Monsanto Company Petition (07-CR-191U) for Determination of Non-regulated Status of Event MON 87460

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MON 87460-4

Draft Environmental Assessment

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Acronyms and Abbreviations

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

GRAS	generally recognized as safe
IP	Identity Preservation
IPCC	Intergovernmental Panel on Climate Change
ISPM	International Standard for Phytosanitary Measure
IPPC	International Plant Protection Convention
LMO	living modified organisms
MOE	margin of exposure
NO_2	nitrogen dioxide
N_2O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NOEL	no observable effect level
NPTII	neomycin phosphotransferase II protein
nptII	neomycin phosphotransferase II protein gene
NRC	National Research Council
PPRA	Plant Pest Risk Assessment
PPA	Plant Protection Act
PRA	pest risk analysis
RNA	ribonucleic acid
TES	threatened and endangered species
TSCA	Toxic Substances Control Act
U.S.	United States
USDA	U.S. Department of Agriculture
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USDA-NOP	U.S. Department of Agriculture-National Organic Program
USC	United States Code
WPS	Worker Protection Standard for Agricultural Pesticides

1 PURPOSE AND NEED

1.1 Regulatory Authority

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

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

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA’s Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

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

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

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain biological control organisms under the Toxic Substances Control Act (TSCA). The EPA is responsible for regulating the sale, distribution and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology.

1.2 Regulated Organisms

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

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

1.3 Petition for Determination of Nonregulated Status: MON 87460 Drought Tolerant Corn

The Monsanto Company of St. Louis, MO, submitted a petition to APHIS in 2010 for determination of nonregulated status for Event MON 87460 drought tolerant (DT) corn (hereafter referred to as MON 87460) (Reeves, 2010). In the event of a determination of nonregulated status, the nonregulated status for MON 87460 would include MON 87460, and any progeny derived from crosses between MON 87460 and conventional corn and crosses of MON 87460 with other biotechnology-derived corn that has been deregulated pursuant to Part 340 and the Plant Protection Act. Event MON 87460 is currently regulated under 7 CFR Part 340. Interstate movements and field trials of MON 87460 have been conducted under permits issued or notifications acknowledged by APHIS since 2002. Data resulting from these field trials are described in the Monsanto Company petition (Reeves, 2010).

1.4 Purpose of Product

MON 87460 is designed to mitigate grain yield loss under water-limited conditions. As detailed in the Monsanto Company petition, the enhanced drought tolerance of MON 87460 results from the introduction and controlled expression of cold shock protein B (*cspB*), a native ribonucleic acid (RNA) chaperone derived from *Bacillus subtilis* (Reeves, 2010). The enhanced drought tolerant phenotype of MON 87460 manifests primarily as reduced yield loss relative to conventional corn when subjected to water-limiting conditions. When MON 87460 was subjected to well-watered conditions, grain yield for MON 87460 was not notably different than conventional corn. Data provided by the Monsanto Company demonstrates that MON 87460 reduces yield loss under water-limiting conditions primarily by minimizing the effect of water deficiency on photosynthesis, stomatal conductance, and carbon fixation on corn growth and development, resulting in an increased number of kernels per ear (Reeves, 2010).

Drought is one of the major limiting factors in corn that prevents realization of optimum grain yield worldwide (Boyer, 1982; Bray et al., 2000). In North America alone, it is estimated that 40 percent of distributed crop loss insurance indemnities are due to sub-optimal water availability (Boyer, 1982). In temperate zone areas of commercial corn production, average global annual losses due to moderate drought are approximately 15 percent, though losses can be much higher under conditions of severe drought (Barker et al., 2005).

1.5 APHIS Response to Petition for Nonregulated Status

Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of genetically engineered organisms, including GE plants such as MON 87460 corn. When a petition for nonregulated status is submitted, APHIS must make a determination if the genetically engineered organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

APHIS has prepared this environmental assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with NEPA regulations (40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372) and the USDA and APHIS NEPA implementing regulations and procedures. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from the deregulation of MON 87460 corn.

1.6 Coordinated Framework Review

MON 87460 does not contain a biotechnology-derived PIP nor is it a biological control organism; thus, EPA does not regulate MON 87460.MON 87460 is within the scope of the FDA

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

policy statement concerning regulation of products derived from new plant varieties, including those produced through genetic engineering. The Monsanto Company initiated the consultation process with FDA for the commercial distribution of MON 87460, and submitted a safety and nutritional assessment of food and feed derived from MON 87460 to the FDA on December 19, 2008. Based on the information the Monsanto Company submitted, and as of December 2010 (BNF No. 000116), FDA has no further questions regarding MON 87460 drought tolerant corn (FDA, 2010).

1.7 Public Involvement

APHIS routinely seeks public comment on draft environmental assessments prepared in response to petitions to deregulate GE organisms. APHIS does this through a notice published in the Federal Register. The issues discussed in this EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments of GE organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of corn using various production methods, and the environmental and food/feed safety of GE plants were addressed to analyze the potential environmental impacts of MON 87460.

This EA, the petition submitted by the Monsanto Company (Reeves, 2010), and APHIS' Plant Pest Risk Assessment (USDA-APHIS, 2010) will be available for public comment for a period of 60 days (7 CFR § 340.6(d)(2)). Comments received by the end of the 60-day period will be analyzed and used to inform APHIS' determination decision of the regulated status of MON 87460 and to assist APHIS in determining whether an Environmental Impact Statement (EIS) is required prior to the determination decision of the regulated status of these corn lines.

1.8 Issues Considered

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

- Management considerations:
  - Acreage and areas of corn production,
  - Cropping practices,
  - Specialty corn production.
- Environmental considerations:
  - Water use and quality,
  - Soil,
  - Climate change,
  - Animals,
  - Plants,
  - Biological diversity, and
  - Gene movement.

- Human health considerations:
  - Public health,
  - Worker safety, and
  - Livestock feed.
- Socioeconomic considerations:
  - Domestic economic environment, and
  - Trade economic environment.

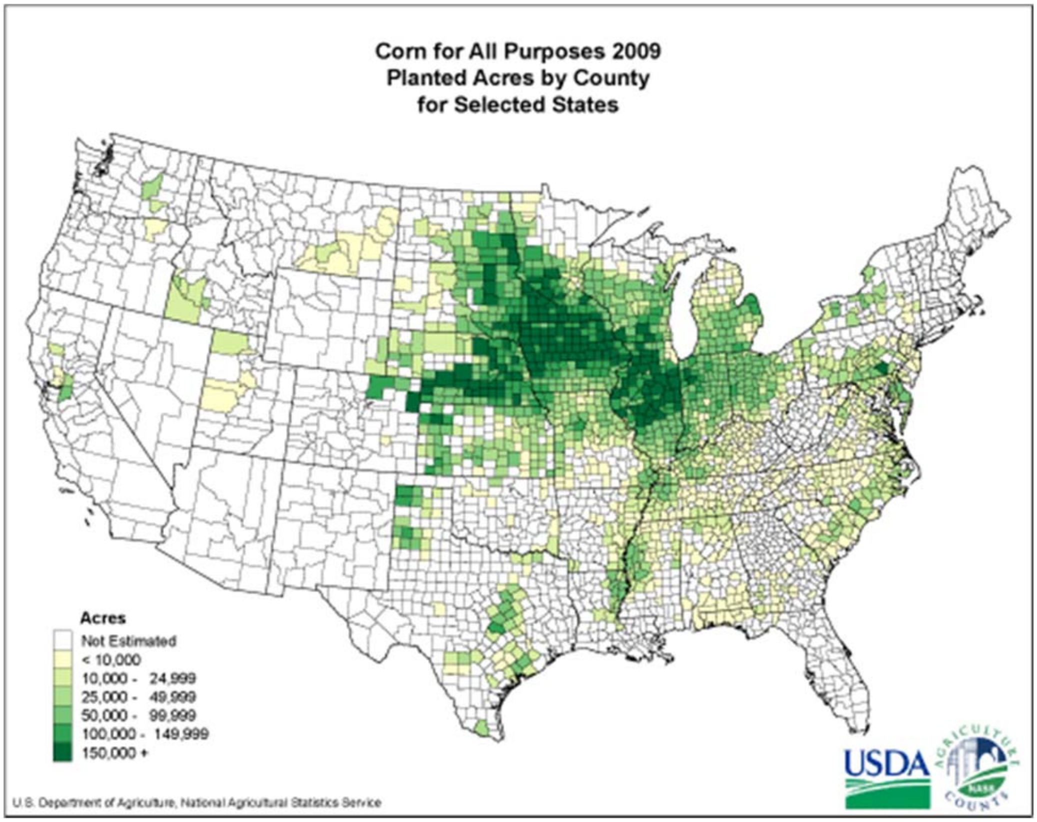
2 AFFECTED ENVIRONMENT

2.1 Agricultural Production of Corn

2.1.1 Current and Projected Acreage

Corn (*Zea mays* L.), a member of the *Maydeae* grass family tribe, is an annual plant cultivated under a variety of production environments (Morris and Hill, 1998). In the U.S., corn is generally cultivated in temperate regions that provide sufficient moisture and an adequate number of frost-free days to reach maturity. U.S. corn production is primarily focused in the Corn Belt, an area that represents approximately 80 percent of annual U.S. corn production and includes Iowa, Illinois, Nebraska, and Minnesota, and parts of Indiana, South Dakota, Kansas, Ohio, Wisconsin, and Missouri (USDA-NASS, 2010b). Figure 1 presents the planted acres of corn in the U.S. in 2009 (USDA-NASS, 2010c). In general, the Corn Belt has an adequate combination of seasonal warm weather, rainfall, and favorable soil conditions for growth. While the Midwest, where approximately 65 percent of U.S. corn is produced, typically experiences a minimum of 30 inches of rainfall annually, the central part of the Great Plains (~26 percent of U.S. corn production) receives an average of 20 inches, making it less optimal for corn production (Lew, 2004).

Figure 1. Corn, planted acres: 2009



Source: (USDA-NASS 2010c).

The U.S. is the world's largest producer and exporter of corn. From 2008 through 2010, the U.S. produced approximately 40 percent of the world's total corn harvest (FAOSTAT, 2008). During the 2009/2010 market year, 86.4 million acres of corn were planted and approximately 13.1 billion bushels of corn were harvested in the U.S. (USDA-NASS, 2010b). In terms of domestic use, animal feed/residuals and biofuel production utilized the majority of produced corn (39 and 35 percent, respectively), whereas lesser amounts were used for exportation to foreign markets (15 percent), ending stock seed (13 percent), food and industrial purposes (10 percent), and seed stock for hybrid seed production (0.17 percent) (USDA-NASS, 2010a).

Each year, the USDA-Economic Research Service (ERS) updates its ten-year projections of supply and utilization for major field crops, including corn, soybeans, and wheat grown in the U.S. At present, U.S. corn growers are on track to slightly increase planted corn acreage from the current level of 88.2 million acres to 92 million acres by 2020 (USDA-ERS, 2011b). This ten-year projection reflects an increased domestic and international demand for U.S. corn, and will be driven by improvements in plant genetics, machinery, and cultivation practices (USDA-ERS, 2010e). Arable land for increased corn planting acreage will result from grower shifts away from soybean or wheat cultivation and from the return of Conservation Reserve Program (CRP) lands to agricultural production (USDA-ERS, 2011b). Representing a reduction from 39.2 million acres to 32 million acres, this return of CRP land back into agricultural production has been stipulated by the Food, Conservation, and Energy Act of 2008 to provide additional cropland to meet future agricultural demands (Farm Bill, 2008).

2.1.2 Agronomic Practices

2.1.2.1 Conventional and GE Corn Production Systems

Conventional farming in this document includes any farming system where synthetic pesticides or fertilizers may be used. Conventional farming covers a broad scope of farming practices, ranging from farmers who only occasionally use synthetic pesticides and fertilizers to those farmers whose harvest depends on regular pesticide and fertilizer inputs. This definition of conventional farming also includes the use of genetically engineered (GE) varieties that have been deregulated by APHIS.

Growers can choose from a large number of corn hybrids produced from traditional breeding or genetic engineering systems (NCGA, 2010). Adoption of GE corn in the U.S. has significantly increased since 2000 on both the state and national level, with 86 percent of all corn planted in 2010 representing a GE variety (Table 1). Additionally, growers can also choose from several different crop management options. Though specific details of these management options differ in terms of geographic cultivation area and end-use market, general management decisions are commonly shared. These include method of tillage, addition of agronomic inputs, and selection of crop rotation system.

Table 1: Adoption of genetically engineered corn varieties by major U.S. corn production states, 2000-2010.

