Syngenta Company Petition for Determination of Nonregulated Status of SYN-05307-1 Rootworm Resistant Corn

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Final Environmental Assessment

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ACRONYMS AND ABBREVIATIONS

µg/g	Micrograms per gram
ACHP	Advisory Council on Historic Properties
AIA	Advanced Informed Agreement
AMS	Agricultural Marketing Service (also USDA-AMS)
AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service (also USDA-APHIS)
ARMS	Agricultural Resource Management Survey
ARS	Agricultural Research Services (also USDA-ARS)
ATTRA	Appropriate Technology Transfer for Rural Areas
BRS	Biotechnology Regulatory Service
Bt	*Bacillus thuringiensis*
C	Centigrade
C3	Three-carbon molecule photosynthetic pathway
C4	Four-carbon molecule photosynthetic pathway
CBD	*Convention on Biological Diversity*
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
CO_2	Carbon dioxide
CRP	Conservation Reserve Program
CRW	Corn Rootworm
Cry	Crystal proteins
EA	Environmental Assessment
EIS	Environmental Impact Statement
EO	Executive Order
EPA	Environmental Protection Agency (also US-EPA)
ER	Environmental Report
ERS	Economic Research Service (also USDA-ERS)
ESA	*Endangered Species Act*
FATUS	Foreign Agricultural Trade of the United States
FAS	Foreign Agricultural Service (also USDA-FAS)
FB_1	Fumonisin B_1
FDA	Food and Drug Administration (also USDHHS-FDA)
FFP	Food, feed, or processing
FIFRA	*Federal Insecticide, Fungicide, and Rodenticide Act*
FESTF	FIFRA - Endangered Species Task Force
FONSI	Finding of No Significant Impact
FR	Federal Register
FWS	Fish and Wildlife Service (also USFWS)
GHG	Greenhouse gases

ACRONYMS AND ABBREVIATIONS

IMS	Information Management System
IP	Identity Preservation
IPM	Integrated Pest Management
IPCC	Intergovernmental Panel on Climate Change
IPPC	International Plant Protection Convention
IRM	Insect Resistance Management
LMO	Living modified organisms
LOQ	Limit of quantification
MJD	Multi-Jurisdictional Database
N_2O	Nitrous oxide
NAPPO	North American Plant Protection Organization
NASS	National Agricultural Statistics Service (also USDA-NASS)
NCGA	National Corn Growers Association
NEPA	*National Environmental Policy Act*
NHPA	*National Historic Preservation Act*
NOP	National Organic Program
NPS	Nonpoint source
NPTN	National Pesticide Telecommunications Network
NRC	National Research Council
NRCA	Natural Resources Conservation Service (also USDA-NRCS)
OECD	Organization for Economic Cooperation and Development
OTA	Organic Trade Association
PIPs	Plant-incorporated protectants
Pmi	Phosphomannose isomerase gene (also known as *manA*)
PMI	Phosphomannose isomerase protein
PPA	*Plant Protection Act*
PPRA	Plant Pest Risk Assessment
PRA	Pest Risk Analysis
RR2	Roundup-Ready© Corn 2
RSPM	Regional Standards for Phytosanitary Measures
SCGO	Seed Corn Growers of Ontario
TSCA	*Toxic Substances Control Act*
US	United States
USACOE	United States Army Corps of Engineers
USDA	United States Department of Agriculture
USDHHS	United States Department of Health and Human Services
US-EPA	United States Environmental Protection Agency (also EPA, USEPA)
USFWS	United States Fish and Wildlife Service (also FWS)
USGC	U.S. Grains Council
Vip	Vegetative insecticidal protein

1 PURPOSE AND NEED

1.1 Regulatory Authority

"Protecting American agriculture" is the basic charge of the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of genetically engineered varieties) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States (U.S.) government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing federal statutes in a manner that ensures 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; and
(3) Agencies are mandated to exercise oversight of genetically engineered organisms only when there is evidence of "unreasonable" risk.

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

APHIS is responsible for regulating GE organisms and plants under the plant pest provision in the Plant Protection Act of 2000, as amended (7 USC § 7701 et seq.) to ensure that genetically engineered organisms do not pose a plant pest risk to the environment.

The FDA regulates genetically engineered organisms under the authority of the *Federal Food, Drug, and Cosmetic Act*. The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from genetically engineered crops comply with their obligations under federal food safety laws, FDA encourages them to participate in a voluntary consultation process. All food and feed derived from genetically engineered crops currently on the market in the United States have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the *Federal Register* (FR) on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food.

The US-EPA regulates plant-incorporated protectants (PIPs) under the *Federal Insecticide, Fungicide, and Rodenticide Act*. US-EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act (FFDCA) and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). The US-EPA is responsible for regulating the sale, distribution and use of pesticides, including pesticides that are produced by an organism through biotechnology.

1.2 Regulated Organisms

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

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

1.3 Petition for Determination of Nonregulated Status: Syngenta Event 5307 Corn

Syngenta Biotechnology, Inc. submitted an initial petition (10-336-01p) to APHIS in 2010, which was revised in 2011 (Syngenta, 2011c), seeking a determination of nonregulated status of Event 5307 rootworm-resistant corn (hereafter referred to as Event 5307 or 5307 corn). Nonregulated status would include 5307 corn, progeny from crosses between 5307 corn and conventional corn, and progeny from crosses of 5307 corn with other transgenic corn that has been determined to have nonregulated status. Event 5307 corn is currently regulated under the PPA.

Interstate movements and field trials of Syngenta 5307 corn have been conducted under permits issued or notifications acknowledged by APHIS from 2005 through 2010. Data resulting from these field trials are described in the petition; (Syngenta, 2011c). Notifications acknowledged and permits issued by APHIS are listed in the petition (Syngenta, 2011c). The test sites represent diverse regions of the U.S., including the major growing areas of the Midwest (Wisconsin, Michigan, Minnesota

Missouri, Iowa, Illinois, Indiana, Kansas, Kentucky, Nebraska, South Dakota, Ohio, Colorado and Arkansas), and winter nurseries in Puerto Rico and Hawaii. Field tests conducted under APHIS oversight allow for evaluation in agricultural settings under confinement measures designed to minimize the likelihood of persistence in the environment after completion of the field trial. Under confined field trial conditions, data are gathered on multiple parameters and used by applicants to evaluate agronomic characteristics and product performance. These data are also valuable to APHIS for assessing the potential for a new variety to pose a plant pest risk. The data evaluated for Syngenta 5307 corn may be found in the APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2011).

1.4 Purpose of Product

Corn rootworm (*Diabrotica*) larvae feed on the roots of growing corn plants and are widespread and major pests of US corn (Hoeft et al., 2000). Corn (*Zea mays* L., maize) derived from Syngenta's transformation Event 5307 contains a unique engineered insecticidal protein, eCry3.1Ab, that is active against three economically important corn rootworm species that cause significant damage to the US corn crop annually. This engineered pesticide provides corn plants with resistance to larval feeding damage by western corn rootworm (*Diabrotica virgifera virgifera*), northern corn rootworm (*D. longicornis barberi*), and Mexican corn rootworm (*D. virgifera zeae*). Event 5307 corn demonstrates efficacy in controlling these damaging pests (see section VIII.b.in (Syngenta, 2011c)).

Corn varieties containing the transgene *ecry3.1Ab* have the potential to displace applications of conventional US-EPA-restricted use rootworm insecticides. The new protein, eCry3.1Ab, may act on target pests via a different protein target, which could reduce the selection pressure on pest populations to evolve resistance to other plant-expressed Cry proteins that also control corn rootworm (section IX in Syngenta 2011c). Growers are expected to derive benefits from 5307 corn as an alternative to the application of conventional insecticides, as well as realize economic benefits through increased crop yield under conditions of pest pressure, and reduced costs of insecticide applications. The availability of 5307 corn is expected to contribute to the significant trend in reduced use of US-EPA-restricted use insecticides and extends the useful life of other commercially available corn rootworm-protected *Bt*-expressing cultivars (Cry3Bb1, Cry34Ab1/Cry35Ab1, and mCry3A corn; section X, (Syngenta, 2011c; USDA-ERS, 2011c).

As identified by the applicant, the benefits of 5307 corn include reduced use of US-EPA-restricted use insecticides (typical extension recommendation shows that 11 of 13 dry or liquid insecticides for corn rootworm are restricted use (Bessin, 2004), improved worker safety due to the reduced exposure of chemical insecticides (Syngenta, 2011c), reductions in the use of fossil fuels to apply chemical insecticides, economic benefits for growers, improved insect resistance management, and increased competition in the marketplace for insect-protected seed products (Syngenta, 2011c).

1.5 APHIS Response to Petition for Nonregulated Status

Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of genetically engineered organisms, including GE plants such as Syngenta 5307 corn. When a petition for nonregulated status is submitted, APHIS must make a determination if the genetically engineered organism is unlikely to pose a plant pest risk. If APHIS determines based on its PPRA that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

APHIS has prepared this environmental assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality's National Environmental Policy Act (NEPA) regulations and the USDA and APHIS NEPA implementing regulations and procedures (40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment that may result from a determination of nonregulated status of Syngenta 5307 corn.

1.6 Coordinated Framework Review

1.6.1 Environmental Protection Agency

The US-EPA regulates plant-incorporated protectants (PIPs) under FIFRA (7 U.S.C. 136 et seq.) and certain biological control organisms under TSCA (15 U.S.C. 53 et seq.). Syngenta has obtained an Experimental Use Permit (67979-EUP-8) from US-EPA that allows for broad-scale field testing of 5307 corn and various breeding stack combinations that include 5307 corn. The Experimental Use Permit was initially granted on June 1, 2010 with effect through February 28, 2012 (US-EPA, 2010c) and was extended (US-EPA, 2012) on March 3, 2011 with effect through December 31, 2013. In connection with this Experimental Use Permit, US-EPA established and then extended (US-EPA, 2011a) a previous temporary exemption from the requirement of a tolerance for eCry3.1Ab residues in corn commodities, pursuant to §408(d) of the Federal Food, Drug, and Cosmetic Act. Phosphomannose isomerase (PMI), the selectable marker protein produced by 5307 corn plants, is exempt from food and feed tolerances (US-EPA, 2004). EPA has granted an exemption from food and feed tolerance for the eCry3.1Ab protein on August 8, 2012.

In April 2011, Syngenta submitted applications to the US-EPA for registration of the eCry3.1Ab PIP in 5307 corn (Appendix B, p. 15, (Syngenta, 2011c)) and in two breeding stacks involving specific GE corn traits that are no longer subject to the requirements of Part 340 and the plant pest provisions of the PPA (US-EPA, 2011f). These breeding stacks include specifically *Bt*11 × MIR604 × TC1507 × 5307 × GA21 and *Bt*11 × MIR162 × MIR604 × TC1507 × 5307 × GA21 corn. In addition to the corn rootworm control provided by 5307 corn, the controls provided by other nonregulated constituents of these stacked combinations are:

- A Cry1Ab protein for lepidopteran control (Bt11);
- A modified Cry3A protein for corn rootworm control (MIR604);
- A Cry1F protein for lepidopteran control (TC1507);
- A double mutated 5-enolpyruvylshikimate-3-phosphate synthase enzyme for glyphosate tolerance (GA21);
- A Vip3Aa20 protein for lepidopteran control (MIR162); and
- A phosphinothricin acetyl transferase enzyme for glufosinate tolerance (*Bt*11 and TC1507).

The US-EPA registration was sought for the PIP in 5307 corn as a stand-alone cultivar (i.e., not part of a breeding stack) will be for a manufacturing-use product; Syngenta will not seek an end-use product registration from US-EPA for 5307 corn (see Section I.C.2., (Syngenta, 2011c).

Rather, commercial registrations were sought from US-EPA for the two breeding stack products that include 5307 corn. A conditional registration was made by EPA for the stacked product, EPA Reg. Number 67979-17 on June 10, 2011. Concurrently, Syngenta also submitted a petition (Petition No. 1F7857) to the US-EPA to establish a nonexpiring exemption from the requirement of a tolerance for eCry3.1Ab residues in food and feed commodities.

1.6.2 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 that are GE, in the Federal Register 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.

Event 5307 corn falls within the scope of the FDA policy statement concerning regulation of food products derived from new plant varieties, including those developed by genetic engineering (US-FDA, 1992 (US-FDA, 1992). Syngenta initiated a voluntary pre-market consultation process with FDA and submitted a safety and nutritional assessment for 5307 corn in January 2011 (Appendix B, Syngenta 2011c). FDA completed the consultation on February 29, 2012 (US-FDA, 2012).

1.7 Public Involvement

APHIS routinely seeks public comment on draft EAs prepared in response to petitions for nonregulated status of GE organisms. APHIS does this through a notice published in the Federal Register. The issues discussed in this EA were developed by considering the public concerns as well as issues raised in public comments submitted for other EAs of GE organisms, concerns raised in lawsuits, as well as those issues of concern that have been raised by various stakeholders. These issues, including those regarding the agricultural production of corn using various production methods and the environmental and food/feed safety of GE plants were addressed to analyze the potential environmental impacts of Syngenta 5307 corn.

This EA, the petition submitted by Syngenta, and APHIS's PPRA were made available for public comment for a period of 60 days (7 CFR § 340.6(d)(2)) on July 13,2012 (77 FR 41366-41367, Docket no. APHIS-2012-0024). Comments received during the comment period were analyzed and used to inform APHIS' determination decision of the regulated status of Syngenta 5307 corn and to assist APHIS in determining whether an Environmental Impact Statement (EIS) is required prior to the determination decision of the regulated status of this soybean variety.

1.8 Issues Considered

The list of issues considered in this draft 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:

Corn Biology

- Persistence in the environment and weediness potential

Corn Production

- Acreage and areas of production
- Agronomic practices
- Specialty systems
- Raw and processed agricultural commodities

Physical Environment

- Water quality and use
- Soil
- Air quality
- Climate

Biological Environment

- Animals
- Plants
- Soil microorganisms
- Biodiversity
- Gene movement in the natural environment

Public Health

- Human health
- Animal (livestock) health
- Worker safety

Socioeconomic Factors

- Domestic economic environment
- Trade economic environment
- Social environment

2 AFFECTED ENVIRONMENT

The Affected Environment section provides an overview of the use and composition of corn, followed by a discussion of the current conditions of those aspects of the human environment potentially impacted by a determination of nonregulated status of 5307 corn. For the purposes of this draft EA, those aspects of the human environment are: corn production practices, the physical environment, biological resources, public health, and socioeconomic issues.

Conventional farming as defined in this document includes any farming system where synthetic pesticides or fertilizers may be used. This definition of conventional farming also includes the use of GE varieties of corn that 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.

2.1 Corn Biology

Maize, or corn, is a member of the *Maydeae* tribe of the grass family *Poaceae* (OECD, 2003 (OECD, 2003). The western hemisphere genera *Zea* and *Tripsacum* are included in the tribe *Maydeae*. The Asian genera of *Maydeae* are *Coix*, *Polytoca*, *Chionachne*, *Schlerachne* and *Trilobachne* (OECD, 2003 (OECD, 2003).

Corn is a robust monoecious (i.e., having separate male and female flowers for each plant) annual plant, which was developed through artificial selection and does not occur in natural ecosystems outside of cultivation (OECD, 2003). The corn plant is adapted for high productivity because it has a large leaf area and a modified photosynthetic pathway that allows it to survive extended periods of drought (Frost and Gillman, 2011). The corn plant, along with a limited number of other plants like sugarcane, millet, and sorghum, uses the C4 photosynthetic pathway. At a biochemical level, these plants convert carbon dioxide (CO_2) into a four-carbon molecule in contrast to the more common photosynthetic pathway in which CO_2 is converted into a three-carbon molecule (Frost and Gillman, 2011). C4 photosynthesis allows the corn plant to produce more dry matter (i.e., in various combinations of carbohydrates, proteins, oils, and mineral nutrients) per unit of water transported than the C3 photosynthetic pathway. Because of their high photosynthetic efficiency, the C4 crops like corn are favored for ethanol production and, also sugarcane but much less favorably (USDA, 2006)

Zea mays is an allogamous plant (i.e., cross-fertilizes by pollen from one flower to stigmas on another) that propagates through seed produced predominantly by cross pollination. (OECD, 2003). Pollen is transferred by wind and, in controlled breeding situations, by humans. Corn mostly can only be crossed experimentally with species of the genus *Tripsacum*, and the progeny are neither environmentally fit nor reproductively robust (USDA-APHIS, 2011); however, wild species of its own genus *Zea* (teosinte: *Z. diploperennis, Z. perennis, Z. luxurians, Z. nicaraguanensis*) may hybridize with corn under natural conditions but these species are rare if occurring at all in the US and no domestic hybridization has been described (see Section 2.4.4, *Gene Movement in the Natural Environment* and (USDA-APHIS, 2011). Corn is not weedy, and does not persist outside of cultivation. There are no reports in which corn propagated vegetatively under field conditions, and the only known propagation method for corn is through seed germination (OECD, 2003). Corn is primarily grown in warm temperate climates. Corn seed is sensitive to cold and typically does not survive freezing winter conditions (OECD, 2003). Consequently, corn has no innate dormancy (OECD, 2003).

Table 1: Transgenic Corn Cultivars Containing Bt-derived Proteins that are no longer subject to the regulatory requirements of 7 CFR Part 340

Cultivar	Filed By/Petition Number	Transgenic feature
Event 176	Ciba Seeds (petition 94-319-01p)	Lepidopteran (European corn borer) resistant, expressing Cry1Ab
MON 80100	Monsanto (petition 95-093-01p)	Lepidopteran resistant, expressing Cry1Ab
*Bt*11	Northrup King Company (petition 95-195-01p)	Lepidopteran resistant, expressing Cry1Ab, and glufosinate tolerant
DBT418	DeKalb (petition 96-291-01p)	Lepidopteran resistant, expressing Cry1Ac, and glufosinate tolerant
MON 809 and MON 810	Monsanto (petition 96-017-01p)	Lepidopteran resistant, expressing Cry1Ab
MON 802	Monsanto (petition 95-317-01p)	Lepidopteran resistant, expressing Cry1Ab, and glyphosate tolerant
CBH-351	AgrEvo (petition 97-265-01p)	Lepidopteran resistant, expressing Cry9C, and glufosinate tolerant
Line 1507	Mycogen (petition 00-136-01p)	Lepidopteran resistant, expressing Cry1F, and glufosinate tolerant
MON 863	Monsanto (petition 01-137-01p)	Corn rootworm resistant, expressing Cry3Bb1
DAS 6275	Dow (petition 03-181-01p)	Lepidopteran resistant, expressing Cry1F, and glufosinate tolerant
DAS 59122	Dow (petition 03-353-01p)	Corn rootworm resistant, expressing Cry34/35Ab1, and glufosinate tolerant
MON 88017	Monsanto (petition 04-125-01p)	Corn rootworm resistant, expressing Cry3Bb1, and glyphosate tolerant
MIR604	Syngenta (petition 04-362-01p)	Corn rootworm resistant, expressing modified Cry3A
MON 89034	Monsanto (petition 06-298-01p)	Lepidopteran resistant, expressing Cry1A.105 and Cry2Ab2
MIR162	Syngenta (petition 07-253-01p)	Lepidopteran resistant, expressing Vip3Aa20

From: (USDA-APHIS, 2011b). http://www.aphis.usda.gov/biotechnology/not_reg.html

Humans have been selectively breeding corn for greater than 4300 years to emphasize desired characteristics such as increased yield and other traits (see review in, (Vigouroux et al., 2011). Beginning in 1996, transgenic corn products were introduced in the US market by seed companies, thereby adding new genetic traits to modern corn varieties. Corn cultivars representing 30 different transformation events are no longer subject to the regulatory requirements of 7 CFR Part 340 (USDA-APHIS, 2011b). These cultivars were genetically engineered to offer insect resistance, herbicide tolerance, and other traits. Sixteen of these cultivars, as listed in Table 1: Transgenic Corn Cultivars Containing Bt-derived Proteins that are no longer subject to the regulatory requirements of

7 CFR Part 340, contain proteins derived from *Bacillus thuringiensis* (*Bt*) and are known as *Bt* corn cultivars. *Bt* corn cultivars assist growers in preventing insect damage that would otherwise cause yield loss. The *Bt* "crystal" proteins (referred to as Cry proteins) in these cultivars are insecticidal against certain Coleoptera or Lepidoptera and exert their insecticidal activity when they:

1. Are ingested by the insect and solubilized in the insect gut;
2. Are activated by specific proteolytic cleavage by midgut enzymes;
3. Bind to specific receptors on the surface of the insect midgut; and
4. Form ion channels in the gut membrane.
5. Affected cells lyse, resulting in midgut damage and death (Vachon et al., 2012)

Bt corn has sublethal effects on pest species as well, such as lower body weight, decreased fecundity and oviposition rate of females (Meissle et al., 2011). Sensitivity to *Bt* toxins may be highest for neonate larvae, but decreases with larval maturation (Meissle et al., 2011).

2.1.1 Persistence in the Environment/Weediness Potential

Corn, a highly domesticated plant (Troyer, 2004) is dependent upon humans for survival (Hallauer, 2004). It does not persist in the environment outside of cultivated areas and does not have a potential to develop as a weed. Corn is not listed on the Federal noxious weed list (USDA-APHIS, 2010a). It is grown throughout the world without any report that it is a weed or that it forms persistent feral populations, although corn seed from a previous year's crop can overwinter in fields and germinate the following year in warmer areas. Manual or chemical measures are often applied to remove these volunteers, but the plants that are not removed do not result in feral populations in following years.

Transgenic insect-resistant corn plants are no better at establishing feral populations than non-transgenic corn (Raybould et al., 2011). A field study of transgenic insect-resistant hybrids, non-transgenic hybrids, and native Mexican landraces planted and allowed to naturally propagate for two years resulted in no viable plants, indicating that the populations had died out (Raybould et al., 2011). There were no differences in the replacement capacity of transgenic corn hybrids and the nontransgenic control hybrids.

2.2 Corn Production

This section describes corn production and yield in the US, current agronomic practices, specialty corn production systems, raw and processed corn commodities. Corn is grown for animal feed, human food, vegetable oil, high fructose corn syrup, starch, fermentation into ethanol, and many other uses.

2.2.1 Production and Yield

Corn is cultivated in temperate regions that provide sufficient moisture and an adequate number of frost-free days to reach maturity. US corn production is primarily focused in the Corn Belt, an area that includes Iowa, Illinois, Nebraska, and Minnesota, and parts of Indiana, South Dakota, Kansas, Ohio, Wisconsin, and Missouri. The Corn Belt has a combination of seasonal warm weather, rainfall, and favorable soil conditions for corn growth. Approximately 67.4 million acres of corn, representing approximately 73 percent of the US total of 91.9 million acres, was planted in these ten states in 2011 (USDA-NASS, 2012a). The planted acres of corn for each county in selected states in 2010 are shown in Fig. 1.

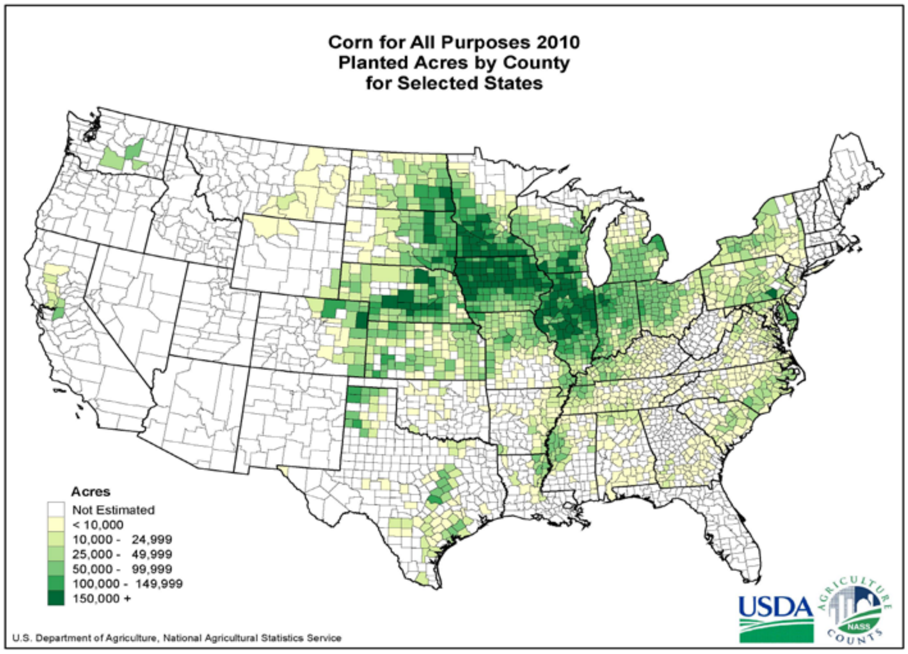

Figure 1: Corn Planted in U.S. by County in 2010

Source: USDA-NASS, 2011c (USDA-NASS, 2011c).

Nationally, planted corn acreage has increased from approximately 75 million acres in 1990 to a peak of nearly 95 million acres in 2008, as shown in Figure 2: US Corn Acres 1992-2012. Corn growers were projected to plant more than 92 million acres of corn in 2011. Harvested acreage lags planted acreage by 5 to 7 million acres each year due to losses from adverse weather and insect damage.

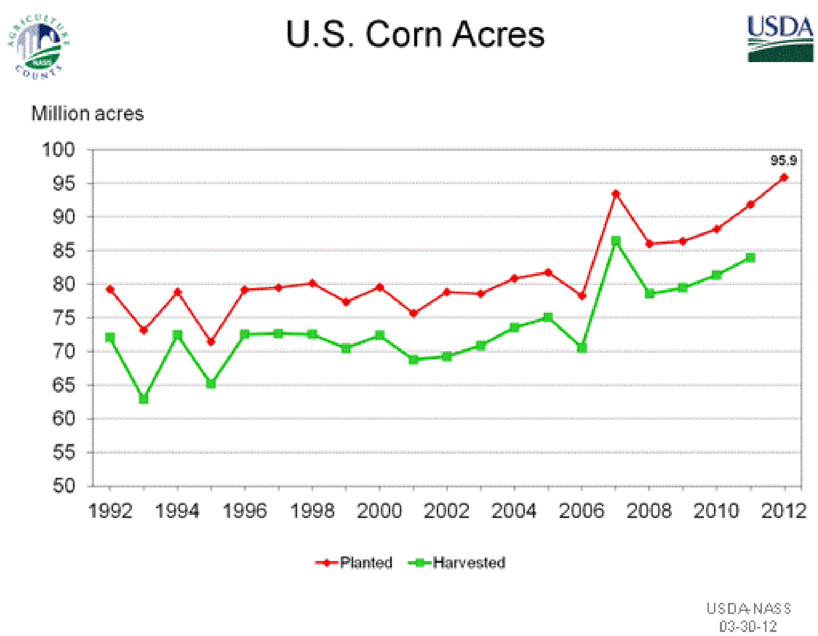

Figure 2: US Corn Acres 1992-2012.

Source: USDA-ERS, 2012, at http://www.nass.usda.gov/Charts_and_Maps/Field_Crops/cornac.asp.

The majority of domestic corn is produced for livestock feed (grain and silage) and fuel (ethanol), comprising 38 and 37 percent, respectively of the market (USDA-NASS, 2011c). Corn for grain production in 2010 was estimated at 12.4 billion bushels, 5 percent below the record high production of 13.1 billion bushels set in 2009 (USDA-NASS, 2012a). Grain yield was approximately 152.8 bushels per acre, 11.9 bushels below the record high yield of 164.7 bushels per acre set in 2009. Since 1990, corn yields have increased by about 2.0 bushels per acre per year (Savage, 2011).

The USDA-Economic Research Service (ERS) provides 10-year projections of supply and utilization for major field crops, including corn, grown in the US. ERS projects that an average of 90.2 million acres of corn will be planted from 2011 through 2020 (USDA-ERS, 2011f). Output in bushels will increase about 10% during this period, according to ERS.

Expanding output is attributable to yield growth. The projected 2010/11 corn yield is based on the simple linear trend since 1990. The longer term trend for 2011/12 and later years reflects an annual yield increase of 2.0 bushels per acre per year, resulting in record corn production in 2011/12 and beyond (USDA-ERS, 2011f). Increases in corn yields have been driven by improvements in plant genetics, machinery, and cultivation practices that have allowed for faster, more precise planting and earlier harvesting (USDA-ERS, 2011b). The latest round of advances in genetics and planting technology is expected to be fully adopted by the early years of the projections. Thus, longer term yield gains are expected to be somewhat slower than during the late 1990s and early 2000s (USDA-ERS, 2011b). Gains may continue to be supported by improved genetics, including advances in plant utilization of water and fertilizer, and seed developers currently include these research directions (Anonymous, 2011).

In 2011, approximately 88 percent of the US corn fields were planted with transgenic crops for pest management (USDA-NASS, 2011a). As described in Section 2.2.2.3, *Insect Management*, and Section 2.2.2, *Weed Management*, the transgenic crops provide insect resistance and herbicide tolerance, as well as production-related traits. Insect-resistant varieties containing *Bt*-derived transgenes comprise about 16 percent of the US corn acreage, and herbicide-tolerant varieties some 23 percent; products combining both traits were planted on 49 percent of the corn acreage (USDA-NASS, 2011a).

2.2.2 Agronomic Practices

Corn growers choose agronomic practices that maximize grain yield. Grain yield can be affected by cropping practices such as crop rotation and tillage techniques, supplemental irrigation based on soil and climate conditions, and methods to manage insects, disease, and weeds. This section describes common agronomic practices for corn.

Crop Rotation and Tillage

Crops grown in rotation typically have higher yields, lower weed biomass, and lower insect populations than those grown continuously (Hicks and Thomison, 2004). ‘Corn is typically rotated with legumes such as soybeans or alfalfa. Corn/soybean rotations have been found to have 9 percent higher yields than corn/corn rotations (Hicks and Hoverstad, 2007). Weed population density and biomass may be reduced using crop rotation (temporal diversification) and intercropping (spatial diversification) strategies (Liebman and Dyck, 1993). The risk of yield losses due to damage from some insects, particularly corn rootworm, decreases when corn is rotated with other crops (Bessin, 2004).

Legumes provide the greatest rotation benefits for corn; the benefit is principally attributed to the nitrogen-fixing property of legumes but other factors (such as increased organic matter and reduced weed seed banks) (Eisenthal, 2011) may also contribute to higher yield. Corn is rotated with soybeans annually in much of the Corn Belt, but oats and alfalfa may also be rotated with corn and soybeans or during fallow years in semi-annual to five-year cycles (Hicks and Thomison, 2004). In 2010, 71 percent of the acres planted in corn were in a rotation program during the last three years (USDA-NASS, 2011b). While tillage in parts of the corn belt remains an effective strategy for controlling buildup of corn rootworm, the appearance of two variant behaviors of rootworm have made this strategy less useful. Because rotation was practiced extensively, Western corn rootworm in some areas began laying eggs in soybean fields for overwintering, which then hatched to attack corn in the spring or early summer of the next season (Gray et al., 2009). A variant of the Northern corn rootworm can extend egg diapause from one to two or three winters, again timing egg emergence until a rotated corn crop might be planted (Levine and Oloumi-Sadeghi, 1991). If the variants are not an issue, then rootworm damage is usually not a problem until the third or subsequent season of continuous corn production (Penn-State-Extension, 2012) unless grass and volunteer corn were common in the planted field the previous year.

Tilling the soil reduces weeds that would otherwise crowd or compete with the corn crop (US-EPA, 2009). Until recently, conventional tillage was commonplace, using moldboard plows prior to planting or after harvest. Reduced or conservation tillage methods have largely replaced conventional methods (for corn, 40% conservation tillage, 24% reduced tillage) (CTIC, 2008). Reduced tillage uses chisel plows and results in less soil disturbance. Conservation tillage also uses chisel plows and includes no-till and focused methods such as strip, ridge, or mulch tillage. The intensive plowing of conventional tillage results in less than 15 percent crop residue (unharvested plant material); reduced tillage is associated with 15 to 30 percent crop residue; and conservation tillage is associated with at least 30 percent crop residue and substantially less soil erosion than other tillage practices (US-EPA, 2009). Because of its low cost and positive impact on soil quality, conservation tillage is currently and widely practiced in the Midwestern US. In 2010, 62 percent of the acres planted in corn used a no-till or minimum tillage method in a USDA survey of program states (USDA-NASS, 2011b) similar to the percentage identified by the CTIC survey (CTIC, 2008).

Irrigation

Soil and water (rainfall or irrigation) are the key resources in all crop production. Soil supports the basic physical, chemical, and biological processes for corn to grow, and specific soil characteristics regulate water flow between infiltration, root-zone storage, deep percolation, and storm water runoff (Christensen, 2002). Corn Belt soils are deep, fertile, and rich in organic material and nitrogen, and the land is relatively level. The warm nights, hot days, and well-distributed rainfall of the region during the growing season are ideal conditions for raising corn. Irrigation early in the season helps establish a uniform stand and water availability, whether by rainfall or irrigation during flowering is critical to achieve good seed set (Beck, 2004).

Corn grown for grain has substantially more irrigated area than any other single crop in the US, about 10.6 million acres in 1997, but only about 15 percent of the total corn acreage is irrigated (Christensen, 2002). Irrigated corn yields are about 29 percent higher than unirrigated corn yields. Irrigated corn is geographically distributed in the Corn Belt: eastern states irrigate only about 3 percent of the total corn area, while western states irrigate about 50 percent (Christensen, 2002).

Insect Management

Management of insect pests typically employs multiple tactics, including cultural control, plant resistance, mechanical control, biological control, chemical control, and integrated pest management:

Cultural Methods: These are practices that alter farm procedures to make the agricultural environment unfavorable to insect growth or survival**.**

Crop Rotation**.** Crop rotation is one of the most utilized methods for rootworm management (Monsanto, 2011b) and is often the lowest cost tactic. Rotation with a non-grass crop reduces the levels of many pests through starvation or eliminating insect reproduction. Section 2.2.2.1, *Cropping Practices*, describes crop rotation practices.

Selection of Planting and Harvest Dates**.** Plant phenology can be manipulated to disrupt synchronization with the phenology of the pest insects. This can be achieved by either delaying or advancing planting dates. Early-planted corn has shown lower susceptibility to corn earworm (*Helicoverpa zea*) and southwestern corn borer (*Diatraea grandiosella*) damage than late-planted crops (Boyd and Bailey, 2001; Koul et al., 2004). The female *D. grandiosella* tends to lay fewer eggs on more mature plants and the plants have already passed their critical developmental stage. Early harvest often produces phenological asynchronies with a pest's life cycle, allowing harvest before the damaging phase occurs. Early-planted corn can be harvested before many fully grown pre-diapause larvae have girdled the mature plants and caused yield losses through lodging of the plants (Koul et al., 2004).

Plant Resistance: Various physical or chemical attributes of a plant may have the ability to deter insects, to allow tolerance of their feeding or to kill them.

Hybrid selection**.** Hybrids vary in their ability to withstand and resist insect pests such as European corn borer. Rapid germination, early vigor, strong ear shanks, tight husks, resistance to stalk rots and other pests, strong stalks, and uniform performance over a wide population range are all factors influenced by hybrid genetics that may influence losses to insects (VanDuyn, 2005). Seedling insects, stalk borers, and ear feeding insects are most influenced by hybrid traits. Some hybrids have European corn borer resistance traits that reduce susceptibility to this pest (VanDuyn, 2005).

