A tolerance is the amount of pesticide residue that can remain on or in food for human consumption or animal feed. Before establishing a pesticide tolerance, EPA is required to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the FQPA. FDA enforces the pesticide tolerances set by EPA.

1.3.3 Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, on May 29, 1992 (57 FR 22984). Under this policy, FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under Federal food safety laws prior to marketing.

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

VCO-01981-5 corn is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced through GE. In 2009, Athenix Corp., now an affiliate of Bayer CropScience LP, submitted an Early Food Safety Evaluation to FDA. Genective had the license for use of VCO-01981-5 from Athenix, and Bayer is now assuming the interest of Athenix in this product. The FDA review for the Early Evaluation (NPC 000012: Agency Response Letter) was completed with no further questions in October, 2010 (FDA, 2010). Genective SA initiated the consultation process with FDA for the commercial distribution of event VCO-01981-5 and submitted a safety and nutritional assessment of food and feed derived from VCO-01981-5 to the FDA on March 5, 2012. FDA has completed the consultation May7, 2013 and FDA has no further questions for the developer (FDA no. BNF-000137).

1.4 Purpose and Need for this APHIS Action

As noted in the previous section, any party can petition APHIS to seek a determination of nonregulated status for a GE organism that is regulated currently under 7 CFR 340. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as Genective VCO-01891-5 corn. When a petition for nonregulated status is submitted, APHIS must determine if the GE organism is unlikely to pose a plant pest risk. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS must respond to the petition from Genective requesting a determination of nonregulated status for VCO-01981-5 corn. APHIS has prepared this EA to consider the potential environmental effects of an agency determination of nonregulated status of VCO-01981-5 corn. This action is consistent with regulations for the National Environmental Policy Act (NEPA) established by the Council of Environmental Quality (CEQ), and those of the 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[2] that may result from a determination of nonregulated status for VCO-01981-5 corn.

1.5 Public Involvement

APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. APHIS does this through a

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

notice published in the *Federal Register*. On March 6, 2012, APHIS published a notice[3] in the *Federal Register* advising the public that APHIS is implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for GE organisms to allow for early public involvement in the process. As identified in this notice, APHIS publishes two separate notices in the *Federal Register* for petitions for which APHIS prepares an EA. The first notice announces the availability of the petition, and the second notice announces the availability of the APHIS decision-making documents. As part of the new process, with each of the two notices published in the *Federal Register*, there is an opportunity for public involvement:

1.5.1 First Opportunity for Public Involvement

Once APHIS deems a petition complete, the petition is made available to the public for 60 days to provide an opportunity to comment on issues regarding the petition itself and give input that will be considered by the Agency as it develops its EA and PPRA. APHIS publishes a notice in the *Federal Register* to inform the public that APHIS will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice. This availability of the petition for public comment is announced in a *Federal Register* notice.

1.5.2 Second Opportunity for Public Involvement

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

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

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

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

<u>Approach 2. For GE organisms that raise substantive new issues not previously reviewed by APHIS.</u> A second approach for public participation is used when APHIS determines that the petition for a determination of nonregulated status is for a GE organism that involves substantive

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

new issues. This could include petitions for a recipient organism that has not previously been determined by APHIS to have nonregulated status or when APHIS determines that gene modifications involves substantive biological, cultural, or ecological issues not previously analyzed by APHIS. Substantive issues are identified based on the Agency's review of the petition and its evaluation and analysis of comments received from the public during the 60-day comment period for the petition.

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

More details about this expansion of opportunities for stakeholder review and comment are available in the *Federal Register* notice[4] published on March 6, 2012.

APHIS has determined that this EA will follow Approach 1. The issues considered in this EA were developed by reviewing the public concerns, including public comments received in response to the *Federal Register* notice (77 F.R. 41357-8) announcing the availability of the petition (i.e., the first opportunity for public involvement previously described in this document), as well as issues noted in public comments submitted for other EAs of GE organisms, and concerns described in lawsuits and expressed by various stakeholders. These issues, including those regarding the agricultural production of corn using various production methods and the environmental and food/feed safety of GE plants, were addressed to analyze the potential environmental impacts of Genective VCO-01891-5 corn.

The public comment period for VCO-01981-5 corn petition closed on September 11, 2012. At its closing, the docket file contained a total of 78 submissions to the docket. Some of the submissions contained multiple attached comments; there were a total of 4,604 public comments. The majority of the comments expressed a general dislike of the use of GE organisms or were form letters sent to all of the dockets which were open at the time that this docket was open. The form letter expressed a concern that there were too many dockets published on the same day. It also referenced other open dockets and potential effects from the use of the subjects of those petitions. Another comment addressed concerns that APHIS' regulations were inadequate to fully regulate GE crops. These issues are outside the scope of this EA. The issues raised that were related to the VCO-01981-5 corn petition included:

- Development of glyphosate resistant weeds.
- The fate of glyphosate in water.
- The effects of glyphosate use on biological organisms.
- Concern that cross-pollination between GE and organic or crops for GE-sensitive markets will affect sales for growers of these crops.
- Concerns that Genective VCO-01981-5 Corn is not approved in all export markets.

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

1.6 Issues Considered

The list of resource areas considered in this EA were developed by APHIS through experience in considering public concerns and issues raised in public comments submitted for 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 in the past. The resource areas considered in this EA can be categorized as follows:

Agricultural Production Considerations:

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

Environmental Considerations:

- Water Resources
- Soil
- Air Quality
- Climate Change
- Animals
- Plants
- Microorganisms
- Biological Diversity

Human Health Considerations:

- Public Health
- Worker Safety

Livestock Health Considerations:

- Livestock Health/Animal Feed

Socioeconomic Considerations:

- Domestic Economic Environment
- Trade Economic Environment

2 AFFECTED ENVIRONMENT

2.1 Agricultural Production of Corn

2.1.1 Acreage and Areas of Corn Production

Corn is the world's most widely cultivated cereal, reflecting its ability to adapt to a wide range of production environments (OECD, 2003). Corn is an annual plant typically grown in zones of abundant rainfall and fertile soils (OECD, 2003). In the U.S., moisture levels and number of frost-free days required to reach maturity are ideal for corn to be grown within temperate regions (see, e.g., (IPM, 2004; IPM, 2007); although corn is reported to have a strong ability to adapt to extreme and variable conditions of humidity, sunlight, altitude, and temperature (OECD, 2003).

In 2009, the U.S. produced 40% of the total world supply of corn (USDA-OCE, 2011b). Corn is cultivated worldwide, including Argentina, South Africa, Brazil, Canada, China, and the former Soviet Union States, including the Ukraine (USDA-OCE, 2011b). Egypt, the EU, Japan, Mexico, Southeast Asia, and South Korea are net importers of corn (USDA-OCE, 2011b). Approximately 15 to 20% of the U.S. corn production is exported (USDA-OCE, 2011b).

Corn is the most widely cultivated feed grain, accounting for more than 95% of total value and production of feed grains (USDA-ERS, 2011f). Corn is grown in all 48 of the continental U.S. states with production concentrated in the Corn Belt, 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, 2010b; USDA-ERS, 2011b). Iowa and Illinois, the two top corn producing states, typically account for slightly more than one-third of the total U.S. crop (USDA-ERS, 2011f). In the U.S. for the 2012 production year, corn was cultivated on over 96 million acres, a 5% increase in corn acreage from 2011(USDA-NASS, 2012a). Within the 2010 acreage, corn for silage was cultivated on approximately 5.6 million acres, or approximately 6% of the total corn production area (USDA-NASS, 2012b). Corn production in 2010 was estimated at 12.4 billion bushels, valued at an estimated $5.18 per bushel in 2010 and $6.20 in 2011 (USDA-NASS, 2012a; USDA-NASS, 2012c). Corn futures are highly variable, and corn on 19 June 2012 traded on the Chicago Board of Trade at $5.74 per bushel for a December 2012 contract; while by 18 July, corn futures traded at $7.86 for the same contract (CME-Group, 2012).

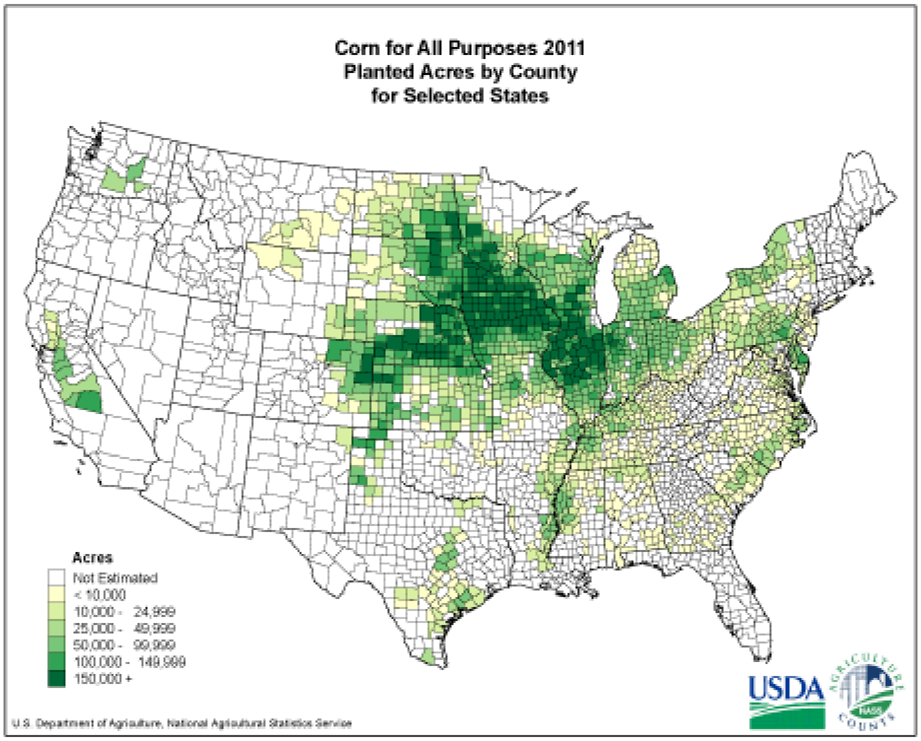

Figure 1: The 2011 Estimated Amount of Planted Corn Acreage by U.S. County in Selected States

Source: (USDA-NASS, 2011d)

Corn acreage in the U.S. increased during the second half of the 2000s. The establishment of a bioethanol industry using corn as a feed stock has been identified as one of the key elements in the increase in acreage devoted to corn, with more than 40% of the corn harvest now dedicated to corn-based biofuel production Wilson, 2011 (Wilson, 2011). Since 2006, many U.S. cotton farmers have converted to corn and soybean because of favorable prices (USDA-ERS, 2009).

Growers can choose from a large number of corn hybrids produced from traditional breeding or GE systems (NCGA, 2009). Like the major commodity crops cotton and soybean, GE varieties of corn have been adopted during the past decade. In 2000, approximately 6% of all corn planted was GE herbicide-resistant, and 25% of the total crop was GE (Benbrook, 2009b). By 2009, 22% of the US corn crop was GE herbicide-resistant and 17% was insect-resistant (Benbrook, 2009a; USDA-ERS, 2010a). As of 2011, it was estimated that approximately 23% of the crop was GE herbicide-resistant only, 16% was GE insect-resistant only, 49% was a stacked gene variety (likely both herbicide resistant and insect resistant), and 88% of the total U.S. corn crop was planted in some GE variety (USDA-NASS, 2011b).

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

Corn planting dates range from late March in Kansas to late May in North Dakota, (IPM, 2007). Corn ideally is planted when soil temperature reaches 55°F at 2-inch depth (IPM, 2007).

Growers can choose from several different crop management practices depending upon geographic cultivation area and end-use market (IPM, 2004; IPM, 2007). Common corn cultivation practices include various methods of tillage, selection of a crop rotation system, and other agronomic inputs.

Tillage

Prior to planting, the soil must be stripped of weeds that would otherwise compete with the crop for space, water, and nutrients. Field preparation is accomplished through a variety of tillage systems, with each system defined by the remaining plant residue on the field. A number of different tillage and planting systems are used in corn production, including primary and/or secondary tillage or no pre-plant tillage operations (IPM, 2007 63). Conservation tillage includes reduced till, mulch-till, eco-fallow, strip-till, ridge-till, zero-till, and no-till (IPM, 2007). Conventional tillage is associated with intensive plowing and leaving less than 15% crop residue in the field; reduced tillage is associated with 15 to 30% crop residue; and conservation tillage, including no-till practices requiring herbicide application on the plant residue from the previous season, is associated with at least 30% crop residue and substantially less soil erosion than other tillage practices (US-EPA, 2009a). Increases in total acres dedicated to conservation tillage have been attributed to an increased use of GE crops including corn, reducing the need for mechanical weed control (USDA-ERS, 2006; USDA-NRCS, 2006b; Towery and Werblow, 2010b). For example, the introduction of herbicide-resistant varieties of cotton and soybean encouraged some growers to adopt conservation practices that had not been previously fully adopted in the field (Givens et al., 2009). However, availability of herbicide-resistant corn was likely not the only driving factor in adoption of these practices, as many corn growers had already adopted conservation tillage practices before the herbicide-resistant corn varieties were introduced to the market (Givens et al., 2009).

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

Crop Rotation

Crop rotations (successive planting of different crops on the same land in subsequent years) are used to optimize soil nutrition and fertility, reduce pathogen loads, control volunteers (carry over in successive years), and limit the potential for weeds to develop resistance to herbicides (IPM, 2004; IPM, 2007; USDA-ERS, 2010b). Corn can be grown successfully in conservation tillage system if rotated with other crops such as wheat and soybeans, which will reduce some of the problems encountered with conservation tillage (IPM, 2007).

Rotations need not be fixed, but dynamic, and increased flexibility of rotations may be favored as growers respond to soil moisture content, yield increases from crop sequence advantages or interference, pest management requirements and market conditions; corn planted by election in dynamic sequences may lead to outperformance of wheat yield over that in 5 year fixed rotations (Tanaka and Liebig, 2012).

In 2010, 71 percent of corn acreage in 19 surveyed states was under some form of rotation (USDA-NASS, 2011c). Cropland used for corn and soybean production is nearly identical in many areas, where over 90 percent of the cropped area is planted in a two-year corn-soybean rotation (Hoeft et al., 2000b).

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.

While soybean-corn rotation is largely practiced in Iowa (USDA-ERS, 2006) and of other Midwest states, recent encouragement has been given to rotate with a third crop such as oats or alfalfa because the sequence may suppress rotation crop pathogens (L. Leandro, Iowa State University: (see Masterson (2010; Leandro and Kull, 2012). A three or four year crop rotation could also potentially reduce total use of herbicides without increasing weed production (Davis et al., 2012).Central and Northern Great Plains rotations using no-till might include wheat, sorghum, dry edible beans, millet, or sunflower (Beck et al., 1998).Southern states include corn in rotation with cotton, soybeans and peanuts (Webster and Nichols, 2012).Recently, there has been an increase in continuous corn rotations due to high corn commodity prices and the strong demand for corn grain (USDA-ERS, 2011b). Consecutive plantings of corn are estimated at around 10% in 10 corn states (USDA-ERS, 2006) and closer to 30% in Iowa (Duffy, 2011). Continuous corn in the Corn Belt frequently requires at-planting or pre-plant pesticide treatments to control corn pests and pathogens as well as supplemental fertilizer treatments (IPM, 2004; Erickson and Lowenberg-DeBoer, 2005; Sawyer, 2007; Stockton, 2007). Corn-to-corn rotations also may require a change in tillage practices. Corn-to-corn cultivation may produce substantially greater quantities of field residue, requiring additional tillage prior to planting (Erickson and Lowenberg-DeBoer, 2005). Continuous corn rotations require more fertilizer treatments to replace diminished soil nitrogen levels and more pesticide applications (Bernick, 2007; Laws, 2007; Erickson and Alexander, 2008). The increased adoption of corn-to-corn rotation, mainly in conventional and GE production systems, has been attributed to rising corn demand and prices (Hart, 2006; Stockton, 2007).

Corn has been reported as a volunteer in crops the year after harvest (Beckett and Stoller, 1988; USDA-APHIS, 2012a). This issue is discussed in Subsection 2.3.2 Plants: *Corn as a Volunteer* and the corresponding impacts analysis in Subsection 4.4.2 Plants: *Corn as a Volunteer.*

Agronomic Inputs

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

Fertilization

Given the importance of nutrient availability to corn agronomic performance, fertilization with nitrogen, phosphorus, and potassium is practiced widely (Ritchie et al., 2008). In 2005 (the date of the last USDA Agricultural Chemical Usage Summary to include corn), fertilizers were applied to 96% of corn acreage in 19 reported states (USDA-NASS, 2006). In a 2010 survey of program states, the USDA-NASS reported that nitrogen was applied to 97% of the 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 (Table 2.(USDA-NASS, 2011a).

Table 2-1: Corn: total fertilizer primary nutrient applications, 2010.

Primary Nutrient	Area Applied (percent)	Applica-tions (number)	Rate per Application (pounds per acre)	Rate per Crop Year (pounds per acre)	Total Applied (million pounds)
Nitrogen	97	1.8	78	140	11,030.9
Phosphate	78	1.2	52	60	3,800.4
Potash	61	1.2	73	79	3,943.5
Sulfur	15	1.2	11	13	166.5

Source: (USDA-NASS, 2011a).

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

Pesticides

Pesticide use, including both insecticides and herbicides, is common in corn production. In 2010, approximately 12% of the corn-planted acreage was treated with insecticides, with the most frequently applied (listed in order of total pounds applied) being chlorpyrifos for corn rootworm and 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), Table 2.2).

Table 2-2: **Corn: total insecticide applications, 2010.**

Insecticide	Area Applied (percent)	Applica-tions (number)	Rate per Application (pounds per acre)	Rate per Crop Year (pounds per acre)	Total Applied (thousand pounds)
Bifenthrin	2	1	0.039	0.039	86
Chlorpyrifos	1	1	0.857	0.875	478
Cyfluthrin	2	1	0.008	0.008	15
Dimethoate	<0.5	1.1	0.481	0.513	52

Lambda-cyhalothrin	2	1	0.016	0.017	24
Permethrin	1	1	0.13	0.13	72
Propargite	<0.5	1	1.721	1.721	109
Spiromesifen	<0.5	1.2	0.194	0.224	59
Tebupirimphos	2	1	0.111	0.111	195
Tefluthrin	3	1	0.115	0.116	242
Terbufos	<0.5	1	0.722	0.722	137
Zeta-cypermethrin	<0.5	1	0.007	0.007	2

Source: (USDA-NASS, 2011a).

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

Although it is generally agreed that insecticide use in U.S. crops has decreased since the introduction of GE insect-resistant crops, the long-term trends related to herbicide use resulting from the utilization of GE technologies are the subject of much debate (Benbrook, 2009b; Fernandez-Cornejo et al., 2009; Brookes and Barfoot, 2010). Benbrook has reported that the adoption of herbicide-resistant crops has resulted in an increase in the volume of herbicides applied to crops (Benbrook, 2009b). Benbrook notes that herbicide use declined between 1996 and 2001 apparently in direct response to the adoption of herbicide-resistant crops; however, since that time, herbicide use has increased (Benbrook, 2009b). Reported increases in herbicide use during the last decade reflect an increase in glyphosate applications as more glyphosate-resistant crops are planted and an associated increase in use of other herbicides used to control glyphosate-resistant weeds (Benbrook, 2009b). Others report a continuing decline in herbicide use with the adoption of GE crops (Fernandez-Cornejo and Caswell, 2006) and in the amount of herbicide active ingredients applied to corn (Brookes and Barfoot, 2010). The contradictory findings have been attributed to the different measurement approaches used by researchers, the manner in which different factors affecting pesticide use such as weather or cropping patterns are controlled for, and how collected data is statistically analyzed (NRC, 2010a).

In 2012, approximately 21% of corn planted in the U.S. possessed resistance to only an herbicide trait that was conferred through biotechnology and another 52% were stacked with other traits including herbicide resistance and insect resistance (Table 2.4:(USDA-NASS, 2012a)). The primary herbicide resistance trait in use has been glyphosate resistance, and the adoption of this trait in other major crops, such as cotton and soybean, is even higher (USDA-APHIS, 2012a). Weed resistance to herbicides is a concern in agricultural production and the wide-spread adoption of herbicide-resistant crops, especially GE-derived glyphosate-resistant crops, has dramatically changed the approach that farmers take to avoid yield losses from weeds, (Gianessi, 2008; Duke and Powles, 2009).

Herbicides were applied to 98% of corn acreage in 2010, with the following four herbicides identified as the most commonly applied: atrazine (61% of the acreage, 51.1 million pounds applied), glyphosate (68% of the acreage, 64.3 million pounds), s-metolachlor (23% of the acreage, 21.8 million pounds), and acetochlor (25% of the acreage, 27.9 million pounds) (USDA-NASS, 2011a) summarized in Table 2.3. The relationship of these herbicide treatments to the adoption of GE varieties is illustrated in Table 2.4 below, which presents the percentage of acres of herbicide-resistant and insect-resistant corn varieties cultivated in 2012. The data on this table suggest that approximately 73% of the total corn acreage in the U.S. was an herbicide resistant hybrid (HT + Stacked hybrids).

Table 2-3: Corn: total herbicide applications, 2010[1].

Herbicide	Area Applied (percent)	Applica-tions (number)	Rate per Applica--tion (pounds per acre)	Rate per Crop Year (pounds per acre)	Total Applied (thou-sand pounds)
2,4-D, 2-EHE	4	1.1	0.39	0.437	1,479
2,4-D, BEE	1	1.6	0.308	0.504	286
2,4-D, dimeth. salt	4	1	0.366	0.379	1,147
2,4-D, isoprop. salt	--	1.3	0.069	0.086	24
Acetochlor	25	1	1.392	1.398	27,921
Acifluorfen, sodium	1	1	0.043	0.043	21
Alachlor	--	1	1.225	1.232	412
Atrazine	61	1.1	0.946	1.034	51,129
Carfentrazone-ethyl	--	1	0.011	0.011	4
Clopyralid	5	1	0.088	0.089	328
Dicamba	--	1	0.126	0.126	23
Dicamba, digly. salt	1	1	0.194	0.194	134
Dicamba, dimet. salt	2	1.2	0.209	0.249	480

Herbicide	Area Applied (percent)	Applica-tions (number)	Rate per Applica--tion (pounds per acre)	Rate per Crop Year (pounds per acre)	Total Applied (thou-sand pounds)
Dicamba, pot. salt	--	1.7	0.246	0.145	116
Dicamba, sodium salt	3	1.1	0.088	0.097	245
Diflufenzopyr-sodium	2	1.1	0.035	0.04	79
Dimethenamid	1	1	0.986	1.02	520
Dimethenamid-P	5	1.1	0.593	0.63	2,603
Flufenacet	1	1	0.329	0.329	280
Flumetsulam	5	1	0.033	0.034	125
Foramsulfuron	--	1	0.029	0.029	9
Glufosinate-Ammonium	2	1	0.296	0.298	515
Glyphosate	7	1.1	0.843	0.931	5,255
Glyphosate amm. salt	1	1.1	0.09	0.095	46
Glyphosate iso. salt	66	1.3	0.824	1.065	57,536
Glyphosate pot. salt	2	1.3	0.936	1.204	1,522
Halosulfuron	--	1.1	0.017	0.019	3
Isoxaflutole	7	1	0.065	0.066	399
Linuron	--	1	1.356	1.356	206
MCPA, sodium slat	--	1	0.427	0.427	173
Mesotrione	17	1	0.116	0.121	1,693
Metolaclor	1	1	1.234	1.276	546

Herbicide	Area Applied (percent)	Applica-tions (number)	Rate per Applica--tion (pounds per acre)	Rate per Crop Year (pounds per acre)	Total Applied (thou-sand pounds)
Nicosulfuron	2	1	0.016	0.016	29
Paraquat	1	1.1	0.641	0.699	468
Pendimethalin	1	1	1.154	1.154	1,385
Primisulfuron	--	1	0.023	0.023	5
Prosulfuron	--	1	0.008	0.008	1
Rimsulfuron	--	1.1	0.014	0.015	48
S-Metolachlor	23	1.1	10.76	1.159	21,831
Saflufenacil	1	1.3	0.059	0.075	40
Simazine	2	1.1	1.038	1.169	2,196
Tembotrione	2	1	0.064	0.064	103
Thiencarbazone-methy	2	1	0.025	0.025	41
Thifensulfuron	2	1	0.007	0.007	11
Topramezone	1	1	0.014	0.014	9
Trifluralin	1	1	0.608	0.608	257

Source: (USDA-NASS, 2011a).

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

Table 2-4: Percentage of Herbicide-resistant, Insect-resistant, Stacked Trait, Total GE Corn, and Total Corn Acreage Planted in Select States in 2012.

State	Herbicide-resistant (%)	Insect-resistant (Bt) (%)	Stacked (%)	Total GE (%)	Total Corn Acreage (1,000 acres)
Indiana	15	9	60	84	6,200
Illinois	18	14	53	85	13,000
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 U.S.	21	15	52	88	96,450

Source: (USDA-NASS, 2012a).

Introduction of herbicide-resistant corn varieties, in particular glyphosate-resistant corn, has not significantly affected corn acreage managed with total herbicide application (Table 2.4). Herbicide application trends are presented in Table 2.5. While the applications of atrazine and acetochlor in corn have been relatively stable, application rates for glyphosate have increased. There are several reasons for the success of glyphosate in the market and the corresponding market sector penetration of glyphosate-resistant crops since their introduction in the mid-late 1990s. Glyphosate 1) works non-selectively on a wide range of plant species; 2) is a relatively low-cost herbicide; 3) enhances 'no-till' farming practices; and 4) has minimal animal toxicological and environmental impact (USDA-APHIS, 2012a).

Table 2-5 Percent of U.S. corn acres[1] treated with herbicides in 1995, 2000, 2005 and 2010.

Herbicide	Percent Corn Acres Treated				Herbicide	Percent Corn Acres Treated			
	1995	2000	2005	2010		1995	2000	2005	2010
2,4-D[2]	13	8	3	4	Glyphosate Ammonium Salt	--	--	--	1
2,4-D, 2-EHE	--[3]	--	3	4	Glyphosate Iso. Salt	--	--	31	66
2,4-DB	--	--	--	1	Glyphosate Potassium Salt	--	--	--	2
2,4-D, Isopropyl salt	--	--	1	--	Halosulfuron	1	--	1	--
Acetochlor	18	25	23	25	Imazapyr	--	2	1	--
Acifluorfen, Sodium	--	--	--	1	Imazaquin	15	--	--	--
Alachlor	8	4	1	--	Imazethapyr	1	3	1	--
Atrazine	65	68	66	61	Isozaflutole	--	3	6	7
Bentazon	2	2	--	--	MCPA Sodium Salt	--	--	1	--
Bromoxynil	8	4	1	--	Mesotrione	--	--	20	17
Butylate	1	--	--	--	Metolachlor	29	12	2	1
Carfentrazone-ethyl	--	1	--	--	Metribuzin	1	2	--	--
Clopyralid	--	9	5	5	Nicosulfuron	13	15	10	2
Cloransulam	--	--	1	--	Paraquat	1	1	1	1
Cynazine	17	--	--	--	Pendimethalin	4	3	2	1

Dicamba	27	21	1	--	Primisulfuron	3	9	2	--
Dicamba Digly. Salt	--	--	2	1	Prosulfuron	--	4	1	--
Dicamba Dimet. Salt	--	3	3	2	Pyridate	--	5	--	--
Dicamba Pot. Salt	--	5	2	--	Rimsulfuron	1	9	8	4
Dicamba Sodium Salt	--	--	4	3	Saflufenacil	--	--	--	1
Diflufenzopyr-Sodium	--	3	4	2	S-Metolachlor	--	16	23	23
Dimethenamid	3	7	1	1	Simazine	3	2	3	2
EPTC	3	1	--	--	Sulfosate	--	--	1	--
Fluazifop	--	3	--	--	Tembotrione	--	--	--	2
Flufenacet	--	2	3	1	Thiencarbazone-methy	--	--	--	2
Flumetsulam	1	10	6	5	Thifensulfuron	1	--	--	2
Foramsulfuron	--	--	2	--	Topramezone	--	--	--	1
Glufosinate-Ammonium	2	--	5	2	Trifluralin	--	--	1	1
Glyphosate	6	9	2	7					

Source (USDA-NASS, 2011a)).