State	GE Corn Varieties (percent of all corn planted)										
	2000	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**
Illinois	17	16	22	28	33	36	55	74	80	84	82
Indiana	11	12	13	16	21	26	40	59	78	79	83
Iowa	30	32	41	45	54	60	64	78	84	86	90
Kansas	33	38	43	47	54	63	68	82	90	91	90
Michigan	12	17	22	35	33	40	44	60	72	75	80
Minnesota	37	36	44	53	63	66	73	86	88	88	92
Missouri	28	32	34	42	49	55	59	62	70	77	79
Nebraska	34	34	46	52	60	69	76	79	86	91	91
North Dakota	-	-	-	-	-	75	83	88	89	93	93
Ohio	9	11	9	9	13	18	26	41	66	67	71
South Dakota	48	47	66	75	79	83	86	93	95	96	95
Texas	-	-	-	-	-	72	77	79	78	84	85
Wisconsin	18	18	26	32	38	46	50	64	75	77	80
Other States	17	20	27	36	46	44	55	67	74	78	82
U.S. total	25	26	34	40	47	52	61	73	80	85	86

Source: (USDA-ERS, 2010a)

Prior to planting, the soil must be stripped of weeds that would otherwise compete with the crop for space, water, and nutrients. Field preparation is accomplished through a variety of tillage systems, with each system defined by the remaining plant residue on the field. Conventional tillage is associated with intensive plowing and less than 15 percent crop residue; reduced tillage is associated with 15 to 30 percent crop residue; and conservation tillage, including no-till practices requiring herbicide application on the plant residue from the previous season, is associated with at least 30 percent crop residue and substantially less soil erosion than other tillage practices (EPA, 2009). Conservation tillage has been associated with higher soil moisture retention when compared to conventional and reduced tillage methods (Smika and Wicks, 1968; Tanaka and Aase, 1987). Because of its low cost and positive impact on soil quality, conservation tillage is currently and widely practiced in the Midwestern U.S. (EPA, 2009).

Corn production typically involves the extensive use of agronomic inputs to maximize grain yield (Olson and Sander, 1988). Agronomic inputs include corn fertilizers to supplement available nutrients in the soil; pesticides to reduce pest plant, insect, and/or microbial populations; and moisture to ensure normal plant growth and development (Cerrato and Blackmer, 1990; M. R. Hall et al., 1992; Howell et al., 1998; Levine, 1991; Smith and White, 1988).

Given the importance of nutrient availability to corn agronomic performance, fertilization with nitrogen, phosphorus, and potassium is widely practiced. In 2005 (the date of the last USDA Agricultural Chemical Usage Summary to include corn) nitrogen was applied to 96 percent of corn acreage at an average of 138 pounds per acre (lb/acre); phosphate was applied to 81 percent of corn acreage at an average rate of 58 lb/acre; and potash was applied at a rate of 84 lb/acre to 65 percent of corn acreage (USDA-NASS, 2006). Like fertilizer application, pesticide use for pest control is also common in corn. Herbicides were applied to 97 percent of corn acreage in 2005, with Atrazine (66 percent), Glyphosate (31 percent), S-metolachlor (23 percent) and Acetochlor (23 percent) representing next the most widely-applied herbicide (USDA-NASS, 2006). Additionally, 23 percent of corn-planted acreage was treated with insecticides, with the most abundantly applied being Tefluthrin (7 percent), Cyfluthrin (7 percent), and Tebupirimphos (6 percent) (USDA-NASS, 2006). While agricultural herbicide use trends resulting from the utilization of GE technologies are the subject of much debate (Benbrook, 2009; Brookes and Barfoot, 2010; Fernandez-Cornejo et al., 2009), it is generally agreed that insecticide use in U.S. crops has decreased since the introduction of GE insect-resistant crop varieties (Benbrook, 2009). In 2010, 63 percent of total U.S. corn acreage was planted with insect-resistant corn (USDA-ERS, 2010a).

In major U.S. corn production regions, moisture availability is strongly correlated with grain yield. For example, four consecutive days of visible wilting prior to tassel emergence can reduce grain yields by 25 percent, while this same duration of stress during silk emergence/anthesis/grain fill can cause a 40 to 50 percent yield reduction (Hesterman and Carter, 1990; McWilliams, 2002). Drought-related reduction in grain yield is mediated through several mechanisms, including reduced grain number, an increase in floral asynchrony, and the abortion of fertilized kernels during ear development (Westgate et al., 2004).

Corn generally requires a steady supply of moisture, though the amount required is dependent on developmental stage. For example, prior to pollination, corn generally requires 0.1 inches per day; during pollination and grain fill, this water requirement increases to a maximum of 0.35 inches per day (McWilliams, 2002). This moisture demand is met by a combination of natural rainfall/stored soil moisture and supplemental irrigation during the growing season (Neild and Newman, 1990). In U.S. corn production areas where supplemental irrigation is practiced, light and frequent irrigation is superior to heavier, less frequent irrigation involving the same overall amount of water (Olson and Sander, 1988). Under conditions of moderate water deficit, corn yields can be reduced by approximately 15 percent; crop failure can also result under more severe drought conditions (Barker, et al., 2005). While conventionally-produced corn hybrids have been produced to exhibit increased drought tolerance, the basic water requirements of corn have not been overcome. Thus, these drought-tolerant varieties will not likely be grown outside of current corn cultivation areas.

Crop rotation is practiced to increase soil fertility and reduce the proliferation of pests and diseases. For example, in a corn-soybean rotation, continuously growing corn for multiple growing seasons can decrease populations of soybean pests, such as soybean cyst nematode (Hoeft et al., 2000). Decisions about crop sequences are guided by many factors, including economic return from differences in input cost, yield potential, and commodity prices. Crops used in rotation with corn vary regionally, but there has been an increase in the number of fields that have a corn-to-corn rotation, as opposed to rotation to another crop other than corn. The increased adoption of corn-to-corn rotation, mainly in conventional and GE production systems, has been attributed to rising corn demand and prices (Hart, 2006; Stockton et al., 2007).

2.1.2.2 Specialty Corn Production Systems

While the vast majority of corn grown in the U.S. is grown as grain for animal feed, ethanol, and industrial uses, approximately 8 percent of corn grown in the U.S. (2005/06 growing season) is specialty corn specified by buyers and end-users of corn (USGC, 2006, 2008). Specialty corns include: sweet, high oil, nutritionally-enhanced corn varieties, and organically-produced varieties (USGC, 2006). Due to premiums offered by end-users and the dramatic adoption by U.S. farmers of GE corn varieties, specialty corn products are receiving increased attention as potentially profitable alternatives to the products of conventional and GE corn production systems (Elbehri, 2007).

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

- Contracts – written agreements detailing responsibilities and duties of both parties including premiums for reaching goals and penalties for failing to attain specifications;
- Tracking and Traceability Systems – correct labeling of all products (planting seeds and harvested material) and testing procedures for identifying and detecting acceptability of materials;
- Quality Assurance Processes – oversight on handling procedures, testing 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.

IP systems that have been shown to be successful in the past include seed certification systems conducted by members of American Organization of Seed Certifying Agencies (AOSCA) (AOSCA, 2009). To maintain the purity of the corn product, this production system is based on controlling, tracking, and documenting each step from seed production to end use (processing plants).

2.1.2.3 Organic Corn Production Systems

Organic farming is defined in this document to include any production system that falls under the USDA-National Organic Program (NOP) definition of organic farming and is a certified organic production system. The NOP is administered by the USDA-Agricultural Marketing Service (AMS). Organic farming operations, as described by the USDA-NOP, require organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. In organic systems, the use of synthetic pesticides, fertilizers, and genetically engineered crops (e.g., MON 87460) is strictly limited or restricted.

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

In 2007 (the date of the last USDA Census of Agriculture), 93.5 million acres of corn were planted in the U.S., yielding 12.7 billion bushels of corn (USDA, 2009). For the same year, USDA-ERS reported that 194,637 acres (0.21 percent) out of a total 93.5 million acres planted were certified organic (USDA-ERS, 2010d).

In 2008, Wisconsin, Iowa, Minnesota, Michigan, New York, Texas, and Nebraska each had more than 10,000 acres of certified organic corn, totaling approximately 69 percent of all certified organic acreage in the U.S. (Table 2) (USDA-ERS, 2010d). Generally, acreage increased from 2007 to 2008, although, in some instances, certain states showed a decrease in the number of certified organic acres.

Table 2: Certified organic corn acreage by state with more than 1,000 acres of certified land in 2007 and 2008.

State	Acreage		State	Acreage	
	2007	2008		2007	2008
California	1,305	2,765	New Mexico	2,700	1,552
Colorado	2,445	3,043	New York	1,909	1,459
Illinois	7,319	8,739	North Dakota	3,292	4,761
Indiana	2,414	2,998	Ohio	8,786	8,969
Iowa	24,944	25,419	Oregon	1,072	1,712
Kansas	2,067	4,637	Pennsylvania	4,482	5,918
Maine	1,025	1,237	South Dakota	5,779	5,564
Maryland	1,009	1,239	Texas	7,710	11,202
Michigan	12,722	12,663	Virginia	1,286	1,472
Minnesota	26,849	27,565	Washington	1,970	2,265
Missouri	7,144	3,765	Wisconsin	27,431	33,619
Nebraska	12,226	10,568	U.S. Total	170,905	193,136

Source: "Certified Organic Grains", Organic Production Data Files (USDA-ERS, 2010d).

2.2 Physical Environment

2.2.1 Water Resources

Corn requires a steady supply of moisture, totaling approximately 4,000 gallons through the growing season to produce 1 bushel of grain (NCGA, 2007). This demand is met by a combination of natural rainfall, stored soil moisture from precipitation before the growing season, and supplemental irrigation during the growing season (Neild and Newman, 1990). Groundwater is the major source for irrigation, used on almost 90 percent of irrigated corn acreage in the U.S. (Christensen, 2002). In 2007, 13.0 million U.S. corn acres were irrigated, reflecting 15 percent of all corn acres harvested for grain (USDA-NASS, 2007).

Agricultural non-point source (NPS) pollution is the primary source of discharge pollutants to rivers and lakes and a major contributor to groundwater contamination. Management practices that contribute to NPS pollution include the type of crop cultivated, plowing and tillage, and the application of pesticides, herbicides, and fertilizers. The primary cause of NPS pollution, however, is increased sedimentation following soil erosion. Agricultural pollutants released by soil erosion include sediments, fertilizers, and pesticides that are introduced to area lakes and streams when they are carried off of fields by rain or irrigation waters (EPA, 2005). Excess sediment can directly affect fish and other wildlife mortality and reduce the amount of light penetration into a body of water. Indirectly, soil erosion-mediated sedimentation can increase fertilizer runoff, facilitating higher water turbidity, algal blooms, and oxygen depletion in a body of water (EPA, 2005).

2.2.2 Soil

Arable land supports a rich and complex community of below ground microorganisms and arthropods. The interaction between the below ground community, plant root suture, and organic residues in the soil is central to a variety of dynamic soil ecological processes, including the decomposition of organic material, subsequent nutrient cycling and release, and the concomitant maintenance of soil structure and composition.

Cultivation of corn directly impacts the qualitative and quantitative attributes of soil. As with any agricultural system, land management options, such as crop type, tillage, and pest management regime have notably greater effects on the biology of the soil than the type of corn cultivated (Griffiths et al., 2007a; Griffiths et al., 2007b). 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 radiatively-active gases that contribute to the greenhouse effect (e.g., carbon dioxide (CO_2) and nitrous oxide (N_2O)) (EPA, 2010b; Lal and Bruce, 1999). Additionally, as previously discussed, land that is prone to degradation is also more likely negatively affect water resource quality and communities of organisms dependent on those water resources.

2.2.3 Air Quality

There are many measures of air quality relevant to agriculture, such as the Clean Air Act (CAA) National Ambient Air Quality Standards (NAAQS) criteria pollutants, greenhouse gases (GHGs), volatile organic compounds (VOCs), pesticides, odors, and airborne allergens. The seven NAAQS criteria pollutants are carbon monoxide (CO), lead, nitrogen dioxide (NO_2), particulate matter between a nominal 2.5 and 10 micrometers in aerodynamic diameter (PM_{10}), particulate matter less than a nominal 2.5 micrometers in aerodynamic diameter ($PM_{2.5}$), ozone (O_3), and sulfur dioxide (SO_2) (EPA, 2010c). Emissions from crop agriculture can be broken down into two main categories – emissions related to working fields, such as dust and equipment emissions, and emissions from the soil and plants.

Agriculture activities (e.g., field preparation, planting, and harvesting) may generate dust plumes (PM_{10} and $PM_{2.5}$) (Holmén et al., 2006). For example, peak levels of particulate concentrations coincide with the peak agricultural harvest season in California's Central Valley (Giles et al., 2006). Emissions released from agricultural equipment (e.g., irrigation pumps and tractors) include CO, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (EPA, 2010b). Greenhouse gas (GHG) emissions from agriculture (crops and livestock) are mainly in the form of methane and nitrous oxide (EPA, 2010b). Other trace gases from agriculture include carbon dioxide and ammonia (Krupa et al., 2006). Atmospheric wet and dry deposition of nitrogen, mineral nutrients, and organic compounds to cropping systems can have feedback effects on trace gas emissions from fields (Krupa, et al., 2006). Agricultural pesticides may also enter the atmosphere through volatilization from soil and plant surfaces and through wind erosion and can be returned to the surface through precipitation or dry deposition processes (Vogel et al., 2008).