Transgenic Plants**.** Corn seed companies have developed a number of transgenic products that incorporate insect resistance traits, as described in Section 2.1, Corn Biology. These products, alone or in combinations with other traits (such as herbicide tolerance), provide corn growers with an additional tool to reduce damage by insect pests

Chemical Management: Insecticides can be used selectively through spot treatments by placing the chemical in the area occupied only by the pest to be controlled. This also helps protect non-target organisms and natural enemies.

Natural Products and Selective Mechanisms**.** Recently developed insecticides are more selective in their toxicity spectrum than some older insecticides. For example, naturally derived products like *Bacillus thuringiensis* and spinosad affect only certain orders of insect pests and work only if they are ingested. Other products are selective because of the way they are presented to the pest. Imidacloprid, for example, works because it is absorbed and incorporated into the corn vascular system and selectively kills sucking insects such as corn leaf aphids, and the chinch bugs and southern corn leaf beetle (BASF-Corp., 2010). As a seed treatment, the chemical exposes only herbivorous insects, and not foraging insects (Lopez and Fernandez-Bolanos, 2011).

Synthetic Chemicals. For rootworm, a variety of US-EPA restricted use pesticides are commonly available for larval control by in-furrow, post-plant or seed treatment (at least 7) and for adult control (at least 11) while for western bean cutworm control, a grower may have at least 9 choices (Krupke et al., 2011).

Mechanical Control: Tillage is able to reduce insect pest populations, by either exposing vulnerable stages to predation, or to desiccation.

Corn Insect Control. Effects of tillage may be extremely variable in different fields or locations, and other environmental factors may also be relevant for effects. Rootworm is not much affected, but other important pests may be, such as wireworms, but these mostly are impacted when grassy weeds are large components of the managed field. Similarly, tillage is important for black cutworm control in weedy situations (Hoeft et al., 2000).

Integrated Pest Management: IPM was introduced in the late 1960s and shifted the emphasis in pest control from a single-tactic, chemically based approach to a multi-tactic, economically based system (Intersociety-Consortium-for-Plant-Protection, 1979; Koul et al., 2004).

Rootworm Control. Before the availability of rootworm resistant hybrids, growers increasingly turned to integrated pest management practices (IPM), which allow them to reduce energy use, environmental risk, and production costs while maintaining the quality of agricultural products and helping improve water, air, and soil quality. IPM is site-specific in nature, and includes prevention, avoidance, monitoring and suppression of weeds, insects, diseases, and other pests. IPM is site-specific in nature, and includes prevention, avoidance, monitoring and suppression of weeds, insects, diseases, and other pests. IPM includes insect scouting or monitoring to determine pest populations; applying compatible alternative biological, cultural, mechanical and chemical controls; and establishing action thresholds for agricultural inputs appropriate to the biology and ecology of the pest (Intersociety-Consortium-for-Plant-Protection, 1979; Morallo-Rejesus and Rejesus, 1992). Timely and targeted delivery of pest management interventions is key to successful IPM. As pesticide usage for control of rootworm declined and growers favored CRW resistant hybrids, however, many decided that the crops did not require the same attentiveness to insect monitoring and to a coordinated mechanism for pest control (Gray, 2000; Gray, 2011b; Gray, 2011c).

Insect Pests of Corn. Corn is susceptible to attack by a variety of insects throughout its life cycle. Insects can be categorized as major and consistent pests, major and sporadic pests, and moderate to minor pests, based on annual destructiveness and their geographic distribution. The most economically significant corn pests include *Diabrotica* species (the corn rootworm complex) and *Ostrinia nubilalis* (European corn borer). The damage inflicted by rootworm larvae can significantly reduce grain yield by interfering with photosynthetic rates, limiting the uptake of water and nutrients, and by increasing the plant's susceptibility to lodging (Oleson et al., 2005). Lodging further reduces the effective grain yield by making the plants more susceptible to breaking, reducing their access to sunlight, and increasing the difficulty with which the grain can be harvested efficiently. Table 2: Corn Insect Pests lists corn insect pests found in the US in several corn growth stages. Among soil inhabiting insects, wireworms and white grubs are important pests (Hoeft et al., 2000) and important above ground principal pests are European and southwestern corn borer and corn earworm.

Table 2: Corn Insect Pests

Growth Stage	Description of Damage	Pests
From planting to full emergence	Seedlings are pulled up and eaten Seeds are bored or completely hollowed out	Seedcorn maggots *(Delia platura)* Seedcorn beetle (*Stenolophus lecontei*) Wireworms *(Melanotus* spp.*)*
Emergence to knee-high corn	Stunting and wilting Unnatural growth (stem twisting or excessive tillering) Sandblasted leaves (leaves with speckled appearance) Removal of plant tissue (chunks of leaves eaten, plants cut off near base, etc.)	White grubs (*Cyclocarpa* spp., *Popillia japonica*, *Phyllophaga* spp.) Grape colaspis (*Colaspis brunnea*) Chinch bug (*Blissus leucopterus*) Black cutworm (*Agrotis ipsilon*) Stink bugs, several species Stalk Borer (*Papaipema nebris*) Thrips, several species Corn flea beetle (*Chaetocnema ectypa*) Sod webworm, several species Southern corn leaf beetle *(Myochorus denticollis)* Billbugs, several species Armyworm (*Pseudaletia unipunctata*)
Knee-high to tasseling corn	Leaf tissues are removed (margin feeding or ragged holes in leaves, elongated lesions) Stalks malformed (gooseneck growth) Holes bored in the stalk	Corn rootworm *(Diabrotica* spp.*)* Fall armyworm (*Spodoptera frugiperda*) Grasshopper, several species European corn borer *(Ostrinia nubilalis)* Southwestern corn borer *(Diatraea grandiosella)* Stalk borer (*Papaipema nebris*)
Tasseling to corn maturity	Leaf tissue removed (chunks of leaf removed) Stalks malformed or broken Tassel damaged (tassel broken, eaten in whorl or discolored) Silks clipped Ear damaged (chunks of kernel removed, chewing damage, ear drop)	Fall armyworm Grasshoppers European corn borer Southwestern corn borer Corn rootworm (especially western corn rootworm) Corn leaf aphid (*Rhopalosiphum maidis*) Corn earworm (*Helicoverpa zea*) Japanese beetle (*Popillia japonica*)

Source: Summarized from (O'Day et al., 1998).

Corn Rootworm - Biology, Feeding Behavior. Corn rootworm are important insect pests in the Corn Belt. There are at least four different corn rootworm taxa in the US: the western corn rootworm

(D. virgifera virgifera), the northern corn rootworm *(D. longicornis barberi*), the Mexican corn rootworm *(D. virgifera zeae*), and the southern corn rootworm *(D. undecimpunctata howardi*; also known as the spotted cucumber beetle; see Figure 3).

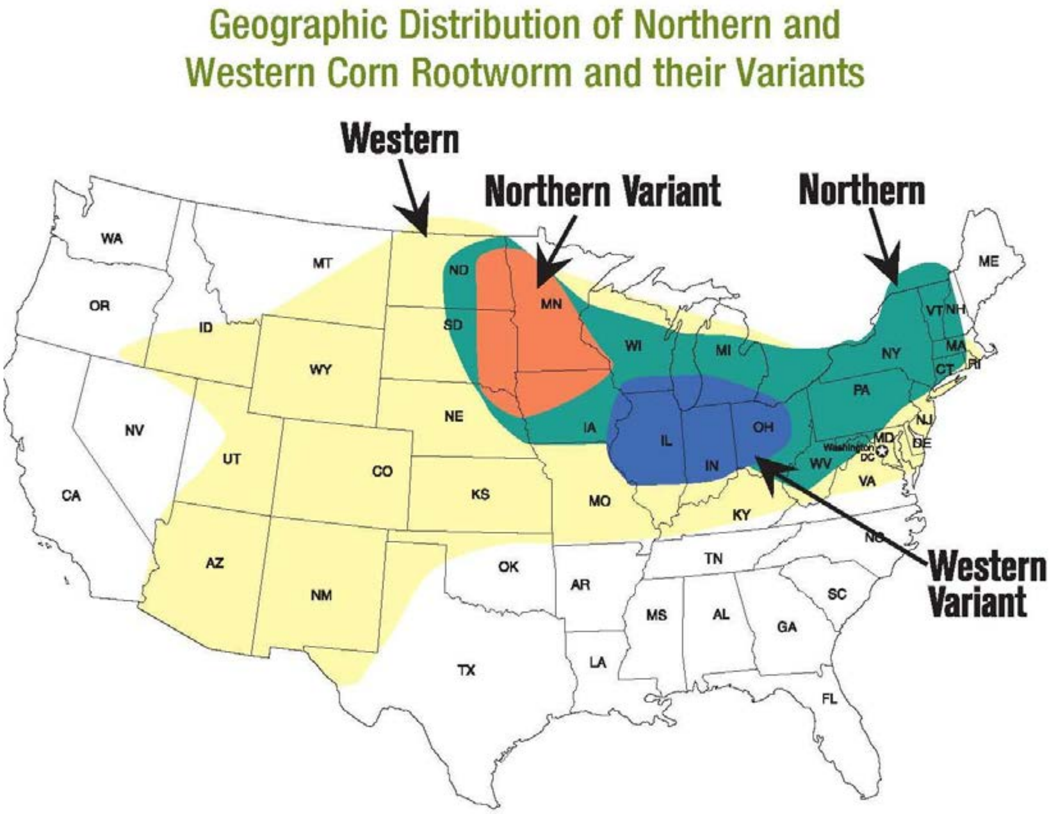

Figure 3: U.S. Geographical Distribution of Northern and Western Corn Rootworm and their Variants. Source: Syngenta, 2011c

Western and northern corn rootworm have similar life cycles. Both have a single generation each year, and corn is the only economic host. In general, corn rootworm cannot complete their life cycle without the food supplied by corn plants. Beginning in July, females lay eggs in the soil at a depth of two to four inches near the base of the corn plant (O'Day et al., 1998). The eggs overwinter, and the onset of hatch ranges from late May to mid-June. Rootworm larvae feed on corn roots for three to four weeks, passing through three growth stages (instars). Second instar larvae are often the first detected because first instars are very small (only 1/16th of an inch long) (O'Day et al., 1998). Western and northern corn rootworm larvae feed first on roots near the soil surface; when these are consumed, the next lower node is attacked. First and second instars leave brown feeding scars (lesions) as they tunnel from root tips to the plant base, destroying root hairs and small roots. Third instars cause the majority of root damage and they generally feed on the large primary roots near the stalk. Larval corn rootworm injury results in yield losses in three ways:

1. Root pruning and tunneling disrupt nutrients and water transport from the root system; during dry periods, when conditions suppress root generation, rootworm damage is amplified.
2. Lack of root support causes goosenecking and lodging, which may limit sunlight capture by the plants and complicate harvesting; and
3. Root feeding promotes invasions by secondary pathogens such as bacteria and fungi which increase the incidence of corn rots (O'Day et al., 1998).

The Mexican corn rootworm has similar biology to the western corn rootworm (both are *D. virgifera* subspecies), but is primarily an economic pest in Texas (Rice, 2004). Additionally, adult corn rootworm beetles can cause silk clipping injury to corn plants, resulting in poor pollination and incomplete kernel set. Southern corn rootworm overwinters as an adult, and is not controlled by *Bt*-expressing hybrids (Alabama-Cooperative-Extension-System, 2012). This rootworm is mostly an economic pest in southern states and also infests the roots of many grass crops and weeds (North-Carolina-State-University, Undated).

Corn Rootworm Management and Economic Losses. The corn rootworm genus, *Diabrotica*, includes some of the most damaging pests of corn. In the US, approximately 20 to 25 million acres of corn were once treated annually with soil insecticides to protect crops from feeding damage caused by corn rootworm larvae (Roehrdanz et al., 2003). Before corn rootworm-protected *Bt* corn varieties were introduced in 2003, an estimated 14 million acres were treated annually with conventional insecticides to control corn rootworm (Syngenta, 2011c); Appendix A of this EA). This translated to the annual application of more than 7.7 million pounds of insecticide active ingredient to corn fields for corn rootworm control (Syngenta, 2011c); Appendix A of this EA). Controlling *Diabrotica* rootworm accounted for the largest single use of conventional insecticides in the US at that time. In 2006 (prior to widespread adoption of transgenic crops for rootworm control), the USDA estimated that corn rootworm caused $1 billion in lost revenue each year (USDA-ARS, 2006), which includes $800 million in yield loss and $200 million in treatment costs for corn growers (Fyksen, 2003).

Corn rootworm can be managed by crop rotation, insecticide application, and hybrid corn with rootworm resistance traits. Because basic biology of the pest may vary from region to region, management techniques may differ regionally. How the crop is grown may greatly affect the selection of management techniques. For example, about 29 percent of US corn acreage is not rotated but rather is planted to continuous corn (Gianessi et al., 2002). Until recently corn rootworm caused damage almost exclusively in fields where corn was grown at least two years in a row. In addition, new strains of corn rootworm have evolved that survive intervening years of a non-corn crop (Levine and Oloumi-Sadeghi, 1991; Gray et al., 2009). Corn producers have used crop rotation (usually with soybeans) to control corn rootworm, but this method has some economic and biological limitations.

Rotations in some growing areas have become less effective for several reasons (1) A biotype of western corn rootworm (the western variant) has appeared in central Illinois, northern Indiana, and parts of Michigan that can lay eggs in soybean fields. The eggs hatch in the following season, coinciding with the corn rotation (Gray et al., 2009). This strain has spread rapidly since it was first observed in 1992 (2) A northern corn rootworm biotype (the northern variant) has exhibited extended diapause in which some eggs can survive through a non-corn rotation to attack corn in a subsequent season (Levine and Oloumi-Sadeghi, 1991). In South Dakota, Minnesota, Iowa, and Nebraska, the new northern corn rootworm biotype can diapause for two winters, which allows the eggs to bypass the rotated crop and hatch in time to feed on the next corn crop (Gianessi et al., 2002). (3) Southern corn rootworm overwinters as an adult and has a varied diet, reducing the effectiveness of crop rotation in controlling this pest (Levine and Oloumi-Sadeghi, 1991; Kuepper, 2002). Larvae of southern corn rootworm can attack more than 200 plant species, including soybeans.

Corn Rootworm Management with Chemicals. Chemical management of corn rootworm includes preventive seed treatments and in-furrow or banded soil applications. In mostly western parts of the

Corn Belt, foliar applications are made later in the season for high populations of adult corn rootworm beetles; without control at that stage, increased rootworm egg deposition will presage increased larval rootworm on corn at that location in the next growing season. In areas where corn rootworm is common, growers basically treat routinely and prophylactically, not usually in response to scouting of insect pest populations (M. Gray in (Pocock, 2007).

Larval Control. The US-EPA has registered numerous insecticide products for the control of corn rootworm larvae (a list of representative products is available (Table C-1, Appendix C in Syngenta, 2011a). The insecticides used to control corn rootworm in conventionally grown corn consist mainly of organophosphates, carbamates, synthetic pyrethroids and phenyl benzyl classes of chemistry. The majority of these products are classified as Restricted Use. Restricted Use Pesticides must be applied by a certified applicator or under the direct supervision of a certified applicator. The US-EPA requires application control measures for such insecticides to limit human and environmental exposure. Applying liquid or granular insecticide at planting-time in bands over the seed or post-planting basally to corn or over-the-row followed by soil cultivation is approved for rootworm control, as are delayed post-planting applications through chemigation (Kansas-State-University-Extension-Service, 2011). In addition, GE corn seed generally is treated with systemic insecticides, such as neonicotinoids, and these kill rootworm larvae (Mullin et al., 2005) and also other seed-attacking insects and some soil insects (Kansas-State-University-Extension-Service, 2011).

Much like resistance to crop rotation techniques, corn rootworm has developed resistance to some chemical insecticides (Meinke et al., 1998). Syngenta believes that “resistance to corn rootworm insecticides may result in increased chemical use” (because growers may attempt to control resistant insects with higher insecticidal doses) “and a greater dependence on insecticide” (because growers may use a different insecticide if the one to which resistance develops is no longer effective; (Syngenta, 2011c); Appendix A of EA). As discussed below in this section, resistance to ineffective plant incorporated protectants in CRW resistant hybrids could also cause the use of insecticides to increase.

Adult Control. Insecticides are used in control strategies for adult rootworm as well. In Kansas and Nebraska, and other parts of the western corn belt, insecticides are frequently used against adult rootworm (M. Gray, in (Grooms, 2009). At least 14 products can be used as foliar sprays to suppress adult egg laying, which would reduce the larvae present in next summer’s corn, if corn on corn rotation is the grower’s plan (Kansas-State-University-Extension-Service, 2011). Scouting abundance of adult insects needs to precede application, and afterwards; if a second insecticide treatment is needed, “two sprays will often be more expensive that a single, planting-time application of a soil insecticide” (Kansas-State-University-Extension, 1995). When adult numbers are high, silk clipping by rootworm adults before pollination can impact yields. Insecticides may also be applied with appropriate timing to forestall this potential for loss (Kansas-State-University-Extension-Service, 2011). Growers are encouraged to plant early since late-planted corn attracts emerging adults to pollinating corn. Increased progeny from these ovipositing females will impact the next season corn crop (Kansas-State-University-Extension-Service, 2011). However, very early planting (before April 18^{th} in Kansas) can increase larval survival in insecticide treated furrows when eggs hatch occurs after degradation of the treatment (Kansas-State-University-Extension-Service, 2011). Corn planted late (June 1 in PA) can be damaged by adult feeding and inhibit pollination, and consequently require adult insecticidal treatment (Calvin, 2003).

Corn Rootworm Resistant Hybrids. Several varieties of transgenic rootworm-resistant corn have been developed by seed producers. Field studies indicate that transgenic rootworm-protected corn provides as good or better efficacy than soil insecticides in protecting corn roots from significant corn rootworm larval injury (Rice, 2004). In an Iowa study, transgenic corn hybrids were 100 percent effective in protecting roots from economic damage (i.e., damage that would result in yield loss), whereas the insecticide was only 63 percent effective and the untreated nontransgenic hybrid offered no protection from insect damage (Rice, 2004). Other trials indicate that location is relevant to results, so that in some sites and with some hybrids compared to the soil insecticide Aztec, hybrids alone did not show less damage or yield than the insecticide treatment (Tinsley et al., 2011). Transgenic rootworm-protected corn for root protection, however, has greater convenience for growers than insecticide application, and protection does not rely heavily upon planting time, weather influences, calibration of application equipment, or soil conditions for optimum performance.

Replacing insecticides with transgenic plants has been shown to reduce the overall volume of insecticide used against the target pest. In the period from 1996 to 2008, the volume of active ingredients in insecticides (Brookes and Barfoot, 2010) applied for control of European corn borer and other lepidopteran pests (beginning in 1996) and corn rootworm (beginning in 2003) has fallen 77%. In 2008 alone, the annual savings in the volume of applied insecticide active ingredient was 4 million kilograms (Brookes and Barfoot, 2010). Typical trials show that yield between insecticide treated non *Bt* cultivars and *Bt*-expressing cultivars are similar, so that need for such insecticides are replaced when rootworm-resistant hybrids are planted under low to moderate CRW pressure (Section 1, (Tinsley et al., 2011)).

The US-EPA requires refuges to minimize the potential for corn rootworm to develop resistance (US-EPA, 2001). The refuge requirements are product-specific and range from 5 to 20 percent of each corn field. The refuge can be a spatial one (percentage of the field area) or as a portion of the seed mix ("refuge in a bag"), depending upon the specific product (US-EPA, 2007a). Varieties with multiple transgenic traits acting against a particular pest typically have smaller percentage requirements for refuges than single-trait products. Additionally, the National Corn Growers Association promotes US-EPA mandated IRM strategies for all *Bt* corn varieties, including corn rootworm-protected cultivars, to minimize the potential for the insects to develop such resistance (NCGA, 2012).

When planting transgenic hybrids, the associated refuges cannot contain *Bt* expressing traits; growers may choose a method for chemical control of rootworm larvae (US-EPA, 2001). The need for insecticides in rootworm control should be determined from insect surveys done in August of the previous year (K. Ostlie, in Pocock (Pocock, 2007). Under low expected rootworm pressure, high dose seed treatment may provide sufficient protection. High rootworm populations the previous crop year may dictate that soil-applied liquid or granular insecticides be used in the following year (Gray, 2011b), although extension staff often recommend granular formulas for better efficacy (M. Rice and M. Gray (Pocock, 2007).

Effects of Available Rootworm Resistant Hybrids on Integrated Pest Management. Crop entomologists note that to some extent, *Bt* crops have led to growers being less concerned about the need for insect scouting to determine pest populations (Gray, 2000; Ostlie, 2011a), or the need to consider and apply compatible alternative biological, cultural, mechanical and chemical controls (Gray, 2011c). The economic value of responding to established action thresholds also may be unappreciated. Planting CRW resistant seed may be seen by some growers as simply 'insurance' against possible rootworm pressure (Wisconsin-College-Agric-Life-Sci., 2009). The unnecessary use of CRW-directed insecticides was similarly an issue as Gray (2000) noted before widespread use of CRW resistant crops began. US-EPA also considers that IPM should be part of the IRM responsibilities of seed sellers and growers (see section D., Insect Resistance Management in (US-EPA, 2001)), especially for decisions involving the refugia.

Development of Resistance to Cry Proteins by Rootworm. Transgenic corn varieties may have limited potential to control corn rootworm if the insects develop resistance to these products. To delay evolution of resistance to transgenic crops producing *Bt* toxins, nearby refuges of corn plants not producing *Bt* toxins for control of the same pests are required by the US-EPA. The refuges promote survival of susceptible pests, which mate with resistant insects and slow the evolution of resistance (Tabashnik et al., 2008). Such refuges are expected to be most effective in slowing resistance when the toxin concentration in the adjacent *Bt* crops is high enough to kill all or nearly all target insects (Meihls et al., 2008).

The widespread use of transgenic *Bt* corn could generate selection pressure for insect resistance (Tabashnik et al., 2008). Yield losses and corn lodging caused by rootworm pressure have been observed in limited areas of planted *Bt*-expressing hybrids and have been attributed to resistance (Hodgson and Gassmann, 2011). The study indicates that the putative resistance of western corn rootworm was localized to areas of continuous corn, and the use of one Cry protein (Gassmann et al., 2011). Discussed later in the Cumulative Impacts section, the potential for resistance to develop to any one product by low dose exposure can be limited by combining *Bt* proteins with different binding sites in the same plants ("pyramiding") (Tabashnik et al., 2008). These varieties with multiple CRW resistant traits are presently available and are sold as part of multi-trait stacks in hybrids from several seed producers. While rootworm damage to hybrids with CRW resistance occurs, significantly increased damage cannot be conclusively attributed to resistance. The presently deployed cultivars are not 'high dose' products and, under pressure of high populations of rootworm, could be expected to have these effects (Monsanto, 2011a) ; (US-EPA, 2010b; Gassmann et al., 2011). Failures to effectively control insect pests may be related to insufficiently high Cry protein concentrations in the transgenic crop (Tabashnik et al., 2008) and for Cry3Bb1, the consequences may only be apparent when hybrids are exposed to high populations of the pest. Laboratory studies of western corn rootworm suggest that resistance also carries fitness advantages such as increased fecundity and earlier larval emergence (Oswald et al., 2011; Oswald et al., 2012). Possible CRW resistance to CryBb1 in multiple field locations is presently being assessed by the seed developer (Monsanto, 2011a). Although unexpected damage to corn expressing Cry3Bb1 is known in at least four states, (Hodgson and Gassmann, 2011) concluded that "the number of fields with resistance… is small at this time."

Genetic analyses of resistant rootworm populations have shown that inheritance of a putative resistance trait is dominant, which can theoretically be overcome if a high enough dosage of the *Bt* toxin is used. This high dosage should render the resistance genes effectively recessive (Gassmann, 2012). However, the success of the refuge mechanism typically presumes that resistance is recessive and a high dose of *Bt* will eliminate heterozygotes having a resistance gene (Gassmann et al., 2009). Alternatively, Oswald et al, (2012) suggest that the proposed Western corn rootworm resistance to *Bt* is controlled by more than one gene (Degree of expression of plant resistance to rootworm may also be ameliorated by soil type and degree of saturation of soil within agricultural fields (Gassman et al., 2012). Evolution of possible insect resistance is influenced by details of insect behavior, including such activities as mating, feeding or patterns of movement (Head and Greenplate, 2012). Mating behavior has been studied in western corn rootworm, and found to be nonrandom (Meihls et al.,

2011) which could affect the frequency of any traits of interest. Rudeen and Gassmann (2012) suggest that in fields with non-Bt corn refuges, larvae may begin feeding on non-*Bt* plants, and then move to complete larval development on *Bt* plants. In fact, any feeding by early larval attacks on roots might allow larvae arriving later to damage corn roots (R. Geisert, personal communication, 2012).
Despite evidence of overwhelmed resistant hybrids, widespread failure of control measures using *Bt* crops has not been observed, in part due to insect resistance management (IRM) strategies, including supplemental pesticide use and refuges (Tabashnik et al., 2008). In the case of *Bt* corn grown in the Corn Belt, refuge acres are typically 5 to 20 percent of the area of the corn field, depending on the product's requirements (US-EPA, 2007a). Greenhouse and laboratory tests suggest that insects under intense selection pressure by Cry proteins over multiple generations may develop resistance rapidly in the absence of a refuge to sustain susceptible populations. These data in combination with the report of field resistance to a *Bt* product further emphasize the importance of effective refuges for resistance management (Meihls et al., 2008). Resistance management strategies, which are mandated by US-EPA's terms of *Bt* corn product registrations (US-EPA, 2001)(Updated Feb 16`, 2011, section V. Bt), Corn Confirmatory Data and Terms and conditions of the Amendment) have been developed for all *Bt* corn products to mitigate the risk of pest resistance and to implement additional measures if resistance occurs.

Integration of Multiple Strategies. In most circumstances, a grower chooses either insecticides or a *Bt*- expressing corn hybrid for rootworm management. However, in some cases because of high pressure from rootworm in previous seasons, it may be advantageous for growers to use both (see recommendation of Monsanto (Monsanto, 2011a); see also Hodgson and Gassmann (Hodgson and Gassmann, 2011). Chemical companies have done field trials, sometimes with the cooperation of universities, to treat CRW resistant corn hybrids with conventional herbicides (e.g., Force 3G, Counter 15G, Fortress 5G, Aztec 4.67G), and in one series of trials have improved yields an average 12 bushels per acre, and in another series, nearly 13 bushels per acre (Grooms, 2009). While an economic benefit was apparent in 70% of the field trial sites (J. Cecil, personal communication, Syngenta (Grooms, 2009), the benefit could not be attributed to corn root worm control alone, but insecticide may have also controlled nematodes, wireworms and other grubs (Grooms, 2009). Application rates in these trials have been at 75% of that recommended for rootworm control at planting. In more recent comparisons in Illinois, but under low to moderate rootworm pressure, soil-applied insecticides rarely resulted in increased yield (Tinsley et al., 2011). Syngenta reports a trial of nearly 100 growers, who used conventional herbicide Force CS or Force 3G on a split plot design, in which one of three rootworm resistant lines were treated, one half with the insecticide, and one half not. In the typically high rootworm pressure areas of N. Illinois, N. Indiana and E. Iowa, growers obtained 10.9 bu/ ac in increased yield with insecticide (Syngenta, 2011b).

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

Disease and Other Pest Management

In addition to direct damage caused by feeding on plant tissue, insects play an important role in the transmission and dissemination of pathogenic organisms during corn development. Soil contains microorganisms, particularly fungi, that may infect plant parts injured by soil-dwelling insects. Primary roots of the seedling and the radical and seminal roots are commonly infected with *Fusarium* species after the roots have served their function and become senescent. Feeding by corn rootworm has been associated with increased frequencies of *Fusarium* infection (Dicke and Guthrie, 1988); rootworm feeding may also lead to increased incidences of stalk rots. These pathogen infections can reduce crop quality, harvestability, and yield.

Crop disease reduces both the quantity and quality of grain harvested. Disease loss estimates for corn production in the US range between 2 and 15 percent each year and reached 20 percent in 1970 with the southern corn leaf blight epidemic (Jeffers, 2004). Losses estimated for diseases are difficult to determine because of (1) Variation in yield potential between different years; (2) Differences in genetic background of germplasm being grown; and (3) Potential for unfavorable environmental conditions.

Major pathogens of no till corn in Iowa (Robertson et al., 2009) include Anthracnose, with leaf blight, top dieback, and stalk rot caused by the fungus *Colletotrichum graminicola*, eyespot disease, caused by the fungus *Kabatiella zeae*, Goss's wilt caused by the bacterium *Corynebacterium nebraskense* with leaf symptoms, gray leaf spot caused by the fungus *Cercospora zeae-maydis* with leaf symptoms and secondary severe stalk rot and lodging and Northern corn leaf blight, caused by the fungus *Helminthosporium turcicum*, with leaf symptoms (For a complete list see Table C-2 in Appendix C, (Syngenta, 2011a) lists corn diseases, their pathogens, the conditions that favor the spread of disease, and current management practices. In addition, mycotoxins such as aflatoxins and fumonisins may accumulate in corn as it matures in the field, and inappropriate storage conditions may facilitate additional fungal deterioration and contribute to the accumulation of aflatoxins (Rooney et al., 2004). A transgenic corn product has not yet been developed specifically to combat mycotoxins, although *Bt* corn used for control of ear-feeding lepidopteran pests has been shown to reduce the incidence of some mycotoxins in grain (Council-For-Biotech-Information, 2001). Minimizing insect damage through pest control measures such as *Bt* corn can reduce the incidence of fungal infection and accumulation of the associated mycotoxins.

Weed Management

Weeds compete with corn for light, nutrients, and water, especially during the first 3 to 5 weeks following emergence of the crop (Wright et al., 2009). Late-season weed infestations do not reduce corn yield nearly as much as early weed competition, but late-season weeds can harbor destructive insect pests. Competitive weeds include nightshade, smartweed, nutsedge, foxtail, velvetleaf, lambs-quarters, pigweed, and waterhemp (Hager, 1998).

Some weeds can survive in crop production systems using herbicide-tolerant crops because of pre-existing herbicide tolerance or because of growth habits or life cycles that help them avoid being treated, such as some winter annual weed species. Weed resistance management training to reduce the potential for weeds to develop tolerance to herbicides has been made available by the Weed Science Society of America in web-based training and other formats to growers and extension trainers and is readily accessible (Ohio-State-Extension, 2011). Industry practice includes weed resistance management training to reduce the potential for weeds to develop tolerance to herbicides (four part training offered by National Corn Growers Association (NCGA, Undated).

Weed control methods differ depending on a number of factors. No single weed control regime is effective for all growing conditions. The management practices that are used by a grower will depend on the types of pests in their field, level of infestation, cropping system, type of soil, cost, weather, time, and labor. An integrated weed management program utilizes a combination of cultural (planting), mechanical (tillage), and chemical (herbicide) methods for consistent, effective weed control (Wright et al., 2009). USDA encourages integrated weed management beginning in 1990 with the in section 1453 of the 1990 Farm Bill (7 U.S.C. 2801 et seq.) (USDA-AMS, 1996) because such management can help prevent the development of weed resistance to herbicides and the emergence of dominant weeds; controlling weedy and invasive plants is currently a program area priority with USDA's NIFA competitive grants program, and this includes "integrated pest management, to manage and control weedy and invasive species" (USDA-NIFA, 2011).

In 2010, herbicide active ingredients were applied to 98 percent of acres planted to corn (USDA-NASS, 2011b). The most widely used herbicide was glyphosate, applied to 66 percent of the planted acreage. Atrazine was applied to 61 percent of the planted acres and acetochlor was applied to 25 percent of the planted acres. Between 1996 and 2009, the glyphosate rate of application per crop year may have risen 39 percent for corn according to projections by Benbrook (Benbrook, 2009) although USDA-NASS surveys between 2005 and 2010 show only a 0.1 pound/acre increase in annual use rate (2010, 1.065 pounds glyphosate/a/yr, and no average increase in applications (USDA-NASS, 2006a; USDA-NASS, 2011c). Overall herbicide (and plant growth regulator) usage increased about 5% between 2005 and 2007 (US-EPA, 2011d).

Herbicide-tolerant corn products have been genetically engineered to allow use of herbicides without harming the crop. Herbicide-tolerant corn has been widely adopted by growers in North America and offers enhanced weed control. In 2010, approximately 70 percent of the US corn crop was herbicide-tolerant (USDA-ERS, 2011a). Currently available transgenic herbicide-tolerant corn cultivars include both glyphosate-tolerant cultivars and glufosinate- (phosphinothricin) tolerant cultivars (USDA-APHIS, 2011b). However, over-reliance on herbicide-tolerant crops may under certain conditions contribute to the development of herbicide-tolerant weeds. Before glyphosate-tolerant crops were introduced, only three weed species in the world were known to have developed resistance to glyphosate (Knezevic, 2010). Glyphosate- or glufosinate-tolerant weeds now found in the US include common waterhemp (*Amaranthus rudis*), horseweed (*Conzya* sp.), giant ragweed (*Ambrosia trifida*), common ragweed (*Ambrosia artemisiifolia*), palmer amaranth (*Amaranthus palmeri*), hairy fleabane (*Conzya conariensis*), Italian ryegrass (*Lolium multiflorum*), rigid ryegrass (*Lolium perenne*), and Johnsongrass (*Sorghum halpense*) (Knezevic, 2010).

Herbicides are used in various ways in combination with tillage strategies. In no-till systems, the herbicide is applied directly to the last season's crop residue. In the other methods, soil is tilled before the herbicide is applied. The amount of herbicide used is somewhat independent of tillage method. Common preplant herbicides might include metolachlor or atrazine, and post plant applications might include glyphosate for Roundup tolerant crops, along with other herbicides (Hartzler and Owen, 2006).

2.2.3 Specialty Corn Systems

Specialty systems include organic corn and specialty products such as white and waxy corn, sweet corn, and popcorn. These corn products comprise about 8 percent of the US corn market 2006 (USGC, 2006).

Organic Crop Production

Organic farming is defined in this document to include any production system that falls under the USDA-National Organic Program (NOP) definition of organic farming and is a certified organic production system. The NOP is administered by the USDA-Agricultural Marketing Service (AMS). Organic farming operations, as described by the USDA-NOP, require organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Excluded methods, as defined by the USDA-NOP, may include the use of synthetic pesticides, fertilizers, and recombinant DNA technology found in GE crops. 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.

Organic certification involves oversight by an accredited, third-party certifying agent of the materials and practices used to produce or handle an organic agricultural product (7 CFR 205.300). This oversight includes an annual review of the certified operation's organic system plan and on-site inspections of the certified operation and its records. Although the National Organic Standards prohibit the use of excluded methods (7 CFR 205.272), they do not require testing for the presence of excluded methods. Thus, NOP certification is dependent on process and not product. With regard to the unintentional presence of GE material in an organic product or operation, a recent USDA-AMS Policy Memorandum clarified that the unintentional presence of GE material will not affect the status of an organic product or operation when the operation has taken reasonable steps to avoid the products of recombinant DNA technology (USDA-AMS-NOP, 2011). However, retailers often require organic and non-GE farmers to verify their harvests through various tests (Ruth, 2003).

In 2008[1], approximately 168,000 acres of certified organic corn were planted (for seed, grain, or silage) (USDA-NASS, 2010a); Table 26), representing 0.20 percent of the 93.6 million acres of corn planted in the US that year (USDA-ERS, 2010a). The top states for harvested organic corn for grain or seed were Iowa, Wisconsin, Minnesota, Michigan and New York (AGMRC, 2010). Organic corn grown for grain or seed produced 15,749,401 bushels from 143,432 harvested acres (USDA-NASS, 2010a); Table 26), or an average of 109.8 bushels per acre.