[1] Survey states:

1995: Delaware, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, North Carolina, Ohio, Pennsylvania, South Dakota, Texas, and Wisconsin.

2000: Colorado, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, New York, North Carolina, North Dakota, Ohio, Pennsylvania, South Dakota, Texas, and Wisconsin.

2005: Colorado, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, New York, North Carolina, North Dakota, Ohio, Pennsylvania, South Dakota, Texas, and Wisconsin.

2010: Colorado, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, New York, North Carolina, North Dakota, Ohio, Pennsylvania, South Dakota, Texas, and Wisconsin.

[2] Dimethylamine salt formulation of 2,4-D

[3] -- = No value

Increased selection pressure resulting from the wide-spread adoption of glyphosate-resistant 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 (Owen, 2008; Duke and Powles, 2009). To deter this trend and to avoid decreased crop yields resulting from weed competition, growers adapt weed management strategies, including the use of herbicides with alternative modes of action (Genective, 2012). Alternative modes of action in this case refer to herbicides which are different with respect to how they act on the plant physiology. Some common modes of herbicide action include chloroacetamide class (acetochlor, metolachlor), HPPD-inhibitors (mesotrione), photosystem-II inhibitors or triazines (atrazine), auxin growth regulators (2,4-D), sulfonylureas or acetolactate synthase inhibitors (nicosulfuron), or amino acid inhibitors (glyphosate), (Ross and Childs, 2011). The practice of consistently using herbicides with alternative modes of action instead of reliance primarily on glyphosate 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; Owen, 2008; Duke and Powles, 2009; Genective, 2012).

The emergence of resistance to herbicides is not exclusive to glyphosate-resistant crops and corresponding weedy species. Tables 2.6 through 2.9 lists those weedy species which have been identified as herbicide-resistant in at least some part of their range. The emergence of herbicide resistance presents continued challenges to growers to understand which herbicide-resistant species is present and the best agronomic practice available to manage the weed.

Table 2-6: U.S. Chloroacetamide-resistant Weeds through December 2012

Scientific Name	Common Name	Year Identified
Lolium multiflorum	Italian Ryegrass	2005

Source: (Heap, 2012).

Table 2-7: U.S. 4-HPPD Inhibitor-resistant Weeds through December 2012

Scientific Name	Common Name	Year Identified
Amaranthus tuberculatus (syn. rudis)	Common Waterhemp	2009

Source: (Heap, 2012).

Table 2-8: **Photosystem II Inhibitor-resistant Weeds through December 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
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).

Table 2-9: **U.S. Glyphosate-resistant Weeds through December 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).

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). Such an integrated weed management approach should combine:

- Rotation of crops – to allow a more varied weed control program
- Rotation of cultural practices – to reduce reliance on herbicides
- Rotation of sequences and mixtures of herbicidal modes of action and chemistry – to reduce the pressure on a specific herbicide group (Powles and Preston, 2009).

Monsanto, the developer of glyphosate, includes the following strategies to advise growers in managing the risk of weed resistance (Monsanto, 2011b):

- Scout fields before and after herbicide application.
- Start with a clean field, using either a burn-down herbicide application or tillage.
- Control weeds early when they are relatively small.
- Rotate herbicides that have different modes of action.
- Use residual herbicides that have different modes of action.
- Use tank-mixes of herbicides that have different modes of action.

- Incorporate other herbicides and cultural practices as part of glyphosate resistant cropping systems where appropriate.
- Use the right herbicide product at the right rate and the right time.
- Control weed escapes and prevent weeds from setting seeds.
- Clean equipment before moving from field to field to minimize spread of weed seed.
- Use new commercial seed as free from weed seed as possible.
- Report any incidence of repeated non-performance on a particular weed to the local crop protection chemical company representative, retailer, or county extension agent.

2.1.3 Organic Corn Production

In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

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

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

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

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

> A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods (USDA-AMS, 2010).

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).

Although conventional corn yields tend to be higher than organic yields, net returns from organic acres continues to be greater than net return from conventional acres, with a 16% premium received for organic growers reported in 2008 (Kuepper, 2002; Coulter et al., 2010; Roth, 2011). Certified organic corn acreage is a relatively small percentage of overall corn production in the U.S.   The most recently available data show 194,637 acres of certified organic corn production in 2008 (Table 6; (USDA-ERS, 2011h). This is 0.16% of the 93.6 million acres of corn planted in 2008 (Table 3; (USDA-ERS, 2011h).

2.2 Physical Environment

2.2.1 Water Resources

Corn is a water sensitive crop with a low tolerance for drought. 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 1 bushel of grain (NCGA, 2007a). The water demand is variable over the growing season, with the greatest water demand during the silk production stage in mid-season. During this stage, the water requirement is estimated at approximately two inches of water per week (or 0.3 inches per day) (Heiniger, 2000; Farahani and Smith, 2011).

This water demand is met by a combination of natural rainfall, stored soil moisture from precipitation before the growing season, and supplemental irrigation during the growing season (Heiniger, 2000; Farahani and Smith, 2011). Groundwater is the major source of water for irrigation and is used on almost 90% of irrigated corn acreage in the U.S. (Christensen, 2002). Corn for grain has substantially more irrigated area than any other single crop in the U.S. (Christensen, 2002). In 2007, 13.0 million U.S. corn acres were irrigated, representing 15% of all corn acres harvested for grain (USDA-NASS, 2009).

Non-point source (NPS) pollution is the primary source of pollutant discharge to rivers and lakes (US-EPA, 2003). Agricultural 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 EPA lists the most frequent cause of impairment in assessed streams and rivers from all sources as pathogens, with sediment second, and nutrients third; pesticides are only the 16th most important (US-EPA, 2012b). The primary cause of agricultural NPS pollution, however, is increased sedimentation in surface waters following soil erosion (US-EPA, 2005). The major contribution to groundwater contamination derives from agricultural areas (nitrogen inputs from fertilizer and manure) and is influenced by regional environmental factors such as precipitation and soil characteristics (US-EPA, 2003). Nutrients in excess are listed as the second cause of impairment in lakes, reservoirs, and ponds, with agriculture listed as the third most probable source of the impairment (US-EPA, 2012b).

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). Increase in sediment loads to surface waters can directly affect fish, aquatic invertebrates, and other wildlife maintenance and survival. It also reduces the amount of light penetration in water which directly affects aquatic plants. Indirectly, soil erosion-mediated sedimentation can increase fertilizer runoff, facilitating higher water turbidity, algal blooms, and oxygen depletion (US-EPA, 2005).

Because of its low mobility in soil, the potential for glyphosate leaching to groundwater is low and its potential movement to surface waters at high levels is considered low (US-EPA, 2009f); however, glyphosate can enter surface and subsurface waters if used in close proximity to water bodies or by runoff from terrestrial applications (WHO, 2005). In water, glyphosate adsorbs to suspended organic and mineral matter and is broken down primarily by microorganisms. In aerobic water, sediment glyphosate has a residual half-life of 7 days, but in anaerobic aquatic sediment settings its residual half-life is approximately 208 days (US-EPA, 2009f). Surfactants may be used with glyphosate because the latter is highly soluble in water and will easily drip off plant surfaces (US-EPA, 2009f).

Coupe et al (2011) recently evaluated the fate of glyphosate and its AMPA degradate on a watershed scale in three Mississippi River basin watersheds and compared results to a watershed in France. They found from 0.06 to 0.86% of glyphosate was transported to surface water, although their samples frequently detected both glyphosate and AMPA (Coupe et al., 2011). Variability was correlated to differences in source strength, rainfall runoff, and flow route. The study concluded the watersheds most at risk for transport of glyphosate have high application rates, rainfall events resulting in overland runoff, and flow routes unfiltered by soil. Glyphosate has not been identified as the cause of impairment to any water bodies classified as such under Section 303(d) of the CWA (US-EPA, 2011d).

Conservation tillage and no-till practices have been shown to minimize soil erosion and runoff to surface water. This is discussed more fully in the following section.

2.2.2 Soil Quality

Corn is cultivated in a wide variety of soils across the U.S. (see, e.g., Corn Crop Profiles, (IPM-Centers, 2013)). The timing for corn planting is variable, but generally starts when soil temperatures reach 50°F (IPM, 2004; IPM, 2007).

Conventional corn tillage traditionally requires that the producer remove all plant residues and weeds from the soil surface prior to planting (primary and secondary tillage), and then continue with shallow tillage to cultivate the soil while the crop is growing to control late emerging weeds (Hoeft et al., 2000a; NCGA, 2007b). This practice results in soil loss to wind and water erosion (NCGA, 2007b).

Conservation practices, including conservation tillage, have been developed to reduce field tillage and thus reduce the corresponding soil loss (USDA-NRCS, 2006c). By definition, conservation tillage leaves at least 30% of the soil covered by crop residue (Peet, 2001). 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 prepared 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). Benefits of reduced tillage practices include retention of soil organic matter and beneficial insects, increased soil water-holding capacity, less soil and nutrient loss from the field, reduced soil compaction, and less time and labor required to prepare the field for planting (Peet, 2001).

Corn cultivation using conservation tillage practices can result in as much as 50% soil cover as residue following harvest (Werblow, 2007). This land cover aids in maintaining soils (Werblow, 2007). Other conservation measures successfully used on corn acres include contour farming, grass buffered drainageways, terraces, and retention/detention ponds (NCGA, 2007b). Increases in total acres dedicated to conservation tillage have been attributed to an increased use of herbicide-resistant GE seed which eliminates the need for mechanical weed control (Towery and Werblow, 2010b) (USDA-NRCS, 2006b) and direct survey of grower's tillage methods following glyphosate resistant seed use showed that corn growers increased adoption of conservation tillage; the percentage who already used these techniques was already high (Givens et al., 2009). Corn cultivation residues in a conservation tillage production system have been identified as causing cool, wet soils along with heavy residues which impede seeding or germination (Werblow, 2007). 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, 2007c; Werblow, 2007). As noted in the discussion of Cropping Practices in Subsection 2.1.2, conservation tillage also has been identified as presenting potential disease management challenges for those growers cultivating corn-to-corn (Robertson et al., 2009).

As reduced tillage practices are adopted, there is a corresponding increase in organic matter in soil. This helps bind soil nutrients resulting in significant reductions in the loss of cropland soil from runoff, erosion, and leaching over time (Leep et al., 2003; USDA-NRCS, 2006b; USDA-NRCS, 2006c; NCGA, 2007b; NCGA, 2007c). 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). This decrease in soil erosion carries a corresponding decrease in non-point source surface water pollution of fertilizer and pesticides (NCGA, 2007b). The reduction in soil erosion also is attributed to a decrease in the number of acres of highly erodible cropland being cultivated (USDA-NRCS, 2006b).

Depending on the physical setting of the agricultural operation, conservation tillage may be required. Farmers, including corn growers, producing crops on highly erodible land are required by law to maintain a soil conservation plan approved by the USDA National Resources Conservation Service (NRCS) (USDA-ERS, 2012a). These soil conservation plans are prepared by the grower pursuant to the 1985 Food Security Act Conservation Compliance and Sodbuster programs to minimize soil erosion (USDA-ERS, 2012a). Corn farmers also are actively involved in state, local, and national programs that idle environmentally sensitive land from crop production, including the Conservation Reserve Program, the Conservation Reserve Enhancement Program, and the Farmable Wetlands Program (NCGA, 2007c).

Pesticide use has the potential to affect soil quality due to impacts to the microbial community, and is discussed further in Subsection 2.3.4, Microorganisms. Glyphosate is rapidly and tightly adsorbed in soil; its adsorption rate is minimally influenced by organic matter, the amount of clay, silt, or sand, and pH, although soil high in phosphate decreases its adsorption (Senseman, 2007), making it more available for plant uptake, microbial degradation, and leaching (Kremer and Means, 2009). Glyphosate is microbially degraded in soil and water and the rate of decomposition varies with the microbial structure and population, having an average soil residual half-life of 47 days (Senseman, 2007).

It has been reported that glyphosate appears to interact with manganese by forming insoluble, stable complexes that either immobilize this element, reducing plant uptake, or preventing reduction in the plant, making it unavailable (Eker et al., 2006; Neumann et al., 2006; Ozturk et al., 2008; Cakmak et al., 2009; Huber, 2010). These studies were not necessarily done on glyphosate resistant crop varieties, however, and most were not conducted in soil, but in nutrient solutions, and in a greenhouse. Huber (2010) and Cakmak et al. (2009) also reported that glyphosate is a broad-spectrum chelate of several other nutrients (e.g., iron, calcium, magnesium, copper, iron, nickel, and zinc); however, these assertions are not without debate. (Hartzler, 2010) agrees that glyphosate could immobilize essential elements temporarily, but offers that it does not specifically target manganese or any other particular element, but instead targets those cations that are most prevalent in the soil. Hartzler (Hartzler, 2010) also reports that areas in which glyphosate interactions with manganese nutrition are reported are also areas with known soil manganese deficiencies. (Camberato et al., 2010) points out that manganese deficiency is not a new phenomenon and is also associated with high pH, low moisture, or high levels of organic matter; furthermore, manganese deficiency is easily recognizable and can usually be resolved through foliar application(s) of manganese fertilizers. One field based report showed that glyphosate resistant lines showed no deficiencies of manganese compared to their near-isoline controls, but sometimes responded with greater yield to manganese treatment, but not consistently; glyphosate resistance does not consistently affect either manganese uptake or responsiveness (Loecker et al., 2010). More recent results also have shown that two applications of glyphosate in the field do not alter leaf mineral content of soybean six weeks after application at either nine or 12 weeks after planting (Duke et al., 2012).

2.2.3 Air Quality

Air emissions from agricultural operations include smoke from agricultural burning, vehicle exhaust associated with equipment used in tillage and harvest, suspended soil particulates associated with tillage, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer (Hoeft et al., 2000a; USDA-NRCS, 2006a; USDA-NRCS, 2006b; Aneja et al., 2009; US-EPA, 2011a). These agricultural activities individually have the potential to cause negative impacts to air quality.

Volatilization of fertilizers, herbicides, and pesticides from soil and plant surfaces also introduces these chemicals to the air. The USDA Agricultural Research Service (ARS) is conducting a long-term study to identify factors that affect pesticide levels in the Chesapeake Bay region airshed (USDA-ARS, 2011). This study determined that volatilization is highly dependent upon exposure of disturbed unconsolidated soils and variability in measured compound levels is correlated with temperature and wind conditions. Another ARS study of volatilization of certain herbicides after application to fields has found moisture in dew and soils in higher temperature regimes significantly increase volatilization rates (USDA-ARS, 2011). Glyphosate has a low vapor pressure and volatilization from soils is not considered an important dissipation mechanism (US-EPA, 1993b).

Pesticide and herbicide spraying introduce air quality impacts from drift and diffusion. Drift is defined by the EPA as "the movement of pesticide through air at the time of application or soon thereafter, to any site other than that intended for application" (US-EPA, 2000). Diffusion is gaseous transformation to the atmosphere (FOCUS, 2008). Factors affecting drift and diffusion include application equipment and method, weather conditions, topography, and the type of crop being sprayed (US-EPA, 2000). The EPA is currently evaluating new regulations for pesticide drift labeling and the identification of BMPs to control such drift (US-EPA, 2009e), as well as identifying scientific issues surrounding field volatility of conventional pesticides (US-EPA, 2010b).

Chang (2011) recently evaluated the occurrence and fate of glyphosate and its degradate AMPA in the atmosphere and rainfall in the Mississippi River basin. They found the frequency of glyphosate in the air and rain was similar to that of other commonly applied herbicides such as atrazine and metolachlor, but its concentration in rain was higher, primarily due to the widespread use of glyphosate for crop production in the region (Chang et al., 2011). AMPA in air was sampled at a range of <0.01 to 0.97 nanograms per cubic meter, initially lower in the application season and increasing as glyphosate degraded in soil to produce the metabolite; its incidence in rain was similar to that of glyphosate. The study also investigated the source of glyphosate in the air and found most occurred from spray application rather than volatilization or transport from windborne soil. Chang et al. Chang (2011) conclude up to 97% of glyphosate may be removed from the atmosphere by weekly rainfall greater than 30 millimeters (1.18 inches).

Many of the conservation plans and practices being developed by corn growers to comply with the Conservation Compliance and Sodbuster programs have an air quality focus which target reductions in air emissions from agricultural operations (USDA-NRCS, 2006a; US-EPA, 2013) . 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; USDA-NRCS, 2006b)). 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 by 2006, 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 (Baker et al., 2005; USDA-NRCS, 2006a)).

2.2.4 Climate Change

Climate change represents a significant and lasting statistical change in climate conditions that may be measured across both time and space. As scientists and the public became more concerned with climate change and the impact that human-derived air pollutants were having on global temperature, the EPA identified CO_2, methane (CH_4), and nitrous oxide (N2O) as the key GHG effecting warming temperatures. While each of these gases occurs naturally in the atmosphere, human activity has significantly increased the concentration of these gases since the beginning of the industrial revolution. The level of human-produced gases accelerated even more so after the end of the Second World War, when industrial and consumer consumption flourished. With the advent of the industrial age, there has been a 36% increase in the concentration of CO_2, 148% in CH_4, and 18% in N_2O (US-EPA, 2012a).

U.S. agriculture may influence climate change through various facets of the production process (Horowitz and Gottlieb, 2010) and conversion of land to agriculture. The major sources of GHG emissions associated with crop production are soil N_2O emissions, soil CO_2 and CH_4 fluxes, and CO_2 emissions associated with agricultural inputs and farm equipment operation (Adler et al., 2007; US-EPA, 2012a). Over the 20-year period of 1990 to 2009, total emissions in the agriculture sector grew by 9.3%, and in 2009, this sector was responsible for 6.3% of total U.S. GHG emissions (US-EPA, 2012a). CH_4 and N_2O were the primary GHG emitted by agricultural activities. Emissions from intestinal (enteric) fermentation and manure management represent about 21% and 8% of total CH_4 emissions from anthropogenic activities, respectively (US-EPA, 2012a). Agricultural soil management activities including fertilizer application and cropping practices were the largest source of N_2O emissions, accounting for 68% of all U.S. N_2O emissions (US-EPA, 2012a).

Emissions of GHG released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide (CO), nitrogen oxides(N_20), methane (CH_4), reactive organic gases, particulate matter, and sulfur oxides (SOx) (US-EPA, 2011a). On-site C emissions from equipment can be reduced by 41% for some crops (i.e., wheat) when changing from conventional tillage to no-till systems and 33% in corn (Nelson et al., 2009). Reduced tillage practices which increased from 1990 to 2004 resulted in reductions of C of 2.4 terragrams in total onsite and offsite C production from energy production (Nelson et al., 2009). Emission of carbon dioxide, a significant GHG gas is associated with several agricultural practices, including land use changes and subsequent energy consumption changes. For example increases may occur when forested land is cleared and planted to row crops, or when perennial crops such as grassland are replaced by an annual crop (US-EPA, 2012a). Energy consumption and their waste gases from new production on these acres also increase CO_2 production.

Tillage contributes to increased GHG because it releases carbon dioxide (CO_2) to the atmosphere, and the exposure and oxidation of soil organic matter (Baker et al., 2005). On-site emissions from energy use can be reduced by 20% for some crops (i.e., wheat) when changing from conventional tillage to no-till systems (Nelson et al., 2009). Sequestration rather than emission can also differ substantially when comparing tillage systems. The difference between sequestered carbon associated with no till compared to that of conventional tillage corn of all production systems is a significant increase of 812 g/m^2 (West and Post, 2002).Crops each have different sequestration changes when no till is compared with conventional till, and the benefit for continuous corn production is 270 g/m^2 C over that of continuous soybean (West and Post, 2002).

The contribution of agriculture to climate change largely is dependent on the production practices employed to grow various commodities, 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, 2012a). 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, 2012a). Conversion of crop land to pasture results in an increase in carbon and nitrogen sequestration in soils (US-EPA, 2012a).

The 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, 2012a). 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, 2011a; US-EPA, 2012a). 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, 2011a; US-EPA, 2012a). 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, 2012a). The EPA has estimated that mineral soil-based cropland areas sequestered over 45.7 Tg CO_2 Eq[5] in 2008, as compared with carbon emissions from organic soil-based croplands of 27.7 Tg CO_2 Eq (US-EPA, 2012a). The adoption of conservation tillage, particularly in the Midwest regions with mineral soil shows the highest rates of carbon sequestration (US-EPA, 2012a).

Changes in agriculture-related GHG production will not be significant unless large amounts of crop plantings produce changes in measureable concentrations. Because this product will be similar to other glyphosate resistant hybrids, APHIS does not anticipate any additional acreage or changes in GHGs produced by VCO-01981-5 hybrids.

Other agriculture related changes affect GHG production. The EPA has identified a net reduction of sequestration of carbon in soil over an 18-year time scale, which results from a declining influence of the Conservation Reserve Program. The CRP had encouraged growers to take marginal lands out of production (US-EPA, 2012a). To a certain extent, the EPA also noted that adoption of conservation tillage resulted in increases in carbon sequestration on those croplands (US-EPA, 2012a). 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, 2012a). This is in contrast to the highest rates of emission which occur in organic soils notably in the southeastern coastal region, the areas around the Great Lakes, and the central and northern agricultural regions along the West Coast (US-EPA, 2012a).

The adoption of GE herbicide-resistant crops such as VCO-01981-5 corn may result in continued adoption of conservation practices by growers. However, after APHIS has determined that a plant is no longer regulated under the plant pest provisions of the PPA or the regulations of Part 340, APHIS does not maintain control over where the crop is grown, the methods used to produce commodities, or the individual choices that growers make.

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[5] 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.

One outcome of the potential effects of agricultural production on climate change is the potential effect of the climate change on agriculture itself. In response to climate change, the current range of weeds and pests of agriculture is expected to increase. Current agricultural practices will need to adapt in response to these changes in the ranges of weeds and pests of agriculture (Field et al., 2007). Climate change potentially also may 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 U.S. 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).

2.3 Biological Resources

Corn production systems in agriculture are host to a variety of animal species. A number of insects feed on corn plants or prey upon other insects inhabiting cornfields and a full complex of six communities of insect species can be found associated with the crop (Robertson et al., 2012).Although cornfields are generally considered poor habitat for birds and mammals in comparison with uncultivated lands because of continual disturbances associated with intense cultivation, the use of cornfields by birds and mammals is not uncommon (Vercauteren and Hygnostrom, 1993; Palmer et al., 2011). Conservation practices incorporated in corn cultivation have brought a positive impact to animal and plant communities through reduced tillage, more carefully controlled and targeted chemical placement (fertilizers and pesticides), and better control of irrigation systems. Many GE crop systems provide opportunities to optimize the introduction and implementation of these practices, and have the potential to create more of these benefits. For example, herbicide resistance in corn and other crops facilitates cultivation with minimal tillage required to control volunteers and weeds (Towery and Werblow, 2010b). This subsection provides an overview of the biotic community associated with cornfields and their surrounding landscapes.

2.3.1 Animal Communities

<u>Mammals and Birds</u>

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

The types and numbers of birds that inhabit cornfields vary regionally and seasonally but for the most part the numbers are low (Patterson and Best, 1996). Most of the birds that utilize cornfields are ground foraging omnivores that feed on corn seed, sprouting corn, and the corn remaining in the fields following harvest. Bird species commonly observed foraging on corn include red-winged blackbird (*Agelaius phoeniceus*), 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 grouse and quail species (Dolbeer, 1990; Patterson and Best, 1996; Mullen, 2011). Following harvest, it is also common to find large flocks of Canada geese (*Branta canadensis*), Snow geese (*Chen caerulescens*), Sandhill cranes (*Grus canadensis*), and other migratory waterfowl foraging in cornfields (Sparling and Krapu, 1994; Taft and Elphick, 2007; Sherfy et al., 2011).

A variety of mammals forage on corn at various stages of production. For the most part, herbivorous and omnivorous mammals feed on the ear at different stages of growth. Large- to medium-sized mammals that are common foragers of cornfields include: 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 which often inhabit woodlots adjacent to cornfields and frequent these fields for both food and cover especially in mid-summer (Vercauteren and Hygnostrom, 1993). The effects of deer herbivory on cornfields have been well-documented. Cornfields are vulnerable to deer damage from emergence through harvest (Vercauteren and Hygnostrom, 1993), but any damage at the tasseling stage most directly impacts yield (Stewart et al., 2007). White-tailed deer are considered responsible for more corn damage than any other wildlife species (Stewart et al., 2007).

In addition to deer, significant damage to corn by raccoons also has been documented (DeVault et al., 2007; Beasley and Rhodes, 2008). Corn has been shown to constitute up to 65% of the diet of raccoons during the late summer and fall (MacGowan et al., 2006).

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

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

Throughout the U.S., the deer mouse is the most common small mammal in almost any agricultural field (Stallman and Best, 1996; Sterner et al., 2003). Deer mice feed on a wide variety of plant and animal matter depending on availability, but primarily feed on seeds and insects. Deer mice have been considered beneficial in agroecosystems because they consume both weed and insect pests (Smith, 2005).

The meadow vole feeds primarily on fresh grass, sedges, and herbs, and also on seeds and grains of field crops. Although the meadow vole may be considered beneficial for its role in the consumption of weeds, this vole can be a significant agricultural pest where abundant when it consumes seeds in the field. Meadow vole populations are kept in check by high intensity agriculture methods, including conventional tillage; this vole is often associated with the field edges where cover is found off the field as well as limited tillage agriculture and strip crops (Smith, 2005).

The lined ground squirrel feeds primarily on seeds of weeds and available crops, such as corn and wheat. This species has the potential to damage agricultural crops, although it also can be considered beneficial when eating pest insects, such as grasshoppers and cutworms (Smith, 2005).

<u>Invertebrates</u>

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

2.3.2 Plant Communities

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

Non-crop vegetation within cornfields is limited by the extensive cultivation and weed control programs practiced by corn farmers. Non-crop vegetation in cornfields is consequently generally associated with vegetative communities adjacent to these fields. Cornfields may be bordered by other field crops or by woodlands, hedgerows, rangelands, pasture and grassland areas. These plant communities may occur naturally or they may be managed for the control of soil and wind erosion.

Corn is generally cultivated as a monoculture. Weed control programs are essential components of corn cultivation and high yield production. Weed control ideally involves an integrated approach that includes herbicide use, crop rotation, weed surveillance, and weed monitoring (Farnham, 2001; IPM, 2004; IPM, 2007; Hartzler, 2008; University-of-California, 2009). Intensive use of any single weed management tactic can cause an ecological shift in the weed community as a result of selection pressure on weed populations, with a corresponding greater prevalence of weed species that are not controlled (Shaw et al., 2011). When a crop like corn is cultivated year after year in the same fields, using the same cultivation practices, the likelihood is high that weed and pest species will increase in these fields and that agronomic inputs may need additional attention (Erickson and Lowenberg-DeBoer, 2005; Sawyer, 2007; Stockton, 2007; University-of-California, 2009; Shaw et al., 2011). Crop rotation should be an important component of a successful weed management program in corn (Ransom et al., 2004; Erickson and Lowenberg-DeBoer, 2005; Stockton, 2007; University-of-California, 2009; Owen et al., 2011). As discussed in Subsection 2.2.2.2, Crop Rotation, since 1991, 75% of planted corn acreage has been grown in some type of crop rotation (USDA-ERS, 2010b).

The types of weeds in and around a cornfield depend on the immediate area in which the corn is planted (IPM, 2004; IPM, 2007; University-of-California, 2009; Purdue, 2011). 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; IPM, 2007; University-of-California, 2009).