2.2.4 Climate Change

Climate change represents a statistical change in climate conditions, and may be measured across both time and space. Production of agricultural commodities is interrelated with climate change on several different levels (Dale, 1997; Rosenzweig and Parry, 1994). U.S. agriculture may act as an affecter of climate change through various facets of the production process. Combustion of fossil fuels in mechanized farm equipment, fertilizer application, and decomposition of agricultural waste products may all contribute greenhouse gases to the atmosphere (Aneja et al., 2009). Greenhouse gases collectively function as retainers of solar radiation, and agriculture-related activities are recognized as both direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) sources of CO_2, methane (CH_4), and N_2O (EPA, 2010a). The U.S. agricultural sector is identified as the second largest contributor to GHG emissions, ranking only behind the energy sector (i.e., electricity production, transportation, and related activities) (EPA, 2010a). Agricultural crop commodities may also affect dynamic geophysical soil processes, such as carbon turnover and sequestration, through tillage and cropping system practices. In general, reduced/conservation tillage practices favor more stable and increased carbon sequestration in the agro-environment (Lal, 2004). Additionally, climate change may also affect agricultural crop production. These potential impacts on the agro-environment and individual crops may be direct, including changing patterns in precipitation, temperature, and duration of growing season, or may cause indirect impacts influencing weed and pest pressure (Rosenzweig et al., 2001; Schmidhuber and Tubiello, 2007).

The impacts of GE crop varieties on climate change are unclear, though it is likely dependent on cropping systems, production practices, geographic distribution of activities, and individual grower decisions. APHIS will continue to monitor developments that may lead to possible changes in the conventional production system likely to result from GE products brought to APHIS for approval. The potential impact of climate change on agricultural output, however, has been examined in more detail. A recent IPCC forecast (IPPC, 2007) for aggregate North American impacts on agriculture from climate change actually projects yield increases of 5 to 20 percent for this century. The IPCC report notes that 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 (IPPC, 2007).

2.3 Animals and Plant Communities and Biodiversity

2.3.1 Animal Communities

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

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

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

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

2.3.2 Plant Communities

The floral community surrounding a corn field is dependent on geography. In certain areas, corn fields can be bordered by other agricultural fields (including those of other corn varieties), woodlands, or pasture and grasslands. From an agronomic perspective, the most relevant members of a surrounding plant community are those that can behave as weeds. Thus, weed pressure is also dependent on geography. Reductions in corn agronomic performance is sometimes associated with weed competition for water, nutrients, and light. U.S. corn yields are threatened by more than 200 weed species annually (Heap, 2008). Common corn field weeds in Indiana includes giant foxtail (*Setaria faberi*), giant ragweed (*Ambrosia trifida*), velvetleaf (*Abutilon theophrasti*), common cocklebur (*Xanthium strumarium*), Canada thistle (*Cirsium arvense*), common lambsquarters (*Chenopodium album*), Johnsongrass (*Sorghum halepense*), fall panicum (*Panicum dichotomiflorum*), and marestail (*Conyza canadensis*) (Childs, 1996). Weeds such as giant foxtail (*Setaria faberi*) and barnyardgrass (*Echinochloa crusgalli*) have been shown to reduce corn yields by up to 14 and 35 percent, respectively (Bosnic and Swanton, 1997; Fausey et al., 1997).

Weediness

In the U.S., corn is not listed as a weed (Crockett, 1977; Holm et al., 1979; Muenscher, 1980). 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 (H. G. Baker, 1965; Galinat, 1988; Keeler, 1989). Like many domesticated crops, corn seed from a previous year's crop can overwinter and germinate the following year. For instance, the appearance of corn seedlings in soybean fields following a corn crop is a common occurrence. Manual or chemical measures are often applied to remove these volunteers, but the plants that are not removed do not typically result in feral populations in subsequent years. Corn does not possess the suite of traits that are characteristics of successful weeds (H. G. Baker, 1965; Keeler, 1989).

APHIS assessed whether MON 87460 is any more likely to become a weed than the isogenic nontransgenic corn line or other corn varieties currently under cultivation. The assessment encompasses a thorough consideration of the basic biology of corn and an evaluation of the unique characteristics of MON 87460 evaluated under field conditions, including potential weediness traits such as seed dormancy and germination, rate of growth and development, flowering, seed dispersal, seed yield, and persistence of free-living populations outside cultivation (See Appendix C). Monsanto collected phenotypic and agronomic field data from field trials conducted at 27 U.S. locations during the 2006 and 2007 growing seasons that included diverse agro-environments representative of the major corn-growing areas of the upper mid-west in the U.S. Likewise, Monsanto also collected complimentary data from four field trials from Chile (Reeves, 2010). In addition, data on abiotic stress tolerance from greenhouse and growth chamber assays were used to characterize the extent of stress tolerance imparted by the insertion of the *cspB* gene and determine whether any potential changes in tolerance enhanced weediness potential in MON 87460.

2.3.3 Biodiversity

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 between 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. Different studies have demonstrated decreases in biological diversity or abundance due to GE crops engineered to accumulate insecticidal proteins or tolerate herbicide application for weed management (Marshall et al., 2003; Pilcher et al., 2005; Ponsard et al., 2002). Alternatively, other studies of GE crops, such as Bt corn, when compared to non-GE crops sprayed with insecticides demonstrate that GE crops do not cause any changes in arthropod abundance or diversity (Chen et al., 2008; Romeis et al., 2006; Torres and Ruberson, 2005; N. Weber, 2009; Wolfenbarger et al., 2008). Some reports show that GE crops may even increase biological diversity in agro-ecosystems (Marvier et al., 2007; Romeis, et al., 2006). Herbicide-tolerant corn, when compared to non-GE corn production, may not result in changes in arthropod abundance and may increase species diversity during different times of the year (Brooks et al., 2003; Haughton et al., 2003; Hawes et al., 2003; Roy et al.; Wolfenbarger, et al., 2008). Since biological diversity can be defined and measured in many ways, APHIS considers determining the level of biological diversity in any crop to be complex and hard to achieve concurrence. Another difficulty with biodiversity studies is separating expected impacts from indirect impacts. For example, reductions of biological control organisms are seen in some Bt-expressing GE crops, but are caused by reduction of the pest host population following transgenic pesticide expression in the GE crop plant.

2.3.4 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 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/distance of sexually-compatible plant species; overlap of flowering phenology between populations; the method of pollination; the biology and amount of pollen produced; and weather conditions, including temperature, wind, and humidity (Zapiola et al., 2008). Seed-mediated gene flow also depends on many factors, including the absence/presence/magnitude of seed dormancy; contribution and participation in various dispersal pathways; and environmental conditions and events.

Corn is self-compatible and wind-pollinated. 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) (Galinat, 1988; Mangelsdorf, 1974; Russell and Hallauer, 1980). 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, 2010), and *Zea perennis* in South Carolina (USDA-NRCS, 2011). Feral populations of the closely related and sexually compatible subspecies of *Z. mays* spp. *parviglumis* have also been described in a single county (Miami-Dade) of Florida (Weber, 2009). Evidence of introgression of genes from corn into U.S. teosinte populations has not been sought but complex mechanisms of incompatibility have been described that are barriers to this potentiality (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.

2.3.4.1 Intraspecies gene flow

Many varieties of corn are cultivated in the U.S. 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. 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 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 (see Appendix B for a detailed list). Spatial and temporal isolation can be one of the most effective barriers to gene exchange between corn crop cultivars (Zapiola, et al., 2008). Current practices for maintaining the purity of hybrid seed production in corn are typically successful for maintaining 99 percent 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; G. Kuepper, 2002; G 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, 2009).

Pollen-mediated gene flow and mitigation

As noted, a primary spatial mechanism to maintain corn genetic purity is isolation distance. A recent paper reviewed studies investigating gene flow and cross-fertilization studies in corn grain production fields, and, using the data from these studies, recommended 50 meters (m) (approximately 164 feet (ft)) 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 presence of physical barriers, and thus pollen dispersal is not equivalent to cross fertilization. Sandivo et al. (2008) 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; W. E. 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 found cross-fertilization to be as high as 2.5 percent 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 in the Jones and Brooks study. Jones and Brooks (1950) investigated the appropriate isolation distance for seed production in open-pollinated varieties, and not in hybrid varieties. Due 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 pollination events. Thus the results from Jones and Brooks (1950) may be an overestimation of cross-fertilization potential for hybrid corn plants. Additional properties also may affect pollen-mediated gene flow from corn and are listed in Appendix B.

Seed-mediated gene flow and mitigation

For gene flow to occur via seeds and result in feral populations of corn, seeds must disperse and establish 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, 1968). 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, or husk (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 unlikely to produce progeny and persisting populations because of the tightly bound nature of the corn seeds to the husk. Specific properties affecting seed-mediated gene flow from corn are listed in Appendix B.

2.4 Human Health

2.4.1 Public Health

In the past 30 years, the public's consumption of corn-based products has more than doubled – corn products have risen from 12.9 pounds annually per capita in 1980 to 33 pounds in 2008; and corn sweeteners have risen from 35.3 pounds annually per capita in 1980 to 69.2 pounds in 2008 (USCB, 2011). During the same time period, the share of corn that is genetically engineered has risen from zero to 80 percent (USDA-ERS, 2010a). Due to concurrent increases in corn production consumption and the increased adoption of GE corn, the general concern with GE corn is exposure through human and animal consumption.

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

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

2.4.2 Worker Safety

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 require all employers to protect their employees from hazards associated with pesticides and herbicides.

Pesticides, including 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, however, involves the design of use restrictions that if followed have been determined to be protective of worker health.

2.5 Livestock Health

Approximately 55 to 60 percent of the corn produced in the U.S. is used for livestock (KyCGA, 2011). As with human consumption of corn, most of the corn used currently for livestock feed is GE (USDA-ERS, 2010a). Similar to human consumption, there is a general concern regarding the impact of GE components on nutritional, allergenic, and toxicological aspects of the food produced by livestock.

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

2.6 Socioeconomic

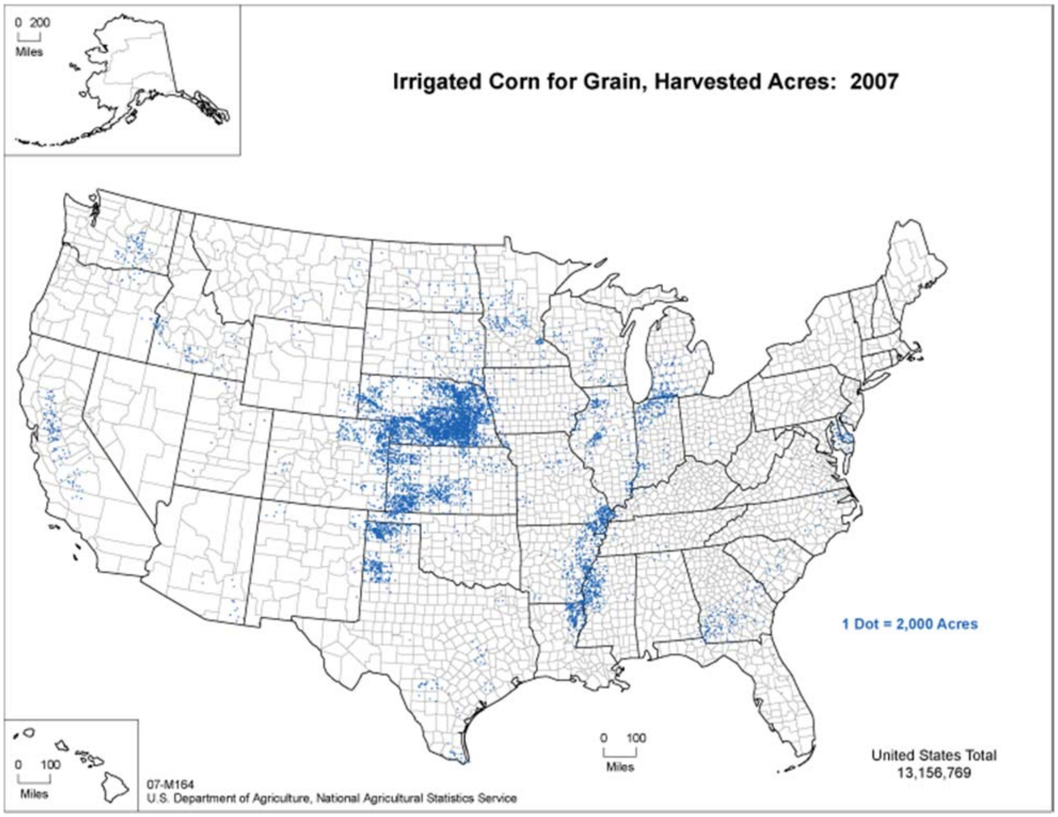
2.6.1 Domestic and Trade Economic Environment

Domestic demand for corn in the U.S. comes from its domestic use for feed, ethanol production, food, and seed, and totaled 11.1 billion bushels in the 2009/10 marketing year (USDA-ERS, 2011b). Exports added another 2 billion bushels to total U.S. corn use. Demand is satisfied almost entirely by domestic supply, with few imports, the U.S. being largely a net exporter of corn. The U.S. produced 13 billion bushels of corn in the 2009/10 marketing year and corn occupied the most acreage of any crop in the country (USDA-ERS, 2011b). In the 2009/10 marketing year, feed was approximately 40 percent of U.S. corn production, ethanol production was about 35 percent of U.S. corn use, food, seed, and industrial uses were approximately 45 percent, and exports the remaining 15 percent (USDA-ERS, 2011b). Seeds constituted approximately 1.7 percent of domestic corn production, with 5.6 percent being used for high fructose corn syrup, glucose and dextrose, and corn starch (USDA-ERS, 2010c).