Insecticides Used in Organic Production. There are a number of insecticides approved for use in certified organic production systems, mainly non-synthetic compounds or biocontrols. Conditions for use of an insecticide must be documented under the National Organic Standard. The Organic Crops Workbook (ATTRA, 2003) lists the approved classes of insecticides used for organic production (Table 3) based on the USDA's regulatory lists of approved and prohibited synthetic and non-synthetic substances (USDA-AMS, 2007).

1 The USDA-NASS conducted a detailed survey of organic farming in 2008. USDA-ERS and USDA-NASS both prepare annual reports of overall crop production that do not provide as detailed information about organic farms. This summary therefore compares organic and non-organic farming in 2008, using USDA-NASS and USDA-ERS data as cited.

Table 3: National List of Approved Insecticides for Organic Production Systems

Class	General Description	Examples	Notes
Botanicals	Derived from plants	pyrethrum, rotenone, sabadilla, neem	Strychnine and nicotine are also botanicals, but are expressly prohibited under the National List; Rotenone, an insecticide approved for use in organic production, is highly toxic to fish.
Biologicals	Insecticides containing disease organisms or toxins derived from disease organisms	*Bacillus thuringiensis*, *Beauveria bassiana*, *Trichoderma harzianum*, Spinosad	Much like synthetic insecticides, insect pests have been observed to develop resistance to biological insecticides.
Spray Oils	Vegetable or animal derived oils Petroleum derived oils (narrow-range oils)	-	Commonly used to control scale and mite pests
Insecticidal soaps	Fatty acid insecticidal soaps	-	Although synthetic insecticides, they are allowed in organic production; May harm predatory mites
Minerals	Mineral-based insecticides	Sulfur, copper products, diatomaceous earth and kaolin clay	Natural minerals like arsenic, lead, and sodium fluoaluminate are prohibited; Sulfur can reduce populations of beneficial insects; Diatomaceous earth can cause respiratory problems in animals and humans
Pheromones	Hormones used in products called *mating disrupters*	-	-

Source: ATTRA, 2003 (ATTRA, 2003).

An integrated strategy (Hazzard and Westgate, 2004) for controlling selected insect pests in corn using organic practices might be comprised of:

1. Monitoring to determine pest pressure and need for treatment and, if necessary;
2. Direct treatment of each ear with a microbial or botanical insecticide carried in vegetable oil to control corn earworm;
3. *Trichogramma* releases and/or foliar applications of *Bt* or spinosad to control European corn borer; and/or
4. Foliar applications of *Bt* or spinosad for fall armyworm control.

<u>Other Specialty Corn Production Systems</u>

Approximately 8percent of corn grown in the US is specialty corn, which includes sweet corn, popcorn, white, waxy, hard endosperm, high oil, non-transgenic, and organic corn (USGC, 2006). These corn varieties are specified by buyers and end-users of corn for production, and premiums are paid for delivering a product that meets purity and quality standards for the corn variety. Due to premiums offered by end-users and the dramatic adoption by U.S. farmers of GE corn varieties, specialty corn products are receiving increased attention as potentially profitable alternatives to the products of conventional and GE corn production systems (Elbehri, 2007).

Product differentiation and market segmentation in the specialty corn industry includes mechanisms to keep track of the grain (traceability) for Identity Preservation (IP) and quality assurance processes (e.g., ISO9001-2000 certification), as well as contracts between growers and buyers that specify delivery agreements (Sundstrom et al., 2002). Systems used by specialty corn growers and end-users to maintain identity of the production include:

Contracts – written agreements detailing responsibilities and duties of both parties including premiums for reaching goals and penalties for failing to attain specifications.

Tracking and Traceability Systems – correct labeling of all products (planting seeds and harvested material) and testing procedures for identifying and detecting acceptability of materials.

Quality Assurance Processes – oversight on handling procedures, testing planting seeds, and testing harvested materials to determine acceptability of use and product requirements, and assuring testing procedures are appropriate.

Closed-Loop Systems – the end-user supplies the planting seeds and guarantees to purchase final products. This may also require that the end-user conduct intermediate procedures such as planting, providing oversight during the growing season, harvesting, and transportation to processing plant.

Identity Preservation Systems – using systems of identity preservation that have been shown to be successful in the past such as the seed certification systems conducted by members of the Association of Official Seed Certifying Agencies (AOSCA, 2011). To maintain the purity of the specialty corn product, this production system is based on controlling, tracking and documenting each step from seed production to end use (processing plants).

2.2.4 Raw and Processed Corn Commodities

Corn is processed to make it more palatable or isolate functional ingredients suitable for specific purposes (Orthoefer and Eastman, 2004). Dry or wet milling is used to separate the bran and germ from the endosperm; wet milling further separates the endosperm into its chemical components, principally starch and protein. Breeding and genetic engineering for certain traits have improved the concentrations of desired ingredients, but there are no differences in handling requirements for processing transgenic and non-transgenic corn except for certain products such as Syngenta's alpha-amylase ("Enogen") corn, which requires special handling procedures to ensure that this corn is not used for unintended purposes (Syngenta, Undated).

2.3 Physical Environment

Water, soil, and air affect, and are affected by, corn agriculture; the methods described in Section 2.2.2, *Agronomic Practices*, may reduce some adverse impacts. This section describes water quality and use, soil characteristics, and air quality impacted by corn agriculture. Climatic conditions, in the context of potential climate change, are also discussed.

2.3.1 Water Quality and Use

Agriculture can affect water quality and use in irrigation. The following subsections describe corn agriculture's impact to water quality and use.

Water Quality

Agricultural nonpoint source (NPS) pollution is the leading source of water quality impacts to rivers and lakes, the second largest source of impairments to wetlands, and a major contributor to contamination of estuaries and groundwater (US-EPA, 2008). The primary cause of NPS pollution is increased sedimentation from soil erosion. Soil erosion can introduce sediments, fertilizers, and insecticides to nearby lakes and streams when they are carried from corn fields by rain or irrigation water (US-EPA, 2008). Insecticides or their degradates have been detected in many of the nation's streams (Gilliom et al., 2007) and agricultural stream sites in the Corn Belt have been documented with chemical herbicide concentrations that exceed the human-health benchmark established by the US-EPA (Gilliom et al., 2007).

Corn plant matter can be transferred to water bodies after field harvest, potentially accumulating in stream or lake sediments (Rosi-Marshall et al., 2007). There are no federal water quality standards for the insecticidal proteins present in transgenic insect-resistant plant varieties. Corn pollen may be deposited into water bodies adjacent to corn fields, contributing to turbidity or suspended solids. However, corn pollen is heavy and wind-borne pollen densities decrease rapidly from the source (Luna et al., 2001). Corn anthesis lasts for up to 14 days, and any pollen deposited into water bodies from adjacent fields during this period is unlikely to remain in suspension (Webster et al., 1999).

Certain agronomic practices, including conservation tillage methods and reduced fertilizer or insecticide application rates, may reduce adverse impacts. The US-EPA recommends (US-EPA, 2008) several Best Management Practices for protecting water quality:

Conservation Tillage - leaving crop residue (plant materials from past harvests) on the soil surface reduces runoff and soil erosion, conserves soil moisture, helps keep nutrients and insecticides on the field, and improves soil, water, and air quality;

Crop Nutrient Management - fully managing and accounting for all nutrient inputs helps ensure nutrients are available to meet crop needs while reducing nutrient movements off fields. It also helps prevent excessive buildup in soils and helps protect air quality;

Pest Management - varied methods for keeping insects, weeds, disease, and other pests below economically harmful levels while protecting soil, water, and air quality; and

Conservation Buffers - from simple grassed waterways to riparian areas, buffers provide an additional barrier of protection by capturing potential pollutants that might otherwise move into surface waters.

Water Use

Corn requires a steady supply of moisture, totaling approximately 4,000 gallons through the growing season, to produce one bushel of grain (SDCGA, 2010). Rainfall, stored soil moisture from precipitation before the growing season, and supplemental irrigation during the growing season provide water for corn, as described in Section 2.2.2.2, *Irrigation*. Supplemental irrigation was used on 12 million acres of corn fields in the US in 2008, reflecting 15 percent of all corn acres harvested for grain (Christensen, 2002). Groundwater is the major source for irrigation, used on almost 90 percent of irrigated corn acreage in the US.

The total amount of water used by corn varies from season to season and location to location, and is dependent on temperature, humidity, soil fertility, wind, solar radiation, total leaf area of the crop and the interaction of these factors (Krantz, 2008). The typical water use by corn in the first 100 days after planting, as calculated from rainfall and irrigation, is illustrated in the graph in Figure 3.

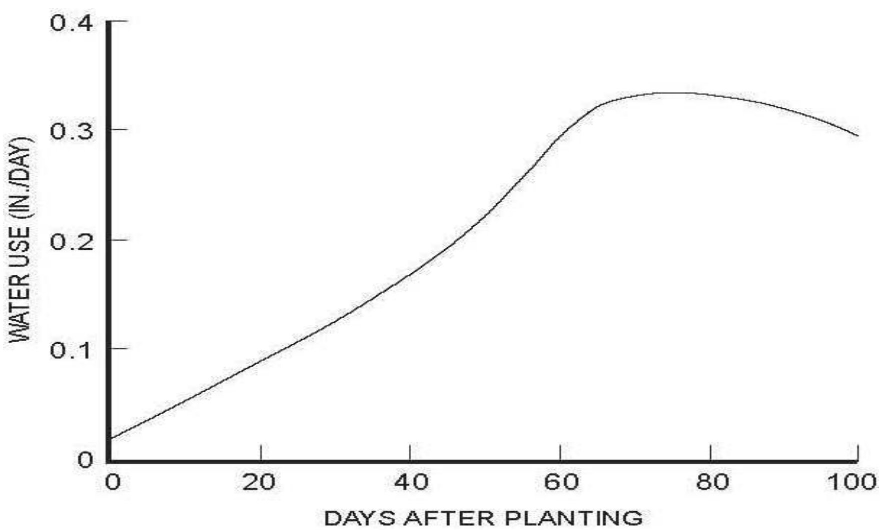

Figure 4: Water Use by Corn Plant in the First 100 Days after Planting

Source: Rhoades and Yonts, 2011.

Corn does not extract water uniformly throughout its rooting depth. Generally, more water is extracted from shallow depths and less from deeper depths. If water is applied to the soil surface, the typical extraction pattern follows the 4-3-2-1 rule: 40 percent of the water comes from the top quarter of the root zone, 30 percent comes from the second quarter, and so on (Krantz, 2008).

2.3.2 Soil

The interaction between the below-ground community of microorganisms and arthropods, plant-root structure, and organic residues in the soil is central to soil ecological processes including decomposing organic material, subsequent nutrient cycling and release, and maintaining soil structure and composition. Cultivating corn directly impacts these biological attributes. Agronomic practices such as crop type, tillage, and pest management regime have greater effects on the biology of the soil than the type of corn that is cultivated (Griffiths et al., 2007). For example, conventional tillage and mechanized harvesting machinery may disturb and expose the top soil surface layer, leaving the land prone to degradation. Soil degradation can lead to a decline in water quality and contribute to the greenhouse effect (Lal and Bruce, 1999). A decline in soil quality and soil resilience enhances the greenhouse effect through emissions of radiatively active gases (CO_2, nitrous oxide [NO_X]) (Lal and Bruce, 1999). Land that is prone to degradation is also more likely to adversely impact water resource quality and communities of organisms dependent on those water resources.

Conservation tillage methods including no-till, ridge-till, low-till and minimum-till leave a crop mulch on the ground to provide a protective cover to the soil between seasons and improve soil fertility by maintaining nutrient-rich organic matter on the field (NCGA, 2007);). Organic matter builds up in the soil, absorbing CO_2 and helping to reduce a significant amount of greenhouse gas.

2.3.3 Air Quality

Air quality may potentially be directly affected by agricultural activities such as burning, tilling, harvesting, spraying, and fertilizing. Smoke from burning agricultural waste releases particulates. Tilling and harvesting with motorized equipment release emissions that include carbon monoxide, NO_X, reactive organic gases, particulate matter, sulfur oxides, and greenhouse gases (GHG) (US-(US-EPA, 2011b). Tillage also releases GHG because of the loss of CO_2 to the atmosphere, and the exposure and oxidation of soil organic matter (Baker et al., 2005). Aerial application of insecticides may cause impacts from drift and diffusion. Insecticides may volatilize after application to soil or plant surfaces and move following wind erosion (Vogel et al., 2008). NO_X may also be released following nitrogen fertilizer application (Aneja et al., 2009). Agriculture, including land-use changes for farming, is responsible for an estimated 6 percent of all human-induced GHG emissions in the US (US-EPA, 2011b). NO_X emissions from agricultural soil management comprise 68 percent of all US N_2O emissions (US-EPA, 2011b).

2.3.4 Climate

Corn agriculture may potentially affect or be affected by climate change (Isermann, 1994; Aneja et al., 2009). Agriculture-related activities are recognized as both direct (e.g., exhaust from motorized equipment) and indirect (e.g., agricultural-related soil disturbance) sources of GHGs (US-EPA, 2011b). Greenhouse gases collectively function as retainers of solar radiation and contribute to climate change. The agricultural sector is identified as the second largest contributor to GHG emissions in the US, ranking only behind the energy sector (US-EPA, 2011b).

Climate change may also potentially affect agricultural crop production. These potential impacts on the agro-environment and individual crops may be direct, including changing patterns in precipitation, temperature, and duration of growing season, or may cause indirect impacts extending the ranges of weeds and other pests (IPCC, 2007b). One recent study (IPCC, 2007a) of aggregate North American impacts on agriculture from climate change projects yield increases of 5 to 20 percent for this century, while other data suggest a reduction in yields (Gillis, 2011). Certain regions of the US are likely to be more heavily impacted than others because water resources may be substantially reduced. North American production is expected to adapt with improved cultivars and responsive farm management (IPCC, 2007b).

2.4 Biological Environment

The biological environment described in this section includes animals, plants, biodiversity, and corn gene movement. Threatened and endangered species are discussed separately in Section 6.

2.4.1 Animals

Corn fields have long been known to be used by birds, deer, and various small mammals (e.g., raccoons (*Procyon lotor*), deer mice (*Peromyscus maniculatus*), meadow voles (*Microtus pennsylvanicus*), and thirteen-lined ground squirrels (*Spermophilus tridecemlineatus*) for feeding and cover.

Bird species that have been observed in row crop fields include, among others, blackbirds (e.g., red-winged blackbirds (*Agelaius phoeniceus*), horned larks (*Eremophila alpestris*), brown-headed cowbirds (*Molothrus ater*), and vesper sparrows (*Pooecetes gramineus*) (Best and Gionfriddo, 1991). Specific bird species can act as beneficial or detrimental members in the agro-environment. For example, red-winged blackbird are often initially attracted to corn fields to feed on insect pests, but then also feed on the corn. Studies have shown that red-winged blackbirds can destroy more than 360,000 tons of field corn and substantial amounts of sweet corn annually (Dolbeer, 1990). Although many birds visit row-crop fields such as corn, numbers are low and few nest there, likely due to overlap between nesting phenology and mechanized harvest (Patterson and Best, 1996; Hoeft et al., 2000).

Deer, such as the white-tailed deer (*Odocoileus virginianus*), find field corn attractive because it functions both as food and cover throughout the latter half of the growing season (Vercauteren and Hygnstrom, 1993). Deer can significantly damage or completely destroy small corn fields that are surrounded by woody or brushy areas; data from the Wisconsin Department of Natural Resources show approximately $915,000 in corn damage from white-tailed deer in 2008 (Koele, 2008). However, deer damage to large corn fields is often limited to a few rows closest to the wooded areas (Neilsen, 1995). Raccoon damage to field corn has increased in recent years (Beasley and Rhodes Jr., 2008). In northern Indiana, Humberg et al. (Humberg et al., 2007) (2007) attributed 87 percent of corn plants damaged across 100 corn fields over two growing seasons to raccoons. The deer mouse is the most common small mammal in some corn production regions (Stallman and Best, 1996; Sterner et al., 2003). Deer mice feed on a wide variety of plant and animal matter, but primarily feed on seeds and insects. They are considered beneficial in agro-ecosystems because they consume both weed and pest insect species. The meadow vole feeds primarily on fresh grass, sedges, and herbs, but also on seeds and grains. Meadow voles also can be considered beneficial for their role in the consumption of weeds, but can be an agricultural pest where abundant Smith (Smith, 2005). The thirteen-lined ground squirrel feeds primarily on seeds of weeds and available crops, such as corn and wheat (Sterner et al., 2003; Smith, 2005). Thirteen-lined ground squirrels have the potential to damage agricultural crops, although they can also be considered beneficial when eating pest insects such as grasshoppers and cutworms.

Although many of the invertebrate organisms found in corn-producing areas are considered pests, such as the corn earworm (*Helicoverpa zea*), European corn borer (*Ostrinia nubilalis*), fall armyworm (*Spodoptera frugiperda*), and the corn rootworm (*Diabrotica* spp.), many others are considered beneficial (Hoeft et al., 2000). For example, numerous invertebrates perform valuable functions, such as pollinating plants (bees), contributing to the decay of organic matter (earthworms), cycling soil nutrients (earthworms), and attacking other pest insects and mites (ladybird beetles).

2.4.2 Plants

Corn fields can be bordered by other agricultural fields (including other corn varieties), woodlands, or pasture and grasslands. From an agronomic perspective, the most relevant members of a surrounding plant community are those that can behave as weeds. Corn agronomic performance can be reduced by weed competition for water, nutrients, and light. US corn yields are threatened by more than 200 weed species annually (Heap, 2011).

Common corn field weeds include giant foxtail (*Setaria faberi*), giant ragweed, velvetleaf (*Abutilon theophrasti*), common cocklebur (*Xanthium strumarium*), Canada thistle (*Cirsium arvense*), common lambsquarters (*Chenopodium album*), Johnsongrass, fall panicum (*Panicum dichotomiflorum*), and hairy fleabane (Childs, 1996)(updated 2011). Weeds such as giant foxtail and barnyard grass (*Echinochloa crusgalli*) have been shown to reduce corn yields by up to 14 (Fausey et al., 1997) and 35 (Bosnic and Swanton, 1997) percent, respectively. Weed management strategies that corn growers use, including strategies to address weed resistance to herbicides, are discussed in Section 2.2.2.5, *Weed Management*.

2.4.3 Soil Microorganisms

Soil bacterial communities are influenced by plant species and cultivars as well as other environmental factors, such as soil type and agricultural practices (Icoz et al., 2008). Plant type and root exudates influence the microorganisms that colonize the rhizosphere (Icoz et al., 2008). While *B. thuringiensis* occurs naturally in soil, growing transgenic *Bt* corn increases the amount of Cry endotoxins present in agroecosystems (Blackwood and Buyer, 2004). Most proteins do not persist or accumulate in soil because they are inherently degradable in soils that have normal microbial populations (Burns, 1982).

During the growth of the plant Cry protein concentrations within the rhizosphere vary and can be affected by microbial activity. In turn, growth of soil microbes depend in part on soil temperature and humidity (Baumgarte and Tebbe, 2005). The degradation of plant biomass is also accompanied by changes in the numbers of microorganisms and the activity of some enzymes involved in the process. Thus, microbial populations differ significantly by season, probably as a result of differences in the water content of soils, ambient temperatures, and plant stage growth at the time of sampling (Icoz et al., 2008).

2.4.4 Biodiversity

Biodiversity within agricultural ecosystems is strongly impacted by agricultural practices , including the type of cultivated plant and crop-specific management practices. Species diversity and abundance in corn agro-ecosystems may differ between transgenic, non-transgenic, and organic corn. Relative to any natural ecosystem, species abundance and richness will generally be less in intensively managed agroecosystems.

Many studies over the last ten years have investigated the differences in biological diversity and abundance between GE and non-GE fields, particularly those GE crops that are resistant to insects (e.g., Bt crops) or herbicides (e.g., glyphosate-tolerant or glufosinate-tolerant crops). Among the numerous studies, conflicting results are often reported. Different studies have demonstrated decreases in biological diversity or abundance due to GE crops engineered to accumulate insecticidal proteins or tolerate herbicide application for weed management (Ponsard et al., 2002). Alternatively, other studies of GE crops, such as Bt corn, when compared to non-GE crops sprayed with insecticides demonstrate that GE crops do not cause any changes in arthropod abundance or diversity (Torres and Ruberson, 2005; Obrist et al., 2006; Chen et al., 2008; Wolfenbarger et al., 2008;

Pioneer, 2009). Some reports show that GE crops may even increase biological diversity in agro-ecosystems (Obrist et al., 2006; Marvier et al., 2007). Herbicide-tolerant corn, when compared to non-GE corn production, may not result in changes in arthropod abundance and may increase species diversity during different times of the year (Brooks et al., 2003; Hawes et al., 2003), (Brooks et al., 2003). Since biological diversity can be defined and measured in many ways, APHIS considers determining the level of biological diversity in any crop to be complex and hard to achieve concurrence. Another difficulty with biodiversity studies is separating expected impacts from indirect impacts. For example, reductions of biological control organisms are seen in some *Bt*-expressing GE crops, but are caused by reduction of the pest host population following transgenic pesticide expression in the GE crop plant.

2.4.5 Gene Movement in the Natural Environment

Corn is self-compatible and wind-pollinated. (Wipff and Fricker, 2002b; Watrud et al., 2004)There are no native plant species that can be pollinated by corn pollen without human intervention (e.g., chromosome doubling or embryo rescue) (Mangelsdorf, 1974; Russell and Hallauer, 1980; Galinat, 1988).

2.5 Public Health

Public health concerns related to corn stem from human consumption of corn and corn products, animal (livestock) consumption of feed corn and corn products, and the indirect effect on human health and worker safety from laborers' exposure to agricultural chemicals.

2.5.1 Human Health

In the past 30 years, the public's consumption of corn-based products has more than doubled – corn products have risen from 12.9 pounds annually per capita in 1980 to 33 pounds in 2008; and corn sweeteners have risen from 35.3 pounds annually per capita in 1980 to 69.2 pounds in 2008 (USCB, 2011). During the same time period, the share of corn that is genetically engineered has risen from zero to 80 percent (USDA-ERS, 2010a; USDA-ERS, 2011a; USDA-ERS, 2011b).

Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from any GE crop 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, applicants who wish to commercialize a GE variety that will be included in the food supply invariably complete a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food; FDA evaluates the submission and responds to the developer by letter.

As noted by the National Research Council (NRC), unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional hybridizing and genetic engineering (NRC, 2004) . GE crops, relative to their conventionally-bred counterparts, are often better characterized due to additional rigor in regulatory requirements (König et al., 2004). The NRC also noted that at the time, no adverse health effects attributed to genetic engineering had been documented in the human population. More recently, the NRC stated that GE crops have had fewer adverse effects on the environment than non-GE crops (NRC, 2010). Reviews on the nutritional quality of GE foods have generally concluded that there are no significant nutritional differences in conventional versus GE plants for food or animal feed (Faust, 2002; König et al., 2004; Flachowsky et al., 2005).

Corn has no known human health risks except allergenicity. The *Food Allergen Labeling and Consumer Protection Act* (2004) requires disclosure of the presence of eight specific food groups which are designated as "major food allergens" on the package labels (US-FDA, 1992). These eight food groups (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybean) account for 90 percent of food allergic reactions in the (US-FDA, 1992). Corn is not designated as a "major food allergen" and the FDA guidance on compliance with the Act does not include reference to corn or refined corn products (Corn-Refiners-Association, 2006). There are no known human health effects from the novel proteins in *Bt* corn.

At present, the prevalence of corn food allergy in the US is exceedingly low, estimated to affect no more than 0.016 percent of the general population (Corn-Refiners-Association, 2006). Exposure to corn allergens can occur externally (direct skin contact) or internally (ingestion). Some attributed symptoms of corn allergy include dermatitis, asthma, urticaria, migraine headache, ulcerative colitis, irritable bowel disease, celiac sprue, and anaphylaxis under severe exposure (US-FDA, 1992). Currently there is no cure for corn allergy. The only mechanism for managing the hypersensitivity is to avoid consuming foods that contain the allergen.

Additional impacts of *Bt* crops on human health. Certain *Bt* corn cultivars can reduce mold infestation on corn grain (Carpenter et al., 2002); Section 1). One study found that transgenic hybrids with cry genes for lepidopteran resistance had fumonisin concentrations as low as 10 percent of those found in non-transgenic counterparts (Munkvold et al., 1999). Any reduction in mold toxins resulting from use of *Bt* corn can provide direct benefits to people and corn-fed livestock by reducing exposure to mycotoxins. In a variety of field studies, lepidopteran-protected corn varieties expressing *Bt* proteins have been shown to have significantly lower levels of the common mycotoxins that are produced by fungal pathogens (Wu, 2006b).

2.5.2 Animal (Livestock) Health

Approximately 55 to 60 percent of the corn produced in the U.S. is used for livestock feed (KyCGA, 2011). As with human consumption of corn, most of the corn used currently for livestock feed would also be GE (USDA-ERS, 2011a).

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

Corn has no known animal (livestock) health risks except from the presence of mycotoxins, which are secondary metabolites produced by certain fungi. Mycotoxins are considered unavoidable contaminants in food as there is no known technology that can completely eliminate their presence in crops. Insect damage is one factor that predisposes corn to mycotoxin contamination, as insect herbivory creates stalk or kernel wounds that encourage fungal colonization. (Wu, 2006a). Mycotoxins are of concern worldwide because of their toxic and carcinogenic effects in humans and animals feeding on infected corn. Table 2-5 provides a list of corn mycotoxins; the two categories of most concern are fumonisins and aflatoxins.

Fumonisins are found exclusively in corn, while aflatoxins are found in a variety of crops including corn, cotton, peanuts and some nuts (Wu, 2006a). Fumonisins are produced by the fungi *Fusarium verticillioides* and *F. proliferatum*. Since their first discovery in 1988, over 28 types of fumonisins have been isolated, of which fumonisin B1 (FB1) is the most common in corn (Wu, 2006b). Fumonisins can be highly toxic to animals, causing diseases such as leukoencephalomalacia in horses and pulmonary edema in swine (Wu, 2006a). Lepidopteran-protected Bt corn hybrids have reduced fumonisin levels (Munkvold et al., 1999).

Aflatoxins are produced by the fungi *Aspergillus flavus* and A. parasiticus, and are the most potent chemical liver carcinogens (Wu, 2006b). In poultry, aflatoxin consumption results in liver damage, impaired productivity and reproductive efficiency, decreased egg production in hens, inferior eggshell quality, inferior carcass quality, and increased susceptibility to disease (Wu, 2006b). In cattle, the primary symptoms are reduced weight gain, liver and kidney damage, and reduced milk production (Wu, 2006b). One analysis of *Bt* on corn at harvest shows that these mycotoxins may be present at half the level as that of transgenic isoline corn (Abbas et al., 2008); review showed that the performance of *Bt* hybrids however, seemed dependent upon heat stress and insect damage (Reddy, 2009). Extensive testing and use have identified no animal (livestock) health risks for transgenic corn products expressing *Bt* proteins (Shimada et al., 2008).

Table 4: List of Corn Mycotoxins Toxic to Animals Consuming Contaminated Feed

Mycotoxin	Fungi Associated	Symptoms/Toxicology
Aflatoxin	*Aspergillus flavus, A. parasiticus*	liver necrosis, liver tumors, reduced growth, depressed immune response, carcinogen
Fumonisin	*Fusarium moniliforme, F. proliferatum*	equine leukoencephalomalacia, porcine pulmonary edema
Deoxynivalenol	*F. graminearum*	feed refusal, reduced weight gain, diarrhea, vomiting
Trichothecenes	*F. graminearum, F. culmorum, F. poae*	alimentary toxic aleukia, necrosis, hemorrhage, oral lesion in broiler chickens
Ochratoxins	*Penicillium verrucosum, Aspergillus ochraceus*	porcine nephropathy; various symptoms in poultry
Citrinin	*Penicillium* spp., *Aspergillus* spp	kidney damage
Cyclopiazonic acid	*Penicillium* spp., *Aspergillus* spp.	Neurotoxin
Sterigmatocystin	*Aspergillus* spp., and others	carcinogen, mutagen

Source: Koennig and Payne, 1999; pg. 4.

2.5.3 Worker Safety

Workers engaged in corn production may encounter insecticides, herbicides, fungicides or fertilizers that may pose a worker health or safety risk unless used in accordance with the US-EPA -established agriculture-specific requirements in the Worker Protection Standard (US-EPA, 1992) that protect field workers from the hazards of chemical exposure. The Occupational Safety and Health Administration requires all employers to protect their employees from hazards associated with agricultural chemicals.

Pesticides are used on most corn acreage in the US, and changes in acreage, crops, or farming practices can affect the amounts and types of pesticides used and thus the risks to workers. Registered pesticides, including the representative products listed in Table C-1 (in Appendix C, (Syngenta, 2011c)) must have use restrictions that, if followed, have been determined to be protective of worker health.

2.6 Socioeconomic

Corn agriculture can affect socioeconomic resources such as the domestic economy, international trade economy, and the social environment. This section describes key current issues within each of these topics.

2.6.1 Domestic Economic Environment

Domestic demand for corn in the US comes from its use for feed, ethanol production, food, and seed, and totaled 11.1 billion bushels in the 2009/2010 marketing year (USDA, 2011b). Exports (as described in Section 2.7.2, *Trade Economy*) added another 2 billion bushels to total US corn demand. Demand is satisfied almost entirely by domestic supply with few imports, the US being largely a net exporter of corn. In the 2009/2010 marketing year, feed was approximately 40 percent of US corn production; food, seed, and industrial uses were approximately 45 percent (including ethanol production, at about 36 percent), and exports the remaining 15 percent (USDA, 2011b).

US corn farms have increased cash receipts from $34.1 billion in 2007 to a projected $62.0 billion in 2011, representing an increase from 22.7 percent of the US crop market to 30.0 percent (USDA-ERS, 2011c). Annual cash receipts for corn as compared to all crops are shown in Table 5.

Table 5: Corn and Crop Cash Receipts

Year	Cash Receipts ($ billions)	
	Corn	All Crops
2007	34.1	150.1
2008	48.4	175.0
2009	42.5	168.3
2010	44.8	172.9
2011	62.0	206.5

Source: USDA-ERS, 2011c; pg. 1.

Net returns for corn farmers fluctuated between $125 and $200 per acre from the mid-1990s until the mid-2000s, but more than doubled in price to nearly $400 per acre in the late 2000s (USDA-ERS, 2011b). Net returns are expected to remain near $350 per acre for the next decade. USDA-ERS attributes the recent increase and projected future high prices to ethanol demand, in part due to the renewable fuel standard component of the *Energy Policy Act* (*Energy Policy Act of 2005*). The recent average annual market price of corn in the (USDA-NASS, 2011g) has been relatively high, due in part to the ethanol demand:

- 2008-- $4.06/bushel
- 2009-- $3.55/bushel
- 2010-- $5.40/bushel

There is a niche market for non-transgenic food and feed in the US, as is evident from private labeling initiatives such as the Non-GMO Project. This initiative offers third-party product verification and labeling for non-transgenic products.[2] There also is a niche market for organic products in the US. Sales of organic products have been growing quickly, from $1 billion in 1990 to $26.7 billion in 2010, with a 7.7 percent increase between 2009 and 2010 alone (Eisenthal, 2011). To satisfy the demand for organic corn, producers have had to adopt specific production practices to maintain and prevent the use of excluded methods as dictated by the NOP. To offset the increase in investment related to these more extensive practices, premiums are often paid for non-transgenic or organic corn. For example, August 2011 non-organic corn in the US averaged $6.88 per bushel (USDA-NASS, 2011e).

Grower selection of strategies for corn rootworm management is dependent upon the price received for corn, so that when the corn is highly valued, then additional strategies can be chosen. While corn price remained in the $2/bushel range from 2002-2006, use of soil applied insecticide attained to about 25 million acres (GfK Kynetic Market Research, database inquiry in, Syngenta 2011 (Syngenta, 2011b) or about 31% of the planted crop. As the price of corn increased between 2006 and 2008 to $3-5/bushel, this coincided with increasing choice of rootworm resistant hybrids, reaching about 35 million acres or 38% of planted acres in 2008 (GfK Kynetic Market Research, database inquiry in, Syngenta, 2011 (Syngenta, 2011b) while 10% of planted acres continued to use insecticide application for larval root worm control. As the price of corn approaches $6/bushel, treatment for expected high rootworm populations with both a *Bt* trait hybrid and soil insecticide such as Force G or Force CS can increase the yield 10.9 bushels/acre and result in a possible $65/acre gain for growers (see Syngenta, 2011 (Syngenta, 2011b). The yield increase may be caused not only by increased corn rootworm control, but also of secondary pests such as wireworms, and Japanese beetle larvae (Syngenta, 2011b).

2.6.2 Trade Economic Environment

Agribusiness is one of the world's largest industries, employing 1.3 billion people and producing $1.3 trillion worth of goods each year (Shelton et al., 2002). The US is the largest world exporter of corn, averaging nearly 50 million metric tons per year between 1990 and 2010 (USDA, 2011b). US corn exports within the last decade peaked at 61 million metric tons in 2007/08 (USDA-ERS, 2009b). In 2010, the total value of US corn exports was nearly $8 billion (USDA-ERS, 2011). During the last half decade, the US share of world corn exports averaged 60 percent; the second largest exporter is Argentina. Japan is the world's largest corn importer, typically followed by South Korea, Mexico, Egypt, and Taiwan (USDA-FAS, 2011).

[2] See Non-GMO-Project website: http://www.nongmoproject.org/.

The primary US corn export destinations are also the largest world importers of corn and do not have major barriers for importing transgenic products. Data on international trade in organic corn are not readily available but trade in organic corn is likely to be a very small share of the total corn trade.

The USDA Interagency Agricultural Projections Committee forecasts near-term production increases for grain products in general, in response to recent global supply-and-demand conditions (USDA, 2011b). Prices are projected to decline globally in the short term as production expands. Steady growth in production and historically high prices are projected long term, through 2020. Assuming that current subsidies and tariffs remain in effect, corn is expected to remain the primary feedstock for US ethanol production, comprising about 36 percent of the total corn use.

2.6.3 Social Environment

Social issues related to corn include farmer and consumer choice, as well as the structure of US corn farms. Farmers have a range of options in agronomic practices, seed products (non-transgenic, transgenic, and organic), and markets for their products. Consumers have a range of corn products to choose from in a free market system such as the US.

Genetic engineering has exerted a downward pressure on food prices by increasing agricultural productivity. Relatively lower food prices presumably allow consumers to choose between a greater variety of products that are now more affordable. Transgenic crops can positively contribute to sustainability for farmers. Traits such as herbicide tolerance and insect resistance, as described in Section 2.2, *Corn Production*, offer opportunities for making agriculture more sustainable (Franke et al., 2011). The advent of the NOP in the US has also increased consumer choice, as is evident by the rapid growth of the organic market segment (*see* Sections 2.2.3.1 and 4.2.2.1).