The use of herbicide-resistant corn provides several weed management advantages to the growers. Broad spectrum post-emergent herbicides such as glyphosate, provide control of weeds early in the cultivation cycle thereby minimizing competition in the fields and providing optimal conditions for corn growth (IPM, 2004; IPM, 2007; University-of-California, 2009). Application of over-the-top post-emergent broad spectrum herbicides to an herbicide-resistant crop allows the grower to decrease the overall use of herbicides before cultivation, reduce the use of soil-applied herbicides, and streamline field cultivation activities for weed control (Marra et al., 2002; O'Sullivan and Sikkema, 2004; Ransom et al., 2004). Glyphosate-resistant crops have been widely adopted because glyphosate is highly effective against many economically important weeds, thus simplifying weed management and facilitating the widespread adoption of no tillage systems (Owen et al., 2011). However, since the introduction of glyphosate-resistant crops, the use of tank mixtures and sequential applications of herbicides with more than one mode of action has declined, as many growers relied exclusively on glyphosate for weed control (Weirich et al., 2011b). The over-reliance on herbicides for weed management and the lack of herbicide diversity impose intense selection pressure on weed populations, resulting in the evolution of herbicide resistance, including resistance to glyphosate (Wilson et al., 2011a). Collectively, the practices used in crop production will ultimately impart selection pressures upon the weed community, resulting in shifts in the relative importance of specific weeds. Agricultural practices with the most impact on weed composition and prevalence are tillage and herbicide regime (Owen, 2008). Weed shifts are illustrated by a previously unimportant weed achieving ecological dominance due to changes in production practices (e.g., Asiatic dayflower) or the evolution of an herbicide-resistant weed biotype resulting from uncritical herbicide-use practices (e.g., common waterhemp) (Owen, 2008; Ulloa and Owen, 2009). In aggressive tillage systems, weed diversity tends to decline and annual grasses and broadleaf plants are the dominant weeds, whereas, in no-till fields, greater diversity of annual and perennial weed species may occur (Baucom and Holt, 2009).

As described in Subsection 2.1.2, Agronomic Practices, while there are numerous tactics that will provide weed management, herbicides have been the dominant approach in corn production (Gianessi and Reigner, 2007; Green and Owen, 2011). Herbicide resistance naturally evolves when a plant survives and reproduces after exposure to a dose of herbicide usually lethal to the wild type, passing this ability down to its future generations (WSSA, 2008). Genetic variability, including herbicide resistance, is exhibited naturally in normal weed populations, although at very low frequencies. When only one herbicide is used year after year as the primary means of weed control, herbicide-resistant plants can quickly reproduce and spread to dominate the plant (weed) population and seed bank (WSSA, 2011). With no change in weed control strategies, in time, the weed population may be composed of more and more resistant weeds (US-NARA, 2010b).

Currently, there are 396 herbicide-resistant weed biotypes that have been reported representing 210 species and infesting an estimated 670,000 fields globally (Heap, 2012). Weeds with evolved resistance to glyphosate have increased since the commercial introduction of the Roundup Ready® glyphosate-resistant crops in 1996 (Owen et al., 2011; Heap, 2012). It should be noted, however, that the GE crop in this case, namely corn, did not directly cause the resistance to evolve as a result of introgression. In addition, there are no near-relative weeds that are compatible with corn that are capable of receiving resistance transgenes (Ellstrand et al., 1999). As of December 2012, there are 24 weed species with evolved resistance to glyphosate world-wide and 13 in the U.S. (Table 2.10) (Owen et al., 2011; Heap, 2012). In the U.S., it is estimated that 11 of the 13 glyphosate-resistant weed species were identified in glyphosate-resistant crop systems and are widely distributed in regions where agriculture predominates. For example, 15 states have from 2 to 7 weed species with evolved resistance to glyphosate (Table 2.11) (Heap, 2012). Table 2.11 illustrates how widespread herbicide-resistant weeds are in the U.S., as the same 15 states with glyphosate-resistant weeds have also identified at least 1 weed species with resistance to 3 to 8 herbicide modes of action.

Table 2-10: U.S. glyphosate-resistant weeds as of December 2012.

System	Species	Year Identified
Weeds identified outside of Roundup Ready® Systems	Rigid Ryegrass (*Lolium rigidum*)	1998
	Hairy Fleabane (*Conyza bonariensis*)	2003

Weeds identified in Roundup Ready® Systems	Annual Bluegrass (*Poa annua*)	2010
	Common Ragweed (*Ambrosia artemisiifolia*)	2004
	Common Waterhemp (*Amaranthus rudis*)	2005
	Giant Ragweed (*Ambrosia trifida*)	2004
	Goosesgrass (*Eleusene indica*)	2010
	Horseweed, Marestail (*Conyza canadensis*)	2000
	Italian Ryegrass (*Lolium multiflorum*)	2001
	Johnsongrass (*Sorghum halepense*)	2005
	Junglerice (*Echinochloa colona*)	2008
	Kochia (*Kochia scoparia*)	2007
	Palmer Amaranth (*Amaranthus palmeri*)	2005

Source: (Heap, 2012)

Many of the glyphosate-resistant weeds are agronomically important and dominant members of weed communities. For example, glyphosate-resistant Palmer pigweed (amaranth) is a major economic problem in the Southeast U.S., while glyphosate-resistant waterhemp is an economically important weed in Midwestern states (Culpepper et al., 2006; Owen, 2008). Other glyphosate-resistant weeds of importance include giant ragweed, common lambsquarters, and horseweed (Owen, 2008; Owen et al., 2011).

As described in Subsection 2.1.2, Agronomic Practices, the most effective weed management programs focus on the inclusion of diverse control tactics in addition to herbicides (Beckie, 2006b; Owen, 2011a; Owen, 2011b). Given that some weeds have evolved multiple resistances to several herbicide mechanisms of action, it is important that growers choose herbicides with diverse mechanisms of action to avoid intense selection from only one or a few herbicides. The key consideration to managing herbicide-resistant weeds is to ensure that the herbicides used continue to have efficacy on the target weeds. Managing weed species that have evolved multiple resistances can be challenging. In corn production where sufficient herbicide mechanisms of action typically are available, (Beckie and Reboud, 2009) recommend the use of herbicides in tank mixtures rather than to simply rotate herbicide modes of action. However, in a study of the efficacy of acetolactate synthase (ALS)-inhibitor mixtures, Wrubel and Gressel

(Wrubel and Gressel, 1994) note that not all mixtures meet all the criteria for resistance management, and the use of mixtures for short-term economic benefit risks increasing widespread resistance to herbicides. Weed scientists recommend the use of an integrated systems approach of including science-based crop improvement and farm management tools developed over the last 60 years, and providing producers reasonable and attractive alternatives for effective weed (Owen et al., 2011; Sellers et al., 2011).

Table 2-11: U.S. states with more than one weed species with glyphosate resistance.

State	Number of weed species with glyphosate resistance	Number of herbicide modes of action with at least one resistant weed species
Arkansas	6	8
California	4	8
Illinois	3	5
Indiana	4	3
Iowa	3	6
Kansas	5	5
Louisiana	2	5
Michigan	2	5
Minnesota	3	4
Mississippi	7	7
Missouri	6	5
North Carolina	2	6
Ohio	3	5
Tennessee	4	6
Virginia	2	4

Source: (Heap, 2012)

Corn as a 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[6]) (USDA-NRCS, 2010). 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). Like many domesticated crops, corn seed from a previous year's crop can overwinter and germinate the following year. 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 possesses few of the characteristics of those plants that are notably successful as weeds (Baker, 1965; Keeler, 1989).

Corn periodically occurs as a volunteer when corn seeds remain in the field after harvest and successfully germinates (Beckett and Stoller, 1988; Davis, 2009; Hager, 2009; Bernards et al., 2010; Johnson et al., 2010; Wilson et al., 2010; Stewart, 2011; Wilson et al., 2011b; USDA-APHIS, 2012a). 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 the season causes ears to drop or lodging to occur which places the ears on the ground where the seed then germinate the following year. 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-resistant corn as a volunteer in subsequent crops modified for resistance to the same herbicide (Beckett and Stoller, 1988; Beckie and Owen, 2007; Davis, 2009; Wilson et al., 2010; Wilson et al., 2011b).

Corn volunteers are limited by the geography in which they initially are planted. Corn generally does not overwinter in those regions where freezing temperatures are reached in the winter; however, corn seeds which are incorporated in the soil during harvest or in fall tillage may overwinter and grow the following spring (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). For genetically-transformed corn plants that have escaped the cultivated field to produce a viable rogue population, off-field plants would need to inherit and express additional unrelated traits that provide selective advantage to a weedy growth habit. Some of these advantageous traits include having large numbers of easily dispersed seeds, a propensity to grow on disturbed ground, an enhanced vegetative propagation, and increased seed dormancy (US-EPA, 2010a). Some literature suggests that these traits do not exist within corn, a species that has been selected for domestication and cultivation under conditions not normally found in natural settings (US-EPA, 2010a). However, other literature

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

clearly notes that GE corn is a problematic volunteer the year after harvest in soybean, dry beans, sugar beets and subsequent corn Crops (Davis, 2009; Bernards et al., 2010; Johnson et al., 2010; Wilson et al., 2010; Stewart, 2011; Wilson et al., 2011b). 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 corn plants per acre (Hager, 2010).

Volunteer corn competes with the intended crop for light, soil moisture, and nutrients (Soltani et al., 2006; Bernards et al., 2010; Wilson et al., 2010). The effect of volunteer corn on the yields of the intended crop depends on the density of the volunteer corn (Davis, 2009; Bernards et al., 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; Alms et al., 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; Alms et al., 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-resistant varieties, is accomplished with the use of various combinations of cultivation practices and herbicides (Beckett and Stoller, 1988; Beckie and Owen, 2007; Sandell et al., 2009). 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 consumed 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).

The adoption of herbicide-resistant crops has changed the approaches which growers can use to reduce crop losses from corn volunteers (Beckie and Owen, 2007). In soybean fields cultivated in rotation with corn where the volunteer corn is glyphosate- or glufosinate-resistant, herbicides with alternate modes of action might be employed (e.g., glufosinate in LibertyLink® soybean to control a Roundup Ready® glyphosate-resistant volunteer corn variety (Minnesota, 2009; Bernards et al., 2010). Post-emergent grass herbicide ACCase inhibitors also are recommended, including quizalofop, fluazifop, fenoxaprop, sethoxydim, and clethodim (Hager, 2009; Bernards et al., 2010; Johnson et al., 2010). ALS inhibitors, such as the sulfonylureas, imidazolinone, and triazolpyrimidine also have been identified for potential control of glyphosate- or glufosinate-resistant corn (Hager, 2009; Wisconsin, 2011). Herbicide tank mix additives are recommended to increase on-plant spray retention and absorption (see (Hager and McGlamery, 1997; Sandell et al., 2009; Johnson et al., 2010). Recommended additives include crop oil concentrate (COC), methylated seed oil (MSO), and ammonium sulfate (Hager and McGlamery, 1997; Johnson et al., 2010; Monsanto, 2010b). 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, 2010b).

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 resistance differs between the current crop and the volunteer (e.g., glufosinate in LibertyLink® Corn to control a glyphosate-resistant variety(Minnesota, 2009). Pre-emergent controls might include Gramoxone Inteon (paraquat) mixed with atrazine (Sandell et al., 2009; Monsanto, 2010b) . 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, 2010b). If the volunteer corn is stacked to express both glyphosate and glufosinate resistance, inter-row cultivation is the only option for post-emergent control within corn (Sandell et al., 2009).

Sorghum has been recommended as an addition to the traditional corn soybean rotation cycle (Stalcup, 2010). There are no post-emergent herbicide options to control volunteer corn in sorghum; the only control option is inter-row cultivation (Sandell et al., 2009). Delayed planting of the sorghum is an option that may be used so as to allow the volunteer corn to germinate and then be destroyed with pre-plant tillage (Sandell et al., 2009). Because of the few options for weed management in sorghum, many growers have switched to other crops (Dreiling, 2010). Herbicide-resistant varieties of sorghum are being developed, including a variety tolerant to ACCase inhibitors (Dreiling, 2010). When such varieties are available, weeds, including volunteer corn, susceptible to the ACCase inhibitor herbicides could be controlled in sorghum (Dreiling, 2010).

Gene Flow to Wild Corn Relatives and to Other Corn Cultivars

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 EPA and determined as not a concern within the continental U.S. (US-EPA, 2010a). The potential for outcrossing or gene escape is defined as the ability of the gene to escape to wild corn relatives and APHIS's Plant Pest Risk Assessment determined that there is no likely route for commercial corn gene flow (USDA-APHIS, 2012a).

Gene flow considerations also include 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 com cultivars. For gene flow to occur between corn varieties, viable pollen must reach a receptive tassel (Lerner and Dana, 2001). This then requires that flowering times must overlap, viable pollen transfer between the varieties must occur, embryo/seeds must develop, and hybrid seed must disperse and establish (see, e.g.(Lerner and Dana, 2001; Diver et al., 2008). Spatial and temporal isolation can be one of the most effective barriers to gene exchange between 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). These practices for maintaining varietal purity are also discussed in Subsection 2.1.3 and 2.1.4 in the context of organic corn and specialty corn systems.

2.3.3 Microorganisms

Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). The main factors affecting microbial population size and diversity include soil type (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). Plant roots, including those of corn, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere. Microbial diversity in the rhizosphere may be extensive and differs from the microbial community in the bulk soil (Garbeva et al., 2004).The structure of soil microbial communities is highly dependent on plant type, the physical and chemical characteristics of the soil, and climate (Garbeva et al., 2004; Marschner et al., 2004; Gupta et al., 2007). As such, potential changes to the soil microbial community as a result of cultivating genetically modified crops has been of research interest (O'Callaghan and Glare, 2001; Kowalchuk et al., 2003; Dunfield and Germida, 2004). There are potential direct and indirect impacts from the large-scale use of GE crops to soil- and plant-associated microbial communities, both in the rhizosphere and bulk soil (Lynch et al., 2004; Motavalli et al., 2004). Direct impacts could possibly include changes to the structural and functional community near the roots due to altered root exudation or the transfer of novel proteins into soil, or a change in microbial populations due to the changes in agronomic practices used to produce GE crops (e.g., use of agricultural chemicals and fertilizers and tillage). Indirect impacts may arise from changes in the amount and composition of residue from the GE crops.

Studies to determine the impact of GE crops on soil microbial communities are mixed. A review of those investigating the impact of GE plants on microbial soil communities completed by Kowalchuk (2003) found that much of the research examining distinctive microbial traits concluded there were minor or no non-target effects; only a few found induced targeted alterations to the composition of the microbial community that usually resulted in the inhibition of plant pathogenic organisms. A similar review by Motavalli (2004) did not find any conclusive evidence that released GE plants were causing significant direct impacts on microbe-mediated soil nutrient transformations and studies of potential indirect impacts were lacking.

Crop rotations influence microorganisms as the chemical and nutrient composition of plants and their residues can promote or suppress diseases, affect levels of organic matter, and diversify nutrient sources for soil biota (Gupta et al., 2007). Tillage systems can alter the physiological and chemical properties and biological composition of soils. No-till promotes retention of soil organic matter, concentrates soil microorganism activity at the soil surface, and increases populations of both disease suppressing and disease promoting fungi, in turn increasing species that feed on fungi (Gupta et al., 2007). Conventional tillage distributes organisms deeper into the soil, while promoting bacteria and bactivorous fauna and increasing residue breakdown accompanied by rapid nutrient mineralization (Gupta et al., 2007). Water is one of the important factors influencing microbial population structure and activity in soil; thus irrigation can have a substantial impact. Soil moisture carries nutrients to microorganisms and supplies hydrogen and oxygen (AgriInfo, 2011). Microbes are most active and populous in the moisture range of 20% to 60%, while excess moisture conditions can create a low oxygen environment beneficial to anaerobic microflora, and too little will not support soil microbial , (Stark and Firestone, 1995; AgriInfo, 2011). Fertilizers may support soil microorganisms by increasing crop growth and residue inputs, building soil organic matter and this providing energy and nutrient sources. But fertilizers may change the relative acidity of soils and may reduce the beneficial symbiosis of some microorganisms with particular plant species (Gupta et al., 2007). Pesticides such as fungicides potentially impact fungal microbiota.

In a comparison of fields planted with glyphosate-resistant and conventional corn and cotton, Locke (2008) found that glyphosate-resistant crops had subtle and dynamic differences in soil microbial populations when compared to non-glyphosate-resistant crops. The authors surmise that the decreased disturbance of the soil and increased level of residue as a result of reduced tillage on the glyphosate-resistant crops allowed for a more diverse microbial population. A 10-year comparison study of GE glyphosate-resistant and non-GE corn and soybean by (Kremer and Means, 2009) found that glyphosate-resistant soybeans, even when not treated with glyphosate, had a lower number and mass of root nodules than that of non-GE soybean, indicating that root exudates from GE crops influence the rhizosphere microbial community.

Glyphosate is readily metabolized by soil microbes, yet its strong adsorption capacity to soil slows this function (Tu et al., 2001). The average half-life of glyphosate is 47 days, yet this rate varies depending on soil structure and microbial population (Senseman, 2007). The primary metabolite from microbial degradation is AMPA, which is further degraded to CO_2 (US-EPA, 1993a; Senseman, 2007). Results of research investigating the impact of glyphosate on the microbial community are mixed (Weaver et al., 2007). For example, Haney (2002) report that glyphosate is mineralized by microorganisms that leads to an increase in their population and activity, while Busse (2001) and weaver (2007) found little evidence of changes to soil microorganism's population and activity, and any declines recorded were small and not consistent throughout the season. It also has been reported that the use of glyphosate increases the colonization of soil-born fungal pathogens such as *Fusarium* (Kremer and Means, 2009; Huber, 2010). Similarly, research by (Camberato et al., 2011) found that some weeds treated with glyphosate and other herbicides had increased incidence of fungal infection, suggesting that some soil fungi are more able to infect a weed after it has been weakened by glyphosate.

They point out, however, that plant pathologists have not observed widespread increases in plant diseases in glyphosate-resistant corn and soybean. In a review of recent studies investigating a potential link between the use of glyphosate and outbreaks of fungal disease, (Powell and Swanton, 2008) did not find sufficient evidence from field trials demonstrating whether a causative relationship exists. Additionally, they found that observed links may be context dependent, as they were found only under controlled laboratory conditions. The authors suggest that to adequately address the effect glyphosate has on fungal diseases, future investigations should consider additional interactive factors, such as inoculum level, weed abundance and community composition, fertility, cultural practices, climate, and soil properties.

2.3.4 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988b; Wilson, 1988a; Wilson et al., 2011b). 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, 1999). The loss of biodiversity results in a need for costly management practices in order to provide these functions to the crop (Altieri, 1999).

The degree of biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management; and 4) extent of isolation of the agroecosystem from natural vegetation (Southwood and Way, 1970b; Southwood and Way, 1970a). Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas. Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest result limit the diversity of plants and animals (Lovett et al., 2003).

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 volunteer vegetation does contribute to weed seeds in the field, but does not contribute to major pest problems in the crop field itself (Sharpe, 2010). Volunteer border vegetation, such as ragweed, goldenrod, asters, and forbs, quickly develops into nesting and brood habitat for quail and a multitude of songbirds (Sharpe, 2010). Maintaining some weeds harbors and supports beneficial arthropods that suppress herbivore insect pests (Altieri and Letourneau, 1982; Altieri, 1999). Research conducted at North Carolina State University and the North Carolina Wildlife Resources Commission found that quail and wintering songbird populations increased when field borders along ditch banks were planted by growers (Sharpe, 2010). Adjacent wild vegetation provides alternate food and habitat for natural enemies to pest herbivores (Altieri and Letourneau, 1982; Altieri, 1999).

Contour-strip cropping is another management practice that can be used to promote wildlife habitat. This practice alternates strips of row crops with strips of solid stand crops (i.e., grasses, legumes, or small grains) with the strips following the contour of the land (Sharpe, 2010). The primary purpose of contour-strip cropping is to reduce soil erosion and water runoff, but the solid stand crop also provides nesting and roosting cover for wildlife (Sharpe, 2010). Grass-legume refuge strips have also been used to increase the population density of predaceous carabid beetles in corn (*Zea mays* L.) 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). Minimizing pesticide exposure of ditches, aquatic habitats, border areas, strip-crop areas, and non-crop habitats may help protect fish and wildlife resources (Palmer et al., 2011).

2.4 Public Health

2.4.1 Consumer Health

In the past 30 years, 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, 2012a). Public health concerns associated with the use of GE corn, such as VCO-01981-5, and GE corn products focus primarily on human and animal (livestock) consumption of GE food and feed commodities. This subsection provides a summary of the principal human health concerns. Similar issues related to livestock use are presented in Subsection 2.5 – Animal Feed.

There are three principal corn product industries in the U.S.: corn refiners, dry millers, and distillers. Corn refiners produce starches, sweeteners, ethanol, feed ingredients, corn oil, organic acids, amino acids, and polyols (CRA, 2011). Dry millers manufacture flaking grits, snack grits, corn meals, and corn flours (NAMA, 2010) and distillers produce beverage and industrial alcohol (CRA, 2006). The production processes in each of these industries frequently involve several sequential mechanical and chemical processes. Depending on the final product, these processes include washing, heating, adjusting pH, steeping in an acid solution, fermentation, mechanical milling and centrifugal separation, extrusions, pressing and solvent extraction, evaporation and filtration, and final refining (CRA, 2006). Each step in the production process reduces residual pesticides in the finished product to non-detectable levels (CRA, 2000). Manufacturing operations also have been shown to degrade and denature proteins in corn, including those proteins introduced through GE. Thus, dietary exposure to functionally active proteins in processed food products can be negligible and below levels of any safety concerns (Hammond and Jez, 2011).

Before a pesticide can be used on a food crop, EPA, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA), must establish a tolerance value establishing the maximum pesticide residue that may remain on the crop or in foods processed from that crop. In addition, the FDA and the USDA monitor foods for pesticide residues and enforce these tolerances (see(USDA-AMS, 2011). Foods derived through 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-GE, 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.,(Herman et al., 2010). 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 antinutrients (Herman et al., 2010).

Antinutrients represent an important element of this comparison. Antinutrients are chemicals produced by a plant which interfere with the absorption and metabolism of the consumed vegetable as well as other foods in the digestive tract (Cordain, 1999). Antinutrients in corn include lectins, which interfere with vitamin absorption and have been associated with cellular level metabolic interference, and trypsin inhibitors, which inhibit protein digestion (Cordain, 1999).

Non-GE corn varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for human food or animal feed safety prior to release in the market. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and labeled properly. As a GE product, however, food and feed derived from VCO-01981-5 corn must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who have wished to commercialize a GE variety that would be included in the food supply have completed a consultation with the FDA. In such 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 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 in food (Hammond and Jez, 2011). 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 European Food Safety Agency (EFSA) and the Australia and New Zealand Food Standards Agency (ANZFS). Genective has provided the FDA with information on the identity, function, and characterization of the genes for VCO-1981-5 corn, including expression of the gene products. The FDA has completed its early food safety evaluation, but has not yet completed its food and nutrition Biotechnology Consultation.

As noted by the National Research Council (NRC), unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional hybridization and genetic engineering (NRC, 2004). The NRC also noted in its 2004 report that no adverse human health effects attributed to genetic engineering 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-resistant crops were advantageous because of their superior efficacy in pest control and concomitant economic, environmental and presumed personal health advantages (NRC, 2010a). Reviews on the nutritional quality of GE foods generally have concluded that there are no biologically meaningful nutritional differences in conventional versus GE plants for food or animal feed (Aumaitre et al., 2002; Faust, 2004; Van Deynze et al., 2004).

Under the FIFRA, all pesticides (which is inclusive of herbicides, insecticides and fungicides) sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2011b). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. All pesticides registered prior to November 1, 1984, such as glyphosate, must also be reregistered to ensure that they meet the current, more stringent standards and have a reregistration review every 15 years (US-EPA, 2011b). Glyphosate was first registered in the U.S. in 1974; the latest reregistration decision for glyphosate was issued in 1993 (US-EPA, 1993b; US-EPA, 2009f; US-EPA, 2009d). It is currently under reregistration review, which began in July 2009 and is scheduled for completion in 2015 (US-EPA, 2009d).

The EPA's role in review of corn is more limited. As VCO-01981-5 corn does not express any pesticidal properties, the EPA has no FIFRA review authority over this corn product. However, if VCO-01981-5 corn provides for a change in use of registered herbicides, the EPA would review proposed label changes relating to these new herbicide uses. However, Genective does not indicate any change in glyphosate use with the crop that would differ from that currently registered for other, similar glyphosate resistant crops.

The USDA has implemented the Pesticide Data Program (PDP) in order to collect data on pesticides residues on food (USDA-AMS, 2011). The EPA uses PDP data to prepare pesticide dietary exposure assessments pursuant to the 1996 Food Quality Protection Act. Pesticide tolerance levels for glyphosate have been established for a wide variety of commodities, including field corn for grain and forage, and are published in the *Federal Register,* 40 CFR §180.364, and the *Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities* (US-EPA, 2011c). Glyphosate tolerance for corn grain is 5.0 parts per million (ppm) (40 CFR §180.364).

Glyphosate is registered under a variety of trade names (e.g., Roundup®, Roundup Ultra®, Glyphomax Plus®, and Abundit Extra®) by several companies. There are currently over 400 active glyphosate products registered under FIFRA Section 3, and over 100 registered for use on terrestrial food crops (US-EPA, 2009c). As mentioned above, it was the most widely-used herbicide on corn in 2010, applied to 66% of herbicide-treated acres in the U.S. (USDA-NASS, 2011c). In that year, the average application rate was approximately 1.07 lb/Ac, with a total of over 57.5 million pounds applied (USDA-NASS, 2011c). Glyphosate is classified as Toxicity Category III or IV, having been found to have low toxicity via the oral, dermal, and inhalation routes (US-EPA, 2009d). Similarly, glyphosate is not classified as a carcinogen or teratogen (US-EPA, 2009d) While neurotoxicity has not been observed in previous studies, new data requirements established under 40 CFR part 158 require acute and subchronic neurotoxicity studies, and an immunotoxicity study to take place for reregistration. The next RED for glyphosate is scheduled to be complete in 2015 (US-EPA, 2009b). Based on toxicological considerations, the EPA Health Effects Division (HED) determined that the main metabolite of glyphosate, AMPA, did not need regulation despite levels observed in foods or feed (US-EPA, 2009d). Glyphosate when used in accordance with the existing labels, have been determined to present no health risk to humans(US-EPA, 2009d).

2.4.2 Worker Safety

Worker hazards in farming are common to all types of agricultural production, and include hazards of equipment and plant materials. Pesticide application represents the primary exposure route to pesticides for farm workers. Pesticides, including herbicides, are used on most corn acreage in the U.S. Changes in acreage, crops, or farming practices can affect the amounts and types of pesticides used and thus the risks to workers. The EPA pesticide registration process, however, involves the design of use restrictions that if followed have been determined to be protective of worker health.

EPA's Worker Protection Standard (WPS) (40 CFR Part 170) was published in 1992 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.

Worker safety precautions and use restrictions are clearly noted on pesticide registration labels. Growers are required to use pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. These restrictions provide instructions as to the appropriate levels of personal protection required for agricultural workers to use herbicides. These may include instructions on personal protective equipment, specific handling requirements, and field reentry procedures (Monsanto, 2007; Nufarm, 2009; DuPont, 2010). These label restrictions carry the weight of law and are enforced by the EPA and the states (FIFRA 7 U.S.C. 136j (a)(2)(G) Unlawful Acts); therefore, it is expected that glyphosate use on Maize Line HCEM485 would be consistent with the EPA-approved labels. Used in accordance with the label, these herbicides have been determined to not present a health risk to workers (US-EPA, 1993b). The worker safety implications of the proposed changes in application rates and use of these two herbicides are discussed in Subsection 4.5.

2.5 Animal Feed

Corn comprises approximately 95% of the total feed grain production and use, with sorghum, barley, and oats making up the remainder (USDA-ERS, 2011b). The production of corn for feed use is a derived demand, i.e., production of corn for feed will vary depending on the number of animals (cattle, hogs, and poultry) being fed corn (USDA-ERS, 2011b). The amount of corn used for feed also depends on the crop's supply and price (USDA-ERS, 2011b).

Corn is valuable as a feed because of its composition, including key nutrients, anti-nutrients and secondary metabolites, protein content, fiber, among others (OECD, 2002b). 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 and from the residuals derived from three major corn industries: corn refining, corn dry millers, and distillers (OECD, 2002b; 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).

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). Corn gluten meal has a high xanthophyll content, a yellow plant pigment, making this product highly valued as a pigmenting ingredient in poultry feeds (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).

As described in Subsection 2.4, Human Health, under FIFRA, all pesticides (including herbicides) sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2011b). All pesticides registered prior to November 1, 1984, such as glyphosate, must also be reregistered to ensure that they meet the current, more stringent standards and should have a reregistration review every 15 years (US-EPA, 2011b). The latest reregistration decision for glyphosate was issued in 1993 and the reregistration review was started in July 2009 (US-EPA, 2009f; US-EPA, 2009d). Before a pesticide can be used on a food or feed crop, the EPA must establish the tolerance value, which is the maximum amount of pesticide residue that can remain on the crop or in foods or feed processed from that crop (US-EPA, 2011e). Glyphosate currently has established tolerances for residues, including established residue concentrations for glyphosate in field corn for forage, grain, and stover , (US-EPA, 2011c). Pesticide tolerance levels for glyphosate have been established for corn and are published in the *Federal Register*, CFR, and the *Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities* (US-EPA, 2011c). The glyphosate tolerance level established for field corn intended for forage is 6.0 ppm and for grain corn is 5.0 ppm (40 CFR §180.364).

