Environmental Report for the Determination of Nonregulated Status for Insect-Resistant and Herbicide-Tolerant 4114 Maize

OECD Unique Identifier:
DP-ØØ4114-3

Associated Petition Number:
11-244-01p

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Submission date:

February 10, 2012

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59122 maize	maize containing event DAS-59122-7
4114 maize	maize containing event DP-ØØ4114-3
ACRE	Average Crop Revenue Election Program
AOPP	aryloxyphenoxy-propionate herbicide
AOSCA	American Organization of Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
BCAP	Biomass Crop Assistance Program
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
Bt	*Bacillus thuringiensis*
Bt11 maize	maize containing event SYN-BTØ11-1
CC	continuous corn rotation
CCS	corn-corn-soybean rotation
CFR	Code of Federal Regulations
CCUR	Center for Crops Utilization Research
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CRP	Conservation Reserve Program
CRW	corn rootworm
Cry1F	protein/gene from *Bacillus thuringiensis* var. aizawai
Cry34/35Ab1	protein/gene from *Bacillus thuringiensis* strain PS149B1
CS	corn-soybean rotation
DCI	data call-in
DDGS	dried distillers grains
DNA	deoxyribonucleic acid
EPA	Environmental Protection Agency
EPA-SAB	Environmental Protection Agency - Scientific Advisory Board
EPTC	s-ethyl dipropylthiocarbamate
ESA	Endangered Species Act
EUP	experimental use permit
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
GDP	gross domestic product
GE	genetically engineered
GHG	greenhouse gas
GM	genetically modified
HFCS	high fructose corn syrup
HRAC	Herbicide Resistance Action Committee
HT	herbicide tolerant
IP	identity preservation
IPCC	Intergovernmental Panel on Climate Change
IPM	Integrated Pest Management
IR	insect resistant
IRAC	Insect Resistance Action Committee
IRM	Insect Resistance Management
IWM	Integrated Weed Management
LTP	lipid transfer protein
MON810 maize	maize containing event MON-ØØ81Ø-6
MON88017 maize	maize containing event MON-877Ø1-2
MON89034 maize	maize containing event MON-85Ø34-3

ACRONYMS AND ABBREVIATIONS (CONTINUED)

NCGA	National Corn Growers Association
NMFS	National Marine Fisheries Service
NOS	national organic standards
NPS	non-point source
NUE	nitrogen use efficiency
NTO	non-target organism
OECD	Organisation for Economic Co-operation and Development
PAT	Phosphinothricin acetyltransferase from *Streptomyces viridochromogenes*
PCR	polymerase chain reaction
PR	pathogenesis-related
RFA	Renewable Fuels Association
RFS	renewable fuel standard
SWCB	southwestern corn borer
TES	threatened and endangered species
USDA	United States Department of Agriculture
USDA-AMS	United States Department of Agriculture Agricultural Marketing Service
USDA-APHIS	United States Department of Agriculture Animal and Plant Health Inspection Service
USDA-ERS	United States Department of Agriculture Economic Research Service
USDA-FSA	United States Department of Agriculture Farm Service Agency
USFWS	United States Fish and Wildlife Service
USDA-NASS	United States Department of Agriculture National Agricultural Statistics Service
USDA-NOP	United States Department of Agriculture National Organic Program
USDA-NRCS	United States Department of Agriculture National Resources Conservation Service
US-DOE	United States Department of Energy
US-EPA	United States Environmental Protection Agency
WPS	worker protection standard
WRM	Weed Resistance Management

1. Purpose and Need

1.1. Purpose of 4114 Maize

Pioneer Hi-Bred, a DuPont business (Pioneer) is submitting an environmental report to the Animal and Plant Health Inspection Service (APHIS) to assess potential impacts of releasing 4114 maize (DP-ØØ4114-3) into the environment if granted nonregulated status.

4114 maize produces the *Bt* proteins Cry1F, Cry34Ab1, and Cry35Ab1, as well as the herbicide tolerance protein PAT. The Cry1F protein confers resistance to certain lepidopteran pests, including European corn borer (*Ostrinia nubilalis*), a major corn pest. This protein and its associated genetic elements are identical to those in DAS-Ø15Ø7-1 maize (hereafter referred to as 1507 maize), which was deregulated by USDA, registered by EPA, and reviewed by FDA in 2001. The Cry34Ab1 and Cry35Ab1 proteins together comprise an active binary insecticidal crystal protein that confers resistance to corn rootworm pests, including western corn rootworm (*Diabrotica virgifera virgifera)*, also a major corn pest. This binary protein and the associated genetic elements are identical to those in DAS-59122-7 maize (hereafter referred to as 59122 maize), which was deregulated by USDA in 2005, registered by EPA since 2005, and reviewed by FDA in 2004. Finally, the PAT protein confers tolerance to the herbicidal active ingredient glufosinate-ammonium at current labeled rates. This protein is identical to the protein found in a number of approved events across several different crops that are currently in commercial use, including 1507 maize and 59122 maize. Corn containing the PAT protein has been commercially grown in the U.S. since 1996. 1507 maize, 59122 maize, and the breeding stack of the two lines, 1507x59122 maize, were jointly developed by Pioneer and Dow AgroSciences and are now licensed broadly across the seed industry. In 2011, commercial products containing 1507x59122 maize were grown on approximately 15.1 million acres or approximately 16% of U.S. corn acres.

If deregulated by APHIS, Pioneer does not intend to commercialize 4114 maize as a stand-alone product. 4114 maize is a single event that will provide an alternative to the breeding stack combination of two previously deregulated events, 1507 maize and 59122 maize, in complex breeding stacks.

Currently, there are seven registered commercial breeding stacks containing 1507x59122 maize in the environment (see section 2.1A. for a list of all commercialized products containing the 1507 maize and 59122 maize events). The number of U.S. corn acres planted to the traits in 4114 maize and the overall acreage or geographical distribution of corn in the U.S. are not expected to change. Additionally, 4114 maize would not be the first event containing two *Bt* traits to be deregulated by USDA. On July 15, 2008, USDA deregulated MON89034, an insect-resistant event that, like 4114 maize, also contains two *Bt* proteins (Cry1A.105 and Cry2Ab2).

Growers are requiring sophisticated stacked products that include insect resistance through *Bacillus thuringiensis (Bt)* traits and herbicide tolerance, as well as native traits such as disease tolerance, drought tolerance, and higher yields. For *Bt* traits, the corn seed industry is transitioning from products with a single mode of action to products with multiple modes of action to extend the durability of the traits that many growers rely on to manage pests. Therefore, it is important that multiple native and transgenic traits — including *Bt* traits with different modes of action — are bred into a single corn product to efficiently meet the needs of growers. 4114 maize, as one component of future *Bt* breeding stack products with its dual insect mode of action and herbicide tolerance, will provide benefits to growers in the form of multi-trait products with enhanced durability and a wider array of germplasm suited for diverse growing regions.

The ability to use 4114 maize containing an insertion at a single breeding locus will reduce the number of breeding loci compared to 1507x59122 maize, thus increasing the speed at which new products will be available to growers. This advantage will increase complexity and expense of breeding multiple traits or events into one corn product which increases with each additional breeding locus. For example, the effort required to breed two transgenic loci into an inbred line is double the effort required for one transgenic locus. Furthermore, each trait locus must be homozygous in an inbred line; as more loci are combined, the proportion of plants that are homozygous for each locus becomes smaller, resulting in more seed discard during the breeding process.

4114 maize is expected to be more efficiently bred into a wide variety of corn genetic backgrounds and with additional traits, thus giving growers more choice in products that offer in-plant insect protection, options for weed management, and customized products for their local growing areas and agronomic needs. The introduction of new corn trait offerings that meet grower needs, such as stacked products containing 4114 maize, is critical to help keep pace with increasing corn demand in the U.S. and globally.

The environmental consequences of introducing 4114 maize into the environment are expected to be similar to 1507x59122 maize. Comparative analyses studies conducted by Pioneer indicate that 4114 maize is comparable to conventional corn with respect to the nutrient composition and agronomic characteristics measured. In general, corn does not possess weediness characteristics and is not considered a weedy or invasive species. Therefore, 4114 maize does not exhibit any characteristics that would indicate it is any more likely than conventional corn to become a weed or plant pest. The potential for gene flow was evaluated by examining corn pollination biology and the hybridization potential and geographic overlap of corn wild relatives. While corn does possess some pollination characteristics favorable to gene flow, the distribution of wild relative populations are limited in the U.S. and there is low fitness or sterility of hybrids; therefore, it is unlikely that the inserted DNA in 4114 maize would be introgressed significantly into these wild relative populations (for further information, see Petition page 144).

1.1A. Action

Pioneer has submitted a petition (11-244-01p) to USDA-APHIS seeking a determination that 4114 maize and all progeny derived from 4114 maize pose no plant pest risk and, therefore, should no longer be a regulated article under 7 CFR Part 340. Since the 4114 maize event is currently regulated under 7 CFR part 340, all interstate movement, importation, and field trials of 4114 maize to date have been conducted under permits issued or notifications acknowledged by APHIS in compliance with those regulations.

Pioneer submitted an application for a seed increase registration for 4114 maize to EPA on April 18, 2011. Seed increase registrations are used by EPA to authorize breeding, and seed production of events such as 4114 maize that will not be sold commercially without first being stacked with other IR traits. Upon EPA registration, 4114 maize will have county and national acreage limitations imposed by the EPA and will be prohibited by law from commercial use on its own. In the future, should Pioneer decide to commercially introduce 4114 maize in the marketplace as one component of a complex breeding stack with other EPA-regulated Plant Incorporated Protectant events, Pioneer would be required by EPA to apply for a Section 3 commercial use registration. As a condition of a commercial use registration, EPA would require that Pioneer develop, administer and oversee an EPA-approved insect resistance monitoring (IRM) program. Under the U.S. government's Coordinated Framework for Regulation of Biotechnology, the USDA and EPA have communicated the role of the EPA in establishing the appropriate IRM plan for *Bt* crops.

Pioneer submitted a food and feed safety and nutritional assessment for 4114 maize to the FDA on December 22, 2011. Pioneer concluded that 4114 maize is as safe and nutritious as other commercially available corn and is in compliance with all applicable requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Pioneer encourages cross-agency communication regarding regulatory approvals and will provide contact information for the EPA Regulatory Action Leader or FDA reviewer for 4114 maize to USDA if requested.

The gene cassettes and proteins produced in 4114 maize have previously been reviewed by U.S. governmental agencies for environmental safety. Table 1 reflects these longstanding regulatory approvals following detailed study and evaluation. The 1507 maize event, containing the Cry1F and PAT proteins, was deregulated by USDA, registered by the U.S. Environmental Protection Agency (EPA), and reviewed by the U.S. Food and Drug Administration (FDA) in 2001. The 59122 maize event, containing the Cry34/35Ab1 and PAT proteins, was reviewed by FDA in 2004, and deregulated by USDA and registered by EPA in 2005. The 1507x59122 maize breeding stack combination was reviewed and registered by EPA in 2005. In addition, the PAT protein has been a component of corn products commercially grown in the U.S. since 1996.

All proteins in 4114 maize have full tolerance exemptions at EPA:

- Cry1F protein in corn: 40CFR §174.520;
- Cry34Ab1 and Cry35Ab1 proteins in corn: 40CFR §174.506; and
- Phosphinothricin acetyltransferase (PAT) in all plants: 40CFR §174.522.

Table 1. Regulatory History of 1507, 59122, and 1507x59122 Maize in the U.S.

Product	Agency	Approval Date
1507 Maize	USDA	August 14, 2001
	FDA	May 18, 2001[a]
	EPA	August 10, 2001; expires September 30, 2015
59122 Maize	USDA	October 7, 2005
	FDA	October 4, 2004[b]
	EPA	August 31, 2005; expires September 30, 2015
1507x59122 Maize	USDA	Not Applicable
	FDA	Not Applicable
	EPA	October 27, 2005; expires September 30, 2015

[a] Indicates completion date of biotechnology consultation.
[b] USDA and FDA separate review of 1507x59122 maize was not legally required because the approved individual events were stacked by conventional breeding.

1.1B. Action Area

Geographic Distribution of Corn

Corn is the largest crop grown in the U.S. in terms of acreage, and is the primary feed grain in the U.S., accounting for 90% of value and production of all feed grains (USDA-ERS, 2010g). In 2011, planted acreage of non-genetically engineered and genetically engineered (GE) corn varieties in the U.S was over 92 million acres, and over 84 million acres were harvested (USDA-NASS, 2011b).

Field corn is grown in most states, with production concentrated in the Heartland region (including Illinois, Iowa, Indiana, eastern portions of South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri). Iowa and Illinois are the top corn-producing states and typically account for slightly more than one-third of the U.S. crop (USDA-ERS, 2009a).

In addition to field corn, other types of corn including organic corn, popcorn, and sweet corn are grown in the U.S. In 2008, the majority of organic corn (194,637 acres) was planted in Wisconsin, Minnesota, and Iowa (USDA-ERS, 2010a). In 2007, over 29 states produced popcorn on 201,000 acres (Hansen, 2011). The majority of popcorn production is located in Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Missouri, Nebraska, and Ohio (The Popcorn Board, 2011). Sweet corn production in 2009 was more than 28,000 acres and mainly planted in California, Florida, Georgia, Michigan, Ohio, New York, and Washington (USDA-

ERS, 2010b). While the range of cultivation of popcorn and sweet corn includes the entire U.S., the total acreage represents 0.2% of corn production in 2007 (USDA-ERS, 2010b; USDA-NASS, 2009b) (For more information see section 2.1D). The map in Figure 1 indicates all corn acres planted by county in the U.S. (USDA-NASS, 2011f).

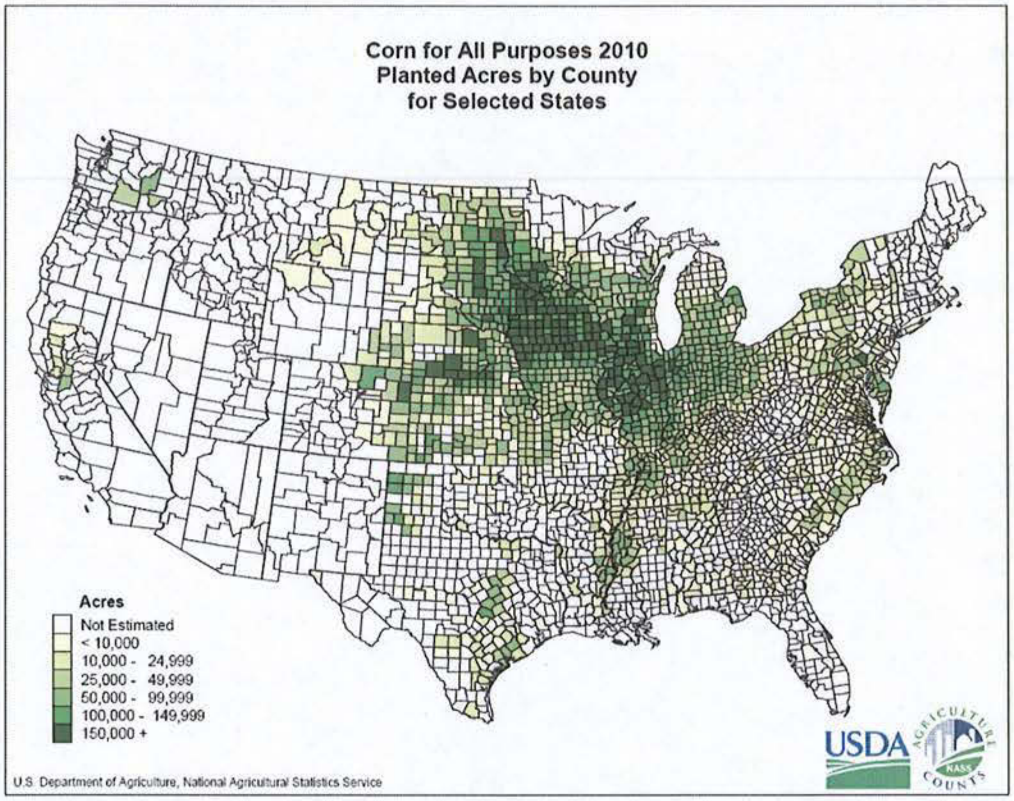


Figure 1. Acres of Corn Planted by County in the U.S.
USDA-NASS, 2011f

In 2011, twenty-eight (28) states saw an increase in the number of corn grain acres harvested from the previous year; those with record highs include Idaho, Utah, and South Dakota (Figure 2). Overall, a trend in increasing U.S. corn acreage has occurred (Figure 2), along with higher yields stemming from improved technology and production practices (USDA-ERS, 2009a).

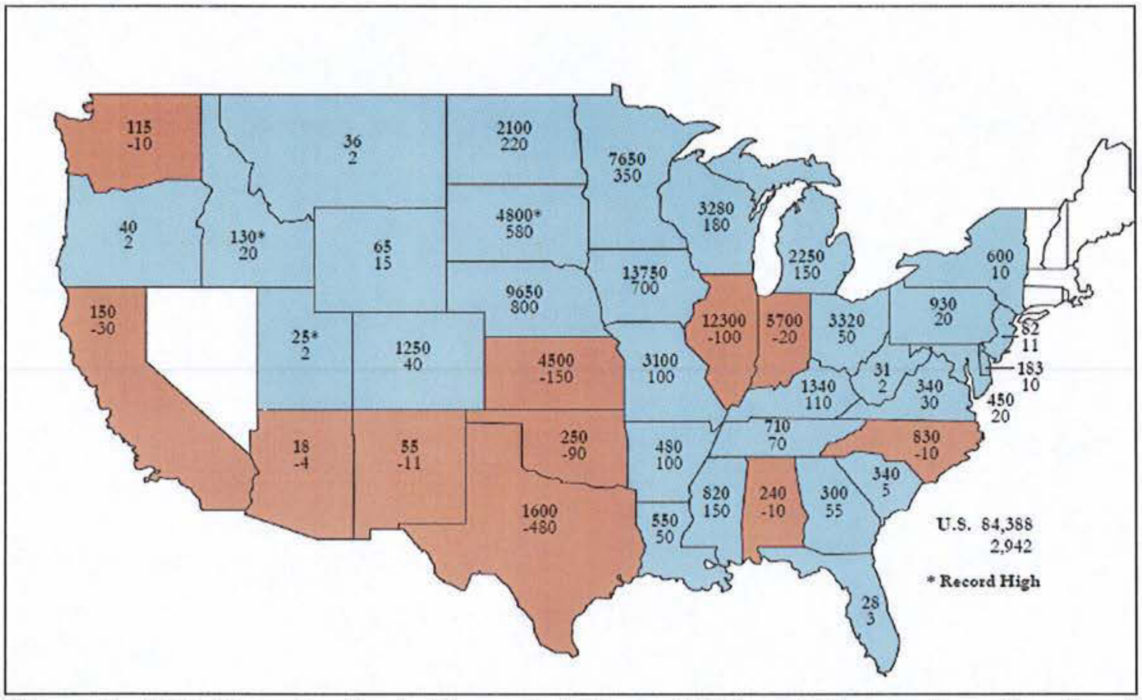


Figure 2. 2011 Corn for Grain Harvested (Acres (000) and Change from Previous Year)

[a] Blue indicates an increase in grain harvested

[b] Red indicates a decrease in grain harvested

[c] No color indicates lack of available data

USDA-NASS, 2011e

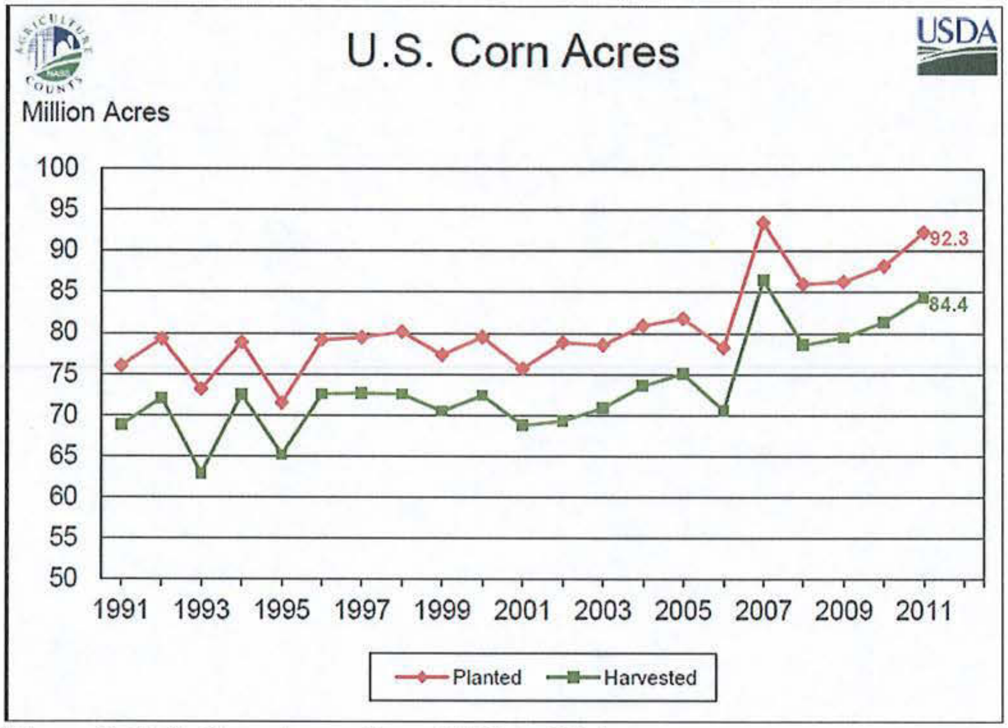


Figure 3. U.S. Corn Acres from 1990 to 2011
USDA-NASS, 2011d

2. Affected Environment

2.1. Agricultural Production of Corn

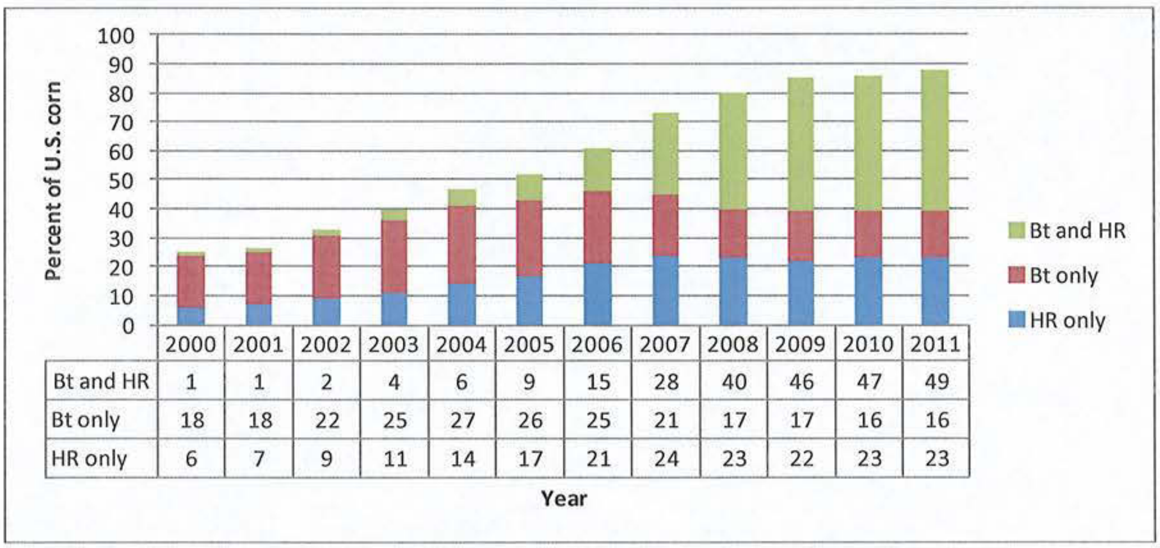
2.1A. Land use

The vast majority of corn acres in the U.S. contain insect resistance (IR) and/or herbicide tolerance (HT) traits (Figure 4). GE crops have been widely adopted by farmers since their introduction in 1996 (USDA-ERS, 2011c). Use of GE crops by farmers has steadily increased because they have allowed for a simpler and more flexible production system that saves management time and reduces pesticide costs (including input costs) (Fernandez-Cornejo and Caswell, 2006). Farmers have also realized environmental benefits such as reduction in pesticide and herbicide use, and better conservation practices (Fernandez-Cornejo and Caswell, 2006).

Corn with both IR and HT traits is referred to as "stacked trait" corn, where the traits are present in a single event or brought together in a single product using conventional breeding. Over the past 11 years, adoption of GE corn in the U.S. has reached 88% of all corn acres planted (Figure 4) with the majority of the GE acres being both IR and HT (49%). The penetration of stacked trait corn has increased over the past decade (Figure 4) as growers have increased their demand for corn with both IR and HT. According to independent agronomist, Pat Lynch, two of the significant factors that contribute to stacked trait adoption include (King, 2010) demand from growers for stacked products, and developments of more stacked traits in industry's breeding programs.

Of the total corn acres planted in 2011, 88% were GE corn varieties, which is an increase from 86% in 2010 (USDA-NASS, 2011c), 85% in 2009, and 80% in 2008 (Figure 4) (USDA-NASS, 2009a). In 2011, 65% of the corn acres in the U.S. were planted with corn containing an IR trait, and 72% of the corn acres in the U.S. were planted with HT corn; these numbers indicate the importance of these traits to growers (USDA-ERS, 2011b).

Stacked gene varieties containing both insect resistance and herbicide tolerance were planted on 49% of the acreage, up 2% from the previous year (USDA-NASS, 2011c). There also remains a market for single-trait corn products. For 2011 plantings, 16% of corn contained an IR trait (but no HT trait), and 23% of corn contained an HT trait (but no IR trait) (Figure 4). The market for single-trait corn products has decreased since its peak in the mid-2000s, which likely reflects the increased adoption of stacked-trait products.



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Bt and HR	1	1	2	4	6	9	15	28	40	46	47	49
Bt only	18	18	22	25	27	26	25	21	17	17	16	16
HR only	6	7	9	11	14	17	21	24	23	22	23	23

Figure 4. Percent of Corn Acres Planted to GE Traits over Time
USDA-ERS, 2011b

In 2010, Brookes and Barfoot described the reasons why farmers were adopting transgenic crop varieties. Factors influencing adoption of IR and HT crops include:

1. IR Crops
    - Reduced risk of crop loss associated with insect pests;
    - Convenience associated with less time spent on crop scouting and/or applying insecticides;
    - Savings in fuel use mainly from reduced number of spray applications and reduced tillage;

- Savings in the use of machinery (for spraying and possibly reduced harvesting times);
- Improved quality (*e.g.* lower levels of mycotoxins in genetically modified insect resistant corn (see microorganism in section 2.3 below));
- Improved health and safety for farmers and farm workers from reduced handling and use of pesticides;
- Easier crop husbandry practices;
- Facilitated second crop cultivation.

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

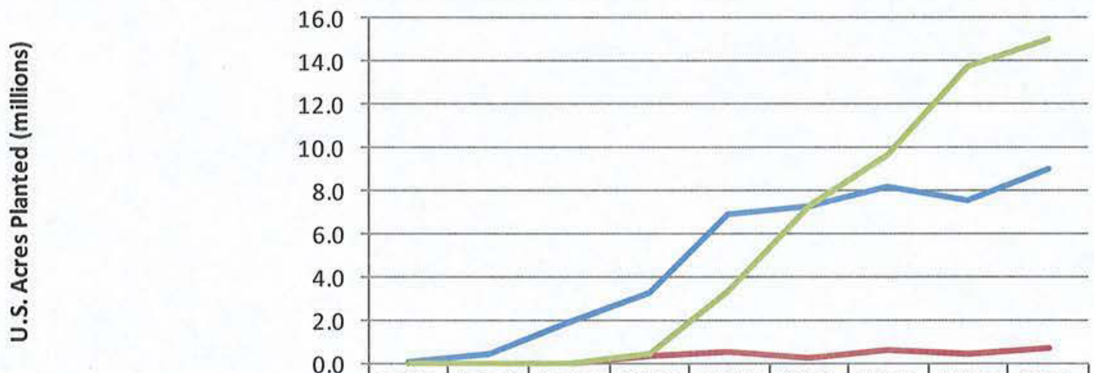
The 4114 maize event is considered a "stacked trait" since it contains IR traits for resistance to certain lepidopteran pests and corn rootworm as well as an HT trait for glufosinate-ammonium tolerance. Although 4114 maize will not be commercialized as a stand-alone alternative to 1507x59122 maize (Herculex Xtra), it may be deployed as a component of current or more complex breeding stacks. As noted above there are 14 current commercial corn products that contain either 1507 maize or 59122 maize and seven products that include both 1507 maize and 59122 maize (Table 2).