US corn farms and their operators are similar in many respects to those of other feed grain crops. According to data from the 2003 Agricultural Resource Management Survey (ARMS), the majority of feed grain farms (84 percent) raised corn (Hoffman et al., 2007); overall feed grain data are therefore generally applicable to corn farms when grain-specific data are not available. Feed grain farms operate more acres per farm, have higher gross and net incomes per farm, and have higher values of farm equity per farm than nonfeed grain farms. Feed grain operators were much more likely to list farming as their occupation and were more likely than operators of nonfeed grain farms to operate a farm organized as a partnership or family corporation (Hoffman et al., 2007). Only 29 percent of all feed grain farms specialized in feed grains, but those farms accounted for 51 percent of all feed grain production, and most of the specialized farms were corn farms (Hoffman et al., 2007).

In 2003, feed grain farms' average annual net cash income was $45,916, compared to $8,875 for nonfeed grain crops (Hoffman et al., 2007). The ratio of cash expense to gross cash income was 75 percent for feed grain farms, compared to 85 percent for nonfeed grainfarms (Hoffman et al., 2007). The total household income (from all sources) for corn farm operators averaged about $70,000 in 2003, nearly $10,000 above the US average household income that year but nearly equal to the average income from nonfeed grain farm families (Hoffman et al., 2007). Off-farm income sources include off-farm employment, investment income, pensions, Social Security payments, and gifts (Hoffman et al., 2007). Additionally, there are four types of government payments to feed grain operators: direct; counter-cyclical and loan deficiency; conservation reserve, wetland reserve, and environmental quality incentives program payments; and other (Hoffman et al., 2007). For corn operators, these programs contribute some 15 percent of their cash income. Direct government payments accounted for about 8 percent of average gross cash income for corn farms in 2003 (Hoffman et al., 2007) while the other three categories comprised another 7 percent of cash income for corn farmers (Hoffman et al., 2007).

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of 5307 corn. To respond favorably to a petition for nonregulated status, APHIS must determine that 5307 corn is unlikely to pose a plant pest risk. Based on its PPRA USDA-APHIS, 2011), APHIS has concluded that 5307 corn is unlikely to pose a plant pest risk. Therefore APHIS must determine that 5307 corn is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Two alternatives are evaluated in this EA: (1) no action and (2) determination of nonregulated status of 5307 corn. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

3.1 No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. Event 5307 corn and progeny derived from 5307 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 5307 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 5307 corn.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRA that 5307 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2011). 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 Proposed Action: Determination That Event 5307 Corn Is No Longer a Regulated Article

Under this alternative, 5307 corn and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. Event 5307 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2011). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of 5307 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 5307 corn is unlikely to pose a plant pest risk, a determination of nonregulated status of 5307 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.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for 5307 corn. 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 5307 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 Event 5307 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 5307 corn, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that 5307 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2011).

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 PPRA (USDA-APHIS, 2011) and the scientific data evaluated therein, APHIS concluded that 5307 corn is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of 5307 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 5307 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2011), 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 Event 5307 Corn 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 5307 corn from conventional or specialty corn production. However, because APHIS has concluded that 5307 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2011), 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 5307 corn based on the location of production of non-GE corn in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' PPRA for 5307 corn, there are no geographic differences associated with any identifiable plant pest risks for 5307 corn (USDA-APHIS, 2011). This alternative was rejected and not analyzed in detail because APHIS has concluded that 5307 corn does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. However, individuals might choose on their own to geographically isolate their non-GE corn production systems from 5307 corn or to use isolation distances and other management practices to minimize gene movement between corn fields. Information to assist growers in making informed management decisions for 5307 corn is available from Association of Official Seed Certifying Agencies (AOSCA, 2011).

3.3.4 Requirement of Testing for Event 5307 Corn

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because 5307 corn does not pose a plant pest risk (USDA-APHIS, 2011), 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 5307 corn would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.4 Comparison of Alternatives

Table 6: Summary of Environmental Consequences 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 6: Summary of Environmental Consequences

Resource	Alternative	
	No Action	Preferred Alternative: Determination of Nonregulated Status
Corn Production		
Production and Yield	Unchanged	Unchanged
Agronomic practices	Unchanged	Unchanged

Specialty Corn systems	Unchanged	Unchanged
Raw and processed corn commodities	Unchanged	Unchanged
Physical Environment		
Water quality and use	Unchanged	Unchanged
Soil	Unchanged	Unchanged
Air quality	Unchanged	Unchanged
Climate	Unchanged	Unchanged
Biological Environment		
Animals	Unchanged	Unchanged
Plants	Unchanged	Unchanged
Soil Microorganisms		
Biodiversity	Unchanged	Improved
Gene movement in the natural environment	Unchanged	Unchanged
Public Health		
Human health	Unchanged	Unchanged
Animal (livestock) health	Unchanged	Unchanged
Worker safety	Unchanged	Improved
Socioeconomics		
Domestic economic environment	Unchanged	Improved
Trade economic environment	Unchanged	Unchanged
Social environment	Unchanged	Unchanged

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 Event 5307 corn does not pose a plant pest risk and therefore should no longer be regulated under 7 CFR 340. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for 5307 corn are described in detail throughout this section. A cumulative impacts analysis is presented in Chapter 5. The agronomic characteristics of this product and its cultivation would not differ under the alternatives except the phenotype of rootworm tolerance selected for this product, and the comparisons aredescribed below.

4.1 Scope of Environmental Analysis

The scope includes any land in the U.S. currently producing corn, any land that is currently producing crops that could incorporate a corn rotation, as well as land that could be converted from inactive cropland to active cropland, and land currently in the Conservation Reserve Program (CRP) that could be removed from the program and farmed. Conversion of grassland, forest, or other land types to cropland as a result of a determination of nonregulated status of 5307 corn would be less likely because these types of conversions have not been notable contributors to cropland over the past 18 years; therefore, APHIS does not consider them to be part of the affected environment in this EA.

To determine areas of corn production, APHIS used data from the National Agricultural Statistics Service (NASS) (USDA-NASS, 2011a; USDA-NASS, 2011c). Corn grain is commercially produced in all states except Alaska. However, the majority of the corn produced in the U.S. is cultivated in 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-ERS, 2011b; USDA-NASS, 2011c), (USDA-NASS, 2011a). Iowa and Illinois, the two top corn-producing states, typically account for slightly more than one-third of the total U.S. corn crop (USDA-ERS, 2011h).

Other Assumptions

The environmental consequences of the different alternatives described above will be analyzed under the assumption that farmers, who produce conventional corn, 5307 corn, or produce corn using organic methods, are using reasonable, commonly accepted best management practices for their chosen system and varieties during agricultural corn production. However, APHIS recognizes that not all farmers follow these best management practices for corn. Thus, the analyses of the environmental affects will also include the assumption that some farmers do not follow these best management practices.

4.1.1 Persistence in the Environment/Weediness Potential

Syngenta assessed agronomic categories that are associated with persistence in agricultural environments, or with changes in status that might be associated with weediness. For the 5307 cultivar Syngenta assessed seed germination and dormancy, growth characteristics, reproductive capability, seed dispersal, and interactions with abiotic stressors and biotic stressors. The 5307 cultivar was compared to suitable control plants (see section VII.a.2, Syngenta, 2011c) and no biologically meaningful differences were observed. Syngenta 5307 is no more likely to be weedy or invasive than the parental cultivar.

4.2 Corn Production

This section describes the potential impacts to agronomic practices, specialty corn systems, and raw and processed corn commodities that may result from the No Action and Preferred Alternatives.

4.2.1 Production and Yield

Acreage and Areas of Corn Production

The amount of transgenic corn planted in the US indicates an increasing trend. Of the total corn acres planted in 2011, 88 percent were transgenic varieties (USDA-NASS, 2011g), up from 61 percent in 2006 (USDA-NASS, 2006a). As described in Section 2.2.1, *Production and Yield*, most increases in corn production are expected to be a result from yield growth rather than increases in planted areas, although corn acreage is expected to vary between 2011 and 2020 by about 2 percent (USDA-ERS, 2011f), likely deriving from acreage converted from other crops and not new production acreage. Substantive changes in corn production acreage and areas are more likely to result from changed market conditions and new federal policies than from any other source.

Arable land for increased corn planting acreage could result from the return of CRP lands to agricultural production. The 2008 US Farm Bill (*Food, Conservation, and Energy Act of 2008*, (FCEA) reduced CRP lands from 39.2 million acres to 32 million acres (FCEA; Section 2103, Paragraph (3)). Available acreage for corn production could increase by this federal policy change. The conversion of CRP acres, if it were to occur, would be independent of the adoption of transgenic corn products; in the period between 2011 and 2020, USDA-ERS predicts, however, that CRP acres should remain around 32 million acres (USDA-ERS, 2011f).

No Action Alternative

The acreage and areas of corn production are not likely to change as a direct or indirect result of the No Action Alternative. Regulated field trials of 5307 corn would only impact small plots of land with no effect on the acreage and areas of corn production. Conventional production practices that use transgenic varieties would likely continue to increase, based on current acreage trends. Current trends in the acreage and areas of production are likely to continue to be driven by market conditions (i.e., increased demand for US corn and corn products for animal feed, ethanol, etc.) and federal policy even if 5307 corn continues to remain a regulated article. It is anticipated that seed with transgenic traits and non-transgenic hybrids would continue to be available under the No Action Alternative. Corn is currently produced in 49 states (all states but Alaska, according to the 2002 Census of Agriculture) and under the No Action Alternative, the range of production would be unchanged. The USDA ERS does not predict any net increases in CRP acreage converted to corn production between 2012 and 2019 (USDA-ERS, 2011f), and so CRP acreage would not be affected by this alternative.

Preferred Alternative

Consistent with the demonstrated lack of agronomic difference and other considerations, acreage and areas of corn production are expected to be unchanged under the Preferred Alternative. Overall impacts would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available.

Agronomic characteristics of Event 5307 corn are similar to other corn varieties currently available and grown in the U.S.; there were no statistically significant differences in most agronomic traits between 5307 corn and a non-transgenic, near-isogenic control hybrid (Syngenta, 2011c). Syngenta studies identified small but statistically significant differences in grain moisture, plant height, the number of heat units to 50 percent pollen shed, and grain yield (Syngenta, 2011c). However, there were no observed deficits in agronomic performance of 5307 corn.

The acreage and areas of corn production are not likely to change as a direct or indirect result of the Preferred Alternative. In 2011, transgenic corn accounted for 88 percent of all corn acres in production in the US and, as noted above, the use of transgenic corn seed has been increasing. In the period 2006-2008, mmost corn growers increased corn acreage at the expense of acreage typically planted to other crops and only 2% converted CRP lands to corn production (USDA-ARS (Wallander et al., 2011)). However, with an increase in price of $1 per bushel, increasing replacement of CRP acres could occur, and economic models generally agree with this forecast (Gill-Austern, 2011). A determination of nonregulated status of 5307 corn is not expected to alter the range of corn cultivation as the new transgenic trait (rootworm resistance) does not otherwise change the plant's agronomic performance compared to non-transgenic varieties (Syngenta, 2011c).

Growers are not expected to change the acreage or areas of corn production as a result of a determination of nonregulated status of 5307 corn. This alternative would not result in new acreage removed from CRP set-asides for corn production if previous trends continue (Wallander et al., 2011) because the traits will not change corn characteristics, and corn acreage is not expected to significantly increase between 2012 and 2017 (USDA-ERS, 2011f). However, as earlier noted, if corn prices increase by $1 per bushel or more, then CRP acres can be predicted to be converted by growers for corn production (Gill-Austern, 2011). Current trends in the acreage and areas of corn production are likely to continue to be driven by market conditions and federal policy if 5307 corn is no longer subject to regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

4.2.2 Agronomic Practices

Crop Rotation and Tillage

Crop rotations are used to optimize soil nutrition and fertility, and reduce pathogen loads. As described in Section 2.2.2, *Cropping Practices*, crop rotation is an effective measure for controlling corn rootworm, although in some areas, variant rootworm populations display behavioral changes that circumvent rotation strategies. Some northern corn rootworm populations have an extended diapause that allows eggs to hatch when the crop rotation returns to corn rather than in the non-corn rotation crop in the growing season that follows corn. A variant western corn rootworm population now lays its eggs in soybean fields rather than corn fields, allowing eggs to hatch in fields rotating to corn.

Tilling the soil reduces weeds that would otherwise crowd or compete with the corn crop. (US-EPA, 2009). Until recently, conventional tillage was commonplace, using moldboard plows prior to planting followed by secondary tillage (Allmaras, et al., 1997 in (US-EPA, 2009)). Reduced or conservation tillage methods have largely replaced conventional methods. Reduced tillage uses chisel plows and results in less soil disturbance. Conservation tillage also uses chisel plows and includes no-till and focused methods such as strip, ridge, or mulch tillage. The intensive plowing of conventional tillage results in less than 15 percent crop residue (unharvested plant material); reduced tillage is associated with 15 to 30 percent crop residue; and conservation tillage is associated with at least 30 percent crop residue and substantially less soil erosion than other tillage practices (US-EPA, 2009).

Conservation tillage methods have been increasingly favored by growers for reducing soil water loss and promoting decreases in soil loss. Because of its low cost and positive impact on soil quality, conservation tillage is currently and widely practiced in the Midwestern US (see map, USDA-NRCS, (USDA-NRCS, 1999), showing substantial parts of corn belt states with 40-60% and 60-90% conservation tillage).

No Action Alternative

Cropping practices, including crop rotation and tillage are not likely to change as a direct or indirect result of the No Action alternative. Cropping practices are likely to continue to be driven by market conditions even if 5307 corn continues to remain a regulated article. The current economics of corn production are driving the change or perceived change in crop rotation practices. Growers make choices to plant certain corn varieties and use certain crop rotation practices based on factors such as yield, weed and disease pressures, cost of seed and other inputs, technology fees, worker safety, potential for crop injury, and ease and flexibility of the production system (Olson and Sander, 1998), ; (Gianessi, 2005). Under the No Action Alternative, the demands for and the price of corn would continue to depend on the market needs for field corn, and corn-to-corn rotations would continue to be used by farmers if this cropping practice meets the economic and marketing strategy for the particular farmer. Regulated field trials of 5307 corn would only impact small plots of land with no effect on cropping practices.

Changes in rotation practices are more likely to result from market conditions than other factors. A recent increase in corn-to-corn rotations has been attributed to the increase in corn prices due to higher demand, driven primarily by ethanol production (Hart, 2006; Vyn, 2006). In fact, corn-on-corn rotation was used prior to the increase in corn for ethanol production (Erickson and Lowenberg-DeBoer, 2005). Corn-on-corn rotations may provide a continual host environment for some insects and diseases. However, in a farm on a corn-soybean rotation, continuously growing corn for multiple seasons can decrease populations of soybean pests, such as soybean cyst nematode. In some areas, corn-on-corn rotation has increased levels of fertilizer inputs (Sawyer, 2007).

Tillage practices are unlikely to change under the no action alternative. Tillage practices will likely remain as it is practiced today by the farming community.

Preferred Alternative

Overall impacts would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Cropping practices such as rotation are not likely to change as a direct or indirect result of the Preferred Alternative. Although high dosage corn rootworm-resistant products could potentially reduce pressure on corn, effective corn rootworm-management for all corn will still require crop rotation as a frequent component for integrated insect control and also to limit development of resistance (Gray, 2011b; Gray, 2011c); Syngenta 5307 appears not significantly more effective than other CRW traits (Hibbard et al., 2011). Stacking with two or more rootworm specific proteins is likely to support better rootworm management. US-EPA asserted that current simulation models "strongly suggest that pyramided PIPs are superior to the current single trait CRW products" (US-EPA, 2009a). Despite a potential relaxation of a need for rotation in CRW control, other benefits of crop rotation (e.g., increased yield, benefits to soil, farm economics) would remain and could be more important to the grower than convenience of continuous corn production.

The current economics of corn production are driving changes in crop rotation practices as farmers seek the most profitable production method. Corn-on-corn ("continuous corn") is used by some growers in response to market demands and expectations of higher economic returns (Erickson and Lowenberg-DeBoer, 2005; Malcolm et al., 2009). A determination of nonregulated status of 5307 corn would not change the price of corn commodities in the US because prices would continue to be set by market demand. A determination of nonregulated status of 5307 corn would not likely affect a farmer's decision to initiate crop rotation, or to increase the overall use of corn-on-corn rotation as a cropping strategy with the US farming community, since in the first case, the overall decision for tillage type may be a global one, with many inputs constraining choices (see Thomason, 2009), and in the second case, a predominantly economic benefit governs the grower choices (Erickson and Lowenberg-DeBoer, 2005).

A determination of nonregulated status of 5307 corn would not directly or indirectly impact tillage practices, because APHIS makes the assumption that growers have previously optimized these practices for maximizing their economic return and in consideration of relative benefits for specific soil or other physical and environmental conditions on their farm operation (examples of the tillage considerations corn growers must make are summarized in certain extension publications (Thomason et al., 2009). Growing Event 5307 corn would not require any different agronomic approaches than with similarly available corn varieties.

Irrigation

As described in Section 2.2.2, *Irrigation*, supplemental irrigation is used in some corn production areas, such as the western portion of the Corn Belt during the growing season and during flowering. Irrigation rates are affected by local climate conditions (seasonal rainfall), and climate change could increase or decrease irrigation rates in some areas.

No Action Alternative

Irrigation practices are not likely to change as a direct or indirect result of the No Action Alternative. Irrigation rates are likely to continue to be driven by climate conditions. Regulated field trials of 5307 corn would be relegated to small plots of land with no effect on irrigation rates.

Preferred Alternative

Consistent with the demonstrated lack of agronomic difference, overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Irrigation practices would not change as a direct or indirect result of the Preferred Alternative. The damage inflicted by corn rootworm larvae can significantly reduce grain yield by interfering with photosynthetic rates and by limiting the uptake of water and nutrients (Syngenta, 2011c). Reducing rootworm-caused damage would only affect plant water efficiency, and not irrigation rates. Similar to the no action alternative, irrigation rates would continue to be dependent upon climate and weather conditions. Because the eCry3.1Ab protein prevents the negative physiological impact of root pruning by rootworm, 5307 corn may allow more efficient use of water and fertilizer (Syngenta, 2011c); Appendix A of the EA).

Insect Management

As described in Section 2.2.2, *Insect Management*, corn growers use a variety of methods, including applying restricted use chemical pesticides (specifically, insecticides), to control insect pests. Broad-spectrum insecticides may impact agriculturally important non-target organisms (US-EPA, 2005 {US-EPA, 2005b #101}), including beneficial insects such as honeybees or insects that prey on other insects. Before the introduction of *Bt*-derived corn varieties, the tools available to growers for insect control consisted of insecticide applications, agronomic practices, and, to a limited extent, the use of corn varieties with a degree of native pest resistance. *Bt*-derived products have a limited activity spectrum and affect only certain orders of insect pests. *Bt*-derived products are active only if they are ingested and activated by certain organisms, and they are selective because only organisms with gut receptors that bind specific *Bt* proteins are affected. Use of broad-spectrum or *Bt*-derived insecticides, however, can result in insects developing resistance to the insecticide.

The introduction of the first *Bt* corn varieties in 1996 provided growers with an effective means of limiting damage caused by the European corn borer. Prior to the introduction of corn rootworm-protected *Bt* corn varieties in 2003, an estimated 14 million acres were treated annually with conventional insecticides to control corn rootworm. This equated to applications of more than 7.7 million pounds of insecticide active ingredients annually in corn fields for the control of *Diabrotica* species (Dubelman et al., 2005). Control of *Diabrotica* spp. accounted for the largest single use of conventional insecticides in the US at that time.

Transgenic varieties for corn rootworm control are as effective, or more effective, than chemical insecticides used for rootworm control (Gianessi, 2005; Tinsley et al., 2011). Available data indicate that broad-spectrum insecticide use in corn agriculture has declined since the introduction of insect resistant corn varieties. Some estimates indicated that reductions in chemical insecticide use on the order of 70 percent (Oehme and Pickrell, 2003) to 75 percent (Rice, 2004) could result from widespread adoption of corn rootworm-protected varieties. For example, Rice (2004) reported that insecticide use for corn rootworm control could be reduced by over 5 million pounds per year if 10 million acres of transgenic corn were planted (compared to approximately 92 million acres of corn planted in the US in 2011).

Increased adoption of corn rootworm-protected corn products may have certain environmental benefits because many of the restricted use chemical insecticides registered for corn rootworm control present a certain level of potential risks to applicators, other agricultural workers, and wildlife. The soil-applied and foliar chemical insecticides for larval and adult corn rootworm control were subject to the greatest use reductions following the adoption of transgenic rootworm-protected corn varieties and include organophosphates, carbamates, pyrethroids, and pyrazoles (Vaughn et al., 2005). Adoption of additional rootworm-protected corn varieties is not expected to markedly reduce the use of insecticidal seed treatments used to control other soil pests such as wireworms and grubs; when used for corn rootworm control, these seed treatment products are applied at a lower rate (e.g., Cruiser 5FS (Syngenta, 2010a). Using soil-applied granular insecticide formulations, application rates for both types of pests may not differ (e.g., Force 3G (Syngenta, 2010b).

Corn rootworm populations have developed resistance to some insecticides and to non-chemical control methods.[3] Resistance to some corn rootworm insecticides may result in increased chemical use (US-EPA, 2010b; US-EPA, 2010e). As an alternative, crops engineered to produce *Bt* toxins that target specific pest taxa have had favorable environmental effects, particularly when replacing broad-spectrum insecticides (NRC, 2010; Carpenter, 2011). Insect-resistant transgenic corn, including stacked-trait varieties with herbicide tolerance, accounted for 65 percent of corn acres planted in 2011 (USDA-ERS, 2011a).

Rootworm-protected *Bt* corn hybrids have been available to US growers since 2003. The current PIP proteins registered for corn rootworm control in field corn are Cry3Bb1 (in MON 863 and MON 88017), Cry34Ab1/Cry35Ab1 (in DAS 59122-7), and mCry3A (in MIR604). As the industry trend is towards combined-trait hybrid offerings, these Cry proteins are available in multiple combinations. From the perspective of preventing or mitigating resistance in target pest populations, the deployment of multiple corn rootworm traits in a single corn hybrid may benefit the durability of the registered PIPs in corn.

No Action Alternative

Trends in insecticide use are not likely to change as a direct or indirect result of the No Action alternative. Corn production, and pesticide use in corn, would remain as it is practiced today by the farming community. Insecticide use rates are likely to continue to decline even if 5307 corn continues to remain a regulated article, as growers will continue to have access to existing insect-resistant corn varieties that are no longer subject to the requirements of Part 340 and the plant pest provisions of the PPA. Growers make choices to use certain pesticides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, fuel costs, worker safety, potential for crop injury, and ease and flexibility of the system (Olson and Sander, 1998; Gianessi, 2005).

Any environmental effects as a result of pesticide use in the agricultural production of corn would remain the same under the No Action Alternative. The availability of other corn rootworm-resistant varieties would continue if 5307 corn continues to remain a regulated article. Corn growers are likely to continue to use the wide spectrum of available conventional pesticides or any of the four other corn rootworm-resistant cultivars that are currently available, as listed in Table 2-1, *Transgenic Corn Cultivars Containing Bt-derived Proteins with Nonregulated Status*. Regulated field trials of 5307 corn would only impact small plots of land with little effect on insecticide use.

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[3] Arthropod populations having pesticide resistance are listed on Arthropod Pesticide Resistance Database.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Corn growers would have a new corn rootworm-control option to use in addition to the three other corn rootworm-resistant Cry proteins that are currently available, as listed in Table 2-1, *Transgenic Corn Containing Bt-derived Proteins with Nonregulated Status*. Similar to the no action alternative, trends in reducing insecticide use are likely to continue.

Similar to the no action alternative, there is concern about the ability of corn rootworm to evolve resistance to control mechanisms that include crop rotation, chemical insecticides, and rootworm-protected *Bt* corn products. Syngenta 5307 corn has demonstrated efficacy against corn rootworm and the eCry3.1Ab protein may have a different mode of action from that of at least one other CRW specific *Bt* (Walters et al., 2010). Consequently, 5307 corn may extend the useful life of other commercially available corn rootworm-protected *Bt* corn cultivars (i.e., containing Cry3Bb1, Cry34Ab1/Cry35Ab1 or mCry3A). However, the activity of the 5307 CRW toxin is not strictly additive with that of pyramided MIR604 lines in field trials or in reports of other combinations of CRW targeted *Bt*s (Hibbard et al., 2011). Nevertheless, the availability of eCry3.1Ab as an additional tool for rootworm control could also reduce the selection pressure on rootworm populations to develop resistance to other methods of pest control. As noted earlier in the Affected Environment section, if more rootworm control efficacy is available through new CRW resistance traits, the need by growers for augmenting their use of CRW resistant traits with insecticides declines, and the applications of restricted use pesticides would be avoided.

Similar to the no action alternative, the widespread use of transgenic *Bt* corn could generate selection pressures on insects for resistance to the plant-incorporated protectants (Tabashnik et al., 2008). To deter this type of resistance, the US-EPA requires refuges to minimize the potential for corn rootworm to develop resistance. The refuge requirements are product-specific and range from 5 to 20 percent of each corn field, and can be spatial (percentage of the field area) or as a portion of the seed mix ("refuge in a bag"), depending upon the specific product (US-EPA, 2007a). Varieties with multiple transgenic traits acting against a particular pest typically have smaller percentage requirements for refuges than single-trait products. The National Corn Growers Association promotes US-EPA mandated Insect Resistance Management strategies for all *Bt* containing corn varieties to corn growers, including corn rootworm-protected cultivars, to minimize the potential for the insects to develop such resistance (NCGA, 2012).

Some corn with the earliest developed CRW resistance trait (Cry3Bb1) has begun to show unexpected damage by rootworm, but apparently these low- or moderate-dose products have been placed under stress by grower noncompliance with refuges (extension surveys, (University-of-Illinois, 2011)), and planting of continuous corn has been an extensive local pattern (Gassmann et al., 2011). Nonetheless, insect resistance to Bt crops has not caused widespread failure of control measures, in part due to insect resistance management (IRM) strategies, requirements for growers to plant refuges of crop varieties lacking similar *Bt* traits and including pesticide use in these refuges and supplemental use on CRW resistant hybrids in some circumstances (Tabashnik et al., 2008). No evidence suggests that the control failures are affecting other CRW resistance traits at higher frequency (Cry 34/35, (Ostlie, 2011b), or MIR 604, (Hibbard et al., 2011), (Gassmann et al., 2011).

<u>Disease and other Pest Management</u>

Crop disease reduces both the quantity and quality of grain harvested. Disease loss estimates for corn production in the US range between 2 and 15 percent each year and reached 20 percent in 1970 with the southern corn leaf blight epidemic. Losses estimated for diseases are difficult to determine because of (1) Variation in yield potential between different years (2) Differences in genetic background of germplasm being grown; and (3) Potential for unfavorable environmental conditions. Estimates of corn yield loss caused by pathogens have ranged from 2 to 17 percent (Smith and White, 1998; Jeffers, 2004).

No Action Alternative

If APHIS does not determine that the Event 5307 has been shown to be appropriate for nonregulated status, continued planting of the variety in test plots will have no impact on disease management. Currently deployed strategies will continue to be used by growers, both for the test plots and in the vicinity of standard crops near test sites.

Preferred Alternative

Availability of the Event 5307 corn will have no impact on disease management issues. Disease resistance traits will continue to be an option chosen frequently by growers as needed in their area, since these are made available as nontransgenic traits commonly incorporated into local commercial offerings.

Weed Management

Yield losses in all crops due to weeds, diseases, and insects were substantial and widespread until the introduction and adoption of crop protection chemicals in the 1950s (Wheeler, 2002). Weeds compete with crops for light, nutrients, water, and other growth factors. If weeds are left uncontrolled, corn cannot be grown economically.

No Action Alternative

If APHIS does not determine that the Event 5307 has been shown to be appropriate for nonregulated status, continued planting of the variety in test plots will have no impact on weed management or of disease management. Currently deployed strategies will continue to be used by growers, both for the test plots and in the vicinity of standard crops to test sites.

Preferred Alternative

Availability of the Event 5307 corn will have no impact on pest management issues, either of weeds or of diseases. Growers will choose either stacked varieties of 5307 corn with herbicide tolerance and manage the crops with herbicides exactly as they do with varieties not expressing the CRW-resisting protein, or make use of other methods of weed control.

4.2.3 Specialty Corn Systems

Organic Crop Production

Certified organic corn acreage is a small but increasing percentage of overall corn production. The most recent data indicates that the certified organic corn acreage in 2008 was approximately 195,000 acres, representing 0.21 percent of the total field corn acreage (USDA-ERS, 2010a) in the US. This was an increase of nearly 50 percent from the 131,000 acres in organic corn production in 2005, which represented 0.16 percent of the total field corn acreage that year. Comparatively, transgenic corn accounted for 80 percent of the 87.3 million acres of field corn planted in 2008, (USDA-NASS, 2008) about 69.8 million acres. That number represents an increase in plantings for transgenic corn since 2005, when transgenic corn accounted for 52 percent of the 81.6 million acres of field corn planted that year (USDA-NASS, 2005), about 42.4 million acres.

Organic corn growers may benefit from transgenic crops grown nearby. Reducing populations of insect pests in transgenic crop fields can help lower population pressure in adjacent fields, organic or not, as is evident from economic analyses of avoided costs. For example, one study found that cumulative yield losses from *Bt* corn-suppressed European corn borer that would have occurred if the populations had remained at historic levels have been valued at over $4.3 billion in a 5-state region over 14 years (Hutchison et al., 2011). Such area-wide pest suppression could conceivably occur following sustained use of rootworm-resistant corn varieties, thus resulting in benefits to organic corn growers.

Organic farming operations, as described by the NOP and administered by the USDA-AMS, must have distinct, defined boundaries and buffer zones between adjoining land not under organic management to prevent unintended contact with prohibited substances (7 CFR 205.272). Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent (7 CFR 205.201). This plan enables the production operation to achieve and document compliance with the NOP, including the NOP prohibition on the use of excluded methods. Excluded methods include methods used to genetically modify organisms or otherwise influence their growth and development by means not possible under natural conditions or processes.

Typically, there is more than one method for farms under organic practices to prevent unwanted pollen or seed from entering their fields including: isolation of the farm, physical barriers or buffer zones between organic production and non-organic production, as well as formal communications between neighboring farms (ATTRA, 2003). The organic plan used as the basis for organic certification should include a description of practices used to prevent or reduce the likelihood of unwanted GE pollen or seed at each step in the farming operation, including planting, harvesting, storing and transporting the crop (ATTRA, 2003). Organic plans should also include mechanisms to monitor the risk of GE pollen or seed co-mingling with the organic crop (Kuepper, 2002). Farmers using organic methods are requested to let neighboring farmers know that they are using organic production practices and request that the neighbors also help the organic farmer reduce unwanted gene flow events (ATTRA, 2003; Krueger, 2007). Thus, commonly used production practices for corn, and the practical methods typically used by corn farmers using organic methods currently provide many measures that greatly reduce the likelihood of accidental gene flow between GE and non-GE corn fields. Efficacy of certified organic plans and practices to prevent the likelihood of unwanted substances is best represented by the parallel increases in both GE corn and organic corn production since 2000. These practices protect organic crops and thus maximize profits and price premiums accorded to corn under organic production. APHIS will assume that farmers are already using, or have the ability to use, these common practices as APHIS' baseline for the analyses of the following alternatives below.

No Action Alternative

Current availability of seed for conventional (both GE and non-GE) corn varieties, and those corn varieties that are developed for organic production, are expected to remain the same under the No Action Alternative. Under the No Action Alternative, 5307 corn and its progeny would continue to be regulated articles under the regulations at 7 CFR part 340. This however, will not change the ready availability of other corn hybrid varieties produced through GE methods. GE corn will continue to represent a large majority of corn production acreage, with GE corn totaling 88 percent of all corn production in the U.S. in 2007 (USDA-ERS, 2010a). Trends of conventional and organic commercial corn production will not change and will remain the same under the No Action Alternative. Planting and production of GE corn varieties and organic corn have both increased due to market demands over the last ten years, and these markets are likely to continue to increase under the No Action Alternative.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. Transgenic corn lines including those that are insect resistant are already in use by farmers. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Event 5307 corn should not present any new and different issues and impacts for organic corn producers and consumers. According to the petition, agronomic trials conducted in a variety of locations in the U.S. demonstrated that 5307 corn is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart. (Syngenta, 2011c). No differences were observed in pollen diameter, weight, and viability. Therefore, 5307 corn is expected to present no greater risk of cross-pollination than that of existing corn cultivars. The practices currently employed to preserve and maintain purity of organic production systems would not be required to change so as to accommodate the production of 5307 corn. Because suppression of corn rootworm populations may occur in the vicinity of 5307 production (analogous to the suppression of lepidopteran pests in other *Bt* expressing hybrids), organic crops should be favorably impacted by lessened rootworm populations and consequently less root damage than when 5307 hybrids are not grown.

A determination of nonregulated status of 5307 corn is unlikely to significantly impact organic farmers that choose not to plant or sell corn products produced through genetic engineering or other non-organic production systems. Despite the wide-spread adoption of conventional and GE corn in the U.S. that amounted to 99.8 percent of total corn production in the U.S. in 2007, organic corn production has also continued to expand in recent years (USDA-ERS, 2010a). This continued expansion of organic corn acreage, though minor relative to non-organic national and state corn production, reinforces the capacity of current organic system plans to avoid use of excluded methods (and thus, loss of NOP certification) and the efficacy of these plans to increasingly produce agricultural products to meet demand of target markets in spite of the overwhelming presence of non-organic farming systems.

States that represented major organic corn production areas ($\geq$ 10,000 acres) in the 2007 Agricultural Census included Iowa, Michigan, Minnesota, New York, and Wisconsin (Table 7). Organic corn production in these states represented 0.16 to 1.25 percent of total corn production in each state. GE varieties currently represent the majority of cultivated corn, organic corn production would still represent a fraction of total corn production. Prescribed NOP methods would continue to be just as effective in preserving certified organic status as they are under the no action alternative.

Table 7: Non-organic and organic corn production (harvested acres) in 2007. Data were calculated from the 2007 Agricultural Census (USDA-NASS, 2009).

State	Total Corn Production (acres harvested)*	Percent Non-organic	Organic Corn Production (acres harvested)**	Percent Organic
Alabama	288,881	100	0	0
Alaska	1	100	0	0
Arizona	61,408	100	0	0
Arkansas	587,858	99.992	45	0.008
California	675,445	99.588	2,780	0.412
Colorado	1,172,893	99.893	1,257	0.107
Connecticut	32,347	99.975	8	0.025
Delaware	200,827	100	0	0.000
Florida	100,542	99.978	22	0.022
Georgia	510,709	99.991	48	0.009
Hawaii	3,641	99.918	3	0.082
Idaho	333,022	99.999	4	0.001
Illinois	13,214,365	99.947	7,031	0.053
Indiana	6,528,585	99.977	1,533	0.023
Iowa	14,075,332	99.841	22,330	0.159
Kansas	3,847,088	99.903	3,746	0.097
Kentucky	1,409,781	99.990	138	0.010
Louisiana	726,897	100	0	0
Maine	28,703	98.631	393	1.369
Maryland	533,903	99.733	1,427	0.267
Massachusetts	21,575	99.754	53	0.246
Michigan	2,658,538	99.465	14,231	0.535
Minnesota	8,352,731	99.726	22,864	0.274
Mississippi	888,049	100	0	0
Missouri	3,332,832	99.898	3,410	0.102
Montana	83,344	99.996	3	0.004
Nebraska	9,438,807	99.903	9,200	0.097
Nevada	6,006	100	0	0
New Hampshire	14,611	99.966	5	0.034
New Jersey	100,766	99.991	9	0.009
New Mexico	136,008	99.512	664	0.488
New York	1,099,413	98.754	13,703	1.246
North Carolina	1,028,533	99.933	689	0.067
North Dakota	2,528,921	99.953	1,189	0.047
Ohio	3,834,164	99.767	8,926	0.233
Oklahoma	301,443	99.999	3	0.001
Oregon	88,692	95.407	4,074	4.593

State	Total Corn Production (acres harvested)*	Percent Non-organic	Organic Corn Production (acres harvested)**	Percent Organic
Pennsylvania	1,427,111	99.653	4,954	0.347
Rhode Island	2,549	100	0	0
South Carolina	388,481	100	0	0
South Dakota	4,841,686	99.933	3,245	0.067
Tennessee	838,499	99.998	16	0.002
Texas	2,121,694	99.859	2,990	0.141
Utah	68,303	100	0	0.000
Vermont	93,876	98.714	1,207	1.286
Virginia	530,781	99.816	974	0.184
Washington	294,929	97.651	6,927	2.349
West Virginia	46,918	100	0	0
Wisconsin	4,074,833	99.247	30,673	0.753
Wyoming	86,740	99.618	331	0.382

Note: * and ** represent corn for grain, corn for silage, popcorn, and sweet corn.
Source: Data were calculated from the 2007 Agricultural Census (USDA, 2009).