2.6 Socioeconomic

Corn is produced for food and feed commodities as well as industrial uses (USDA-ERS, 2011b). Corn is the most widely cultivated feed grain in the U.S., accounting for more than 95% of total value and production of feed grains (James, 2009; USDA-ERS, 2011b). Corn is grown in all 48 of the continental U.S. states with production concentrated in the Corn Belt, 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, 2010b; USDA-ERS, 2011b; USDA-NASS, 2012a). 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, 2011b).

2.6.1 Domestic Economic Environment

In the 2012 production year, corn was cultivated on over 96 million acres, a 5% increase in corn acreage from 2011 (37.4 million hectares) (USDA-NASS, 2012a). In 2011, corn for silage was cultivated on approximately 5.9 million acres, or approximately 6% of the total corn production area for that year , (USDA-NASS, 2012b). GE herbicide-resistant corn comprised approximately 21% of the total corn acreage in the U.S., insect-resistant varieties comprised 15% of the acreage, and stacked varieties comprising 52% of the total corn acreage (USDA-NASS, 2012a)). The costs for GE corn seed are higher than that for conventional 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, 2010a). This seed premium includes a technology fee for the cultivation of the seed (NRC, 2010a).

Corn production in 2011 was estimated at 12.44 billion bushels, valued at an estimated $5.15 to $5.65 per bushel (i.e., a total value of $64.1 – 70.3 billion). In 2012, production was estimated at 12.38 billion bushels (USDA-NASS, 2012b). The value of the corn crop varies over time in response to market conditions. 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, 2012). U.S. prices for corn, although declining somewhat over the course of the year, are expected to remain high because of the continued demand for corn for ethanol, animal feed, and exports (James, 2009; USDA-NASS, 2012a; USDA-OCE, 2012).

Corn processed for human consumption and industrial uses accounts for about one-third of domestic corn utilization (USDA-ERS, 2011b). During processing, corn is either wet or dry milled depending on the desired end products: wet millers process corn into high-fructose corn syrup (HFCS), glucose and dextrose, starch, corn oil, beverage alcohol, industrial alcohol, and fuel ethanol. Dry millers process corn into flakes for cereal, corn flour, corn grits, corn meal, and brewers grits for beer production (USDA-ERS, 2011b).

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

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

The adoption of GE corn in U.S. has reduced costs and improved profitability levels on the farm (Carpenter et al., 2002; Brookes and Barfoot, 2010). These cost reductions are a result of reductions in average herbicide and pesticide use per field, and corresponding reductions in tillage and associated field cultivation costs (Carpenter et al., 2002; Brookes and Barfoot, 2010). Other benefits to the grower from adoption of GE crops have included (Carpenter et al., 2002; Brookes and Barfoot, 2010):

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

Herbicide-resistant corn has been cultivated commercially since 1997. Adoption of a GE herbicide-resistant weed control system has reduced grower costs and increased profitability, with average 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). Recently, these net cost savings have decreased as a consequence of an increase in the price of glyphosate and other weed control programs (Brookes and Barfoot, 2010).

Continued demands for corn for ethanol have resulted in some shifts in the corn/soybean rotation in some areas (Hart, 2006). Corn and soybeans frequently were cultivated in two year rotation, but as the demand for corn for ethanol increased, many growers in the upper Midwest converted to a three year rotation schedule, with two consecutive years of corn followed by a year of soybean (Hart, 2006). Although there are certain economic benefits from this change, there also are some costs. Tillage costs may increase in the second year of corn, for example, if the crop residues from the first corn year prevent no-till planting in the second year (Babcock and Hennessy, 2006). Corn after corn rotations also can impact pest and weed problems as certain corn-specific pests and weeds overwinter in the corn residues remaining in the field (Babcock and Hennessy, 2006). These impacts can be managed through greater crop monitoring, increased applications of pesticides and selection of appropriate hybrids (Babcock and Hennessy, 2006 233).

An important concern currently facing U.S. farmers, including corn farmers, is the emergence of glyphosate-resistant weeds (Johnson and Gibson, 2006; Foresman and Glasgow, 2008; Hurley et al., 2009; Johnson et al., 2009), a result of the repeated, wide spread, and sometimes exclusive use of glyphosate on corn, cotton, and soybean crops resistant to the pesticide (Beckie, 2006b; Duke and Powles, 2009). As of 2012, there were 13 different weed species with glyphosate-resistant populations ranging across 25different U.S. states (Heap, 2012) (see Subsection 2.3.2, Plants Communities, Table 2.10 and 2.11). Comparing the typical glyphosate-resistant weed management programs to a typical nonherbicide-resistant weed management program, Sankula and Blumenthal (2004; Sankula, 2006) estimated that farmers saved $9.49 to $10.15 per acre in weed management costs. Based on 2007 survey data, Hurley, Mitchell, and Frisvold (2009), found that farmers planting more glyphosate-resistant corn reported lower weed management costs.

Surveys indicate that farmers prefer to address glyphosate-resistant weeds by using additional herbicides with different modes of action (Johnson and Gibson, 2006;

Foresman and Glasgow, 2008; Johnson et al., 2009). Weirich et al. (2011b) investigated the effect of grower adoption of alternative glyphosate weed resistance management programs, finding they increased cost substantially, though they did not statistically significantly decrease net returns due to higher yields. These results suggest that growers may be able to effectively respond to glyphosate resistance using weed BMPs without substantially affecting their returns.

2.6.2 Trade Economic Environment

Corn is the dominant feed grain traded internationally (James, 2009; USDA-OCE, 2011a; USDA-OCE, 2012). In 2011/2012, the U.S. produced approximately 37% of the total world supply of corn (USDA-OCE, 2011a; USDA-OCE, 2012). Corn is cultivated worldwide, including in the European Union, Argentina, South Africa, Brazil, Canada, China, and the former Soviet Union States, including the Ukraine(USDA-OCE, 2011a; USDA-OCE, 2012). GE Corn is cultivated on 27% of all corn acreage worldwide (James, 2009).

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, 2012). Approximately 15 to 20% of the U.S. corn production is exported, with the volume of exports projected to to decrease in the next several years in the face of increased competition from lower-priced South American supplies (DAS, 2010; USDA-OCE, 2011a; USDA-OCE, 2012). Egypt, the EU, Japan, Mexico, Southeast Asia, and South Korea are net importers of corn (Brookes and Barfoot, 2010; USDA-OCE, 2011a; USDA-OCE, 2012). China is projected to become a net importer of corn to support its expanding livestock and industrial sectors (James, 2009; USDA-OCE, 2011a; USDA-OCE, 2012). The increase in China's imports is expected to account for one-third of the growth in world corn trade(USDA-OCE, 2011a; USDA-OCE, 2012). 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. Specific end uses also may require identity protection throughout the export supply chain. Value enhanced, specialty corn is an important part of the U.S. export market for corn. High oil corn, for example, is in high export demand as a replacement for animal fats in feed rations (USDA-FAS, 2004). As discussed in Subsection 2.1.4, Specialty Corn Production, the challenges associated with maintaining variety identity in international commodity movement increases the costs, as well as the premiums paid, for these specialty crops (USDA-FAS, 2004).

GE corn, such as VCO-01981-5 are excluded by some countries sensitive to the importation of GE crops. Other countries may lag approval of new US GE corn varieties and these may cause disruptions in international trade when they are inadvertently incorporated into feed grain shipments or specialty corn fractions such as corn gluten (See, e.g., ICTSD(ICTSD, 2005)

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of Genective VCO-01981-5. To respond favorably to a petition for nonregulated status, APHIS must determine that event VCO-01981-5 is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2012a), APHIS has concluded that event VCO-01981-5 is unlikely to pose a plant pest risk. Therefore, APHIS must determine that event VCO-01981-5 is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Two alternatives are evaluated in this EA: (1) no action and (2) determination of nonregulated status of event VCO-01981-5. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

3.1 No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. Event VCO-01981-5 corn and progeny derived from VCO-01981-5 corn would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of VCO-01981-5 corn and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of VCO-01981-5 corn.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment that VCO-01981-5 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012a). 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 VCO-01981-5 Corn is No Longer a Regulated Article

Under this alternative, VCO-01981-5 corn and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. VCO-01981-5 is unlikely to pose a plant pest risk (USDA-APHIS, 2012a). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of VCO-01981-5 corn and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that event VCO-01981-5 is unlikely to pose a plant pest risk, a determination of nonregulated status of VCO-01981-5 corn is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to VCO-01981-5 corn and progeny derived from this event if the developer decides to commercialize VCO-01981-5 corn.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for VCO-01981-5. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for VCO-01981-5 corn. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

3.3.1 Prohibit Any VCO-01981-5 Corn from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of VCO-01981-5 corn, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that VCO-01981-5 is unlikely to pose a plant pest risk (USDA-APHIS, 2012a).

In enacting the Plant Protection Act, Congress found that

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

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

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

Based on the Plant Pest Risk Assessment (USDA-APHIS, 2012a) and the scientific data evaluated therein, APHIS concluded that VCO-01981-5 is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of VCO-01981-5 corn.

3.3.2 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that VCO-01981-5 is unlikely to pose a plant pest risk, and it is the only line in the petition, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3.3.3 Isolation Distance between VCO-01981-5 and Non-GE Corn Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating VCO-01981-5 from conventional or specialty corn production. However, because APHIS has concluded that VCO-01981-5 is unlikely to pose a plant pest risk (USDA-APHIS, 2012a), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of VCO-01981-5 corn based on the location of production of non-GE corn in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' plant pest risk assessment for VCO-01981-5, there are no geographic differences associated with any identifiable plant pest risks for VCO-01981-5 (USDA-APHIS, 2012a). This alternative was rejected and not analyzed in detail because APHIS has concluded that VCO-01981-5 does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. However, individuals might choose on their own to geographically isolate their non-GE corn production systems from VCO-01981-5 corn or to use isolation distances and other management practices to minimize gene movement between VCO-01981-5 and non-GE fields. Information to assist growers in making informed management decisions for VCO-01981-5 is available from Association of Official Seed Certifying Agencies (AOSCA, 2010).

3.3.4 Requirement of Testing for Presence of VCO-01981-5

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because VCO-01981-5 does not pose a plant pest risk (USDA-APHIS, 2012a), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for VCO-01981-5 would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.4 Comparison of Alternatives

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

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

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied—risk assessment (USDA-APHIS, 2012b)
Management Practices		
Acreage and Areas of Corn Production	Yearly fluctuation but no or small net increase of acreage and no new regions of corn planted	Unchanged from No Action Alternative
Agronomic Practices	Cropping practices will remain the same as current practices for commercial corn production	Unchanged from No Action Alternative
Pesticide Use	Herbicide use patterns unlikely to change	Herbicide use of some types may decrease

Corn Seed Production	Fluctuates yearly somewhat; foreign seed production is used to respond to specific needs	Unchanged
Organic Corn Production	Yearly production not affected by conventional corn production	Unchanged
Environment		
Land Use	Corn acreage generally stable but fluctuates yearly	VCO-01981-5 corn is not expected to have any effect on land use
Water Resources	Herbicides in water fluctuate with weather, climate and usage	VCO-01981-5 corn is not expected to have any effect on water
Soil	Glyphosate in soil has a short half-life. Conservation tillage may be increasing slightly	VCO-01981-5 corn is not expected to have any effect on soil
Air Quality	Air quality (particulates) affected by tillage and weather	VCO-01981-5 corn is not expected to have any effect on air quality
Climate Change	Climate changes affected by land use, tillage and greenhouse gases	VCO-01981-5 corn is not expected to have any effect on climate change
Animals and Plants		
Animals	Vertebrates interact infrequently with corn agriculture; invertebrates not likely to have new impacts from corn production compared to any other agricultural production	VCO-01981-5 corn and glyphosate is not expected to have any effect on vertebrate animals or most invertebrate animals. Unchanged from the No Action Alternative
Plants	Natural vegetation highly reduced near farms; herbicide resistant weeds increasing	VCO-01981-5 corn is not expected to have any new effect on plants or resistance
Gene Movement	No gene flow to wild plants; gene flow to other corn easily controlled. Horizontal gene flow not observed	VCO-01981-5 corn is not expected to have any effect on vertical or horizontal gene flow

Soil Microorganisms	Microorganisms affected by tillage, agronomic activity and pesticides	VCO-01981-5 corn is not expected to have any novel effect on soil microorganisms
Biological Diversity	Contemporary agriculture impacts diversity but new impacts not likely to be significant	VCO-01981-5 corn is not expected to have any effect on biological diversity
Human and Animal Health		
Risk to Human Health	EPA rates glyphosate impacts from glyphosate resistant corn as having no reasonable certainty of harm	VCO-01981-5 corn does not have any adverse human health effects. Unchanged from No Action
Risk to Animal Feed	Corn is a major feed protein for animal nutrition; quality is unchanging and adequate to animal needs	VCO-01981-5 supplies no changes in animal nutrition compared to other corn
Socioeconomic		
Domestic and Economic Environment	Corn seed with various traits has a competitive market in the US, with four major seed suppliers, and over a hundred smaller ones	VCO-01981-5 would be just anotyer glyphosate resistant corn, potentially replacing others in the domestic corn seed market
Trade Economic Environment	Corn export levels decreased by 23% from 2010 to 2012 in the US	VCO-01981-5 corn production would have no substantial differences from existing corn
Other Regulatory Approvals	Completed FDA early food safety consultation; final consultation completed. EPA tolerance exemptions and conditional pesticide registrations granted	Completed FDA early food safety consultation, final consultation completed. EPA tolerance exemptions and conditional pesticide registrations granted
Compliance with Other Laws		
CWA, CAA, Eos	Fully compliant	Fully compliant

4 ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking no action and a determination by the agency that VCO-01981-5 does not pose a plant pest risk. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for VCO-01981-5 are described in detail throughout this section. A cumulative effects analysis is presented for each potentially affected environmental concern. Certain aspects of this product and its cultivation would be no different between the alternatives: those instances are described below.

4.1 Scope of Analysis

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for VCO-01981-5 corn are described in detail throughout this section. An impact would be any change, positive or negative, from the existing (baseline) conditions of the affected environment (described for each resource area in Section 2.0). Impacts may be categorized as direct, indirect, or cumulative. A direct impact is an effect that results solely from a proposed action without intermediate steps or processes. Examples include soil disturbance, air emissions, and water use. An indirect impact may be an effect that is related to but removed from a proposed action by an intermediate step or process. Examples include surface water quality changes resulting from soil erosion due to increased tillage, and worker safety impacts resulting from an increase in herbicide use.

A cumulative effects analysis is also included for each environmental issue. A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Examples include breeding VCO-01981-5 with other deregulated events. If there are no direct or indirect impacts identified for a resource area, then there can be no cumulative impacts. Cumulative impacts are discussed in Section 5.

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

Although the preferred alternative would allow for new plantings of VCO-01981-5 to occur anywhere in the U.S., APHIS will limit the environmental analysis to those areas that currently support corn production. To determine areas of corn production, APHIS used data from various official USDA sources.

4.2 Agricultural Production of Corn

Best management practices are commonly accepted, practical ways to grow corn, regardless of whether the corn farmer is using organic practices or conventional practices with non-GE or GE varieties. These management practices consider crop-specific planting dates, seeding rates, and harvest times, among others. Over the years, corn production has resulted in well-established management practices that are available through local Cooperative Extension Service offices and their respective websites. The National Information System for the Regional Integrated Pest Management (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 soybean production states can be reviewed (IPM-Centers, 2013).

Genective's studies demonstrate that agronomic characteristics and cultivation practices required for VCO-01981-5 corn are essentially indistinguishable from practices used to grow other corn varieties, including other herbicide-resistant varieties (Genective, 2012; USDA-APHIS, 2012a). None of the BMPs currently employed for corn production is expected to change if VCO-01981-5 corn 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 VCO-01981-5 corn resulting from management practices associated with the No Action and Preferred Alternative are the same.

4.2.1 Acreage and Area of Corn Production

No Action Alternative: Acreage and Area of Corn Production

Based on current acreage trends, conventional corn production practice along with GE varieties will likely continue to increase in acreage under the No Action Alternative. As discussed in Subsection 2.1 – Agricultural Production of Corn, this trend towards increase in corn cultivation is not a result of cultivation of new farm land or conversion of conservation reserves to corn, but is instead a consequence of the grower's substitution of corn for other crops to take advantage of current crop pricing(Wallander et al., 2011). Corn currently is produced commercially in 48 states (USDA-NASS, 2012b; USDA-NASS, 2012a) and under the No Action Alternative, the number of states involved in corn cultivation is not expected to change.

Since 2006, U.S. corn planted acreage has increased as market prices have favored the planting of corn over alternative crops, such as cotton (USDA-NASS, 2011b; USDA-NASS, 2012a). The increase in corn acreage has been linked to the increase in demand for corn as a feed stock for ethanol for biofuel (Hart, 2006; USDA-ERS, 2010c). The increase in acreage has involved all varieties of corn and is occurring throughout the corn growing areas (USDA-ERS, 2010c). The USDA has estimated that over 90 million acres of corn will be required to meet the demands of ethanol, livestock, and export (Hart, 2006). The increased acreage to fulfill the added requirements for ethanol production is expected to come from the upper Midwest and eastern Great Plains areas (Hart, 2006).

Preferred Alternative: Acreage and Area of Corn Production

Genective's studies and USDA-APHIS analyses demonstrate that agronomic characteristics and cultivation practices required for VCO-01981-5 corn are essentially indistinguishable from other corn varieties, including other herbicide-resistant varieties

(Genective, 2012; USDA-APHIS, 2012a). There are no changes in agronomic characteristics in VCO-01981-5 corn that would result in an increase in acreage devoted to corn or a change in the range where corn is already cultivated in the U.S. (USDA-APHIS, 2012a). 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. This trend is not specific to a single GE corn variety (Wallander et al., 2011). VCO-01851-5 corn provides growers with the ability to use the broad spectrum herbicide glyphosate with other corn herbicides for weed control, since glyphosate is a suitable tank mix partner for nearly fifty other herbicides (Monsanto, 2010a; Genective, 2012).

Results of the agronomic and morphologic assessments conducted by Genective indicate that the introduced herbicide resistance trait does not confer any competitive advantage in terms of weediness (USDA-APHIS, 2012a). Genective asserts that VCO-01981-5 corn will be a replacement product for other varieties of corn currently cultivated, so new acreage is not expected to accommodate the cultivation of VCO-01981-5 corn (Genective, 2012). The glyphosate resistance trait, already in commercial use for fifteen years, is not expected to extend the range of cultivation for VCO-01981-5 corn outside of existing cultivation areas (Genective, 2012).

The Preferred Alternative, i.e., a determination of nonregulated status of VCO-01981-5 corn, is therefore not expected to increase corn production, either by its availability alone or associated with other factors, or result in an increase in overall acreage of GE corn. Potential impacts would be similar to the No Action Alternative.

4.2.2 Agronomic Practices

As discussed in Subsection 2.1.2 – Agronomic Practices, corn cultivation requires significant management considerations regarding tillage, rotation strategy, agricultural inputs, and pesticide inputs. Decisions concerning corn agronomic practice are dependent on grower want and need, and ultimately reflective of geography, weed and disease pressure, economics of management strategies, and production system (rotation) flexibility (Heiniger, 2000; Farnham, 2001; University-of-Arkansas, 2008). For example, corn intended for grain is likely to require less tillage and less frequent herbicide or pesticide application compared to that needed in corn for seed; hybrid corn for grain production has increased vigor and increased resistance to pests and diseases of hybrid corn varieties relative to inbred corn lines used in seed production. In some cases, choice of management practice may dictate marketability of a corn product, with certain agricultural consumer sectors stipulating requirements and restrictions regarding corn production methods.

Glyphosate-resistant crops have become adopted widely since their introduction in the mid-late 1990s for several reasons. Glyphosate works non-selectively on a wide range of plant species, is a relatively low-cost herbicide, enhances ‘no-till’ farming practices, and has minimal animal toxicological and environmental impact. However, increased selection pressure resulting from the wide-spread adoption of glyphosate-resistant crops, along with the reductions in the use of other herbicides and weed management practices, has resulted in both weed population shifts and growing numbers of glyphosate-resistant individuals among some weed populations (Owen, 2008; Duke and Powles, 2009). In order to respond to the consequences, and to avoid decreased crop yields that result from weed competition, growers must continue to adapt their weed management strategies, including the use of 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 EPA's assessment of herbicide usage in cornfields showed that the use of glyphosate increased dramatically from 1987 to 2001; by comparison, 2,4-D usage remained essentially unchanged during that time (Kiely et al., 2004). In 2005, 77 different herbicides were applied to 97% of corn acreage planted in 19 states representing 93% of all corn planted in the U.S (USDA-NASS, 2006). In the 2010 follow-up to that survey, the herbicide most widely used on corn was glyphosate, rather than atrazine as in the 2005 survey, although atrazine was still used on the majority of corn acres; metolachlor and acetochlor remained at the same relative usage rates (USDA-NASS, 2011a).

Table 4-1: Changes in Major Herbicide Use between 2005 and 2010

Herbicide	2005 million # herbicide	2005 % acres treated	2010 million # herbicide	2010 % acres Treated
Atrazine	75	66	51	61
Glyphosate	25	31	64	76
Metolachlor	26	23	22	24
Acetochlor	30	23	28	25

Crop rotation in corn is conducted to optimize soil nutrition and fertility, reduce pathogen loads, and control corn pests (IPM, 2004; IPM, 2007). Crop rotation practices have been described previously in Section 2.

<u>No Action Alternative: Agronomic Practices</u>

Under the No Action Alternative, corn agronomic practices, as described in Section 2.1.2, involving the application of external inputs such as fertilizers, fungicides, herbicides, and insecticides are expected to remain as practiced today by the farming community. Growers will continue to have access to existing nonregulated GE corn varieties, including glyphosate-resistant corn, as well as non-GE corn varieties. Growers likely will continue to experience the emergence of glyphosate-resistant weeds, requiring modifications of crop management practices to address these weeds. These changes may involve all of the techniques identified by Beckie (Beckie, 2006b) including applying herbicide sequences, selecting and deploying herbicide mixtures, employing maximal herbicide rates, making special applications to resistant weed sites, altering cropping systems, using tillage, and controlling weed seed spread.

Current corn management practices are likely to continue under the No Action Alternative. Growers will continue to choose certain pesticides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system, (Heiniger, 2000; Farnham, 2001; University-of-Arkansas, 2008). No-till production of corn will continue to increase under the No Action Alternative, effectively mitigating the negative impacts of conventional tillage and associated soil erosion (Fawcett and Caruana, 2001). Agronomic practices involving the application of external inputs, such as herbicides, pesticides, and moisture, will remain as it is practiced today.

Under the No Action Alternative, growers likely will continue to experience the continued emergence of glyphosate-resistant weeds, requiring modifications of crop management practices to address these challenges, including the use of alternative herbicides for weed control, mechanical cultivation practices (Benbrook, 2009b).

Typical of the types of management for field corn in Iowa is the listing of 13 herbicides used pre-emergence in sequence with glyphosate, 17 applied post-emergence as a tank mixture with glyphosate, and use of Ignite with Liberty Link hybrids (Iowa-State-University, 2012).In addition, 54 herbicide premixes or co-packs were cited, some containing different herbicides than would be sold individually for application to corn (Iowa-State-University, 2012), Numerous options exist for use of herbicides with a mode of action different from glyphosate, to either respond to glyphosate resistant weeds, or to deter development of such weeds.

Any effects due to crop rotation, tillage, and pesticide use in the agricultural production of seed corn and commercial corn will remain the same under the No Action Alternative. Rotation strategies for corn under the No Action Alternative will continue as practiced today, with market demand and available technology strongly influencing corn rotation practices.

Preferred Alternative: Agronomic Practices

A determination of nonregulated status of VCO-01981-5 corn is not expected to result in changes in the current corn cropping practices, because this glyphosate resistant corn trait is already a large part of the commercial market for seed corn. APHIS has determined that there are no actions that would aggregate with effects of the proposed action to effect changes in crop rotation, tillage, or agronomic inputs. Genective's studies demonstrate VCO-01981-5 corn is essentially indistinguishable from other corn varieties used in terms of agronomic characteristics and cultivation practices (Genective, 2012; USDA-APHIS, 2012a). Thus, glyphosate application timing, frequency or rates would not be expected to change from current levels. Options for use of numerous herbicides to either respond to existing glyphosate resistant weeds or to deter their development will continue to be available to growers that are deploying the VCO-01981-5 corn with glyphosate resistance. Strategies to manage weeds and deter future weed resistance, in addition to herbicide use, will also be available to growers, so that cultural control as well as tillage options will continue to be used by corn producers.

4.2.3 Organic Corn Production

Organic production plans prepared pursuant to the National Organic Program (NOP) include practical methods to protect organically-produced crops from accidental contamination with GE materials. The natural cross-pollination of GE corn with organic corn is a concern for some organic growers (Coulter et al., 2010). 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 formal communications between neighboring farms (NCAT, 2003; Baier, 2008; Roth, 2011). These practices follow the same system utilized for the cultivation of Certified seed under the AOSCA procedures. During the cultivation period, cross-pollination is managed by recognizing corn pollen dispersal patterns and maintaining adequate distances between fields (Thomison, 2009; Mallory-Smith and Sanchez-Olguin, 2010). A minimum isolation distance of 250 feet between varieties is recommended; whereas, 700 feet is preferred for complete isolation (Diver et al., 2008).

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

Organic corn acreage has increased over time concurrent with the increase in GE corn cultivation. Since 1995, organic corn acreage has increased from approximately 32,000 acres to over 194,000 acres in 2008 (USDA-ERS, 2011g). Since its introduction in 1995, GE corn is now cultivated on over 88% of the U.S. acreage (USDA-NASS, 2012a). This concurrent growth of organic crops and GE corn is indicative of the successful adoption of these coexistence strategies. Historically, organic corn production represents a small percentage (approximately, 0.2%) of total U.S. corn acreage (USDA-ERS, 2011g). The percentage of corn acreage dedicated to organic corn is not anticipated to change under either the No Action or the Preferred Alternative.

<u>No Action Alternative: Organic Corn Production</u>

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

It is important to note that the current NOP regulations do not specify an acceptable threshold level for the presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2010). However, certain markets or contracts may have defined thresholds which growers need to attain (Non-GMO-Project, 2012).

Preferred Alternative: Organic Corn Production

GE corn lines including those that are herbicide-resistant are already in use by farmers. VCO-01981-5 corn should not present any new and different issues and impacts for organic and other specialty corn producers and consumers.

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

According to the petition, agronomic trials conducted in 2008 in a variety of locations in the U.S. demonstrated that VCO-01981-5 corn is not significantly different in plant growth, yield, and reproductive capacity from its nonGE counterpart (USDA-APHIS, 2012a). No differences were observed in pollen diameter, weight, and viability. Therefore, VCO-01981-5 corn is expected to present a no greater risk of cross-pollination than that of existing corn cultivars. The practices currently employed to preserve and maintain purity of organic production systems would not be required to change to accommodate the production of VCO-01981-5 corn.

Historically, organic corn production represents a small percentage (approximately, 0.2%) of total U.S. corn acreage (USDA-ERS, 2011h). It likely would remain small regardless of whether new varieties of GE or non-GE corn varieties, including VCO-01981-5 corn, become available for commercial corn production.

Accordingly, a determination of nonregulated status of VCO-01981-5 corn is not expected to have a significant impact on organic corn production.

4.3 Physical Environment

Agricultural production of corn may affect segments of the physical environment including, but not limited to water resources, soil quality, air quality, and climate change (USDA-ERS, 2005; USDA-ERS, 2010b).

4.3.1 Water Resources

No Action Alternative: Water Resources

Under the No Action Alternative, current land acreage and agronomic practices, including irrigation, tillage, and nutrient management associated with corn production would not be expected to change. Growers would continue to cultivate glyphosate resistant varieties already on the market and continue the agronomic practices and inputs associated with those varieties. These practices and inputs would include the use of glyphosate as an herbicide as part of the weed management strategy. No expected changes to water use associated with corn production is expected for this alternative.