Corn is grown in the entire continental U.S. Despite this broad cultivation range, most U.S. production is centered in the Corn Belt. The Corn Belt includes Iowa, Illinois, Nebraska, and Minnesota, and parts of Indiana, South Dakota, Kansas, Ohio, Wisconsin, and Missouri, and represents approximately 80 percent of U.S. annual corn production (USDA-NASS, 2010a).

Corn production requires approximately 20 inches of soil moisture during the growing season to achieve maximum yields. Many U.S. corn-producing states have average annual precipitation below 20 inches annually. Among those states, those with most non-irrigated acreage of corn harvested are North Dakota, Colorado, Montana, New Mexico, and Wyoming. The states with the most irrigated acreage of corn harvested are Nebraska, Kansas, Texas, Colorado, and California (USDA, 2009). Of these, all but California are in the Great Plains area of corn production. Figure 2 shows the corn acres harvested for grain in the U.S. that are irrigated (USDA-NASS, 2007b).

Figure 2. Irrigated corn for grain, harvested acres: 2007.



Source: 2007 Census Publications, Ag Atlas Maps, Crops and Plants (Map 07-M164, USDA-NASS 2007b).

Table 3: Relative importance of farms and corn in local economies.

Area	Share (percent) of Farms in Total Gross Domestic Product (2007)[a]	Share (percent) of Corn in Total Crop Acreage (2010)[b]
California	1.24	14.30
Colorado	1.05	21.69
Kansas	3.00	20.89
Minnesota	2.12	37.72
Montana	3.89	24.03
Nebraska	6.93	46.07
New Mexico	1.72	46.07
North Dakota	10.29	9.43
South Dakota	9.03	28.16
Texas	0.79	10.07
Wyoming	1.07	5.41
United States	1.00	27.55

Sources: (a) Bureau of Economic Analysis, Gross Domestic Product by State, Crop and Animal Production (NAICS 111 and 112); (b) National Agriculture Statistics Service, Acreage, Area Planted for All Purposes.

Table 3 shows the relative importance of farming and corn in the 11 states mentioned above and in the U.S. The first column shows the share of state gross domestic product (GDP) generated by crop and animal farms. This does not include GDP generated by supporting activities (e.g., for soil preparation, harvesting, or post-harvesting), nor does it include transportation activities or processing and commercialization of products downstream from farm production. In all listed states but Texas, farms generate a higher share of GDP than the U.S. average. The second column shows the share of corn in total crop acreage as an indicator of the relative importance of corn in crop farming in each state. Given the value of corn as feed, corn also has an important role in animal farms.

Additionally, there is a niche market for non-GE food and feed in the U.S., as evidenced by private labeling initiatives such as the Non-GMO Project, that offers third-party product verification and labeling for non-GE products (Non-GMO-Project, 2010). There also is a growing niche market for organic products in the U.S. Sales of organic products have been growing quickly, having grown from $1 billion in 1990 to $24.8 billion in 2009, representing a 5.1 percent between 2008 and 2009 (OTA, 2010). However, in the case of organic corn production, there is some evidence that supply might be lagging behind demand (Greene et al., 2009). To satisfy the demand for either organic or non-GE corn, producers have had to adopt specific production practices to maintain and prevent the contamination of excluded methods as dictated by the USDA-NOP. To offset the increase in investment related to these more extensive practices, premiums are often paid for non-GE or organic corn. For example, in 2007, conventional corn averaged $4.19/bushel, whereas organic corn averaged $7.08/bushel (N. Weber, 2009).

The U.S. is the largest world exporter of corn. Trade in feed for livestock has been a driver of trade in corn (USDA-ERS, 2011b). Japan is the world's largest corn importer, typically followed by South Korea, Mexico, Egypt, and Taiwan (USDA-FAS, 2010b). During the last half decade, the U.S. share of world corn exports averaged 60 percent, the second largest exporter being Argentina (USDA-ERS, 2011b).

The primary U.S. corn export destinations are also the largest world importers of corn and do not seem to have major barriers for importing GE products. In Japan there are no restrictions for import of GE varieties that have been approved for commercialization in Japan. In the case of genetically engineered varieties not yet approved in Japan, a 1 percent presence in feed is still allowed, as long as it has been approved by an exporting country with safety assessments equivalent to Japan's. There is no restriction after approval. Labeling is mandatory for GE food when the GE content can be detected and if the GE ingredient is one of the first three ingredients of a product and accounts for more than 5 percent of its total weight (Greuere, 2006). Mexico imports and consumes regularly existing varieties of GE corn (USDA-FAS, 2008b). South Korea has similar approval processes as Japan and requires labeling for GE animal feed (USDA-FAS, 2008). Taiwan requires labeling for products containing more than 5 percent GE content (USDA-FAS, 2008c). Egypt is a large consumer of GE crops, including corn, soybeans, and vegetable oils (USDA-FAS, 2006).

Data on trade in organic corn is not readily available but given that U.S. corn imports are relatively small and that U.S. organic corn production is a small share of the total, trade in organic corn is likely to be a very small share of the total corn trade.

The affected trade economic environment is defined as those countries with which the U.S. engages in corn feed, seed and food trade. Therefore, the trade economic environment most likely affected by deregulating DT Corn would be those countries who import DT Corn feed, seed and food.

The affected domestic environment is defined as any land in the U.S. that is currently producing crops that could incorporate a corn rotation, as well as land that could be converted from inactive cropland to active cropland, and land currently in the CRP that could be removed from the program and farmed.

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of Monsanto Company MON 87460 corn. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87460 is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2010) APHIS has concluded that MON 87460 is unlikely to pose a plant pest risk. Therefore APHIS must determine that MON 87460 is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Two alternatives will be evaluated in this EA: (1) no action and (2) determination of nonregulated status of MON 87460. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

3.1 No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. MON 87460 and progeny derived from MON 87460 would continue to be regulated articles under the regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of MON 87460 and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MON 87460.

This alternative is not the preferred alternative because APHIS has concluded through a PPRA (USDA-APHIS, 2010) that MON 87460 is unlikely to pose a plant pest risk. Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

3.2 Preferred Alternative: Determination that MON 87460 CORN Is No Longer a Regulated Article

Under this alternative, MON 87460 and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR Part 340. MON 87460 is unlikely to pose a plant pest risk (USDA-APHIS, 2010). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87460 and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that MON 87460 is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87460 is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to MON 87460 and progeny derived from this event if the developer decides to commercialize MON 87460.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 87460. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for MON 87460. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

3.3.1 Prohibit Any MON 87460 from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of MON 87460, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MON 87460 is unlikely to pose a plant pest risk (USDA-APHIS, 2010).

In enacting the Plant Protection Act, Congress found that

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

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

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

Based on our Plant Pest Risk Assessment (USDA-APHIS 2010) and the scientific data evaluated therein, APHIS concluded that MON 87460 is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87460.

3.3.2 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that MON 87460 is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3.3.3 Isolation Distance between MON 87460 and Non-GE Corn Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating MON 87460 from conventional or specialty corn production. However, because APHIS has concluded that MON 87460 is unlikely to pose a plant pest risk (USDA-APHIS, 2010), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of MON 87460 based on the location of production of non-GE corn in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' PPRA for MON87460, there are no geographic differences associated with any identifiable plant pest risks for MON 87460 (USDA-APHIS, 2010). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87460 does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Nevertheless, APHIS is not expecting significant effects. However, individuals might choose on their own to geographically isolate their non-GE rose productions systems from MON 87460 or to use isolation distances and other management practices to minimize gene movement between corn fields. Information to assist growers in making informed management decisions for MON 87460 is available from Association of Official Seed Certifying Agencies (AOSCA 2004).

3.3.4 Requirement of Testing for MON 87460

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because MON 87460 does not pose a plant pest risk (USDA-APHIS, 2010), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for MON 87460 would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.4 Comparison of Alternatives

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

Table 4: Summary of Potential Impacts and Consequences of Alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS 2010)
Management Practices		
Acreage and Areas of Corn Production	Unchanged	Minimal
Cropping practices	Unchanged	Unchanged
Pesticide use	Unchanged	Unchanged
Seed Corn Production	Unchanged	Unchanged
Organic Farming	Unchanged	Unchanged
Impact to Specialty Corn	Unchanged	Unchanged
Environment		
Water use	Unchanged	Unchanged
Soil	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Animals	Unchanged	Unchanged
Plants	Unchanged	Unchanged
Biological Diversity	Unchanged	Unchanged
Gene Movement	Unchanged	Minimal
Human and Animal Health		
Risk to Human Health	Unchanged	Unchanged
Risk to Worker Safety	Unchanged	Unchanged
Risk to Animal Feed	Unchanged	Unchanged
Socioeconomic		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Social Environment	Unchanged	Unchanged
Other U.S Regulatory Approvals	**FDA completed consultations**	**FDA completed consultations**
Compliance with Other Laws		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
CWA, CAA, EOs	Fully compliant	Fully compliant

*Unchanged – no significant change expected
*Minimal – possibly small changes but no significant differences

4 ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking no action and a determination by the agency that MON 87460 does not pose a plant pest risk. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON 87460 are described in detail throughout this section. A cumulative effects analysis is also included for each affected environment. Certain aspects of this product and its cultivation would be no different between the alternatives: those are described below.

4.1 Scope of Environmental Analysis

The scope includes any land in the U.S. currently producing corn, any land that is currently producing crops that could incorporate a corn rotation, as well as land that could be converted from inactive cropland to active cropland, and land currently in the Conservation Reserve Program (CRP) that could be removed from the program and farmed. Conversion of grassland, forest, or other land types to cropland as a result of deregulating MON 87460 would be less likely because these types of conversions have not been notable contributors to cropland over the past 18 years; therefore, APHIS does not consider them to be part of the affected environment in this EA. Furthermore, as described below, MON 87460 is unlikely to significantly increase future corn acreage beyond USDA-ERS projected expansion in irrigated U.S. corn production regions. The MON 87460 trait is intended to increase grain yield security under conditions of moderate water stress. Minimum moisture requirements are similar between MON 87360 and conventional corn and therefore MON 87360 is not anticipated to expand corn acreage into areas not currently used for corn production.

To determine areas of corn production, APHIS used data from the National Agricultural Statistics Service (NASS) 2007 Census of Agriculture to determine where corn is produced in the United States (USDA, 2009). Corn grain was commercially produced in all states except Alaska.

4.2 Other Assumptions

The environmental consequences of the different alternatives described above will be analyzed under the assumption that farmers, who produce conventional corn, MON87460, or produce corn using organic methods, are using reasonable, commonly accepted best management practices for their chosen system and varieties during agricultural corn production. However, APHIS recognizes that not all farmers follow these best management practices for corn. Thus, the analyses of the environmental affects will also include the assumption that some farmers do not follow these best management practices.

The environmental consequences will be discussed under the context of the MON 87460 phenotype presented in the Monsanto 87460 Petition for Determination of Nonregulated Status. In summary, MON 87460 does not exhibit improved grain yield relative to the near-isogenic control corn variety when subject to well-watered conditions. When other indicators of MON 87460 agronomic performance are compared to a variety of regionally-adapted corn reference hybrids and the near-isogenic control variety, MON 87460 neither significantly nor consistently performs beyond the observed range of variation, further reinforcing the lack of increased agronomic performance in MON 87460 under well-watered conditions (Reeves, 2010).

When subject to water-limited conditions ($\leq$50 percent field capacity), MON 87460 displays significantly less yield loss relative to the near-isogenic control corn variety. However, other measures of the MON 87460 phenotype do not significantly deviate from the range of values produced by the near-isogenic control or regionally-adapted corn reference hybrids Combined with data demonstrating no significant differences between MON 87460 or its control corn variety in rate of soil moisture depletion, root:shoot ratio, and cold, heat, and salt stresses, the quantified agronomic attributes of MON 87460 under water-limited conditions confirms its single and predicted phenotype (Reeves, 2010). These data provide multiple lines of evidence indicating that the *cspB* trait plays a physiological role in modulating plant drought response through increased photosynthetic efficiency and does not provide an absolute increase in the rate of soil water depletion or improved fitness outside the agricultural environment (Plant Pest Risk Assessment (PPRA) for MON 87460 (APHIS, 2011)).

4.3 Agricultural Production of Corn

4.3.1 Current Acreage and U.S. Cultivation Range

USDA-APHIS is tasked with protecting the health and value of American agriculture and natural resources. Continued regulation of genetically engineered organisms and encouragement of best management practices, regardless of farmer decision to cultivate GE or non-GE crop varieties, represents two central, practical methods to maintain and improve U.S. agricultural productivity.