Table 2. EPA Registrations* for Commercial Corn Products Containing 1507 and/or 59122 Maize

Bt Event(s)	Product Name	Company	EPA Reg. Number	Initial Date of Registration
1507	Herculex I	Pioneer Hi-Bred	29964-3	May 18, 2001
		Mycogen Seeds (c/o Dow Agrosciences LLC)	68467-2	
59122	Herculex Rootworm	Pioneer Hi-Bred	29964-4	Aug. 31, 2005
		Mycogen Seeds (c/o Dow Agrosciences LLC)	68467-5	
1507 x 59122	Herculex XTRA	Mycogen Seeds (c/o Dow Agrosciences LLC)	68467-6	Oct. 27, 2005
		Pioneer Hi-Bred	29964-5	
MON89034 x 1507 x MON88017 x 59122	Genuity SmartStax	Monsanto Company	524-581	July 20, 2009
		Mycogen Seeds (c/o Dow Agrosciences LLC)	68467-7	
1507 x MON810	Optimum Intrasect	Pioneer Hi-Bred	29964-7	Feb. 24, 2010
1507 x MON810 x 59122	Optimum Intrasect Extreme	Pioneer Hi-Bred	29964-8	Feb. 24, 2010
90% 1507 x 59122 + 10% 1507	Optimum AcreMax 1	Pioneer Hi-Bred	29964-6	April 30, 2010
90% 59122 + 10% non-Bt	Optimum AcreMax RW	Pioneer Hi-Bred	29964-10	April 30, 2010
Bt11 x MIR162 x 1507	Agrisure Viptera 3220	Syngenta Seed Inc.	67979-15	March 29, 2011
95% MON89034 x 1507 x MON88017 x 59122 + 5% non-Bt	Genuity SmartStax RIB Complete	Monsanto Company	524-595	April 8, 2011
		Mycogen Seeds (c/o Dow Agrosciences LLC)	68467-16	
Bt11 x 1507 x MIR604 x 59122	Agrisure 3122	Syngenta Seed Inc.	67979-17	June 10, 2011
90% 1507 x MON810 x 59122 + 10% non-Bt	Optimum AcreMax Xtra	Pioneer Hi-Bred	29964-11	Aug. 26, 2011
95% 1507 x MON810 + 5% non-Bt	Optimum AcreMax	Pioneer Hi-Bred	29964-12	Aug. 26, 2011
1507 x MIR604	Optimum Trisect	Pioneer Hi-Bred	29964-13	September 30, 2011

* Registered as of 1/31/12. Shaded rows indicate products containing both 1507 maize and 59122 maize.
Note: The traits displayed above only include the insect portion of the product; however, the product may also contain HT trait(s).

In 2011, the area of 1507 maize planted was 9 million acres, the area of 59122 maize planted was 0.7 million acres, and the area of 1507x59122 maize was 15.1 million acres (Figure 5). *Bt* corn products containing only 59122 maize for corn rootworm protection have never been widely planted because growers who have rootworm pressure typically also have pressure from lepidopteran pests. *Bt* corn products containing only 1507 maize have been popular with growers because there are many geographies with lepidopteran (but no corn rootworm) pressure. Stacked trait products containing 1507 maize and 59122 maize have increased in acreage every year since 2006. This acreage is expected to continue to increase because the 1507 maize and 59122 maize events are widely licensed across the biotech seed industry; however, the increase in acreage is unlikely to be attributable to the possible deregulation of 4114 maize.



	2003	2004	2005	2006	2007	2008	2009	2010	2011
Products containing 1507 maize	0.1	0.4	1.9	3.3	7.0	7.3	8.2	7.6	9.0
Products containing 59122 maize	0.0	0.0	0.0	0.4	0.5	0.3	0.6	0.4	0.7
Products containing 1507 and 59122 maize	0.0	0.0	0.0	0.4	3.4	7.3	9.7	13.8	15.1

Figure 5. U.S. Acreage of Corn Containing 1507, 59122, or 1507x59122 Maize
Pioneer Marketing, 2011

Additional Land Use Considerations

Most of the land in the U.S. that is suitable for agriculture is used for crop production. However, sometimes growers choose to set aside agricultural land for conservation purposes. The conservation reserve program (CRP), administered by the USDA's Farm Service Agency (FSA), is the largest private lands conservation program in the U.S. Under this program, USDA contracts with farmers to retire highly erodible or other environmentally sensitive farmland for a period of 10-15 years, during which time the farmers receive a dependable source of income. While the land is under contract, it is converted to trees, grassland, wildlife cover, or other conservation uses that provide various environmental benefits. These benefits may include protection of or improvements in water quality (both surface and ground), wildlife habitat creation, carbon sequestering, protection of soil productivity, and reduction of wind erosion (USDA-FSA, 2009). The number of acres in CRP varies from year to year. In 2011, there were 32 million cumulative acres enrolled in CRP, the lowest amount in the past seven years. The peak year of the last seven was 2007, when 36.5 million acres were enrolled (USDA-FSA, 2009). There are significant penalties when an agricultural producer elects to leave the program before the contract expiration date, including repayment of rent plus interest for the years the acres were under contract.

2.1B. General Agronomic Practices

Cropping Practices

Today, growers can choose from hundreds of corn hybrids marketed by companies that produce seed. Hybrids differ generally in traits and agronomic characteristics including disease and pest resistance and length of growing period (Olson and Sander, 1988). Regardless of the producer, corn is grown in similar ways throughout the U.S., especially in the Midwestern Corn Belt.

Corn is generally cultivated in temperate regions that provide sufficient moisture through rainfall or irrigation and an adequate number of frost-free days to reach maturity (Runge, 2002). Several tillage methods are currently available to help prepare the seedbed for a given crop (see Tillage section below). The optimum planting date for corn is usually in April or May but is influenced by environmental conditions, seed variety, and other local factors. Harvest generally occurs from mid-to-late September through November.

Once corn has emerged from the ground, it grows at a rate largely determined by temperature assuming nutrients, subsoil moisture, and rainfall are adequate. The nutrient requirements (apart from CO_2 from the air, and H_2O) are nitrogen, phosphorus, potassium, magnesium, calcium, and sulfur, and trace elements including copper, manganese, iron, boron, sodium, chlorine, molybdenum, and zinc (Runge, 2002).

Weed control methods differ depending on a number of factors including regional practices, grower resources, and crop trait; the techniques may be direct (*e.g.,* mechanical[a], biological[b], and chemical[c]) or indirect (*e.g.,* cultural[d]) (Hoeft *et al.*, 2000). Control of weeds and insects in corn production is essential to obtain good crop yield (KSU, 2007). Generally, growers will manage a range of pests simultaneously and will likely choose from a number of techniques to effectively and efficiently manage pests in their fields. In 2010, the most prevalent pest management practice was scouting for weeds (USDA-NASS, 2011a).

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[a] Includes tillage (Table 3) and mowing.
[b] Using organisms (*i.e.* insects or pathogens) that are natural enemies to control weeds.
[c] Herbicide application.
[d] Crop rotation and hand removal of weeds

Ultimately, the management practices utilized 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. Practices to cope with pests, nutrient needs, and moisture and temperature requirements vary regionally.

Tillage

Farmers have choices for how they use tillage to prepare the soil for seeding; to reduce weed growth; and to incorporate fertilizer, manure, and organic matter into the soil (Horowitz *et al.*, 2010). The types of tillage utilized by growers include conservation tillage (no-till, ridge-till, and mulch-till), reduced tillage, and intensive (*i.e.,* conventional) tillage (Table 3). Conventional tillage is associated with intensive plowing and less than 15% crop residue at the soil surface; reduced tillage is associated with 15 to 30% crop residue; and conservation tillage, including no-till practices, is associated with at least 30% crop residue. No-till practices result in substantially less soil erosion than other tillage practices (Table 3).

Conservation tillage systems have advantages over full tillage in that they minimize adverse impacts on water quality, conserve soil moisture, reduce soil erosion, and reduce labor and energy requirements (KSU, 2007; USDA-ERS, 2005a). The major limitations to adoption of soil-conserving tillage systems for some farmers include: additional management skill requirements, expectations of lower crop yields and/or economic returns in specific geographic areas or situations, negative attitudes or perceptions, and institutional constraints (USDA-ERS, 2005a). The different tillage systems have different effects on yield, depending on location. According to the 2010 national averages, the yield for conventional tillage resulted in only a 0.5% yield advantage over no-till. However, there are regional, soil-related, and cropping system variations in this response. No-till fields tended to have greater yields than conventional tillage in the south and west regions. The two tillage systems had similar yields in the central U.S., and no-till typically produced somewhat lower yields than conventional tillage in the northern U.S. No-till had greater corn yields than conventional tillage on moderate- to well-drained soils, but slightly lower yields than conventional tillage on poorly drained soils. Corn yields tended to benefit more from no-till in crop rotation as compared to continuous cropping (DeFelice *et al.*, 2010).

About 20% of corn acres in the United States are currently produced using no-tillage practices (DeFelice *et al.*, 2010). Corn, cotton, soybean, and rice no-till practices have been increasing by 1.5% per year (Horowitz *et al.*, 2010). This increase in no-till is due to growers seeking to reduce input costs and labor, and to comply with government conservation programs (DeFelice *et al.*, 2010). Because of its low cost and positive impact on soil quality, conservation tillage is currently widely practiced in the Midwestern U.S. (US-EPA, 2009a).

GE crops have encouraged conservation tillage, but in individual cases, tillage is useful in preventing and managing weeds that display herbicide tolerance. Recently, in some areas of the U.S., individual growers with glyphosate-tolerant weeds in fields have turned to tillage to help control those populations (Duke and Powles, 2009). No-till practices may use an increased amount of herbicides compared to conventional tillage; however, increased herbicide use is not an inherent characteristic of no-tillage farming, as there are alternative ways for weed management even without returning to soil tillage and cultivation such as: avoiding the maturation and seeding of weeds in the first place by not allowing weed growth even in the off season; depleting seed bank and then cover field with mulch to create an invisible no-till seeding; and soil and cover crop rotation (Friedrich, 2005).

Table 3. Description of Tillage Practices

Type of Tillage	Definition	Tillage Tools	Percent Crop Residue Cover Remaining in Field[a]
Intensive or Conventional	Full tillage - includes primary and secondary tillage operations	Primary tillage is performed in the fall (or spring) with a moldboard plow followed in the spring by secondary tillage (disking (twice) or disking and using a soil finisher or other such equipment); followed by planting	Less than 15%
Reduced	Intensity of tillage reduced (no use of moldboard)	Tillage performed with a chisel plow, often followed by a field cultivator, or other such equipment; followed by planting	15-30%
Conservation			
No-till	The soil is left undisturbed from harvest to planting except for nutrient injection	Planting accomplished in a narrow seedbed or slot created by coulters, row cleaners, disk openers, or other such equipment	30% or more
Ridge-till	The soil is left undisturbed from harvest to planting except for nutrient injection	Planting is completed in a seedbed prepared on ridges with sweeps, disk openers, coulters, or row cleaners (residue is left between ridges)	30% or more
Mulch-till	The soil is disturbed prior to planting	Tillage performed with chisels, field cultivators, disks, sweeps, or blades; followed by planting	30% or more

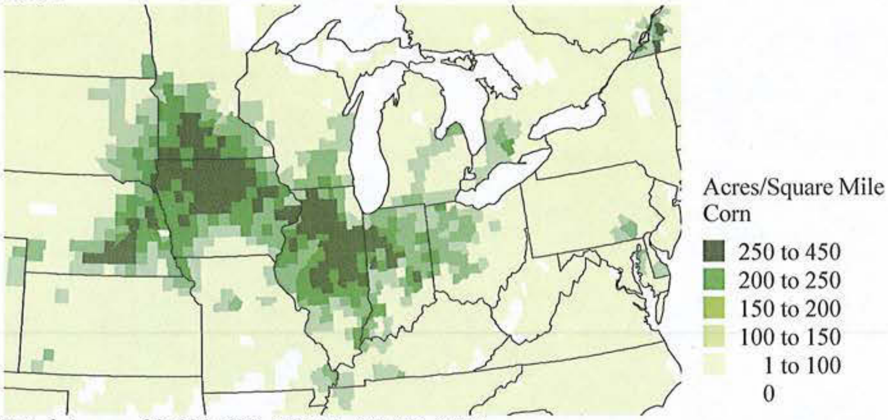
[a] The amount of crop residue (e.g. leaves, stalks, etc.) left in the field following harvest.
Sandretto and Payne, 2006

Rotation

Crop rotations (successive planting of different crops on the same land) are used to optimize soil nutrition and fertility and reduce pathogen loads (Hoeft *et al.*, 2000). Finding a balance between economic returns and increasing productivity or stability can sometimes present a challenge when designing a crop rotation (Hoeft *et al.*, 2000). Crops used in rotation with corn vary regionally, and some regions can withstand less crop rotation than others (Hirtzer, 2011; Hoeft *et al.*, 2000). In recent years, the economic advantages of growing corn have outweighed the benefits of crop rotation for some growers. High corn yields and grain prices, as well as challenges with soybean diseases in some areas, have incentivized growers to increase corn acres in their operations. This means growing two or more corn crops before rotating back to soybeans or other crops (Butzen, 2006).

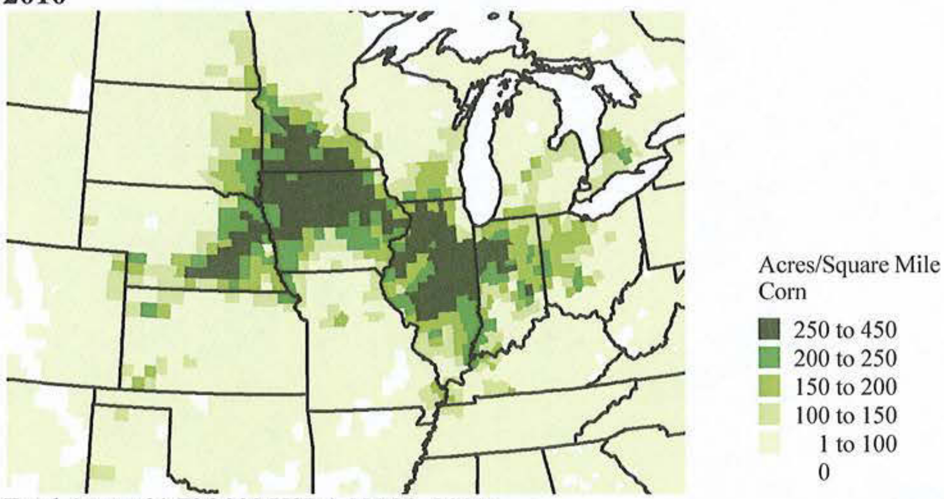
The high global demand for corn-produced ethanol is increasing corn prices relative to soybean prices. The increased corn demand and commodity prices encourage more corn-on-corn acreage, rather than corn-soybean rotations, which in turn contributes to overall increased U.S. corn acreage (Doerge, 2007). Figure 6 shows the increased density of corn planted in the Midwest from 2003 to 2010, possibly indicating that growers are planting more corn and most likely not rotating with soybean as often.

2003



Total Acres: 82,439,600 USDA-NASS, 2003

2010



Total Acres: 91,796,900 USDA-NASS, 2011c

Figure 6. U.S. Total Corn Planted Area Density

There are significant compromises and consequences associated with switching from the traditional corn-soybean (CS) rotation of the past two decades to a continuous corn (CC) system. Growing CC requires more management than the traditional CS rotation, involves more risk of increased disease and insect pest pressure, and is not necessarily more profitable than the CS rotation, even when relative commodity prices point to a preference for corn over soybean (Vyn, 2006). Three major consequences of CC production are yield loss, increased tillage (no-till is not practical for CC production) and additional fertilizer applications (Vyn, 2006). An additional issue with CC rotation may be build-up of resistance by corn rootworm and other pests to management practices, most notably *Bt.*

Long-term studies have been conducted in an attempt to isolate the factors associated with yield reduction in CC rotations compared with CS rotations. Iowa State University performed a long-term study to determine if nitrogen was a limiting factor in yield response in corn-on-corn vs. corn-soybean rotation. The study was conducted from 2000-2007 across multiple Iowa locations; researchers applied the maximum amount of nitrogen at each site (Al-Kaisi *et al.*, 2008). The results indicated that addition of more nitrogen was not sufficient to overcome the yield penalty for CC; CS rotations produced better corn yields even with high nitrogen rates, especially in poor growing seasons (Table 4).

Table 4. Rotation Study Involving 46 Sites in Iowa from 2000-2007 at Maximum Nitrogen Response

Year	Corn/soybean rotation	Corn-on-corn rotation	Difference	% Difference
	bu/acre			
2000	160	158	2	1.3
2001	146	115	31	21.4
2002	155	120	35	22.7
2003	162	119	44	26.9
2004	203	203	-1	-0.3
2005	190	161	29	15.3
2006	197	181	15	7.8
2007	199	172	27	13.6
Average	*178*	*154*	*24*	*14.2*

Al-Kaisi *et al.*, 2008

The performance of a CC system is very complex and multifaceted. Yield reductions are often associated with CC due to a host of factors such as allelopathy, autotoxicity, increased residue, residue breakdown products, organic acids, nitrogen issues, lower soil temperatures (especially with no-till in poorly drained soils), reduced plant stand, and slower early vegetative growth (Al-Kaisi *et al.*, 2008). Slower growth could result in delayed tasseling and silking, as well as delayed maturity with an increased risk of fall frost damage. Continuous corn can impact soil biological diversity by limiting microbial biomass that is essential for nutrient cycling. Production of CC often encourages the use of intensive tillage because of the increased residue production. More intensive tillage negatively affects microbial diversity and the soil's physical, chemical, and biological condition (Al-Kaisi *et al.*, 2008).

The CC trend in the Corn Belt is expected to continue for the foreseeable future employing the many existing commercialized varieties of corn. A return to greater crop rotations will likely be based on economic factors such as crop prices and pesticide costs and availability of a particular GE corn product.

In the Southern U.S., CC corn may be grown as well, although rotation of corn with soybeans and/or cotton is also practiced. The Deep South states of Louisiana, Mississippi, Alabama, Georgia and South Carolina have a more balanced rotation between corn, soybean and cotton, and peanuts become a much more significant rotation crop (Pioneer Marketing, 2012).

The corn-cotton crop rotation in the South has been in practice since at least the 1950s, primarily because it increases cotton yields compared to continuous cotton production (Doerge, 2010). Long-term studies have found that cotton lint yields are about 10 to 12% more the first year after corn, and about 5% more the second year after corn, compared with continuous cotton. Most of the yield increase is attributed to control of reniform nematode (*Rotylenchulus reniformis*) populations, which can reduce yields as much as 50% when infestations are severe (Doerge, 2010).

In spite of the benefits of rotation, cotton growers' preference for simplicity and the recent increase in cotton commodity prices have encouraged continuous cotton production. U.S. farm programs favoring continuous cotton also diminished the financial incentive to use any form of crop rotation. However, increasing nematode pressure, loss of affordable and effective nematicides from the market, more flexible farm programs, and benefits of rotation have increased interest in the corn-cotton crop rotation among producers. Many growers are re-evaluating their cropping systems based on these changes (Doerge, 2010).

Pesticide Use

Pesticides may be classified according to their function, chemical nature, formulation, site or commodity on which they are used, or where they are applied (Munkvold *et al.*, 2006). Pesticide types include herbicides, insecticides, fungicides, nematicides, miticides, fumigants, plant growth regulators and other miscellaneous conventional pesticides such as rodenticides (Grube *et al.*, 2011). In 2007, 80% of all U.S. pesticide use occurred in the agricultural sector. The top ten pesticides used in terms of pounds of active ingredient (a.i.) applied in the agricultural market included the following seven herbicides: glyphosate, atrazine, metolachlor-S, acetochlor, 2,4-D, and pendimethalin; and four fumigants: metam sodium, dichloropropene, methyl bromide, and chloropicrin (Grube *et al.*, 2011). No insecticides qualify for this list.

Pesticide use steadily increased after WWII and first peaked in 1982, when crop acreage was at a record-high. This peak in pesticide usage can be attributed to multiple factors: increased planted acreage, a greater proportion of acres treated with pesticides, and higher application rates. Herbicide use accounted for 75% of the total pesticides used in agriculture and most of the increase (Anderson and Magleby, 1997).

Total pesticide usage declined between 1982 and 1990 as commodity prices fell and large amounts of land were taken out of production by Federal programs (USDA-ERS, 2005c). During the 1990s to the early 2000s, pesticide use saw a peak in 1997, with 579.3 million lbs of a.i. applied in the U.S. on major agricultural crops (Osteen and Livingston, 2006).

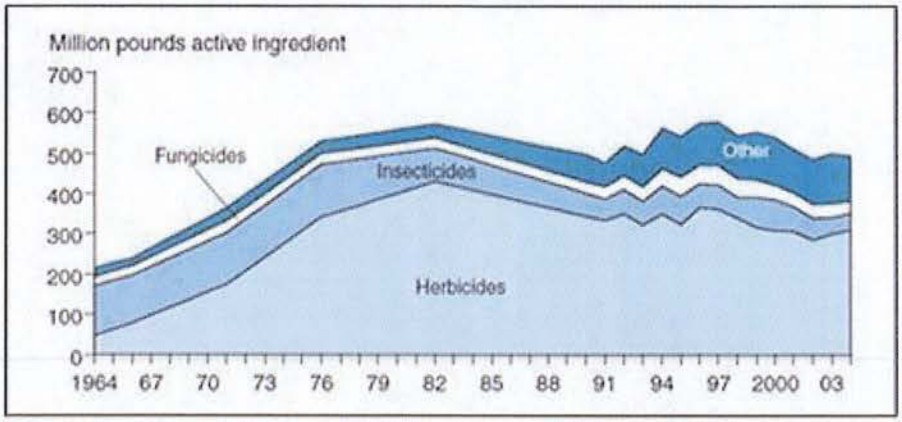


Figure 7. Pesticide Use on Major Crops 1964 to 2004[a]

[a] Linear interpolation of use estimates between survey years from 1964 to 1990.
Osteen and Livingston, 2006

For corn specifically, the number of acres treated with pesticides has risen since 2004 (although the amount of pesticidal active ingredients applied to corn has decreased—see Insecticide Use section below). The increase in treated corn acres is a result of a significant increase in insecticidal seed treatment use and a modest increase in foliar fungicide use (Figure 8). The latter two pesticides are used by growers for preventative purposes. The use of insecticide seed treatments has increased from approximately 20% of corn acres treated in 2004 to approximately 90% in 2009-2011 (Figure 8). There has been a decline over the last several years in the use of soil/foliar insecticides, in part due to the adoption of *Bt* crops (Brookes and Barfoot, 2010). Use of herbicides on corn has remained steady and very high (more than 95% of corn acres treated).

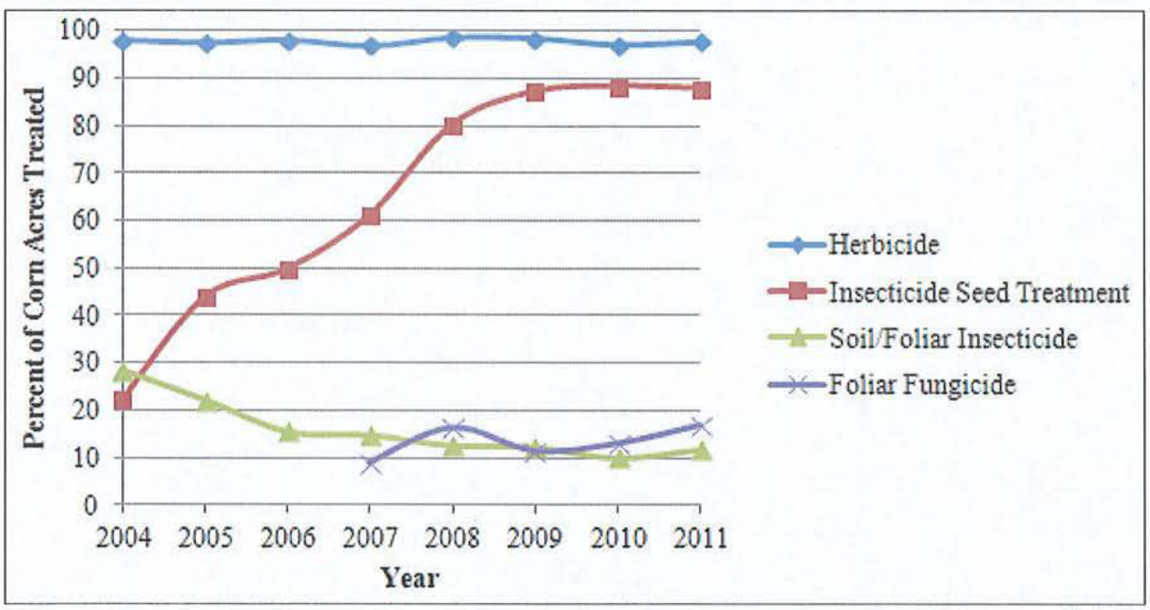


Figure 8. Percent of Total Corn Acres Treated with Pesticides from 2004-2011
Pioneer Marketing, 2011

Herbicide Use

Uncontrolled weed populations can cause significant yield losses in corn. Among U.S. crops, corn is one of two crops that suffers the greatest aggregate production losses due to weeds (Swinton *et al.*, 1994). In 2010, herbicide active ingredients were applied to 98% of acres planted to corn, and almost two-thirds of all pesticide active ingredients used on corn were herbicides (USDA-NASS, 2011a). In 2010, glyphosate was the most widely used herbicide, followed by atrazine and acetochlor in second and third, respectively (USDA-NASS, 2011a).

As shown in Figure 9, the use of glufosinate on total corn acres has remained stable and low over the past decade (2-6% of total U.S. corn acres treated with glufosinate during 2001-2011. Although many GE corn products include glufosinate tolerance, many growers choose not to spray glufosinate (unless they have specific glyphosate-resistant weed problems) for the following reasons:

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

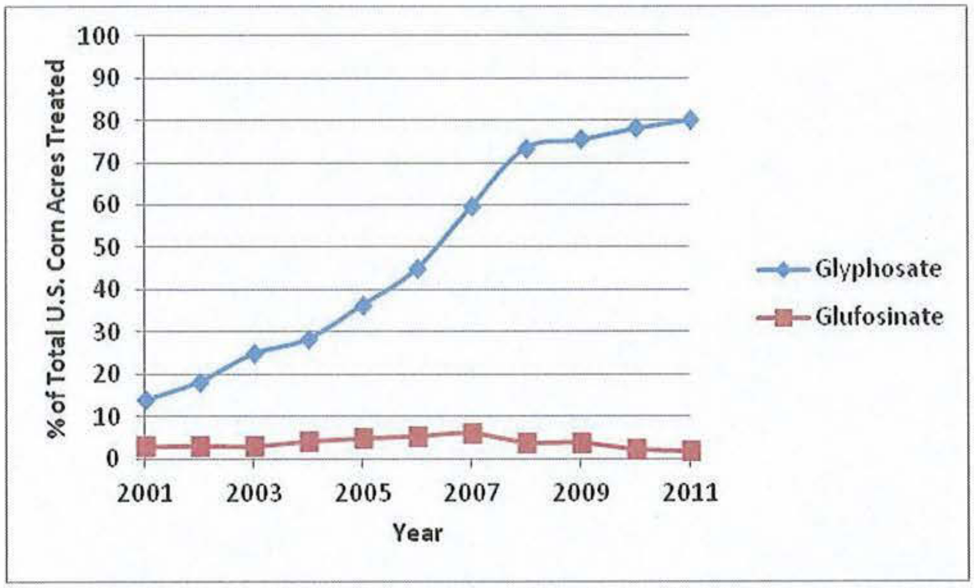


Figure 9. Percent of U.S. Corn Acres Treated with Glyphosate or Glufosinate
Pioneer Marketing, 2011

Glyphosate use, on the other hand, increased dramatically from 2001 to 2008 (14% to 73%) and more slowly from 2008 to 2011 (73% to 80%) (Figure 9). Based on these trends, glyphosate use may continue to increase slightly each year. Most corn growers now demand that virtually all GE corn products on the market today include glyphosate tolerance based on glyphosate's record as safe, inexpensive, and effective way to remove weeds. Although there are confirmed instances of glyphosate-resistant biotypes of certain weed species, glyphosate continues to be an effective herbicide for most growers in most situations.