As discussed in Subsection 4.2.1, Acreage and Area of Corn Production, corn is expected to continue to be a major crop in the U.S., with a predicted increase in production from approximately 88 million acres of land in 2010 to between 90 and 92 million acres through 2020 (USDA-OCE, 2011a). Current agronomic practices associated with corn production that have potential to impact water quality or quantity include tillage, agricultural inputs such as fertilizer and pesticide use, and irrigation. The majority of herbicide-resistant corn grown in the U.S. is glyphosate-resistant (Duke and Powles, 2009).

As discussed above in Subsection 4.3.2, Soil Quality, more diverse weed management tactics, potentially including more aggressive tillage practices that can affect soil erosion, may be needed to address the increasing emergence of glyphosate-resistant weeds (Beckie, 2006b; Owen et al., 2011; Owen, 2011a). Increased tillage could result in more soil erosion that could consequently increase sedimentation and residual pollutant loading of nearby waters. The particular mix of weed management tactics selected by an individual producer, however, are dependent upon many factors such as the agroecological setting, the problem weed type, and agronomic and socioeconomic factors important to farmers (Beckie, 2006b). As discussed in Subsection 2.2.1, Water Resources, fertilizer and pesticide use has the potential to impact water quality. In 2010, fertilizer (primarily nitrogen) was applied to the majority of corn acres, and herbicides applied to 98% of planted corn (USDA-NASS, 2011c). Of the treated acres, glyphosate was the most commonly applied herbicide active ingredient that year (USDA-NASS, 2011c). When used consistent with registered uses and EPA-approved labels, glyphosate presents minimal risk to surface and groundwater. Irrigation from surface and subsurface sources can reduce water quantity and impact water quality by the used water acquiring increased sediment, nutrients, and chemicals adsorbed to soil that is subsequently leached to groundwater, or returned to surface water. Recent estimates indicate only about 11.0% of corn acreage was irrigated in the U.S in 2010.(NCGA, 2011).

<u>Preferred Alternative: Water Resources</u>

VCO-01981-5 corn's nonregulated status under the Preferred Alternative would present another glyphosate-resistant corn and weed management option to farmers. It is expected VCO-01981-5 corn would replace other glyphosate-resistant corn varieties and, therefore, not change the overall acreage or area of corn production in the U.S. that potentially impacts water resources through sedimentation and residual pollutant loading from runoff. As discussed in Subsection 4.2.1, Acreage and Area of Corn Production, herbicide-resistant corn comprised 73% of all planted corn acreage in 2012 and the majority of herbicide-resistant corn is glyphosate resistant (Duke and Powles, 2009; USDA-NASS, 2012a). As VCO-01981-5 corn is similar in its growth and agronomic characteristics to its control cultivars and other nonregulated glyphosate-resistant maize lines (USDA-APHIS, 2012a), no changes to irrigation and other agronomic practices such as fertilizer and pesticide applications, including herbicides, that have the potential to affect water quality or quantity, would occur as a result of this alternative.

Since planted VCO-01981-5 corn is expected to replace other glyphosate-resistant corn acreage, its nonregulated status would not affect the recent trend to broaden weed management practices, including more tillage that may increase erosion, and thereby sediment loading to surface waters. The impacts of the Preferred Alternative to water resources, therefore, would be the same as the No Action Alternative.

4.3.2 Soil Quality

No Action Alternative: Soil Quality

Land acreage and agronomic practices associated with conventional corn production are not expected to change in response to the No Action Alternative.

Agronomic practices associated with GE and non-GE corn crop production that benefit soil quality include contouring, use of cover crops to limit the time soil is exposed to wind and rain, introduce certain soil nutrients, crop rotation, and windbreaks. Other agronomic practices utilized in non-GE and GE corn production that potentially impact soil quality include tillage for crop establishment, fertilizer, weed control, and pesticide application.

The production of conventional herbicide-resistant GE corn utilizes EPA-registered pesticides for insect and plant pest management, including glyphosate. In 2010, herbicides were applied to 98% of cropland planted to corn (USDA-NASS, 2011c). Pesticides (including herbicide, insecticide, and fungicide) consist of active ingredients that control pests and inert ingredients to facilitate their application. In 2010, 66% of all active ingredients applied to corn treated with pesticides were herbicidal (USDA-NASS, 2011c), indicating their widespread use and potential to affect the environment The amount of herbicides other than glyphosate applied to corn has declined over the last decade (NRC, 2010b) (see Subsection 4.2.2, Agronomic Practices). The environmental risks of pesticide use are assessed by the EPA in the pesticide registration process and are regularly re-evaluated by the EPA to maintain their registered status under FIFRA. In this process, steps to reduce pesticide residuals and persistence in soil are included on a pesticide’s label and approved by the EPA.

As discussed in Subsection 2.2.2, Soil Quality, there have been several reports of the long-term use of glyphosate immobilizing manganese and potentially reducing plant uptake or ability to utilize this nutrient (Eker et al., 2006; Neumann et al., 2006; Ozturk et al., 2008; Cakmak et al., 2009; Huber, 2010). Additional investigations are required to determine the scope and characterization of glyphosate interactions with nutrients. The current understanding is manganese-glyphosate interaction resulting in manganese problems appears to occur in areas where manganese deficiency already exists (Hartzler, 2010), and producers can address it with agronomic practices designed to augment manganese (Camberato et al., 2010).

The development of glyphosate-resistant weeds or weed management tillage practices potentially impact soil quality. A variety of strategies should be utilized in addressing glyphosate-resistant weeds, including applying the right strength of herbicide, rotating herbicide modes of action, crop rotation, spot treatments, vigilant scouting, and hand weeding (Gunsolus, 2002; Sellers et al., 2011). In the long term, more diverse weed management tactics potentially including more aggressive tillage practices that can affect soil quality may be needed to address the increasing emergence of glyphosate-resistant weeds (Beckie, 2006a; Owen et al., 2011; Owen, 2011a). The particular mix of weed management tactics selected by an individual producer is dependent upon many factors, including the agroecological setting, the problem weed type, and agronomic and socioeconomic factors important to farmers (Beckie, 2006b).

Preferred Alternative: Soil Quality

Approving the petition for a determination of nonregulated status to VCO-01981-5 corn would not affect soil quality. VCO-01981-5 corn would likely replace other commercially available glyphosate-resistant corn cultivars because most corn acreage is currently planted to either herbicide-resistant-only corn or herbicide-resistant corn varieties stacked with other GE traits (Duke and Powles, 2009; USDA-NASS, 2012a). The area and acreage of corn production potentially impacting soil quality would not change as a result of the Preferred Alternative.

VCO-01981-5 corn is agronomically and compositionally equivalent to other glyphosate resistant corn, and other GE and non-GE corn varieties currently in commercial production (Genective, 2012; USDA-APHIS, 2012a). Agronomic practices such as tillage and the application of agricultural chemicals that could impact soil quality or its community structure and function would not change from those currently used for production of other nonregulated glyphosate-resistant corn varieties.

Since it is expected to replace other glyphosate-resistant cultivars, the nonregulated status of VCO-01981-5 corn would not affect weed management practices or their effects on soil quality. As discussed above, more diverse weed management tactics potentially including more aggressive tillage practices that can affect soil quality may be needed to address the increasing emergence of glyphosate-resistant weeds (Beckie, 2006b; Owen et al., 2011; Owen, 2011a). As described under the No Action Alternative, the weed management tactics selected by an individual producer would be dependent upon many factors (Beckie, 2006b). Weed management practices needed for the production of VCO-01981-5 corn would be no different than those used in other commercially available glyphosate-resistant corn cultivars.

Under the Preferred Alternative, the amount of herbicides other than glyphosate applied to corn would likely continue to decline as they have for the last decade (NRC, 2010a) (see Subsection 4.2.2, Agronomic Practices). The application of glyphosate is not expected to change as a result of approving VCO-01981-5 corn's nonregulated status, as no change in the registered use or label of this herbicide is proposed and, as discussed in Subsection 4.2.1, Acreage and Area of Corn Production, the cultivar is anticipated to replace other glyphosate-resistant corn varieties. As discussed above, the impact of glyphosate on manganese availability for uptake by crops after its application is an issue that may be addressed with common practices used to augment deficient soil nutrients. VCO-01981-5 corn is agronomically similar to other GE and non-GE corn varieties and would most likely replace other glyphosate-resistant varieties, the same methods used to address manganese deficiency in current corn production would also be used with VCO-01981-5 corn; therefore, impacts to soil quality under the Preferred Alternative would be the same as the No Action Alternative.

4.3.3 Air Quality

No Action: Air Quality

Under the No Action Alternative, current impacts to air quality associated with land acreage and cultivation practices associated with corn production are not likely to be affected.

Corn is the most widely produced feed grain in the U.S., so its production practices can substantially impact air quality. Tillage prepares the ground for planting, may control weeds, incorporates nutrients and herbicides into soil, and is useful for other functions such as controlling water flow through a field (see Subsection 2.1.2, Agronomic Practices). Tillage exposes soil to wind erosion and utilizes motorized equipment that produces emissions. To the extent that the adoption and cultivation of GE corn varieties allows the grower to adopt conservation tillage practices (Towery and Werblow, 2010a), air quality improvement associated with these practices would be expected to follow. The USDA reports that in 2010, up to 74.5% of planted corn acres were produced under conservation tillage practices ranging from no-till to reduced till (USDA-ERS, 2011d). Reduced tillage generates fewer particulates (dust) and potentially contributes to lower rates of wind erosion releasing soil particulates into the air, benefitting air quality (Fawcett and Towery, 2002). Conservation tillage also reduces equipment emissions due to decreased usage. More recently, these benefits may be eroding if growers employ more aggressive tillage to control the increasing resistance of weeds to herbicides, including glyphosate-resistant weeds (Beckie, 2006b; Owen et al., 2011; Owen, 2011a). Weed management methods, however, vary from farm to farm, dependent upon the agroecological setting, the problem weed type, and agronomic and socioeconomic factors important to farmers (Beckie, 2006b).

Pesticide application in corn production has the potential to impact air quality while actively applied through spray drift, afterward by volatilization off of plant and soil surfaces, and by windborne soil containing residuals in areas where a pesticide has been dispensed (see Subsection 2.2.3, Air Quality, for detailed discussion). Glyphosate is the most common herbicide active ingredient applied to herbicide-treated corn in the U.S. (USDA-NASS, 2011c). The EPA is currently evaluating new regulations for pesticide drift labeling and the identification of BMPs to control such drift (US-EPA, 2009e), as well as identifying scientific issues surrounding field volatility of conventional pesticides (US-EPA, 2010b). Agricultural production of existing nonregulated GE and conventional corn mostly require EPA-registered pesticides for insect and plant pest management, including glyphosate. Glyphosate has a low vapor pressure and volatility from soils (US-EPA, 1993b). Glyphosate's EPA-approved label provides measures for minimizing the potential air quality impacts from its use. When used in accordance with registered uses and EPA-approved labels, glyphosate poses minimal risks to air quality. Increasing or decreasing the acreage of corn production and its associated agronomic practices with emissions potentially impact air quality. As discussed in Subsection 4.2.1, Acreage and Area of Corn Production, corn is a major crop in the U.S., expected to maintain current production levels through 2020 (USDA-OCE, 2011a). Global market forces determine the price of corn, which in turn affects grower decisions on how much to plant (USDA-OCE, 2011a).

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

Preferred Alternative: Air Quality

VCO-01981-5 corn is agronomically and compositionally equivalent to its control cultivars, and other GE and conventional corn varieties currently in commercial production (Genective, 2012; USDA-APHIS, 2012a). No changes to agronomic practices that are sources of emissions or positively contribute to air quality such as the amount, type and timing of tillage, equipment use, irrigation, and the application of fertilizers or pesticides would result from determining VCO-01981-5 corn nonregulated. The commercial use of glyphosate is expected to remain the same if VCO-01981-5 corn were determined nonregulated, since the cultivar would replace other glyphosate-resistant corn varieties, and no changes to glyphosate's registered use or label are proposed. Approximately 73% of planted corn in the U.S. is herbicide resistant, and of that, most is glyphosate resistant (Duke and Powles, 2009; USDA-NASS, 2012a) (see Subsection 4.2.1, Acreage and Area of Corn Production, for detailed discussion).

VCO-01981-5 corn would not likely change the development of glyphosate-resistant weeds or the methods used for their control that may impact air quality, since it is expected to replace other glyphosate-resistant corn cultivars. In summary, there are no new impacts to air quality posed by a determination of nonregulated status for VCO-01981-5 corn. The potential impacts to air quality under the Preferred Alternative are, therefore, similar to the No Action Alternative.

4.3.4 Climate Change

No Action Alternative: Climate Change

Current agronomic practices associated with conventional corn production and current GE corn varieties which contribute to GHG emissions, including tillage, cultivation, irrigation, pesticide application, fertilizer applications, and use of agriculture equipment, are not expected to change if VCO-01981-5 corn remains a regulated article. Land acreage and cultivation practices associated with corn production would not be affected. To the extent that the adoption and cultivation of GE corn varieties allows the grower to implement conservation practices, GHG emissions are expected to continue to be reduced commensurate with the air quality improvements anticipated from adoption of conservation tillage practices.

The major sources of GHG emissions associated with crop production are soil N_2O emissions, soil CO_2 and CH_4 fluxes, and CO_2 emissions associated with agricultural inputs and farm equipment operation (US-EPA, 2012a). Agricultural practices that produce CO_2 emissions include liming and the application of urea fertilization (i.e., nitrogen) to agricultural soils, and CH_4 produced by enteric fermentation and animal manure management. Agricultural soil management activities including fertilizer application and cropping practices are the largest source of N_2O emissions in the U.S. (US-EPA, 2012a). Corn crop production primarily affects climate-changing emissions through: (1) fossil fuel burning equipment used for production and nitrogen fertilization producing CO_2; and, (2) cropping production practices including residue management and tillage (see Subsection 2.2.4, Climate Change, for detailed discussion). The adoption of herbicide-resistant crops and the attendant increase in conservation tillage has been identified as providing climate change benefits. Conservation tillage practices increase crop residue on the surface, promoting the production of SOC and protecting the soil from erosive forces that would release SOC back to the air. These practices also reduce the use of emissions-producing equipment normally used in tilling. The USDA has estimated approximately 74.5% of planted corn acres in 2010 were produced under conservation tillage practices ranging from no-till to reduced till (USDA-ERS, 2011d). Recent increases in the incidence of herbicide-resistant weeds, including glyphosate, may require increased tillage to effect control (Beckie, 2006b; Owen et al., 2011; Owen, 2011a). This could potentially release more SOC sequestered in upper soil layers; however, the particular weed management methods employed by individual farmers would be dependent on many factors unique to the individual farm, including its agroecological setting, the particular problem weed type, and on-farm economics (Beckie, 2006b).

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

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

Preferred Alternative: Climate Change

Because corn line VCO-01981-5 is similar to other GE and non-GE corn cultivars in terms of its growth habit, agronomic properties, disease susceptibility, and composition (USDA-APHIS, 2012a), the agronomic practices required to cultivate corn line VCO-01981-5 would be no different than those used to produce other herbicide-resistant corn cultivars. Therefore, no changes to agricultural practices that could affect GHG emissions would be expected from determining nonregulated status for VCO-01981-5. To the extent that the cultivation of a corn variety expressing resistance to glyphosate allows a grower to minimize conventional tillage and increase the adoption of conservation tillage practices, the potential impacts associated with the Preferred Alternative would be the same as those under the No Action Alternative.

Because corn line VCO-01981-5 is another glyphosate-resistant cultivar similar to other commercially available glyphosate-resistant corn varieties, and the majority of planted corn in the U.S. is herbicide resistant (73% in 2012) primarily consisting of glyphosate-resistant cultivars (Duke and Powles, 2009; USDA-NASS, 2012a), it would likely replace other glyphosate-resistant cultivars rather than expand the production of glyphosate-resistant cultivars. Conferring nonregulated status to corn line VCO-01981-5 would not likely change the development of glyphosate-resistant weeds, since it is expected to replace other glyphosate-resistant corn acreage; thus, no change to GHG emissions would occur from use of fossil fuels, release of SOC, or carbon sequestration in plant residue and soils under the Preferred Alternative. As discussed under the No Action Alternative above, more diverse weed management tactics, potentially those including more aggressive tillage practices that can affect GHG emissions, may be needed in the long term to address the increasing emergence of glyphosate-resistant weeds (Beckie, 2006b; Owen et al., 2011; Owen, 2011a). Since corn line VCO-01981-5 is expected to replace other glyphosate-resistant cultivars, its nonregulated status would not alter weed management practices and their effects on GHGs contributing to climate change; therefore, the potential impacts to climate change under the Preferred Alternative would be similar to the No Action Alternative.

4.4 Biological Resources

4.4.1 Animal Communities

No Action Alternative: Animal Communities

Under the No Action Alternative, conventional and GE corn production will continue as currently practiced while VCO-01981-5 corn remains a regulated article. This includes the cultivation of other glyphosate-resistant corn varieties. Potential impacts of GE and non-GE corn production practices on non-target terrestrial (insect, bird, and mammal) and aquatic (fish, benthic invertebrate, and herptile) species would be unchanged.

Corn production potentially impacts animal communities through the conversion of wildlife habitat to agricultural purposes. As discussed in Subsection 2.2., Acreage and Area of Corn Production, corn was produced on over 96 million acres in 2011, an increase of approximately 4.5 million acres over 2011 (USDA-NASS, 2012a). Corn is expected to continue to be a major crop in the U.S. through 2020 (USDA-OCE, 2011a). A wide array of wildlife occupy or use habitats that are within or adjacent to cornfields (see Subsection 2.3.1, Animal Communities). While cornfields are less suitable for wildlife than adjacent pasture, fallow fields, windbreaks, or shelterbelts, those in conservation tillage management provide greater benefit for wildlife than those in more intensive tillage Under this tillage regime, greater diversity in plant species would occur and so provide more habitat and potential food sources, soil would be less disturbed, and potentially sediment and agricultural pollutant loading of nearby surface waters would be reduced, improving water quality (Brady, 2007; Sharpe, 2010).

Glyphosate-resistant corn varieties have been approved as nonregulated since 1997 (USDA-APHIS, 2012b), and the majority of corn cultivated today is herbicide resistant (USDA-ERS, 2011a), primarily glyphosate-resistant (Duke and Powles, 2009). All glyphosate-resistant corn varieties currently available on the market have been evaluated for their food and feed safety impacts by the FDA. The EPSPS protein that confers glyphosate resistance in GA21 (similar to VCO-01981-5 corn) is corn-derived, and 99.3% identical to its non-herbicide-resistant corn comparators (Monsanto, 1997). This EPSPS has been earlier evaluated by the FDA, who found no safety concerns from its consumption as animal feed (US-FDA, 1998). The EPSPS from VCO-01981-5 corn is derived from the soil inhabiting species, *Arthrobacter globiformis,* which is not a plant pest. Consumption of nonregulated glyphosate-resistant corn presents minimal risk to animal communities. A final food and feed consultation with the FDA for VCO-0198101851-5 corn was submitted by Genective on March 5, 2012 (to be noted as BNF-00137). FDA and was completed May7, 2013.

Current corn agronomic practices potentially impacting animal communities include application of agricultural inputs, such as fertilizer, herbicides, and pesticides. Both fertilizer and pesticides are applied to the majority of corn acres in the U.S. (USDA-NASS, 2011c) and potentially impact non-target wildlife from ingestion or spray drift. Glyphosate is the primary herbicide applied to herbicide-treated corn acreage in the U.S. (USDA-NASS, 2011c). As discussed in Subsection 2.1.2, Agronomic Practices, there are several glyphosate formulations (US-EPA, 2009c) that differ in the timing and amount of application to field corn. The environmental risks of glyphosate herbicides are assessed by the EPA in the pesticide registration process. The glyphosate is currently undergoing registration review scheduled for the final decision in 2015 (US-EPA, 2009b). As discussed in Subsection 2.3.1, Animal Communities, the registered uses for glyphosate pose minimal risk to animals, but spray drift may adversely impact non-target plants that provide habitat. When used consistent with the EPA-registered uses and labels, glyphosate application in corn presents minimal risk to animal communities. In 2010, 66% of all active ingredients applied to corn treated with pesticides were herbicidal (USDA-NASS, 2011c).

More diverse weed management tactics potentially including more aggressive tillage practices that can affect animal communities may be needed to address the increasing emergence of glyphosate-resistant and other herbicide-resistant weeds , (Beckie, 2006b; Owen et al., 2011; Owen, 2011a). As discussed above, more intensive tillage can reduce wildlife habitat and contribute to increased sedimentation and pollutants in runoff to nearby surface waters, affecting water quality that could impact wildlife. The particular mix of weed management tactics selected by an individual producer would be dependent upon many factors, including the agroecological setting, the problem weed type, and agronomic and socioeconomic factors important to farmers (Beckie, 2006b).

Preferred Alternative: Animal Communities

Glyphosate-resistant corn varieties have been deregulated since 1997 (USDA-APHIS, 2012b), and the majority of corn cultivated today is herbicide resistant (USDA-ERS, 2011a), primarily glyphosate-resistant (Duke and Powles, 2009). All glyphosate-resistant corn varieties currently available on the market have been evaluated for their food and feed safety impacts by the FDA. The EPSPS protein that confers glyphosate resistance in GA21 (similar to VCO-01981-5 corn) is corn-derived, and 99.3% identical to its non-herbicide-resistant corn comparators (Monsanto, 1997). This EPSPS has been earlier evaluated by the FDA, who found no safety concerns from its consumption as animal feed (US-FDA, 1998). Similarly, the cp4 epsps now expressed in numerous glyphosate resistant corn and soybean varieties has been evaluated by the FDA, who likewise agreed that these are not materially different in composition, safety, and other relevant parameters from corn grain and forage currently on the market (US FDA BNF-000071) The EPSPS from VCO-01981-5 corn is derived from the soil inhabiting species, *Arthrobacter globiformis*. A final food and feed consultation with the FDA for VCO-0198101851-5 corn was submitted by Genective on March 5, 2012 (to be noted as BNF-00137). FDA has completed the consultation May 7, 2013 and has no further questions for the developer.

As part of the assessment for the proposed action, APHIS has evaluated the potential effects of each alternative on a wide array of wildlife species and their habitats occurring in the U.S. Under the Preferred Alternative, VCO-01981-5 corn may be available as another glyphosate-resistant corn as a weed management option for farmers. As stated above, the majority of corn planted in the U.S. today is herbicide resistant (Duke and Powles, 2009; USDA-ERS, 2011a). As such, it is expected that VCO-01981-5 corn will be another option to other currently available glyphosate-resistant corn varieties and would replace these varieties and not change the acreage or area of corn production in the U.S. (see Subsection 4.2.1, Acreage and Areas of Corn Production). VCO-01981-5 corn is similar in its growth and agronomic characteristics to other nonregulated glyphosate-resistant corn lines (Genective, 2012; USDA-APHIS, 2012a); hence, no changes to agronomic practices such as cultivation, crop rotation, irrigation, tillage, or agricultural inputs with potential impacts to wildlife and their habitat would likely occur under this alternative.

As discussed in Subsection 2.5, Animal Feed, a final food consultation with the FDA for VCO-01981-5 corn was submitted by Genective on March 5, 2012 (BNF-00137). FDA completed the consultation May7, 2013. As discussed in the No Action Alternative, the food safety of the EPSPS protein conveying glyphosate resistance was previously established by an FDA early food safety evaluation. Because the composition of VCO-01981-5 corn is similar to other nonregulated glyphosate-resistant corn lines (Genective, 2012), with no expected hazards associated with its consumption, the risk of VCO-01981-5 corn affecting wildlife species is also unlikely, regardless of exposure.

Commercial use of glyphosate is not expected to change if the petition for nonregulated status of VCO-01981-5 corn is approved. Based upon information provided by Genective (Genective, 2012), VCO-01981-5 corn is similar in its growth characteristics to other nonregulated glyphosate-resistant corn. No changes to the registered uses or labels of glyphosate products would be required to cultivate VCO-01981-5 corn. Consequently, there would be no difference in the potential of VCO-01981-5 corn cultivation to impact wildlife or habitat from that of other nonregulated glyphosate-resistant corn varieties. When used consistent with the EPA-registered uses and labels, glyphosate application in VCO-01981-5 corn fields presents minimal risk to animal communities.

Approving VCO-01981-5 corn as nonregulated would not change the development of glyphosate-resistant weeds or the methods used for their control that may impact animal communities, such as increased tillage. As discussed above, VCO-01981-5 corn would likely replace other glyphosate-resistant corn cultivars that currently comprise 73% of corn cultivars (USDA-NASS, 2012a).

Based on the above, there would be no change in the effects on animal communities from the no action alterative if the preferred alternative is adopted.

4.4.2 Plant Communities

No Action Alternative: Plant Communities

Corn can be grown in a wide number of environments, dependent upon appropriate soil profiles, and locations where weather is not limiting (Iowa-State-University, 2002). Plants communities are varied and adapted to local climate and soil, as well as the frequency of natural or human-induced disturbance (Smith and Smith, 2003). Non-crop vegetation in cornfields is limited by farmers' cultivation and weed control practices. Plants communities adjacent to cornfields commonly include other crops, borders, hedgerows, windbreaks, pastures, and other natural vegetation. The majority of U.S. corn acres are planted with GE herbicide-resistant corn cultivars, and genetically engineered traits do not change the adaptation to the various agronomic environments in which corn hybrids can be produced.

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

Weeds are the most important pest in agriculture, competing for light, nutrients, and water and can significantly affect yields (Gibson et al., 2005; Baucom and Holt, 2009).

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

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

Deterring development of glyphosate resistant weeds is a topic frequently addressed to growers by University extension staff, seed developers, and corn producers associations, among many others. State specific advice, as for example, in Iowa, has identified existing methods that would be highly relevant to corn growers (Owen, 2011a). Owen (2011a) has noted that simplicity and convenience of depending solely on glyphosate "has run its course" and that diversity in weed management strategies (integrated weed management) is needed. He calls for (1) use of herbicide tank mixes, with specific knowledge of existing weed resistances on the farm (2) redundant herbicides for control of key weeds (3) multiple herbicides at each application (4) inclusion of mechanical and cultural strategies. Specific weeds of high concern for resistance development such as horseweed (*Conyza canadensis*) have been shown to be effectively controlled by combinations of herbicides, such as mesotrione and atrazine and other combinations (Armel et al., 2009). Likewise, combinations of these can be used for control of Palmer amaranth, common waterhemp, and giant ragweed (see review in Owen (2011b).Similarly, multistate successes with two or three herbicides pre-emergence have been demonstrated for giant ragweed, common lambsquarters, and giant foxtail, which build on use of atrazine (Loux et al., 2011). While atrazine is already widely used (see Table 2.5) and weed resistance to atrazine is known in Corn Belt states (Heap, 2012), some state weed extension staff continue to see a place for its use in corn production (Owen, 2011b). The extent of weed resistance in Iowa is yet comparatively small, with state-wide estimate of about 1% of acres infested with glyphosate resistant weeds (Hartzler, 2011) (out of 14 million acres of corn planted in Iowa in 2012 (USDA-NASS, 2012a). However, some estimates place row crop glyphosate resistant water hemp as being found on 20% of Iowa acres (Corn-and-Soybean-Digest, 2013). Corn growers are aware that overuse of glyphosate as principle herbicide results in weed resistance (multistate survey from 2005: (Givens et al., 2011), and alternative strategies are both available and being publicized by a variety of expert resources (as noted in sections 2.3.2 and 4.4.2).