Other Specialty Corn Production Systems

As with the processes described above for seed production, specialty corn growers and end users maintain the identity of their products by contracts, tracking and traceability systems, quality assurance programs, closed loop systems, and identity preservation systems.

Specialty crop growers employ practices and standards for seed production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops (Bradford, 2006). These management practices include maintaining isolation distances to prevent pollen movement from other corn sources, planting border or barrier rows to intercept pollen, changing planting schedules to ensure flowering at different times, and employing natural barriers to pollen (Wozniak, 2002; ATTRA, 2003; Bradford, 2006; Thomison, 2009). These management practices allow the grower to meet standards for the production of specialty crop seed, maintain genetic purity, and protect the genetic diversity of corn (Bradford, 2006).

No Action Alternative

Other specialty corn production systems are not likely to change as a direct or indirect result of the No Action Alternative. Specialty products are likely to continue to be protected by the identity-preservation systems established in the industry even if 5307 corn continues to remain a regulated article. Regulated field trials of 5307 corn would only impact small plots of land with no effect on other specialty corn production systems.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Other specialty corn production systems are not likely to change as a direct or indirect result of the Preferred Alternative. Transgenic corn lines including those that are insect resistant are already in use by farmers. Event 5307 corn should not present any new and different issues and impacts for specialty corn producers and consumers. According to the petition, agronomic trials conducted in a variety of locations in the U.S. demonstrated that 5307 corn is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart (Syngenta, 2011c). No differences were observed in pollen diameter, weight, and viability. Therefore, 5307 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 specialty corn production systems would not be required to change so as to accommodate the production of 5307 corn.

4.2.4 Raw and Processed Corn Commodities

As described in Section 2.2.4, *Raw and Processed Corn Commodities*, there are no differences in handling requirements for processing transgenic and non-transgenic corn.

No Action Alternative

Raw and processed corn commodities are not likely to change as a direct or indirect result of the No Action Alternative. Raw and processed corn commodities would continue to be handled in accordance with regulatory standards and industry practices even if 5307 corn continues to remain a regulated article. Regulated field trials of 5307 corn would only impact small plots of land with no effect on raw or processed commodities.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Raw and processed corn commodities are not likely to change as a direct or indirect result of the Preferred Alternative. Based on Syngenta's field trials, compositional profiles of grain and forage from 5307 corn hybrids are equivalent to those of the corresponding non-transgenic hybrids and commercial hybrids (Syngenta, 2011c). Apart from the expected insect control benefits and associated benefits in crop yield and crop health, 5307 corn hybrids are agronomically equivalent to their non-transgenic counterparts (Syngenta, 2011c). Similar to the no action alternative, grain channeling and stewardship plans preserving and documenting product purity would continue and would not change as a result of a determination of nonregulated status of 5307 corn. Raw and processed corn commodities would continue to be handled in accordance with regulatory standards and industry practices.

4.3 Physical Environment

This section describes the potential impacts to water quality and use, soil, air quality, and climate that may result from the No Action and Preferred Alternatives.

4.3.1 Water Quality and Use

Water Quality

As described in Section 2.3.1, *Water Quality*, the primary cause of agricultural NPS pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. To a limited extent, some corn plant matter may be deposited in water courses adjacent to fields. Agronomic practices such as conservation tillage, crop nutrient management, pest management, and conservation buffers help protect water quality from agricultural runoff (Hoeft et al., 2000).

No Action Alternative

Water quality is not likely to change as a direct or indirect result of the No Action Alternative. Water quality would continue to be regulated by federal programs (some of which have been delegated to certain states) and agronomic practices to protect water quality would continue to be implemented even if 5307 corn remains a regulated article. Chemical insecticide use would likely continue to be reduced as transgenic corn products with insect resistance traits are developed, marketed, and adopted. Tillage practices would likely remain unchanged, so no increase in runoff into water sources would be observed. Crop nutrient management, pest management practices, and use of conservation buffers would likely be unchanged. Regulated field trials of 5307 corn would only impact small plots of land with no effect on water quality.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Water quality is not likely to change as a direct or indirect result of the Preferred Alternative. Tillage practices would not likely change because of adoption of this crop, nor would other agricultural practices such as fertilizer application, pest management or provision of buffers if this crop were adopted. Similar to the no action alternative, water quality would continue to be regulated by federal programs (some of which have been delegated to certain states) and agronomic practices to protect water quality would continue to be implemented (such as a high percentage of acres under conservation tillage).

Event 5307 corn does not contain any substances which have the potential to affect water quality and has no compositional differences from other commercial corn varieties, aside from the eCry3.1Ab protein. The eCry3.1Ab protein concentrations in 5307 corn are lowest at senescence, when grain is harvested, and any residual eCry3.1Ab protein is likely to degrade significantly during the period between harvest and transfer of any plant matter to the waterways (Syngenta, 2011c). In aquatic or terrestrial conditions any residual toxicity to target Lepidoptera of a related *Bt* expressed in corn does not persist for any longer than two weeks, and limited non target effects seem related to interactions between plant genetics and the environment, and not the *Bt* protein (Jensen et al., 2010). Water quantity in soil may have no effect on degradation, nor may pH, but increasing temperature increases degradation of Cry proteins (Feng et al., 2011).

Similar to the no action alternative, chemical insecticide use would continue to be reduced as transgenic corn products with insect-resistance traits are developed, marketed, and adopted, potentially improving water quality. Chemical herbicide use is not likely to change as a result of a determination of nonregulated status of 5307 corn.

<u>Water Use</u>

As described in Section 2.3.1, *Water Use*, the production of a bushel of corn requires some 4,000 gallons of water, by either rainfall or supplemental irrigation. Section 2.2.2, *Irrigation* explains that transgenic corn products do not affect irrigation rates also required by other corn varieties.

No Action Alternative

Water use is not likely to change as a direct or indirect result of the No Action alternative. Even if 5307 corn continues to remain a regulated article, irrigation rates would continue to be driven by local conditions (e.g., climate, water availability, water pumping capacity, and fuel and electrical costs). Regulated field trials of 5307 corn would only impact small plots of land with no effect on water use.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Water use is not likely to change as a direct or indirect result of the Preferred Alternative. As described in Section 4.2.1.3, *Irrigation*, 5307 corn does not change corn's water requirements. Similar to the no action alternative, irrigation rates would continue to be driven by local conditions.

4.3.2 Soil

As described in Section 2.3.2, *Soil*, agronomic practices such as crop type, tillage, and pest management regimes have greater effects on the biology of the soil than the type of corn cultivated. Degraded soil structure and composition may lead to decreased water retention, a decrease in soil carbon aggregation and net positive carbon sequestration, and increased greenhouse gas emissions. Conservation tillage methods can reduce these adverse effects (Holland, 2004) and full tillage by corn growers is declining ((Schimmelpfennig and Ebel, 2011) Table 8).

No Action Alternative

Soil characteristics are not likely to change as a direct or indirect result of the No Action Alternative. The adoption of insect-resistant corn varieties would be expected to continue. Corn growers would continue current agronomic practices and further declines in conventional tillage methods are expected even if 5307 corn remains a regulated article (Schimmelpfennig and Ebel, 2011) Table 8). Regulated field trials of 5307 corn would only impact small plots of land with no effect on soil characteristics.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Soil characteristics are not likely to change as a direct or indirect result of the Preferred Alternative. Event 5307 corn production would not change cultivation practices for transgenic or non-transgenic corn. Corn growers would continue current agronomic practices and would not change patterns of adoption of conservation tillage methods regardless of a determination of nonregulated status of 5307 corn. Event 5307 corn would not adversely impact soil composition. Most proteins do not persist or accumulate in soil because they are inherently degradable in soils that have normal microbial populations (Burns, 1982; Marx et al., 2005). Cry proteins from *B. thuringiensis* are rapidly degraded in a variety of soil types and these proteins do not accumulate

(Head et al., 2002; Mendelsohn et al., 2003; Dubelman et al., 2005). The eCry3.1Ab protein has been shown to have no biological activity after two weeks of incubation in "live" (with active microbes) loam soil (Syngenta, 2011c). For some Cry proteins residual amounts of *Bt* proteins may persist for extended periods (Feng et al., 2011), but at biologically insignificant quantities.

4.3.3 Air Quality

As described in Section 2.3.3, *Air Quality*, agricultural activities such as burning, tilling, harvesting, spraying pesticides, and fertilizing, including the emissions from farm equipment, can directly affect air quality. Aerial application of insecticides may impact air quality from drift, diffusion, and volatilization of the chemicals, as well as motor vehicle emissions from airplanes or helicopters.

No Action Alternative

With regard to transgenic corn with insect resistance traits, tilling, harvesting, and fertilizing practices do not vary between transgenic and non-transgenic agricultural varieties. Air quality impacts from aerial application of insecticides may vary between transgenic corn varieties with insect resistance traits and non-transgenic varieties because less insecticide application would be needed for transgenic varieties. Air quality is not likely to change as a direct or indirect result of the No Action Alternative. Corn growers would likely continue current trends in agricultural activities even if 5307 corn remains a regulated article. Regulated field trials of 5307 corn would only impact small plots of land with no effect on air quality.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Similar to the no action alternative, indirect air quality benefits (Section 4.2.2, *Insect Management*,) may result from the use of insect resistant crops because of a reduction of aerial application of corn rootworm pesticides used in adult rootworm suppression. Spray application of insecticides could continue to be reduced if additional insect-resistant varieties are adopted by growers because 5307 corn would give growers another option to resist damage by corn rootworm. However, because use of CRW resistant hybrids is not expected to greatly increase, air quality is not likely to change as a direct result of the Preferred Alternative. Corn growers would continue current trends in agricultural activities if 5307 corn is no longer subject to the regulatory requirements of 7CFR part 340 or the plant pest provisions of the Plant Protection Act.

4.3.4 Climate

U.S. agricultural crop production is identified as a major source of GHG emissions, second only to the U.S. energy sector. Crop production activities contribute directly to emissions of GHGs through a variety of processes, including the direct combustion of fossil fuels to support mechanized activities, abundance and frequency of agricultural chemical application (such as fertilizers) and other management practices, and the degradation of agricultural residues in the field or processing plant. Classes of crops planted are relevant to climate change, through crop dependent management practices and soil impacts. Additionally, geographic location and soil composition may also affect climate change through alterations in dynamic geophysical soil processes. Climate change itself may force changes to agricultural practices by altering agricultural weed and pest pressure (IPCC, 2007a).

Indirect effects of new crops will be determined by the traits engineered into organisms and the management strategies used in the production of these organisms.

As described in Section 2.3.4, *Climate*, agriculture-related activities are recognized as both direct sources of greenhouse gases (GHGs) (e.g., exhaust from motorized equipment) and indirect sources (e.g., agriculture-related soil disturbance, fertilizer production) Transgenic crops in general have reduced the release of GHGs from agriculture, equivalent to removing 5 million cars from the roads each year (Brookes and Barfoot, 2005), although the portion attributable directly to insect-resistant corn products is not known.

The climate can also affect agricultural crop production, and climate change could affect corn yields either positively or negatively.

No Action Alternative

Under the No Action Alternative, 5307 corn use would be limited to areas APHIS has approved for regulated releases. Agronomic management practices and phenotypic characteristics regarding 5307 corn are similar to those of conventional corn; thus, differences of impacts between corn varieties would be minimal. Additionally, measurable effects from these confined field releases would be minor due to the small scale of management and acreage relative to current corn production systems in the U.S. There are no other characteristics of transgenic corn products with insect resistance traits and non-transgenic corn that would be expected to be different in response to climate change.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. A determination of nonregulated status of 5307 corn is unlikely to significantly affect current corn management practices. Management decisions will be similar for both 5307 corn and conventional corn ,resulting in similar effects on climate change, including tillage, agricultural chemical application, and rotational strategies from corn agricultural production. In particular, due to the continued availability of herbicide choice in 5307 corn management, no-till or reduced till practices will likely continue to mitigate soil erosion, stabilizing soil quality attributes and reducing GHG emissions.

Agronomic performance and phenotypic characteristics of 5307 corn is not significantly different from conventional corn, with the exception of a different Cry protein to deter CRW infestation. Accordingly, the physical impact of 5307 corn on climate change is not anticipated to be significantly different from that of conventional corn. Intensive management will continue to be practiced on a scale similar to current levels of U.S. corn production, because of the phenotypic equivalence of 5307 corn and conventional corn.

4.4 Biological Environment

This section describes the potential impacts to animals, plants, biodiversity, and gene movement in the natural environment, that may result from the No Action and Preferred Alternatives.

4.4.1 Animals

As described in Section 2.4.1, *Animals*, corn fields may be temporarily or permanently occupied by invertebrates, birds, reptiles and amphibians, and mammals. Aquatic organisms may reside in water bodies adjacent to corn fields. Animals can have positive, negative, or no effect on corn production.

Insect-resistant corn varieties are targeted to certain invertebrate species that negatively impact corn. Table 2-1, *Transgenic Corn Cultivars Containing Bt-derived Proteins with Nonregulated Status*, lists the transgenic corn cultivars containing Cry or Vip proteins for insect resistance that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. These cultivars are Lepidopteran (European corn borer and other species) or Coleopteran (corn rootworm) resistant.

No Action Alternative

The following paragraphs summarize potential exposure pathways and available information on the effects of Cry proteins on non-target invertebrates, aquatic organisms, birds, and mammals.[4] Conventional broad-spectrum insecticides are potentially toxic to invertebrates and vertebrates (including humans) as discussed in Section 2.2.2.3, *Insect Management*. The US-EPA requires application control measures for certain Restricted Use insecticides, including several used for corn rootworm control, to limit human and environmental exposure. *Bt* foliar sprays contain Cry proteins and are approved insecticides for use in organic production systems to control moths, beetles, mosquitoes, and flies (Lepidoptera, Coleoptera, and Diptera), and exhibit low toxicity to non-target organisms.

Non-Target Invertebrates. Transgenic *Bt* crops, including corn, containing Cry proteins could potentially affect non-target invertebrates that directly consume *Bt* plant material or are exposed via Cry protein residues in soil, water, or prey species. However, for a Cry protein to exert toxicity, the appropriate activating enzyme(s) and receptor binding sites would need to exist in the midgut of the non-target species, and sufficiently high concentrations of active Cry protein would have to reach these binding sites.

Non-target invertebrates as well as certain arthropods may feed or reside on corn plants: species that feed extensively on corn plants may be pests. The more likely route of exposure to transgenic proteins is consumption of prey that have fed on transgenic corn plants or consumed transgenic pollen if prey is scarce (Harwood et al., 2005). The concentration of Cry proteins in the prey of non-target arthropods will vary depending on the prey species, its developmental stage, and the concentration of Cry protein in plant parts on which they are feeding. Several studies have examined the concentration of a representative Cry protein (Cry1Ab) in herbivores relative to the concentration in plants on which they are feeding. In general, the results show that herbivorous arthropods contain lower concentrations of *Bt* toxin than the plants on which they are feeding:

- Sucking insects, such as aphids, contain only trace amounts of Cry1Ab when feeding on *Bt* corn (Raps et al., 2001; Dutton et al., 2002; Head et al., 2002; Obrist et al., 2006a);
- Lepidopteran larvae contain between 0.1 and 0.25 times the concentration of Cry1Ab in *Bt* corn on which they are feeding (Dutton et al., 2002; Obrist et al., 2006a);

[4] Potential impacts to threatened and endangered species are separately discussed in Section 4.4.5.

- Thrips (*Frankliniella tenuicornis*) contain up to 0.35 times the concentration of Cry1Ab in *Bt* corn, although adults contain about half this amount and pupae less than 1/40th the concentration in larvae (Obrist et al., 2005); and
- Spider mites (*Tetranychus urticae*) have been found to contain between 0.7 and approximately 4.6 times the concentration of Cry1Ab in *Bt* corn (Dutton et al., 2002; Obrist et al., 2006a; Obrist et al., 2006b; Álvarez-Alfageme et al., 2008)

Multiple indicator species have been exposed to purified *Bt* proteins in direct feeding studies; these studies have typically not shown any hazard to the tested species, despite exposure to very high test concentrations under "no choice" conditions where the species was continually exposed through its diet. Some laboratory studies have found an effect, but concluded through refinement of exposure models and estimates, or via field studies, that the effect was not adverse or not representative of field conditions (Duan et al., 2010).

Corn rootworm predators could ingest Cry proteins when consuming corn rootworm that have ingested *Bt* corn plant material. A study of a transgenic corn product expressing the Cry3Bb1 protein found no significant effects on predators for any measured parameter (including larval development, physical characteristics, and mortality) (Ahmad et al., 2006).

Honey bees could potentially forage for corn pollen and therefore could be exposed to Cry proteins (Severson (Severson and Parry, 1981). Honey bees can successfully rear young on a diet of 100 percent corn pollen; however, it is unlikely that corn pollen regularly comprises more than 50 percent of their diet (Babendreier et al., 2004). Laboratory studies indicate that Cry proteins have no adverse effects on honey bees (Duan et al., 2008).

A meta-analysis of 74 laboratory studies of Cry protein toxicity and 52 field studies of *Bt* crops containing the same Cry proteins revealed that laboratory studies correctly predicted the reduced field abundance of certain non-target Lepidoptera exposed to lepidopteran-active proteins (Duan et al., 2010) . In the case of predators consuming prey that had fed on lepidopteran-active *Bt* plants, some laboratory tri-trophic studies identified reduced abundances that were, nevertheless, not observed under field conditions; thus, the laboratory studies overestimated risk. However, laboratory studies incorporating tri-trophic interactions of lepidopteran-active *Bt* plants, herbivores, and parasitoids were better correlated with the decreased field abundance of parasitoids than were direct-exposure assays. This result is not surprising because many parasitoids are associated specifically with target pests of *Bt* crops. Control of pest species by *Bt* crops can be expected to indirectly affect the abundance of their specialist parasitoids under field conditions. In similar studies with Coleopteran-active Cry proteins and *Bt* plants, the meta-analysis revealed no adverse effects on survival in laboratory studies or field abundance for any functional group of non-target arthropods examined, including Coleopteran and non-Coleopteran species.

Transgenic insect-resistant products may reduce broad-spectrum insecticide use, as described in Section 4.2.1.4, *Insect Management*. Since the commercialization of *Bt* crops, there have been a substantial number of field studies that have demonstrated that non-target invertebrates are generally more abundant in *Bt* cotton and *Bt* corn fields than in non-transgenic fields managed with chemical insecticides (US-EPA, 2007a). These studies demonstrate that, not only are the *Bt* crops not causing any unreasonable adverse effects in the environment, but arthropod prevalence and diversity is greater in *Bt* crop fields.

Aquatic Non-Vertebrate Organisms A potential route of exposure of aquatic organisms to insecticidal proteins from *Bt* corn is through pollen deposited into water bodies adjacent to corn fields. As explained in Section 4.3.1, *Water Quality*, corn pollen is heavy and wind-borne pollen densities decrease rapidly from the source. Any pollen deposited into water bodies from adjacent fields during the corn anthesis period (up to 14 days) is unlikely to remain in suspension. In addition, the bioactivity of transgenic proteins is likely to degrade in pollen grains deposited in water (Prihoda, 2008).

Unharvested corn material deposited in water bodies as litter could also potentially introduce Cry proteins to aquatic organisms. However, significant degradation of protein is likely to occur during the period between harvest and transfer to the waterways (Syngenta, 2011c) and between when the material is deposited in waterways and when it becomes palatable to aquatic organisms.

Fish. Commercially raised fish may be exposed to corn grain containing Cry proteins. About 30 percent corn grain by weight is typical in commercial fish feeds used in aquaculture (NRC, 1983). Fish feed is heat-treated during preparation and it is likely that Cry proteins in feed prepared from insect-resistant corn would be at least partially denatured by heat and lose activity. Corn in fish feed is unlikely to comprise 100 percent insect-resistant corn grain (USDA-NASS, 2011a). The mode of action of most Cry proteins is highly specific to insects and is not biologically active in vertebrate species, including fish (Syngenta, 2011c).

Birds The principal potential route of exposure of birds to Cry proteins is through ingestion of kernels. Some birds such as crows (*Corvus brachyrhynchos*), grackles (*Quiscalus quiscula*), and sandhill cranes (*Grus canadensis*) uproot sprouting corn to feed on the germinating kernels (Steffey et al., 1999; Blackwell et al., 2001; Sterner et al., 2003). Red-winged blackbirds typically slit open husks with their bills and puncture kernels in the milk stage (Steffey et al., 1999). Blackbirds also forage for spilled kernels and weed seeds in corn stubble (Linz et al., 2003). Wild birds are unlikely to consume a diet of 100 percent corn kernels. The diets of red-winged blackbirds and common grackles, for example, are comprised of up to 50 percent corn kernels (McNichol et al., 1979); Homan et al., 1994 (Homan et al., 1994). The mode of action of most Cry proteins is highly specific to insects and these proteins are not biologically active in vertebrate species, including birds Syngenta, 2011c (Syngenta, 2011c). Cry proteins are therefore are not expected to adversely affect non-target vertebrates (Shimada et al., 2006).

Mammals The principal potential route of exposure of wild mammals to Cry proteins from *Bt* corn is through ingestion of corn kernels. Rodents such as thirteen-lined ground squirrels, deer mice, house mice, prairie and meadow voles (*Microtus* spp.), and woodchucks feed on germinating corn seeds (Syngenta, 2011c). Larger mammals such as white-tailed deer typically nip off ear tips and raccoons chew through husks. Wild mammals are unlikely to consume a diet of 100 percent corn kernels. For example, the proportion of corn kernels in wild rodent diets varies greatly according to species, but can be up to 73 percent (Syngenta, 2011c). The mode of action of most Cry proteins is highly specific to insects and these proteins are not biologically active in vertebrate species, including mammals (Syngenta, 2011c). Cry proteins are therefore are not expected to adversely affect non-target vertebrates (Shimada et al., 2006).

Overall Conclusion

Non-target species of animals would not be affected as a direct or indirect result of the No Action alternative. Animal exposure to genetically modified crops containing Cry proteins would be nearly identical to current conditions even if 5307 corn continues to remain a regulated article. Approved genetically modified crops containing Cry proteins would continue to be used by growers and there would be no change in animal exposure rates outside of controlled environments. Pesticide usage would continue to have the same effects on animal species. Chemical insecticides would continue to be applied, following current trends in application rates, and organic corn growers would continue to apply microbial *Bt* foliar sprays. Regulated field trials of 5307 corn would only impact small plots of land with controlled animal incursions.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Non-target species of animals are not likely to be affected as a direct or indirect result of the Preferred Alternative. Under the preferred alternative, animal exposure to genetically modified crops containing Cry proteins would be similar to current conditions.

Event 5307 corn has been demonstrated not to adversely impact non-target species. Syngenta fed various nontarget organisms with the eCry3.1Ab protein to establish a no observable adverse effect concentration (NOAEC) or level (NOAEL). This value was then compared to the Environmental Exposure Concentration (EEC) and Daily Dietary Dose (DDD) values to make judgments about risk. The effects studies identified any potential for eCry3.1Ab proteins to cause adverse effects in representative nontarget organism species representing a corn ecosystem. In each study, a representative species was exposed to a high concentration or dose of eCry3.1Ab. No harmful effect of such exposure on survival was observed in any species tested, and the concentration of eCry3.1Ab in each study can be interpreted as the minimum value of the NOAEC for the mortality endpoint. Computing a ratio of the NOAEC to the EEC or DDD results in the toxicity exposure ratio (TER). This ratio is also known as the 'margin of exposure' or 'margin of safety.' A TER $\geq$ 1.0 provides a degree of confidence that the absence of adverse effects in these hazard studies with indicator species is predictive of the safety of eCry3.1Ab in cultivation of 5307 corn for nontarget organisms in general. The larger the TER, the higher the degree of confidence in the safety judgment and the lower the risk. Table 4-2 contains the NOAEC and corresponding TER values for each indicator test species (Syngenta, 2011c).

Table 8: Nontarget organism TER values for eCry3.1Ab.

TER values are computed as the ratio of NOAEC: EEC (or NOAEC: DDD) and are based on estimates of exposure to eCry3.1Ab via cultivation of 5307 corn.

Test Species	NOAEC/NOAEL	EEC or DDD	TER
Bobwhite quail	900 mg/kg bw	0.80 mg/kg bw	1100
Mouse	2000 mg/kg bw	1.10 mg/kg bw	1800
Honeybee	50 µg/g diet	0.07 µg/g diet	710
Spotted ladybird beetle	353 µg/g diet	5.07 µg/g diet	70
Flower bug	400 µg/g diet	5.07 µg/g diet	79
Carabid beetle	400 ug/g diet[1]	0'34 ug/g diet	1200 (mortality) 1200 (weight)

Rove beetle	400 µg/g diet	0.34 µg/g diet	1200
Earthworm	4.06 µg/g soil	0.34 µg/g diet	12
Freshwater shrimp	100% 5307 corn	< 100% 5307 corn	> 1
Farmed fish	41% 5307 corn grain	9.5% 5307 corn grain	4.3

1 This NOAEC is based on the mortality endpoint for this species; a 20% reduction in weight was observed

Bt and Activity Spectrum of Cry protein. Syngenta's plant tissue studies determined that, on a fresh-weight basis, the concentrations of eCry3.1Ab in individual samples across all locations and plant stages ranged from less than the lower limit of quantification (< LOQ)[5] to 71.21 micrograms per gram (µg/g) in leaves, 0.40 µg/g to 9.29 µg/g in roots, 1.60 µg/g to 7.29 µg/g in kernels, < LOQ[6] to 0.09 µg/g in pollen and 1.70 µg/g to 28.64 µg/g in whole plants (Syngenta, 2011c). Activity spectrum data indicate that the insecticidal effects of eCry3.1Ab are limited to certain species of the Chrysomelidae family of Coleoptera. The eCry3.1Ab protein demonstrates no Lepidopteran activity, despite containing sequences from a Lepidopteran-active protein (Syngenta, 2011c). demonstrating the specificity of the eCry3.1Ab protein. There would be no additional risk to animals from widespread cultivation of 5307 corn.

Well-characterized modes of action, physicochemical properties, and results of safety studies (as summarized below) demonstrate that the eCry3.1Ab protein present in 5307 corn presents no evidence of risk of harm for avian, fish, or mammalian species. Laboratory testing has similarly shown no adverse effects on survival associated with exposures of eCry3.1Ab in a range of non-target invertebrate species (Syngenta, 2011c).

Non-Target Invertebrates. Syngenta has conducted laboratory tests on six species representing non-target invertebrates potentially exposed to eCry3.1Ab via cultivation of 5307 corn. In summary, there were no statistically significant differences in survival between treatment and control groups of:

1. Honey bees (*Apis mellifera*) Syngenta, 2011c (Syngenta, 2011c),
2. Spotted ladybird beetle larvae (*Coleomegilla maculata*) (Syngenta, 2011c),
3. *S*econd-instar flower bugs (*Orius laevigatus*) (Syngenta, 2011c),
4. Larvae of *Poecilus cupreus*, a carabid beetle (Syngenta, 2011c),
5. Adult rove beetles (*Aleochara bilineata*) (Syngenta, 2011c), or
6. Adult earthworms (*Eisenia fetida*) (Syngenta, 2011c).

Aquatic Non-Vertebrate Organisms. Syngenta has conducted laboratory tests on two species representing aquatic organisms potentially exposed to eCry3.1Ab via cultivation of 5307 corn. Aquatic concentrations of eCry3.1Ab are expected to be far below those at which biological activity is observed among known eCry3.1Ab-sensitive species. In summary, there were no statistically significant differences between treatment and control groups of adult gammarid freshwater shrimp (*Gammarus fasciatus*) (Syngenta, 2011c).

[5] LOQ for leaves was 0.02 [µg/g] (Syngenta, 2011; pg. 88).

[6] LOQ for pollen was 0.08 µg/g (Syngenta, 2011; pg. 88).

Possible exposure of nontarget aquatic invertebrate organisms to other *Bt* toxins has been considered, and the most recent has been an analysis of possible environmental effects of Cry1Ab contained within decomposing plant tissues (Jensen et al., 2010). Studied by comparing *Bt* expressing corn with near isolines, no consistent pattern of environmental impact of either the *Bt* expressing corn or its isoline on nontarget aquatic shredders was detected (Jensen et al., 2010).

Fish. There were no statistically significant differences between treatment and control groups of juvenile channel catfish (*Ictalurus punctatus*) (Syngenta, 2011c).

Birds. Syngenta has conducted laboratory tests on two species representing birds potentially exposed to eCry3.1Ab via cultivation of 5307 corn. In summary, there were no statistically significant differences in survival or overall performance between treatment and control groups of juvenile bobwhite quail (*Colinus virginianus*) (Syngenta, 2011c) or broiler chickens (*Gallus gallus domesticus*) (Syngenta, 2011c).

Mammals. Syngenta has conducted laboratory tests on one species representing mammals potentially exposed to eCry3.1Ab via cultivation of 5307 corn. There were no statistically significant differences between treatment and control groups of mice (*Mus musculus*) (Syngenta, 2011c).

Overall Conclusions. Syngenta initiated a voluntary pre-market consultation process with FDA and submitted a Safety and Nutritional Assessment (Appendix B, (Syngenta, 2011a). The assessment demonstrated that the introduced proteins, eCry3.1Ab[7] and phosphomannose isomerase (PMI),[8] in 5307 corn are not toxic to human and animal consumers and have minimal allergenic potential. Additionally, Syngenta's assessment showed that 5307 corn is nutritionally equivalent to non-transgenic corn and other corn in commerce.

A determination of nonregulated status of 5307 corn would not substantively change the overall usage of transgenic corn products with insect resistance traits. Similar to the no action alternative, other approved genetically modified crops containing Cry proteins have been demonstrated to have no adverse effects on animals and would continue to be used by growers. Pesticide usage would continue to have the same effects on animal species. Similar to the no action alternative, chemical insecticides would continue to be applied, following current trends in application rates, and organic corn growers would continue to apply microbial *Bt* foliar sprays. Adoption of 5307 corn may reduce the use of broad-spectrum insecticides, with a consequent reduction of potential impacts on the diversity of non-target insects (Dively, 2005; Marvier et al., 2007). Additionally, because it represents a new tool for corn rootworm control, the use of 5307 corn could help reduce the likelihood that rootworm resistance to chemical pesticides would increase (Syngenta, 2011c) because growers will have an effective new resistance trait, and one whose efficacy can be enhanced by pyramiding with other CRW resistance traits. This could help avoid future increases in the use rates of chemical insecticides that might otherwise result if current use rates became less effective in controlling rootworm.

Event 5307 corn is not substantively different in its effects on non-target species from other approved insect-resistant corn products with Cry proteins. The eCry3.1Ab protein present in 5307 corn has a unique binding site in the target pest but acts by the same general mechanism (i.e., pore formation in

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7 US-EPA has issued a temporary tolerance exemption for eCry3.1Ab in corn (Federal Register 76:180; Pgs. 57653-57657; US-EPA. 2011a) and Syngenta has petitioned for a non-expiring tolerance exemption.

8 US-EPA has granted a permanent tolerance exemption for PMI in all crops (40 CFR Part 180.1252; US-EPA. 2007b).

the target pest gut) as the approved Cry protein products that are currently available for use by growers. As described in Section 2.2.2, *Insect Management*, some species of corn rootworm have developed resistance to certain chemical pesticides. Similarly, insects may develop resistance to the insecticidal proteins in transgenic *Bt* crops. US-EPA has required refuges of non-transgenic corn alongside plantings of CRW resistant hybrids, which should minimize the potential for insects to develop resistance. Extension entomologists further suggest planting pyramided CRW resistance traits to provide multiple modes of action against the target insects, as well as incorporating additional strategies (Gray, 2011c). These issues are more fully discussed in the cumulative impacts section.

4.4.2 Plants

As described in Section 2.4.2, *Plants*, corn fields can be bordered by other agricultural fields (including other corn varieties), woodlands, or pasture and grasslands. The most agronomically important members of a surrounding plant community are those that behave as weeds. Section 2.2.2, *Weed Management*, explains the range of methods that growers use for weed control, including integrated weed management. These methods may be cultural (planting), mechanical (tillage), and chemical (herbicide), or some combination thereof. As described in Section 2.1.1, *Persistence in the Environment/Weediness Potential*, cultivated corn is not a weed and transgenic cultivars currently on the market have not changed corn's weediness potential.

No Action Alternative

Plants would not be affected as a direct or indirect result of the No Action Alternative. Under the No Action Alternative, weed management methods would continue following current trends and practices. Regulated field trials of 5307 corn would only impact small plots of land with controlled plant exposures. No impacts to plant species compared to any effects from current agronomic practices are anticipated.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Plants would not be affected as a direct or indirect result of the Preferred Alternative. Event 5307 corn expresses no herbicidal traits. Event 5307 corn production would not change land acreage or cultivation or cropping practices for transgenic or non-transgenic corn. Event 5307 corn does not have increased persistence in the environment or weediness potential compared with non-transgenic corn (Syngenta, 2011c). No changes in impacts to non-weed plant species compared to any effects from current agronomic practices are anticipated.

4.4.3 Soil Microorganisms

Soil bacterial communities are influenced by plant species and cultivars as well as other environmental factors, such as soil type and agricultural practices (Icoz et al., 2008). Microorganisms that colonize the rhizosphere are affected by plant type and root exudates influence the (Icoz et al., 2008)). While *B. thuringiensis* occurs naturally in soil, growing transgenic *Bt* corn increases the amount of Cry endotoxins present in agroecosystems (Blackwood and Buyer, 2004). As noted in Section 4.3.2, *Soil*, most proteins do not persist or accumulate in soil because they are inherently degradable in soils that have normal microbial populations (Burns, 1982).

The numbers of microorganisms and the activity of some enzymes involved in the degradation of plant biomass differ significantly by season, probably as a result of differences in the water content of soils, ambient temperatures, and plant stage growth at the time of sampling (Icoz et al., 2008). Cry protein concentrations in the rhizosphere vary during the growth of the plant and can be affected by microbial activity, which depends in part on soil temperature and humidity (Baumgarte and Tebbe, 2005).

No Action Alternative

Soil microorganisms would not be affected as a direct or indirect result of the No Action alternative. The use of transgenic corn producing Cry proteins and the use of other *Bt*-derived insecticides would continue following current trends. Regulated field trials of 5307 corn would only impact small plots of land with controlled plant exposures.