At present, U.S. farmers are projected to increase planted corn acreage from 86.5 million acres in 2009/10 to 92 million acres in 2020/21(USDA-ERS, 2010b, 2011b). The Midwest (~65 percent) and the Great Plains (~26 percent) represent the major corn-producing regions of the U.S. GE corn varieties represent a progressively increasing proportion of total U.S. corn planted, ranging from a low of 25 percent in 2000 to 86 percent in 2010 (USDA-ERS, 2010a). While the majority of currently commercialized GE corn varieties represent either herbicide-tolerant (e.g., glyphosate-, glufosinate-tolerant or other herbicide) or insect resistant (i.e., *Cry* protein expression) varieties, an increasing proportion are varieties with multiple stacked traits (i.e., herbicide-tolerant and insect-resistant) (USDA-ERS, 2010a).

During the market year September 2009 through August 2010, 86.4 million acres of corn were planted and approximately 134 million bushels of corn were harvested (USDA-ERS, 2010b). Of the total harvest, about 39 percent was used for animal feed and residuals, 35 percent was used for biofuels production, 10 percent was used for food and industrial purposes (not including alcohol for fuel), 0.17 percent was used as seed stock for hybrid seed production, 13 percent remained as ending stock seed, and 15 percent was exported for various uses in overseas markets (USDA-APHIS, 2010).

4.3.1.1 No Action Alternative: Current Acreage and U.S. Cultivation Range

Under the No Action Alternative, MON 87460 and its progeny would continue to be regulated articles under the regulations at 7 CFR part 340.. Independent of the No Action Alternative, both U.S. total corn acreage and the proportion of acreage planted with GE corn varieties is expected to incrementally increase through 2019, as indicated by USDA-ERS projections and previous trends of GE corn adoption (USDA-ERS, 2011b). Increased demand for animal feed in the livestock industry, favorable net returns for corn ethanol production, and the readily available number of regionally-adapted corn hybrid varieties is likely to sustain this increase in domestic corn cultivation, with additional corn acreage planted primarily at the expense of other crops (e.g., wheat and soybean) (USDA-ERS, 2011b). Former CRP land returned into agricultural production may also provide land for additional corn acreage, though this contribution is likely to be minimal due to minimal projected net reduction in U.S. CRP acreage from 2011 to 2020 (USDA-ERS, 2011b).

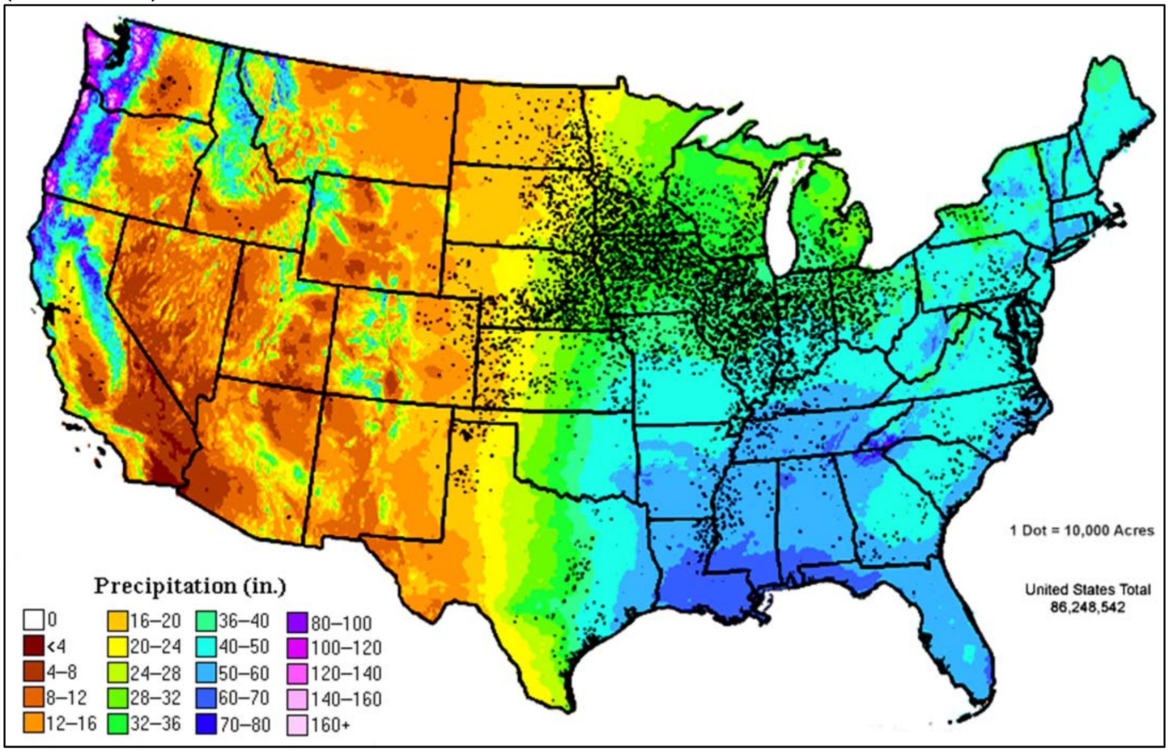
Conventional corn production with GE varieties will continue to increase independently of a determination of non-regulated status of MON 87460, based on overall trends from previous years, and USDA-ERS modeling projections of corn production and demand. Market demand across all consumer sectors is anticipated to dictate overall increases in U.S. corn acreage. Corn will continue to be commercially cultivated in 49 U.S. states, with the majority of production centered in Midwestern U.S. Corn Belt states under the No Action Alternative.

4.3.1.2 Preferred Alternative: Current Acreage and U.S. Cultivation Range

MON 87460 is designed to provide increased yield security in current corn-producing areas that are subject to moderate drought stress. As indicated in data presented by the Monsanto Company and the APHIS Plant Pest Risk Assessment of MON 87460 (Reeves, 2010; USDA-APHIS, 2010) the phenotype of MON 87460, with the exception of reduced yield loss under conditions of moderate drought stress, is similar to that of conventional corn. Like other domesticated corn varieties, MON 87460 does not exhibit traits that would allow it to establish outside the agricultural environment. Consequently, the cultivation range of MON 87460 is similar to that of conventional corn. A determination of nonregulated status of MON 87460 under the Preferred Alternative will likely lead to cultivation in areas that already support economically viable corn production.

In general, areas such as the Midwestern U.S. Corn Belt or any other region that receives sufficient precipitation ($\geq$30 inches) to routinely support high levels of corn production are unlikely to adopt MON 87460 due to a lack of improved agronomic performance under well-watered conditions (Figure 3). These well-watered corn production regions generally do not require supplemental irrigation and represented 85 percent of total corn cultivation area in 2007. A determination of nonregulated status of MON 87460 is unlikely to lead to adoption and significantly expand corn acreage in these areas primarily due to the absence of grower benefit when subject to well-watered conditions.

Figure 3. Average values for U.S. corn harvest and average annual precipitation (1971-2000).



Source: Data derived from the PRISM climate group database (http://www.prism.oregonstate.edu/) and USDA-NASS (USDA-NASS, 2007).

When subject to water-limited conditions (≤50 percent field capacity), MON 87460 displays significantly less yield loss while retaining similar measures of growth and developmental characteristics relative to conventional corn. Corn production regions subject to frequent moderate drought conditions may require supplemental irrigation, including the western dryland Great Plains and similar regions, and these represented 15 percent of all corn production regions in 2007. A determination of nonregulated status of MON 87460 under the Preferred Alternative is unlikely to significantly increase future corn acreage beyond USDA-ERS projected expansion in irrigated U.S. corn production regions. The MON 87460 trait is intended to increase grain yield security under conditions of moderate water stress. Minimum moisture requirements are similar between MON 87360 and conventional corn. When grown in water-limited field and greenhouse conditions, MON 87460 corn exhibits classic drought sensitivity symptoms, including reductions in yield, plant height, ear height, seedling vigor, and expected changes in plant height, chlorophyll content, and leaf roll (Reeves, 2010). The magnitude of these changes in MON 87460 under drought conditions is similar to that of water-limited conventional corn, with increasing water deficit producing increasingly severe growth and developmental symptoms. Taken in total, these data demonstrate that the negative effects of drought stress in MON 87460 are not alleviated and strongly suggest that areas unable to support economically viable production of conventional corn will also not support production of MON 87460, thus precluding the significant expansion of acreage in current irrigated corn production areas.

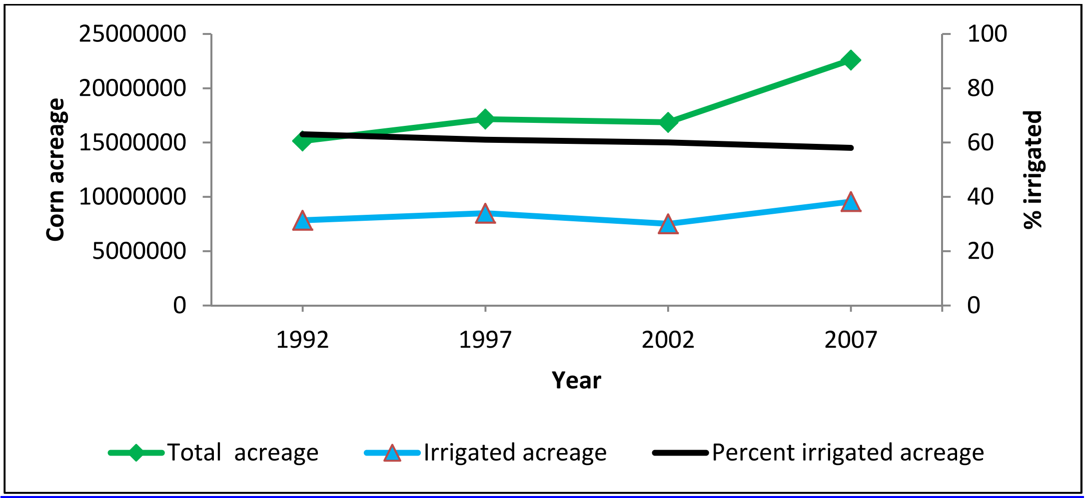
It is prudent to acknowledge, however, that the reduced yield phenotype of MON 87360 does not exceed the natural variation observed in regionally-adapted varieties of conventional corn (representing different genetic backgrounds) (Reeves, 2010). Thus, equally comparable varieties produced through conventional breeding techniques are readily available in irrigated corn production regions. Despite the availability of conventional drought tolerant corn varieties in these irrigated corn production regions, recent agronomic trends suggest that increases in corn acreage are often undertaken at the expense of other crops (e.g., wheat) on arable land or the return of former agricultural land (i.e., CRP land) into productivity, and not through cultivation of novel areas never managed for agricultural production now or in the foreseeable future (Table 5). Additionally, irrigated corn acreage and percent irrigated corn acreage in the Great Plains region has been relatively stable, despite the availability of conventionally-produced drought tolerant corn varieties (Figure 4). The increase in corn acreage in 2007 was observed across the U.S. in general, and was not specific to the Great Plains dryland region (USDA-ERS, 2010b). This further suggests that MON 87460, with its reduced yield phenotype not exceeding that observed in conventionally-produced drought tolerant corn varieties, will not significantly alter present trends in irrigated corn acreage.

Several reasons can be advanced for why corn acreage will not expand into areas not currently used for corn production. Existing drought tolerant varieties and conventional corn have similar moisture requirements and physiological responses to drought as do MON 87460. Also, adoption of MON 87460 is unlikely in the corn production in regions that are 85 percent well-watered and not requiring supplemental irrigation. Although conventionally-produced drought tolerant corn has been accessible to growers, there has been no associated expansion into novel areas in corn production regions. For these reasons, APHIS does not anticipate that a determination of nonregulated status of MON 87460 will significantly increase corn acreage beyond projected values nor alter current trends in crop production.

Table 5. Acreage for major field crops and Conservation Reserve Program (CRP) assumptions, long-term projections (USDA-ERS, 2011b).

	Planted Acreage (million acres)											
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
Planted acreage, eight major crops												
Corn	86.5	88.2	92.0	91.5	91.0	90.5	90.5	90.5	91	91.5	92.0	92.0
Sorghum	6.6	5.4	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0
Barley	3.6	2.9	3.2	3.2	3.2	3.2	3.2	3.2	3.2	3.2	3.2	3.2
Oats	3.4	3.1	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Wheat	59.2	53.6	57.0	55.5	54.5	53.0	52.0	51.5	51.5	51.5	51.0	51.0
Rice	3.1	3.6	3.3	3.2	3.2	3.2	3.3	3.3	3.3	3.3	3.3	3.3
Upland Cotton	9.0	10.8	12.8	12.5	12.2	12.0	11.9	11.8	11.8	11.7	11.7	11.6
Soybeans	77.5	77.7	78.0	78.3	78.5	79.0	79.5	79.5	79.5	79.5	79.5	79.5
Total	248.9	245.3	255.3	253.2	251.1	249.9	248.9	248.8	249.3	249.7	249.7	249.6
CRP acreage assumptions												
Total CRP	33.7	31.4	31.9	31.9	31.9	31.9	31.9	32.0	31.9	31.9	31.9	31.9
Total plus CRP	282.6	276.7	287.2	285.0	283.0	281.9	280.8	280.8	281.2	281.6	281.6	281.5

Figure 4. Total, irrigated, and percent irrigated corn acreage in the western dryland Great Plains.