For risks of weed resistance to glyphosate, USDA in its various units is funding programs aimed at understanding weed resistance development, and managing crops to avoid resistance. At the Agricultural Research Service, this includes research programs whose goal is providing "recommendations for appropriate rotation frequencies of both crops and herbicides to stymie evolution of weed resistance and shifts to naturally tolerant weed species, and cause a general reduction in weed populations" as described in the Action Plan for 2008-2013 of the National Program 304, Crop Protection and Quarantine (USDA-ARS, 2010). The USDA, National Institute of Food and Agriculture (NIFA) recognizes the need for a broad collaboration of federal, state, academic and industry endeavors to provide responses to these and other risks to which agriculture may be exposed and provides competitive grant awards, such as those of Westra and Chisolm (2012) and Davis and Tranel (2012) to support research directed toward weed resistance. USDA presently devotes substantial funds to support research, teaching and outreach programs (especially through the support of USDA-Extension staff and programs in individual States) for herbicide resistance management, and awarded to agricultural researchers and growers. Additionally, farmer organizations such as the National Corn Growers Association offer online training to their members for averting development of weed resistance (http://ncga.adayana.com/). The Weed Science Society of America has produced a five-module training course for certified crop protection specialists and others titled "Current Status of Herbicide Resistance in Weeds" which is also available online (http://www.pentonag.com/wssa.wrm). Seed technology developers such as Monsanto offer courses for certified pesticide applicators, such as "Weed Resistance Management (WRM) in Agronomic Row Crops & Trees, Nuts & Vines" (http://www.pentonag.com/CA/AZWRM). Finally, state extension services also provide documents online that supply information and management tactics for prevention of herbicide resistance, such as that from University of Minnesota (Gunsolus, 2008).

Volunteer herbicide-resistant arises from spilled corn from the previous cropping season. Existing agronomic practices, however, are effective in the management of such volunteer corn. Glyphosate-resistant volunteer corn may be controlled by the application of corn-active herbicides (e.g., ACCase and ALS inhibitors), mechanical means, and rotation of crops with resistance to different herbicide modes of action (Beckie and Owen, 2007; Zollinger et al., 2011).

The application of an herbicide in corn production has the potential to impact non-target plant communities through spray drift, volatilization (evaporation), its adsorption to soils incorporated in runoff, leaching, and cleaning and disposal of the equipment used to dispense it. Glyphosate is toxic to most terrestrial and aquatic plants, inducing plant death. The herbicide has low leaching potential, low vapor pressure, and low volatility from soils (US-EPA, 1993b; Senseman, 2007) and these properties show low potential for damage from volatility. In its 1993 glyphosate reregistration decision, the EPA required additional studies concerning vegetative vigor, droplet size spectrum, and a drift field evaluation that did not affect the reregistration eligibility of the herbicide (US-EPA, 1993a). The potential effects of glyphosate spray drift are minimized when growers follow EPA-approved labels that provide detailed measures to manage spray drift; these measures include applying only during optimal wind conditions and temperature inversions and at appropriate humidity, adjusting spray droplet size and sprayer boom heights and including drift reduction additives, and judicious use of aerial spraying from aircraft (Monsanto, 2010a).

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

The reproductive morphology of corn encourages cross-pollination between corn plants and there is no evidence (genetic or biological barriers) to indicate that gene flow is restricted between genetically modified, conventional, and organic corn. Spatial and temporal isolation can be the most effective barriers to gene exchange between corn crop cultivars. Requirements and methods to ensure seed and crop purity are discussed in more detail in Subsections 2.1.3, Organic Corn Production, and 2.1.4, Specialty Corn Production.

Corn does not possess the characteristics for efficient seed-mediated gene flow. Through thousands of years of selective breeding by humans, corn has been extensively modified to depend on human cultivation for survival (Doebley, 2004). As a result of its domestication, corn is not able to survive in the wild and also has several traits that greatly reduce its ability to disperse via seeds (OECD, 2003). Corn seed dispersed after harvest may survive in fields and develop into volunteer plants, but such volunteers are controlled with common agronomic practices (see Subsection 2.3.2, Plant Communities

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

Corn line VCO-01981-5 would have no impacts to plants communities adjacent to or within agroecosystems that would be different from currently available glyphosate-resistant corn cultivars. As discussed in Subsection 4.2.2, Agronomic Practices, the agronomic and phenotypic characteristics of VCO-01981-5 have been evaluated in field trials (Genective, 2012) and determined by APHIS to be similar to its comparator corn cultivars (USDA-APHIS, 2012a). VCO-01981-5 would, therefore, be cultivated similarly to other glyphosate-resistant corn, and have impacts to plant communities similar to those described under the No Action Alternative.

Nonregulated VCO-01981-5 would not be expected to increase or decrease the development of glyphosate-resistant weeds. As another glyphosate-resistant corn cultivar option, VCO-01981-5 would likely replace other glyphosate-resistant corn cultivars without changing the application of glyphosate to corn. No changes to glyphosate's registered uses or labels for the cultivation of VCO-01981-5 are proposed by Genective, and no increase in glyphosate-resistant corn production acres is anticipated.

APHIS has determined that there are no phenotypic differences between VCO-01981-5 and control lines that would contribute to enhanced weediness (USDA-APHIS, 2012a). Herbicide-resistant corn such as VCO-01981-5 has the potential to impact other crops in the same fields or adjacent fields in later seasons as volunteers. As VCO-01981-5 is similar to other nonregulated corn cultivars, its volunteers would be controlled by common agronomic practices as discussed under the No Action Alternative.

APHIS evaluated the potential for gene flow between VCO-01981-5 and other corn cultivars. Phenotypic testing of VCO-01981-5 and agronomic trials have demonstrated the cultivar is similar to other glyphosate-resistant corn varieties (USDA-APHIS, 2012a). Therefore, its potential for gene flow and weediness would be no different than other corn varieties currently on the market as described under the No Action Alternative.

4.4.3 Microorganisms

No Action Alternative: Microorganisms

Soil microorganisms are important in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004). They may also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). As described in Subsection 2.3.3, Microorganisms, the main factors affecting microbial population size and diversity include soil and plant type, and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva et al., 2004). Plant roots, including those of corn, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere.

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

The primary agents degrading glyphosate in soil and water are microorganisms feeding on the herbicide (Senseman, 2007). As discussed in Subsection 2.3.3, Microorganisms, investigations into the toxicity of glyphosate to microorganisms have produced varied results. Earliest studies investigating the impact of glyphosate on soil microorganisms did not detect adverse effects under field use conditions, such as on specific, limited functional properties of soil bacteria, such as nitrification, or specific species of soil bacteria; others found minor effects that could not be separated from changes in habitat, and still others reported effects at or near normal glyphosate use rates, but in most cases, the effects were minor and temporary (Giesy et al., 2000). In more recent experiments, glyphosate was applied to two different soil types, and glyphosate stimulated bacterial biomass up to 25 fold and utilization of all carbon substrates by culturable bacteria increased substantially (Ratcliff et al., 2006). As summarized by Hart (2009) while some studies have found effects of glyphosate or the glyphosate resistant crop, many more have shown only minor, transient effects. In the case of glyphosate resistant corn, neither crop effect nor glyphosate effects resulted in changes to the rhizosphere, denitrifying bacteria, or fungi (Hart et al., 2009). Later work showed that glyphosate could directly decrease rhizosphere populations of three types of soil bacteria around roots of glyphosate resistant soybean (Zobiole et al., 2011). Glyphosate applied to soils may reduce soil microbial diversity (Barriuso and Mellado, 2012) but less than that of acetochlor (a common, corn herbicide) applied pre-emergence; in three year observations and with different soil types glyphosate did not impact microbial phyla diversity (Barriuso et al., 2011). Other authors show that bacterial biomass can be reduced 7 days after treatment in soybean rhizosphere, in soil previously unexposed to glyphosate, but that biodiversity does not change in response to glyphosate (Lane et al., 2012). The inconsistent results of these observations suggest that any effects of glyphosate may not be easily distinguished from multiple other influences, including soil, cultivar type, growth stage of the plant, and experimental details (Hart et al., 2009; Farago and Faragova, 2010).

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

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

<u>Preferred Alternative: Microorganisms</u>

Approving the petition for nonregulated status of VCO-01981-5 is not expected to result in any new impacts to microbial communities. VCO-01981-5expresses the *grg23ace5 epsps* gene to make an EPSPS protein (Genective, 2012; USDA-APHIS, 2012a). This gene is derived from *Arthrobacter globiformis,* a common soil-inhabiting bacterium. As such, nothing new or unique would be introduced into the environment that may impact the microbial community under the Preferred Alternative.

VCO-01981-5 has been determined to be agronomically and compositionally similar to other nonregulated glyphosate-resistant corn varieties (USDA-APHIS, 2012a). It is not expected to change the acreage or area of glyphosate-resistant corn production that potentially would expand the use of glyphosate herbicide with potential impacts to soil microorganisms. VCO-01981-5 is another glyphosate-resistant corn cultivar likely to replace other nonregulated glyphosate-resistant corn varieties. Approximately 73% of corn cultivated in the U.S. today is herbicide-resistant and the majority of herbicide-resistant corn is glyphosate-resistant , (Duke and Powles, 2009; USDA-NASS, 2012a). Because VCO-01981-5 is agronomically similar to other glyphosate-resistant and conventional corn, its cultivation would not change the agronomic practices needed for its cultivation, such as amount and rate of glyphosate application.

4.4.4 Biodiversity

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

All the plants, animals, and microorganisms interacting in an ecosystem contribute to biodiversity (Wilson, 1988a) that provides valuable life functions. In agriculture, biodiversity contributes to critical functions such as pollination, genetic introgression, biological control, nutrient recycling, and other processes the loss of which requires costly management (Altieri, 1999). Concerns regarding the potential impacts to biodiversity associated with the introduction of GE crops (and crops in general) include the loss of diversity, which can occur at the crop, farm, or landscape scale (Visser, 1998; Ammann, 2005; Carpenter, 2011) see Subsection 2.3.4, Biodiversity).

At the crop scale, research suggests that developing GE crops has introduced novel genes that has not decreased crop diversity because of widespread use of the traits in multiple breeding programs, and the technology enables the introduction of novel genes in crops (Ammann, 2005; Carpenter, 2011). Additionally, the concern for the loss of genetic variability has led to the establishment of an extensive network of genebanks (van de Wouw et al., 2010), including an active collection of more than 14,000 accessions of corn at the ARS North Central Regional Plant Introduction Station at Iowa State University, Ames, Iowa (USDA-ARS, 2005). These collections are shared with researchers worldwide, which helps ensure a continuous reservoir of genetic diversity for future crop development. Under this alternative, growers have access to existing nonregulated herbicide-resistant and other GE corn varieties, as well as other non-GE corn varieties, while VCO-01981-5 corn would remain a regulated article.

At the farm scale, agronomic practices that can impact biodiversity include cropping practices (e.g., strip or contour cropping, crop rotation), soil conservation practices that maintain grass strips, windbreaks and shelterbelts and the like, tillage, and the application of agrochemicals. The rotation of crops and strip contour cropping provide varied habitat that can benefit biodiversity. Recently, there has been an increase in corn-to-corn rotation given the profitability of corn production (USDA-ERS, 2011b). As discussed in Subsection 2.1.2., Agronomic Practices, continuous corn production must be highly managed to maintain productivity, which can be less beneficial to biodiversity; however, the practice does accumulate more crop residue that benefits some species. The establishment of soil conserving grass and other vegetative borders stabilize soil that maintains additional wildlife habitat, and improves the quality of existing habitat (such as surface water quality) that contributes to biodiversity. Allowing unproductive field edges to become managed wildlife habitat promotes diversity in both plants and animal species (Sharpe, 2010).

Modern agricultural practices may simplify the agricultural landscape, with the result that beneficial arthropods may be adversely affected (Landis et al., 2005). On the other hand, the adoption of conservation tillage has been noted to increase resource diversity within agricultural settings, including refuge habitat, which can then support a larger community of beneficial organisms (Landis et al., 2005).

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

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

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

The greatest direct impact of agriculture on biodiversity on the landscape scale results from the loss of natural habitats caused by the conversion of natural ecosystems into agricultural land (Ammann, 2005). A literature review by (Carpenter, 2011)revealed that increases in crop yields, such as may be attained with GE crops (including herbicide-resistant corn) have the potential to reduce impacts to biodiversity by allowing less land to be converted to agriculture than would otherwise be necessary; however, substantial gains in yields have generally not been obtained by herbicide-resistant cultivars unless higher yielding cultivars are modified with an herbicide-resistant trait (USDA-NRCS, 2010).

Adoption of GE technology has the potential to impact diversity at the farm scale by affecting a farm's biota, including birds, wildlife, invertebrates, soil microorganisms, and weed populations. For example, an increase in adoption of conservation tillage practices is associated with the use of GE herbicide-resistant crops (Givens et al., 2009). Less tillage provides more wildlife habitat by allowing other plants to establish between crop rows. Conservation tillage leaves a higher rate of plant residue and increases soil organic matter (Hussain et al., 1999; Towery and Werblow, 2010b) which benefit soil biota by providing additional food sources and energy (USDA-NRCS, 1996). In addition, invertebrates that feed on plant detritus and their predators as well as the birds and other wildlife that feed on them, may benefit from increases in conservation tillage practices (Towery and Werblow, 2010b) (Carpenter, 2011). Ground-nesting and seed-eating birds, in particular, have been found to benefit from greater food and cover associated with conservation tillage (SOWAP, 2007).

Herbicide use in agricultural fields may impact biodiversity by decreasing weed quantities or causing a shift in weed species present in the field, which may affect those insects, birds, and mammals that utilize these weeds. The quantity and type of herbicide use associated with GE crops, however, is dependent on many variables, including cropping systems, type and abundance of weeds, production practices, and individual grower decisions.

As with farm-scale diversity, use of herbicides at the landscape scale also has the potential to impact biodiversity (Chamberlain et al., 2007). Area-wide herbicide application may increase certain populations of invertebrates and wildlife that benefit from conservation tillage, whereas species that are dependent on the targeted weeds may be negatively impacted.

Further, potential impacts to landscape-scale diversity can be related to the effects of herbicides on non-target animal and plant species. Assessments of the toxicity of glyphosate to animal species indicate a minimal risk to animals, but it may cause adverse effects to plants composing the animals' habitat. As discussed in Subsection 2.3.1, Animal Communities, glyphosate was found by the EPA to be no more than slightly toxic to birds, moderately toxic to practically nontoxic to fish, and practically nontoxic to aquatic invertebrates and honeybees (US-EPA, 1993a). Spraying herbicides onto crops has the potential for inadvertent contact and damage to non-target plants; the EPA is currently evaluating additional labeling requirements concerning BMPs for controlling pesticide spray drift (see Subsection 2.3.2, Plants Communities). While herbicide use potentially affects biodiversity, the application of pesticides in accordance with registered uses and label instructions, and careful management of chemical spray drift, minimizes the potential impacts from their use.

Preferred Alternative: Biodiversity

Under the Preferred Alternative, VCO-01981-5 corn would be extended a nonregulated determination, providing growers an additional glyphosate-resistant corn variety. VCO-01981-5 corn is functionally the same other GE and non-GE corn with regard to agronomic characteristics, growth, reproductive habit, utilization of resources, and production practices (Stine, 2011; USDA-APHIS, 2011b; Genective, 2012; USDA-APHIS, 2012a). The preferred alternative is unlikely to have any direct effects on non-target organisms associated with exposure to its gene products and the modified EPSPS protein expressed by the cultivar. The genetic material in and proteins produced by VCO-01981-5 is similar to those of the nonregulated corn varieties in commercial production (USDA-APHIS, 2012a).

Area-wide herbicide application may negatively impact species that are dependent on the targeted weeds, reducing diversity. As stated above, the majority of corn cultivated in the U.S. is treated with herbicides and glyphosate is the most-applied herbicide to corn (USDA-NASS, 2011e). Potential impacts to landscape-scale diversity can be related to the effects of herbicides on non-target animal and plant species. Assessments of the toxicity of glyphosate to animal species indicate a minimal risk to animals, but it is toxic to targeted plants and may affect non-targeted plants and animals through spray drift, volatilization (i.e., evaporation) and runoff. Inadvertent exposure may cause adverse effects to plants composing animal habitats that could lead to a decrease in biodiversity. As discussed in Subsection 2.3.1, Animal Communities, glyphosate was found by the EPA to be no more than slightly toxic to birds, moderately toxic to practically nontoxic to fish, and practically nontoxic to aquatic invertebrates and honeybees (US-EPA, 1993b). The EPA is currently evaluating additional labeling requirements concerning BMPs for controlling pesticide spray drift (see Subsection 2.3.2, Plant Communities). While herbicide use potentially affects biodiversity, the application of pesticides in accordance with registered uses and label instructions, and careful management of chemical spray drift, minimizes the potential impacts from their use.

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

Because VCO-01981-5 corn is another glyphosate-resistant cultivar option, it would likely replace other glyphosate-resistant corn varieties without expanding the acreage or area of corn production that could impact farm and landscape-scale biodiversity. Approximately 73% of corn planted in the U.S. in 2012 was herbicide resistant, and the majority of herbicide-resistant corn is glyphosate-resistant (Duke and Powles, 2009; USDA-NASS, 2012a). Also, based on its similarity to other corn as described above, VCO-01981-5 corn would not result in changes to agronomic practices such as crop rotation, soil conservation, tillage, weed management, or pesticide use that potentially impact farm- or landscape-scale biodiversity.

Based on the above information, APHIS has concluded the Preferred Alternative would not have impacts to crop-, farm-, or landscape-scale biodiversity any different than other currently available glyphosate-resistant corn cultivars. As such, the effects on biodiversity under this alternative would be the same as the No Action Alternative.

4.5 Public Health

4.5.1 Consumer Health

No action alternative

As discussed in Subsection 2.1.1, Acreage and Area of Corn Production, 88% of corn grown in the U.S. in 2012 was GE (USDA-NASS, 2012a). The majority of GE herbicide-resistant corn grown in the U.S. is glyphosate resistant (Duke and Powles, 2009). Authors have suggested that the human health concerns associated with GE crops include the potential toxicity of the introduced genes and their products, the expression of new antigenic proteins, and/or altered levels of existing allergens (Malarkey, 2003; Dona and Arvanitoyannis, 2009). Previous studies of the EPSPS protein, which confers glyphosate resistance, found that the EPSPS protein expressed through genetic engineering poses no potential for toxicity or allergenicity (Harrison et al., 1996; Ridley et al., 2002; Batista et al., 2005; Hoff et al., 2007; Herouet-Guicheney et al., 2009). Some people are allergic to corn, but corn is not included in the FALCPA as one of the most common food allergens (see Subsection 2.4.1, Consumer Health). An additional concern with GE food crops is the potential for increased levels of anti-nutrients (Dona and Arvanitoyannis, 2009). As discussed in Subsection 2.4.1, Consumer Health, there are several naturally occurring anti-nutrients found in corn, including phytic acid, DIMBOA, raffinose, and low levels of trypsin and chymotrypsin inhibitors (OECD, 2002a).

It should be noted also that a previous biotechnology consultation of a similar EPSPS protein that confers glyphosate resistance was completed by the FDA on the GA21 corn variety (BNF No. 000051) on February 10, 1998 (US-FDA, 1998). The final biotechnology consultation with the FDA was completed May 7, 2013 for food safety following production of VCO-01981-5 corn and under the Preferred Alternative food safety would be no different from those of other glyphosate-resistant corn cultivars as described for the No Action Alternative.

Under the No Action Alternative agricultural production of nonregulated GE and non-GE corn employ EPA-registered pesticides for insect and plant pest management, including glyphosate. Glyphosate may also be applied to regulated VCO-01981-5 corn cultivated under confined conditions. The environmental risks of pesticide use are assessed by the EPA in the pesticide registration process and a pesticide is regularly reevaluated by the EPA to maintain its registered status under FIFRA. The human health effects from exposure to glyphosate have been evaluated by the EPA. The 1993 glyphosate RED presents the data used by the EPA for chemical reregistration (US-EPA, 1993b). As previously discussed in Subsection 2.4.1, Consumer Health, the review for reregistration began in July 2009; the EPA is currently conducting a comprehensive human health assessment for all uses of glyphosate and its salts (US-EPA, 2009c). The glyphosate RED presents the EPA's analysis of the toxicity, carcinogenicity, and developmental toxicity of this herbicide. Glyphosate is classified as having low toxicity via the oral, dermal, and inhalation routes and is not classified as a carcinogen or teratogen (US-EPA, 2009c), (US-EPA, 2009d). Moreover, neurotoxicity has not been reported in any acute, subchronic, chronic, developmental, or reproductive studies, although additional studies will occur as part of the current review process (US-EPA, 2009d). Based on additional toxicity tests, the EPA determined the main glyphosate metabolite AMPA does not require regulation (US-EPA, 2009d).

As presented in Subsection 2.4.1, Consumer Health, pesticide tolerance levels for glyphosate on field corn such as VCO-01981-5 corn have been established (US-EPA, 2011c). Tolerances are the limits on the amount of pesticide that may remain on or in foods marketed in the U.S., that are established for every pesticide based on its potential risks to human health. The maximum tolerance level for glyphosate in field corn is 5.0 ppm for grain (40 CFR §180.364).

VCO-01981-5 corn is a GE variety of corn that has been modified to add resistance to the herbicide glyphosate (Genective, 2012). This resistance was conferred using a sequence of DNA derived from the soil bacterium, *Arthrobacter globiformis.* The grg23 *epsps* gene was modified for enhanced temperature stability as the grg23ace5 epsps gene and which was subsequently reintroduced back into the corn DNA. The EPSPS ACE5 enzyme product is similar to that produced by the GE GA21 corn that was previously determined as nonregulated (USDA-APHIS, 2012b). In addition, except for the CaMV 35S terminator, all sequences including promoter, intron, and chloroplast transit peptide inserted into event VCO-01981-5 corn are either derived from the corn genome or from other non pest sequences. As discussed above, studies have found that the EPSPS protein expressed in glyphosate-resistant crops is safe and that the VCO-01981-5 corn is compositionally similar to, and is as safe and nutritional as, the same non-GE crops (Ridley et al., 2002; Batista et al., 2005; Genective, 2012). Composition of GE EPSPS containing crops is not altered by herbicide treatment (Taylor et al., 1999), nor would there be expectation that it might be so altered. As discussed in Subsection 2.4.1, Consumer Health, Genective (through a predecessor organization, Athenix Corporation) initiated a consultation with the FDA by submitting an early food safety evaluation of the ACE5 epsps protein expressed in VCO-01981-5 corn (NPC 000012: Agency Response Letter) on 10/07/2009 (early food safety evaluation of new non-pesticidal proteins). FDA completed its evaluation with no further questions on 10/15/2010 (US-FDA, 2010). Because VC-01981-5 corn is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced through genetic engineering, Genective initiated the consultation process with FDA for the commercial distribution of event VCO-01981-5. Genective submitted a safety and nutritional assessment of food and feed derived from VCO-01981-5 corn to the FDA on March 5, 2012 (BNF-000137). FDA has completed the consultation May 7, 2013.

In Genective's study of anti-nutrients, raffinose, phytic acid and trypsin inhibitors were not significantly different from non-GE controls or reference hybrids (Genective, 2012). In Genective's study of 51 nutrients and anti-nutrients in VCO-01981-5 corn, a few were significantly different from the non-GE control, but all were found to be within the ranges expected of commercial corn (Genective, 2012). Similarly, in a study of the CP4 EPSPS protein conferring glyphosate resistance in other corn hybrids, Ridley (2002) found the genetic modification to confer glyphosate resistance did not significantly change any of the 51 biologically and nutritionally important components evaluated.

Under the Preferred Alternative, pesticide tolerance levels for glyphosate on field corn would not change. Tolerances are the limits on the amount of pesticide that may remain on or in foods marketed in the U.S. established for every pesticide based on its potential risks to human health. As specified in 40 CFR §180.364, the glyphosate tolerance level for field corn grain is 5.0 ppm. As discussed in Subsection 4.2.2, Agronomic Practices, the use of glyphosate in corn production would be unaffected by the nonregulated status of VCO-01981-5 corn. The application rate of glyphosate in corn would not likely change as a result of the Preferred Alternative since VCO-01981-5 corn is expected to replace other glyphosate-resistant corn cultivars (see Subsection 4.2.1, Acreage and Area of Corn Production), is similar to other nonregulated glyphosate-resistant cultivars in its cultural requirements, and no change to the registered use of glyphosate is proposed.

4.5.2 Worker Safety

No action alternative

It has been suggested that the importance producers place on worker safety, perceived increased simplicity and flexibility of farm management, and decreased risk in production can be partially attributed to the high rate of adoption of GE crops (NRC, 2004).

There are no data indicating that workers exposed to herbicide-resistant corn (raw or byproducts), such as that which might occur during production, transportation, and milling, have experienced adverse reactions. While a small portion of the population does suffer from corn allergies, the EPSPS protein that confers glyphosate resistance in VCO-01981-5 corn has been determined not to be an allergen (see Subsection 2.4.1, Human Health).

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

Preferred Alternative

Potential risks to occupational handlers and growers during glyphosate application to VCO-01981-5 corn would be the same as those presented under the No Action Alternative. There would be no increased risk to workers' health or safety from exposure to VCO-01981-5 corn or byproducts during typical agricultural-related activities. Moreover, as discussed above, the application rate of glyphosate would not likely change and no change to the registered use of glyphosate is proposed under the Preferred

Alternative. Potential risks to farm workers from the use of glyphosate would be the same as the No Action Alternative.

4.6 Animal Feed

No Action Alternative: Animal Feed

As described in Subsection 2.5, Animal Feed, most of the corn produced in the U.S. is for animal feed that is consumed primarily by cattle, poultry, and swine , (NCGA, 2011; USDA-ERS, 2011b). Corn comprises over 95% of the total feed grain produced in the U.S. (USDA-ERS, 2011b). In 2012, corn was grown on over 96 million acres (USDA-NASS, 2012a) and measurably produced in all states but Alaska (USDA-NASS, 2009). As discussed in Subsection 2.5, Animal Feed, 45% of the corn consumed in the U.S. in 2010 was used for animal feed (Fig. 6 (Schnepf, 2011)). In 2012, 73% of the corn produced in the U.S. was genetically engineered to be resistant to herbicides, consisting primarily of glyphosate-resistant cultivars (Duke and Powles, 2009); (USDA-NASS, 2012a). The amount of corn that is used for feed is dependent on a number of factors such as the number of animals that are fed corn, its supply and price, the amount of supplemental ingredients added, and the supply and price of competing ingredients (USDA-ERS, 2011b). Under the No Action Alternative, corn forage, silage, grain, and refined corn feed products from currently cultivated GE herbicide-resistant and conventional corn varieties are utilized by livestock producers.

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

Genective (through a predecessor organization, Athenix Corporation) initiated a consultation with the FDA by submitting an early food safety evaluation of the ACE5 epsps protein expressed in VCO-01981-5 corn (NPC 000012: Agency Response Letter) on 10/07/2009. FDA completed its evaluation with no further questions on 10/15/2010 (US-FDA, 2010). Because VCO-01981-5 corn is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced through genetic engineering, Genective SA initiated the consultation process with FDA for the commercial distribution of event VCO-01981-5 corn. Genective submitted a safety and nutritional assessment of food and feed derived from VCO-01981-5 corn to the FDA on March 5, 2012 (BNF-000137). FDA completed the consultation May 7, 2013.

A biotechnology consultation for a similar EPSPS protein was completed by the FDA on the GA21 corn variety (BNF No. 000051) on February 10, 1998 (US-FDA, 1998). No food safety issues were found by the FDA in their review of Monsanto's safety and nutritional assessment of GA21 corn and the modified EPSPS protein.

The preferred alternative is not likely to result in any additional use of glyphosate, since this corn event will likely only replace other similar corn. This herbicide currently has established tolerances for residues, including established residue concentrations for glyphosate in field corn for forage, grain, and stover. The EPA establishes tolerances to regulate the amount of pesticide residues that can remain on food or feed commodities as the result of pesticide applications(US-EPA, 2011c). The tolerance level is the maximum residue level of a pesticide that can legally be present in food or feed, and if pesticide residues are found to exceed the tolerance value, the food is considered adulterated and may be seized.

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

Preferred Alternative: Animal Feed

As described for the No Action Alternative, the amount of corn that is used for feed is dependent on several factors, including price, supply, and the number of animals that are fed corn (USDA-ERS, 2011b). Because herbicide-resistant corn is the majority of corn produced in the U.S. today, and most of that is glyphosate resistant (USDA-ERS, 2011a), VCO-01981-5 corn would likely replace other glyphosate-resistant cultivars without impacting the supply of corn for animal feed.

Genective has submitted compositional and nutritional characteristics of VCO-01981-5 corn grain and forage to APHIS (Genective, 2012). Samples of VCO-01981-5 corn and its comparators that were sprayed with glyphosate were collected from six different field trial locations (four for grain samples and two for forage samples) and analyzed for comparable nutritional components in accordance with Organisation for Economic Co-operation and Development (OECD) guidelines (OECD, 2002a). Tested parameters include proximates (protein, fat, carbohydrates, fiber, ash, calcium phosphorus and moisture), minerals, amino acids, fatty acids, vitamins, isoflavones, and antinutrients and secondary metabolites (i.e., ferulic acid, phytic acid, trypsin inhibitor, raffinose, inositol, and ρ-coumaric acid) (Genective, 2012). VCO-01981-5 corn is similar in compositional and nutritional characteristics to other varieties of GE and non-GE corn (Genective, 2012; USDA-APHIS, 2012a).