Assessment of herbicide is not limited to comparing the quantities of herbicidal active ingredient applied, but also considers the effect that HT crops have had on mixes of herbicides used. Toxicity and persistence in the environment vary across pesticides, and the same amount of any two ingredients may have different impacts on human health and the environment; various active ingredients in use in herbicides vary widely in toxicity and in persistence in the environment (Sanvido *et al.*, 2007). Glyphosate and glufosinate are herbicides that are considered less toxic to the environment than those previously used such as alachlor, 2,4-D, atrazine, butylate and EPTC (Benbrook, 2001; Sanvido *et al.*, 2007).

In addition, it is important to assess herbicides according to their mode of action. With increasing reports of glyphosate-resistant weeds, it is important to advocate the use of herbicides with different modes of action. For additional information on herbicide resistance and weed resistance management see Weed Resistance Management section below.

Insecticide Use

In the U. S., insecticide use has been decreasing, with the exception of insecticide seed treatments that growers use to ensure their seeds are protected from early season soil insect pests (Figure 8). One contributing factor to the overall reduction of insecticide use is *Bt* corn (USDA-ERS, 2011e). The use of *Bt* corn has steadily increased over the past decade with 65% of all corn acres planted with *Bt* corn in 2011 (Figure 4).

By growing *Bt* corn it was estimated that in 2005, the total volume of insecticides was reduced by 10% (Brookes and Barfoot, 2006). The need for *Bt* products is evident in that both European corn borer and the corn rootworm species (*Diabrotica ssp.*) are major corn insect pests throughout the U.S. Monetary losses resulting from feeding damage and insect control for each pest exceed $1 billion each year (Gray *et al.*, 2009; Ostlie *et al.*, 2002). *Bt* corn enables reduction in grower exposure to chemicals, a reduction in the use of insecticides that are highly toxic to humans and the environment, and a reduction in input costs by decreasing the number of times a grower must go over the field for tillage and insecticide applications (US-EPA, 2010c; US-EPA, 2010b). Overall, the reduction of insecticide use has contributed to the environmental and economic sustainability of farming operations.

Seed Treatments

Due to grower demands in 2004, industry began to sell more seed products coated with insecticidal treatments. Insecticidal seed treatments are now used on the majority of corn seeds sold to growers as a preventative measure. Insecticides target insects that attack corn seeds, seedlings, and roots of corn including rootworm, cutworm, wireworm, seed corn maggot and grubs/colaspsis (Pioneer Marketing, 2011).

Fungicide Use

The application of fungicidal chemicals (except for seed treatments) varies among growers. Diseases are unpredictable but some of the common fungal diseases on corn include seed rot, common rust, eyespot, gray leaf spot, Anthracnose leaf blight, northern corn leaf spot, and northern corn leaf blight (Hoeft *et al.*, 2000; Ruhl, 2007).

In the past, fungicide applications on hybrid corn were mostly regarded as too costly. However, more recently, new foliar fungicides in the strobilurin and triazole classes have been registered on corn in the U.S. These fungicides are more effective than older contact fungicides due to systemic activity, some curative activity and longer protection. In addition, companies have pursued more corn fungicide registrations after submitting soybean fungicide registrations for Asian soybean rust (Munkvold and Gorman, 2006). These corn registrations have been, in part, a response to an increased disease risk associated with increased corn-following-corn acres and reduced tillage practices. The increase in disease risk, together with the higher price of corn and and increased visibility of fungicides through marketing, has been responsible for changes in corn fungicide management practices. As a result, fungicide applications on corn became more common since 2007 (Robertson *et al.*, 2007b). Growers have noticed an increase in yield in corn from using foliar fungicides. Additionally, research indicates that foliar fungicides may increase yield and may provide an economic benefit; accordingly, foliar fungicides are currently at their highest historical levels (Brooks, 2011; Robertson *et al.*, 2007a).

Integrated Pest Management

Integrated Pest Management (IPM) is a commonly employed methodology to comprehensively manage pest threats and prevent or delay weed development or pest resistance. IPM techniques include prevention, avoidance, monitoring, and suppression of weeds, insects, diseases, and other pests. IPM combines the practices of several pest management programs into one overall program designed to minimize the impact on growers and environment. IPM practices are specific to the crop, region, and pest. In many cases, adoption of IPM leads to a reduction in overall pesticide use, lower production costs, and improvement in water, air, and soil quality (Coble and Ortman, 2009).

IPM was first advocated in 1972 by President Nixon's Council on Environmental Quality and in 1979 by President Carter. President Clinton's Administration set a goal of implementing IPM programs on 75% of managed acres in the U.S. by the year 2000. Over the years, the challenge has been how to measure IPM adoption. This continues to be difficult because an IPM system for a given crop will vary with growing region and season, the emergence of new pests, and changes in production practices (Shennan *et al.*, 2001). There have been advances in methodology, but a complete, practical, and accepted method to measure IPM adoption is not yet available (Fernandez-Cornejo and Jans, 1999).

A 1994 report by Vandeman *et al.*, found that 69% of the soybean acres and 65% of the corn acres were "scouted." Scouting is an integrated weed management (IWM) practice and is the systematic collection of pest and crop data from the field (*e.g.* weed distribution, growth stage, population, crop stage, etc.) for weeds, diseases, and insects. Data from a 1996 published survey in an Economic Research Service Report (1999) indicated that soybean and corn farmers reported scouting for weeds on 79% and 88% of their acreage, respectively. A more recent survey conducted in Wisconsin reported that 71% of the farmers who participated in the survey scouted for weeds, insects, and diseases on a regular basis (Hammond *et al.*, 2006).

Under an IPM program, pesticide applications are made according to the economic thresholds of a crop based on information gathered during routine scouting. Pesticide applications are just one approach that may be used to manage a pest. Other IPM approaches for pest management include: crop rotation, tillage, adjusting the time of harvest, trap crops, and the use of biotechnology. Specifically, in recent years, biotechnology has enabled development of stacked-traits that confer resistance to multiple pest risks.

Scouting for certain insects should occur during strategic periods during the growing season. Insect pests that may be found in corn fields include: billbug, black cutworm, corn earworm, corn rootworm (larva and adult), European corn borer, fall armyworm, flea beetle, grape colaspsis, Japanese beetle, seedcorn beetle, seedcorn maggot, stalk borer, western bean cutworm, white grub, and wireworm (Figure 10 illustrates the prevalence of these pests in the Midwest where corn production is concentrated). Growers should be knowledgeable throughout the growing season of the types of insects present in their corn fields.

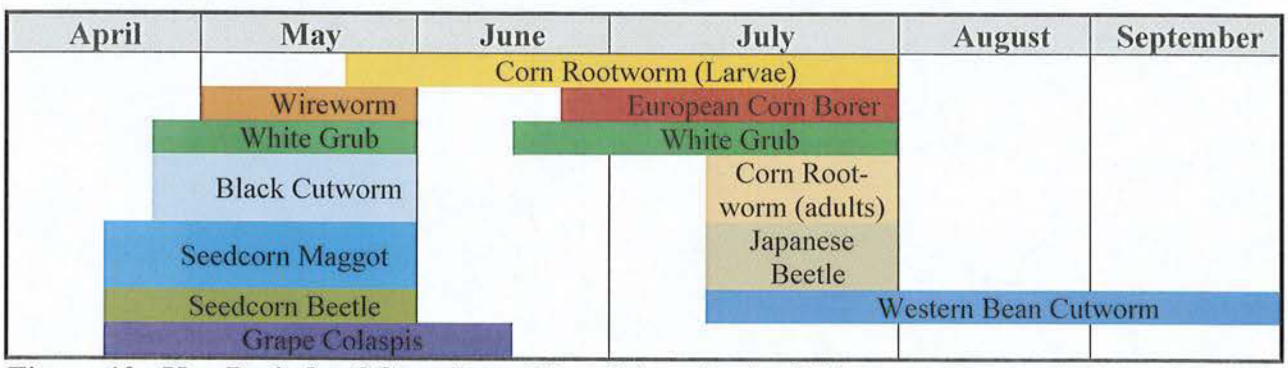


Figure 10. Key Periods of Corn Insect Pest Injury in the Midwest
Pioneer, 2011a

Insect Resistance Management

As a condition of *Bt* registrations by EPA, registrants are required to implement an Insect Resistance Management (IRM) program. As part of this program, growers of traditional *Bt* corn products are required to plant a non-*Bt* refuge to delay the development of insect resistance. A refuge can consist of a field, block, or strip of non-*Bt* corn that, depending on the technology, does not contain a *Bt* trait for controlling certain lepidopteran pests including the European corn borer and/or corn rootworms (Pioneer, 2011b). Within this refuge, susceptible target insects can feed, mate, and reproduce without exposure to the *Bt* plants/protein(s). Future mating interactions of these susceptible insects with those insects that are exposed to the *Bt* proteins will ensure that *Bt*-susceptibility is passed on to the next generation.

Recently, EPA has approved integrated refuge products otherwise known as "refuge in a bag." Integrated refuge products refer to the blending of *Bt* seeds with refuge seeds together in a single bag of seed. The non-*Bt* seeds are randomly planted throughout the field to serve as a refuge for producing susceptible insects. The seed company thereby facilitates the grower compliance with refuge planting requirements, as the company ensures that each bag is blended with appropriate amount of refuge seed.

EPA also requires registrants to educate their sales force and customers in meeting refuge requirements and to assess refuge compliance by its customers through third party on-farm assessments and grower surveys. Registrants must also continue to conduct research on IRM and closely monitor and report any development of resistant insect populations (Pioneer, 2011b). Growers of traditional *Bt* corn products must sign agreements incorporating refuge requirements as part of the IRM program.

Pioneer and DuPont Crop Protection participate in industry efforts related to mitigating or managing insect resistance through membership in an industry-based group, the Insect Resistance Action Committee (IRAC, 2011b). The IRAC is a technical group which is part of the industry association CropLife International and focuses on preventing or delaying resistance development in insects. IRAC facilitates communication and education about insect resistance and promotes development of insect resistance management strategies (IRAC, 2011b). Included in IRACs structure are issue-specific work groups, with one addressing biotechnology. The biotechnology work group's objectives are to act as an authoritative source of IRM information for industry, promote practical approaches to insect monitoring, develop unified messaging related to resistance incidents, deliver practical IRM messaging through industry educational seminars and conferences, and promote IRM considerations as a critical part of biotech crop development activities (IRAC, 2011a). Pioneer is also a member of the Agricultural Biotechnology Stewardship Technical Committee (ABSTC), a coalition of agricultural biotechnology companies/technology providers that are *Bt* corn registrants who work together to address scientific issues central to the responsible stewardship of products developed through plant biotechnology. This committee also has a technical sub-team that addresses scientific questions addressing insect resistance management. Their focus has been centered on insect resistance monitoring, which relies on annual field sampling and laboratory assays to detect resistance development within target insect populations.

Bt corn hybrids have proven very effective for managing their targeted insect pests since being introduction in 1996. However, there is current information that suggests pockets of western corn rootworm may be developing resistance to one type of *Bt* corn (Gassmann *et al.*, 2011). Furthermore, resistance has been confirmed to fall armyworm to Cry1F in Puerto Rico (US-EPA, 2010b).

Weed Resistance Management

There are effective herbicides to control weed populations in fields, and numerous mechanical and cultural practices available to growers. Although the feasibility, effectiveness, and economics of adopting certain weed management practices is highly site dependent, reliance on herbicides for weed management has continued to increase for the past several decades (Bridges, 1994). Some of the most common weeds in cornfields located in North Central Region of the U.S. include: cressleaf groundsel, purple deadnettle, biennial wormwood, Asiatic dayflower, hophornbeam copperleaf, giant ragweed, burcucumber, wild buckwheat, kochia, lambsquarters, complex waterhemp, palmer amaranth, star-of-Bethlehem, white campion, wild four o'clock, and pokeweed (Iowa State University Extension, 2003).

The repeated use of herbicides has led to the development of resistant weeds. Cases of weed resistance date back as far as the 1950s. By the 1990s, 81 weed species contained individuals (or biotypes) that were resistant to one or more herbicides. Today, that list includes approximately 372 biotypes distributed across the globe, including 13 glyphosate-resistant weed species reported in the U.S. (Heap, 2011). However, glufosinate resistance is not a major concern in the U.S.; presently, there is only one domestic glufosinate resistant weed, Italian ryegrass located in Oregon (Avila-Garcia and Mallory-Smith, 2011a). This issue should be carefully managed.

Herbicide resistance refers to the ability of a weed to survive and reproduce following exposure to a dose of the herbicide that would normally be lethal to the wild type (Prather *et al.*, 2000). Resistance may occur in weeds by random and infrequent mutations, including mutation induced by herbicide exposure (Powles and Preston, 2006). If an herbicide is continually used on a population of weeds, a resistant biotype may successfully reproduce and become dominant in the population (Prather *et al.*, 2000). To add to the complexity of weed resistance, a recent study concluded that glyphosate-resistant Italian ryegrass exhibited glufosinate-resistance even though it had never been exposed to the herbicide. The study concluded that just because the sites of action of these two herbicides are different does not preclude the possibility that one mechanism could affect the translocation of both herbicides. If more cases of cross resistance to these two herbicides are identified, new weed management strategies will be required that include herbicides with alternative sites of action and/or nonchemical methods (Avila-Garcia and Mallory-Smith, 2011b).

DuPont along with other companies, weed scientists, and university scientists are constantly working to design management strategies/practices to help control weeds and to develop alternative HT crops for growers (Service, 2007). To minimize the development of herbicide resistant weeds, Pioneer and DuPont Crop Protection helped develop WRM programs through participation in industry coalitions such as the Herbicide Resistance Action Committee (HRAC). The HRAC is an industry-based group whose mission is to support a cooperative approach to the manage herbicide resistance by facilitating communication and cooperation between industry, government researchers, advisors, and growers (HRAC, 2009). WRM uses all available strategies to manage weed populations in an economically and environmentally sound manner. Such strategies include cultural, mechanical, chemical, and biological methods.

Specific recommendations include:

- Using alternative weed management practices, such as mechanical cultivation, delayed planting, and weed-free crop seeds.
- Cleaning equipment before leaving fields suspected to have resistant weeds to minimize the spread of weed seed.
- Scouting fields prior to the application of any herbicide to determine the species and the need for an herbicide application.
- Scouting fields after application to detect weed escapes or shifts and applying alternative control methods to avoid seed deposition in the field.
- Using full label rates and tank mix partners when using herbicides.
- Using mixtures or sequential treatments of the herbicides having a different mode of action.
- Limiting the number of applications of a single herbicide(s) with the same mode of action in a single growing season and in successive years.
- Rotating crops with an accompanying rotation of herbicides to avoid using herbicides with the same mode of action in the same field.
- Using cover crops and other methods to reduce weed seeds in the soil, where practical (Pioneer, 2011c).

2.1C. Corn Processing Practices

A corn kernel is made up of four major components: starch, fiber, protein, and oil. Corn can be processed in different ways to tap into these components and use them in all kinds of products. There are three basic methods for processing corn kernels: "dry milling" and "wet milling" (NCGA, 2011c). Both corn processing methods involve fractioning the kernels into component parts. Once separated, these component parts are more valuable, thus the term "value added processing." There are three primary forms of value added processing of corn today:

1. ***Corn wet milling*** *(also referred to as* ***corn refining)*** *breaks up the kernel both chemically and mechanically.*

2. ***Corn dry milling*** *is the mechanical fractionation of the corn kernel. An alternative dry milling process, called alkaline cooking, is an ancient process (dates back to the Aztecs) whereby corn dough (called masa) is made from whole corn. This process is used for the production of tortillas and tortilla chips (Hansen and Van der Sluis, 2004).*

3. ***Dry grind ethanol*** *(a form of dry milling) grinds whole dry corn and then makes a mash by combining it with water, enzymes, and yeast which is fermented into ethanol. This process consumes the starch fraction of the kernel. Three products result from this process: ethanol, carbon dioxide, and dried distillers grains (DDGS) (See Ethanol Production below).*

Wet milling starts with softening the kernel in hot water and sulfur dioxide prior to further fractionation and processing (OECD, 2002; Tate & Lyle, 2011). Products produced in the wet milling process include germ meal, oil (further processed into margarine, cooking oil, baking and frying fats), corn gluten feed, corn gluten meal, and starch (further processed into ethanol and sweeteners) (OECD, 2002).

Products produced in the dry milling process include flour, meal, germ meal, oil, beverage and fuel ethanol, distillers dried solubles, flaking grits, hominy feed, and grits (OECD, 2002). Starch, oil, grits, bran, meal, and flour from corn wet and dry milling are primarily used in foods (OECD, 2002). Over 90% of the starch Americans use is produced from corn (NCGA, 2011c). The majority of starch is converted to sweeteners, such as corn syrup, high fructose corn syrup, maltodextrins and dextrose, and also fermented into ethanol (OECD, 2002). A significant portion of U.S. corn, 4.1%, goes to the production of high-fructose corn syrup as an end product (NCGA, 2011c). Approximately 6.9% comprises food purposes such as starch, sweeteners, cereal/other, seed, and beverage alcohol (NCGA, 2011c). Starch is used for food such as bakery products/mixes, condiments, candies, and prepared (snack, dessert, meat) foods (CCUR, 2009). Sweeteners are used for soft drinks, candies, bakery products/mixes, condiments (jams, jellies, dressings), and prepared foods (CCUR, 2009). Whole corn is consumed as popcorn, sweet corn, and alkali processed grain for tortillas and snack chips (CCUR, 2009), though these uses comprise a very minor usage segment.

The major product produced from the dry grind ethanol process is ethanol. This value added process results in 90% of the ethanol produced today (RFA, 2011b). Other products that result from the dry-grind ethanol plants include wet and dry distillers grains (DDGS), wet and DDGS with solubles, modified "wet cake" (a blend of wet and DDGS), and condensed distillers solubles (Shurson and Noll, 2005). DDGS serve as livestock feed for cattle, swine and poultry (see Ethanol Production below).

2.1D. Specialty Corn Production

Specialty corn production requires identity preservation (IP) practices to prevent cross-pollination of different corn types. Cross-pollination in corn is achieved by wind and gravity dispersal of the shedding pollen. Unlike all other major grain crops such as wheat, rice, and barley, the corn plant has separate male and female flowering parts. During the flowering stage, pollen shed and silking are necessary steps to produce the next generation of seeds. Because of the separation of the male and female parts, cross-pollination of corn plants occurs with high frequency. However, pollen viability is reduced in a matter of hours under high temperature and low humidity, and the majority of maize pollen is unlikely to be dispersed significant distances outside the originating field (for further discussion, see Petition page 145). Reliable IP practices can be employed to prevent the likelihood of cross-pollination (Brittan, 2006).

IP grains are frequently referred to as specialty, high value, premium, or niche market grains. They are produced with a specific end use in mind, the possibilities of which include human food, animal feed, cosmetics, pharmaceuticals, or industrial use (Massey, 2002). Unique requirements in the specialty corn industry include mechanisms to keep track of the grain (traceability) for 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 of planting seeds, and testing of harvested materials to determine acceptability of use and product requirements, and assuring testing procedures are appropriate; and
- 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.

An example of a successful IP system includes seed certification practices conducted by members of American Organization of Seed Certifying Agencies (AOSCA) (AOSCA, 2009). To maintain the purity of the corn product, this system is based on controlling, tracking, and documenting each step from seed production to end use (processing plants). In the field, isolation requirements must be met for the corn to be considered IP. For example, for a field to meet non-GE corn grain program requirements, growers have fields with the following parameters:

1. A distance of 660 feet from any GE corn;
2. For fields over 20 acres, distance may be modified by post pollination removal of 16 adjacent rows if isolation is less than 165 feet;
3. For fields over 20 acres, distance may be modified by post pollination removal of eight adjacent rows if isolation is between 165 and 660 feet; and
4. A distance adequate to prevent mechanical mixture shall separate fields from any other seed producing crop (AOSCA, 2000).

IP corn acreage is typically limited in states where end users of specialty corn are not located. Types of corn specialty products include those listed in Table 5.

Table 5. Types of Specialty and Identity Preserved (IP) Corn

High oil corn
White corn
Waxy corn
Blue corn
Yellow food grade corn
High amylose corn
Low phytate corn
Nutritionally enhanced corn
Heat stable amylase corn
Popcorn
Organic corn
Non-GMO corn

Thomison and Geyer, 2004; Internal Correspondence, 2011

In 2002, overall the leading specialty/IP corn states included Illinois, Iowa, Nebraska, and Indiana. Primary specialty/IP corn production by state is described below:

- Waxy corn is grown primarily in Missouri, Minnesota, Iowa, and Indiana
- White corn is grown in Indiana, Illinois, Kentucky, Tennessee, Missouri, Iowa, Nebraska, Texas, and California, with Texas and Kentucky being the major producers (Internal Correspondence, 2011)
- Non-GMO corn is grown in Indiana, Illinois, Kentucky, Ohio, Tennessee, Missouri, Iowa, Nebraska, Texas, and California

2.1E. Organic Corn Production Practices

Organic farming, as defined in this document, includes 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 USDA's Agricultural Marketing Service (AMS). Organic farming operations, as described by the NOP, require organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods. Excluded methods include a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes. In organic systems, the use of synthetic pesticides, fertilizers, and genetically engineered crops is strictly limited. 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 (NOS), including the prohibition on the use of excluded methods.

Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards. To verify this process compliance, an accredited organic certifying agent conducts an annual review of the certified operation's organic system plan and makes on-site inspections of the certified operation and its records. Organic growers may use the following practices to exclude GE products from their fields and products: planting only organic seed; planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times; and employing adequate isolation organic certification of a production or handling operation is a process claim, not a product claim. Distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields. Although, the NOS prohibit the use of GE products, they do not require testing of inputs or products for the presence of GE products. The presence of a detectable residue of GE products alone does not necessarily constitute a violation of the NOS (USDA-AMS, 2005). Because the organic certification is a process certification, the unintentional presence of GE products will not affect the status of an organic product or operation when the operation 1) has not used GE products and 2) has taken reasonable steps to avoid contact with the GE products as detailed in their approved organic system plan.

Adoption of organic farming systems in general showed strong gains between 2002 and 2008, averaging a 15% annual increase in cropland acreage during this period. While the adoption rate remains high, the overall adoption level is still low—only about 0.7% of all U.S. cropland was certified organic in 2008 (USDA-ERS, 2010a).

Organic corn has been increasing over the years. In 1995, organic corn acreage was 32,650 acres; in 2008, the acres increased to 194,637 acres, which was 0.21% of the total corn acres planted (USDA-ERS, 2010e). Most states plant organic corn with the top three states being Wisconsin, Minnesota, and Iowa in 2008 (see Table 6) (USDA-ERS, 2010d). There has been an increasing trend in organic corn production over the years, but organic corn still remains a minor contributor to the overall U.S. corn production.

Table 6. 2008 Certified Organic Corn Acreage by State

State	Corn Acreage
Wisconsin	33,619
Minnesota	27,565
Iowa	25,419
Michigan	12,663
New York	11,459
Texas	11,202
Nebraska	10,568
Ohio	8,969
Illinois	8,739
Pennsylvania	5,918
South Dakota	5,564
Other[a]	32,951
Total	194,637

[a] Sum acreage of states with <5,000 organic corn crop acreage
USDA-ERS, 2010d based on information from USDA-accredited state and private organic certifiers.

2.1F. Ethanol Production

Ethanol, also called ethyl alcohol, is produced by the fermentation of sugars from any feedstock that contains plentiful natural sugars or polysaccharides that can be converted to sugar. Ethanol, or a blend of ethanol and gasoline, can be used as a liquid motor fuel. Corn is the primary feedstock used to produce ethanol in the U.S., and 36.5% ($24.1 billion) of the corn grain produced is fermented into fuel ethanol (NCGA, 2011c; USDA-ERS, 2010f).

Ethanol accounts for a small share in the overall gasoline market, but use of U.S. corn for ethanol production has important implications for domestic crop and livestock production, as well as for global trade and international markets. The U.S. produced 13.2 billion gallons of ethanol fuel in 2010 (NCGA, 2011c). By the middle of the next decade, ethanol production (by volume) is expected to represent less than 10 % of annual gasoline use in the U.S. (USDA-ERS, 2010f). While corn-based ethanol can contribute to the nation's fuel supply, that contribution is relatively small in the gasoline market; however, corn-based ethanol can have large effects in the agricultural sector. Corn, most likely, will remain the primary feedstock for U.S. ethanol production until other bioenergy technologies come to fruition (USDA-ERS, 2010f) and until that time, corn will continue to be the basis upon which the ethanol industry grows. 2011 predictions for starch-based ethanol production could approach, and will probably surpass, 13.5 billion gallons, as processes to convert grain into fuel and feed improve. New demand from higher level ethanol blends like E15, E20, and E85 as well as the potential for continued export opportunities show promise for starch-based ethanol use to exceed the 2011 Renewable Fuels Standard "renewable biofuel" requirement of 12.6 billion gallons (RFA, 2011b).

Ethanol production plants are mostly found in the Midwestern Corn Belt, so corn can be easily transported for processing. Currently, there are approximately 204 ethanol plants in production or under construction/expansion in 29 states, (Figure 11) (RFA, 2011b). In the U.S., corn planted for ethanol production is currently over 4 million acres and is projected to be over 5 million acres in 2020 (USDA-ERS, 2011d). In 2010, the ethanol industry contributed $53 billion to the U.S. GDP and supported more than 400,000 jobs. Further, the ethanol industry produced $36 billion for Americans in 2010, with farmer income seeing the largest increase as a result of the higher demands for ethanol feedstock.

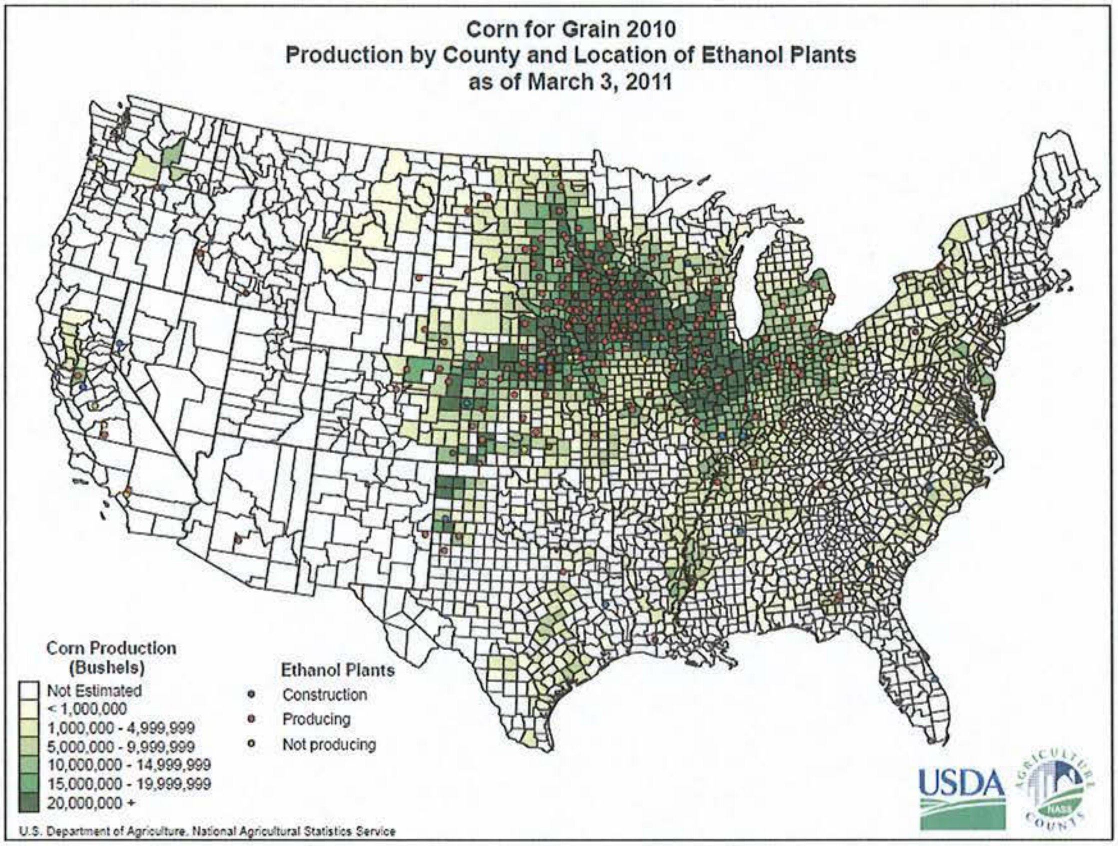


Figure 11. Ethanol Production Plants Located in the U.S.
USDA-NASS, 2011g

Distillers Grains

Both the wet mill and dry-grind processes utilize only the starch portion of the corn kernel for ethanol production. The remaining protein, fat, fiber, and other nutritional components remain available for use as animal feed.