Cry proteins are typically expressed in all or most tissues throughout the plant's life cycle, potentially creating routes of exposure for soil organisms through root exudation, trophic level interactions, plant decomposition after harvest, and toxin persistence in the soil (Devare et al., 2004). However, different effects of *Bt* plants on microbial communities in soil, ranging from no effects to minor and statistically significant effects, have been reported (Icoz et al., 2008). One study concluded that plant variety (but not the presence of Cry proteins) had a significant but transient effect on the numbers of microorganisms and the activities of enzymes involved in the degradation of plant biomass (Icoz et al., 2008), while another study found no deleterious effect of growing corn-rootworm-resistant *Bt* corn on microbial biomass, activity, or bacterial community structure (Devare et al., 2004).

Cry proteins derived from *Bt* are rapidly degraded in a variety of soil types and the proteins typically do not accumulate in soil (Head et al., 2002; Mendelsohn et al., 2003; Dubelman et al., 2005). Soil type has a large effect on the microbial community and availability of Cry proteins (Blackwood and Buyer, 2004). Certain Cry proteins may adsorb rapidly to clay minerals, on the clay-sized fraction of soil, on humic soils, and on complexes of montmorillonite-humic acids aluminum hydroxypolymers (Saxena and Stotzky, 2001). Some field studies on the persistence of Cry proteins released by transgenic plants showed that Cry proteins do not persist and degrade rapidly in soil, although a small fraction may be protected from biodegradation in the plant matrix or bound on surface-active particles (Icoz et al., 2008). No impacts to soil microorganisms compared to any effects from current agronomic practices are anticipated.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Soil microorganisms would not be affected as a direct or indirect result of the Preferred Alternative. Syngenta conducted a laboratory study to examine the fate of eCry3.1Ab in live soil. A rapid decline in eCry3.1Ab bioactivity was observed: no biological activity above background control levels was detected after 14 days of eCry3.1Ab incubation in live soil (Syngenta, 2011c). The Cry protein present in 5307 corn does not bioaccumulate and a laboratory study demonstrated that eCry3.1Ab biological activity is rapidly degraded in healthy soils. If growers are not using corn traits with insect resistance, they may instead treat for rootworm with insecticides. A comparison of a corn rootworm resistant *Bt* corn variety and a non-transgenic control corn treated with a conventional insecticide concluded that the addition of the conventional insecticide had greater effects on the microbial function in soil and decaying roots than did *Bt* corn (Lawhorn et al., 2009).

The US-EPA has concluded that *Bt* crops have a positive effect on soil flora compared to non-selective synthetic chemical pesticides (US-EPA, 2001); IIC53). Even though *Bt* is ubiquitous in soils, the presence and release of *Bt* toxins from the aboveground and belowground parts of *Bt*-expressing plants may influence microbial diversity. *Bt* toxins have been found to be present in most tissues of *Bt* plants (Sivasupramaniam et al., 2008). However, studies have found no differences in microbial biodiversity or activity between fields cultivated with *Bt* corn or the corresponding non-*Bt* corn (Icoz et al., 2008).

Other Cry proteins released in root exudates of *Bt* corn or from the degradation of biomass of *Bt* corn are not toxic to earthworms, nematodes, protozoa, bacteria, or fungi (Saxena and Stotzky (Saxena and Stotzky, 2001). The US-EPA has determined that Cry proteins do not have any measurable adverse effect on microbial populations in the soil and that horizontal transfer of genes from transgenic plants to soil bacteria has not been demonstrated (US-EPA, 2001) section IIC). No changes in impacts to soil microorganisms compared to any effects from current agronomic practices are anticipated.

4.4.4 Biodiversity

Biodiversity in an agroecosystem depends on the diversity of vegetation within and around the agroecosystem; permanence of crops within the agroecosystem; intensity of management; and the extent of isolation from natural vegetation (Altieri, 1999). Determining the level of biological diversity associated within any crop agroecosystem is complex because biological diversity can be defined and measured in many ways. Another difficulty with biodiversity studies is separating expected impacts from indirect impacts. For example, reductions of biological control organisms are seen in some *Bt*-expressing transgenic crops but are caused by reduction of the pest host population rather than as a direct effect (USDA-APHIS, 2011).

Many studies over the last 10 years have investigated the differences in biological diversity and abundance between transgenic and non-transgenic crop fields, particularly those transgenic crops that are resistant to insects (e.g., *Bt* crops) or herbicides (e.g., glyphosate- or glufosinate-tolerant). Conflicting results are often reported. Some studies have found negligible to modest decreases in biological diversity or abundance attributed to crops genetically engineered to produce insecticidal proteins or tolerate herbicide application for weed management (Marshall, 2003, pg 85); (Ponsard et al., 2002; Pilcher et al., 2005). Other studies compared *Bt* crops to non-transgenic crops that were unsprayed or sprayed with insecticides and found that *Bt* crops do not cause any overall changes in arthropod abundance or diversity (Torres and Ruberson, 2005; Obrist et al., 2006; Chen et al., 2008; Wolfenbarger et al., 2008). A review of over 360 research papers concluded that there is no evidence of landscape-level effects from *Bt* crops (Carpenter, 2011). Compared to the use of broad-spectrum insecticides in agriculture, *Bt* crops may increase biological diversity in agroecosystems by reducing broad-spectrum insecticide use, thus allowing more non-target species to survive (Obrist et al., 2006; Marvier et al., 2007). Transgenic crops may generally increase the productivity of cultivated lands, so biodiversity is protected because additional land is not needed for the same volume of crop production (Raven, 2010).

No Action Alternative

Biodiversity would not be affected as a direct or indirect result of the No Action Alternative. Biodiversity within agroecosystems would continue to be affected by agricultural practices following current trends. Growers would continue to have access to existing nonregulated insect-resistant corn varieties, and adoption of new transgenic corn varieties would be expected to continue even if 5307 corn continues to remain a regulated article. Regulated field trials of 5307 corn would only impact small plots of land with controlled animal and plant incursions. No changes in biodiversity compared to effects from current agronomic practices are anticipated.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Similar to the use of other insect resistant crops, biodiversity would be improved as a direct result of the Preferred Alternative as chemical pesticide use rates would likely decrease because of the introduction of this insect-resistant cultivar. Event 5307 corn production would not change land acreage or cultivation practices for transgenic or non-transgenic corn. Event 5307 corn incorporates a Cry protein with a similar receptor-specific mode of action as other Cry proteins present in approved insect-resistant corn cultivars and does not have increased persistence in the environment or weediness potential over non-transgenic corn (Syngenta, 2011c). As described in Section 4.2, *Corn Production*, 5307 corn does not exhibit any different agronomic traits, apart from resistance to corn rootworm, or require different agronomic practices. As described in Section 4.4.1, *Animals*, and Section 4.4.2, *Plants*, animal and plant species that typically inhabit corn production areas would be managed the same as other for other insect-resistant corn products currently available to growers.

4.4.5 Gene Movement in the Natural Environment

Corn is a highly domesticated plant with limited gene movement in the natural environment, and gene movement from transgenic corn is not any different than that of other cultivated corn varieties (USDA-APHIS, 2011). As described in Section 2.2.5, *Persistence in the Environment/Weediness Potential,* corn is dependent upon humans for survival. Cultivated corn has limited sexual compatibility with its closest relative, teosinte, but no wild populations of teosinte exist in the US outside of some feral populations in Florida (USDA-NRCS, 2011a).

No Action Alternative

Corn's characteristic of limited gene movement in the natural environment would not be affected as a direct or indirect result of the No Action alternative. Corn breeding by traditional or transgenic means would continue even if 5307 corn continues to remain a regulated article. Regulated field trials of 5307 corn would only impact small plots of land with minimal potential for exposure to sexually compatible plants (i.e., other corn plants). No changes in gene movement characteristics of current corn varieties are anticipated.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Corn's characteristic of limited gene movement in the natural environment would not be affected as a direct or indirect result of the Preferred Alternative. Corn can only be crossed experimentally with the genus *Tripsacum*, and does not persist outside of cultivation. The only known propagation method for corn is through seed germination. Like many domesticated crops, corn seed from a previous year's crop can overwinter and germinate the following year. Corn seedlings may appear in soybean fields following a corn crop in a corn on soybean rotation. These plants do not result in sustained populations in subsequent years. Corn does not possess the suite of traits that are characteristic of successful weeds. Event 5307 corn has no more potential for gene introgression to sexually compatible wild relatives than other transgenic or non-transgenic corn varieties since characteristics such as pollen longevity and others were not different from comparator corn varieties (Syngenta, 2011c).

An extensive review of information relevant to the potential risks of horizontal gene transfer for *Bt* crops to soil microbes was conducted by the US-EPA. No evidence of horizontal gene transfer under field conditions was found, and there was only equivocal evidence for horizontal gene transfer under laboratory conditions designed to maximize the recovery of transformants (US-EPA, 2001); section IIC16). The codons in the *ecry3.1Ab* gene are optimized for expression in plants, and hence the gene is likely to have low sequence homology with genes of soil microbes (Syngenta, 2011c). Consequently, horizontal gene transfer of *ecry3.1Ab* from 5307 corn to soil microbes is highly unlikely and the probability of spread of *ecry3.1Ab* outside corn cultivation by horizontal gene transfer is also negligible (Eede et al., 2004). No changes in gene movement characteristics compared to current corn varieties are anticipated.

4.5 Public Health

This section describes the potential impacts to human health, animal (livestock) health, and worker safety that may result from the No Action and Preferred Alternatives.

4.5.1 Human Health

The general public is often concerned about the potential impacts that transgenic products could have on human health because of possible toxic or nutritional effects of the products, or how the product might change the allergenicity of food products. Insecticidal Cry proteins from *B. thuringiensis* have a long history of safe use in food crops (US-EPA, 2001)(updated 2011). Their modes of action are highly specific within narrow ranges of related insect species, and are not relevant to mammals or other vertebrates. PMI, the selectable marker protein produced by 5307 corn plants, is exempt from food and feed tolerances (US-EPA, 2004).

The US-EPA requires seed registrants to submit tests of potential toxicity and allergenicity of the transgenic proteins in *Bt* corn cultivars before they can be approved for human consumption. All tests that have been performed for adverse mammalian impact from ingesting Cry proteins have been negative, even at extremely high doses (Wu, 2006a). The toxicity of insecticidal *Bt* proteins depends on binding to specific receptors present in the insect midgut. With regard to the specific Cry proteins produced in *Bt* crops, research demonstrates that this specificity limits each protein's toxic effect to certain insect species.

As described in Section 1.1, *Regulatory Authority*, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from transgenic products must be in compliance with all applicable legal and regulatory requirements. Transgenic products for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. To date, all transgenic crops marketed in the US have been the subject of pre-marketing consultations with the FDA (FDA, 2006).

No Action Alternative

Human health is not likely to be affected as a direct or indirect result of the No Action Alternative. Other transgenic *Bt* corn varieties no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act would continue to be available and used as food for human consumption. Cry proteins of *Bt* corn products are not toxic to humans and do not have any known allergenic properties for humans (Randhawa et al., 2011). Human exposure to 5307 corn would be limited to those individuals involved in cultivation under regulated conditions. Regulated field trials of 5307 corn would only impact small plots of land with no potential for exposure to the general public. Exposure to existing transgenic and non-transgenic corn would not change under this alternative.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Human health is not likely to be affected as a direct or indirect result of the Preferred Alternative. The donor organism for the source genes used to create eCry3.1Ab is *B. thuringiensis,* a ubiquitous soil bacterium. The eCry3.1Ab protein is derived from a family of *Bt* proteins that has a long history of safe use in food crops (US-EPA, 2001)(updated 2011).

The Cry proteins of *Bt* corn products, including 5307 corn, are not toxic to humans and do not have any known allergenic properties for humans (Randhawa et al., 2011; US-EPA, 2011d). A discussion on the mechanism of action for eCry3.1Ab, its spectrum of activity, and its lack of toxicity to non-coleopteran species is presented in the Petition (Syngenta, 2011c); and the Safety and Nutritional Assessment (Raybould et al., 2011), 2011a; Appendix B). A comprehensive assessment of the safety of eCry3.1Ab demonstrated that the protein is nontoxic to mammals and unlikely to be a food allergen (US-EPA, 2001);(Syngenta, 2011c). The eCry3.1Ab protein does not share significant amino acid similarity with known protein toxins, is nontoxic to mice at a very high dose, is rapidly degraded in simulated mammalian gastric fluid, and the insecticidal mode of action is not relevant to mammals. The eCry3.1Ab protein is not likely to become a food allergen because it is not derived from a known source of allergenic proteins, it does not have significant amino acid sequence identity to known allergenic proteins, it is rapidly degraded in simulated mammalian gastric fluid, it is not glycosylated, and it is labile upon heating at temperatures of 37ºC and above (Syngenta, 2011).

The PMI marker protein present in 5307 corn raises no human health concerns with respect to toxicity or allergenicity (US-EPA, 2004). The PMI protein does not share significant amino acid homology with known protein toxins, it is nontoxic to mice at a very high dose, and it is rapidly degraded in simulated mammalian gastric fluid. PMI is not likely to become a food allergen because it is not derived from a known source of allergenic proteins, it does not have any significant amino acid sequence identity to known allergenic proteins with implications for its allergenic potential, it is rapidly degraded in simulated mammalian gastric fluid, it is not glycosylated, and it is labile upon heating at temperatures of 37ºC and above.

Under the preferred alternative, the general public would primarily come in contact with the introduced transgenic proteins (i.e., eCry3.1Ab and PMI) through dietary exposure to food and products derived from 5307 corn, although most processed products would contain no detectable eCry3.1Ab or PMI residues. Laboratory, greenhouse, growth chamber, and field investigations with 5307 corn confirmed that there were no changes in seed, pollen, plant phenotype, or composition parameters suggestive of increased plant pest risk. Assessments of the grain and forage from multiple US field sites demonstrate that 5307 corn is nutritionally and compositionally equivalent to, and as safe and nutritious as, its non-transgenic counterpart (Syngenta, 2011c). Syngenta initiated a voluntary pre-market consultation process with FDA and submitted a Safety and Nutritional Assessment (Appendix B (Syngenta, 2011c)). The assessment demonstrated a lack of toxicity and allergenicity of 5307 corn for human and animal consumption.

4.5.2 Animal (Livestock) Health

As described in Section 2.5.2, *Animal (Livestock) Health,* livestock ingestion of feed from transgenic crops, with subsequent human ingestion of livestock food products, is a potential concern about transgenic crops.

No Action Alternative

Animal (livestock) health would not be affected as a direct or indirect result of the No Action alternative. Section 2.2.1, *Production and Yield*, explains that approximately 39 percent of the corn produced in the US is used for livestock feed and most of the corn used currently for livestock feed is transgenic. As discussed in Section 4.6.1, *Human Health*, Cry proteins are not expected to be allergenic, toxic, or pathogenic in mammals or poultry. Additionally, no gene transfer to gastrointestinal flora is expected. Insecticidal Cry proteins from *B. thuringiensis* have a long history of safe use in feed crops (US-EPA, 2001). Their modes of action are highly specific within narrow ranges of related insect species, and are not relevant to mammals, including domestic livestock, or other vertebrates. Cry proteins also have a history of safe consumption in the context of other food and feeds (US-FDA, 2010). Additionally, the selectable marker PMI protein produced by 5307 corn plants is exempt from food and feed tolerances (US-EPA, 2004).

Livestock would not be exposed to 5307 corn if it continues to remain a regulated article. Other transgenic *Bt* corn varieties no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act will continue to be available and used as feed for animal consumption. Exposure to existing transgenic and non-transgenic corn would not change under this alternative. Regulated field trials of 5307 corn would only impact small plots of land with no potential for exposure to livestock.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Animal (livestock) health is not likely to be affected as a direct or indirect result of the Preferred Alternative. Under the preferred alternative, livestock would primarily come in contact with the introduced eCry3.1Ab and PMI proteins in 5307 corn through feed products derived from 5307 corn. The eCry3.1Ab protein is derived from a family of *Bt* proteins that has a long history of safe use in food crops. There are no animal health or environmental concerns with respect to toxicity or allergenicity of eCry3.1Ab or PMI (US-EPA, 2004; Syngenta, 2011a) Appendix B). Exposure to existing transgenic and non-transgenic corn would not change under this alternative. A compositional analysis concluded that forage and grain from 5307 corn hybrids are considered similar in composition to forage and grain from both the non-transgenic comparator and conventional corn hybrids (Syngenta, 2011c). Event 5307 corn will be as safe and nutritious as conventional corn for livestock. Syngenta initiated a voluntary pre-market consultation process with FDA and submitted a Safety and Nutritional Assessment for 5307 corn in January 2011 (Syngenta, 2011a); Appendix B). The assessment demonstrated a lack of toxicity and allergenicity of the eCry3.1Ab and PMI proteins in 5307 corn for human and animal consumption. No adverse impacts to livestock, either directly or indirectly, are expected from a determination of nonregulated status for 5307 corn.

4.5.3 Worker Safety

As described in Section 2.5.3, *Worker Safety*, pesticides, including US-EPA restricted use insecticides and herbicides, are used on most corn acreage in the US. The EPA's Worker Protection Standard (WPS) (US-EPA, 1992); 40 CFR Part 170.1, *Scope and Purpose*) requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.

The restrictions and precautions for worker safety associated with several conventional insecticides for rootworm control include:

1. Protective clothing (chemical-resistant gloves and other skin protection, eye protection, respirators, etc.) or other measures (closed-system applications) to minimize applicator exposure;
2. Minimum worker reentry intervals post application; and
3. Minimum preharvest intervals post application.

No Action Alternative

During agricultural production of corn, agricultural workers and pesticide applicators may be exposed to a variety of US-EPA -registered pesticides during application of these chemicals to crops. These chemicals would be expected to include those products currently used for insect pest and plant pest management. Under the No Action Alternative, exposure to these agricultural chemicals during corn production would remain the same as under current conditions.

Agricultural workers and pesticide applicators would continue to be exposed to a variety of US-EPA -registered pesticides such as those approved for control of corn rootworm (Table 4-1) under the No Action alternative. Chemical insecticide use rates would likely continue to decrease as a result of the continued use of insect-resistant transgenic corn products. Large-scale cultivation of transgenic *Bt* corn has increased since its introduction in 1996. A number of studies indicate that the application of pesticides has decreased since the introduction of transgenic crops (Kleter et al., 2007), reducing exposure of agricultural workers to the hazards of pesticide mixing, loading and application.

US-EPA requires several types of data for *Bt* PIPs to provide a reasonable certainty that no harm to workers will result from the aggregate exposure of these proteins. None of the *Bt* proteins registered as plant pesticides in the US are toxic or have been shown to have any significant effect on humans (US-EPA, 2010b).

Approved transgenic *Bt* corn cultivars would continue to be used even if 5307 corn continues to remain a regulated article. Regulated field trials of 5307 corn would only impact small plots of land with limited potential for exposure to agricultural workers. Under the No Action alternative, agricultural workers and pesticide applicators would continue to be exposed to a variety of chemicals.

Table 9: Commercially Available Corn Breeding Stack Combinations with Insect Control Traits

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

Sources NCGA website http://ncga.com/know-before-you-grow/ and Pioneer website http://www.pioneer.com/home/site/about/products/product-traits-technology/optimum-acre-max/

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Similar to the No Action alternative, US-EPA-registered pesticides that are currently used for corn production would continue to be used by growers under the Preferred Alternative. Agricultural production with 5307 corn does not require any change to the agronomic practices or chemicals currently used (i.e., pesticides) for conventional corn. Therefore, worker safety issues associated with the agricultural production of 5307 corn would remain the same as those under the No Action Alternative.

As described in Section 4.2.2, *Insect Management*, trends in reduced insecticide use are likely to continue as a direct result of the Preferred Alternative. The safety and convenience of planting insect-protected corn compared to the application of conventional insecticides are consistently cited by growers as benefits of transgenic crops (Brookes and Barfoot, 2011). The further adoption of *Bt* transgenic varieties, including 5307 corn, would continue to extend these benefits to workers. If 5307 corn should replace CRW resistant varieties that are showing increased rootworm damage, less insecticide would need to be used to augment these older CRW resistant varieties. As a result, agricultural workers and pesticide applicators would likely benefit from the use of 5307 corn due to a reduction in the use of corn rootworm insecticide applications and the number of acre-treatments per year.

4.6 Socioeconomics

This section describes the potential impacts to the domestic economic environment, trade economic environment, and social environment that may result from the No Action and Preferred Alternatives.

4.6.1 Domestic Economic Environment

As described in Section 2.6.1, *Domestic Economy*, domestic demand for corn in the US comes primarily from its use for feed, ethanol production, food, and seed. In 2011, transgenic products comprised 88 percent of the planted corn to satisfy this demand (USDA-ERS, 2011b). The transgenic traits include herbicide tolerance, insect resistance, and other traits. Approximately 65 percent of the US corn crop in 2011 was comprised of *Bt* corn (USDA-ERS, 2011b). Overall, harvest security and quality is better with *Bt* corn. Farm income is positively impacted by *Bt* corn by reducing production costs or increasing revenues. Pest-resistant corn generally has a positive impact on farm income due to cost savings from reduced pesticide use (Brookes and Barfoot, 2011).

Section 2.2.2, *Insect Management*, explains that the corn rootworm family is one of the most damaging corn pests, and was often referred to as the "billion dollar bug" due to annual yield losses and control costs (Metcalf, 1986), prior to the introduction of transgenic cultivars for rootworm control in 2003. Seed companies have developed transgenic crops with corn rootworm resistance specifically to address this economic loss. Four corn rootworm-resistant traits (MON 863, DAS 59122-7, MON 88017 and MIR604 corn) are currently available to corn breeders to control this economically important pest (Table 2-1).

No Action Alternative

The domestic economy would not be affected as a direct or indirect result of the No Action alternative. Growers would continue to make choices to plant certain corn varieties and use certain crop rotation practices based on factors such as yield, weed and disease pressures, cost of seed and other inputs, technology fees, worker safety, potential for crop injury, and ease and flexibility of the production system (Olson and Sander, 1998; Gianessi, 2005). The No Action alternative would not affect available options for growers and therefore not affect the domestic economy. Event 5307 corn would remain a regulated article and would require an APHIS permit or notification for release into the environment. As noted in section 4.2.3., cultural methods will continue to be used by organic and specialty growers to confine pollen flow, and thus gene movement, and no expectation that continued field trials of this or other GE crops will result in any additional adventitious presence of GE traits into corn. Regulated field trials of 5307 corn would only impact small plots of land with no impact on the domestic economy.

Preferred Alternative

The domestic economic environment could be positively affected as a direct and indirect result of the Preferred Alternative. Under the preferred alternative, growers would have an additional tool to use against corn rootworm that would directly reduce economic loss from this pest. The Preferred Alternative could indirectly result in economic benefit from increased competition in the seed market. The availability of multiple corn rootworm-resistant products could increase grower choice and price competition, potentially resulting in lower seed prices for growers. The availability of 5307 corn could also assist in managing insect resistance to existing *Bt* corn products for corn rootworm control. To the extent that the planting of 5307 corn results in a decrease of insecticide applications in those circumstances when corn rootworm that have developed resistance to existing *Bt* corn products, or results in an increase in yields, farms adopting 5307 corn might experience an increase in net income. Event 5307 corn hybrids demonstrated an average grain yield advantage of 63 bushels per acre over control hybrids in the presence of intense larval rootworm pressure during field tests (Appendix A; this EA, Supplemental Information on Insecticide Use with Traits in Corn). Growers are expected to realize a real-world increase in yield and would therefore likely realize direct economic gain from this product (Syngenta, 2011c); and Appendix A, this EA).

Specialty and Organic Corn. Similar to the no action alternative, a determination of nonregulated status of 5307 is not expected to have an adverse impact on specialty or organic corn products. As noted in section 4.2.3., organic corn production is increasing along with that of commodity corn. A determination of nonregulated status of 5307 corn is unlikely to significantly impact specialty or organic farmers that choose not to plant or sell corn products produced through genetic engineering or other non-organic production systems. Despite the wide-spread adoption of conventional and GE corn in the U.S. that amounted to 99.8 percent of total corn production in the U.S. in 2007, organic corn production has also continued to expand in recent years (USDA-ERS, 2010a). This continued expansion of organic corn acreage, though minor relative to non-organic national and state corn production, reinforces the capacity of current organic system plans to avoid use of excluded methods (and thus, loss of NOP certification) and the efficacy of these plans to increasingly produce agricultural products to meet demand of target markets in spite of the overwhelming presence of non-organic farming systems. The overwhelming majority of organic growers have no concerns that admixture of organic seed with GE traits was an issue for their organic production (88% in an Organic Seed Alliance survey (Organic-&-Non-GMO-Report, 2010b). Additionally, 5307 corn will not increase the possibility of adventitious presence of GE seed in organic corn or specialty production to any greater extent than that of other, similar varieties, because its agronomic production processes and biological properties of the variety are not different from other corn rootworm-resistant varieties currently available and being used by growers.

4.6.2 Trade Economic Environment

As described in Section 2.6.2, *Trade Economy,* the primary US corn export destinations are also the largest world importers of corn and do not have major barriers for importing food or feed commodities produced from transgenic crops, including those with insect resistance traits. Nevertheless, import of each specific trait requires separate application and approval by the importing country. Developing countries' demand for corn has increased steadily for the past three decades, propelling the global trade market above 70 million metric tons every year since 1999/2000 (USDA-ERS, 2009b). Corn imports to European Union countries have declined steadily since the Common Agricultural Policy limited grain imports and EU membership has expanded (USDA-ERS, 2011c).

No Action Alternative

The trade economic environment would not be affected as a direct or indirect result of the No Action alternative. Genetically modified corn varieties, including *Bt* varieties, would continue to be developed and available in the trade market. Event 5307 corn would remain a regulated article and would require an APHIS permit or notification for release into the environment. Regulated field trials of 5307 corn would only impact small plots of land with no impact on the worldwide corn trade.

Preferred Alternative

The trade economic environment would not be affected as a direct or indirect result of the Preferred Alternative. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. Worldwide market conditions and destination country approval of transgenic crop commodities would continue to be factors for international corn prices, without regard to the presence or absence of 5307 corn on the market. Deregulating 5307 corn would not adversely impact the trade economy and may potentially enhance it through more efficient production of corn supplies worldwide.

Syngenta has applied to Canadian agencies for approval of the unconfined environmental release and food and feed use of corn commodities and processed goods containing 5307 corn (Syngenta, 2011c). To avoid adversely affecting international trade in corn commodities exported from the US (and Canada), regulatory filings for 5307 corn import approvals have been made in Japan, South Korea, Taiwan, Australia/New Zealand, South Africa, Columbia and the European Union. Applications are planned for additional countries including Mexico, China, the Philippines, Indonesia, and Russia. (Syngenta, 2011c), section I.C.3). The trade economic impacts associated with a determination of nonregulated status of 5307 corn are anticipated to be similar to the No Action alternative.

4.6.3 Social Environment

As described in Section 2.6.3, *Social Environment,* farmers have a range of options in agronomic practices, seed products to choose from, and opportunities for sale to customers. Consumers have a range of corn products to choose from.

According to data from the 2010 Agricultural Income and Finance Outlook, farms growing corn are expected to benefit from increased sales at higher prices. Increases in prices are a function of anticipated increases in domestic uses, including bioethanol, as well as exports for feed (USDA-ERS, 2011b). Prices received for feed grains, including corn, increased 107% from 2003 to 2008 as a direct result of the increase in ethanol production (USDA-ERS, 2011b). During this same time period, production costs have increased also, with the cost of seed rising 67% (USDA-ERS, 2011b). The USDA projected that increases in average income for corn growers over 14% in 2010 as a direct result of an increase in expected cash receipts while expenses remained somewhat stable (USDA-ERS, 2011b).

No Action Alternative

The social environment would not be affected as a direct or indirect result of the No Action alternative. Event 5307 corn would remain a regulated article and would require an APHIS permit or notification for release into the environment. The cropping and marketing decisions made by corn growers are unlikely to be influenced by the selection of this alternative. Consumers would continue to have a range of corn products available to choose from. Regulated field trials of 5307 corn would only impact small plots of land with no impact on the social environment.

Preferred Alternative

Overall impacts of a determination of nonregulated status of 5307 corn would be similar to the No Action Alternative. Event 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. The social environment would not be affected as a direct or indirect result of the Preferred Alternative. Event 5307 corn is not expected to confer any competitive advantage in terms of weediness or to extend the range of cultivation outside of existing cultivation areas. A determination of nonregulated status of 5307 corn is not expected to significantly expand the number of corn acres and corn acreage is expected to remain relatively stable. No changes to farms producing corn feed grains would be likely, nor would changes to income of these farms, or of government payments to these farms. Consumer choice would be unchanged by a determination of nonregulated status of 5307 corn.

5 CUMULATIVE EFFECTS

This section describes the potential cumulative effects that may result from the Preferred Alternative. The CEQ regulations define a cumulative effect as "the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative effects can result from individually minor but collectively significant actions taking place over a period of time." (CEQ, 1978; 40 CFR Part 1508, Section 1508.7, Cumulative impact).

5.1 Methodology and Assumptions

Based on the information provided in Sections 4.2 through 4.6, which is summarized in Table 3-1, the Preferred Alternative would not adversely impact the physical, natural, social, or economic environment. Furthermore, as discussed throughout this section, there are no past, present or reasonably foreseeable actions that, in aggregate with the Preferred Alternative would adversely affect these resources.

5.2 Reasonably Foreseeable Future Actions

Transgenic corn varieties marketed in the US today typically contain multiple transgenic traits, some of which have been combined by traditional breeding between different cultivars that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. In the event that APHIS reaches a determination of non-regulated status of 5307 corn, this corn variety could potentially be combined with non-transgenic and other transgenic corn cultivars by traditional breeding techniques, resulting in a plant variety that, for example, may be resistant to one or more herbicides and contain other insect-resistance traits that are no longer subject to the regulatory requirements of 7CFR Part 340. APHIS's regulations at 7 CFR Part 340 do not provide for agency oversight of transgenic corn varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 unless it can be positively shown that such stacked varieties were to pose a likely plant pest risk. To date, none of the GE corn varieties that have been determined to no longer be regulated articles pursuant to Part 340 and the Plant Protection Act and used for commercial corn production or corn breeding programs subsequently have been found to pose a plant pest risk.

There is no certainty that 5307 corn will be stacked with any particular non-transgenic or transgenic variety (one no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act), as company plans and market demands play a significant role in those business decisions. Predicting all potential combinations of stacked varieties that could be created using commercially available non-transgenic and transgenic corn cultivars corn cultivars is hypothetical and purely speculative.

Syngenta has indicated (Syngenta, 2011c) that it intends to offer 5307 corn for sale to US growers in two combinations comprised of the insect protection and herbicide tolerance traits; these traits are listed as A and B in Table 10 (immediately following below). Syngenta has requested authorization from the US-EPA for distribution of these stacked products (Syngenta, 2011a); Appendix A of the EA), with specific combinations of insecticidal traits for each product.

Table 10: Planned Stacking Combinations*

Cultivar	Traits	Combination
5307	Corn rootworm resistant	A, B
*Bt*11	Lepidopteran resistant and glufosinate tolerant	A, B
MIR604	Corn rootworm resistant	A, B
TC1507	Lepidopteran resistant and glufosinate tolerant	A, B
GA21	Glyphosate tolerant	A, B
MIR162	Lepidopteran resistant	B

* Stacks with specified traits are marked as a "A" Combination (first four traits) or as a "B" combination (all traits)

The proposed hybrids A and B listed in Table 5-1 would combine two corn rootworm-active proteins (eCry3.1Ab from 5307 corn and mCry3A from MIR604 corn) that each provide control of western, northern, and Mexican corn rootworm. The hybrids would also combine lepidopteran-specific *Bt*-derived proteins that would deliver broad-spectrum control of economically important lepidopteran pests. Finally, these hybrids would also express traits that confer tolerance to glyphosate and glufosinate herbicide applications as weed-control options. Apart from 5307 corn, all of the cultivars derived from other transgenic events in these breeding stacks are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

For purposes of cumulative impact analysis, reasonably foreseeable future actions include the potential for stacking certain already approved transgenic corn cultivars with 5307 corn, or for creating new stacks with similar combinations of traits. The analysis will consider those insect resistance and herbicide tolerance traits found in the breeding stacks currently approved for sale or use in the US, as listed in Table 9.

5.3 Cumulative Effects Analysis

A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Among the cumulative impacts considered are stacking of the Syngenta 5307 corn with herbicide resistance traits, and for pyramiding with additional CRW resistance traits, because Syngenta plans to market 5307 in specified combinations (Syngenta, 2011c).

5.3.1 Corn Production

GE corn varieties are planted on the majority of corn acres in the U.S. (88 percent of acreage in 2011) (USDA-NASS, 2011a). Acreage of transgenic corn planted with herbicide-tolerant varieties declined in 2008, although corn varieties with insect resistance, whether alone or stacked with an herbicide tolerance trait, are planted more readily than those varieties conferring tolerance to herbicides alone (see, analysis of petition DP-098140-6: (USDA-APHIS, 2009)). Stacked products combining insect resistance and herbicide tolerance (and potentially other traits) are likely to continue to be introduced (for example, Monsanto has in development an RNA interference product with rootworm resistance (Ostlie, 2011b; Fraley, 2012). Regardless if the regulatory status of 5307 corn changes, it is likely that a trend towards increased multiple insect protection traits will continue, since these afford growers increased convenience and protection.

Event 5307 corn and any hybrid progeny produced from it (including eCry3Ab inclusion) within stacks of other traits will not require significantly different crop production practices compared to other corn varieties that are currently available to growers. Therefore, a determination of nonregulated status of 5307 corn is not anticipated to have any cumulative effect on existing corn hybrids when incorporated with the eCry3Ab trait. As a result, no cumulative effects would be expected on production and yield, agronomic practices such as pesticide use, crop rotation, tillage, irrigation, disease management, or weed management related to US corn production or on specialty and organic crops or to raw and processed corn.

Insect Management. As noted in Table 6 and discussed in Section Agronomic Practices, *Agronomic Practices*, the Preferred Alternative is expected to have the possible effect of reducing insecticide use. The past and current actions potentially contributing to cumulative effects on this resource are the pest management strategies that include conventional insecticide and herbicide use, crop rotation practices, and the introduction of transgenic corn varieties and their increasing use. The array of transgenic corn cultivars currently available (2012 growing season) for insect pest management is listed in Table 9: Commercially Available Corn Breeding Stack Combinations with Insect Control Traits. The future actions potentially contributing to a cumulative effect are the combination of 5307 corn cultivars exhibiting Coleopteran resistance that are stacked in transgenic corn with Lepidopteran resistance or herbicide tolerance or both, as listed in Table 10.

Insecticide use. Corn rootworm has evolved resistance to some chemical insecticides and also to crop rotation practices that have historically been used to control these economically destructive pests (Van Rozen and Ester, 2010). As described in Section 2.2.2, *Insect Management*, use of conventional (chemical) pesticides to control corn rootworm has been reduced since the introduction of transgenic *Bt* corn for insect control. As described in Section 4.2.2, *Insect Management*, insecticide use as an alternative to use of CRW resistant hybrids is likely to continue to be reduced under the preferred alternative. If single rootworm resistance traits should show continuing susceptibility to high CRW pressure, then some growers may see continuing need to treat corn at planting or post-planting with only insecticides and avoid use of *Bt* traits. Alternatively, growers may decide to use insecticides with single trait *Bt* corn to respond to high populations of CRW, as suggested by corn extension entomologists (Gray, 2011b; Ostlie, 2011b). As earlier noted, sites of failure of *Bt*-expressing hybrids are infrequent, and are associated with growing areas where continuous corn has been a multiple-season pattern (Gassmann et al., 2011).