A biotechnology consultation of the EPSPS protein that confers glyphosate resistance in the VCO-01981-5 corn variety has been completed (See Subsection 4.5, Public Health). Genective submitted a safety and nutritional assessment of food and feed derived from VCO-01981-5 corn to the FDA in March 2012 in support of the consultation process with the FDA for the commercial distribution of VCO-01981-5 corn (Genective, 2012). Animal health under the Preferred Alternative would not change when compared to the No Action Alternative.

As discussed above, label restrictions for glyphosate's application to corn prohibits harvesting the grain prior to seven days after application and the interval for harvesting or feeding the vegetation is dependent on the individual glyphosate product label. As discussed in Subsection 4.2.2, Agronomic Practices, the registered uses of glyphosate on VCO-01981-5 corn or other corn would not change as a result of the Preferred Alternative, nor would herbicide label restrictions for feeding corn after treatment. Similarly, no change to the EPA-established tolerances of glyphosate in treated corn intended for forage or grain harvested for animal feed that could impact animal health would be required for of VCO-01981-5 corn.

4.7 Socioeconomic Impacts

4.7.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Environment

Under the No Action Alternative, farmers and other parties who are involved in production, handling, processing, or consumption of corn have access to existing nonregulated herbicide-resistant, conventional, GE, and organic corn varieties. In terms of value, corn is the primary U.S. crop exceeding $76.4 billion in 2011 (USDA-NASS, 2012c), and it is expected corn would retain current planted acreage levels at least until 2020 (USDA-OCE, 2011a). Almost all of the U.S. corn supply (91.4% in 2011/12) comes from new annual domestic production (USDA-ERS, 2012b). In the 2011/12 marketing year, less than half (41.4%) of domestic corn usage was for feed, while approximately 45.6% of domestic use was for the production of ethanol (USDA-ERS, 2012b). Total operating costs for U.S. corn production were $332.34 per planted acre (USDA-ERS, 2012c). Corn is widely produced in the U.S. (see Subsection 2.1.1, Acreage and Area of Corn Production, Figure 1). The most productive and profitable regions are the Heartland and Northern Crescent (USDA-ERS, 2012c). As discussed in Subsections 2.1.3, Organic Corn Production, and 2.6.1, Domestic Economic Environment, organic corn production is a small portion of the U.S. corn market. The value of corn produced for grain or seed from organic-certified farms in the U.S. in 2008 was nearly $111.5 million (USDA-NASS, 2010a).

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

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

Farmers have recently broadened weed management to treat herbicide-resistant weeds which may be impacting yields, leading to more variety in herbicide application and increased tillage, potentially incurring higher production costs. Weirich (2011b), however, investigated the economic effects of alternative glyphosate weed resistance management programs, finding that although they increased cost substantially, higher yields offset these costs such that no statistically significant decrease in net returns occurred. Their study suggests growers may be able to effectively respond to glyphosate resistance using weed BMPs without substantially affecting their returns.

As indicated in Subsection 2.1.1, Acreage and Area of Corn Production, the trend over the last several years in the U.S. has been to stack herbicide resistance with primarily insect-resistant traits. Developers have recently sought approvals for corn varieties that have multiple herbicide and insect resistance, as well as other value added traits ((USDA-APHIS, 2012b). Herbicide-resistant-only corn has consistently comprised approximately 22 to 23% of planted corn in the U.S. since 2007 (USDA-ERS, 2011a). Only two companies hold the licenses for the majority of herbicide-resistant corn in the U.S.: Monsanto patented glyphosate-resistant corn technology and offers varieties in their Roundup Ready® corn lines, and Bayer CropScience licenses glufosinate-resistant corn in their LibertyLink® corn lines. Glufosinate-resistant corn has been commercially available even longer than glyphosate-resistant corn, but has not been as successful, thought to be due to the higher cost of glufosinate and its more restrictive application timings to smaller plants to increase its efficacy (Owen, 1999; Green and Owen, 2011). Growers have perceived a lack of competition in the U.S. herbicide- and insect-resistant seed corn market based on substantial increases in the price of GE seed in the last several years (Neuman, 2010). This observation may correlate with the ongoing concentration of the U.S. seed market since passage of the Plant Variety Protection Act in the 1970s established proprietary rights for certain plant varieties (Fernandez-Cornejo, 2004). In 2011, corn seed comprised approximately 25% of total per acre operating costs for farmers (USDA-ERS, 2012c). Industry has responded that the quality of seed offered has improved, and new GE traits have been added that lower costs associated with improved insect and weed control, among other production costs (Neuman, 2010).

<u>Preferred Alternative: Domestic Economic Environment</u>

Availability of VCO-01981-5 corn could potentially impact agronomic inputs and associated on-farm costs as well as the U.S. domestic corn market. Under the Preferred Alternative, VCO-01981-5 corn would be extended nonregulated status. Farmers and other parties who are involved in the production, handling, processing, or consumption of corn would have access to VCO-01981-5 corn.

VCO-01981-5 corn has been determined to be similar in its composition, growth habits, and cultural requirements to its comparators and other nonregulated glyphosate-resistant corn (Genective, 2012; USDA-APHIS, 2012a). Since this new cultivar is glyphosate-resistant and would directly compete with other glyphosate-resistant corn varieties, the market share of other glyphosate-resistant corn may diminish. As discussed above, herbicide-resistant corn dominates U.S. corn production, either as herbicide-resistant-only varieties or stacked with other traits; therefore, VCO-01981-5 corn would likely replace other glyphosate-resistant corn cultivars without impacting corn acreage or production area that may affect domestic markets. As another glyphosate-resistant corn cultivar in the market, nonregulated VCO-01981-5 corn may increase competition, the extent of which is dependent upon growers finding value in it. As discussed above, growers may currently choose from glyphosate, glufosinate, and glyphosate stacked with imidazolinone resistance traits. It is reasonable to assume VCO-01981-5 corn may be stacked with other traits, similar to other glyphosate-resistant corn cultivars. APHIS assumes that the technology fees for VCO-01981-5 corn seed would be consistent with those charged by developers for other GE crop varieties already in the marketplace. APHIS has no control over the establishment of these technology fees, and each grower must make an independent determination as to whether the benefits of the GE variety would offset those technology access costs.

Since VCO-01981-5 corn is similar in growth habits and cultural requirements to other nonregulated herbicide-resistant, GE and non-GE corn varieties (Genective, 2012), no changes to agronomic inputs or practices would be anticipated that may impact on-farm costs for corn producers or the U.S. domestic corn market. As discussed above, farmers are broadening their weed control tactics in response to developing herbicide-resistant weeds, including glyphosate-resistant weeds (see Subsection 2.3.2, Plant Communities, Table 2.10). These BMPs increase costs of production; however, the costs appear to be offset by increases in yields, having little negative impact to net returns (Weirich et al., 2011a). As discussed above, VCO-01981-5 corn is similar to and expected to replace other glyphosate-resistant cultivars, and would, therefore, have no effect on the development of herbicide-resistant weeds or weed management practices different than those identified for the No Action Alternative.

Certified organic corn cannot include GE cultivars in the U.S. (USDA-AMS, 2010). As discussed under the No Action Alternative, the organic corn market serves a smaller consumer niche for corn in the U.S. corn market. Because VCO-01981-5 corn's similarity to other corn in its reproductive characteristics, it is expected U.S. organic producers would continue to meet organic certification requirements as outlined in Subsection 2.1.3, Organic Corn Production, by implementing standard practices to preserve the identity of their organic corn crop.

Based upon the above, APHIS has found that the preferred alternative would have potential domestic economic impacts no different than those currently observed under the No Action Alternative for other glyphosate-resistant corn varieties.

4.7.2 Trade Economic Environment

No Action Alternative: Trade Economic Environment

Under the No Action Alternative, VCO-01981-5 corn would continue to be a regulated article. Farmers, processors, and consumers in the U.S. would not have access to VCO-01981-5 corn, but do have access to existing nonregulated herbicide-resistant and non-GE corn varieties, as do the major U.S. corn export competitors.

The U.S. is the leading exporter of corn in the world market (see Subsection 2.6.2, Trade Economic Environment), while other important exporters are Argentina, Brazil, and Ukraine. In the 2011/2012 marketing year (August to September), the U.S. exported approximately 37% of the world's corn while Japan, Mexico, and South Korea were the major importers (USDA-FAS, 2012). In 2011, corn exports were worth approximately $13.7 billion (USDA-ERS, 2012d). U.S. corn supply, the value of the U.S. dollar and other currencies, oil prices, U.S. and international agricultural policy, the U.S. and international biofuels sector, livestock and meat trade, prices, and population growth are all factors affecting where and how much of U.S. corn is exported (USDA-ERS, 2011c); (USDA-OCE, 2011a). In addition, consumer perception of GE crop production and products derived from GE crops may present barriers to trade. Over the past decade, U.S. corn export share has eroded as exports have remained relatively stable while global exports have increased by almost 20% (See Subsection 2.6.2, Trade Economic Environment). U.S. share of world corn production has declined as well, even as total world production increased. This is attributed to greater domestic use of U.S. corn, smaller corn crops, and increased competition from other major corn exporters such as Argentina, Brazil, and Ukraine (USDA-FAS, 2012), countries with increasing GE herbicide- and insect-resistant corn production acreage (Brookes and Barfoot, 2010).

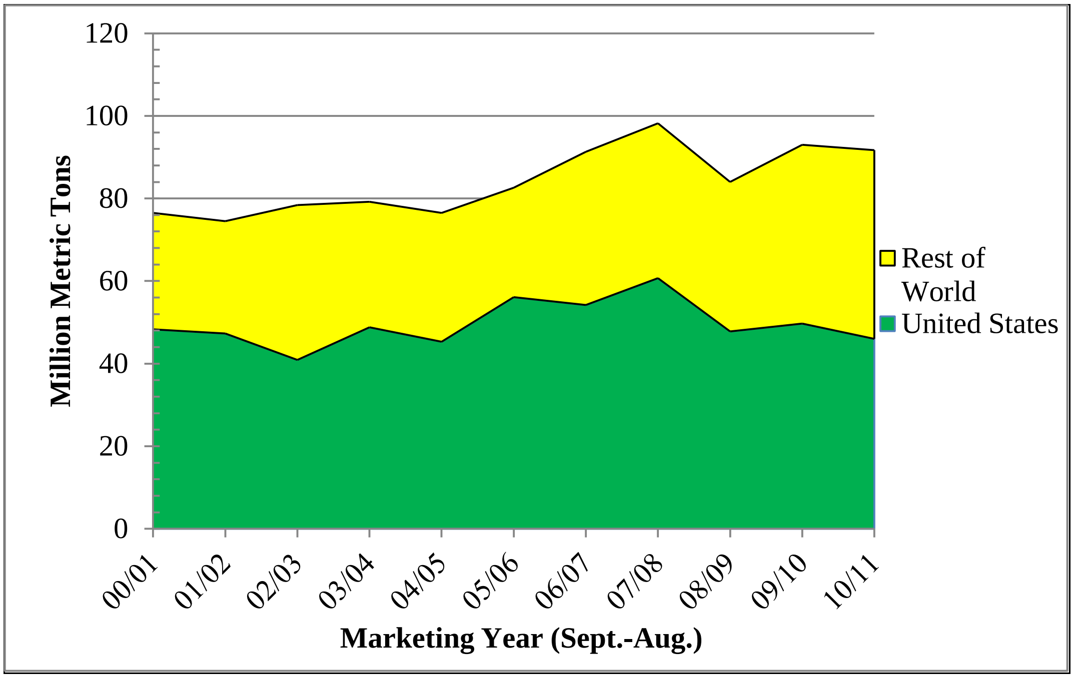

Figure 2: US and world corn exports for marketing years 2000/2001 to 2010/2011.

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

Market years extend from September to August. Major world exporters include Argentina, Brazil, Canada, China, EU-27, India, Paraguay, Romania, Serbia, South Africa, Thailand, Ukraine and Zambia as well as other smaller exporting countries. Note that the US percentage of corn exports in relation to overall world exports declined at the end of the last decade.

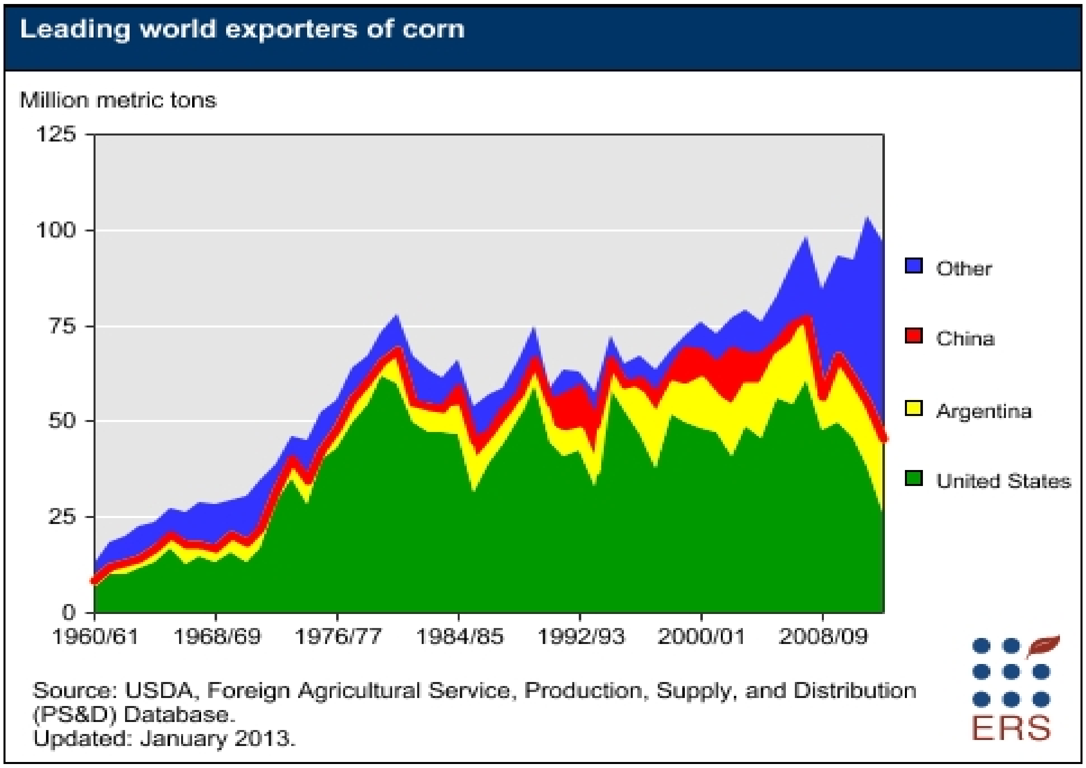

Figure 3: US and major exporters of corn for marketing years 1960/1961-2011/2012.

Source: (Capehart, 2013).

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

Farmers in the U.S. and abroad have begun to utilize BMPs to control glyphosate or other herbicide-resistant weeds, but these BMPs have not necessarily increased costs (Weirich et al., 2011a) such that the competitiveness of U.S. corn and trade economic environment would be affected. Increasing herbicide weed resistance is also occurring in other countries producing herbicide-resistant crops, including U.S. corn export competitors (for example, Argentina and Brazil (Heap, 2012) that would likely incur increases in production cost to mitigate the incidence of glyphosate-resistant weeds, similar to the U.S. experience.

As of publication of this EA, Genective is likely to submit applications for regulatory approval to export VCO-01981-5 to Canada, the EU and to Japan for cultivation and use as food and feed. Canada is not a major corn export competitor of the U.S.; in the 2011/2012 market year, Canadian corn exports equalled only about 1.3% of the U.S. corn exports that year (USDA-FAS, 2012).

<u>Preferred Alternative: Trade Economic Environment</u>

Under the Preferred Alternative, VCO-01981-5 would be determined nonregulated and available to U.S. growers. Availability of VCO-01981-5 could potentially impact the corn seed, feed, and food trade. VCO-01981-5 is compositionally and agronomically similar to its comparators and other nonregulated glyphosate-resistant corn (Genective, 2012; USDA-APHIS, 2012a). As such, it is not expected to affect the seed, feed, or food trade any differently than other nonregulated glyphosate-resistant corn varieties (see Subsections 4.7.1, Domestic Economic Environment). As another glyphosate-resistant corn cultivar, VCO-01981-5 is expected to replace other glyphosate-resistant cultivars to the extent growers find value. Approval of the request to determine nonregulated status to VCO-01981-5 would, therefore, not likely increase the U.S. supply of corn that may affect trade. As discussed above, other countries are increasing their production of herbicide-resistant corn, including glyphosate-resistant cultivars, and are becoming significant export competitors to U.S. corn trade. Because the U.S. and other countries already have access to other glyphosate-resistant corn cultivars, and VCO-01981-5 presents another option of glyphosate-resistant corn, its availability only to U.S. producers would not likely significantly impact the economic trade environment. As noted above, Genective plans to submit applications to Canada for import clearance of VCO-01981-5 (Genective, 2012); however, Canada is not a major U.S. corn export competitor.

As discussed in Subsection 4.4.2, Plant Communities, the cultivation of VCO-01981-5 would not change the development of glyphosate-resistant weeds nor affect the BMPs to control glyphosate-resistant weeds any differently than other nonregulated glyphosate-resistant corn. These BMPs would not necessarily increase costs such that the competitiveness of U.S. corn and trade economic environment would be affected, as the increased costs may be offset by increased yields (Weirich et al., 2011a).

As discussed under the No Action Alternative, global corn export markets respond to many factors, including consumer perception of GE crops and derived products. As another glyphosate-resistant corn cultivar, the availability of VCO-01981-5 for production in the U.S. would not likely affect foreign consumer perception of GE corn products or those global forces shaping the U.S. corn trade economic environment.

5 CUMULATIVE IMPACTS

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

5.1 Assumptions Used for Cumulative Impacts Analysis

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

Potential reasonably foreseeable cumulative effects are analyzed under the assumption that farmers, who produce conventional or organic corn and VCO-01981-5, have used in the past and would continue to use reasonable, commonly accepted BMPs for their chosen system and varieties during agricultural corn production. APHIS recognizes, however, that not all farmers will use such BMPs. Further, the cumulative impact analysis assumes that it is not necessary to change the use pattern of glyphosate on the glyphosate-resistant VCO-01981-5 variety. Hence, APHIS will use current glyphosate labels as the basis for its potential past, present, and reasonably foreseeable impacts from the use of and exposure to glyphosate. APHIS assumes growers of VCO-01981-5 will adhere to the EPA-registered uses and EPA-approved labels for all pesticides applied to this crop.

Crop varieties that contain more than one GE trait, known as a “stacked” hybrid, are currently found in agricultural production and in the marketplace. If APHIS approves the petition for nonregulated status for VCO-01981-5 corn, it would likely be combined with non-GE and GE corn varieties through traditional breeding techniques. Stacking of nonregulated GE crop varieties using traditional breeding techniques is common practice and is not regulated by APHIS. As of 2012, corn with only herbicide-resistant traits comprised 21% of the U.S. corn grown, but a greater proportion was stacked with both herbicide- and insect-resistant traits (52%) (USDA-NASS (USDA-NASS, 2012a)). Stacking would involve combining VCO-01981-5 corn with other corn varieties having GE traits such as herbicide, insect, and/or drought resistance, which are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Such stacked varieties could provide growers with several options such as combining several herbicides with different modes of action for control of weeds; therefore, as part of the cumulative impacts analysis, APHIS will assume that VCO-01981-5 corn would likely be combined with commercially available herbicide and insect-resistant varieties of corn as a reasonably foreseeable future action.

Whether VCO-01981-5 corn would be stacked with any particular nonregulated GE variety is unknown, as company plans and market demands play a significant role in those business decisions. In addition, the adoption level of VCO-01981-5 corn would depend on the extent producers value the traits offered by stacked versions of VCO-01981-5 corn over other available stacked corn varieties and comparative pricing compared to other HT corn varieties.

5.2 Cumulative Impacts: Acreage and Area of Corn Production

The Preferred Alternative is not expected to directly cause a measurable change in agricultural acreage or area devoted to conventional or GE corn cultivation or corn grown for seed in the U.S. (see Subsections 4.2.1, Acreage and Area of Corn Production). The majority of corn grown in the U.S. is GE and herbicide resistant (USDA-ERS, 2011a). Long-term projections show planted corn maintaining between approximately 90 and 92 million acres a year through 2020, about the same as the 96 million acres planted to corn in 2012 (USDA-OCE, 2011a; USDA-NASS, 2012a). Because VCO-01981-5 is another glyphosate-resistant corn cultivar agronomically and compositionally similar to other commercially available glyphosate-resistant corn cultivars, and herbicide-resistant corn is currently approximately 73% of all planted corn and most U.S. corn is glyphosate-resistant (USDA-NASS, 2012a), it is expected that VCO-01981-5 would replace other similar cultivars without expanding the acreage or area of corn production. There are no anticipated changes to the availability of GE and non-GE corn varieties on the market under either alternative. The Preferred Alternative, therefore, would have no impacts to acreage or area of corn production and corn grown for seed different than the No Action Alternative.

The potential future development and cultivation of VCO-01981-5 glyphosate-resistant corn stacked with other herbicide-resistant, insect-resistant, and/or other GE traits is not likely to change the area or acreage of corn production. Despite the availability of these cultivars, corn production acreage is expected to remain relatively stable until 2020 (USDA-OCE, 2011a).

5.3 Cumulative Impacts: Agronomic Practices

In the preceding analysis, the potential impacts from a determination of nonregulated status to VCO-01981-5 corn were assessed. The agronomic characteristics evaluated for VCO-01981-5 corn encompassed the entire life cycle of the corn plant and included germination, seedling emergence, growth habit, vegetative vigor, days to pollen shed, days to maturity, and yield parameters. The compositional analysis included the major constituents (carbohydrates, protein, fat, and ash), minerals, vitamins, amino acids, fatty acids, secondary metabolites, antinutrients, phytosterols, and nutritional impact. VCO-01981-5 corn is agronomically and compositionally similar to other GE and non-GE corn varieties (Genective, 2012; USDA-APHIS, 2012a). As a result, and as determined in Section 4, Environmental Consequences, the potential impacts under the Preferred Alternative for all the resource areas analyzed would be the same as those described for the No Action Alternative.

The potential impacts from the use of herbicides under the Preferred Alternative would be the same as those of the No Action Alternative (see Subsections 4.2, Agricultural Production of Corn; 4.3, Physical Environment; 4.4, Biological Resources; 4.5, Human Health; and 4.6, Animal Feed). The methods of application and use rate for herbicides to be applied to VCO-01981-5 corn would not change from those already approved for use on other nonregulated glyphosate-resistant corn cultivars. The total amount of the mix of herbicides that could be applied to VCO-01981-5 corn would be limited by the authorized EPA-registered uses and the total application amount allowed by law. Glyphosate and other pesticides are registered by the EPA under FIFRA and are reviewed and reregistered every 15 years to assess potential toxicity and environmental impact. In order to be registered for use, a pesticide must be able to be used without unreasonable risks to people or the environment. Pesticide residue tolerances for glyphosate and other herbicides and pesticides are listed in 40 CFR §180.364 and include acceptable concentrations for corn grain and forage. In addition, the safety precautions and EPA-labeled instructions for the application of pesticides would not change under the Preferred Alternative, ensuring continued human health and worker safety (see Subsection 4.5, Public Health).

The herbicide glyphosate has been implicated by some in reductions of plant mineral uptake or nutrition (see review in (Duke et al., 2012). As noted by Duke (2012) the work showing such reduction has almost all been done in the greenhouse on glyphosate resistant soybean. Notable also is work that shows such changes in nutrition in response to glyphosate are most different at dosage rates beyond the single application label rate (Zobiole et al., 2012). Also, although some mineral nutrition depression with glyphosate can be detected, these appear to be "within the normal ranges for these crops" (Duke et al., 2012). Finally, when field trials are performed using label rates, content of 13 minerals was not lower following either one or two applications of glyphosate in either leaves or seed (Duke et al., 2012). APHIS concludes that there is no consistent evidence for an effect of glyphosate on mineral nutrition of soybean, and not likely of corn, either.

VCO-01981-5 corn stacked with other herbicide-resistant traits would, however, narrow the options for herbicidal management of volunteer corn. In crop rotations where soybean or some other broadleaf cultivar is rotated with corn, an approved grass herbicide could be used to control volunteer corn (Sandell et al., 2011). In continuous corn cropping systems with the same herbicide resistances, control becomes more complicated and must be accomplished through other means such as tillage (Sandell et al., 2011). Loux et al. 2011(2011) recommend careful rotation planning to eliminate this potential problem. VCO-01981-5 stacked with insect-resistant traits would be no more likely to exhibit increased weediness characteristics than other currently available glyphosate- and insect-resistant stacked GE corn cultivars. Similarly, stacked VCO-01981-5 is not expected to exhibit any gene flow characteristics different from the parent transformation events (i.e., crop lines) that would pose a plant pest risk.

Under the Preferred Alternative, extending a determination of nonregulated status to VCO-01981-5 is not expected to result in changes to current corn cropping practices. Studies conducted by Genective demonstrate that, in terms of agronomic characteristics and cultivation practices, VCO-01981-5 corn is similar to other corn varieties currently grown (Genective, 2012; USDA-APHIS, 2012a). Consequently, no changes to current corn cropping practices such as tillage, crop rotation, or agricultural inputs associated with the adoption of VCO-01981-5 are expected (see Subsection 4.2.2, Agronomic Practices).

5.4 Cumulative Impacts: Organic Corn Production

Based upon recent trends, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share (see Subsection 4.2.3, Organic Corn Production). As described above, the majority of corn in 2012 was GE and herbicide resistant (USDA-NASS, 2012a). Since 1994, 27 GE corn events or lines have been determined by APHIS to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (USDA-APHIS, 2012b). U.S. organic corn production acreage grew 83% from 32,650 acres in 1995 to 194,637 acres in 2008, and remained at about 0.2% of total U.S. corn acreage from 2005 to 2008 (USDA-ERS, 2011g). Availability of another GE glyphosate-resistant corn variety, such as VCO-01981-5 under the Preferred Alternative, is not expected to impact the organic production of corn any differently than other GE varieties grown in the past or presently under the No Action Alternative.

5.5 Cumulative Impacts: Physical Environment

As discussed in Subsection 4.3, Physical Environment, the Preferred Alternative would have the same potential impacts to water, soil, air quality, and climate change as that of nonregulated glyphosate-resistant corn varieties presently available. Agronomic practices that have the potential to impact soil, water and air quality, and climate change such as tillage, agricultural inputs (fertilizers and pesticides), and irrigation would not change because VCO-01981-5 is agronomically similar to other glyphosate-resistant corn and other GE and non-GE corn. Other practices that benefit these resources, such as contouring, use of cover crops to limit the time soil is exposed to wind and rain, crop rotation, and windbreaks would also be the same between the No Action and Preferred Alternatives. Because of its similarity to other nonregulated glyphosate-resistant corn and the fact that most cultivated corn in the U.S. is glyphosate resistant, adoption of VCO-01981-5 would replace other similar cultivars without changing the acreage or area of corn production that could impact water, soil, air quality, and climate change. No difference in impacts to these resources would occur between the Preferred and No Action alternatives.

If the petition for nonregulated status for VCO-01981-5 is approved and it is stacked with other GE herbicide-resistant traits, depending on the extent of its adoption, it may contribute to sustaining conservation tillage in U.S. corn production that both directly and indirectly impacts water, soil, and air quality. Stacking VCO-01981-5 with other herbicide-resistant traits would enable use of a combination of different herbicide modes of action to be applied to corn, an approach recommended by Dill et al. (Dill et al., 2008) to preserve the utility of glyphosate resistance technology. This approach has been proposed to mitigate the future development of herbicide-resistant weeds (Duke and Powles, 2009), which may reduce the need for tillage for weed management (Owen, 2011a), thus, benefiting soil, water, and air quality. Consequently, stacking with additional herbicide resistant traits would also reduce GHG emissions from soil and emissions from associated fuel-burning equipment that can contribute to climate change. Reduced tillage improves habitat value through increased water quality, availability of waste grain, retention of cover in fields, and increased populations of invertebrates (Brady, 2007; Sharpe, 2010). Similarly, stacking multiple herbicide resistance into a single cultivar may sustain conservation tillage rates that promote greater plant diversity in fields while retaining crop yields which subsequently would improve soil quality and reduce soil erosion, sustaining both crop and non-crop plants (see Subsection 2.2.2, Soil Quality).