Approximately 90% of the ethanol produced today comes from the dry-grind process (RFA, 2011a). Each 56-pound bushel of corn processed by a dry-grind facility results in the production of approximately 17 pounds of distillers grains and 2.8 gallons of fuel ethanol. Approximately 4.1 billion bushels of corn were processed by dry-grind facilities in 2009-2010, meaning nearly 31.5 mmt of distillers grains were produced. This marks more than a 10-fold increase in distillers grains production over the last decade (RFA, 2011a).

By-products from dry-grind ethanol plants include wet and dry distillers grains (DDGS), wet and DDGS with solubles, modified "wet cake" (a blend of wet and DDGS), and condensed distillers solubles (Shurson and Noll, 2005). In 2010, distillers grains produced by the ethanol industry displaced the need for 1.2 billion bushels of corn for the livestock industry (NCGA, 2011d). The high crude fat content of high quality corn DDGS distinguishes it from the other by-products, and the high availability of phosphorus in DDGS makes it an attractive and economical partial replacement for supplemental inorganic phosphorus sources in cattle, swine, and poultry diets (Figure 12) (Shurson and Noll, 2005).

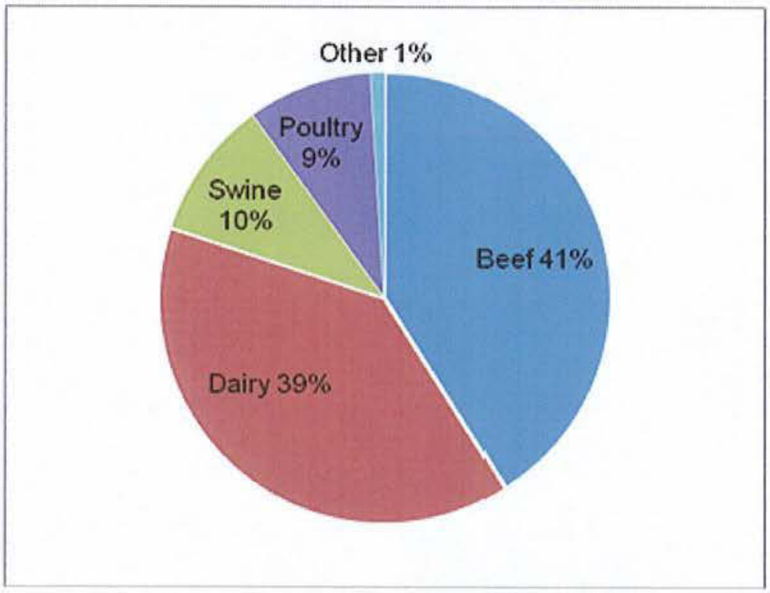


Figure 12. Estimated 2010 Distillers Grain Consumption by Species
RFA, 2011b

Wet mill ethanol plants processed about 500 million bushels of corn in 2009-2010. Approximately 13 pounds of corn gluten feed and 2.5 pounds of corn gluten meal are produced per bushel of corn processed by a wet mill, meaning the industry produced an estimated 2.9 mmt of gluten feed and 550,000 metric tons of gluten meal in 2009-2010. Corn gluten feed and meal production has remained relatively constant in the last decade, as the majority of growth in ethanol production has come from the dry-grind process (RFA, 2011a).

The rapid growth of the fuel ethanol industry in the U.S. has created increased supplies of corn by-products available for livestock and poultry feeds. The estimated market value of feed co-products from ethanol production in 2009-2010 was $3.8 billion. An estimated additional $1 billion was realized through sales of corn oil, a high-value co-product of the wet mill ethanol process and some dry-grind ethanol processes (RFA, 2011b; RFA, 2011a).

In the 2009-2010 marketing year, the U.S. ethanol industry generated approximately 35 million metric tons (mmt) of high-quality feed, making the renewable fuels sector one of the larger feed processing segments. U.S. grain ethanol co-product volumes are expected to have approached 39 mmt in 2010/11 (RFA, 2011a).

The beverage alcohol industry also produces grain by-products in the form of DDGS (whiskey distilleries) or brewer's grains (beer manufacturing). All of these by-products are nutritionally different and have different economic value in various types of animal and poultry feeds. Whiskey distilleries use a blend of corn, rye, and wheat to make DDGS, whereas brewer's grains are comprised primarily of barley.

Cellulosic Ethanol

Cellulose, a polymer of D-glucose, is the main component of plant cell walls and is the most common organic compound on earth. When cellulose is broken into simple sugars, it can be converted into ethanol, referred to as "cellulosic ethanol." Because of the prevalence of plant cellulose, cellulosic ethanol production can be expanded far beyond ethanol levels produced from grain starch. It is estimated that cellulosic ethanol production may displace 30% of U.S. petroleum needs by the mid-21st century (Baker and Zahniser, 2006; US-DOE, 2011). New cellulosic ethanol sources being investigated include biomass feedstocks composed of:

- Agricultural residues (leftover material from crops, such as the stalks, leaves, cobs, and husks of corn plants);
- Forestry wastes (chips and sawdust from lumber mills, dead trees, and tree branches);
- Municipal solid waste (household garbage and paper products);
- Food processing and other industrial wastes (black liquor, a paper manufacturing by-product); and
- Energy crops (fast-growing trees and grasses) such as switchgrass, *Miscanthus*, and poplar, developed just for this purpose (US-DOE, 2011; USDA-ERS, 2009b).

Corn stover would be the largest source of biomass for cellulosic ethanol production in the U.S. Removal of large amounts of corn stover from fields can cause issues with soil erosion or soil fertility. As a result, investigations on how to balance the use of corn stover for production of cellulosic ethanol and not adversely affect corn fields are ongoing (Graham *et al.*, 2007; Wilhelm *et al.*, 2010). The wealth of sources for cellulosic ethanol and the subsequent expected production increases provide great promise for new jobs and economic growth in the U.S., beyond the "grain belt" area where corn ethanol production occurs. As of February 2010, there were approximately 20 cellulosic ethanol production facilities under construction in the U.S. (RFA, 2010; US-EPA, 2011b).

Economic Incentives for Producing Cellulosic Ethanol

Both the 2008 Farm Bill and the Energy Independence and Security Act of 2007 (H.R. 6) provide economic incentives for cellulosic biofuel producers. Under the 2008 Farm Bill, the credits to the producer cannot exceed $1.01 per gallon, and producers that are located within an economically practicable distance from a biomass facility are eligible for financial assistance for crop establishment costs and annual payments for biomass production under the Biomass Crop Assistance Program (BCAP). Under H.R. 6, there are the following incentives:

- Authorizes $500 million annually for FY08-FY15 for the production of advanced biofuels that have at least an 80% reduction in lifecycle greenhouse gas (GHG) emissions relative to current fuels.
- Authorizes $25 million annually for FY08-FY10 for research and development and commercial application of biofuels production in states with low rates of ethanol and cellulosic ethanol production.

Ethanol production and growth of the ethanol industry have important implications for the U.S. corn market. In 2010, the U.S. produced 13.2 billion gallons of ethanol fuel (NCGA, 2011c). It is anticipated that the demand for this alternative fuel source will continue. As a result, the demand for corn as the primary source of ethanol will continue. Alternate sources of ethanol fuel (e.g., cellulosic ethanol) are being investigated, but corn will continue as the major source for this type of fuel. In addition, the by-products from the dry grind ethanol process will continue to serve as a source of livestock feed. The uses associated with ethanol production have important implications on the demands for corn in the U.S. in the future.

2.2. Physical Environment

Soil Quality

Cultivation of corn directly impacts the qualitative and quantitative attributes of soil. Land management options, such as crop, tillage, and pest management regime have notably greater effects on the soil biology than the type of corn cultivated (Griffiths *et al.*, 2007b; Griffiths *et al.*, 2007a). For example, conventional tillage and mechanized harvesting machinery may disturb and expose the top soil surface layer, leaving the land prone to degradation. In turn, degradation of soil structure and composition may lead to decreased water retention, a decrease in soil carbon aggregation and net positive carbon sequestration, and increased emission of gases that contribute to the greenhouse effect (*e.g.*, carbon dioxide (CO_2) and nitrous oxide (N_2O)) (Lal and Bruce, 1999; US-EPA, 2010c). Additionally, land that is prone to degradation is also more likely to negatively affect water resource quality and communities of organisms dependent on those water resources. The commercialization of GE crops has enabled implementation of lesser impact tillage and improved pest management strategies.

Water Resources

The amount of corn cultivation has been increasing over the last five years due to the demand for food and fuel by a rising population; this increased cultivation subsequently impacts U.S. water use and quality. Almost one-third of all U.S. cultivated acres are dedicated to corn[e] and corn plants consume a substantial amount of water during growth (NCGA, 2011c; NCGA, 2011a). Corn cultivation requires approximately 4,000 gallons of water to produce 1 bushel (NCGA, 2007). In 2010, 12.4 billion bushels of corn were harvested in the U.S. (NCGA, 2011c) resulting in the use of approximately 600,000 gallons of water per acre for each growing season (NCGA, 2007). In 2010 about 11.0 million corn acres (approximately 9% of all corn acres planted for grain) were irrigated, with the balance acres receiving only the ambient rainfall (NCGA, 2011c). Farms employing no-till practices on their fields which is facilitated by GE corn varieties, saved \$3.5 billion dollars in water treatment and waterway management in 2010 (NCGA, 2011c).

Agricultural pollutants released by soil erosion include sediments, fertilizers, and pesticides that are introduced to area lakes and streams when they are carried from fields by rain or irrigation waters (US-EPA, 2005). Excess sediment can directly affect fish and other wildlife mortality and can reduce the amount of light penetration into a body of water decreasing the available sunlight for aquatic plants. Indirectly, soil erosion-mediated sedimentation can increase fertilizer/nutrient content in runoff, facilitating higher water turbidity, algal blooms, and oxygen depletion in a body of water (US-EPA, 2005).

These effects on water quality are characterized as agricultural non-point source (NPS) (US-EPA) pollution. NPS is the primary source of discharge pollutants to rivers and lakes and is a major contributor to groundwater contamination (US-EPA, 2005). Agricultural management practices that contribute to NPS pollution include the type of crop cultivated; the extent of plowing and tillage; and the amount of pesticides, herbicides, and fertilizers applied. The primary cause of NPS pollution, however, is caused by increased sedimentation following soil erosion.

Fertilizers are applied to soil to replace necessary nutrients lost during crop growth. Fertilizers may be in the form of biosolids, industrial waste, manure, or synthetic products manufactured via chemical processing (US-EPA, 2011c); of those listed, synthetic fertilizers are the major source of applied nutrients (USDA-ERS, 2005b). The three major fertilizer nutrients are nitrogen, phosphate, and potash. The environmental effects caused by the release of excess nitrogen into the environment are of particular concern.

Nitrogen is essential to plants during growth and development. Plants incorporate nitrogen in the form of ammonium or nitrate (Ferguson, 2000); however, the majority of nitrogen's natural occurrence in the environment is in a chemically inert form unavailable to plants (Ferguson, 2000). To increase bioavailable nitrogen, naturally occurring diatomic nitrogen (two bound

[e] 92.3 million acres of corn were planted out of 319.2 million acres dedicated to major crops (USDA-NASS, 2011b).

nitrogen atoms) must be "fixed"[f] by nitrogen-fixing bacteria contained within the soil, or an already "fixed" form of nitrogen must be applied to cropland.[g] Much of the nitrogen released into the environment to aid in plant growth eventually makes its way into rivers, lakes and oceans. By virtue of its nutrient function, this nitrogen-containing runoff fertilizes blooms of algae that deplete oxygen and can leave vast "dead zones" in their wake. In these hypoxic zones, no fish or typical sea life can survive (Biello, 2008). Moreover, nitrogen contamination in drinking water can impart human health concerns not only related to ingestion of nitrogen, but also to algal-related toxins from algal blooms caused by nitrogen-containing run-off (US-EPA, 2005).

Air Quality

Many agricultural activities affect air quality including smoke from agricultural burning, tillage, planting/cultivating/harvest emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer (Aneja *et al.*, 2009). These agricultural activities have potentially adverse environmental impacts on air quality.

Tillage contributes to the release of GHG (Lal, 2003) because of the loss of CO_2 to the atmosphere and the exposure and oxidation of soil organic matter (Baker *et al.*, 2005). Emissions released from agricultural equipment (*e.g.,* irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (US-EPA, 2009b). Agriculture, including land-use changes for farming, is responsible for an estimated 7% of all human-induced GHG emissions in the U.S. Nitrous oxide may also be released following the use of nitrogen fertilizer (US-EPA, 2009b). Approximately 69% of all U.S. nitrous oxide emissions are due to agricultural soil management (US-EPA, 2011c). Aerial application of pesticides may also cause impacts from drift and diffusion. Furthermore, pesticides may volatilize after application to soil or plant surfaces (Vogel *et al.*, 2008).

Climate Change

Climate change may be interrelated with agriculture in several relevant ways. The production of agricultural commodities is one of the many human activities that could contribute GHG to the air (Aneja *et al.*, 2009; Isermann, 1994). First, this may occur through the combustion of fossil fuels to run farm equipment, the use of fertilizers, or the decomposition of agricultural waste products (crop residues and animal wastes). Second, different types of plants (for example, trees, grasses, or field crops) can have different levels of contribution to climate change (Cole *et al.*,

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[f] "Fixed" refers to diatomoic nitrogen chemically transformed to a form capable of reacting with other elements such as oxygen, hydrogen, or carbon).

[g] Reported nitrogen application recommendations for grains from corn, sorghum, oats, wheat/rye, and barley are relatively similar ranging between 0.75-1 lb or N/unit of expected yield, while recommended amounts for small grains and grass hay are much higher (17 and 50 lbs N/unit of expected yield, respectively). Notably, these recommendations should be considered in conjunction with other relevant evaluation criteria related to nutrient management (Penn State Extension, 2011)

1997; Freibauer *et al.*, 2004). The location and the soil types in which they are planted also affect production of GHG (Flessa *et al.*, 1998). Third, climate change itself may force changes to agricultural practices by extending the ranges of agricultural weeds and pests (IPCC, 2007).

In response to climate change, the current range of weeds and pests of agriculture is expected to change, and current agricultural practices may be required to change as well (IPCC, 2007). A recent forecast for aggregate North American impacts on agriculture from climate change projects yield increases of 5-20% for the first decades of this century. However, certain regions of the U.S. will be more heavily impacted because water resources may be substantially reduced. While agricultural impacts on existing crops may be significant, North American production is expected to adapt with improved cultivars and responsive farm management (IPCC, 2007; O'Donoghue *et al.*, 2011).

2.3. Biological Resources

Animal Communities

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

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

Intensively cultivated lands, such as those used in corn production, provide less suitable habitat for wildlife use than that found in fallow fields or adjacent natural areas. As such, the types and numbers of animal species found in cornfields are less diverse by comparison. Cornfields, however, have been shown to provide both food and cover for wildlife, including a variety of birds as well as large and small mammals (Palmer *et al.*, 1992; Vercauteren and Hygnstrom, 1993).

The types and numbers of birds that inhabit cornfields vary regionally and seasonally but for the most part the numbers are low (Patterson and Best, 1996). Most of the birds that utilize cornfields are ground foraging omnivores that feed on corn seed, sprouting corn, and the corn remaining in the fields following harvest. Bird species commonly observed foraging on corn include red-winged blackbird (*Agelaius phoeniceus*), horned lark (*Eremophila alpestris*), brownheaded cowbird (*Molothrus ater*), vesper sparrow (*Pooecetes gramineus*), ring-necked pheasant (*Phasianus colchicus*), wild turkey (*Meleagris gallopavo),* American crow (*Corvus brachyrhynchos*), and various grouse and quail species (Dolbeer, 1990; Mullen, 2011; Patterson and Best, 1996). Following harvest, it is also common to find large flocks of Canada geese (*Branta canadensis*), snow geese (*Chen caerulescens*), sandhill cranes (*Grus canadensis*), and other migratory waterfowl foraging in cornfields (Sherfy *et al.*, 2011; Sparling and Krapu, 1994; Taft and Elphick, 2007).

A variety of mammals forage on corn at various stages of production; for the most part, herbivorous and omnivorous mammals feed on the ear at various stages of growth. Large-to-medium-sized mammals that are common foragers of cornfields include: white-tailed deer (*Odocoileus virginianus*), raccoon (*Procyon lotor*), feral pigs (*Sus scrofa*), and woodchuck (*Marmota monax*). The most notable of these is the white-tailed deer which often inhabit woodlots adjacent cornfields and frequent these fields for both food and cover throughout the latter half of the corn growing season (August, September) (Vercauteren and Hygnstrom, 1993). The effects of deer herbivory on cornfields have been well-documented. Cornfields are vulnerable to deer damage from emergence through harvest (Vercauteren and Hygnstrom, 1993), but any damage at the tasseling stage most directly impacts yield (Stewart *et al.*, 2007). White-tailed deer are considered responsible for more corn damage than any other wildlife species (Stewart *et al.*, 2007).

In addition to deer, significant damage to corn by raccoons also has been documented (Beasley and Rhodes, 2008; Devault *et al.*, 2007). Corn has been shown to constitute up to 65% of the diet of raccoons during the late summer and fall (MacGowan *et al.*, 2006). As with these larger mammals, small mammal use of cornfields for shelter and forage also varies regionally and includes (Nielsen, 2005):

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

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

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

Plant Communities

Corn production acreage is host to many plant species, including a number that are regarded as weeds. The landscape surrounding a corn field varies depending on the region. In certain areas, corn fields may be bordered by other corn or any other crop. Fields may also be surrounded by wooded or pasture/grassland areas. Therefore, the types of vegetation, including weeds, around a corn field depend on the area where the corn is planted. A variety of weeds dwell in and around corn fields and those species will vary depending on the geographic region where corn is planted.

In the U.S., corn is not considered a weed nor is it listed as a weed on the U.S. federal or state noxious weed lists (USDA-NRCS, 2011d; USDA-NRCS, 2011c). Corn does not possess the suite of traits that are characteristic of successful weeds (Baker, 1965; Keeler, 1989) (for further information, see Petition page 143). Furthermore, corn is grown throughout the world without any report that it is a serious weed or that it forms persistent feral populations. Corn is poorly suited to survive without human assistance and is not capable of surviving as a weed (Keeler, 1989). Like many domesticated crops, corn seed from a previous year's crop can overwinter and germinate the following year. The appearance of corn seedlings in soybean fields following a corn crop (volunteer corn) is a common occurrence. Manual or chemical measures are often applied to remove these volunteers, but the plants that remain do not result in feral populations in subsequent years.

Volunteer corn that isn't removed from a field reduces yield like any other weed species by competing with the crop for available resources such as light, nutrients and water. Since grain fill by volunteer plants is severely reduced relative to hybrid corn, resources taken away from the crop do not result in an equivalent amount of grain production by volunteer plants. Volunteer corn is at a competitive disadvantage with hybrid corn for two reasons. First, volunteer plants are F2s, meaning that unlike the F1 generation, their pollination has been coordinated to produce high-yield hybrid plants; these F2 volunteers may not share all the characteristics of the F1 generation and may suffer lower yield potential compared to F1 hybrid plants (see Seed-Mediated Gene Flow below). Second, University of Minnesota research found that volunteer corn plants typically lagged one to six leaf stages behind the corn crop. At high enough volunteer plant densities, crop yield can be negatively affected. South Dakota State University research demonstrated corn yield loss approaching 13% when volunteer corn density was extremely high, about 15,000 plants/acre (Jeschke and Doerge, 2010). However, this is a highly unlikely scenario.

Of the available control options, the first and best management strategy for volunteer corn prevention is collecting as much grain as possible during harvest, rather than leaving grain on the ground. Growers should also strive to reduce stalk lodging and ear droppage that lead to volunteer corn. Additionally, no-till practices do not incorporating dropped seed into the soil and thereby foster an environment much less conducive to successful germination and emergence. Long-term, no-till growers rarely report a problem with volunteer corn in their corn-after-corn fields. If farmers are using crop rotation, they may control volunteers using selective herbicides and cultivation (Jeschke and Doerge, 2010).

Microorganisms

The soil environment in and around corn fields is complex and rich in microorganisms and arthropods. The corn root system modifies soil through its close association with bacteria, fungi, protozoa, and mites (Bais *et al.*, 2006). Bacteria typically represent the most abundant microorganism in the soil followed by fungi. These microorganisms play an important role in the ecology of the soil, including impacting the nutrimental cycling and the availability of nutrients for plant growth (OECD, 2003).

Because of concerns of the potential impacts of cultivating GE crops with *Bt* proteins on soil communities, the decomposition rates of GE crops with *Bt* proteins versus non-GE crops have been studied (Icoz and Stotzky, 2008). While many studies have assessed the potential effects of *Bt* proteins on microbial biomass, community structure, community function, and enzymatic processes, there is little evidence that soil microorganisms or soil ecosystem level processes are negatively impacted by *Bt* proteins in soil or by the cultivation of GE crops. One study specifically characterized the potential effects of cultivating Cry1F and Cry1Ab expressing corn on microorganism community structure (assessed by shifts in phospholipid fatty acid profiles) or function (assessed through carbon substrate utilization profiles) in three different soil types (Blackwood and Buyer, 2004). Results from this study demonstrated that, under laboratory conditions, the structure and function of microorganism communities were not affected by Cry1F or Cry1Ab proteins.

Soil function can be further examined by the rate of corn tissue degradation over time. One study reported that under laboratory conditions, *Bt* corn tissue took longer to decompose than non-*Bt* corn tissues (Flores *et al.*, 2005); however, other laboratory based studies have demonstrated that there is no difference between *Bt* and non-*Bt* corn decomposition rates

(Hopkins and Gregorich, 2003). Similarly, under field conditions, no differences between GM and non-GM crop decomposition rates have been demonstrated. For instance, the decomposition rates of *Bt* cotton and *Bt* corn did not differ from the decomposition rates of non-*B*t cotton and corn (Lachnicht *et al.*, 2004; Tarkalson *et al.*, 2008).

Bt proteins generally have a short half-life in soil environments when tested in laboratory assays. *Bt* proteins do not persist or accumulate in soil over time and in fields where *Bt* crops have been grown over successive years (Clark *et al.*, 2005; Icoz and Stotzky, 2008; Shan *et al.*, 2008) (for further information, see Petition page 149). Limited data indicate that *Bt* proteins do not have a measurable effect on microbial populations in the soil. Horizontal transfer of genes from transgenic plants to soil bacteria has not been recorded. Current studies of *Bt* in soil show a negligible effect on bacteria, actinomyces, fungi, protozoa, algae, nematodes, springtails, or earthworms. In addition, crops planted in areas that were previously planted with *Bt* crops did not take up residual *Bt* protein from the soil (US-EPA, 2010b). Other research findings conclude no *Bt*-related risks have evolved from the decomposition of *Bt* corn leaves for the meso- and macrofauna soil community (Hönemann *et al.*, 2008). Although a minimal transient increase and shift in microbial populations may result from the presence of transgenic plant tissue in soil, no adverse effects have been attributed to the *Bt* protein (US-EPA, 2010b).

Biodiversity

Biodiversity may be defined as the degree of variation in life forms for a given ecosystem (in this case, agricultural production of row crops in the U.S.). Biodiversity is strongly impacted by agricultural practices, including the type of cultivated plant and its associated management practices. Species diversity and abundance in corn agro-ecosystems may differ among conventional, GE, and organic production systems. Relative to any natural ecosystem, species abundance and richness will generally be less in intensively managed agro-ecosystems. 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. For example, studies have demonstrated both decreases and increases in biological diversity due to GE crops engineered to accumulate insecticidal proteins or tolerate herbicide application for weed management (Marshall *et al.*, 2003; Ponsard *et al.*, 2002). Biological diversity can be defined and measured in many ways, and determining the level of biological diversity in any crop can be complex, so it is not surprising that concurrence can be difficult to achieve. As another example, some studies have shown *Bt* proteins do not persist, but may degrade differently in different soil types. The difference appears to primarily be the result of differences in microbial activity, which in turn is dependent on soil type, season, crop species, crop management practices, and other environmental factors that vary with location and climate zones (Carpenter, 2011). Another difficulty with biodiversity studies is separating direct impacts from indirect impacts. For example, reductions of biological control organisms are seen in some *Bt* crops, but are caused by reduction of the pest host population following transgenic pesticide expression in the GE crop plant (Naranjo, 2009).

It is important to understand the potential impact GE crops have had on crop diversity, biodiversity of wild relatives, non-target soil organisms, weeds, land use, non-target above-ground organisms, and area-wide pest suppression in the context of the impacts of general agricultural practices on biodiversity. A recent review article (Carpenter, 2011) sums up a substantial body of literature on the impact on biodiversity after 15 years of commercial cultivation of GE crops. Overall, the review finds that currently commercialized GE crops have reduced the impacts of agriculture on biodiversity through enhanced adoption of conservation tillage practices, reduction of insecticide use, the use of more environmentally benign herbicides, and increasing yields to alleviate pressure to convert additional land into agricultural use (Carpenter, 2011). Previous reviews have reached the general conclusions that GE crops have had little to no negative impact on the environment and, more recently, that GE crops have had fewer adverse effects on the environment than non-GE crops produced conventionally (Carpenter, 2011).

Modern agriculture is the result of a long process of plant domestication to create new and better agricultural produce for society. Conventional breeding has focused on improving economic efficiency, and as such has narrowed the number and genetic basis of current crops. It has been estimated that 7,000 plant species have been used for human consumption, but that just four crops (wheat, corn, rice, and potato) provide one-half of the total world food production and 15 crops contribute two-thirds (Carpenter, 2011). Crop genetic diversity is considered a source of continuing advances in yield, pest resistance, and quality improvement. It is widely accepted that greater varietal and species diversity would enable agricultural systems to maintain productivity over a wide range of conditions. Particularly, in light of climate change, maintaining and enhancing the diversity of crop genetic resources is of increasing importance to ensure the resilience of food crop production (Carpenter, 2011).

Long-range effects of cultivation of *Bt* proteins on the invertebrate community structure in *Bt* crop fields have been carefully addressed. A meta-analysis of the data collected from 42 field studies indicated that non-target invertebrates are generally more abundant in *Bt* cotton and *Bt* corn fields than in non-transgenic fields managed with insecticides (Marvier *et al.*, 2007). A comprehensive review of short- and long-term field studies on the effects of invertebrate populations in *Bt* corn and cotton fields indicated that no unreasonable adverse effects are taking place as a result of wide-scale *Bt* crop cultivation (Sanvido *et al.*, 2007). 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 (Chen *et al.*, 2008; Romeis *et al.*, 2006; Torres and Ruberson, 2005; Weber *et al.*, 2009; Wolfenbarger *et al.*, 2008). Additionally, HT corn, when compared to non-GE corn production, may not result in changes in arthropod abundance but may increase species diversity during different times of the year (Brooks *et al.*, 2003; Haughton *et al.*, 2003; Hawes *et al.*, 2003; Roy *et al.*, 2003; Wolfenbarger *et al.*, 2008). Some reports show that GE crops may even increase biological diversity in the agro-ecosystem (Marvier *et al.*, 2007; Romeis *et al.*, 2006).

Pest populations have declined in some areas with high adoption rates of *Bt* crops, which benefits growers of other host crops and reduces the overall need for insecticide use. The potential non-target impacts of insect resistant *Bt* crops on above-ground invertebrates have been studied extensively, with several hundred studies comparing effects of *Bt* and non-*Bt* crops. Several comprehensive reviews of the literature have been published, concluding that effects on natural enemies were observed only when *Bt*-susceptible, sub-lethally damaged herbivores were used as prey or host, with no indication of direct toxic effects. Field studies have confirmed that the abundance and activity of parasitoids and predators are similar in *Bt* and non-*Bt* crops. Pioneer identified only one study that addressed the potential impacts of stacked crops on non-target above-ground invertebrates. A two-year farm-scale evaluation of 81 commercial fields in Arizona found that insecticides used on conventional cotton were related to reduced diversity of non-target insects. However, the effects of cotton cultivation, whether transgenic or not, were found to result in similar effects on biodiversity compared with diversity in adjacent non-cultivated sites (Carpenter, 2011).