Bt protein resistance. A key issue related to the use of *Bt* corn for insect control is delaying or avoiding the development of resistance to *Bt* proteins in insect pests. The widespread use of transgenic *Bt* corn could generate selection pressures for insect resistance (Tabashnik et al., 2008). However, there is no indication that the widespread use of insect resistant *Bt* crops havecaused any overall failure of these hybrids, even though as earlier noted, four states have reported such events. Certain fields with a history of corn-on-corn rotations or high rootworm populations have experienced such failures but often with hybrids expressing one trait, Cry3Bb1 (Gassmann et al., 2011; Gray, 2011a).

IRM strategies have been successfully developed and used to reduce the likelihood of developing *Bt* insect resistance, including the US-EPA requirement that growers plant nearby refuges with corn varieties lacking the *Bt* trait. Although one recent study indicates that in some fields in Iowa, western corn rootworm may have developed resistance to Cry3Bb1 protein (Gassmann et al., 2011) under high rootworm pressure, such resistance has not yet been confirmed (Monsanto, 2011a) and detailed analysis of a possible genetic basis of the resistance has not been completed. Recently, no evidence has been provided that suggests that the control failures are affecting other CRW resistance traits (Cry 34/35, (Ostlie, 2011a), or MIR 604, (Gassmann et al., 2011; Hibbard et al., 2011). However, recent reports (Kaskey, 2012) (Zukoff, personal communication) suggest some cross resistance between Cry3Bb1 and Syngenta's rootworm resistance trait. New CRW resistance traits are in development (Gassmann et al., 2011; Ostlie, 2011b) and pyramids of two transgenic corn traits with different modes of action against the target pest should limit the potential for resistance to develop to any one product (Tabashnik et al., 2008). Event 5307 could be stacked with a CRW resistance to obtain this desired effect. Syngenta's MIR604 rootworm-resistant cultivar may have a different mode of action than 5307 corn (Walters et al., 2010) and thus supports the rationale for a pyramided product having greater ability to disrupt development of CRW resistance.

Event 5307 corn could provide corn growers with an additional trait that could be rotated with existing traits in the marketplace, which include four other corn rootworm-control cultivars. Most of these traits may be pyramided, and new corn varieties might be constructed with multiple combinations to avoid overuse of any one pair of traits in a corn-growing area. Event 5307 corn could allow additional combinations for more effective IRM strategies. Because the eCry3.1Ab protein operates via a unique mode of action, introduction of the 5307 corn into hybrid pyramids could also extend the useful life of the other commercially available corn rootworm-protected products (i.e., the PIPs Cry3Bb1, Cry34Ab1/ Cry35Ab1, and mCry3A) (Syngenta, 2011c); Appendix A of this EA). As noted in the petition, Syngenta 5307 trait would only be deployed as a pyramided and stacked product (Syngenta, 2011c).

Increased use of transgenic *Bt* corn has been correlated with reduced use of or reliance on insecticides to control corn rootworm. Under high CRW pressure, *Bt* hybrids may sometimes be correlated with higher corn yields than can typically be achieved with insecticides alone, but may not provide an advantage under low to moderate CRW pressure (Baumgarte and Tebbe, 2005; Aneja et al., 2009) ; (Tinsley et al., 2011). Thus, when combined with past, present, and reasonably foreseeable future actions, the cumulative effects of the Preferred Alternative may result, in some cases, in an increase in corn yields, further reduction of insecticide use, and a reduced likelihood that corn rootworm populations will develop resistance to Cry proteins, extending the effectiveness of these tools.

Weed Management. Herbicide-tolerant transgenic corn cultivars have been developed to allow use of herbicides to control weeds without harming the crop. As described in Section 2.2.2.5, *Weed Management*, herbicide-tolerant corn has been widely adopted by growers in North America. Currently available transgenic herbicide-tolerant corn cultivars include multiple glyphosate- or glufosinate- (phosphinothricin) tolerant cultivars (USDA-APHIS, 2011b).

In 2011, approximately 72 percent of the US corn crop was planted to transgenic varieties that were herbicide tolerant (USDA-ERS, 2011a). Over-reliance on herbicide-tolerant crops and single herbicides may under certain conditions promote the development of herbicide-tolerant weeds (Johnson et al., 2009), although neglect of other strategies to suppress weeds, such as cultural controls, multiple modes of action, and crop rotation are likely equal contributors to weed resistance (Beckie, 2006). Weeds can potentially survive in crop production systems because of natural tolerance to the chemical(s) and because of growth types or life cycles that help them avoid being treated, such as some winter annual weed species. As described in Section 2.2.2.5, *Weed Management*, some weeds have also developed herbicide tolerance because the increased use of herbicide-tolerant corn has encouraged some growers to use predominately one herbicide and fail to use standard practices to prevent weed herbicide resistance that were common before herbicide tolerant crops were commercialized. Weed resistance management training to reduce the potential for weeds to develop tolerance to herbicides has been made available by the Weed Science Society of America in web-based training and other formats to growers and extension trainers and is readily accessible (Ohio-State-Extension, 2011). Because there are numerous herbicides available, including ones such as triazine class herbicides (including atrazine), as well as transgenic corn varieties tolerant to two different herbicides available, growers have the potential to rotate herbicide use, rather than relying on a single herbicide.

Herbicide Use. Event 5307 corn does not have an herbicide tolerance trait. However, Syngenta has indicated that 5307 will likely be stacked with other transgenic corn cultivars that do have herbicide tolerance traits (Table 5-1). Weed management methods would generally follow-current practice for similar traits already available in commercial hybrid seed. With the proposed stacked product that has been identified by Syngenta, including two available traits for herbicide tolerance, growers could continue using predominantly glyphosate for weed control, or glufosinate for resistant weeds, or use glyphosate and glufosinate separately and sequentially on the same crop. The two herbicides could also be used alternately in consecutive crop production years to optimally manage weed resistance. It should be noted that glufosinate resistant corn is already available, so growers can already alternate glufosinate tolerance with glyphosate tolerance in rotations; significant changes in glufosinate use in corn would not be expected.

As described in Section 2.2.2, *Weed Management*, glyphosate application rates increased slightly between 2005 and 2010 and it is reasonable to conclude that they will continue to do so. Weeds may continue to develop tolerance to herbicides, as with any crop and weed management system. Stacking 5307 corn with herbicide tolerance traits is unlikely to significantly change current trends in herbicide use and increasing weed tolerance to herbicides. When combined with the past, present, and reasonably foreseeable future actions, the Preferred Alternative would have a negligible cumulative effect on herbicide use or weed tolerance to herbicides.

Specialty or Organic Corn Production. A determination of nonregulated status of 5307 corn will not change market demands for corn produced through organic methods or specialty corn crops. A determination of nonregulated status of 5307 corn will add another GE corn variety to the conventional corn market. Conventionally produced corn (including GE corn) represents the vast majority of corn in states that produce organic corn, and a determination of nonregulated status of Syngenta 5307 corn is not anticipated to significantly increase GE corn production in these areas. Event 5307 corn should not present any new and different issues and impacts for specialty or organic corn producers and consumers. According to the petition, agronomic trials conducted in a variety of locations in the U.S. demonstrated that 5307 corn is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart (Syngenta, 2011c). No differences were observed in pollen diameter, weight, and viability. Therefore, 5307 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 specialty and organic production systems would not be required to change to accommodate the production of 5307 corn.

5.3.2 Physical Environment

A determination of nonregulated status of 5307 corn is not anticipated to have any direct or indirect cumulative effect on water quality or use; soil; air quality; or climate. A determination of nonregulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. A determination of nonregulated status for of 5307 corn is not expected to alter the range of corn cultivation as the new transgenic trait (rootworm resistance) does not otherwise change the plant's agronomic performance compared to non-transgenic varieties (Syngenta, 2011c). Agronomic practices such as pesticide use, fertilizer use, crop rotation, tillage, irrigation, disease management, or weed management for 5307 corn are similar to other corn varieties that are currently available for use by growers.

5.3.3 Biological Environment

A determination of nonregulated status of Syngenta 5307 corn is not anticipated to have any direct or indirect cumulative effect animals, plants, soil microorganisms or biodiversity. A determination of nonregulated status of 5307 corn would not substantively change the overall usage of transgenic corn products with insect resistance traits. Event 5307 corn is not substantively different in its effects on non-target species from other approved insect-resistant corn products with Cry proteins. Other approved genetically modified crops containing Cry proteins have been demonstrated to have no measurable adverse effects on animals or microbial populations in the soil and would continue to be used by growers. Event 4307 corn does not possess weedy characteristics, and is unlikely to introgress into wild plants or to corn agriculture.

Biodiversity. The past and current actions potentially contributing to a cumulative effect on biodiversity are the introduction of transgenic corn varieties and their increasing use. The future actions potentially contributing to cumulative effects on biodiversity are any combination of 5307 corn stacked with transgenic corn cultivars exhibiting insecticidal properties or herbicide tolerance.

This cumulative effects analysis focuses on potential changes in biodiversity that may result from impacts to non-target plants and animals within the agroecosystem. Other aspects of biodiversity would not be affected

Several traits expressing different Cry proteins are incorporated into various *Bt* corn varieties to provide insect resistance, including resistance to lepidopteran and coleopteran pests. US-EPA conducted a comprehensive environmental assessment of the registered *Bt* PIPs in 2001 (US-EPA, 2001) IIC1 and in four other individual PIPs (e.g., m-Cry3A, (US-EPA, 2010d). Although other *Bt* corn cultivars incorporating Cry proteins have been introduced in the intervening 10 years, and many of the PIPs in earlier cultivars were re-registered in 2010, the 2001 US-EPA review provides a general assessment of the risks to biodiversity associated with *Bt* corn varieties. Summarizing then-existing published studies and US-EPA's reviews of submitted studies on potential Cry protein impacts to non-target species (vertebrates and invertebrates), US-EPA has concluded that "the weight of evidence from the reviewed data indicate that there is no hazard to non-target wildlife from the continued registration of *Bt* crops" (US-EPA, 2001) section IIC81). Minimal to undetectable adverse impacts, and in some cases beneficial impacts, to non-target insect populations were shown (US-EPA, 2001).

New coleopteran-specific *Bt*s however, could have differing activities on nontarget organisms, although activities are not tested against one another; GE trait developers individually test for impacts on representative vertebrate and invertebrate animals. Because one group of insects that would most likely be affected by rootworm toxins are other coleopteran insects, non-target beetles such as the rove beetles (Staphylinidae) are often used to make assessments of effects on biodiversity. When three guilds of rove beetles were examined in fields with vegetative stage *Bt*-expressing plants, plots of DAS 59122-7 (rootworm toxins Cry34Ab1and Cry 35Ab1), DAS 59122-7 X Cry 1F (rootworm toxin X lepidopteran toxin), and an isogenic control, only the DAS 59122-7 plots were associated with a significantly larger activity density of predatory rove beetle larvae than the control or stacked hybrid plots, although only 33% larger. Despite this observation, none of the treatment plots, including isogenic controls or the insecticide treated controls contained lower activity densities (Balog et al., 2011). Thus, based on this information it appears that rove beetle biodiversity was not impacted by exposure to plant-expressed *Bt*s.

Pyramiding of multiple rootworm toxins has begun to be studied in field plots (Hibbard et al., 2011). In these studies the stacking of 5307 corn with Syngenta MIR604 decreased adult rootworm emergence across all replications and environments in field test sites when compared to the single toxin-expressing hybrids. However, as indicated in the study reports, the two genes responsible for resistance in each line are apparently not acting entirely independently, since the numeric product of relative percentage survivorship for each line (5307 and for MIR604) should be the same as the measured survivorship in the dual toxin corn. However, similar survivorship was not attained. The results of the adult emergence study showed neither synergism nor complete additivity.

The commercial *Bt*s active on rootworm have a history of narrow toxicity, and do not have impacts even on related nontarget coleopteran insects (see APHIS' previous petitions for nonregulated status, APHIS 2011b). The two CRW toxin traits proposed for pyramids by Syngenta, 5307 (eCry3.1 Ab) and MIR604 (mCry3A) have been assessed for potential to impact nontarget organisms using a strategy acceptable to US-EPA (D.Ward, Syngenta, pers. comm. 2011). Although nontarget effects are clearly not expected based upon single toxin *Bt* assessments, possible effects were sought by empirical methods to assess antagonism, potentiation, additive toxicity or synergism. Such effects can be studied in insects susceptible to the toxin, rather than choosing a large variety of test insects none of which likely have any sensitivity to the Cry proteins. These assays have been accomplished in the Colorado potato beetle (Syngenta study no. TK 0026862: CBI), and shared with APHIS and US-EPA. Incomplete additivity of apparently independent mechanisms leading to mortality were demonstrated and it appears that synergism in sensitive organisms does not occur. The conclusion is consistent with a determination that nontarget insects are not likely to be impacted, since even in sensitive organisms (the Colorado potato beetle), no unexpected synergism to the stacked Cry proteins could be demonstrated.

As noted in section 2.2.2.3, various chemical treatments are applied to seed of the rootworm specific corn traits; recently this nearly always includes a systemic neonicotinoid (Smith et al., 2004). When species richness within three coleopteran families was assessed throughout a growing season, no differences were detected in fields of isoline and Cry3Bb1 varieties when seeds were treated or when rows were conventionally treated with pyrethroids (during the silking stage), although the isoline had higher coleopteran abundances (Leslie et al., 2010). Mortality deriving from exposure of coleopteran species to the neonicotinoid seed treatments had previously been demonstrated in laboratory analyses and not from exposure to Cry3Bb1. Specific impacts on certain species from the neonicotinoid exposed Coleoptera were not different from those found when these species were exposed to pyrethroids by field application. No end-of-growing-season impacts on coleopteran species followed from use of the Cry3Bb1 hybrid crop (Leslie et al., 2010).

Studies have also concluded that the use of *Bt* crops, rather than broad-spectrum insecticides, could allow larger populations of beneficial insects and non-pest herbivores to persist in planted fields

(Pilson and Prendeville, 2004). Yu and colleagues (Franke et al., 2011) following a comprehensive survey of *Bt*-expressing corn hybrids also concluded that these have no direct detrimental effects on non-target organisms, and these hybrids may allow an increase of beneficial insects and consequently, improve natural control of pests.

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

In general, applying less toxic herbicides (e.g., glyphosate to glyphosate tolerant crops) may be more environmentally beneficial than traditional herbicides with non-GE crops (Pilson and Prendeville, 2004). However, site specific impacts on a species level basis are not always as clear. Birds that consume weeds targeted by the herbicides could potentially be impacted if the weed seed is significantly reduced, as for example, granivorous birds in herbicide tolerant corn in farm scale trials (Chamberlain et al., 2007). These relationships and the actual impact on biodiversity are difficult to determine. For example, one study suggested that reductions in monarch butterfly (*Danaus plexippus*) populations overwintering in Mexico might be attributed in part to loss of host milkweed (*Asclepias syriaca*) plants in the Corn Belt from the extensive use of glyphosate (Brower et al., 2012). Other studies (Davis, 2012) suggest that monarch populations are very dynamic because of the high reproductive potential of this species, and no similar reduction was observed in populations studied in the US.

The hybrids under consideration by Syngenta would combine two rootworm-active proteins that each provide control of western, northern, and Mexican corn rootworm but do not compete for the same binding site in western corn rootworm gut membranes (Syngenta, 2011c). With the proposed pyramided product, including two available traits for herbicide tolerance, growers could continue using predominantly glyphosate for weed control, or could tank-mix both, or use them sequentially on the same crop, or use them alternately in consecutive crop production years to optimally manage weed resistance. Used according to US-EPA designated conditions, impacts on biodiversity of plant species should be no different than that expected from impacts of the two individual herbicide traits. Under these practices, development of resistant weeds could decrease, which could have small but not significant impacts on plants associated with the margins of the agroecosystem.

Section 5.3.2. *Corn Production*, subsection *Herbicide Use*, explains that stacking 5307 corn with herbicide-tolerance traits may incrementally increase the use rates or displacement of certain herbicides, potentially contributing but to a negligible degree to increased weed tolerance to herbicides. Stacking with other insect-resistance traits would potentially decrease broad-spectrum insecticide use, cumulatively reducing the selection pressure for insect resistance and adverse impacts to non-target insects.

5.3.4 Public Health

There are no expected impacts on human health related to the Preferred Alternative. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the Preferred Alternative to affect public health, work safety or animal feed. A determination of non-regulated status of 5307 corn would provide growers with an alternative to other transgenic corn rootworm-protected varieties that are currently available. The eCry3.1Ab protein is derived from a family of *Bt* proteins that has a long history of safe use in food crops (US-EPA, 2001) (updated 2011). Worker safety issues related to agronomic practices and the use of pesticides during agricultural production of 5307 corn would remain the same under both alternatives. Agricultural production with 5307 corn does not require any change to the agronomic practices or chemicals currently used (i.e., pesticides) for conventional corn.

5.3.5 Socioeconomics

From an analysis of direct and indirect effects of 5307 corn in Chapter 4 on Socioeconomic Issues, no cumulative effects of existing products with incorporation of the eCry3Ab are likely to occur in the domestic economic environment, trade economic environment, and social environment.

Domestic Economic Environment. The actions potentially contributing to cumulative effects on the domestic economy are the introduction of transgenic corn varieties and their increasing use. Similar to currently available CRW corn products, farmers are expected to economically benefit from the introduction of 5307 corn. Combining insect resistance traits and herbicide tolerance traits in a single stacked product would likely convey the individual economic benefits of each trait to farmers and seed companies. The corn rootworm species are the most damaging corn pests, affecting as much as 32 million acres each year. Prior to the introduction of rootworm-protected GE corn varieties to the market, corn rootworm cost US farmers nearly $1 billion annually in crop losses and control costs (Rice, 2004). Using corn rootworm-protected varieties offsets these costs by increasing yield and reducing the risk, cost, and time associated with insecticide use (Rice, 2004). Seed companies and growers could also see an economic benefit, from increased profits. Similar benefits are expected from insect-resistant crops targeted at other economically significant pests. For example, lepidopteran-active *Bt* corn has remained effective against the European corn borer for more than a decade, yielding billions of dollars of estimated benefits to farmers in the Midwestern US. The cumulative economic benefit to corn growers in a five-state region over a 14-year period ending in 2009 has been estimated at $6.9 billion (Hutchison et al., 2011). These growers include many who did not plant *Bt* corn varieties, but nevertheless benefited from area-wide suppression of European corn borer populations as a result of sustained *Bt* corn use in the region.

Herbicide-tolerant transgenic corn also has benefits for the domestic economy. For farmers, the general increase in yield, reduction in some input costs, improvement in pest control, increase in worker safety, and time-management benefits have generally outweighed the additional costs of transgenic seed (NRC, 2010). Herbicide-tolerant crops have not greatly increased yields but have generally improved weed control and improved farmers' incomes by saving time.

The Preferred Alternative would positively affect, both directly and indirectly, the domestic economy. Growers would have a broader range of tools to use to control insect pests if 5307 corn is determined to have nonregulated status, directly reducing economic loss from economically important pests. A review of a similar stacked corn hybrid, SmartsStax, showed considerable monetary benefit to growers in the Corn Belt who plant this hybrid compared to previously selected products (Marra et al., 2010). Although the specific domestic economy benefits for Syngenta 5307 cannot be calculated because of the variability and complexity of the market and unavailability of appropriate research, it is assumed that growers will make rational decisions to maximize economic gain from their operations, and 5307 corn stacked with other transgenic corn traits will increase the varieties available to growers.

6 THE ENDANGERED SPECIES ACT AND APHIS SECTION 7 PROCESS

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

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

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

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

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action ―may affect‖ listed species or critical habitat. To facilitate 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 (PPA) of 2000 (Title IV of Public Law 106-224). This process is described in a decision tree document, which is presented in Appendix B. APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

APHIS‘ regulatory authority over GE organisms under the PPA is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR § 340.1). After completing a plant pest risk analysis, if APHIS determines that 5307 corn does not pose a plant pest risk, then 5307 corn would no longer be subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that the article is no longer regulated. As part of its

Environmental Assessment (EA) analysis, APHIS is analyzing the potential effects of 5307 corn on the environment including any potential effects to threatened and endangered species and critical habitat. As part of this process, APHIS thoroughly reviews the genetically engineered product information and data related to the organism (generally a plant species, but may also be other genetically engineered organisms). For each transgene/transgenic plant, APHIS considers the following information and data:

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

In following this review process, APHIS, as described below, has evaluated the potential effects that approval of a petition for nonregulated status of 5307 corn plants may have, if any, on Federally-listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. Based upon the scope of the 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 is commercially produced from the USFWS Environmental Conservation Online System (ECOS; as accessed 1/28/2013 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp). Prior to this review, APHIS considered the potential for 5307 corn to extend the range of corn production and also the potential to extend agricultural production into new natural areas. As described further in the next section, there is no reason to believe that 5307 corn would be grown in areas outside of where corn in currently grown. Accordingly, the issues discussed herein focus on the potential environmental consequences of approval of a petition for nonregulated status of 5307 corn on TES species and critical habitat in the areas where corn is currently commercially grown.

6.1 Potential Effects of 5307 Corn on TES

The analysis of potential effects considered the potential for 5307 corn to extend the range of corn production and the potential to expand agricultural production into new areas. Event 5307 corn does not express any phenotypic traits that would allow it to be commercially viable outside of the existing range of corn cultivation, and is targeted specifically for use in the regions where corn rootworm is a recognized agricultural pest (see *Geographic Distribution of Northern and Western Corn Rootworm and their Variants*, in *Corn Rootworm Biology, Feeding Behavior and Economic Loss*; Chapter 2, Section 2.2.2, *Insect Management*). As described in Section 4.2.2, *Agronomic Practices*, considering that 88 percent of the corn currently grown in the US is genetically modified, it is expected that 5307 corn, if the petition for nonregulated status is approved, would be planted in areas where corn is currently grown. The agronomic analyses show that 5307 corn would use the same agronomic practices – including the same fertilizers, herbicides, fungicides, irrigation, crop rotations, and tillage – as non-transgenic corn hybrids. There is no hazard associated with the cultivation of 5307 corn that would be different from production of non-transgenic corn. 5307 corn like other varieties of corn cannot naturalize (as discussed in Chapter 2, Section 2.1, *Corn Biology*) and has no potential to become weedy. Potential effects on habitat from 5307 corn are thus limited to those associated with typical commercial corn production, in areas where commercial corn has been historically produced. Therefore, production of 5307 corn would not affect the baseline condition of natural habitat, including designated critical habitat, of any listed species.

Corn, including 5307 corn, has no sexually compatible relatives found in natural areas, and is only able to reproduce with other corn plants in the US (USDA-APHIS, 2011). Therefore, 5307 corn would not be sexually compatible with any listed threatened or endangered plant species or plant proposed for listing. Since there are no listed species that are sexually compatible with corn and production of 5307 corn would be limited to those areas already in corn production, no effect would be expected on listed plant species.

APHIS considered the possibility that 5307 corn could serve as a host plant for a threatened or endangered species. A review of the species list indicates that this would not occur. There are no members of the genus *Zea* that serve as a host plant for any threatened or endangered species.

The biosafety studies conducted by Syngenta (Syngenta, 2011c) show no toxic effects to birds, earthworms, fish, freshwater shrimp, non-target insects, or mammals, and show that the insecticidal effects of 5307 corn are limited to corn rootworm larvae, which are not pollinators. As described in the Petition, Syngenta evaluated the composition and nutritional quality of 5307 corn and compared its composition to the composition of a corresponding non-transgenic corn variety and other corn varieties for which composition data were available. The data suggest that there is no difference in composition and nutritional quality between 5307 corn and commercial corn varieties. Therefore, 5307 corn would have no effect on non-target animals that consume it, or on listed animal species, including animals such as insects (with the possible exception of those susceptible to the eCry3.1Ab protein), bats or birds that may be pollinators of plants.

Apart from the transgene that encodes eCry3.1Ab in 5307 corn, 5307 corn also contains the gene *pmi* (also known as *manA*) that encodes the selectable marker PMI enzyme, which is not a toxin and is exempt from both food and feed tolerances following an US-EPA analysis (US-EPA, 2004). Event 5307 corn does not express additional proteins, natural toxicants, allelochemicals, pheromones, or hormones, etc. that could directly or indirectly affect a listed species or species proposed for listing. Based on the compositional equivalency of 5307 corn to corn varieties currently in production (Syngenta, 2011c), the only potential stressor to TES species is that which could occur because of the inclusion of the eCry3.1Ab transgene (Syngenta, 2011c).

A safety assessment(Syngenta, 2011c) conducted on 5307 corn showed that the insecticidal activity of eCry3.1Ab is limited to certain chrysomelid species within the order Coleoptera. The Cry proteins, in general, are highly specific toxins for limited taxa of insects and have no significant activity on other organisms in the environment (US-EPA, 2001, updated 2011). Feeding assays have determined a No Observed Adverse Environmental Concentration for each of a collection of eleven indicator organisms that proved to be between 4.3 and 1200 times higher than the Estimated Environmental Concentration to which these would likely be exposed (except for freshwater shrimp, for which higher NOAEC could not be practically provided because of difficulty providing higher Cry protein to the test organisms) (Syngenta, 2011c). The chrysomelids shown to be sensitive to the insecticidal effects of eCry3.1Ab are the larvae of the western corn rootworm (*Diabrotica virgifera virgifera*), northern corn rootworm *(D. longicornis barberi)*, Mexican corn rootworm (*D. virgifera zeae)*, and the Colorado potato beetle *(Leptinotarsa decemlineata)*.[9] The eCry3.1Ab protein demonstrates no lepidopteran activity, despite containing sequences from a lepidopteran-active protein (Cry1Ab, as in MON 810; (Walters et al., 2010). The high specificity of the eCry3.1Ab protein makes it unlikely that non-target or threatened or endangered insects would be affected.

The review of the species list identified insect species of the order Coleoptera that were further evaluated for the possibility of effects from exposure to 5307 corn. The consideration of protected species is limited to Coleoptera in corn growing regions, as this is the insect group to which corn rootworm belongs, and the insecticidal protein produced in 5307 corn (eCry3.1Ab) has been shown to be active only on certain Coleoptera and not on other invertebrate or vertebrate species. Three coleopteran-specific Cry proteins currently expressed in commercial corn have been analyzed by US-EPA, and the agency concludes for one of these that Cry34Ab1/Cry35Ab1 will have "no adverse effect on endangered and threatened species listed by the US Fish and Wildlife Service is expected from the Event DAS-59122-7 corn registration (US-EPA, 2005) and also that "the Agency is aware of no identified significant adverse effects of Cry34/35Ab1 proteins on the abundance of non-target beneficial organisms in any population in the field, whether they are pest parasites, pest predators, or pollinators." Analysis of effects on a susceptible coleopteran, *L. decemlineata*, showed that the eCry3.1Ab protein did not act to synergize the effects of a second Cry protein, MIR604 (CBI, Syngenta, submitted to US-EPA), with which Syngenta proposes to pyramid into new commercial hybrids (Syngenta, 2011c). Lack of synergism in a susceptible species is evidence that no such interactions are likely to occur with nontarget species possibly exposed to this protein. The Preferred Alternative's lack of potential impacts to the named species is also discussed in Section VIII D. and VIII E. of the Syngenta petition (Syngenta, 2011c).

Data on listed coleopteran species and critical habitat were obtained from the US Fish and Wildlife Service (http://www.fws.gov/species/). County-level species location information was obtained from a work product of the FIFRA Endangered Species Task Force (FESTF) including the Information Management System (IMS) and the NatureServe Multi-Jurisdictional Database (MJD) licensed by FESTF.[10] This database contains county-level species data provided from the USFWS and crop data from the USDA Census of Agriculture. This provides the best available aggregated data on federally listed species habitat and occurrence. Syngenta Crop Protection LLC is a full member of FESTF and has access to this licensed dataset. This database provides information only for extant species locations.

A total of 18 coleopteran species listed by the USFWS were identified as Endangered or Threatened under the ESA (ECOS; as accessed 1/28/2013 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp)., three of which do not occur in counties of corn-growing regions (see Figure 1). There is one coleopteran species proposed for listing as threatened, along with proposed critical habitat - the coral pink sand dunes tiger beetle

9 The Colorado potato beetle is not a pest of corn, but it is sensitive to eCry3.1Ab in direct laboratory feeding studies.

10 See the FESTF website at http://www.festf.org/visitors/default.asp.

(*Cicindela albissima*). This species is restricted to sand dune habitat and is found only in Kane County, Utah, and would not be expected to be found in corn growing areas. (ECOS; as accessed 1/28/2013 at http://ecos.fws.gov/tess_public/SpeciesReport.do?listingType=P). One listed species, the Valley elderberry longhorn beetle (*Desmocerus californicus dimorphus*), has been proposed for delisting (http://www.gpo.gov/fdsys/pkg/FR-2012-10-02/pdf/2012-23843.pdf). Table 11 lists the 15 threatened or endangered species of Coleoptera found within corn-growing regions. Critical habitat, where established by the USFWS, is also indicated.

Table 11: Threatened or Endangered Coleopteran Species Occurring in Corn Growing Regions

Scientific Name	Family	Common Name	ESA Status	Critical Habitat
Batrisodes texansus	Staphylinidae	Coffin Cave mold beetle	Endangered	None
Batrisodes venyivi	Staphylinidae	Helotes mold beetle	Endangered	Bexar Co., TX
Brychius hungerfordii	Halipidae	Hungerford's crawling water beetle	Endangered	None
Cicindela dorsalis dorsalis	Carabidae	Northeastern beach tiger beetle	Threatened	None
Cicindela nevadica lincolniana	Carabidae	Salt Creek tiger beetle	Endangered	Lancaster and Saunders Co., NE
Cicindela puritan	Carabidae	Puritan tiger beetle	Threatened	None
Desmocerus californicus dimorphus	Ceramby-cidae	Valley elderberry longhorn beetle	Threatened	Sacramento Co., CA
Elaphus viridus	Carabidae	Delta green ground beetle	Threatened	Solano Co., CA
Heterelmis comalensis	Byrrhoidae	Comal Springs riffle beetle	Endangered	Hays and Comal Co., TX
Nicrophorus americanus	Silphidae	American burying beetle	Endangered	None
Rhadine exilis	Carabidae	None	Endangered	Bexar Co., TX
Rhadine infernalis	Carabidae	None	Endangered	Bexar Co., TX
Rhadine persephone	Carabidae	Tooth Cave ground beetle	Endangered	None
Stygoparnus comalensis	Dryopidae	Comal Springs dryopid beetle	Endangered	Hays and Comal Co., TX
Texamaurops reddelli	Staphylinidae	Kretschmarr Cave mold beetle	Endangered	None

Source: FIFRA Endangered Species Task Force (FESTF)

Refined geospatial analysis showed that only three of the 15 coleopteran species co-occur with potential corn production locations:

- Kretschmarr Cave mold beetle (*Texamaurops reddelli*),
- American burying beetle (*Nicrophorus americanus*), and
- Salt Creek tiger beetle (*Cicindela nevadica lincolniana*).

The analysis showed that there would be no exposure of two of these species to 5307 corn. The **Kretschmarr Cave mold beetle** inhabits small isolated caves within the Edwards Limestone formation in Texas (USFWS, 1988), making contact with corn unlikely. The **American burying beetle** relies on carrion (mammals, birds, reptiles) as a food source (US-FWS, 2011) and would not be expected to ingest 5307 corn or its insecticidal protein because it does not eat corn or insects. The **Salt Creek tiger beetle** is a predatory beetle that feeds on other insects, and due to its observed proximity to corn production areas, it may conceivably be exposed to very low eCry3.1Ab concentrations (compared to levels measured in 5307 corn) via predation. While predation upon arthropods containing trace amounts of eCry3.1Ab is possible, the beetle's predatory habits would greatly limit the opportunity for such exposure. Salt Creek tiger beetle larvae are known to prey on insects from the entrance of permanent burrows built in saline stream banks and barren salt flats of saline wetlands - habitats which do not occur in cornfields (USFWS, 2005). Critical habitat for this beetle includes pasture land that is unlikely to be used for corn production because it is mostly saline marsh (US-FWS, 2010), and 5307 corn has no characteristics to make it more likely to be planted on this habitat than any other variety. Therefore, any exposure of Salt Creek tiger beetles to even trace amounts of eCry3.1Ab via their prey would be unlikely. Further, if such exposure were to occur, no measurable hazard is predicted. The Salt Creek tiger beetle is a member of the Carabidae family. Biosafety analyses documented in the Petition (Syngenta, 2011c) showed no effects of eCry3.1Ab on the survival of carabid beetles when tested at levels 62 times greater than the worst-case estimated environmental concentration.[11]

After reviewing the potential effects of 5307 corn on the environment that could result from approval of a petition for nonregulated status of 5307 corn, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed threatened or endangered species or species proposed for listing. APHIS considered the effect of 5307 corn production on designated critical habitat or habitat proposed for designation and could identify no difference from effects that would occur from the production of other corn varieties. Corn is not considered a particularly competitive plant species and is ecologically limited to production by human populations. Corn is not considered weedy and feral populations of corn have not been identified in the U.S. 5307 corn is not sexually compatible with, or serves as a host species for, any listed species or species proposed for listing. Consumption of 5307 corn by any listed species or species proposed for listing will be either unlikely or will not result in a toxic or allergic reaction. Based on these factors, APHIS has determined that approval of a petition for nonregulated status for 5307 corn would have no effect on listed threatened or endangered species or species proposed for listing and would not affect designated critical habitat or habitat proposed for designation. Because of this no effect determination, consultation under Section 7(a)(2) of the Act or the concurrence of the USFWS or NMFS is not required.

7 Consideration of Executive Orders and Other Federal Laws Relating to Environmental Impacts

As required by the CEQ, this Chapter considers the Executive Orders (EOs) and other federal laws related to the potential environmental impacts of the Preferred Alternative.

7.1 Executive Orders with Domestic Implications

Four EOs have domestic implications that are relevant to the environmental assessment of the petition to deregulate 5307 corn.

7.1.1 Executive Order 12898: Environmental Justice

EO 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (EO 12898 of February 11, 1994), 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 or low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.

[11] The worst-case estimate assumes that the organisms' diet is comprised of 100 percent 5307 corn material.

Each alternative was analyzed with respect to EO 12898. Neither alternative is expected to have a disproportionate adverse effect on minorities or low-income populations. As presented in the Environmental Consequences section, no significant impacts were identified in the analyses conducted on human health, physical environment, or animal and plant communities.

Event 5307 corn is not significantly different from other transgenic or non-transgenic corn. As described in Chapter 4, Section 4.4.1, *Animals*, the eCry3.1Ab and PMI proteins do not pose a hazard to humans. A voluntary FDA consultation for food and feed use of 5307 corn was initiated in January 2011 (Appendix B, (Syngenta, 2011a). Data and information provided by Syngenta support the safe use of 5307 corn and indicate that it will be as nutritious and wholesome as other corn current used as food and feed (Syngenta, 2011c). Based on this information, 5307 corn is not expected to have a disproportionate adverse effect on minorities or low-income populations.