Values represent the average of irrigated acreage in Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming (USDA, 2009)

4.3.1.3 Cumulative Effects: Current Acreage and U.S. Cultivation Range

Cumulative effects of a determination of nonregulated status of MON 87460 are unlikely. Neither the No Action Alternative nor Preferred Alternative of a determination of nonregulated status of MON 87460 will directly cause an increase in agricultural acreage devoted to corn production beyond projected USDA-ERS increases. There are no anticipated changes to the availability of GE and non-GE corn varieties on the market under either alternative. The projected increase in corn acreage that occurs independently of MON 87460 will be sustained by both market demand for corn products and the large number of corn hybrid varieties that are readily available to growers.

4.3.2 Cropping Practices

Corn is an extensively managed crop plant, requiring significant management considerations regarding tillage, agricultural inputs, and rotation strategy. Decisions concerning corn agronomic practice are dependent on grower want and need, and ultimately reflective of external factors including geography, weed and disease pressure, economics of management of yield, and production system [rotation] flexibility (Giannessi, 2005; Olson and Sander, 1988). For example, corn intended for grain is likely to require less tillage and frequency of herbicide/pesticide application relative to seed corn, due to the increased vigor and increased resistance to pest and disease of hybrid corn varieties relative to inbred corn lines. Consequently, choice of management practice often dictates marketability of a corn product, with certain agricultural consumer sectors stipulating requirements and restrictions regarding corn production methods.

Of the numerous agricultural inputs required for corn grain production, moisture readily impacts growth and yield. Inadequate moisture at any stage of development is detrimental to the plant, though water deficit during grain fill is most strongly correlated with reduced kernel number and weight. For example, four consecutive days of visible wilting prior to tassel development or anthesis can reduce grain yields by 25 percent. This same duration of stress during grain fill can cause a 40 to 50 percent yield reduction (Hesterman and Carter, 1990). In contrast to water stress impacts during vegetative growth, subsequent irrigation after water-deficient conditions cannot mitigate the negative impacts of drought on corn productivity and grain yield.

4.3.2.1 No Action Alternative: Cropping Practices

Under the No Action Alternative, MON 87460 will continue to be regulated, and corn production will continue as currently practiced. Corn will continue to be cultivated under a variety of management strategies and sold to a variety of markets. Maintaining the regulated status of MON 87460 under the No Action Alternative will not impact number of corn varieties available for growers, a large number estimated between 1000 (Pioneer, 2008) and 4000 (Monsanto, 2010). Widespread adoption of GE corn will continue in the U.S., easily accounting for the majority of corn produced.

Current corn management practices are likely to continue under the No Action Alternative. Growers make choices to use certain pesticides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Olson and Sander, 1988). No-till production of corn will continue to increase under the No Action Alternative, effectively mitigating the negative impacts of conventional tillage and associated soil erosion (Fawcett and Caruana, 2001). Additionally, agronomic practices involving the application of external inputs, such as herbicide, pesticide, and moisture, will remain as it is practiced today. As an example of the pesticides used during the production of field corn, the Pesticide Action Network has an online database, including a detailed description of all the pesticides used in corn agriculture in California (Kegley et al., 2010). It lists the top 50 pesticides (e.g., herbicides, insecticides, fungicides) used in California corn production. Any effects due to crop rotation, tillage and pesticide use in the agricultural production of seed corn and commercial corn will remain the same under the No Action Alternative. Rotation strategies for corn will continue as practiced today, with market demand and available technology strongly influencing corn rotation practices, under the No Action Alternative.

4.3.2.2 Preferred Alternative: Cropping Practices

Under the Preferred Alternative, a determination of nonregulated status of MON 87460 is unlikely to significantly impact cropping practices in non-irrigated corn production regions, as these regions already receive sufficient precipitation to limit adoption. These corn cropping practices include tillage choices, type and frequency of agricultural inputs, and crop rotation strategies. Consequently, corn cropping practices in these regions are unlikely to be significantly impacted by MON 87460 due to the low likelihood of adoption.

A determination of nonregulated status of MON 87460 and adoption in target regions, including the western dryland Great Plains and similar areas subject to frequent and moderate drought stresses, is also unlikely to significantly impact corn cropping practices. MON 87460 exhibits similar agronomic and growth characteristics to conventional corn, with the exception of reduced grain yield loss under water-limiting conditions. Consequently, it is not anticipated that MON

87460 will significantly differ from conventional corn in responding to fertilizer or moisture application. In particular, MON 87460 displays similar soil moisture depletion rates and physiological responses to water-limiting conditions as conventional corn, strongly suggesting that irrigation practices for optimal grain yield between MON 87460 and conventionally-produced drought tolerant corn varieties will not differ.

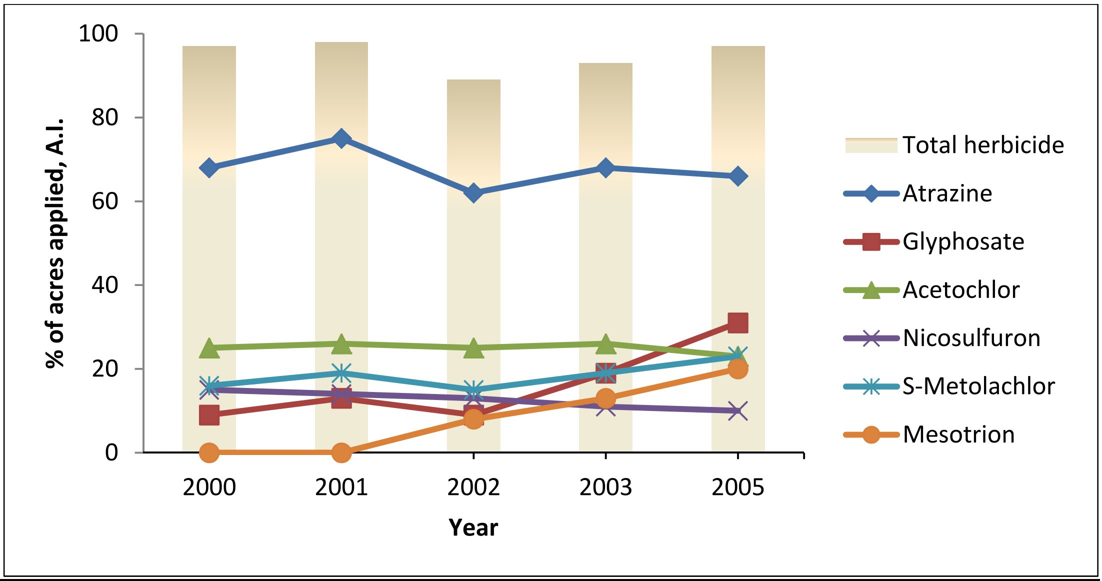
MON 87460 is designed to constitutively express the *E. coli cspB* RNA chaperone. No pesticide (e.g., glyphosate tolerance or *Bt* protein production) traits are co-engineered into the MON 87460 event. Despite the absence of herbicide tolerant or insect resistant traits in MON 87460, pesticide use is not anticipated to change existing trends following its adoption in irrigated corn production regions. While agricultural trends in total pesticide use is currently debated (Benbrook, 2009; Fernandez-Cornejo, et al., 2009), adoption rates of GE herbicide-tolerant or pesticide-resistant corn varieties in select western dryland Great Plains states that participate in the USDA-ERS Corn Estimating Program (Table 6) indicate that substantial corn acreage is subject to regular pesticide application. Introduction of herbicide-tolerant corn varieties, in particular glyphosate-tolerant corn, has not significantly affected corn acreage managed with total herbicide application (Figure 5). However, MON 87460 may facilitate a shift in specific herbicide product use. While use trends in the six most frequently applied herbicides in 2005 demonstrate relatively stable total herbicide use, both glyphosate and mesotrione application area have progressively increased since 2000 (Figure 5). If MON 87460 is offered without tolerance to glyphosate, it may signal a shift away from glyphosate and an increased reliance on other herbicide products. Similarly, a shift could also occur in insecticide application, if the drought tolerant trait were offered without an insect-resistance trait in MON 87460. Given typical corn offerings, corn hybrid varieties produced with MON 87460 will be highly likely to be stacked with other nonregulated pesticide traits since stacks of traits represent an increasing proportion of commercially-available corn varieties (Table 6). Based upon this observation, overall impact to current corn pesticide use practices are likely to be minimal. Adoption rates of stacked varieties are also likely to increase over time, as demonstrated by previous trends (USDA-ERS, 2010a). Accordingly, because of the popularity of herbicide tolerant crops, levels of tillage are likely to continue as currently practiced.

Table 6. Percentage of herbicide-tolerant, insect-resistant, stacked trait, and total GE corn in select Great Plains states.

State	Herbicide tolerant (%)	Insect resistant (Bt) (%)	Stacked (%)	Total GE (%)
Kansas	28	22	40	90
Nebraska	24	27	45	96
North Dakota	34	22	37	93
South Dakota	29	6	60	95
Wyoming	27	18	40	85

Source: (USDA-ERS, 2010a).

Figure 5. Herbicide application trends in U.S. corn production, 2000-2005.



Source: (http://www.nass.usda.gov/).
Note: Trends represent the six most frequently applied herbicides in corn (2005)

4.3.2.3 Cumulative Effects: Cropping Practices

A determination of nonregulated status of MON 87460 is not anticipated to have any cumulative effect on tillage, agricultural input practices, or rotation strategies related to U.S. corn production. MON 87460, with the exception of the phenotype of reduced yield loss under conditions of moderate drought stress, will not require significantly different crop production practices compared to other corn varieties. The requirements for crop rotation, tillage, and herbicide and pesticide use for both MON 87460 and any hybrid progeny produced from it will be exactly the same as those used for current corn varieties available to growers.

4.3.3 Organic

Certified organic corn represented 0.2 percent (194,637 acres) of the 93.6 million planted U.S. corn acres in 2007 (USDA-ERS, 2010d). The 2007 certified organic corn acreage represents an increase of approximately 9 percent from the 131,000 certified organic acres in 2005. Based on certified organic trends, it can be anticipated that organic acreage devoted to corn production will increase over time.

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

Typically, there is more than one method for farms under organic practices to prevent unwanted pollen or seed from entering their fields including: isolation of the farm, physical barriers or buffer zones between organic production and non-organic production, as well as formal communications between neighboring farms (NCAT, 2003). The organic plan used as the basis for organic certification should include a description of practices used to prevent or reduce the likelihood of unwanted GE pollen or seed at each step in the farming operation, including planting, harvesting, storing and transporting the crop (Krueger, 2007; G Kuepper, et al., 2007; Riddle, 2004). Organic plans should also include mechanisms to monitor the risk of GE pollen or seed co-mingling with the organic crop (G Kuepper, et al., 2007). Farmers using organic methods are requested to let neighboring farmers know that they are using organic production practices and request that the neighbors also help the organic farmer reduce contamination events (Krueger, 2007; NCAT, 2003). Thus, commonly used production practices for corn, and the practical methods typically used by corn farmers using organic methods currently provide many measures that greatly reduce the likelihood of accidental gene flow between GE and non-GE corn fields. Efficacy of certified organic plans and practices to prevent the likelihood of unwanted substances is best represented by the parallel increases in both GE corn and organic corn production since 2000. These practices protect organic crops and thus maximize profits and price premiums accorded to corn under organic production. APHIS will assume that farmers are already using, or have the ability to use, these common practices as APHIS' baseline for the analyses of the following alternatives below.

4.3.3.1 No Action Alternative: Organic

Current availability of seed for conventional (both GE and non-GE) corn varieties, and those corn varieties that are developed for organic production, are expected to remain the same under the No Action Alternative. Under the No Action Alternative, MON 87460 and its progeny would continue to be regulated articles under the regulations at 7 CFR part 340. This however, will not change the ready availability of other corn hybrid varieties produced through GE methods. GE corn will continue to represent a large majority of corn production acreage, with GE corn totaling 86 percent of all corn production in the U.S. in 2007 (USDA-ERS, 2010a). Trends of conventional and organic commercial corn production will not change and will remain the same under the No Action Alternative. Planting and production of GE corn varieties and organic corn have both increased due to market demands over the last ten years, and these markets are likely to continue to increase under the No Action Alternative.