Knowledge gained over the past 15 years since GE crops have been commercially grown indicates that the impacts of GE crops on biodiversity are positively balanced. By increasing yields, decreasing insecticide use, increasing the use of more environmentally friendly herbicides, and facilitating the adoption of conservation tillage, GE crops have already contributed to increasing agricultural sustainability (Carpenter, 2011).

Threatened and Endangered Species

One of the main concerns for a possible adverse environmental effect due to the cultivation of GE crops is the threat to the biodiversity in the environments where such plants will be cultivated. In any ecosystem, including agro-ecosystems, hundreds of species are sustained in food webs, above and below ground, based on cultivated plants as the main primary producers; therefore, numerous species at higher trophic levels can come in contact with plant metabolites either directly or indirectly. GE crops developed to control insect pests are purposefully hazardous to their target pest species. All other organisms active in the agro-ecosystem and in adjacent habitats are not intended to be harmed by these GE plants and, therefore, can operationally be defined as non-target organisms (NTOs), including threatened and endangered species (TES) (Arpaia, 2010).

To protect TES, the Endangered Species Act (ESA) of 1973[h], as amended, is one of the most far-reaching wildlife conservation laws ever enacted by any nation. The purpose of the ESA is to conserve endangered and threatened species and the ecosystems on which they depend as key

[h] 16 USC 1531 *et seq.*

components of America's heritage. Before a plant or animal species can receive the protection provided by the ESA, it must first be listed as threatened and endangered. To implement the ESA, the U. S. Fish & Wildlife Service (US-FWS) works in cooperation with: the National Marine Fisheries Service (NMFS); other federal, state, and local agencies; tribes; non-governmental organizations; and private citizens.

In the U.S. there are over 1200 TES, and various TES may be present in or around agricultural fields that include GE crops. Corn is grown in almost every state in the U.S., with the majority of production in the Midwest.

Because of previous cultivation of 1507 maize and 59122 maize, the Cry 34/35Ab1, Cry1F, and PAT proteins in 4114 maize have been present in the environment from GE corn for the last six or more years (for further information, see Petition, page 20) with no known adverse effects on TES. The safety of these proteins to non-target organisms (which can be surrogates for TES) and the specificity of the proteins to target insect pests are discussed in the Petition on page 151. The environmental risk assessments previously conducted by USDA and EPA for 1507 maize and 59122 maize concluded that TES would not likely impact the cultivation of 1507 maize or 59122 maize. A more detailed discussion of the potential impact of 4114 maize on threatened and endangered arthropods, including the low probability that key TES Lepidoptera and Coleoptera species would be found in cultivated corn fields, can be found in the Petition on page 161.

Table 7 identifies TES that are present in the top five corn producing states. None of these TES are known to be affected by GE corn.

Table 7. List of TES in the Top Five Corn Producing States

Animal Species	State[a]				
	Iowa	Illinois	Minnesota	Nebraska	Indiana
Bat, Indiana	x	x			
Higgins eye (pearlymussel)	x	x	x	o	
Plover, piping except Great Lakes watershed	x		o	x	o
Plover, piping Great Lakes watershed		x	x		x
Shiner, Topeka	x		x	x	
Snail, Iowa Pleistocene	x	x			
Sturgeon, pallid	x	x		x	
Tern least interior pop.	x	x		x	x
Beetle, American burying	o	o	o	x	o
Mapleleaf, winged Entire[b]	o	o	x	o	o
Mussel, scaleshell	o	o	o	i	o
Pimpleback, orangefoot (pearlymussel)	o	x			x
Pocketbook, fat	o	x			x
Wolf, gray[c]	o	o	o	x	o
Wolf, gray Minnesota			x		
Amphipod, Illinois cave		x			
Bat, gray		x			x
Butterfly, Karner blue		x	x		x
Butterfly, Mitchell's satyr					x
Clubshell Entire Range[c]		x			x
Dragonfly, Hine's emerald		x			o
Fanshell		x			x
Mucket, pink (pearlymussel)		x			x
Blossom, tubercled (pearlymussel) Entire Range[b]		o			
Puma (=cougar), eastern		o			o
Purple cat's paw (=purple cat's paw pearlymussel) Entire range[b]		o			o
Riffleshell, northern		o			x
Ring pink (mussel)		o			o
Wartyback, white (pearlymussel)		o			x
Lynx, Canada (Contiguous U.S. DPS)			x		
Crane, whooping except where experimental population, non-essential				x	
Tiger beetle, Salt Creek				x	
Curlew, Eskimo				i	
Ferret, black-footed[d]				i	

Table 7. List of TES in the Top Five Corn Producing States (continued)

Animal Species	State				
	Iowa	**Illinois**	**Minnesota**	**Nebraska**	**Indiana**
Catspaw, white (pearlymussel)					x
Pigtoe, rough					x
Snake, copperbelly water[e]					x
Pearlymussel, cracking Entire Range[b]		o			o

[a] An 'x' indicates that a species is listed in the state and occurs in the state, an "o" indicates that a species is listed in the state but does not occur in the state, and an "'i" indicates that a species is not listed in the state but occurs in the state.
[b] Except where listed as experimental populations
[c] Lower 48 states, except MN, MT, ID, portions of eastern OR, eastern WA, north-central UT, and where experimental population, non-essential (EXPN) Mexico
[d] Entire population, except where EXPN
[e] Indiana north of 40 degrees north latitude, Michigan, Ohio

As of December 2011, 61 insect species were listed on the U.S. Fish and Wildlife Service website as threatened or endangered (US-FWS, 2011a). Twenty-one of these insects are in the order Lepidoptera and 15 are in Coleoptera, with the remaining representing insects of other orders. Almost all of the species of Lepidoptera and Coleoptera currently listed were added prior to the deregulation and registration of 1507 maize and 59122 maize, which contain the same *Bt* proteins as 4114 maize, with the exception of two coleopteran species, the Salt Creek Tiger Beetle (*Cicindela nevadica lincolniana*) and the Casey's June Beetle (*Dinacoma caseyi*) (US-FWS, 2010; US-FWS, 2011b). Neither organism's preferred habitat is corn or cultivated crops/agricultural areas (US-FWS, 2010; US-FWS, 2011b).

Threatened and Endangered Arthropods

The impact of the proteins expressed by 4114 maize on threatened and endangered arthropods can be evaluated by comparing previous assessments of 1507 (Cry1F) maize and 59122 (Cry34/35Ab1) maize by both USDA and EPA expressing the same proteins. Both agencies concluded that threatened and endangered species would not likely be impacted by the cultivation of either event (US-EPA, 2010b; US-EPA, 2010c; USDA-APHIS, 2001; USDA-APHIS, 2005).

For 1507 maize, USDA considered the impact of the Cry1F protein on two lepidopteran species, the Karner blue butterfly (*Lycaeides melissa samuelis*) and Mitchell's satyr butterfly (US-FWS, 2011a; USDA-APHIS, 2001). USDA concluded that both species would not be expected to be present in or close to corn fields; therefore it is not likely there would be any impact of 1507 maize cultivation (USDA-APHIS, 2001). For 59122 maize, USDA considered the impact on one primary threatened and endangered coleopteran species, the American burying beetle (US-FWS, 2011a; USDA-APHIS, 2005). The habitat for the American burying beetle is not likely to be found in active agriculture fields, including corn fields; therefore, the beetle would have a low probability of exposure to the *Bt* proteins in 4114 maize (USDA-APHIS, 2005).

EPA has made similar conclusions for other lepidopteran and corn rootworm resistant corn events and has not identified any new threatened or endangered species that would be impacted by their cultivation (US-EPA, 2009c; US-EPA, 2010c; US-EPA, 2010a). Furthermore, EPA examined the habitats of the other threatened and endangered insect species in the orders Diptera, Hemiptera, Odonata and Orthoptera and found that their host plants are primarily found in dune, meadow or prairie, or open forest habitats and are not closely associated with row crop production (US-EPA, 2009c; US-EPA, 2010c).

Detailed Lepidopteran Reviews

The most likely route of exposure of non-target Lepidoptera to transgenic proteins from 4114 maize would be via pollen deposition on host plants (*i.e.,* milkweed) in corn fields and in field margins (for further information, see Petition page 157). Weed control practices render the likelihood of having host plants growing within the confines of the corn field remote; therefore, the most realistic exposure of non-target lepidopteran to corn pollen would be via incidental ingestion of corn pollen on host plants located in field margins. EPA has previously concluded that there was a possibility that off-site pollen flow from *Bt* corn fields might have adverse effects on federally listed threatened or endangered Lepidoptera because of the selectivity of Cry1 proteins for certain lepidopteran species. EPA noted, however, that the majority of listed lepidopteran species have very restricted habitat ranges.

Examination of an overlay map showing the county level distribution of lepidopteran species relative to corn production counties in the U.S. as listed by the U.S. Fish and Wildlife Service in 1997 as in (US-EPA, 2010b) shows that as a rule, listed lepidopteran species do not occur in agricultural areas where corn is grown nor is corn considered a host plant for these species (US-EPA, 2010b). However, the map does indicate there is an overlap with corn production that is restricted to the Karner blue butterfly *(Lyceides melissa samuelis),* which is discussed in more detail below.

Karner Blue Butterfly: In its 2010 review of Cry1Ab and Cry1F, EPA determined that the Karner blue butterfly is found along the northern extent of the range of wild lupine (its host plant), where there are prolonged periods of winter snow pack, primarily in parts of Wisconsin, Michigan, Minnesota, Indiana, New Hampshire, and New York. The only state with no corn cultivation overlap is New Hampshire. Wild lupine's preferred habitat is dry, sandy soils in pine barrens, oak savannah, forest trails, and previously disturbed habitats such as utility rights-of-way, military installations, airports, highway corridors, sand roads, and abandoned sand pits (US-EPA, 2010b).

EPA concluded that Cry1 proteins are broadly active against Lepidoptera; some activity against the Karner blue would not be surprising (US-EPA, 2010b). However, toxicity testing of Karner blue larvae directly is not possible due to its endangered status. EPA discussed previous studies that tested the susceptibility of lepidopterans to Cry1 proteins and resulted in different LC50 values for different species (Luttrell *et al.*, 1999). An additional study discussed demonstrating that the Karner blue larvae were susceptible to a formulated microbial *Bt* product based on the *Bt kurstaki* HD-1 strain that contains Cry1 proteins (Herms *et al.*, 1997; US-EPA, 2010b). EPA conceded that it could be assumed that the karner blue may be susceptible to Cry1Ab, and perhaps to Cry1F, if levels of toxin in ingested pollen are high enough to adversely affect Karner blue butterflies. But, EPA also stated that the results demonstrated by Herms *et al.* (1997) showed that the Karner blue has susceptibility similar to the gypsy moth when exposed to a microbial *Bt* formulation containing Cry1 proteins, and the gypsy moth is recognized as less susceptible to Cry1Ab protein than European corn borers. Since the levels of *Bt* pollen found in the field are not toxic to European corn borers (the target pest), levels toxic to the Karner blue are also not expected (US-EPA, 2010b).

In a later discussion regarding overlap of corn pollen shed and larval emergence for Cry1Ab and Cry1F, EPA (reference) considered that the Karner blue larvae are relatively less likely to be feeding during or following the period of corn pollen shed. An analysis of pollen shed overlap with Karner blue larvae was submitted to EPA and the report indicated that there are 35 counties where Karner blue butterflies are found and corn is grown. EPA also considered additional data from the U.S. FWS, which indicated that there are 38 counties where the Karner blue is found and corn is grown. For 11 of these counties, overlap of pollen shed in certain corn hybrids and Karner blue larvae was not expected. For the other counties, the possible overlap does not happen every year, nor does is happen for more than a day or two during larval feeding. In addition, if pollen does fall on wild lupine plants, the studies done on corn pollen shed for the monarch butterfly Data Call-In (DCI) have shown that rain and wind remove large amounts of pollen. Other studies concluded that *Bt* protein in corn pollen degrades relatively rapidly in sunlight (CBI, 2001). EPA further surmised that the rapid removal of corn pollen from plant leaves and the rapid degradation of *Bt* protein in corn pollen reduces the likelihood that Karner blue larvae will encounter *Bt* protein (US-EPA, 2010b).

EPA conducted an ecological risk assessment using available data, and determined that there will be no effect on the Karner blue from the *Bt* corn registrations. The Agency based its determination on a number of factors including (1) if wild lupine were to grow adjacent to *Bt* corn fields, the amount of corn pollen shed from such fields onto the wild lupine would be insufficient to constitute a hazard to the Karner blue; (2) relevant data and information indicate that there will be relatively little, if any, wild lupine growing in the areas immediately adjacent to corn fields that are reestablished from fallow fields; (3) the amount of corn pollen shed from corn fields to adjacent areas is low; (4) available data suggest that there may be limited overlap between the period of pollen shed from corn fields with the period of Karner blue larval emergence (US-EPA, 2010b).

Monarch Butterfly: In recent years, concerns related to *Bt* crop's effect on the Monarch butterfly (*Danaus plexippus)* have surfaced. While the Monarch butterfly is not an endangered species, it is a species of historical concern to the public. Overall, the available information indicates a very low probability of risk to Monarch butterflies (*Danaus plexippus)* in areas beyond the near edge of corn fields. Inside corn fields and at the near edge of corn fields there is low probability of monarch larvae encountering a toxic level of pollen for the *Bt* corn products covered by this risk assessment. Consideration of factors limiting exposure, such as relatively low monarch breeding and pollen shed overlap in much of the Corn Belt, the distribution of milkweed plants within corn fields compared to other milkweed habitats, the egg laying and feeding activity of monarch larvae, together with the low toxicity of the *Bt* corn products covered by this assessment, indicate a low probability for adverse effects on monarch larvae.

Further, the potential impact of 1507 maize on the monarch butterfly was studied. The data indicated that 1507 maize would not pose a risk to monarch butterfly larvae (Shanahan and Stauffer, 2000; US-EPA, 2010b; USDA-APHIS, 2001). Additionally, a laboratory feeding study was conducted that exposed monarch butterfly larvae to 1507x59122 maize pollen, containing both the Cry1F and Cry34/35Ab1 proteins, at up to 1600 pollen grains/cm^2 on milkweed leaves (US-EPA, 2010c). The results of the feeding study showed no reduction in the survival, weight gain, development, and leaf consumption of the larvae and no sub-chronic effects were seen (US-EPA, 2010c). The pollen contained the Cry1F and Cry34/35Ab1 proteins; therefore, the results of this study would be applicable to assessment of 4114 maize.

Detailed Coleopteran Reviews

American Burying Beetle: In its review of Cry34/35Ab1, EPA included a discussion of the American burying beetle. Examination of an overlay map showing corn production counties as compared to the county-level distribution of the 16 endangered/threatened coleopteran species (as currently listed by the FWS) indicated that an overlap was generally restricted to the American burying beetle (*Nicrophorus americanus*) (US-EPA, 2010c). The American burying beetle's habitat includes deciduous forest, grassland, and agricultural areas. EPA concluded that because both larvae and adult insects feed exclusively on carrion with some limited adult predation, there would be little chance of exposure to *Bt* protein due to their feeding habits (US-EPA, 2010c). After careful review of the available data, EPA determined that exposure of American burying beetle to harmful levels of subject corn tissue (in the case of EPA's 2010 review, Cry34/35Ab1 corn tissue) was not expected.

Other Endangered Coleoptera: Only two coleopteran species, the Salt Creek Tiger Beetle (*Cicindela nevadica lincolniana*; Family: Carabidae) and the Casey's June Beetle (*Dinacoma caseyi;* Family: Scarabidae), have been added to the threatened and endangered insect species list (US-FWS, 2010; US-FWS, 2011b) since the approvals of 1507 maize and 59122 maize. However, the Salt Creek Tiger Beetle is the only one of the two found in the Corn Belt, specifically in Nebraska (Lancaster and Saunders counties), which is the third largest state for corn cultivation (US-FWS, 2010; USDA-NASS, 2010a). This beetle's critical habitats have been characterized as non-vegetated stream banks or edges that are in saline or freshwater wetlands, and the beetles prefer to be within a few meters of these habitats (US-FWS, 2010). Wetland areas, stream edges, or saline wetlands are not likely to be planted with corn. The Casey's June beetle is not found in any of the top corn growing states, and in fact is found in only one area in the U.S. near Palm Springs, California. This beetle's preferred habitat is sandy areas associated with desert scrub vegetation located on alluvial fans, much like the area it currently inhabits in Riverside County, California.[i] While corn is grown in California, it is grown in counties farther north near San Francisco (USDA-NASS, 2010b). Based on preferred habitat, it is highly unlikely that these beetles will be exposed to the Cry34/35Ab1 protein from 4114 maize. EPA also concluded that a review of the preferred habitats of other coleopteran species, listed as endangered by the U.S. Fish and Wildlife Service, indicated that no exposure to harmful levels of the subject protein (Cry34/35Ab1 protein) would take place (US-EPA, 2010c) due to the lack of exposure and geographical and habitat limitations. These other coleopteran species are located in non-corn production areas and/or their habitat does not encompass agricultural areas.

Ladybird Beetle Species: Toxicity of the Cry1F and Cry34/35Ab1 protein on representative non-target coleopteran species was evaluated for both 1507 maize and 59122 maize (Hunst and Rood, 2004; Shanahan and Stauffer, 2000; US-EPA, 2010b; US-EPA, 2010c; USDA-APHIS, 2001; USDA-APHIS, 2005). The lady beetle *Hippodamia convergens* was tested with the Cry1F and Cry34/35Ab1 proteins. In addition, *Coleomegilla maculata* was also tested for Cry34/35Ab1. None of the species tested showed significant adverse effects from the proteins, and the margins of exposure were greater than 13-fold. In addition, the EPA reviewed data from two studies that provided additional evidence for lack of impact of Cry34/35Ab1 on non-target Coleoptera. In one study, the toxicity of the purified Cry34/35Ab1 protein to carabid beetles (*Poecilus cupreus*) was assessed (US-EPA, 2010c). No statistically significant differences were observed in the populations fed Cry34/35Ab1 and the control. This study confirmed that, at field concentrations, there would be no impact of the proteins on carabid beetles. In the second study, the possibility of impact of the Cry34/35Ab1 protein in predator-prey feeding interactions was examined (US-EPA, 2010c). There was no effect on ladybird beetle (*Coleomegilla maculata*) larvae that were consuming aphids that had been feeding on corn plants expressing the Cry34/35Ab1 protein. Because levels of the Cry34/35Ab1 protein in 4114 maize pollen are comparable to or lower than those of 59122 maize, these studies and their conclusions are relevant to 4114 maize.

Based on these studies, non-target coleopteran species, including threatened or endangered Coleoptera, are not likely to be impacted by the Cry1F and Cry34/35Ab1 proteins at the expected environmental concentrations for 4114 maize (for more information, see Petition page 158).

Corn Gene Flow

Gene flow is a biological process that facilitates the production of hybrid plants, introgression of novel alleles into a population, and evolution of new plant genotypes. Gene flow to and from an agro-ecosystem can occur on both spatial and temporal scales. In general, plant pollen tends to represent the major reproductive propagule that can transverse space, while both seed and vegetative propagules tend to promote the movement of alleles across time and space. The rate

[i] Federal Register / Vol. 76, No. 184 / Thursday, September 22, 2011.

and success of gene flow is dependent on numerous external factors in addition to the donor/recipient plant. General external factors related to pollen-mediated gene flow include the presence, abundance, and distance of sexually-compatible plant species; overlap of flowering biologic cyclic events between populations; the method of pollination; the biology and amount of pollen produced; and weather conditions, including temperature, wind, and humidity (Mallory-Smith and Zapiola, 2008). Seed-mediated gene flow (*e.g.*, gene flow from volunteer plants) also depends on many factors, including the absence, presence, and magnitude of seed dormancy; contribution and participation in various dispersal pathways; and environmental conditions and events.

Corn is self-compatible and wind-pollinated (for more information, see Petition page 145). In the U.S., there are no native plant species that can be pollinated by corn pollen without human intervention (*e.g.*, chromosome doubling or embryo rescue) (US-EPA, 2010c). However, teosinte (wild progenitor of corn) can sometimes be found as introduced populations in botanical gardens and as feral populations of *Zea mexicana* in Florida, Alabama, Maryland (USDA-NRCS, 2011b), and *Zea perennis* in South Carolina (USDA-NRCS, 2011a). Feral populations of the closely related and sexually compatible subspecies of *Z. mays* spp. *parviglumis* and ssp. *mexicana* have also been reported in Florida, Maryland, and Alabama (USDA-NRCS, 2011b; USDA-NRCS, 2012). Evidence of introgression of genes from corn into U.S. teosinte populations has not been sought, but complex mechanisms of incompatibility have been described (Kermicle and Evans, 2010).

Corn plants do not produce clonal structures nor can corn plants produce vegetative propagules. Therefore, asexual reproduction and gene flow as a result of dispersal of vegetative tissues does not occur with corn.

Intra-Species Gene Flow

Many varieties of corn are cultivated in the U.S. In order for gene flow to occur between corn varieties, flowering of the populations must overlap, pollen transfer must occur, embryo/seeds must develop, and hybrid seed must disperse and establish. Corn is a monoecious, out-crossing, wind-pollinated crop that produces abundant, large, and heavy pollen. The reproductive morphology of corn encourages cross-pollination between corn plants and there is no evidence (genetic or biological barriers) to indicate that gene flow is inherently restricted between genetically modified, conventional, and organic corn.

A variety of plant properties, environmental conditions, and imposed conditions can affect movement of genes between corn cultivars. These considerations apply separately to include both pollen-mediated gene flow as well as seed-mediated gene flow. Spatial and temporal isolation can be one of the most effective barriers to gene exchange between corn crop cultivars (Mallory-Smith and Zapiola, 2008). Current practices for maintaining the purity of hybrid seed production in corn are typically successful for maintaining 99% genetic purity, though higher instances of out-crossing can occur (Ireland *et al.*, 2006). For example, the NOP has requirements for organic plans to address pollen flow from GE crops that include recommendations for spatial isolation(Krueger, 2007; Kuepper *et al.*, 2007). The Association of Official Seed Certifying Agencies (AOSCA) also has information for specialty corn crops, and a protocol for growing non-GE corn (AOSCA, 2000).

Pollen-Mediated Gene Flow

As noted, a primary spatial mechanism to maintain corn genetic purity is isolation distance. In 2008, a review of studies investigating gene flow and cross-fertilization studies in corn grain production fields was conducted. Using the data from these studies, 50 meters (m) (approximately 164 feet (ft)) was recommended as the distance needed to isolate GE corn from non-GE corn (Sanvido *et al.*, 2008). The authors limited their analysis to studies that confirmed fertilization in the non-GE corn plants, and excluded studies on pollen dispersal that only measured pollen flow, because pollen flow does not necessarily result in fertilization (Sanvido *et al.*, 2008). Successful cross-fertilization requires many different biological and physical factors, such as synchrony of flowering between corn fields, viability of pollen, and absence of physical barriers, and thus pollen dispersal alone is not a measure of cross fertilization. (Sanvido *et al.*) analyzed existing studies and found that the cross-fertilization rate in non-GE corn typically remained below 0.5 percent at this distance . This result was validated when large scale studies were analyzed for cross-fertilization events (Henry *et al.*, 2003; Weber *et al.*, 2007).

An isolation strategy alone may or may not be adequate for limiting gene flow, depending upon seed varieties used and local conditions. One study by Jones (1950) found cross-fertilization to be as high as 2.5% at 660 ft, which is the isolation distance used by AOSCA to isolate corn fields for seed production (AOSCA, 2009). One potential reason for the discrepancy between this study and many other gene flow studies in corn may be due to the type of corn used; Jones and Brooks (1950) investigated the appropriate isolation distance for seed production in open-pollinated varieties, not in hybrid varieties. Due to the biology of open-pollinated varieties, these types of plants may be more receptive to pollen over a longer period of time than hybrid corn plants (Sanvido *et al.*, 2008), allowing for a greater chance of cross-fertilization events.

For gene flow to occur between corn varieties, flowering of the source and sink populations must overlap, pollen transfer must occur, embryo/seeds must develop, and hybrid seed must disperse and establish. A recent study indicated that cross-pollination of commercial corn cultivars at 100 feet downwind from the source of genetically modified corn was 1%, and this proportion declined exponentially to 0.1% at 130 feet and further declined to 0.03% at 160 feet. At 160 feet, the farthest distance measured, .03% cross-pollination was detected (US-EPA, 2000). For production of foundation seed, a distance of 660 feet has generally been required to mitigate out-crossing between different genotypes. The relatively large size of corn pollen and its short viability period under most conditions reduce long distance transfer for purposes of outcrossing. Under conditions of high temperature or low humidity, corn pollen may only survive for a matter of minutes. Under more favorable conditions in the field or with controlled handling in the laboratory, pollen life may be extended to several hours.

Seed-Mediated Gene Flow

In order for gene flow to occur via seeds and result in feral populations of corn, seeds must disperse and establish themselves in new habitats. Through thousands of years of selective breeding by humans, corn has been extensively modified to depend on human cultivation for survival (Galinat, 1988). Several key weedy traits that would contribute to crop escape – traits associated with ferality and volunteerism – have been selectively reduced in corn, resulting in a domesticated crop species not equipped for survival without management (Gould and Shaw, 1983). Also, several traits greatly reduce the ability of corn to disperse via seeds. Humans have selected corn to produce seeds that do not shatter and cannot disperse from the cob, and corn seeds are tightly bound within a protective sheath of leaves (*i.e.* husks) (Galinat, 1988). Corn seeds also lack dormancy, preventing easy persistence between seasons in fields or in the weed seed bank. While corn grains or cobs left in fields after harvest can result in volunteers in the following year, these volunteers are not likely to produce progeny and persisting populations because of the tightly bound nature of the corn seeds to the cob.

2.4. Human Health

Consumer Health

The primary food uses of corn are from grain, and approximately 10% of U.S. corn grain is used for food products (NCGA, 2011c). Although corn is widely grown worldwide with overall production at over 700 million tons per year and is the fourth most consumed food calorically, it is not considered a major allergenic food (Hefle *et al.*, 1996; Moneret-Vautrin *et al.*, 1998). In a few case studies, allergenic reactions were reported and corn allergens identified. Specifically, the 9 kDa Zea m 14 protein (*i.e.,* the corn lipid transfer protein (LTP)) was identified as the major allergenic protein in corn (Fasoli *et al.*, 2009; Pastorello *et al.*, 2000; Pastorello *et al.*, 2003). LTPs are small proteins that facilitate the transfer of phospholipids and other lipids across membranes. These proteins are widely distributed throughout the plant kingdom and belong to the pathogenesis-related (PR) protein family (Hoffmann-Sommergruber, 2002). The Cry1F, Cry34Ab1, Cry35Ab1, and PAT proteins are neither related to LTPs nor involved in lipid transfer across membranes.

The Cry1F, Cry34Ab1, and Cry35Ab1 proteins were derived from *Bt*, which is a naturally-occurring, common bacterium that is not a known mammalian pathogen and is present in soil, dust, insects, and leaves (McClintock *et al.*, 1995; Schnepf *et al.*, 1998; US-EPA, 1998). Some strains of *Bt* have been shown to be opportunistic pathogens; however, this pathogenicity was not related to the *Bt* proteins (Hernandez *et al.*, 1999). *Bt* microbial preparations containing Cry proteins have been used safely as pesticide sprays for decades, and have been deemed to pose no toxic effects to mammals (US-EPA, 1998). These proteins have been present in commercial corn varieties such as 1507, 59122, and/or 1507x59122 maize since 2003, 2006, and 2006, respectively.

The PAT protein from *Streptomyces viridochromogenes* has a safe history of exposure to humans, animals, and the environment. The source organism *S. viridochromogenes* is widespread in soil and is not associated with human, animal, or plant pathogens (Hérouet *et al.*, 2005). Related PAT proteins are found in at least six other species of common soil bacteria, none of which have been reported as toxic or allergenic to humans or animals (Hérouet *et al.*, 2005). Furthermore, PAT has been a protein present in commercial corn events, as well as other crops, since 1996.