As described in Chapter 4, Section 4.2.2, *Agronomic Practices*, the cultivation of corn varieties with similar insect resistance traits have been associated with a decrease in the volume of insecticides being applied. If insecticide applications are reduced, there may be a beneficial effect on minority populations. These populations might include farm workers and their families, and other rural dwelling individuals who are potentially exposed to insecticides through aerial application, groundwater, or other routes of exposure.

7.1.2 Executive Order 13045: Protection of Children

EO 13045, *Protection of Children from Environmental Health Risks and Safety Risks* (EO 13045 of April 21, 1997), 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. This EO requires each federal agency (to the extent permitted by law and consistent with the agency's mission) to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

Each alternative was analyzed with respect to EO 13045. Neither alternative is expected to have a disproportionate adverse effect on children. As presented in the Environmental Consequences section, no significant impacts were identified in the analyses conducted on human health or the physical environment.

Event 5307 corn is not significantly different from other transgenic or non-transgenic corn. As described in Chapter 4, Section 4.4.1, *Animals*, the eCry3.1Ab and PMI proteins do not pose a hazard to humans. A voluntary FDA consultation for food and feed use of 5307 corn was initiated in January, 2011 (Appendix B (Syngenta, 2011a). Data and information provided by Syngenta support the safe use of 5307 corn and indicate that it will be as nutritious and wholesome as other corn current used as food and feed (Syngenta, 2011a; Syngenta, 2011c). Based on these analyses, 5307 corn is not expected to have a disproportionate adverse effect on children.

As described in Chapter 4, Section 4.2.2, *Agronomic Practices*, the cultivation of corn varieties with similar insect resistance traits have been associated with a decrease in the volume of insecticides being used. If insecticide applications are reduced, there may be a beneficial effect on children that might be exposed to the chemicals. Similar to minority populations, these children might include families of farm workers and other rural dwelling individuals who are exposed to insecticides through aerial application, groundwater contamination, or other routes.

7.1.3 Executive Order 13112: Invasive Species

EO 13112, *Invasive Species* (EO 13112 of February 3, 1999), requires federal agencies to 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.

All corn varieties, including 5307 corn, require human assistance to persist beyond a first generation of corn plants that may arise from spilled seed; they do not establish self-propagating populations. Corn does not possess traits that are characteristic of invasive species (Baker, 1965); (Keeler, 1989), ; (Galinat, 1988). As described in Section 4.4.5, *Gene Movement in the Natural Environment*, 5307 corn plants are very similar in agronomic characteristics to other corn varieties that are currently grown and are not expected to become weedy or invasive. Accordingly, the Preferred Alternative would not raise concerns addressed by EO 13112, *Invasive Species*.

7.1.4 Executive Order 13186: Migratory Birds

EO 13186, *Responsibilities of Federal Agencies to Protect Migratory Birds* (Federal Register 66:3853, January 10, 2001), requires each federal agency to avoid and minimize, to the extent practicable, adverse impacts on migratory bird populations when conducting agency actions.

Although migratory birds forage in corn fields, as described in Section 4.4.1, *Animals*, 5307 corn is not expected to have any adverse impacts on migratory birds because the eCry3.1Ab protein is not biologically active in avian species. To confirm the absence of any impact on avian species, Syngenta has conducted an eCry3.1Ab toxicity study on juvenile bobwhite quail and a 5307 corn feeding study on broiler chickens, in which no harmful effects to quail or chickens were observed (Syngenta, 2011c). A determination of non-regulated status of 5307 corn therefore is not expected to have a negative effect on migratory bird populations.

7.2 Executive Orders with International Implications

EO 12114, *Environmental Effects Abroad of Major Federal Actions* (Federal Register 44:1957, January 4, 1979), requires federal officials to take into consideration any potential environmental effects outside the US, its territories, and possessions that may result from actions being taken.

All of the existing national and international regulatory authorities and phytosanitary regimes that currently apply to introduction of new corn cultivars internationally apply equally to those covered by an APHIS determination of non-regulated status under 7 CFR Part 340. International trade of 5307 corn subsequent to a determination of non-regulated status for the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC, 1997).

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, 1997). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC set a standard for the reciprocal acceptance of phytosanitary certification among the 177 nations that have signed or acceded to the convention (IPPC, 2011). In April 2004, a standard for pest risk analysis (PRA) of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to the existing *International Standard for Phytosanitary Measure No. 11* (IPPC, 2004). The standard acknowledges that LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The *Cartagena Protocol on Biosafety* (the Protocol) 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 includes those modified through biotechnology. The Protocol came into force on September 11, 2003, and 161 countries are currently parties to it (CBD, 2011). Although the US is not a party to the CBD and thus not a party to the Protocol, US exporters will still need to comply with domestic regulations that importing countries that are parties to the Protocol have put in place 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 US government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (http://usbiotechreg.nbii.gov). These data will be available to the Biosafety Clearinghouse. International trade of 5307 corn would be conducted in compliance with the Protocol.

Biosafety and biotechnology consensus documents, guidelines, and regulations, are managed by APHIS in accordance with the requirements of the North American Plant Protection Organization (NAPPO) and 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). The Preferred Alternative is not expected to affect APHIS's participation in NAPPO or the OECD.

North American Biotechnology Initiative is a forum for information exchange and cooperation on agricultural biotechnology issues for the US, Mexico, and Canada. Bilateral discussions on biotechnology regulatory issues are also held regularly with other countries including Argentina, Brazil, Japan, China, and South Korea. Several countries, including Argentina, Brazil Australia, Canada, China, Columbia, Japan, Mexico, New Zealand South Korea, the Philippines, South Africa, and the European Union, have already approved *Bt* corn varieties to be grown or imported for food or feed (CERA, 2010).

As described in Section 4.6.2, *Trade Economic Environment*, the Preferred Alternative is not expected to affect the US corn export market since Syngenta is actively pursuing regulatory approvals for 5307 corn in countries with functioning regulatory systems for genetically modified organisms and that import corn from the US or Canada. Regulatory filings for 5307 corn import approvals have been made in Australia, Japan, New Zealand, South Africa, South Korea, Taiwan, and the European Union Syngenta, (Syngenta, 2011c). Applications are planned for additional countries including Mexico, China, the Philippines, Indonesia, and Russia (Syngenta, 2011c).

7.3 Other Federal Laws

7.3.1 Clean Water Act

The *Federal Water Pollution Control Act* (commonly referred to as the Clean Water Act) (*Federal Water Pollution Control Act*, as amended, 33 USC 1251-1376) and implementing regulations (USACOE, various dates; 33 CFR Parts 320 through 332; US-EPA, various dates; 40 CFR Parts 230 through 233) require entities that discharge regulated materials to certain surface water bodies (including wetlands) obtain authorization to do so from federal or state agencies under various permit programs.

Cultivation of 5307 corn is not expected to lead to the increased production of corn in U.S. agriculture. As described in Section 4.3.1, *Water Quality and Use*, water quality is not likely to change as a direct or indirect result of the Preferred Alternative. A determination of nonregulated status of 5307 corn would not result in a change of agricultural practices or any new discharge of pollutants to surface water bodies. Water quality would continue to be regulated and agronomic practices to protect water quality would continue to be implemented in the event of a determination of nonregulated status of 5307 corn. Chemical insecticide use would continue to be reduced as transgenic corn products with insect-resistant traits are developed, marketed, and adopted. Cultivating 5307 corn would not require Clean Water Act permits different than those already required for agricultural activities.

7.3.2 Clean Air Act

The *Clean Air Act Amendments of 1990* (commonly abbreviated as the Clean Air Act; as amended, 40 USC 7401-7671) and implementing regulations (US-EPA, various dates; 40 CFR Parts 50 through 99) require entities that discharge regulated materials into the atmosphere obtain authorization to do so from federal or state agencies under various permit programs.

Cultivation of 5307 corn is not expected to lead to the increased production of corn in U.S. agriculture. As described in Section 4.3.3, *Air Quality*, the Preferred Alternative is not likely to directly change air quality. Event 5307 corn production would not change land acreage or cultivation practices for transgenic or non-transgenic corn. Air quality would be indirectly improved if aerial application of corn rootworm pesticides is reduced. Corn growers would continue current trends in agricultural activities in the event of a determination of nonregulated status of 5307 corn. Spray application of insecticides could continue to be reduced as additional insect-resistant products are adopted by growers because 5307 corn would give growers another option to combat corn rootworm. Cultivating 5307 corn would not require Clean Air Act permits different than those already required for agricultural activities.

7.3.3 National Historic Preservation Act

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 5307 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.

A determination of nonregulated status of 5307 corn 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 5307 corn. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of US-EPA registered pesticides. Applicant's adherence to US-EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of 5307 corn is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the corn production regions. The cultivation of 5307 corn does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

7.3.4 Federal Laws Regarding Unique Characteristics of Geographic Areas

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of 5307 corn.

The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property; do not cause any alterations of property, wildlife habitat, or landscapes; and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of 5307 corn. The product will be deployed on agricultural land currently suitable for production of corn, will replace existing varieties, and is not expected to increase the acreage of corn production. This action would not convert land use to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to 5307 corn including the use of US-EPA registered pesticides. Applicant's adherence to US-EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of 5307 corn, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to corn production sites.

7.4 Regulations, Policies, and Executive Orders

Clean Air Act Amendments of 1990, as amended. Codified at 40 USC § 7401-7671.

Energy Policy Act of 2005. Public Law 109-58. August 8, 2005. Codified at 42 USC § 15801 *et seq.*

Endangered Species Act of 1973, as amended. Public Law 93-205. Codified at 7 USC § 126 and 16 USC § 1531 *et seq*.

Executive Office of the President, Office of Science and Technology Policy. 1986. *Coordinated Framework for Regulation of Biotechnology*. Published in the Federal Register (FR) at 51 FR 23302 on June 26, 1986.

Executive Order 12114 of January 4, 1979. *Environmental Effects Abroad of Major Federal Actions*. Published at 44 FR 1957 on January 4, 1979.

Executive Order 12898 of February 11, 1994. Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations. Published at 59 FR 7629 on February 11, 1994.

Executive Order 13045 of April 21, 1987. *Protection of Children from Environmental Health Risks and Safety Risks*. Published at 62 FR 19883 on April 21, 1987.

Executive Order 13112 of February 3, 1999. *Invasive Species*. Published at 64 FR 6183 on February 3, 1999.

Executive Order 13186 of January 10, 2001. *Responsibilities of Federal Agencies to Protect Migratory Birds*. Published at 66 FR 3853 on January 10, 2001.

Executive Order 13563 of January 18, 2011. *Improving Regulation and Regulatory Review*. Published at 76 FR 14 on January 21, 2011.

Federal Food, Drug, and Cosmetic Act, as amended. 1938. Public Law 75-717. Codified at 21 USC § 301 *et seq*.

Federal Insecticide, Fungicide, and Rodenticide Act, as amended. 1940. Public Law 80-104. Codified at 7 USC § 136 *et seq*.

Federal Water Pollution Control Act (Clean Water Act). 1948. Public Law. 845. Codified at 33 USC § 1251 *et seq*.

Food, Conservation, and Energy Act of 2008. Public Law 110-234. May 22, 2008. Codified at 7 USC § 8711 *et seq*., and § 8751 *et seq*.

National Environmental Policy Act, as amended. 1970. Public Law 91-190. Codified at 42 USC § 4321 *et seq*.

National Historic Preservation Act of 1966, as amended. Public Law 89-665. October 15, 1966. Codified at 16 USC § 470 *et seq.*

Plant Protection Act. 2000. Title IV of the *Agriculture Risk Protection Act of 2000.* Public Law 106-224. Codified at 7 USC § 7701 *et seq*.

Toxic Substances Control Act, as amended. 1976. Public Law 94-469. Codified at 15 USC § 2601 *et seq*.

United States Army Corps of Engineers (USACOE). Various dates. 33 CFR Parts 320 through 332.

United States Department of Agriculture (USDA). 1990. *Policy of Noxious Weed Management*. Departmental Regulation Number 9500-10. Washington, DC: USDA.

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USDA-APHIS. 1987. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests. 7 CFR Part 340.

USDA-APHIS. 1995. National Environmental Policy Act Implementing Procedures. 7 CFR Part 372.

United States Department of Health & Human Services - Food and Drug Administration (USDHHS-FDA). 1992. *Statement of Policy: Foods Derived From New Plant Varieties*. 57 FR 22984, May 29, 1992.

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9 LIST OF PREPARERS

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Appendix A Supplemental Information on Insecticide Use with Traits in Corn

An article written by Lynn Grooms for Farm Industry News describes how some corn growers are now using soil insecticides with traits.[1] This article nicely summarizes the circumstances under which it could be advantageous for a grower to apply conventional insecticide when rootworm-protected *Bt* corn varieties have been planted. Root feeding damage by corn rootworms (*Diabrotica* spp.) has always been costly for U.S. growers. Before introduction of the first rootworm-protected *Bt* hybrids growers had two options for limiting damage caused by these pests: crop rotation and application of conventional insecticides. Rotation gradually lost its effectiveness in certain regions of the Midwest with the spread of a western corn rootworm variant that had developed an affinity for laying eggs in soybean fields and an extended diapause northern corn rootworm variant that could survive the rotation. Insecticide applications have historically not been made on the majority of planted acres (Figure 1) because the low price of corn (Figure 2) did not always justify the expense and most growers did not have the equipment necessary for their application. Furthermore, environmental factors often limited the effectiveness of insecticide applications.

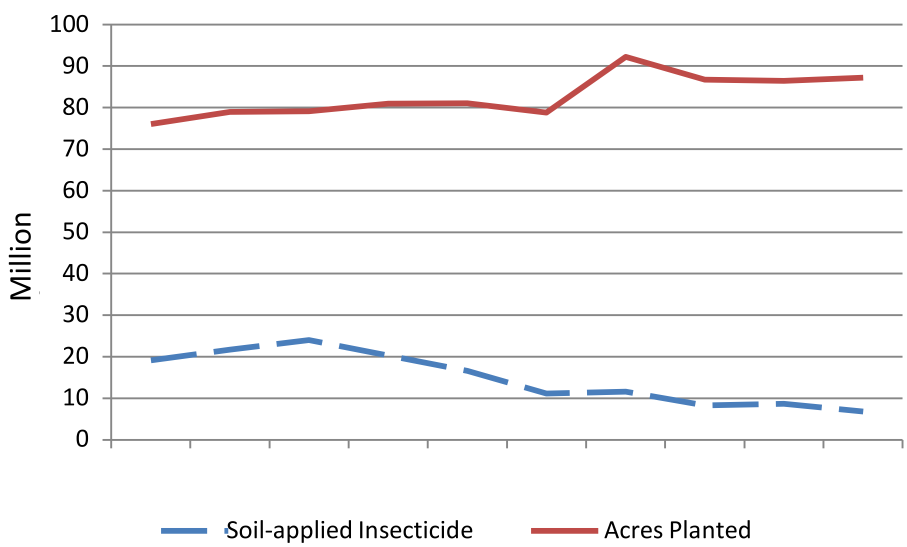

Figure 1. Total acres of corn planted annually in the continental U.S. and acres of corn treated annually with a soil-applied conventional insecticide (excluding seed treatments). GfK Kynetec Market Research, database query (2011).

The first genetically engineered corn varieties offering protection from rootworm feeding damage entered the market in 2003. Today there are many varieties available to growers containing one or more of the following events determined to have nonregulated status that are active against corn rootworms: MON 88017, DAS-59122-7, and MIR604. These hybrids have been rapidly adopted by growers because they provide better protection from root feeding damage and are

[1] CRW Combos. February 1, 2009. http://farmindustrynews.com/corn-rootworm-traits/crw-combos

more convenient to use than conventional insecticides; 52% of corn acres in 2011 were planted with hybrids containing these traits (Figures 2 and 3). As trait acreage has increased, acres treated with conventional insecticides have decreased (Figure 3). Only 6.8 million corn acres were treated with a soil-applied insecticide in 2011, a 72% reduction from acres treated in 2003. This trend validates assumptions made ten years ago by U.S. regulatory agencies that introduction of corn rootworm protection traits had the potential to significantly reduce insecticide use.

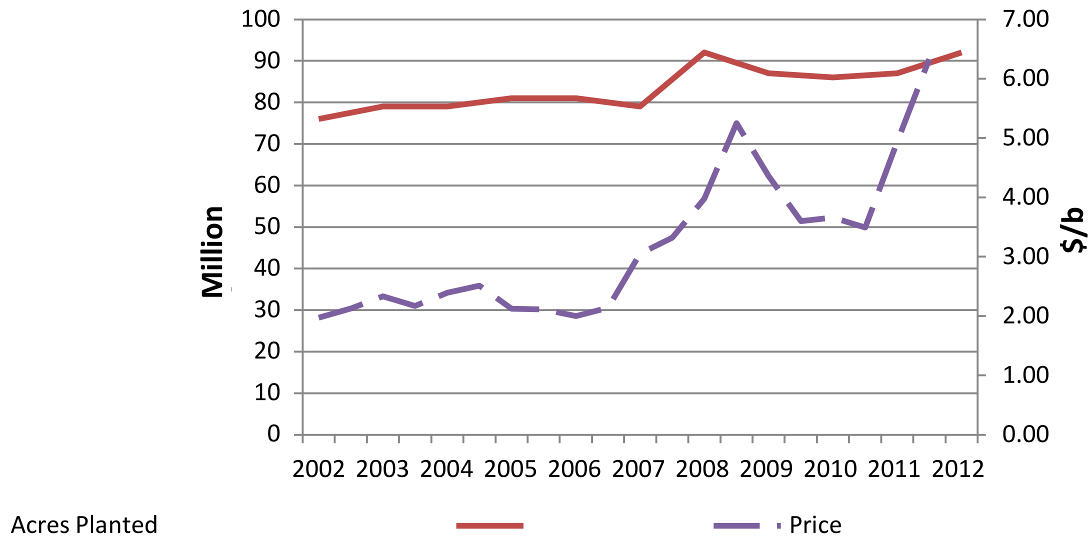

Figure 2. U.S. corn acres planted annually and average price of corn received ($/bu). USDA National Agricultural Statistics Service Charts and Maps 2011 (http://www.nass.usda.gov/Charts_and_Maps/index.asp)

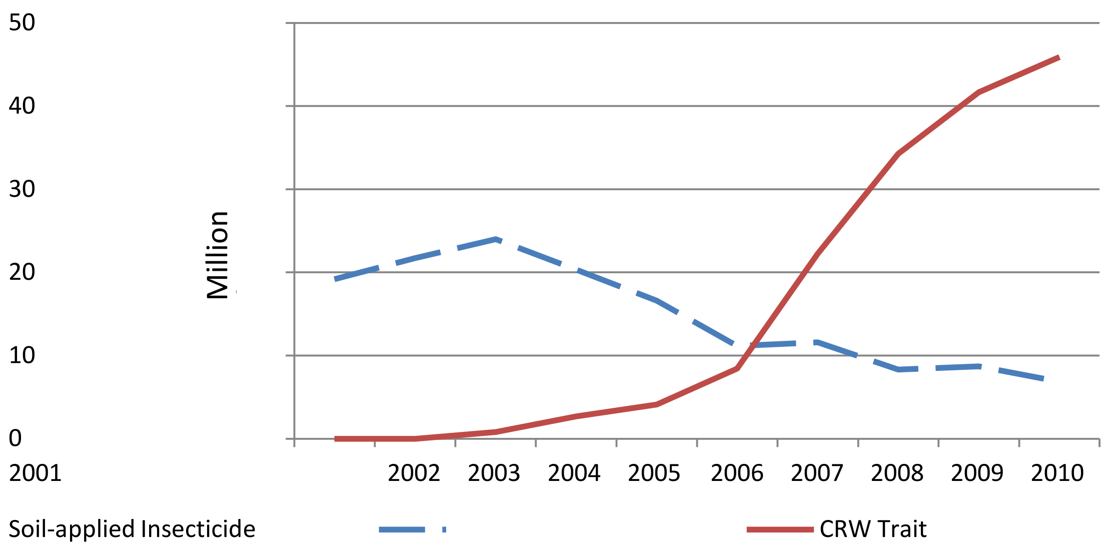

Figure 3. U.S. corn acres planted with a corn rootworm-protected trait hybrid and acres treated with a soil-applied insecticide (aerial, banded, banded before press wheel, banded behind press wheel, banded in- furrow and broadcast applications). GfK Kynetec Market Research, database query (2011).

The introduction of corn varieties that were genetically engineered to resist *Diabrotica* feeding damage provided growers with a powerful and environmentally friendly new tool for protecting their corn crops. However, the *Bt* trait technology does not provide 100% root protection under all environmental circumstances. Unlike the *Bt* toxins that are active against lepidopteran species, the toxins produced in rootworm-protected varieties currently on the market are not high dose. When high corn rootworm larval populations are present (*i.e.*, high pressure) significant root feeding damage can occur in traited varieties.[2] Such damage has recently been reported by university extension services.[3,4] Certain regions of the corn belt are at greater risk of having high rootworm larval pressure (Figure 4). This region spans eastern Colorado through Nebraska, Iowa, and northern Illinois. Higher populations of the rotation-resistant rootworm variants have been reported in this area. Much continuous corn is planted in this area because it contains a relatively high density of ethanol mills and livestock feeding yards.

Figure 4. General region of the US corn belt at greater risk of high corn rootworm larval populations (red shaded area). Source: Syngenta Market Research.

Field trials conducted by University of Illinois researchers in 2008 demonstrated that under high rootworm pressure substantial root feeding damage can occur in traited plants.[5] Under such Conditions, additional root protection can be obtained when traited corn is deployed in combination with a conventional insecticide. Figure 5 presents results for 2008 corn rootworm

[2] A root damage rating for unprotected plants exceeding 2.0 on the NIS is generally regarded as reflecting "high rootworm pressure".

[3] University of Illinois Extension. The Bulletin. Pest Management and Crop Development Information for Illinois (http://bulletin.ipm.illinois.edu/). Issue No. 23 Article 3 (2008); Issue No. 24 Article 4 (2009); Issue No. 23 Article 2 (2010).

[4] University of Illinois Extension (2011). On Target. Annual review of University of Illinois insect management trials (http://ipm.illinois.edu/ontarget/2011report.pdf)

[5] Oleson, J.D., Y. Park, T.M. Nowatzki, and J.J. Tollefson (2005). Node-injury scale to evaluate root injury by corn rootworms (Coleoptera: Chrysomelidae). *J. Econ. Entomol.* **98**:1-8.

damage trials conducted at two locations in Illinois. The entire data set from these trials is available online;[6] only selected results from the DeKalb and Perry locations are presented here. The purpose of these trials was to compare the effectiveness of multiple corn rootworm control technologies available to growers. The following entries were replicated in a randomized complete block design and rated at both locations:

- Soil-applied Force[∨] CS (tefluthrin insecticide) on hybrid 34P89
- YieldGard VT (event MON 88017) in hybrid DKC 63-42
- Soil-applied Force CS on YieldGard VT in hybrid DKC 63-42
- Hybrid DKC 63-46 (untreated isoline)
- Herculex Xtra (event DAS-59122-7) in hybrid 34P94
- Soil-applied Force CS on Herculex Xtra in hybrid 34P94
- Hybrid 34P89 (untreated isoline)

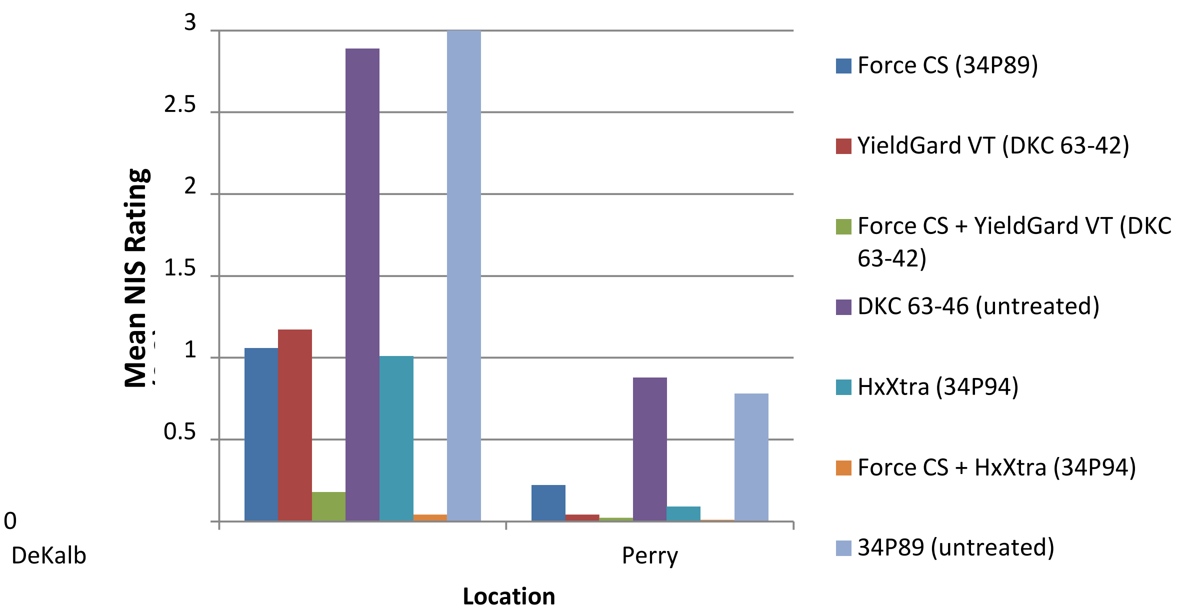

Figure 5. Selected root damage ratings from University of Illinois product efficacy trials conducted at DeKalb and Perry, Illinois during the 2008 corn growing season. Root feeding damage was rated according to the Iowa State University node-injury scale (NIS). Mean ratings from four replicated plots are presented. Force CS was applied at 0.46 oz/ac in a 5-inch band over the planted row.

Heavy corn rootworm larval pressure was present in the 2008 trial conducted at DeKalb as evidenced by the mean NIS ratings >2.0 for the two unprotected isoline entries. Conventional insecticide used alone or a rootworm protection trait used alone offered significant protection from root feeding damage but not complete protection. Under this high rootworm pressure the

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[6] Steffey, K. (2008). The Bulletin. Pest Management and Crop Development Information for Illinois (http://bulletin.ipm.illinois.edu/). Issue No. 23 Article 3 (October 3, 2008).

[∨] Registered trademark of Syngenta

mean NIS ratings at DeKalb for Force CS, YieldGard VT, and Herculex Xtra entries were similar and close to 1.0. When either trait was deployed with the conventional insecticide, root feeding damage was minimal; mean NIS ratings fell to 0.05-0.18. When rootworm pressure is high, growers would likely benefit from deploying traited corn in combination with a conventional insecticide.

In contrast, rootworm pressure at the Perry location was not very high; mean NIS ratings were <1.0 in the unprotected isoline entries. Under these conditions the traits provided nearly complete protection from root feeding damage. The incremental reduction in NIS rating obtained by deploying trait in combination with an insecticide was inconsequential. Thus, there would be no economic incentive for a grower to invest in a chemical application.

In addition to *Diabrotica* spp., there are other soil dwelling insects that feed on corn roots, for example, Japanese beetle larvae, cutworms, and wireworms. These insects are not controlled by the rootworm-active *Bt* toxins in traited varieties. Historically, damage caused by these pests was considered minor compared to that caused by corn rootworms. However, when the price of corn exceeds $6/bu, controlling these secondary pests may be economically worthwhile for some growers.

Changing market conditions have led some growers to consider use of a conventional insecticide in combination with planting a rootworm-protected variety. Increasing global demand for livestock feed and domestic ethanol production has acted to drive corn prices to record high levels, currently in excess of $6/bu. Between 2001 and 2010 the average cost of an insecticide soil application in corn ranged from $11.24/ac to $12.70/ac. If applying a soil insecticide to a traited acre produces a yield benefit of ε3 bushels it would be economically worthwhile for a grower to make such an application. This assumes the grower has the equipment to apply the insecticide and can anticipate conditions where such a yield benefit would be obtained. Results of 96 on-farm comparison trials conducted by growers in 2011 indicate that yield benefits can often be obtained when traited corn is deployed with the soil-applied insecticide Force CS or Force 3G (see Figure 6). These trials were conducted in locations that are typically under high rootworm pressure: northern Illinois, northern Indiana, and eastern Iowa. The average yield difference between insecticide-treated and nontreated fields was 10.9 bu/ac with the yield gain attributable to insecticide treatment. This represents a potential $65/ac gain for growers.

As described in the petition for deregulation, Syngenta will commercialize Event 5307 corn in a breeding combination with its corn rootworm-protected corn trait, MIR604 previously determined to have nonregulated status. This combination will offer two benefits: 1) enhanced protection from rootworm feeding damage in a breeding stack configuration, and 2) reduction in insect resistance risk when roots contain multiple toxins active against rootworm larvae. The results of Syngenta trait performance trials conducted between 2005 and 2009 demonstrate that enhanced protection from rootworm feeding damage is obtained when Event 5307 is introgressed into established corn lines containing Event MIR604. The results of trials conducted at 21 locations throughout the Corn Belt are summarized in Figure 7.

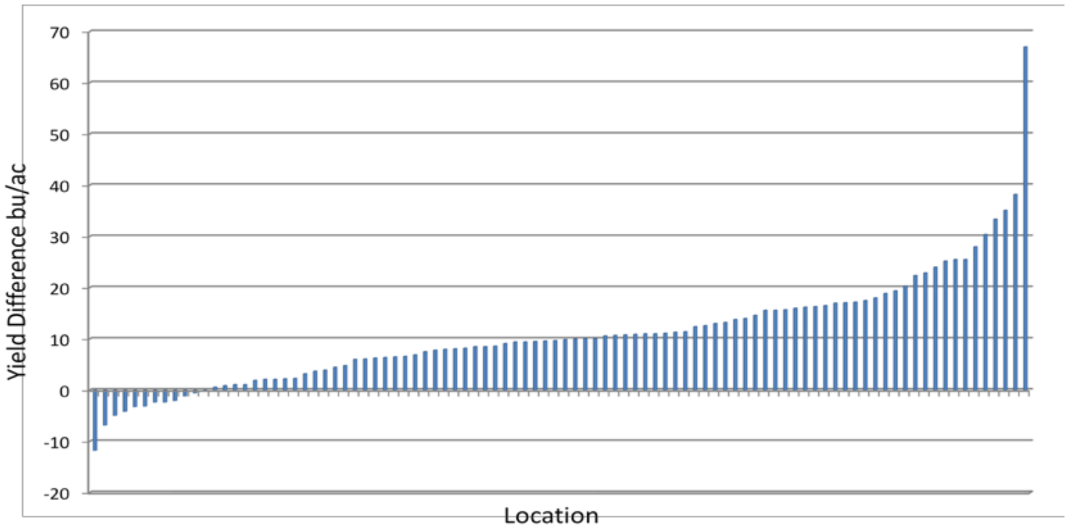

Figure 6. Results of 96 grower comparison trials conducted during 2011. In a split field design growers compared yield from insecticide treated and non-treated fields. Whole fields were planted with a single corn rootworm traited hybrid (YieldGard VT, Herculex Xtra, or Agrisure RW). Half the field received a soil application of Force insecticide, either the CS or 3G formulation, and the other half of the field was not treated with insecticide. Fields were managed according to local practices. Each half of the field was harvested separately and yield was measured. The chart presents the difference in yield for each split field trial: [yield with insecticide – yield without insecticide = yield difference].

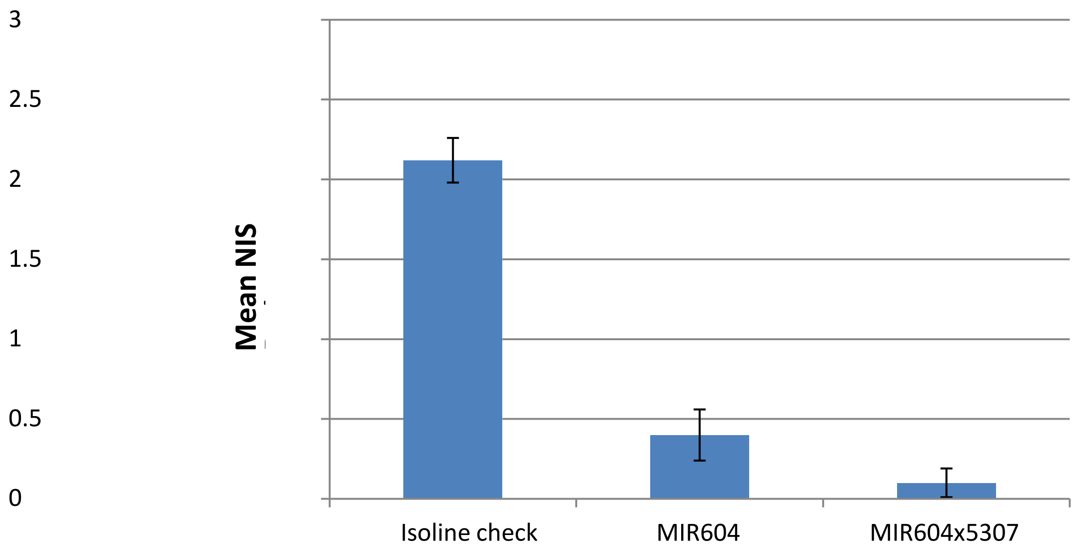

Figure 7. Summary root damage ratings from Syngenta trait performance trials conducted at 21 locations between 2005 and 2009 in the U.S. corn belt. [NIS – Syngenta modified scale for 4" root pruning]

Some growers are applying conventional insecticides to fields planted with transgenic corn varieties containing a rootworm protection trait. A multitude of factors influence this grower decision, including the high price of corn, planting in areas with high rootworm larval populations, limitations on trait performance for currently available varieties, and the presence of secondary soil insect pests. A decision to deregulate Event 5307 corn would provide no additional incentive for growers to apply conventional insecticide to traited acres. Quite the contrary would be true. Deregulating 5307 corn would provide for enhanced rootworm protection of Syngenta's currently available trait when rootworm populations are high, thus reducing the economic incentive for a grower to apply insecticide.

Appendix B Decision Tree on whether Section 7 Consultation with FWS is Triggered for Petitions

This decision tree document is based on the phenotypes (traits) that have been field tested under APHIS oversight (for a list of approved field tests, visit Information Systems for Biotechnology.) APHIS will re-evaluate and update this decision document as it receives new applications for field testing of new traits that are genetically engineered into plants.

BACKGROUND

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

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

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

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

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

1) Is the transgenic plant sexually compatible with a TE plant[12] without human intervention?

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

3) Does the transgene product or its metabolites have any significant similarities to known toxins[13])?

4) Will the new phenotype(s) imparted to the transgenic plant allow the plant to be grown or employed in new habitats (e.g., outside agro-ecosystem)[14]?

5) Does the pest resistance[15] gene act by one of the mechanisms listed below? If the answer is **YES** then a consultation with U.S. Fish and Wildlife Service is **NOT** necessary.

   A. The transgene acts only in one or more of the following ways:
      As a structural barrier to either the attachment of the pest to the host, to penetration of the host by the pest, to the spread of the pest in the host plant (e.g., the production of lignin, callose, thickened cuticles);
      In the plant by inactivating or resisting toxins or other disease causing substances produced by the pest;
      By creating a deficiency in the host of a component required for growth of the pest (such as with fungi and bacteria);
      By initiating, enhancing, or potentiating the endogenous host hypersensitive disease resistance response found in the plant;
      In an indirect manner that does not result in killing or interfering with normal growth, development, or behavior of the pest;
   B. A pest derived transgene is expressed in the plant to confer resistance to that pest (such as with coat protein, replicase, and pathogen virulence genes).

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

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

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

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

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

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

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

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