4.3.3.2 Preferred Alternative: Organic

A determination of nonregulated status of MON 87460 is unlikely to significantly impact organic farmers that choose not to plant or sell corn products produced through genetic engineering or other non-organic production systems. Despite the wide-spread adoption of conventional and GE corn in the U.S. that amounted to 99.8 percent of total corn production in the U.S. in 2007, organic corn production has also continued to expand in recent years (USDA-ERS, 2010d). This continued expansion of organic corn acreage, though minor relative to non-organic national and state corn production, reinforces the capacity of current organic system plans to avoid use of excluded methods (and thus, loss of NOP certification) and the efficacy of these plans to increasingly produce agricultural products to meet demand of target markets in spite of the overwhelming presence of non-organic farming systems.

States that represented major organic corn production areas ($\geq$ 10,000 acres) in the 2007 Agricultural Census included Iowa, Michigan, Minnesota, New York, and Wisconsin (Table 7). Organic corn production in these states represented 0.16 to 1.25 percent of total corn production in each state. Despite the presence of millions of corn acres produced through excluded methods, no organic grower in this, or any other organic corn production region, has lost organic certification status. Thus, presently certified methods to maintain organic production as prescribed by the National Organic Program is effective in the maintenance of organic corn production. Accordingly, regions that are not anticipated to adopt MON 87460, GE varieties currently represents the majority of cultivated corn, organic corn production would still represent a fraction of total corn production and prescribed NOP methods would be just as effective in preserving certified organic status.

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

State	Total Corn Production (acres harvested)*	Percent Non-organic	Organic Corn Production (acres harvested)**	Percent Organic
Alabama	288,881	100	0	0
Alaska	1	100	0	0
Arizona	61,408	100	0	0
Arkansas	587,858	99.992	45	0.008
California	675,445	99.588	2,780	0.412
Colorado	1,172,893	99.893	1,257	0.107
Connecticut	32,347	99.975	8	0.025
Delaware	200,827	100	0	0.000
Florida	100,542	99.978	22	0.022
Georgia	510,709	99.991	48	0.009
Hawaii	3,641	99.918	3	0.082
Idaho	333,022	99.999	4	0.001
Illinois	13,214,365	99.947	7,031	0.053
Indiana	6,528,585	99.977	1,533	0.023
Iowa	14,075,332	99.841	22,330	0.159
Kansas	3,847,088	99.903	3,746	0.097
Kentucky	1,409,781	99.990	138	0.010
Louisiana	726,897	100	0	0
Maine	28,703	98.631	393	1.369
Maryland	533,903	99.733	1,427	0.267
Massachusetts	21,575	99.754	53	0.246
Michigan	2,658,538	99.465	14,231	0.535
Minnesota	8,352,731	99.726	22,864	0.274

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

State	Total Corn Production (acres harvested)*	Percent Non-organic	Organic Corn Production (acres harvested)**	Percent Organic
Mississippi	888,049	100	0	0
Missouri	3,332,832	99.898	3,410	0.102
Montana	83,344	99.996	3	0.004
Nebraska	9,438,807	99.903	9,200	0.097
Nevada	6,006	100	0	0
New Hampshire	14,611	99.966	5	0.034
New Jersey	100,766	99.991	9	0.009
New Mexico	136,008	99.512	664	0.488
New York	1,099,413	98.754	13,703	1.246
North Carolina	1,028,533	99.933	689	0.067
North Dakota	2,528,921	99.953	1,189	0.047
Ohio	3,834,164	99.767	8,926	0.233
Oklahoma	301,443	99.999	3	0.001
Oregon	88,692	95.407	4,074	4.593
Pennsylvania	1,427,111	99.653	4,954	0.347
Rhode Island	2,549	100	0	0
South Carolina	388,481	100	0	0
South Dakota	4,841,686	99.933	3,245	0.067
Tennessee	838,499	99.998	16	0.002
Texas	2,121,694	99.859	2,990	0.141
Utah	68,303	100	0	0.000
Vermont	93,876	98.714	1,207	1.286
Virginia	530,781	99.816	974	0.184
Washington	294,929	97.651	6,927	2.349
West Virginia	46,918	100	0	0
Wisconsin	4,074,833	99.247	30,673	0.753
Wyoming	86,740	99.618	331	0.382

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

4.3.3.3 Cumulative Effects: Organic

Under both the No Action Alternative and the Preferred Alternative, a determination of non-regulated status of MON 87460 will not change market demands for corn produced through organic methods. A determination of nonregulated status of MON 87460 will add another GE corn variety to the conventional corn market. Conventionally produced corn (including GE corn) represents the vast majority of corn in states that produce organic corn, and a determination of nonregulated status of MON 87460 is not anticipated to significantly increase GE corn production in these areas. Thus, presently-approved methods for the production of organic corn are sufficient to preserve certified organic status. Organic corn production will likely increase in spite of the surrounding conventional corn production whether or not MON 87460 is deregulated pursuant to Part 340 and the Plant Protection Act.

4.4 PHYSICAL ENVIRONMENT

4.4.1 Water Usage and Water Quality

Approximately 4,000 gallons of water is required to produce 1 bushel of corn (NCGA, 2007). Water use by corn is generally related to growth and development; prior to tassel development/anthesis, corn generally requires 0.1 inches per day; during grain fill, this water requirement increases to generally 0.3 inches per day (McWilliams 2002). Relative to other monocot crop plants, corn generally requires more water for optimal grain yield; however, this amount is generally less than dicot crop plants, due to increased photosynthetic efficiency in carbon fixation.

Agricultural non-point source (NPS) pollution is the primary source of discharge pollutants to above- and underground bodies of water. Many different factors affect that NPS pollution frequency and amount, including the type of crop cultivated, plowing and tillage, and the application of fertilizers, herbicides, and pesticides (EPA, 2005). Discharge pollutants can occur in the form of direct chemical contaminants (fertilizer, herbicide, or pesticide derived) or direct physical particulates (erosion-related sediments), and indirectly contribute to higher water turbidity, increased algal blooms, and decreased oxygen content in a body of water (EPA, 2005).

4.4.1.1 No Action Alternative: Water Usage and Water Quality

Under the No Action Alternative, management practices that affect NPS frequency and abundance in current corn production systems would not change. MON 87460 will continue to be regulated, and thus, its interaction with water quality and usage will continue to be limited to areas that were approved for regulated release by APHIS. Water use and water quality in these release areas will not change, as MON 87460 will continue to share management practices with conventionally produced corn.

4.4.1.2 Preferred Alternative: Water Usage and Water Quality

The physiological response of MON 87460 is similar to that of conventional corn, with the only exception being reduced yield loss under water-limiting conditions. When subject to water deficit, both MON 87460 and conventional corn display similar magnitudes of effect on corn drought stress indicators, including but not limited to plant height, days to 50 percent pollen shedding/silking, grain moisture, and leaf chlorophyll content. The reduced yield loss phenotype of MON 87460 is not enabled by increased water uptake, as demonstrated by several lines of evidence. Firstly, patterns of shoot and root fresh/dry weight between MON 87460 and conventional corn are not significantly different under well-watered or water-limited conditions (Reeves, 2010). If water uptake were increased in MON 87460, it is plausible that shoot/root fresh weight would be increased in MON 87460 while root/shoot dry weight remained similar compared to conventional corn. This pattern, however, was not observed and its absence suggests that water uptake is not increased in MON 87460. The absence of increased water uptake is further validated by soil moisture depletion studies, where no significant differences in soil moisture depletion rates were observed between MON 87460 and conventional corn (Reeves, 2010). Taken in total, the physiological evidence and recorded measures of moisture depletion strongly indicate that MON 87460 does not inherently transport more water than conventional corn. Consequently, MON 87460 is unlikely to directly and significantly impact soil moisture availability, abundance, and usage in corn production regions any differently than conventional corn.

Additionally, water quality is unlikely to be significantly affected by a determination of nonregulated status of MON 87460. NPS pollution represents a major source of water quality impacts on above- and underground bodies of water. A major contributing factor to NPS pollution is soil erosion-mediated sedimentation and the resulting detrimental effects on soil structure and agrochemical runoff. The correlation between tillage practice and soil erosion is well documented, as is the correlation between no-tillage or reduced-tillage production systems, adoption rates of herbicide tolerant crops, and improved soil structure and quality. No-tillage or reduced-tillage strategies in corn production are contingent on continued herbicide use. MON 87460 is not anticipated to significantly affect herbicide use, and thus, is not anticipated to significantly affect no-till or reduced-till systems currently utilized in corn production systems. Accordingly, adoption of MON 87460 is unlikely to cause changes in current water quality trends associated with corn production practices.

4.4.1.3 Cumulative Effects: Water Usage and Water Quality

A determination of nonregulated status of MON 87460 is not anticipated to have any cumulative effect on water use or quality in current corn production regions. Water use is not significantly different between MON 87460 and conventional corn. Additionally, water quality as the result of NPS pollution in corn production regions is unlikely to be significantly different between MON 87460, as no-tillage or reduced tillage strategies will continue to be available and utilized in corn production regions.

4.4.2 Soil

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 several microbial groups such as bacteria, fungi, and protozoa (Bais et al., 2006). These interactions are generally complex and occur through multiple pathways. 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. Collectively, microbial and arthropod groups play an important and particular role in the nutriment cycling capacity of the soil (Hoeft, et al., 2000; OECD, 2003). Specific crop management practices used for GE plants, such as pesticide applications, tillage, and application of inorganic and organic fertilizers can alter soils and the microbial and arthropod populations associated with it.

4.4.2.1 No Action Alternative: Soil

Under the No Action Alternative, APHIS would not deregulate MON 87460, and its use would be limited to areas APHIS has approved for regulated releases. Interactions with the soil would be limited to the areas approved for regulated releases, and would be minor if any, due to the small proportion of land compared to commercial corn production acreage. Therefore, there would be negligible impacts on soil under the No Action Alternative.

4.4.2.2 Preferred Alternative: Soil

Under the Preferred Alternative, MON 87460 is not anticipated to significantly impact the quality of the soil on which it is cultivated, nor is it likely to significantly affect microbial populations or arthropod populations and the dynamic soil processes those organisms modulate. As previously described, tillage practice is strongly correlated with soil quality in agricultural production systems. The use of no-till or reduced till practices is unlikely to be significantly impacted by a determination of nonregulated status of MON 87460, as herbicide application strategies will continue to be available to facilitate use of low impact tillage practices.

Microbial and arthropod soil populations may be impacted by a corn crop through degradation of plant tissue following harvest and direct interaction with soil fauna through the corn root system. Compositional analysis of MON 87460 forage tissue (i.e., stems and leaves) revealed no significant or consistent differences between it and conventional corn. Additionally, analysis of the gene products produced by MON 87460, the neomycin phosphotransferase II and cold shock protein B have been shown to be safe for the environment (Reeves, 2010). In particular, the NPTII protein has regularly been used in the selection of many transgenic crop varieties that have been deregulated pursuant to Part 340 and the Plant Protection Act, further demonstrating the safety of this protein. Because of the similarities in composition between MON 87460 and conventional corn, and the examined safety of the MON 87460 gene products, it is not anticipated that degradation of MON 87460 plant tissue following grain harvest will significantly impact microbial and arthropod soil populations compared to conventional corn.

4.4.2.3 Cumulative Effects: Soil

APHIS identified no impacts on the affected environment for soil as a result of the Proposed Action. Therefore, no cumulative effects on the affected environment for Soil were identified as a result of the Preferred Alternative.

4.4.3 Air Quality

Air quality may be affected by a variety of agricultural-related activities, including smoke from agricultural burning, tillage, traffic and harvest emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizers (Aneja, et al., 2009; Hoeft, et al., 2000). These agricultural activities individually have potentially adverse environmental impacts on 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 (J. B. 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 (EPA, 2010b). Nitrous oxide may also be released following the use of nitrogen fertilizer. Aerial application of pesticides may cause impacts from drift and diffusion. Pesticides may volatilize after application to soil or plant surfaces and move following wind erosion (Vogel, et al., 2008).

4.4.3.1 No Action Alternative: Air Quality

Under the No Action Alternative, MON 87460 interactions with the air would be limited to the areas that were approved for regulated releases by APHIS. Cultivation practices associated with corn production would not be affected. Air quality would still be affected by agronomic practices associated with corn cultivation and commercial corn production such as tillage and pesticide application.

4.4.3.2 Preferred Alternative: Air Quality

As previously discussed in Section 4.3.3, cropping practices associated with corn cultivation and commercial production, including tillage and pesticide application, are not likely to be different between MON 87460 and conventional corn. Thus, a determination of nonregulated status of Mon 87460 will not change the use of tillage, use of agriculture equipment, irrigation, pesticide applications and fertilizer applications in commercial corn production.

The agronomic performance and physical impact of MON 87460 is similar to that of conventional corn, except under water-limiting conditions. When subject to water-limiting conditions, MON 87460 exhibits a reduced yield phenotype. Accordingly, the physical impact of MON 87460 on air quality is not anticipated to be significantly different from that of conventional corn, due to the requirement of similar intensive management practices between MON 87460 and conventional corn.

4.4.3.3 Cumulative Effects: Air Quality

APHIS has not identified any cumulative impacts for this issue. A determination of nonregulated status of MON 87460 is expected to on air quality due to similar cropping practices between MON 87460 or conventional corn. Both MON 87460 and conventional corn require intensive cropping practices for optimum grain yield, resulting in no cumulative impact on air quality related to those cropping practices.