Mycotoxins: Chemicals known as mycotoxins are produced by fungi, and they are toxic or carcinogenic to animals and humans. The most commonly occurring mycotoxins on corn are produced by the fungal genus *Fusarium*, and are known as fumonisins (Munkvold and Hellmich, 2000). There are several different kinds of fumonisins: FB1, FB2, FB3, FB4, FA1, and FA2 (Marasas, 1996). Another class of corn mycotoxins, the well-known group of aflatoxins, is produced by the genus *Aspergillus*. The economic impact of aflatoxins is greater than that of other mycotoxins, because they can be passed into milk upon dairy cow's consumption of contaminated grain (Munkvold and Hellmich, 1999).

Injury by insect pests can be an important factor for mycotoxin development in corn. Insect pests promote the growth of mycotoxin-producing fungi in two ways: 1) they carry fungal spores from the plant surface to the surfaces of damaged kernels, and 2) they create entry wounds on the kernels for the fungi. Even when the insect pests do not directly carry fungal spores to the corn wounds, ambient spores deposited later on tissue wounded by pest feeding are more likely to infect the plant (Munkvold and Hellmich, 1999). Field studies have shown that damage due to southwestern corn borer (SWCB) can increase aflatoxin levels (Windham *et al.*, 1999). Documented toxicological effects of fumonisins in laboratory studies include toxicity and carcinogenicity in rats, cytotoxicity to mammalian cell cultures, and phytotoxicity to weeds and other plants including tomatoes (inhibiting growth and chlorophyll synthesis) (Marasas, 1996). When mycotoxin contamination occurs in corn, the potential damages can be both economic costs to growers and health risks to humans and livestock.

One of the benefits of *Bt* corn is that it has drastically reduced contamination by the mycotoxin fumonisin. This is because *Bt* corn is far less prone to insect injury, which in turn prevents the growth of fumonisin producing fungi. Certain events of *Bt* corn, such as MON810 and Bt11, can reduce fumonisin levels by as much as 90% (Munkvold and Hellmich, 2000). This reduction in corn also reduces the exposure and potential negative effects to livestock and presumably to humans as well. Therefore, *Bt* corn can potentially reduce mortality and morbidity among livestock and, presumably, humans (US-EPA, 2010b).

Worker Health

Agriculture is one of the most hazardous industries for U.S. workers. As a result, Congress directed the National Institute of Occupational Safety and Health to develop a program to address high-risk issues related to occupational workers. In consideration of the risk of pesticide exposure to field workers, EPA revised its Worker Protection Standard (40 CFR Part 170) in 1992 to further protect field workers from the hazards of pesticide exposure. Furthermore, the Occupational Safety and Health Administration requires all employers to protect their employees from hazards associated with pesticides.

Pesticides, especially herbicides, are used on most corn acreage in the U.S., and changes in acreage, crops, or farming practices can affect the amounts and types of pesticides used and thus the risks to workers. Pesticide registration involves the design of use restrictions that, when followed, have been determined to protect worker health. *Bt* corn products labeled for general use offer an alternative to restricted use products and provide growers and other occupational workers greater safety. Additionally, it provides fewer adverse environmental impacts, compared to use of chemical insecticides (US-EPA, 2010c; US-EPA, 2010b).

The *Bt* proteins in 4114 maize, Cry34/35Ab1 and Cry1F are expected to be safer for handlers, applicators, farmers, and the public than chemical pesticides in current use. Twenty-five of the 39 registered conventional insecticides used to control corn rootworm (CRW) are classified as "Restricted Use," 12 have the "Danger" label classification, and several are in Agency Special Review[j] (*e.g.*, dimethoate, phorate, and terbufos). Each year there are confirmed reports of human illness associated with these registered chemical insecticides (US-EPA, 2010a).

Adoption of Cry34/35Ab1 and Cry1F corn hybrids has the potential to reduce occupational, farmer, and public health risks associated with the manufacture, transportation, storage, handling, application, and disposal of conventional insecticides, by providing a safer alternative for corn rootworm control (US-EPA, 2010c; US-EPA, 2010b).

2.5. Animal Feed

Of the corn grain that is used for feed, the greatest percentage is consumed by beef cattle, followed by poultry, hogs, and dairy cattle (Figure 13; (NCGA, 2011c). A number of different products from the corn plant and from grain processing may be used as feed.

The whole corn plant or its residue from harvesting is frequently used as animal feed. Silage, derived from the above-ground portions of the corn plant, is an important feed ingredient for feedlot cattle and dairy cattle and preserves more than 90% of nutrients (OECD, 2002). In 2009,

[j] EPA uses the Pesticide Special Review process when it has reason to believe that the use of a pesticide may result in unreasonable adverse effects on people or the environment. The Special Review process usually involves intensive review of only a few or just one potential risk. The review involves evaluating existing data, acquiring new information and/or studies, assessing the identified risk and determining appropriate risk reduction measures.

approximately 7% of the U.S. corn crop was used for silage (USDA-NASS, 2010a). In addition, stalks from harvested corn plants can be grazed by ruminants in the field (OECD, 2002).

Corn ears, without shelling (*i.e.*, removing the grain from the cob), can be ground directly for ruminant feed (OECD, 2002). When ears are shelled to remove the grain, remnant cobs can also be used in animal feed (OECD, 2002). Corn grain can be fed to animals with minimal processing and can be fed whole, rolled, ground, or steam flaked (OECD, 2002). Rolled or ground grain is fed to swine and poultry (OECD, 2002). Corn grain added to pet foods is ground, cooked, and pelleted or extruded (OECD, 2002).

As described earlier, processed products from the milling and ethanol fermentation processes are also fed to livestock. A by-product of the wet milling process, corn gluten meal, is fed to ruminants, poultry, and swine (OECD, 2002; USDA-NASS, 2007). The ethanol fermentation process produces a co-product called distillers dried grains/solubles or corn gluten feed that is used as animal feed to dairy and beef cattle, poultry, and swine (USDA-ERS, 2009b; USDA-ERS, 2010f; USDA-NASS, 2007).

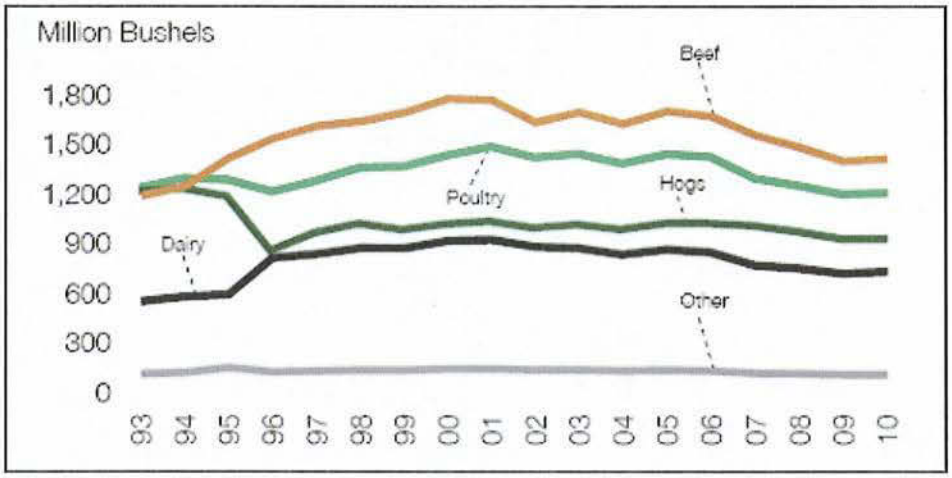


Figure 13. U.S. Corn Fed by Animal Group, 1993-2010
NCGA, 2011c

2.6. Socioeconomic

Domestic Economic Environment

Corn is the largest crop grown in the U.S. in terms of both acreage and net value. Corn has multiple downstream uses for feed, fuel, and food that are significant for U.S. and global supply. In the U.S. in 2010, over 12 billion bushels of corn were produced from nearly 81 million harvested acres, with a resulting crop value of $65.97 billion (NCGA, 2011c; USDA-NASS, 2011c). Financial breakouts for feed, fuel, and food uses are $25.5 billion, $24.1 billion, and $6.7 billion, respectively (NCGA, 2011c). Notably, the market values of feed and ethanol are very similar, and three quarters of the corn used in the U.S. is used for these two purposes.

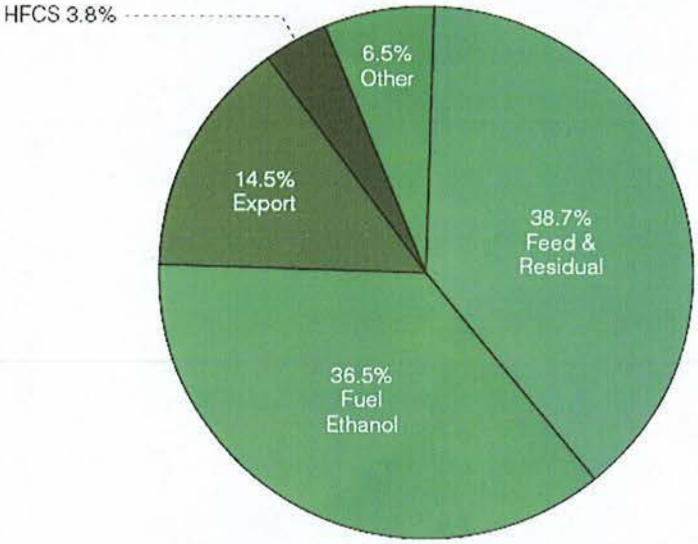


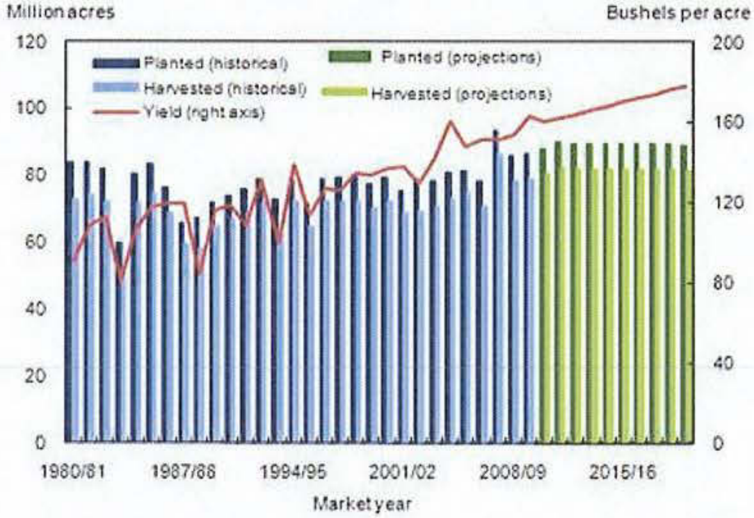
Figure 14. U.S. Corn Usage by Segment, 2010
HFCS: High-fructose corn syrup.
Note: The "Other" category includes food use at approximately 6.3% and seed use at approximately 0.2%.
NCGA, 2011c

Corn has the highest financial returns in the feed grain sector (USDA-ERS, 2010c). Additionally, the projected 2011-12 corn prices are expected to be between approximately $6.20 and $7.20 per bushel due to the increased demand and limited supply of corn (Johnson, 2011). Based on the predicted increased demand for corn as source material for ethanol production presented in section 2.1F, as well as the expected higher net returns for corn relative to other crops, cultivated corn acres are expected to rise slightly in coming years and corn yields are expected to rise significantly (USDA-ERS, 2010c). Over the past decade, these yield increases were a result of improvements in seed varieties and agronomic practices.

According to the USDA, these improvements will continue to increase yields in the future:

> *"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. 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."* and, *"Gains continue to be supported by improved genetics, including advances in plant utilization of water and fertilizer."* (USDA-ERS, 2010c).

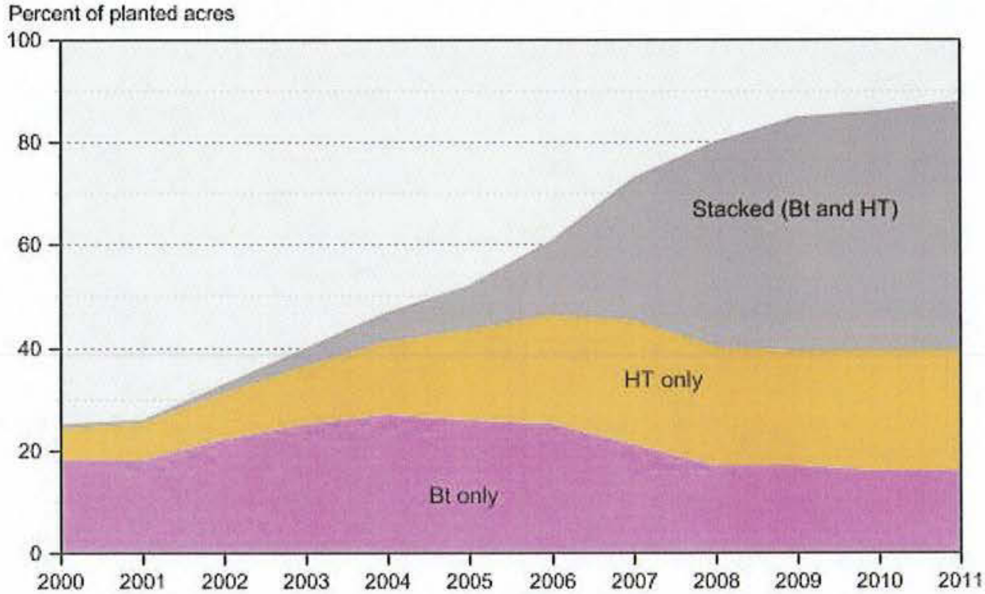
USDA's projections for corn acres planted and corn yields can be observed in Figure 15 below.



Source: *USDA Agricultural Projections to 2019*, February 2010.
Economic Research Service, USDA.

Figure 15. U.S. Corn Area and Yield
USDA-ERS, 2010c

A significant portion of corn cultivated in the U.S. is genetically engineered. In 2011, 88% of corn grown in the U.S. was genetically engineered; insect resistant varieties accounted for approximately 65% of all corn acreage (USDA-ERS, 2011a). These numbers were each 2% above those in 2010 [86% and 63% respectively (USDA-ERS, 2011a)]. The increasing and overall high percentage of cultivated genetically engineered corn demonstrates farmers' acceptance of the technology as beneficial and valuable to their overall business operations. Figure 16 illustrates both the adoption trend in genetically engineered corn, as well as the adoption of HT and *Bt* corn specifically.



Source: Data for 2000-11 are available in the ERS data product, Adoption of Genetically Engineered Crops in the U.S., table 1.

Figure 16. Adoption of Genetically Engineered Corn in the U.S. by Trait, 2000-2011
USDA-ERS, 2011a

Corn acres are expected to increase slightly and any major increases in corn output are expected to be a result of yield increases. To keep pace with increasing corn demand both domestically and globally, new corn trait offerings must be designed to assist farmers with increasing crop yields through protective benefits.

Trade Economic Environment/Export Markets

In 2010, the U.S. exported 14.5% (or roughly $9.6 billion) of the corn it produced (Figure 14; (NCGA, 2011c). The U.S. contributes approximately 55% of the corn for the world export market (NCGA, 2011c). The largest customers for U.S. corn in 2009-10 were Japan, Mexico, South Korea, Taiwan, Egypt, and Canada (NCGA, 2011c).[k] USDA predicts that the overall global export market for corn is expected to increase between 2010 and 2020; however, the U.S. share of corn trade is expected to decrease (USDA-ERS, 2010c). This decrease in U.S. export is expected to be offset by domestic corn use increases for ethanol production and corn based-sweeteners (USDA-ERS, 2010c). A visual representation of the predicted export market for corn is presented in Figure 17.

[k] In terms of international grain trade and Pioneer's 4114 maize event as a component of current or new complex stacked-trait products, will be registered in international markets to ensure grain compliance upon import. Pioneer will not commercialize any of its products in any country, including 4114 maize, until such time that all appropriate international regulatory clearances have been obtained.

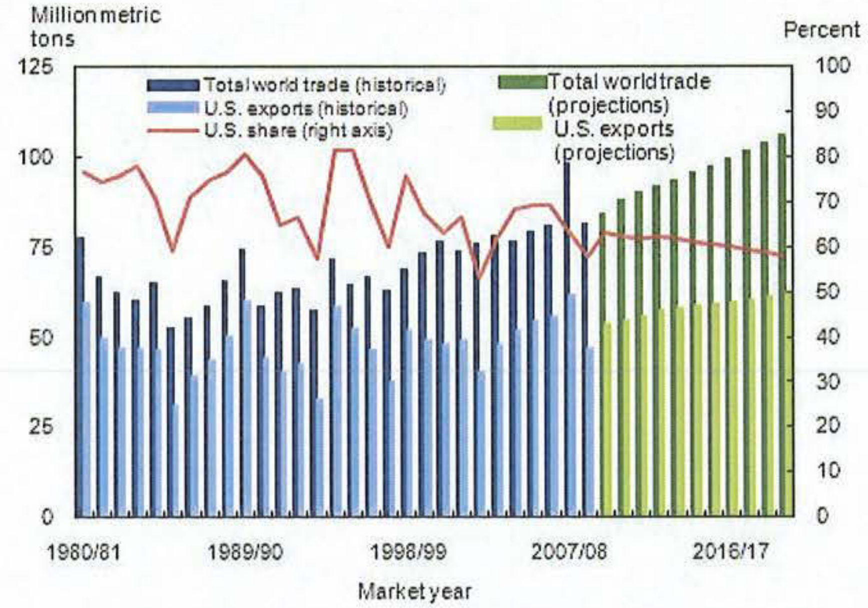


Figure 17. World and U.S. Corn Trade
Source: USDA-ERS, 2010c

Increased global demand for meat is expected to boost world consumption of feed; however, production constraints will preclude most importing countries from increasing their own corn production commensurately to meet the demand, resulting in an increase in the global grain trade (USDA-ERS, 2010c). While China historically has been a large exporter, during the 2010-20 time frame it is predicted to become a net importer of corn (USDA-ERS, 2010c); Argentina will hold its position as the second largest exporter; and Ukraine is expected to increase its role as an exporter of corn to become the third largest corn exporter internationally (USDA-ERS, 2010c). Additionally, steady long-run growth in the livestock sectors of developing countries in Latin America, Asia, North Africa, and the Middle East are projected to account for much of the growth in world coarse grain imports during the next decade (USDA-ERS, 2010c).

In addition to grain exports, the U.S. also contributes heavily to export markets for corn-derived products. In 2010 the U.S. sent a record 350 million gallons of ethanol to overseas markets and for the first time became a net exporter of fuel ethanol generating a trade surplus of $556 million (Figure 18) (RFA, 2011b; USDA-FAS, 2011).

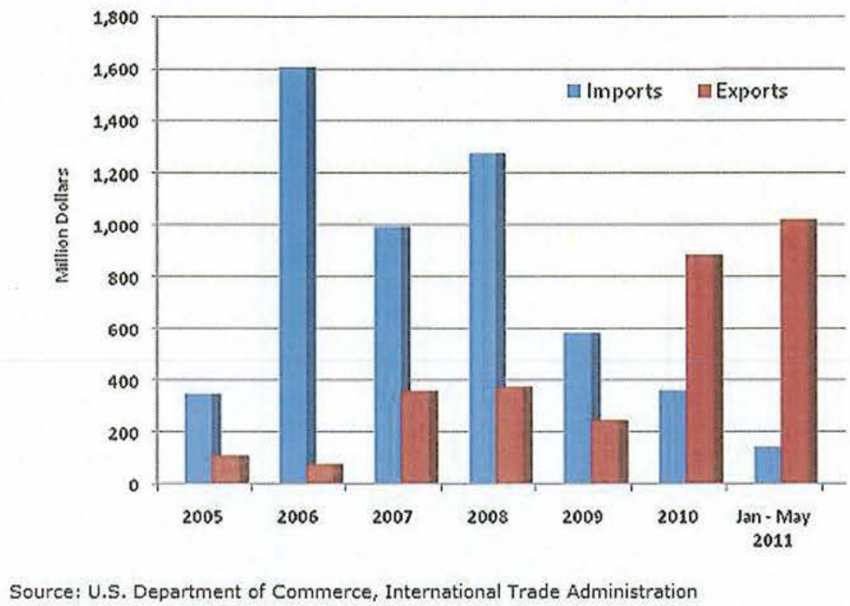


Figure 18. U.S. Ethanol Trade Balance, 2005-2011
Source: USDA-FAS, 2011

In USDA's publication, "*U.S. on Track to become World's Largest Ethanol Exporter in 2011*" (USDA-FAS, 2011) the ethanol export market is discussed as follows:

> *"…in 2010 the United States became the global low-cost ethanol producer, manufacturing 13.2 billion gallons – enough to not only meet U.S. demand for 12 billion gallons of fuel ethanol, but also to generate $825 million in export revenues. Through the first five months of 2011, the United States has already exceeded the 2010 export level and is on pace to surpass Brazil as the world's largest ethanol exporting nation in 2011.";*
>
> and
>
> *"2011 is off to an even more impressive start, with U.S. ethanol exports through May approaching 400 million gallons, valued at more than $1 billion, surpassing the total for all of 2010."*

The increase in ethanol production also increased the amount of distillers grains (DDGS) (*i.e.* livestock feed) available for export, which reached a record 9 million metric tons in 2010. Mexico is the top importer of U.S. DDGS products; however China's imports of DDGS have increased significantly since 2008/2009 making them the third largest importer of this product (Giamalva, 2011; USDA-FAS, 2010). Table 8 lists the countries to which the U.S. exports DDGS with associated amounts.

Table 8. U.S. Production, Exports, and Average Unit Value of DDGS, 2005-2009 and January-October 2009 and 2010, Thousand Metric Tons

	2005	2006	2007	2008	2009	Interim 2009	Interim 2010
Production	9,000	12,000	14,600	23,000	30,500	NA	NA
Exports	1,062	1,252	2,357	4,510	5,641	4,561	7,567
Mexico	128	367	708	1,189	1,459	1,195	1,396
Canada	105	122	318	772	804	603	839
China	0	0	1	9	542	336	2,163
All Other	828	763	1,330	2,541	2,836	2,426	3,170
	Average Unit Value, U.S. Dollars per Metric Ton						
China	--	--	112	221	186	178	197
All Other	106	129	166	217	170	171	168

Giamalva, 2011

3. Alternatives

4114 maize is a new transformation event that, if deregulated, will provide an alternative in complex breeding stacks to the breeding stack combination of two previously approved events (1507 maize, which expresses the Cry1F and PAT proteins, and 59122 maize, which expresses the Cry34Ab1, Cry35Ab1, and PAT proteins).

As a new event with all genes located at a single locus, 4114 maize will be bred more efficiently into new product offerings for growers that are customized to their local insect protection and agronomic needs. The safety of the introduced proteins in 4114 maize has been previously evaluated by regulatory agencies in the U.S., as referenced above, and there is a history of safe use and exposure.

Table 9 briefly summarizes the results for each of the issues raised in the Environmental Consequences (Section 4) for the following alternatives:

- **Alternative A**: **No Action**—Continuation as a Regulated Article.
- **Alternative B**: **Preferred Alternative**—Determination that 4114 maize is no longer a Regulated Article.

Table 9. Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	**Alternative A: No Action** (Continued use of 1507x59122 Maize)	**Alternative B: Determination of Non-regulated Status** (Use of 4114 Maize in Complex Breeding Stacks as an Alternative to 1507x59122 Maize)
Meets Purpose and Need	**No**	**Yes**
Not Likely to Pose a Plant pest Risk	Satisfied through use of regulated field trials	Awaiting USDA-APHIS plant pest risk assessment
Agricultural Production		
Land use	Unchanged	Unchanged
General Production Practices	Unchanged	Unchanged
Pesticide use	Unchanged	Unchanged
Specialty Crop Production	Unchanged	Unchanged
Organic Production	Unchanged	Unchanged
Physical Environment		
Soil Quality	Unchanged	Unchanged
Water resources	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Biological Resources		
Animal Communities	Unchanged	Unchanged
Plant Communities	Unchanged	Unchanged
Biodiversity	Unchanged	Unchanged
Human Health		
Consumer health	Unchanged	Unchanged
Worker health	Unchanged	Unchanged
Animal Feed	Unchanged	Unchanged
Socioeconomic		
Domestic Economic	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Cumulative Effects	Unchanged	Unchanged
Other Regulatory Approvals	Unchanged for existing deregulated GE organisms	Completion of FDA consultation pending; Section 3 application pending at EPA

4. Environmental Consequences and Cumulative Impacts

4.1. Agricultural Production

4.1A. Land use

The largest crop acreage in the U.S. is corn, with most of its production located in the Midwest. In the last several years there has been an increase in planted corn acres largely due to the increasing demands for ethanol and growers' pursuit of perceived higher economic returns. Currently, 88% of corn planted is GE, and future trend analysis indicates that GE crops will continue to be adopted but at a slower pace than previous years (USDA-ERS, 2010c; USDA-ERS, 2011a). Total corn production acreage is projected to increase slightly but then level off by year 2018; however, corn yields will continue to increase (USDA-ERS, 2010c).

- **Land Use - No Action Alternative**

  Current trends of land use in corn production, including GE corn, will likely continue unchanged. Under the No Action Alternative, areas where corn is grown would still use the breeding stack of 1507x59122 maize and therefore land use would not be impacted. 4114 maize would still be a regulated article grown only through regulated field trials.

- **Land Use - Approved Petition Alternative**

  Although it is difficult to predict adoption rates of HT, IR, or stacked IR/HT GE corn in the U.S., the availability of Pioneer 4114 maize would not materially change the number of acres of GE corn. The Cry1F, Cry34/35Ab1 and PAT traits in 4114 maize are currently used in approximately 16% of the total corn production in 2011. 4114 maize would not be commercialized as a stand-alone product, but is expected to replace the "breeding stack" of 1507x59122 maize (Cry1F, Cry34/35Ab1, and PAT) in complex breeding stacks. A determination of non-regulated status for 4114 maize would not significantly increase or decrease the annual acreage planted with corn or the geographic distribution of corn cultivation in the U.S.

- **Cumulative Impacts - Land Use**

  Currently 1507x59122 maize is a component of many HT and IR stacked trait products, and 4114 maize as an alternative to 1507x59122 maize is also expected to be a component of these same HT and IR stacked trait products. In the short to mid-term, the number of stacked trait combinations is not expected to change if 4114 maize is deregulated. However, it is possible the variety of hybrids and germplasm utilized for a given stacked trait combination could increase slightly, resulting in increased availability of products. This could, in turn, slightly increase the market penetration and acreage of the HT and IR traits, although market demand will be a much bigger factor.

Overall the deregulation of 4114 maize will not impact land use in terms of the geographic areas or acreage planted to corn. In the short to mid-term, there will be no impacts on the amount and type of stacked trait corn products planted in the U.S. In the long term there could be some small shifts in the amount or type of stacked trait products that use 4114 maize, but these shifts will be minimal compared to the overall market drivers for stacked trait products.

4.1B. General Production Practices

Cropping Practices

Growers make choices to plant certain varieties and use certain cropping practices, based on factors such as yield, weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system. Changes in cultivation or management practices such as planting times, row spacing, irrigation, crop residue management, tillage or pesticide use are based on individual requirements. 4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. The cultivation and management practices for 1507x59122 maize are similar to conventional corn. Pioneer studies demonstrate 4114 maize is essentially indistinguishable from other corn varieties used in terms of agronomic characteristics and cultivation practices.

- **Cropping Practices - No Action Alternative**

  Under the No Action Alternative, the production of corn will not change from the current cropping practices. Growers will continue to make choices on which existing corn variety and cropping practices are best for their needs.

- **Cropping Practices – Approved Petition Alternative**

  Approval of 4114 maize will not change cropping practices as they are presently performed. It has been determined that 4114 maize effectively features the same phenotypic, agronomic, ecological, and compositional characteristics as 1507x59122 maize and it is anticipated that cropping practices will also be similar. 4114 maize is expected to be more efficiently bred into a wide variety of corn genetic backgrounds and with additional traits, thus giving growers more choice in products that offer in-plant insect protection and that are customized to their local growing areas and production practices. In 2011, the products using 1507x59122 maize were planted on approximately 16% [1] of the total U.S. corn acres.

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[1] 4114 maize in the environment was calculated by dividing the number of acres of 1507x 59122 by total corn acres in 2011.