5.6 Cumulative Impacts: Biological Resources

The impacts of the Preferred Alternative to animal and plants communities, microorganisms, and biodiversity as discussed in Subsection 4.4, Biological Resources would be no different than that experienced under the No Action Alternative. VCO-01981-5 corn is both agronomically and compositionally similar to other nonregulated glyphosate-resistant corn; thus, it would not require any different agronomic practices to cultivate, and does not represent a safety or increased weediness risk any differently than other currently available glyphosate-resistant corn. Availability of VCO-01981-5 corn would not impact the development of glyphosate-resistant weeds or the trend to broaden weed management tactics to effect control over herbicide-resistant weeds, as it is expected to replace other glyphosate-resistant cultivars without expanding the acreage or area of corn production or changing the application rates of glyphosate (see Subsection 4.4.2, Plant Communities).

VCO-01981-5 corn would be another glyphosate-resistant corn cultivar that could be stacked like other nonregulated glyphosate-resistant GE corn. Potential future stacking of VCO-01981-5 corn might include development of hybrids using other currently available nonregulated corn varieties expressing resistance to other herbicides, or resistance to select insect pests by stacking with one of the biopesticidal Bt genes. For example, a new cultivar combining glyphosate and glufosinate resistance with insect resistance became available for the 2012 planting season (Monsanto, 2011a). APHIS regulations under 7 CFR part 340 do not provide for Agency oversight of stacked varieties combining GE varieties with previously approved nonregulated status, unless it can be positively shown that such stacked varieties are likely to pose a plant pest risk. No evidence suggests an impact of such combined traits, and in fact, existing evidence supports the non-impact of such stacking. As typically observed, neither glyphosate use nor cultivars with glyphosate resistance have a consistent impact on soil microbiota (see sect 4.4.3). Similarly neither glufosinate resistant plants nor the herbicide glufosinate changed the community profile of rhizosphere bacteria when 16s rRNA was assessed in products of PCR analyzed for single-strand conformation polymorphism (Schmalenberger and Tebbe, 2002). Whether VCO-01981-5 would be stacked with any particular nonregulated GE variety is unknown, as company plans and market demands play a significant role in those business decisions. In addition, the adoption level of VCO-01981-5 would depend on the extent producers value the traits offered by stacked versions of VCO-01981-5 over other available stacked corn varieties.

VCO-01981-5 corn would likely be stacked with insect-resistant corn varieties that express the Bt endotoxin. Based on studies undertaken to assess the potential impacts of the Bt endotoxin to the monarch and other non-target butterflies, as well as factors such as the location of corn production and the characteristics of corn pollen, the EPA determined that the potential risk to non-target butterflies is low (US-EPA, 2002). In the near future, any VCO-01981-5 corn stacked with insect-resistant (Bt) traits would likely replace other currently nonregulated stacked GE corn varieties with herbicide and insect resistance. Any insect-resistant trait that may be developed in the future and stacked with VCO-01981-5 would be subject to APHIS, EPA, and FDA approval. The adoption of stacked VCO-01981-5 corn would be contingent on the extent growers see value in the traits expressed in comparison to other commercially available corn cultivars with similar herbicide- and insect-resistant traits.

There are no differences in the potential for gene flow and weediness between the No Action and Preferred Action Alternatives. Only limited populations of compatible relatives of domesticated corn with limited intercrossing ability are found within the U.S.; hence, there is not a significant risk of gene movement between corn and its wild or weedy maize relatives (US-EPA, 2010a; USDA-APHIS, 2012a). Additionally, corn seed does not possess the characteristics for efficient seed-mediated gene flow, does not establish wild or feral populations, and is dependent on human cultivation for survival (OECD, 2003; Doebley, 2004). The risk of gene flow and weediness of VCO-01981-5 corn is no greater than that of other nonregulated glyphosate-resistant corn varieties.

5.7 Cumulative Impacts: Public Health and Animal Feed

Food and feed derived from GE corn must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release onto the market to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food. As discussed in Subsections 4.5, Public Health and 4.6, Animal Feed, VCO-01981-5 would have no adverse effect to human health or livestock. Athenix (a predecessor organization to Genective S.A.) submitted data for a new protein consultation for grg23ACE5 EPSPS in 2009, and FDA completed their response letter on 15 October 2010. Genective submitted a safety and nutritional assessment of food and feed derived from VCO-01981-5 corn to the FDA on March 5, 2012 and FDA completed the consultation May 7, 2013 (BNF-000137). The final notice is posted on the FDA website for Final Biotechnology Consultations (http://www.fda.gov/Food /Biotechnology/Submissions/ucm225108.htm). A food safety evaluation of the related EPSPS protein for the GA21 corn variety was completed by the FDA (BNF No. 000051) on February 10, 1998, which found no safety concerns (US-FDA, 1998). In addition, the potential environmental impacts from the cultivation of glyphosate-resistant corn varieties have been thoroughly evaluated by APHIS (see http://www.aphis.usda.gov/biotechnology /not_reg.html). No differences in food and feed safety would be presented when comparing the Preferred and No Action alternatives.

Under the preferred alternative, VCO-01981-5 would likely be stacked with insect-resistant corn varieties that express the Bt endotoxin. In accordance with 40 CFR part 174, all the currently nonregulated insect-resistant corn varieties that contain the Bt endotoxin are exempt from the requirement of tolerance in feed commodities. In the near future, any VCO-01981-5 stacked with insect-resistant (Bt) traits would likely replace other currently non-regulated stacked GE corn varieties with herbicide and insect resistance. Any insect-resistance trait that may be developed in the future and stacked with VCO-01981-5 would be subject to APHIS, EPA, and FDA approval. The adoption of stacked VCO-01981-5 corn would be contingent on the extent growers see value in the traits expressed in comparison to other commercially available corn cultivars with similar herbicide- and insect-resistant traits.

In the near term, any additional GE traits that may be stacked with VCO-01981-5 have already been deregulated. . As discussed above in Subsection 4.5 Public Health and 4.6 Animal Feed, food and feed derived from GE corn must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release onto the market. All varieties of GE corn with which VCO-01981-5 would be stacked have undergone, or are expected to undergo, this process to ensure their safety as food and feed products.

5.8 Cumulative Impacts: Domestic Economic Environment

As discussed above, based on its similarity to other nonregulated corn cultivars, VCO-01981-5 corn would potentially replace other glyphosate-resistant corn cultivars without impacting corn acreage or production area that may affect domestic markets. Additionally, since VCO-01981-5 corn is agronomically and compositionally similar to other commercially available corn, there would be no changes to agronomic inputs or practices from approving the nonregulated status to VCO-01981-5 that may impact on-farm costs for corn producers or the domestic economic environment, including the organic corn market. As mentioned above, VCO-01981-5 would not likely impact differently the development or treatment of herbicide-resistant weeds or their associated costs in crop losses. Nor would methods to effect control of such herbicide resistant weeds in VCO-01981-5 differ compared to methods used in other glyphosate resistant corn hybrids. Impacts of the Preferred Alternative on the domestic economic environment would therefore be no different than those sustained under the No Action Alternative.

Corn varieties with single and multiple herbicide resistance or insect resistance are already widely available, representing 73% of U.S. corn acreage in 2012 (see Subsection 2.1.1, Acreage and Area of Corn Production). While the adoption of herbicide-resistant-only corn has remained relatively level and the production of insect-resistant-only corn has decreased since 2007, the adoption of stacked varieties that confer resistance to herbicides and insects has steadily increased from 1% of planted corn acres in 2000 to 49% in 2011 (USDA-ERS, 2011a). As such, it is expected that VCO-01981-5 corn would likely be stacked with insect-resistant traits and would have impacts similar to other such stacked corn cultivars already on the market. Agronomic practices, including inputs for production of VCO-01981-5 stacked with insect resistance, would be no different than those needed to cultivate other commercially available corn with the same resistances; thus, changes to on-farm costs for corn producers or to the U.S. domestic corn market would be unlikely. VCO-01981-5 corn may also be stacked with other nonregulated GE traits; however, predicting these potential combinations would be purely speculative. Overall, it is unlikely that any cumulative impact to the domestic economic environment would result from a stacked product consisting of VCO-01981-5 and other readily-available GE traits.

5.9 Cumulative Impacts: Trade Economic Environment

Under the Preferred Alternative, it is possible VCO-01981-5 corn would not be approved for import into other countries. Because the U.S. and other countries already have access to other glyphosate-resistant corn cultivars, and VCO-01981-5 corn presents another option of glyphosate-resistant corn similar to cultivars already in the marketplace, its availability only to U.S. producers would not likely significantly impact the economic trade environment. Only 15% of domestically produced U.S. corn is dedicated to the export market (USDA-ERS, 2011c), and the extent of VCO-01981-5 corn would be dependent on whether growers find value in another glyphosate-resistant cultivar. If VCO-01981-5 corn were not approved for import by other countries but would be approved as nonregulated in the U.S., it would not likely affect the supply of U.S. corn eligible for import to other countries. Likewise, if it were approved both in the U.S. and for import by other countries, based on its similarity to other glyphosate-resistant corn cultivars and the likelihood it would replace other such cultivars without increasing the acreage or area of corn production, VCO-01981-5 corn would still be unlikely to affect the supply of U.S. corn available for export. If it were approved in the US, but not for import by other countries, growers may find that more limited options were available for grain sales (Stebbins and Plume, 2011), but again, any significant impact on exports would be unlikely because the growers would likely hesitate to grow the crop and large quantities would not be produced.

As discussed in Subsection 2.6.2, Trade Economic Environment, U.S. corn exports have remained relatively stable over the last decade, a period in which other corn varieties with stacked glyphosate and other traits have been brought to market. Global export markets respond to many factors and are unlikely to change with the commercial availability of another glyphosate-resistant corn cultivar such as VCO-01981-5 corn alone, or stacked with other currently available traits.

6 THREATENED AND ENDANGERED SPECIES

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

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

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

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

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

APHIS met with USFWS officials on June 15, 2011, to discuss whether APHIS has any obligations under the ESA regarding analyzing the effects of herbicide use associated with all GE crops on TES. As a result of these joint discussions, USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on herbicide use associated with GE crops currently planted because EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under FIFRA. APHIS has no statutory authority to authorize or regulate the use of glyphosate or any other herbicide. Under APHIS' current Part 340 regulations, APHIS only has the authority to regulate VCO 01981-5 corn or any GE organism as long as APHIS believes they may pose a plant pest risk (7 CFR § 340.1). APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms.

After completing a plant pest risk analysis, if APHIS determines that VCO 01981-5 corn seeds, plants, or parts thereof do not pose a plant pest risk, then VCO 01981-5 corn would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that VCO 01981-5 corn is no longer regulated. As part of its EA analysis, APHIS is analyzing the potential effects of VCO 01981-5 corn on the environment including, as required by the ESA, any potential effects to threatened and endangered species and critical habitat. As part of this process, APHIS thoroughly reviews the GE product information and data related to the organism (generally a plant species, but may also be other genetically engineered organisms). For each transgene/transgenic plant, APHIS considers the following:

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

Consistent with this review process, APHIS, has evaluated the potential effects that approval of a petition for nonregulated status for VCO 01981-5 corn may have, if any, on Federally-listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, APHIS obtained and reviewed the USFWS list of TES species (listed and proposed) for each state where corn hybrids are commercially produced from the USFWS Environmental Conservation Online System (USFWS, 2012). Prior to this review, APHIS considered the potential for VCO 01981-5 corn to extend the range of corn production and also the potential to extend agricultural production into new natural areas. Genective/Bayer's studies demonstrate that agronomic characteristics and cultivation practices required for VCO 01981-5 corn are essentially indistinguishable from practices used to grow other corn varieties, including other herbicide-resistant varieties of corn (Genective, 2012; USDA-APHIS, 2012a). Although VCO 01981-5 may be expected to replace other varieties of corn currently cultivated, APHIS does not expect the cultivation of VCO 01981-5 to result in new corn acres to be planted in areas that are not already devoted to corn production. Accordingly, the issues discussed herein focus on the potential environmental consequences of the determination of nonregulated status of VCO 01981-5 corn on TES species in the areas where corn is currently produced.

APHIS focused its TES review on the implications of exposure to the grg23ace5 EPSPS protein in VCO 01981-5, the interaction between TES and VCO 01981-5 corn, including the potential for sexual compatibility and the ability to serve as a host for a TES, and the ability to affect plants and habitat by naturalizing in the environment.

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6.1 Potential Effects of VCO-01981-5 corn on TES

Threatened and Endangered Plant Species and Critical Habitat

The agronomic data provided by Genective/Bayer were used in the APHIS analysis of the weediness potential for VCO 01981-5 corn and potential to affect TES. Agronomic studies conducted by Genective/Bayer's tested the hypothesis that the weediness potential of VCO 01981-5 corn is unchanged with respect to conventional corn used in hybrid seed production (Genective, 2012; USDA-APHIS, 2012a). No differences were detected between VCO 01981-5 corn and conventional corn in growth, reproduction, or interactions with pests and diseases, other than the intended effect of tissue-specific herbicide resistance (USDA-APHIS, 2012a). Potential of corn weediness is low, due to domestication syndrome traits that generally lower overall fitness outside an agricultural environment (Stewart et al., 2003). Mature corn seeds have no innate dormancy, are sensitive to cold, and in colder climates, many do not survive in freezing winter conditions, although volunteers can be an issue in many locations. Corn has been cultivated around the globe without any report that it is a serious weed or that it forms persistent feral populations (USDA-APHIS, 2012a). Corn cannot survive in the majority of the country without human intervention, and it is easily controlled if volunteers appear in subsequent crops. APHIS has concluded that the determination of nonregulated status of VCO 01981-5 corn does not present a plant pest risk, does not present a risk of weediness, and does not present an increased risk of gene flow when compared to other currently cultivated corn varieties (USDA-APHIS, 2012a).

APHIS evaluated the potential of VCO 01981-5 corn to cross with a listed species. As discussed above and in the analysis of Gene Movement and Weediness, APHIS has determined that there is no risk to unrelated plant species from the cultivation of VCO 01981-5 corn. Corn is an annual, wind-pollinated crop which lacks sexually compatible wild relatives in the U.S., except for occasional botanical garden specimens (USDA-APHIS, 2012a). After reviewing the list of threatened and endangered plant species in the States where seed corn hybrids are grown, APHIS determined that VCO 01981-5 corn would not be sexually compatible with any listed threatened or endangered plant species or plant proposed for listing as none of these listed plants are in the same genus nor are known to cross pollinate with species of the genus *Zea*.

Based on agronomic field data, literature surveyed on corn weediness potential, and no sexually compatibility of any TES with corn, APHIS has concluded that VCO 01981-5 corn will have no effect on threatened or endangered plant species or on critical habitat.

Threatened and Endangered Animal Species

Genective has presented information on the food and feed safety of VCO 01981-5 corn, and compared the VCO 01981-5 corn variety with conventional varieties currently grown. There were no toxins or allergens associated with this event, and the grg23ace5 EPSPS protein is similar to the EPSPS proteins that are present in many GE crop plants. These have been analyzed in numerous EAs prepared for petitions for nonregulated status (Monsanto, 2010, Monsanto, 1996). Compositionally, VCO 01981-5 corn was determined to be the same as conventional varieties. Compositional elements compared included moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and antinutrients (Genective, 2012). Results presented by Genective/Bayer show that the incorporation of the grg23ace5 epsps gene and the attendant expression of the grg23ace5 EPSPS protein in VCO 01981-5 corn does not result in any biologically-meaningful differences between VCO 01981-5 corn and the non-transgenic hybrid. Therefore, there is no expectation that exposure to the protein or the plant will have any effect on T&E animal species that may be exposed to VCO 01981-5 corn.

The FDA has concluded its review of Genective/Bayer's submittal of safety and nutritional data for VCO 01981-5 corn and on May 7, 2013, had no additional questions for the developer (FDA, 2013). Genective/Bayer 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 VCO 01981-5 corn (Genective, 2012). These safety studies included evaluating protein structure and function, including homology searches of the amino acid sequences with comparison to all known allergens and toxins, an in vitro digestibility assay of the proteins, an acute oral toxicity feeding study in mice, and a feeding study in broiler chickens. VCO 01981-5 corn protein was previously determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and was degraded rapidly and completely in gastric fluid (Genective, 2012). At this time, the FDA has completed consultation on VCO 01981-5. A copy of the FDA consultation is available at the FDA website (FDA Biotechnology Consultation Note to the File and is assigned no.BNF-000137).

APHIS considered the possibility that VCO 01981-5 corn could serve as a host plant for a threatened or endangered species. A review of the species list reveals that there are no members of the genus *Zea* that serve as a host plant for any threatened or endangered species.

Considering the compositional similarity between VCO 01981-5 corn and other varieties currently grown and the lack of toxicity and allergenicity of the grg23ace5 EPSPS protein, APHIS has concluded that exposure and consumption of VCO 01981-5 corn would have no effect on threatened or endangered animal species.

Conclusion

After reviewing the possible effects of allowing the unregulated environmental release of VCO-01981-5 corn, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. Therefore, a detailed species by species analysis of effects is not necessary. APHIS also considered the potential effect of approval of a petition for nonregulated status of VCO-01981-5 corn 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. Corn is not sexually compatible with, or serves as a host species for, any listed species or species proposed for listing. Consumption of VCO-01981-5 corn by any listed species or species proposed for listing will not result in a toxic or allergic reaction. Based on these factors, APHIS has concluded that approval of a petition of nonregulated status for VCO-01981-5 corn, and the corresponding environmental release of this corn variety will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or NMFS are not required.

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

7.1 Executive Orders with Domestic Implications

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

- ***Executive Order (EO) 12898 (US-NARA, 2010a), "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 EPSPS protein establish the safety of VCO-01981-5 corn and its products to humans, including minorities, low-income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken with nonregulated VCO-01981-5 corn.

Human toxicity has also been thoroughly evaluated by the EPA in its development of pesticide labels for glyphosate (US-EPA, 1993b; US-EPA, 2009c; US-EPA, 2009d). Pesticide labels include use precautions and restrictions intended to protect workers and their families from exposures. APHIS assumes that growers will adhere to herbicide use precautions and restrictions. As discussed in Subsection 4.5, Public Health, the potential use of glyphosate on VCO-01981-5 corn at the proposed application rates would be no more than that currently approved for other nonregulated glyphosate-resistant corn and found by the EPA not to have adverse impacts to human health when used in accordance with label instructions. It is expected that the EPA and ERS would monitor the use of VCO-01981-5 corn to determine impacts on agricultural practices, such as chemical use, as they have done previously for herbicide-resistant products.

Based on these factors, a determination of nonregulated status of VCO-01981-5 corn is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

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

> ***EO 1311 (US-NARA, 2010a), "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.

Field corn is not listed in the U.S. as a noxious weed species by the Federal government, nor is it listed as an invasive species by major invasive plant data bases (USDA-NRCS, 2010). As discussed in Subsection 2.3.3, Gene Flow and Weediness, cultivated corn seed does not have the ability to survive in the wild and requires human involvement for seed dispersion (OECD, 2003). In addition, corn seed lacks dormancy, will not produce a persistent seed bank, and is large and heavy and not easily dispersed by wind or water (Mallory-Smith and Zapiola, 2008); therefore, the chance of corn becoming invasive as a result of seed dispersion is not likely. As discussed in Subsection 2.3.3, Gene Flow and Weediness, there are some populations of closely related and sexually compatible subspecies of *Z. mays* within the U.S.; however, these populations are small and are limited to collections in botanical gardens, some feral populations in some southeastern states, and small forage crops in some western states. While corn and various teosinte species are culturally and biologically similar, and gene exchange between these groups has been documented, no successful weedy species has evolved and the potential for gene flow between *Z. mays* and sexually compatible wild relatives is not considered a significant agricultural or environmental risk (US-EPA, 2010a). As such, the potential for a weedy species of corn to develop as a result of outcrossing with VCO-01981-5 corn is considered to be highly unlikely.

Volunteer corn can become extensive in crop fields, competing with desired crops for light, moisture, and nutrients (Wilson et al., 2011b). There have been reports of some volunteer glyphosate-resistant corn occurring in fields, even if glyphosate-resistant corn was not planted the previous year, thought to be a result of transgene pollen movement (Beckie and Owen, 2007). While pollen mediated gene transfer can occur, as discussed in Subsection 2.3.3, Gene Flow and Weediness, gene flow decreases rapidly with separation distance. Recommended methods to control volunteer corn include using a combination of techniques such as alternating the glyphosate-resistant corn with non-GE crops, or with GE crop cultivars having resistance to herbicides with different modes of action, and then application of that herbicide post-emergence. For example, growers could plant LibertyLink® soybean and treat it with glufosinate (Beckie and Owen, 2007). Others successfully utilize graminicides to control glyphosate-resistant corn in crops not susceptible to the herbicide. See Subsection 2.3.2, Plant Communities, for a more extensive discussion on controlling volunteer corn. Non-GE corn, as well as other GE herbicide-resistant corn varieties, is widely grown in the U.S. Based on historical experience with these varieties, and the data submitted by the developer and reviewed by APHIS, VCO-01981-5 corn plants are similar in fitness characteristics to other corn varieties currently grown; hence, they are not expected to become weedy or invasive (USDA-APHIS, 2012a).

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

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

Migratory birds may be found in cornfields as corn is a nutrient-rich food source for fat synthesis prior to migration (Krapu et al., 2004). Several species of birds are also known to forage for insects and seeds found in and adjacent to cornfields (Best et al., 1990; Tremblay et al., 2001; Puckett et al., 2009). As discussed in Subsection 4.4.1, Animal Communities, data submitted by the developer indicates that levels of key nutrients, minerals, antinutrients, and secondary metabolites in VCO-01981-5 corn were similar to the comparators, by extension the antecedent GA21 variety, and other commercial corn varieties (Genective, 2012). As discussed in Subsection 2.5, Animal Feed, a final food consultation with the FDA for VCO-01981-5 corn was submitted by Genective on March 5, 2012 and is still pending. It will be posted on the FDA website Final Biotechnology Consultations when completed. The food safety of the EPSPS protein conveying glyphosate resistance was previously assessed by the FDA in an earlier food safety evaluation, and as such no new evaluation is required for VCO-01981-5 corn commercial distribution (US-FDA, 2011). Based on APHIS' assessment of VCO-01981-5 corn, it is unlikely that a determination of nonregulated status would have a negative effect on migratory bird populations.

The environmental effects associated with glyphosate are summarized in the EPA RED for the herbicide (US-EPA, 1993b). Testing indicates that ecological toxicity of glyphosate is no more than slightly toxic to birds and does not exceed the agency's LOC (US-EPA, 1993b); however, in accordance with new requirements under 40 CFR part 158, acute avian oral toxicity data for a passerine species (perching birds) is required for the current glyphosate registration review. Based on these factors, it is unlikely that a determination of nonregulated status VCO-01981-5 corn would have a negative effect on migratory bird populations.

7.2 International Implications

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

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of VCO-01981-5 corn. All 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 APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of VCO-01981-5 corn subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC, 2010). The purpose of the IPPC “is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control” (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

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

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

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

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the Organization for Economic Cooperation and Development (OECD).

NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures (RSPM) No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO, 2003).

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

7.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the potential changes in corn production associated with a determination of nonregulated status to VCO-01981-5 corn (see Subsections 4.2.1, Acreage and Area and 4.2.2 Agronomic Practices) and determined that the cultivation of VCO-01981-5 corn would not lead to the increase in, or expand the area of, corn production that could impact water resources or air quality any differently than currently cultivated corn varieties. The herbicide resistance conferred by the genetic modification to VCO-01981-5 corn is not expected to result in any changes in water usage for cultivation compared to current corn production. As discussed in Subsections 4.3.1, Water Resources, and 4.3.3, Air Quality, there are no expected significant negative impacts to water resources or air quality from potential use of glyphosate or other pesticides associated with VCO-01981-5 corn production. Based on these analyses, APHIS concludes that a determination of nonregulated status for VCO-01981-5 corn would comply with the CWA and the CAA.

7.4 Impacts on Unique Characteristics of Geographic Areas

A determination of nonregulated status of VCO-01981-5 corn is not expected to impact unique characteristics of geographic areas such as parklands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

Genective has presented results of agronomic field trials for VCO-01981-5 corn that demonstrate there are no differences in agronomic practices, between VCO-01981-5 corn and currently available glyphosate-resistant corn varieties like GA21 (Genective, 2012; USDA-APHIS, 2012a). The common agricultural practices that would be carried out in the cultivation of VCO-01981-5 corn are not expected to deviate from current practices, including the use of EPA-registered pesticides. The product is expected to be cultivated by growers on agricultural land currently suitable for production of corn, and is not anticipated to expand the cultivation of corn to new, natural areas.

The Preferred Alternative does not propose major ground disturbances or new physical destruction or damage to property, or any alterations of property, wildlife habitat, or landscapes; moreover, no prescribed sale, lease, or transfer of ownership of any property is proposed. This action is limited to a determination of nonregulated status to VCO-01981-5 corn. This action would not convert land use to non-agricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to VCO-01981-5 corn, including the use of EPA-registered pesticides. The Applicant's adherence to EPA label use restrictions for all pesticides is expected to mitigate potential impacts to the human environment.

With regard to pesticide use, a determination of nonregulated status to VCO-01981-5 corn is not likely to result in changes to the use of glyphosate on corn, including application timing and rates and annual maximum allowable applications. APHIS assumes that the grower will closely adhere to EPA label use restrictions for glyphosate.

Glyphosate was assessed by the EPA in 1993 and is currently under reregistration review scheduled for completion in 2015 (US-EPA, 2009b). Potential impacts to unique geographic areas have been considered by the EPA in its evaluation of glyphosate. In 1993, the EPA completed a reregistration analysis for glyphosate which considered human health risk and ecological risks associated with potential exposure to glyphosate in multiple pathways (US-EPA, 1993b).

As a result of court orders and settlements, an endangered species assessment evaluating the potential impacts of the use of glyphosate on the federally threatened California Red Legged Frog is underway (US-EPA, 2009c). The EPA has requested initiation of formal consultation with the USFWS under Section 7 of the ESA to address the potential effects of glyphosate on the CRLF (US-EPA, 2009c). The EPA's formal consultation request for the CRLF was based on the potential for direct and indirect effects due to decreases in prey items, as well as potential impacts to habitat (See Section 6, Threatened and Endangered Species).

In 2004, the EPA made a "not likely to adversely affect" determination from the use of glyphosate on 11 ESUs of salmon and steelhead in California and an ESU of salmon in southern Oregon (US-EPA, 2004) (see Section 6, Threatened and Endangered Species). Formal consultation with the NMFS was initiated by EPA on October 12, 2004 to fulfill a Consent Decree entered into between EPA and the Californians' for Alternatives to Toxics in regards to the potential effects of various pesticides usage on plants and certain threatened and endangered salmon or steelhead species.

While this consultation is ongoing, the EPA has allowed glyphosate to remain on the market, and it is approved for continued use in accordance with all label requirements. Submittals to this analysis can be found at the Regulations.gov website under docket designation EPA-HQ-OPP-2009-0361.

The Agency plans to conduct a comprehensive ecological risk assessment, including an endangered species assessment, for all uses of glyphosate and its salts (US-EPA, 2009c). Assessments to determine impacts on unique geographic areas include:

- An ecological risk assessment to determine whether the use of glyphosate has "no effect" or "may affect" federally listed TES or their designated critical habitat; and
- A spray drifts buffer zone analysis to evaluate potential exposure reductions to non-target aquatic and terrestrial plants.

The information gathered during the ecological and endangered species risk assessment will be used by the EPA to make the registration review decision.

Based on these findings, including the assumption that label use restrictions are in place to protect unique geographic areas and that those label use restrictions are adhered to, a determination of nonregulated status to VCO-01981-5 corn is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

7.5 National Historic Preservation Act (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.

APHIS' proposed action, a determination of nonregulated status of VCO-01981-5 corn is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

APHIS' Preferred Alternative would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of nonregulated status of VCO-01981-5 corn.

APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property 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 VCO-01981-5 corn is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

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