- **Cumulative Impacts - Cropping Practices**

  No cumulative impacts are expected, as corn production practices will not change with the deregulation of 4114 maize. Pioneer's 4114 maize would not use different cropping practices than what is currently being used on genetically engineered and conventional products. Furthermore, it is unlikely that 4114 maize would result in changes of cropping practice with future multi-trait products; results in change to stacked corn products cropping practices would be due to other transgenic properties unrelated to 4114 maize.

Tillage

Growers also make choices on how they prepare the soil for planting; reduce weeds; and incorporate fertilizer, manure, and organic matter into the soil. Genetically engineered HT crops have encouraged conservation tillage. In recent years, the proportion of growers using no-till practices in the U.S. has been increasing. The increase in the use of no-till or minimum-till may be correlated to the increased adoption of HT crops. However, in some areas of the U.S., HT crops have seen an increase of conventional tillage due to the presence of glyphosate-resistant weeds but largely not glufosinate-resistant weeds (Duke and Powles, 2009). 4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. The tillage practices for 1507x59122 maize are similar to other HT corn.

- **Tillage - No Action Alternative**

  The trend toward increased use of conservation tillage for corn cultivation will not be positively or negatively impacted under the No Action Alternative. Growers have existing choices of IR and HT stacked varieties which are compatible with reduced tillage practices.

- **Tillage - Approved Petition Alternative**

  Approval of 4114 maize will not impact the trend toward increased conservation tillage. 4114 maize will be more efficiently incorporated into a wide variety of corn genetic backgrounds with additional traits. These traits will be compatible with reduced tillage practices that are currently employed.

- **Cumulative Impacts - Tillage**

  GE corn allows growers to use tillage methods that conserve soil health and moisture and reduce soil erosion (Duke and Powles, 2009). There are already HT and IR corn varieties in the marketplace and 4114 maize will provide a molecular-stack market alternative to these existing varieties; therefore, a determination of nonregulated status for 4114 maize will have no cumulative impact on tillage practices.

Crop Rotation

In the Midwest Corn Belt, corn is commonly grown in rotation with soybeans. In other areas of the U.S., corn is rotated with many different crops including: cotton, legumes, oats, canola, and sunflower. In general, crop rotation practices help manage diseases, insects, and weeds; conserve soil moisture; and increase organic matter and soil fertility. Additional benefits have been identified for corn grown on ground that was previously planted with soybeans. These benefits include: higher yields, lower nitrogen fertilizer expense, lower pest control costs, lower tillage costs (if corn after soybeans facilitates conservation tillage), and more timely planting and harvesting. However, due to current high corn prices, growers are turning to continuous corn practices. 4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. The crop rotation practices for 1507x59122 maize are similar to conventional corn.

- **Crop Rotation - No Action Alternative**

  Under the No Action Alternative, the type of crop rotation will continue to be based on several criteria including: market needs, sustainability, yield, disease control, and cultural practices. Alternative stacked IR with HT varieties will be available if 4114 maize is not deregulated and these varieties can be incorporated into current rotational practices.

- **Crop Rotation - Approved Petition Alternative**

  Approval of 4114 maize will not change crop rotation practices. Recommendations for growers planting 4114 maize will take into account existing crop rotation practices, just as they do currently for conventional and other IR and HT corn varieties. The availability of 4114 maize will not significantly alter grower decisions regarding rotational practices.

- **Cumulative Impacts - Crop Rotation**

  Rotational practices are the same for both HT and IR stacked corn and conventional corn. The agronomic properties of 4114 maize are similar to currently available commercial corn lines, including 1507x59122 maize. A determination of nonregulated status for 4114 maize will have no cumulative impact on rotational practices.

Pesticide Use

The choice of control methods for insect, weed, and disease pests is dependent on individual grower circumstances and anticipated pest pressure. In general, the use of insecticide seed treatments, herbicides, and foliar fungicides has increased, while the use of soil and foliar insecticides has decreased over the years. 4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. The pesticide use for 1507x59122 maize is similar to other stacked IR and HT corn varieties currently on the market.

- **Pesticide Use - No Action Alternative**

  Under the No Action Alternative, pest management decisions for alternative stacked IR and HT varieties will continue to be governed by individual grower circumstances and pest pressure. Growers will continue to make decisions on the amount, type, and methods in which pesticides are used for corn production.

- **Pesticide Use - Approved Petition Alternative**

  Approval of 4114 maize will not change the pesticide usage in corn production. Since 4114 maize is expected to replace the alternative breeding stack of 1507x59122 maize, the amount, type, and methods of pesticides used will be similar. Insecticide, fungicide and herbicide use in corn fields will not be impacted by a determination of non-regulated status for 4114 maize.

- **Cumulative Impacts - Pesticide Use**

  Pioneer's 4114 maize will have no effect in the way that pesticides are used in the environment from current practices on 1507x59122 maize. The use of insecticides, herbicides, and fungicides will be unchanged in the event that 4114 maize is deregulated. There will be no significant cumulative impact in the foreseeable future.

Insecticide Use

Corn is susceptible to a variety of insect pests throughout its developmental cycle. Insect pest problems have the potential to drastically reduce crop yield and quality. Crop losses attributable to the European corn borer and corn rootworm infestations have been well characterized and are significant. The introduction of transgenic cultivars which express Cry1F protein for lepidopteran resistance and Cry34/35Ab1 protein for corn rootworm resistance have provided U.S. corn growers with a powerful tool to effectively protect crop yields and environmental benefits (Marvier *et al.*, 2007). By growing *Bt* corn, it was estimated that in 2005, the total volume of insecticides was reduced by 10% (Brookes and Barfoot, 2006). 4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. The insecticide use for 1507x59122 maize is similar to other IR corn varieties currently on the market.

- **Insecticide Use - No Action Alternative**

  Under the No Action Alternative, growers will continue to ask for *Bt* products, including stacked trait products. The trend for planting *Bt* stacked products has been one of significant increase since 2006 and this trend is not likely to change in the near future. Alternative stacked IR varieties will be available if 4114 is not deregulated. These varieties may result in a continued decrease in insecticide use in corn.

- **Insecticide Use - Approved Petition Alternative**

  Approval of 4114 maize will have no impact on insecticide use. Transgenic cultivars, which express Cry1F protein for lepidopteran resistance and Cry34/35Ab1 protein for corn rootworm resistance, are currently in the marketplace. To the extent that pesticides are currently used on products containing 1507x59122 maize, the same will be true for products containing 4114 maize.

- **Cumulative Impacts - Insecticide Use**

  The availability of 4114 maize in complex breeding stacks with future IR traits with expanded pest spectrum could enable further reduction in the amount of insecticides used in the environment. If this happens, the use of insecticides in the foreseeable future could decrease.

Multiple Trait Corn Use

The majority of corn products grown in the U.S. today contain at least one IR trait and one HT trait (often in one transgenic event, such as 1507 maize, 59122 maize, MON88017 maize, and Bt11 maize). In addition, there is a strong demand for corn products that have glyphosate tolerance. Even if a corn product contains a glufosinate tolerance gene, growers prefer to use glyphosate for weed control. Therefore, many corn products grown in the U.S. today contain two HT traits.

The newer *Bt* corn products contain multiple IR traits brought together using conventional breeding (1507x59122 maize) or molecular stacking (MON89034). A "pyramid" is a product containing two or more *Bt* traits that target the same insect pests (*i.e.*, 1507xMON810 maize, which contains Cry1F and Cry1Ab for pyramided control of European corn borer and other lepidopteran pests). Corn products with "pyramided" *Bt* traits enable refuge reduction and refuge integration (*i.e.*, blended refuge "in the bag") while maintaining trait durability. Growers want multiple traits in GE corn seed products to effectively control pests and have the most desirable refuge deployment strategy for their operations. The penetration of stacked trait corn has increased over the past decade (Figure 4) and is expected to increase further as growers continue to demand corn with multiple IR traits.

In addition, there are several new traits under development by technology providers, some of which have been deregulated by USDA or are under review. These include the following:

- corn with tolerance to 2,4-D and certain aryloxyphenoxy-propionate (AOPP) herbicides (*e.g.,* quizalofop, cyhalofop, and haloxyfop)
- corn with yield protection under drought stress
- *Bt* corn with next-generation corn rootworm resistance
- corn with heat-stable α-amylase for ethanol production

As these traits become commercially available, it is likely they will be combined using conventional breeding with previously deregulated IR and HT traits.

- **Multiple Trait Corn Use - No Action Alternative**

  Under the No Action Alternative, there may be no impact on the use of multiple trait corn. 4114 maize will not be commercialized as a stand-alone product, but it is an alternative to 1507x59122 maize in complex breeding stacks. The industry will continue to develop new corn products by incorporating 1507x59122 maize in multiple trait products. However, the resources required to breed two transgenic events into new products and germplasm are double the resources required to breed one transgenic event into new products and germplasm. This inefficiency may prolong development of new multiple trait corn products and the time it takes to reach the marketplace more than if 4114 maize were deregulated and available for use.

- **Multiple Trait Corn Use - Approved Petition Alternative**

  If 4114 maize is deregulated, it will not be commercially deployed as a stand-alone product. 4114 maize will be used in combination with other deregulated GE corn varieties in multiple trait products. Deregulation would allow breeders to stack 4114 maize with other GE traits using a more streamlined process than the current practice of using 1507x59122 maize. Multi-trait products that growers expect and demand would enter the marketplace at a potentially faster pace.

- **Cumulative Impacts – Multiple Trait Corn Use**

  In the long term, as additional novel traits are deregulated (*e.g.,* drought tolerance, herbicide tolerance or increased nitrogen efficiency traits), 4114 maize may be a component of complex breeding stacks with these events. Because 4114 maize is able to be used in breeding programs more efficiently than 1507x59122 maize, it is possible new stacked trait combinations might be developed more rapidly or more novel trait combinations might be deployed. However, this impact will be minimal compared to unrelated market demand.

Herbicide Use

Agricultural herbicide use in the U.S. has been increasing but the active ingredients are less toxic to humans and the environment (Sanvido *et al.*, 2007). The herbicide glufosinate ammonium was registered as an herbicide in 1993. The herbicide degrades rapidly in microbially active soils, it readily binds to soil particles, and its short-lived metabolites have not been found to accumulate in the environment. The adoption of GE HT crops has allowed farmers to use herbicides (glyphosate and glufosinate) herbicides that are considered less toxic to the environment than those previously used such as alachlor, 2,4-D, atrazine, butylate and EPTC (Benbrook, 2001; Miller *et al.*, 2010; NPIC, 2009; PMEP, 2012).

- **Herbicide Use - No Action Alternative**

  Under the No Action Alternative, 4114 maize would not be available for use in complex breeding stacks, and growers would continue to plant existing varieties of glufosinate-tolerant corn. Corn acreage and adoption has been increasing but glufosinate use has remained relatively low and stable. No increase in glufosinate use is predicted if 4114 maize remains a Regulated Article.

- **Herbicide Use - Approved Petition Alternative**

  Because 4114 maize is a single-event alternative to an existing breeding stack corn variety, and because the seasonal use rate of glufosinate on 4114 maize will be identical to existing glufosinate corn varieties in the market, commercialization of 4114 maize is not expected to change the amount of glufosintate herbicide used on corn. If there were to be an increase in glufosinate resistant weeds, there could be a modest increase in herbicides other than glufosinate if corn growers use alternative herbicides to control resistant weed populations. However, this potential increase in the use of alternative herbicides would occur whether or not 4114 maize is deregulated and is likely to be very minor, given that glufosinate is not widely used on corn (Figure 9). Overall, no significant change in the amount or type of herbicides used on corn is anticipated as a result of a determination of non-regulated status for 4114 maize.

- **Cumulative Impacts - Herbicide Use**

  The proposed application rates for glufosinate are identical to those currently approved for use on corn. When used in accordance with the EPA label restrictions, the use of an EPA registered herbicide is anticipated to present minimal risks to human health and the environment. Because changes in herbicide use for products containing 4114 maize are not expected, no cumulative effects have been identified for herbicide use.

Fungicide Use

Prior to 2007, foliar fungicide applications in corn were only used by growers with a history of disease problems in their fields or for an anticipated outbreak. Since 2007, fungicide use has increased as a result of potential economic and yield benefits. Currently, in 2011, the use of foliar fungicides is at its highest (more than 15 million acres). 4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. The fungicide use on 1507x59122 maize is similar to conventional corn.

- **Fungicide Use - No Action Alternative**

  Under the No Action Alternative, the amount, type, and method of fungicide use in corn will not be impacted. Disease risk, the higher price of corn, and fungicide marketing will continue to drive fungicide management decisions.

- **Fungicide Use - Approved Petition Alternative**

  Approval of 4114 maize will not impact fungicide use. Growers will continue to use fungicides if there is a need to manage diseases and/or a potential economic gain.

- **Cumulative Impacts - Fungicide Use**

  A determination of nonregulated status of 4114 maize is not expected to result in changes in corn fungicide use in the foreseeable future. There are no past, present, or reasonably foreseeable actions to aggregate with effects of the proposed action to affect changes in fungicide use.

Integrated Pest Management

IPM techniques include prevention, avoidance, monitoring, and suppression of weeds, insects, diseases, and other pests. IPM combines techniques from each sector of prevention, avoidance, monitoring, and suppression into one overall system. IPM practices are specific to the crop, region, and pest. In many cases, adoption of IPM leads to a reduction in overall pesticide use, lower production costs, and improvement in water, air, and soil quality. 4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. The IPM practices for 1507x59122 maize are similar to conventional corn.

- **Integrated Pest Management - No Action Alternative**

  Under the No Action Alternative, effective IPM practices that are used by U.S. corn growers will likely continue unchanged. Alternative stacked IR and HT varieties will be available if 4114 maize is not deregulated and effective IPM practices can be used with these alternative stacked IR and HT varieties.

- **Integrated Pest Management - Approved Petition Alternative**

  Approval of 4114 maize will not impact IPM. The IPM practices that are currently used by growers with any corn varieties will continue to be the same regardless of whether 4114 maize is present in the environment.

- **Cumulative Impacts - Integrated Pest Management**

  Deregulation of 4114 maize will not change IPM practices and therefore no cumulative impacts are anticipated in the foreseeable future.

Integrated Resistance Management

IRM is of great importance because of the threat insect resistance poses to the future use of *Bt* plant-incorporated protectants and *Bt* technology as a whole. The need for proactive insect resistance detection and insect monitoring is critical to the longevity of *Bt* technology. EPA mandates that registrants monitor for insect resistance to the *Bt* toxins. This monitoring program provides an important early warning sign to development of resistance in the field and determines if current IRM strategies are effective. Grower participation (*e.g.*, reports of unexpected damage) is also important for monitoring. Effective IRM can reduce the risk of resistance development (US-EPA, 2010b). Suspected resistance of corn rootworm was reported in 2011 with four states having suspected western corn rootworm resistance to CryBb1 (Kilman, 2011). This report reinforces the need for growers to follow IRM practices for *Bt* corn.

EPA and technology providers understand the need to improve IRM compliance and monitoring and are actively working to refine current practices. These will likely result in future changes to IRM.

- **Integrated Resistance Management - No Action Alternative**

  Under the No Action Alternative, 4114 maize will continue to be a regulated article. Alternative stacked IR products will be available if 4114 maize is not deregulated, and effective IRM practices will be used with these products.

- **Integrated Resistance Management - Approved Petition Alternative**

  4114 maize will not be commercialized as a stand-alone product, and any breeding stacks of 4114 maize with other IR traits will have an IRM program reviewed and approved by EPA prior to registration. IRM requirements and best practices will be appropriate for any stacked trait products containing 4114 maize.

- **Cumulative Impacts - Integrated Resistance Management**

  The availability of a single event to replace two events in complex breeding stacks of IR events may facilitate the more rapid breeding and development of multi-trait, multi-mode of action IR products, which in turn may increase the speed at which more durable products are brought to the market. Therefore, the cumulative impact of deregulation of 4114 maize on IRM practices will be neutral or positive.

Weed Resistance Management

Growers using GE crops have various options for weed control methods, including herbicides. The large majority of corn fields are planted with glyphosate-tolerant corn and sprayed with glyphosate. Since the adoption of glyphosate-tolerant crops, several studies have shown that even though more glyphosate is being sprayed, overall there has been a reduction in toxicity of herbicides over time. Glyphosate and glufosinate are also less toxic and harmful to the environment than many other herbicides currently available (Sanvido *et al.*, 2007). If growers decide that glufosinate-tolerant corn is not suitable for their fields, growers can choose to use other HT corn varieties. There could be a modest increase in herbicides other than glufosinate if corn growers use alternative herbicides to control resistant weed populations. 4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. The WRM practices for 4114 maize are identical to1507x59122 maize.

- **Weed Resistance Management - No Action Alternative**

  A determination of non-regulated status for 4114 maize will have no impact on the use of glufosinate herbicide or change the weed management practices that growers use.

- **Weed Resistance Management - Approved Petition Alternative**

  Because 4114 maize is an alternative to 1507x59122 maize in complex breeding stacks, deregulation of 4114 is not expected to change WRM practices. Any potential use of alternative herbicides to control glufosinate-resistant weeds would happen whether or not 4114 maize is deregulated. Overall, no change in the WRM practices used in GE corn fields is anticipated as a result of a determination of non-regulated status for 4114 maize.

- **Cumulative Impacts - Weed Resistance Management**

  The amount of glufosinate used on 4114 maize will be identical to existing glufosinate-tolerant varieties (because the seasonal use rate is identical), so the availability of 4114 maize will not positively or negatively affect WRM. In the foreseeable future, 4114 maize could be stacked with additional current or future herbicide traits. In this case, it would be important to develop an appropriate stewardship plan for these products.

4.1C. Corn Processing Practices

Corn processing breaks corn kernels up into its component parts. Corn can be further enhanced by adding wet or dry milling techniques. Products produced in the wet milling process include germ meal, oil (further processed into margarine, cooking oil, baking and frying fats), corn gluten feed, corn gluten meal, and starch (further processed into ethanol and sweeteners) (OECD, 2002). Products produced in the dry milling process include flour, meal, germ meal, oil, beverage and fuel ethanol, distillers dried solubles, flaking grits, hominy feed, and grits (OECD, 2002). Corn grain may also be cooked in alkali and finely ground to produce what is known as *masa*, which is used for tortillas and snack chips (OECD, 2002). 4114 maize is compositionally and nutritionally equivalent to conventional maize, and therefore the processing practices for products containing 4114 maize will be equivalent to conventional and other GE corn varieties.

- **Corn Processing Practices - No Action Alternative**

  Under No Action Alternative, corn processing would not be impacted.

- **Corn Processing Practices - Approved Petition Alternative**

  Approval of 4114 maize would not impact corn processing practices. 4114 maize is equivalent to conventional and other GE corn varieties currently on the market in terms of composition and intended end uses. Therefore, there would be no impact to corn processing practices if 4114 maize was deregulated.

- **Cumulative Impacts - Corn Processing Practices**

  No cumulative effects have been identified for corn processing practices.

4.1D Specialty Corn Production

Specialty crop acreage of products, such as those mentioned in Table 5, is small compared to commodity corn acreage. These specialty markets rely on established identity preservation practices to maintain the purity of the crop and processed fractions as demanded by end users, such as food processors. There are certain specialty corn products on the market today, such as white and waxy, that contain 1507x59122 maize. To the extent that 1507x59122 maize is bred into these specialty corn products, 4114 maize may be used as an alternative to 1507x59122 maize.

- **Specialty Corn Production - No Action Alternative**

  Specialty corn production would not be impacted by a No Action Alternative for 4114 maize.

- **Specialty Corn Production - Approved Petition Alternative**

  Approval of 4114 maize would not impact specialty corn production. 4114 maize is a breeding alternative to 1507x59122 maize, which is currently being used in specialty corn products. If 4114 maize was deregulated, it would likely be used in stacked-trait specialty corn products as well.

- **Cumulative Impacts - Specialty Corn Production**

  No cumulative effects have been identified for specialty corn production.

Ethanol Production

The future of U.S. ethanol is diverse but corn will likely continue to be the major crop used for ethanol production until alternative biofuel technologies are developed. Currently, most any market grade corn variety can be used for ethanol production. 1507x59122 maize and 4114 maize are compositionally equivalent to conventional maize. Products containing 1507x59122 maize are currently used for ethanol production. To the extent that 1507x59122 maize is used for ethanol production, 4114 maize may be used as an alternative to 1507x59122 maize.

- **Ethanol Production - No Action Alternative**

  Under the No Action Alternative, 4114 maize would remain a regulated article and there would be no changes to ethanol production.

- **Ethanol Production - Approved Petition Alternative**

  Approval of 4114 maize would not impact ethanol production. 4114 maize is a breeding alternative to 1507x59122 maize, which is currently being used in ethanol production. If 4114 maize was deregulated, it would likely be a component of corn products used for ethanol production as well.

- **Cumulative Impacts - Ethanol Production**

  In the foreseeable future, there will likely be an increased demand for ethanol production and continued high commodity prices for corn grain. Because of this, growers may choose not to re-enroll agriculture land in CRP when their contracts expire. If ethanol demands drive the conversion of CRP acres to corn production, this would occur whether or not 4114 maize was deregulated. Thus, there will be no cumulative impact.

4.1E. Organic Production

Organic farming is a small (approximately 0.7% of all U.S. cropland) but viable production system. The benefits of organic farming include: reduced input costs, conservation nonrenewable resources, high-value market capture, and improved farm income (USDA-ERS, 2010a). Because 4114 maize is a GE event, it will not be used in organic products.

- **Organic Production - No Action Alternative**

  If 4114 maize remains a regulated article, it will continue to be grown under the USDA permit or notification with appropriate isolation measures and will therefore not impact organic production.

- **Organic Production - Approved Petition Alternative**

  Under the Approve Petition Alternative, commercial production of organic corn would not change. Growers of organic corn will continue to produce crops that meet NOP standards. Since 4114 maize would not be used in organic production, its introduction would not have positive or negative effects on organic corn.

- **Cumulative Impacts - Organic Production**

  No significant cumulative effects on corn production are anticipated as a result of approving the petition for nonregulated status of 4114 maize. In the foreseeable future, the majority of the corn market is expected to be HT and IR stacked traits (Figure 4). Currently, there are IP practices that facilitate the prevention of cross-pollination between genetically engineered and organic corn production. Because 4114 maize would replace 1507x59122 maize in complex breeding stacks and would not add additional corn acres beyond current levels, organic growers would not need to increase IP activities related to existing organic corn fields. Moreover, 4114 maize exhibits no agronomic or reproductive differences from conventional corn in terms of gene flow and therefore will have no cumulative impact.

4.2. Physical Environment

Soil Quality

The soil environment in and around crop fields is complex and rich in microorganisms and arthropods. Plants can have direct or indirect chemical, physical and biological effects on the soil. Bacteria typically represent the most abundant microbes in the soil followed by fungi. Microbes play an important and particular role in the nutrient cycling capacity of the soil (Iowa State University Extension, 2003). Specific crop management practices used for corn, such as pesticide applications, tillage, and application of inorganic and organic fertilizers can alter soils and the microbial and arthropod populations associated with it. 4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. The crop management practices for 4114 maize will be the same as for 1507x59122 maize.

- **Soil Quality - No Action Alternative**

  Since 4114 maize would not be available in commercial products under this alternative, soil quality would not be affected by a No Action Alternative.

- **Soil Quality - Approved Petition Alternative**

  The specific crop management used for stacked trait products containing 4114 maize will be the same as products containing 1507x59122 maize. Therefore, no impacts on soil quality are anticipated if 4114 maize is deregulated.

- **Cumulative Impacts - Soil Quality**

  Pioneer's 4114 maize will have no effect in the way that pesticide applications, tillage, and application of inorganic and organic fertilizers currently impact soil health. Therefore, there will be no significant cumulative impact on soil quality in the foreseeable future.

Water Resources

Agriculture is a major user of ground and surface water in the U.S., accounting for 80% of the nation's consumptive water use and over 90% in many western states (USDA-ERS, 2004). Water is used both for irrigation purposes and when mixing and applying pesticides. 4114 maize is agronomically equivalent to conventional maize and has no additional or different water needs than existing corn lines (including 1507x59122 maize and conventional corn).

- **Water Resources - No Action Alternative**

  If 4114 maize was not deregulated it would continue to be grown under USDA permit or notification. Water resources would be consistent with its current usage, resulting in no impact for water usage.

- **Water Resources - Approved Action Alternative**

  Approval of 4114 maize will not change water use practices. Growers will make individual decisions regarding water use practices for products containing 4114 maize, just as they currently do for conventional and other GE corn varieties. The availability of 4114 maize will not significantly alter grower decisions regarding water use.

- **Cumulative Impacts - Water Resource**

  The EPA has considered the potential impacts to water resources from *Bt* proteins and applications of glufosinate including label use restrictions and handling guidance intended to prevent impacts to water. When glufosinate is used in accordance with these EPA label restrictions, the impacts to water resources are expected to be the same as those under the No Action Alternative where this herbicide is already used.

In the foreseeable future 4114 maize could be stacked with an agronomic trait such as drought tolerance. If this occurred, there could be some degree of cumulative impact on water resources; however, this impact would be no different than if future drought tolerance traits were stacked with 1507x59122 maize.

Air Quality

Air quality may be affected by a variety of agriculture-related activities, each of which individually has the potential to adversely impact air quality. Tillage contributes to the release of GHGs because of the loss of CO_2 to the atmosphere and the exposure and oxidation of soil organic matter. Emissions released from agricultural equipment include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides. Nitrous oxide may also be released following the use of nitrogen fertilizer. Aerial application of pesticides may cause impacts from drift. Pesticides may volatilize after application to soil or plant surfaces.. 4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. The activities mentioned above will be the same for 4114 maize as for 1507x59122 maize.

- **Air Quality - No Action Alternative**

  Under the No Action Alternative, 4114 maize would not be available for use in complex stacked trait products. Air quality would still be affected by agricultural practices associated with production of commercial corn crops such as tillage, pesticide application, and the use of agricultural equipment.

- **Air Quality – Approve Petition Alternative**

  Agricultural practices that impact air quality will be the same for corn products that contain 4114 maize as they are for products 1507x59122 maize. The agronomic characteristics of 4114 maize are not different from conventional corn. Therefore, the deregulation of 4114 maize is not likely to impact air quality differently from agricultural practices employed with corn varieties on the market today.

- **Cumulative Impacts - Air Quality**

  No significant positive or negative cumulative impact on air quality is anticipated in the foreseeable future if USDA deregulates 4114 maize.

Climate Change

The influences that GE agriculture may have on global climate change are unclear, though global climate change is likely more dependent upon cropping systems, production practices, geographic distribution facilities, and individual grower decisions rather than the GE traits themselves. Production of agricultural commodities is one of the many human activities that could possibly increase GHGs that affect climate. Carbon dioxide (CO_2), nitrogen dioxide (NO_2), and methane (CH_4) may be produced through the combustion of fossil fuels to run farm equipment, the use of fertilizers, or the decomposition of agricultural waste products including crop residues and animal wastes. Classes of crops planted are relevant to climate change, as are the locations and the soil types in which they are planted. Climate change itself may force changes to agricultural practices by extending the ranges of agricultural weeds and pests (IPCC, 2007). 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. 4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. Activities such as: fuel use, fertilizer use, and decomposition of agricultural waste products will be the same for 4114 maize as for 1507x59122 maize.

- **Climate Change - No Action Alternative**

  If 4114 maize was not deregulated it would continue to be grown under USDA permit or notification. There would be negligible GHG effect from these confined environmental releases.

- **Climate Change - Petition Approved Alternative**

  A determination of non-regulated status for 4114 maize would not change the use of tillage, agricultural equipment, irrigation, pesticide applications, or fertilizer applications as they apply to 1507x59122 maize or other GE or non-GE corn, and would not likely impact climate change. Any climate changes that occur will happen whether or not 4114 maize is deregulated.

- **Cumulative Impacts - Climate Change**

  Products containing 4114 maize will most likely only be planted in agricultural fields that are in production today where products containing 1507x59122 maize are currently planted. Corn acreage will not increase based on deregulation of 4114 maize. Additionally, agricultural practices will not change due to the deregulation of 4114 maize. No significant cumulative impacts on climate change are anticipated in the foreseeable future as a result of USDA deregulating 4114 maize.

4.3. Biological Resources

Animal Communities

Corn fields are used by many different animals for food and cover. There are some animals such as birds and deer mice that can be both beneficial and detrimental to corn fields. However, other animals such as deer and raccoons can significantly damage small corn fields. Mammalian wildlife exposure to the *Bt* proteins is likely; however, the mammalian toxicology information gathered to date does not show a hazard to wild or domesticated mammals

Invertebrate organisms are also present in corn-producing areas; as with mammals, many of these invertebrate organisms can be beneficial, detrimental, or both to corn production. The 4114 maize proteins, Cry1F and Cry34/35Ab1, target certain specific invertebrate organisms such as lepidopteran species and corn rootworm species, respectively. The lack of adverse effects of these proteins on non-target organisms was confirmed through laboratory assays and field assessments. Based on these safety studies for 1507 maize and 59122 maize, the Cry1F and Cry34/35Ab1 proteins are not expected to adversely affect other invertebrates and all vertebrate organisms, including non-target birds, mammals, and humans, because of the high specificity of these insecticidal proteins to certain insect order (for further information, see Petition page 151).

- **Animal Communities - No Action Alternative**

  Under the No Action Alternative, any environmental releases of 4114 maize will be as a confined field trial under APHIS regulation and would not have a significant effect on animal communities.

- **Animal Communities - Petition Approved Alternative**

  If deregulated, 4114 maize would be expected to replace some of the acres currently planted with products containing 1507x59122 maize, but would not be expected to cause new corn acres to be planted in areas that are not already in agricultural use. Therefore, there would be no increase in the potential for animal communities to be exposed to proteins expressed in 4114 maize. The availability of 4114 maize would not result in altered or increased application of pesticides or herbicides, and 4114 maize is compositionally equivalent to conventional corn; therefore, no significant impacts on animal communities are anticipated.

- **Cumulative Impacts - Animal Communities**

  Based on the safety of the Cry34/35Ab1, Cry1F, and PAT proteins expressed in both 4114 maize and 1507x59122 maize, the compositional similarity of 4114 maize to non-GE corn and the absence of any changes in agricultural practices (*e.g.*, land use or pesticide application). Therefore, no significant cumulative impacts on animal communities are anticipated as a result of approving the petition for nonregulated status of 4114 maize.

Plant Communities

Corn production acreage is host to many plant species, including a number that are regarded as weeds. The landscape surrounding a corn field varies depending on the region. In certain areas, corn fields may be bordered by other corn or any other crop. Fields may also be surrounded by wooded or pasture/grassland areas. Therefore, the types of vegetation, including weeds, around a corn field depend on the area where the corn is planted. A variety of weeds dwell in and around corn fields and those species will vary depending on the geographic region where corn is planted.

A common occurrence in continuous corn fields is volunteer corn plants originating from germination of grain from the previous season. Corn volunteers can reduce yield like any other weed species by competing with the crop for available resources such as light, nutrients, and water. Control of volunteer corn plants can be accomplished with appropriate herbicides, taking into account the tolerance of the current crop and any tolerance of the previously planted corn variety. 4114 maize shows no altered capacity to be weedy, to become invasive of natural habitats, or to establish feral populations. 4114 maize is an alternative to 1507x59122 maize in complex breeding stacks and currently there has been no reported impact of 1507x59122 maize on plant communities.

- **Plant Communities – No Action Alternative**

  Under the No Action Alternative, any environmental releases of 4114 maize would be as small confined field trials under APHIS regulation and would not have a significant effect on plant communities.

- **Plant Communities- Approved Petition Alternative**

  A determination of non-regulated status of 4114 maize would not have an effect on plant communities. Present corn agricultural practices for 1507x59122 maize would be also be used for products containing 4114 maize. Weeds and corn volunteers within fields of products containing 4114 maize would be managed using mechanical, cultural, and chemical control, as weeds are now managed in current corn systems.

- **Cumulative Impacts - Plant Communities**

  No significant cumulative impact on plant communities is anticipated as a result of approving the petition for nonregulated status of 4114 maize.

Microorganisms

Microorganisms play an important and particular role in the ecology of the soil, including nutrimental cycling and the availability of nutrients for plant growth (OECD, 2003). As the plant tissue residue degrades in the agricultural field, soil dwelling organisms may be exposed to these proteins if they persist in soil, and aquatic organisms could be exposed from water runoff. For soil dwelling or aquatic organisms, protein exposure is highly dependent on protein degradation and dissipation in soils. Most *Bt* proteins do not persist or accumulate in soil over time (Clark *et al.*, 2005; Icoz and Stotzky, 2008). Similarly, the soil dissipation of Cry1F and Cry34/35Ab1 proteins is very rapid.

Numerous published studies indicate that exposure to *Bt* protein produced in IR crop plants does not adversely affect soil microorganisms (Oliveira *et al.*, 2008; Sanvido *et al.*, 2007). In addition, *Bt* toxin released from root exudates and biomass of *Bt* corn has no apparent effect on earthworms, nematodes, protozoa, bacteria, and fungi in soil (Saxena *et al.*, 2002). Other research findings conclude no *Bt*-related risks have evolved from the decomposition of *Bt* corn leaves for the meso- and macrofauna soil community (Hönemann *et al.*, 2008). Although a minimal transient increase and shift in microbial populations may result from the presence of transgenic plant tissue in soil, no adverse effects have been attributed to *Bt* protein (US-EPA, 2010c). 4114 maize is an alternative to 1507x59122 maize in complex breeding stacks and contains the same *Bt* proteins (Cry1F and Cry34/35Ab1). There has been no reported impact of 1507x59122 maize on microorganisms.

- **Microorganisms - No Action Alternative**

  Under the No Action Alternative, environmental releases of 4114 maize would be under APHIS regulation and no changes in impacts on microorganisms are anticipated.

- **Microorganisms - Approved Petition Alternative**

  Similar agronomic practices between 4114 maize and other GE and non-GE corn suggest that cultivation of products containing 4114 maize would not negatively or positively affect microorganisms. The proteins expressed in 4114 maize are currently found in the environment and have not impacted microorganisms. Therefore, if 4114 maize were deregulated there would be no impact on microorganisms currently in the environment.

- **Cumulative Impacts - Microorganisms**

  No significant cumulative impact on plant communities is anticipated as a result of approving the petition for nonregulated status of 4114 maize.

Biodiversity

Biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management, including selection and use of insecticides and herbicides; and 4) extent of isolation of the agroecosystem from natural vegetation (Altieri, 1999). The introduction of woodlots, fencerows, hedgerows, wetlands or windbreaks are ways to enhance biodiversity in large scale monocultures. Additional enhancement strategies include intercropping (the planting of two or more crops simultaneously to occupy the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), and addition of organic matter (compost, green manure, animal manure, etc.) (Altieri, 1999). The adoption of GE crops, with the concomitant reduction in insecticide use and enhanced soil conservation practices, has contributed to the increase in biodiversity.

Biodiversity is highly managed in agricultural systems where farmers want to encourage high yields from their corn crop and will intensively manage the plant communities for weeds. Animal pests, particularly insect and other pest species will also be managed through chemical and cultural controls to protect the crop from damage. Therefore, the biological diversity in agricultural systems may be lower than in the surrounding habitats. The primary aim of an agricultural field is not to promote biodiversity, which is better delivered via a natural ecosystem, but it should avoid negatively impacting it. 4114 maize is an alternative to 1507x59122 maize in complex breeding stacks and contains the same *Bt* proteins (Cry1F and Cry34/35Ab1). There has been no reported impact of 1507x59122 maize on biodiversity.

- **Biodiversity - No Action Alternative**

  Under the No Action Alternative, any environmental releases of 4114 maize would be as small confined field trials under APHIS regulation and would have no significant effect on biodiversity.

- **Biodiversity - Approved Petition Alternative**

  If 4114 maize was deregulated by the USDA, there would be no anticipated differences in the animal and plant species compared to those that typically inhabit 1507x59122 maize agricultural fields. Therefore, there are no anticipated impacts on biodiversity.

- **Cumulative Impacts - Biodiversity**

  4114 maize is equivalent to 1507x59122 maize, which has been available in the market since 2006 without any apparent negative impacts on biodiversity. 4114 maize does not exhibit traits that would differentiate it from 1507x59122 maize that is currently commercially available. Therefore, no cumulative or long-term impact on biodiversity is anticipated due to the deregulation of 4114 maize.

Corn Gene Flow

Corn is a self-pollinated and wind-pollinated species that is sexually compatible with its closest relative, teosinte, and with members of the genus *Tripsacum*, although to a much lesser degree (Mangelsdorf, 1974; OECD, 2003). Hybridization of corn with teosinte would most likely occur in geographical areas south of the U.S. and crosses between corn and *Tripsacum* species are extremely difficult. *Tripsacum* species have one less chromosome than corn but can hybridize with corn; however, it is very difficult, requires special techniques, and the hybrids have a high degree of sterility, and are genetically unstable (US-EPA, 2011a).

The evaluation of agronomic and phenotypic properties of 4114 maize, including those characteristics associated with reproductive biology, indicated no biological meaningful differences that are likely to affect the potential for gene flow from 4114 maize to other corn varieties.

- **Corn Gene Flow - No Action Alternative**

Under the No Action Alternative, any environmental releases of 4114 maize would be as small confined field trials under APHIS regulation and would have no significant effect on gene flow.

- **Corn Gene Flow - Approved Petition Alternative**

Gene flow from 4114 maize to relatives is extremely unlikely due to lack of relatives in the U.S. in regions where corn is typically grown. Pollen-mediated gene flow from 4114 maize to U.S. populations of *Zea* or *Tripsacum* species is not likely, with the limited exception of potential gene flow to feral populations of *Zea mays spp. parviglumis* in Florida and to a lesser extent, *Tripsacum floridanum*, also in Florida. Differences in flowering time between corn and these species, and current geographic separation of these species from the majority of U.S. corn production, make the occurrence of natural crosses in the U.S. very minor. Volunteer-mediated gene flow is of minimal concern due to the lack of seed dispersal and feral traits in corn.

The consequences of gene flow and introgression of the transgenic traits from 4114 maize to the same species is anticipated to be the same as 1507x59122 maize. Therefore, the impact of deregulation of 4114 maize on corn gene flow as anticipated to be negligible.

- **Cumulative Impacts - Corn Gene Flow**

  4114 maize does not exhibit traits that would differentiate it from 1507x59122 maize that is currently commercially available. Therefore, no cumulative or long-term impact on gene flow is anticipated due to the deregulation of 4114 maize.

Threatened and Endangered Species

Corn production systems in agriculture are host to many animal species. Mammals and birds may seasonally use grain, and invertebrates can feed on the plant during the entire growing season. All other organisms active in the agro-ecosystem and in adjacent habitats are not intended to be harmed by GE plants and, as a consequence, can operationally be defined as non-target organisms (NTOs), which includes threatened and endangered species (TES) (Arpaia, 2010).

One of the safety considerations for GE crops is their potential effect on these organisms. Effects can be due to toxicity or allergenicity of novel proteins, altered expression of plant-produced toxicants and anti-nutrients, or the formation of novel toxins as a desired or unintended consequence of the genetic modification. Additionally, the effects of changes in agricultural practices, such as increased application of chemicals registered for use with the new crop, should be considered.

Wildlife in and around corn fields are of interest due to potential exposure to 4114 maize grain and plant residue. The toxic potential of genetically engineered crops is typically evaluated by examining the amino acid sequence homology of novel proteins to known toxins and, where appropriate, feeding animals and insects appropriate plant fractions to test whole grains, purified proteins, or other appropriate plant fractions.

A wide variety of toxicology studies conducted over the past 40 years has established the safety of the microbial preparations of *Bt* including their expressed insecticidal Cry proteins (Betz *et al.*, 2000). The allergenicity and toxicity of the Cry1F, Cry34Ab1, and Cry35Ab1 proteins has been assessed and all three are not likely to be potential allergens or toxins to humans or animals. Based on quail and mouse toxicological studies for Cry1F, both EPA and USDA concluded that the protein was not likely to have an adverse effect on vertebrates, including non-target birds, mammals, and humans (US-EPA, 2010a; USDA-APHIS, 2001). EPA and USDA made similar conclusions for Cry34Ab1 and Cry35Ab1 on the basis of poultry, mouse, and rainbow trout toxicological studies (US-EPA, 2010c; USDA-APHIS, 2005). Providing additional evidence for the lack of toxicity of the Cry1F and Cry34/35Ab1 proteins, recently published rodent feeding studies showed no toxicological effects of diets containing 1507 maize and 1507x59122 maize grain (Appenzeller *et al.*, 2009; MacKenzie *et al.*, 2007). Additional feeding studies for laying hens, swine, beef cattle, and dairy cows with diets containing 1507 maize and 59122 maize have all shown no differences in nutritional equivalency from diets containing conventional corn

(Faust *et al.*, 2007; Huls *et al.*, 2008; Jacobs *et al.*, 2008; Scheideler *et al.*, 2008; Sindt *et al.*, 2007; Stein *et al.*, 2009).

Additionally, for 1507 maize, USDA considered the impact of the Cry1F protein on two lepidopteran species, the Karner blue butterfly (*Lycaeides melissa samuelis*) and Mitchell's satyr butterfly (US-FWS, 2011a; USDA-APHIS, 2001). USDA concluded that both species would not be expected to be present in or close to corn fields; therefore, it is not likely there would be any impact of 1507 maize cultivation (USDA-APHIS, 2001). For 59122 maize, USDA considered the impact on one primary threatened and endangered coleopteran species, the American burying beetle (US-FWS, 2011a; USDA-APHIS, 2005). From review of preferred habitats, this beetle was not likely to be found in active corn fields and therefore would not be exposed significantly to the Cry34/35Ab1 protein from 4114 maize (USDA-APHIS, 2005) (for further information, see Petition page 160).

4114 maize is an alternative to 1507x59122 maize in complex breeding stacks. 4114 maize is comparable in agronomic characteristics and compositional characteristics to conventional corn except for the presence of the introduced proteins, Cry1F, Cry34Ab1, Cry35Ab1, and PAT. These proteins are toxic to the targeted plant pest and have no significant effect on TES in the environment. The potential impact on TES of products containing 4114 maize will be equivalent to products containing 1507x59122 maize.

- **Threatened and Endangered Species - No Action Alternative**

  Identified TES are generally found outside of agricultural fields. Habitats within fields will be unaffected by a No Action decision. Any environmental releases of 4114 maize would be as small confined field trials under APHIS regulation and would have no significant effect on TES that live or forage in agricultural fields, since the Cry 34/35Ab1, Cry1F, and PAT proteins are unlikely to have an adverse effect on TES.

- **Threatened and Endangered Species - Approved Petition Alternative**

  4114 maize is safe for animal consumption and will not adversely affect various NTOs that might consume seeds or other parts of the plant. The safety data related to non-target surrogate organisms in the classes of Lepidoptera and Coleoptera support 4114 maize's low likelihood of adversely impacting any threatened or endangered species. In addition, 4114 maize deregulation is not expected to increase corn acreage or geography; therefore, corn acres would not be expected to increase in areas near TES habitats. Based on the evidence supporting the environmental safety of 4114 maize, the deregulation of 4114 maize is unlikely to pose a risk TES.

- **Cumulative Impacts - Threatened and Endangered Species**

  In the foreseeable future, it is unlikely that 4114 maize will have a significant positive or negative cumulative impact on TES in the environment.

4.4. Human Health

Consumer Health

Under the FFDCA, it is the responsibility of food manufacturers to ensure that the products they market are safe and properly labeled. Food derived from corn products containing 4114 maize must be in compliance with all applicable legal and regulatory requirements. GE organisms for food may undergo a voluntary consultation process with the FDA prior to release onto the market. Corn is not a common allergenic food. The modification in 4114 maize did not cause significant compositional changes relative to conventional corn that would increase allergenicity or toxicity, or alter the nutritional profile of corn derived from 4114 maize.

As stated above, the proteins produced in 4114 maize have been reviewed by U.S. governmental agencies for food safety. The 1507 maize event, containing the Cry1F and PAT proteins, was deregulated by USDA, registered by the EPA, and reviewed by the FDA in 2001 (Table 1). The 59122 maize event, containing the Cry34/35Ab1 and PAT proteins, was reviewed by FDA in 2004, and deregulated by USDA and registered by EPA in 2005. The 1507x59122 maize breeding stack combination was reviewed and registered by EPA in 2005. In addition, the PAT protein has been a component of corn products commercially grown in the U.S. since 1996, and all proteins in 4114 maize have full tolerance exemptions established by EPA. Currently, 4114 maize is also under review at FDA and EPA.

One of the benefits of *Bt* corn is that it has drastically reduced contamination by the mycotoxin fumonisin. This is because *Bt* corn is far less prone to insect injury, which in turn prevents the growth of fumonisin producing fungi. Certain events of *Bt* corn, such as MON810 and *Bt*11, can reduce fumonisin levels by as much as 90% (Munkvold and Hellmich, 2000). This reduction decreases the exposure and presumably any resulting negative effects of fumonisin to both livestock and humans.

4114 maize is an alternative to 1507x59122 maize in complex breeding stacks. 4114 maize is comparable in compositional characteristics and nutritional safety to conventional corn

- **Consumer Health - No Action Alternative**

  Under the No Action Alternative, 4114 maize would continue to be regulated by USDA and grown under permit or notification and would not be available for use in complex breeding stacks. Therefore, there would be no impact on consumer health.

- **Consumer Health - Approved Action Alternative**

  It has been reported that use of *Bt* corn generally may reduce levels of the mycotoxin fumonisin in corn grain. To the extent there is reduced mycotoxin levels in 1507x59122 maize, it is anticipated the same hold true for 4114 maize. Therefore, it is not likely any positive or negative impact on consumer health would occur with the deregulation of 4114 maize.

- **Cumulative Impacts - Consumer Health**

  No significant positive or negative cumulative impacts on human health are anticipated as a result of approving the petition for nonregulated status of 4114 maize.

Worker Health

EPA's Worker Protection Standard (WPS) (40 CFR Part 170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.

Bt products can substantially reduce the health and environmental risks associated with the use of traditional chemical insecticides. Corn varieties containing Cry1F and Cry 34/35Ab1 will potentially decrease the reliance on conventional pesticides when used as part of an integrated pest management program. Reductions in the use of conventional pesticides would eliminate the need to transport, mix, apply, and dispose of these pesticides, reduce spray-drift and run-off associated with some of the registered alternatives, and reduce potential adverse effects to non-target organisms. Increased use of Cry1F and Cry 34/35Ab1 protected corn would also improve worker protection as compared to chemical insecticides (US-EPA, 2010b).

4114 maize was developed as an alternative for 1507x59122 maize in complex breeding stacks. The reduction in pesticide use for products containing 1507x59122 maize will be similar to products containing 4114 maize.

- **Worker Health - No Action Alternative**

  During agricultural production of corn, agricultural workers and pesticide applicators may be exposed a variety of 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, 4114 maize would continue to be grown under USDA permits and notifications and worker exposure to these agricultural chemicals would be unchanged.

- **Worker Health - Approved Petition Alternative**

Because 4114 maize is an alternative to 1507x59122 maize in complex breeding stacks, deregulation of 4114 maize is not expected to positively or negatively impact worker health.

- **Cumulative Impacts - Worker Health**

It is possible that future IR traits, combined with 4114 maize in stacked trait products, could enable a further reduction in insecticide use due to efficacy against insects for which insecticides are currently used. Likewise, development of insect resistance to *Bt* traits may occur. In this case, there may be a return to previous levels of insecticide use. However, these potential changes in insecticide use would happen whether or not 4114 maize was deregulated. Therefore, no significant positive or negative cumulative impacts on worker health are anticipated as a result of approving the petition for nonregulated status of 4114 maize.

4.5. Animal Feed

Updated bioinformatic analyses support the original conclusions that the Cry1F, Cry34/35Ab1, and PAT proteins are not likely to be toxins. Additionally, 1507x59122 maize has been commercially available in the U.S. since the 2006 growing season with no reports of toxicity. There have been numerous studies on the safety of 1507 maize and 59122 maize to animals. These data support the conclusion that the Cry1F, Cry34/35Ab1, and PAT proteins in 4114 maize are not likely to be potential toxins to animals, and therefore, support the food and feed safety of these proteins.

4114 maize is compositionally comparable to current conventional corn varieties. Pioneer evaluated the composition of 4114 maize grain that included crude protein, crude fat, crude fiber, acid detergent fiber (ADF), neutral detergent fiber (NDF), ash, carbohydrates, fatty acids, total amino acids, key anti-nutrients, and key secondary metabolites. Compositional analyses of forage included crude protein, crude fat, crude fiber, ADF, NDF, ash, carbohydrates, calcium, and phosphorus. In total, data from 69 different analytical components (60 in grain, nine in forage) were analyzed. All values for 4114 maize were within the ranges for the commercial corn lines (*i.e.*, tolerance intervals) or within published literature ranges for corn (for further information, see Petition page 101).

The 1507 maize event, containing the Cry1F and PAT proteins, was reviewed by the FDA in 2001 (Table 1). The 59122 maize event, containing the Cry34/35Ab1 and PAT proteins, was reviewed by FDA in 2004. In addition, the PAT protein has been a component of corn products commercially grown in the U.S. since 1996, and all proteins in 4114 maize have full tolerance exemptions established by EPA. Currently, 4114 maize is also under review at FDA and EPA.

- **Animal Feed - No Action Alternative**

  Under the No Action Alternative, 4114 maize would continue to be regulated by USDA and grown under permit or notification and would not be available for use in complex breeding stacks. Therefore, there would be no impact on animal feed.

- **Animal Feed - Approved Petition Alternative**

  The grain and forage of 4114 maize are comparable to conventional corn with respect to nutrient composition and the proteins in 4114 maize have been determined to be safe; therefore, there would be no impact on animal feed if 4114 maize was deregulated.

- **Cumulative Impacts - Animal Feed**

  No significant cumulative impacts on animal health are anticipated as a result of approving the petition for nonregulated status of 4114 maize.

4.6. Socioeconomic Impacts

Domestic Economic Environment

With a crop value of $65.97 billion in 2010, the U.S. corn crop is the most valuable and productive of all crops. In 2011, 88% of corn grown in the U.S. was genetically modified; insect resistant varieties accounted for approximately 65% of all corn acreage (Figure 4). The increasing and overall high percentage of cultivated genetically modified corn demonstrates farmers' acceptance of the technology as beneficial and valuable to their overall business operations.

Through tax incentives and import tariffs and a federal mandate to increase the use of renewable fuels in gasoline, government policy has stimulated the growth of corn production for use in the production of ethanol. The Energy Policy Act of 2005 established a 7.5 billion-gallon target for renewable fuels in gasoline by 2012 and a tax credit of 51 cents per gallon of ethanol blended with gasoline (US-DOE, 2012). These policies are expected to continue in the foreseeable future and add to the incentive for corn production. The recent expansion in demand for corn for ethanol production is projected to slow, however, reflecting moderate growth of gasoline consumption in the U.S. and limited potential for further market penetration. The share of corn use for ethanol is expected to remain at 36% and the share of exports to grow from 16 to 17%. Commodity prices are projected to remain historically high. According to the USDA, corn acreage is projected to stay the same from 2011 through 2020 (USDA-ERS, 2011d).

Even with the expected acreage increase, conversion of CRP acreage to new corn acres is not expected to increase. The 2008 Farm Bill reduced the maximum acreage allowed in the CRP to 32 million, 7.2 million acres below the 2004 enrollment (Stubbs, 2011). It is unknown what the 2012 Farm Bill will change in regards to the CRP.

4114 maize was developed as an alternative to 1507x59122 maize in complex breeding stacks and will not be commercialized as a standalone product. IR and HT stacked trait products represent 49% of the market. They continue to be in demand by growers and the trend of stacked traits will likely continue into the foreseeable future, especially as technology developers continue to pyramid IR traits for reduced refuge and enhanced durability.

- **Domestic Economic Environment - No Action Alternative**

  Under the No Action Alternative, 4114 maize would remain a regulated article and would require an APHIS permit or notification for release into the environment. There would be no impact on the domestic economic environment.

- **Domestic Economic Environment - Approved Petition Alternative**

  Deregulation of 4114 maize and its availability for use in complex breeding stacks is neither expected to increase U.S. corn acreage nor impact commodity prices. Multi-trait corn products may be able to be brought to the market more quickly and efficiently because of the efficiencies of using one event in complex breeding stacks rather than two (*i.e.,* 1507x59122 maize); however, this is not expected to affect grower costs or profitability, number of corn acres planted, amount of U.S. corn grain produced, or commodity prices. Therefore, no significant impacts on the domestic economic environment are anticipated as a result of deregulation of 4114 maize.

- **Cumulative Impacts - Domestic Economic Environment**

  In the foreseeable future, Federal policies such as crop insurance, marketing loans, direct and countercyclical payments, and the Average Crop Revenue Election (ACRE) program may influence decisions of planting corn (as opposed to other crops or as opposed to non-agricultural uses of land) and add to the incentive for corn production. These policies and their outcomes may occur whether or not 4114 maize is deregulated. Based on global demand for corn grain and the amount of corn reserves, commodity prices will continue to fluctuate based on the economy, whether or not 4114 maize is deregulated. Therefore, no significant cumulative impacts on the domestic economic environment are anticipated as a result of approving the petition for nonregulated status of 4114 maize.

Trade Economic Environment

In 2010, the U.S. exported 14.5% (or roughly $9.6 billion) of the corn it produced (Figure 14). As discussed in Section 2.6 above, the U.S. contributes approximately 55% of the corn for the world export market, and the largest customers for U.S. corn in 2009-10 were Japan, Mexico, South Korea, Taiwan, Egypt, Canada and China[m]. USDA predicts that the overall global export market for corn will increase between 2010 and 2020; however, the U.S. share of corn trade is expected to decrease because of increased domestic use of corn for ethanol production and corn based-sweeteners. The U.S. is expected to continue to export ethanol and by-products from the production of ethanol.

4114 maize was developed as an alternative to 1507x59122 maize in complex breeding stacks and will not be marketed as a standalone product. 4114 maize has been shown to be compositionally and agronomically equivalent to conventional corn (other than its intended insect efficacy). Products containing 4114 maize will have the same global uses as products containing 1507x59122 maize, once appropriate regulatory authorizations are obtained in key export countries for products containing 4114 maize.

- **Trade Economic Environment - No Action Alternative**

  Under the No Action Alternative, 4114 maize would remain a regulated article and would require an APHIS permit for release into the environment. There would be no impact on the trade economic environment.

- **Trade Economic Environment - Approved Petition Alternative**

  Although the primary U.S. corn export destinations do not present major barriers to trade in GE products, Pioneer would need to obtain necessary authorizations for products containing 4114 maize in destination countries before commercialization to avoid adversely affecting current trade flows. In the absence of any practical method of separating commodity corn, 4114 maize grain, meal, and oil will be co-mingled with other varieties, including GE varieties that have all necessary approvals in major export markets. Under the Approve Petition Alternative, Pioneer would perform a market assessment, in consultation with the value-chain, for products containing 4114 maize and would obtain appropriate regulatory approvals for these products in major U.S. export markets with functioning regulatory systems prior to release for commercial production,

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[m] In terms of international grain trade and Pioneer's 4114 maize event, authorizations will be pursued in international markets to ensure grain compliance upon import. Pioneer will not commercialize any of its products, including those containing 4114 maize, until such time that all international necessary regulatory clearances have been obtained from countries with functioning regulatory systems.

as requested by the grain industry (NCGA, 2011b). Upon obtaining all necessary regulatory approvals, stacked products containing 4114 maize would be commercialized in the U.S. similar to other corn products and would be similarly exported. Based on Pioneer's overall registration/approval strategy for products containing 4114 maize and the intent for 4114 maize to replace 1507x59122 maize in complex stacked trait products, it is unlikely that there would be significant impact to the trade economic environment from the deregulation of 4114 maize.

- **Cumulative Impacts - Trade Economic Environment**

In the foreseeable future, it is possible that new countries could become significant importers of U.S. corn grain or those existing countries that import U.S. corn grain would no longer need to. Countries without regulations for the import of GE products could develop them. In addition, countries that already have such regulations could modify them, rescind previous authorizations, or require additional data for previously approved products. Global demand for corn grain and its byproducts could increase more rapidly than projected or unexpectedly decrease. However, 4114 maize is an alternative to 1507x59122 maize and will only be deployed in complex breeding stacks that will need to undergo appropriate regulatory authorizations in key export countries with functioning regulatory systems. The above-mentioned changes to the trade economic environment may happen whether 4114 maize is deregulated or not and would impact all GE corn products similarly. Therefore, no significant cumulative impacts on the trade economic environment are anticipated as a result of deregulating 4114 maize.

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