4.4.4 Climate Change

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

4.4.4.1 No Action Alternative: Climate Change

Under the No Action Alternative, APHIS would not deregulate MON 87460, and its use would be limited to areas APHIS has approved for regulated releases. Agronomic management practices and phenotypic characteristics regarding MON 87460 are similar to those of conventional corn; thus, impact between corn varieties would be minimal. Additionally, measurable effects from these confined field releases would be minor due to the small scale of management and acreage relative to current corn production systems in the U.S.

4.4.4.2 Preferred Alternative: Climate Change

A determination of nonregulated status of MON 87460 is unlikely to significantly affect current corn management practices. Management decisions regarding agricultural affecters of climate change, including tillage, agricultural chemical application, and rotational strategies are not anticipated to differ between MON 87460 and conventional corn. In particular, due to the continued availability of herbicide choice in MON 87460 management, no-till or reduced till practices will likely continue to mitigate soil erosion, stabilizing soil quality attributes and reducing GHG emissions.

Agronomic performance and phenotypic characteristics of MON 87460 is not significantly different from conventional corn, with the exception of reduced yield loss under water-limiting conditions. Accordingly, the physical impact of MON 87460 on climate change is not anticipated to be significantly different from that of conventional corn. Intensive management will continue to be practiced on a scale similar to current levels of U.S. corn production, because of the phenotypic equivalence of MON 87460 and conventional corn.

4.4.4.3 Cumulative Effects: Climate Change

APHIS has not identified any cumulative effects for this issue. Agronomic and phenotypic equivalence between MON 87460 and conventional corn, with the exception of reduced yield loss under water-limiting conditions, is not anticipated to significantly impact current corn production strategies, and thus, current agricultural impacts on climate change.

4.5 Animal and Plant Communities

4.5.1 Animal Communities

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. The cumulative effects analysis for this issue is found below at "Cumulative Effects: Plants, Animals, Biodiversity."

4.5.1.1 No Action Alternative: Animal Communities

Under the No Action Alternative, environmental releases of MON 87460 would be under APHIS regulation, as they have since 2002 (USDA-APHIS, 2010). Animal incursions would be limited to regulated field trials and there would be no change in impacts on animals. A consultation with FDA was successfully completed for CSPB and NPTII proteins of MON 87460 (Appendix A), which demonstrated a lack of toxicity and allergenicity of MON 87460 for human and animal consumption. Based upon the FDA consultation, APHIS supports Monsanto's conclusions that MON 87460 is considered safe for animal consumption. USDA analysis shows that while some increase in corn acres is expected, CRP lands in 2011 through 2020 will not change significantly, so although some of these lands may be used for new corn production, these conversions to corn will likely be limited.

4.5.1.2 Preferred Alternative: Animal Communities

Under the Preferred Alternative, MON 87460 would be deregulated. The agronomic practices used to produce MON 87460 are the same as those used to produce conventionally grown corn.

The introduced gene products of MON 87460 do not contain pesticidal activity and are not aimed at any target organisms as a control measure. Therefore, the evaluation of potential effects on animals of MON 87460 focuses solely on the nontarget impacts from MON 87460, especially the introduced proteins, CSPB and the NPTII marker protein. APHIS analyzed the potential impacts of MON 87460 on animal species including (1) exposure from directly contacting or consuming MON 87460, (2) exposure from increased use of pesticides or herbicides, and (3) conversion of CRP land to MON 87460 corn production.

Several phenotypic (i.e., appearance or observable physical characteristics) and agronomic (i.e., relating to soils and crop production) traits encompassing five general data categories were evaluated for MON 87460 including: (1) phenotypic growth and development, including vegetative and reproductive growth, (2) germination and dormancy, (3) pollen viability and morphology, (4) plant interactions with insects, diseases, and abiotic stressors, and (5) persistence in cultivated fields or areas outside of cultivation (Reeves, 2010). No differences between MON 87460 and non-drought-tolerant corn were noted except for the intended drought-tolerant trait.

CSPB is not known to exert any effects on pest and non-pest organisms. Arthropod (pest and beneficial) abundance was assessed and indicated no significant impact on non-target organisms. APHIS concludes that no species exposed to MON 87460 showed adverse consequences and that MON 87460 is not different in its environmental interactions relative to conventional corn. Because no differences in physical traits or characteristics were observed between MON 87460 and conventional corn, it is not expected that MON 87460 would impact the behavior of arthropods found in or around corn fields.

MON 87460 is not expected to have nutritional effects on any animal species (including threatened and endangered species) that feed on it. Grain and forage samples of MON 87460 and a control from several locations were evaluated for major nutrients and secondary metabolites (Reeves, 2010). The results indicate that MON 87460 is compositionally and nutritionally equivalent to conventional corn except for the expression of the transgene proteins (CSPB and NPTII).

The transgene proteins in MON 87460 are not expected to affect animals through toxicity or allergenicity. The donor organism of the CSPB protein, *Bacillus subtilis*, is not pathogenic, is often used as a food additive, is present in many fermented foods, and has a history of safe consumption. The FDA acknowledged that enzyme preparations from *Bacillus subtilis* are generally recognized as safe (FDA, 1999). The petitioner assessed the risks to humans and animals from the transgene proteins present in the foods and feeds derived from MON 87460, and the results indicated no adverse effects, even at the highest tested dose levels (Reeves, 2010). Furthermore, the CSPB protein represents no more than 0.00007 percent of the total protein in the grain of MON 87460, and neither transgene protein shares any amino acid sequence similarities with known allergens, gliadins, glutenins, or protein toxins that have adverse effects on mammals. Because there is no toxicity or allergenicity potential with the transgene protein of MON 87460, there would be no direct or indirect toxicity or allergenicity impacts on wildlife species that feed on corn or the associated biological food chain of organisms. A consultation with FDA was successfully completed for CSPB and NPTII proteins of MON 87460 (Appendix A), which demonstrated a lack of toxicity and allergenicity of MON 87460 for human and animal consumption.

Former CRP land returned into agricultural production may also provide land for additional corn acreage, although this contribution is likely to be minimal because of small net reduction in U.S. CRP acreage by 2020 (USDA-ERS, 2011b). In the event that farmers converted current CRP land to MON 87460 production, some birds and mammals that use CRP land for food and/or cover may be displaced to nearby areas of similar habitat. The animals that could be present in CRP areas would vary depending on the region and type of habitat. The CRP was initially established to protect land against soil erosion by taking lands out of agriculture production and planting native vegetation. In turn, the native vegetation provided habitat to wildlife, most notably birds. Many bird species, such as grassland birds (e.g., grasshopper sparrows [*Ammodramus savannarum*], lark buntings [*Calamospiza melanocorys*], western meadowlarks [*Sturnella neglecta*], bobolinks [*Dolichonyx oryzivorus*]), ring-necked pheasants (*Phasianus colchicus*), sage grouse (*Centrocercus urophasianus*), quail (family Odontophoridae), and waterfowl use CRP land (Ferris and Siikämaki, 2009).

The introduced gene products of MON 87460 do not contain pesticidal activity and are not aimed at any target organisms as a control measure. As discussed in Cropping Practices Section (4.3.3.2 Preferred Alternative), MON 87460 does not contain any herbicide tolerant or insect resistant traits and adoption of MON 87460, either on its own or stacked with currently deregulated pesticide traits, is not anticipated to significantly change current corn agricultural practices.

APHIS has reviewed and accepts the data submitted by the applicant, which are similar to the data submitted during the FDA consultation process for the CSPB and NPTII proteins of MON 87460 (Appendix A). No major impacts on animals, either directly or indirectly, are expected from deregulating MON 87460; impacts would be similar to the No Action Alternative.

4.5.2 Plant Communities

Corn production acreage is host to many plant species as well. 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; those species will also vary depending on the geographic region where the corn is planted. Corn itself is not sexually compatible with any other plant species found in the U.S. The cumulative effects analysis for this issue is found below at "Cumulative Effects: Plants, Animals, Biodiversity."

4.5.2.1 No Action Alternative: Plant Communities

Under the No Action Alternative, environmental releases of MON 87460 would be under APHIS regulation, as they have since 2002 (USDA-APHIS, 2010). No changes in impacts on plant species compared to any current effects due to conventional corn varieties are anticipated.

4.5.2.2 Preferred Alternative: Plant Communities

MON 87460 is not expected to become more invasive in natural environments, compete with native vegetation, or have any different effect on habitat than conventional corn (USDA-APHIS, 2010). Corn struggles to survive without human assistance and does not possess traits that are characteristic of successful weeds (H. G. Baker, 1965; Galinat, 1988; Keeler, 1989). Like many domesticated crops, corn seed from a previous year's crop can lie dormant over winter and germinate the following year. For example, corn seedlings often established themselves in soybean fields following a corn crop. Physical or chemical methods are often applied to eradicate these corn seedlings. Any seedlings not removed do not typically result in feral populations in subsequent years.

<u>Possible Weediness of MON 87460</u>

For the majority of the agronomic traits assessed, there were no statistically significant differences between MON 87460 and nontransgenic control (Reeves, 2010). No biologically meaningful differences were detected in the germination and dormancy of seed from MON 87460. In particular, the absence of hard seed supports a conclusion of no increased weediness potential of MON 87460 compared to conventional corn for germination and dormancy characteristics (Reeves, 2010). No differences were detected in pollen morphology or viability between MON 87460 and the control (Reeves, 2010). Results from the genotype-environmental interaction assessments also support the conclusion that MON 87460 has no increased susceptibility or tolerance to specific diseases, arthropods, or abiotic stressors beyond drought. Development of a deep root system is typically one of the agronomic traits that have the potential to enhance weediness in the natural environment. However, that may not be the case with corn, as inbred lines with poor early root development exhibited higher yields under drought stress than ones with accelerated early development of roots (Bruce et al., 2002). It has been reasoned that the improved performance of corn cultivars to drought stress probably comes from better water use efficiency (Messmer et al., 2009). Finally, MON 87460 was not altered in its ability to volunteer in cultivated fields or survive in areas not managed for agricultural production compared to conventional corn.

The data submitted to APHIS indicate that MON 87460 exhibits no characteristics that would improve the ability of this corn to survive without human intervention, and that its cultivation will not interfere with the cultivation of other corn hybrids or result in its uncontrolled spread into non-agricultural environments. Because MON 87460 does not possess traits of a successful weed and would not spread into non-agricultural environments, there would be no impact to natural environments or habitats.

<u>Possible Weediness of MON 87460 if Hybridized with Other Plants</u>

MON 87460 is not expected to form hybrids with any plant species (including threatened and endangered species). APHIS evaluated the potential for gene flow to occur from MON 87460 to sexually compatible wild relatives. As stated previously, cultivated corn 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; Wilkes, 1967). Corn and teosinte are genetically compatible, wind-pollinated, and can hybridize when close to each other, which is only likely to occur in Mexico and Guatemala because teosinte is not present in the U.S., except for a few small feral populations of *Zea mexicana* in Alabama, Florida, Maryland (USDA-NRCS, 2010), and *Zea perennis* in South Carolina (USDA-NRCS, 2011). *Tripsacum* species have one less chromosome than corn but can hybridize with corn, although it is very difficult and requires special techniques, and the hybrids have a high degree of sterility and are genetically unstable (Mangelsdorf, 1974). Crosses between corn and *Tripsacum dactyloides* can be made, but only through human intervention and, even then, it is extremely difficult (CFIA, 1994). MON 87460 is not likely to hybridize with sexually compatible species in the U.S. because of differences in factors such as flowering time, geographical separation, and development factors (Doebley, 1990a, 1990b; Ellstrand et al., 2007; Galinat, 1988). *Tripsacum dactyloides* and *Tripsacum floridanum* would not be affected by MON 87460 because of the difficulty of hybridizing with these species. The potential impact due to the limited potential for gene flow into teosinte is not expected to be any different than that of other cultivated corn varieties. Based on these considerations, MON 87460 would pose no direct or indirect impacts on sexually compatible wild relatives.

Other Possible Impacts

The introduced gene products of MON 87460 do not contain pesticidal activity and are not aimed at any target organisms as a control measure. As discussed in Cropping Practices Section (Preferred Alternative), MON 87460 does not contain any herbicide tolerant or insect resistant traits and adoption of MON 87460, either on its own or stacked with currently deregulated pesticide traits, is not anticipated to change current corn agricultural practices.

Minor impacts on plant populations could occur if farmers converted current CRP land to MON 87460 production. The extent of impacts depends on the amount of CRP land converted to agriculture. However, the USDA (USDA-ERS, 2011b) sees no increase in corn acreage from 2011 through 2020 and little change in CRP land; and an increase in corn in 2011 appears to be at the expense of wheat acreage. As previously noted, cropland in the U.S. has been declining as more cropland has been converted to other types of land than other types of land have been converted to cropland (NRCS, 2011).

Overall, no major impacts on plants, either directly or indirectly, are expected from deregulating MON 87460; impacts would be similar to the No Action Alternative.

4.5.3 Biodiversity

Biological diversity, or the variation in species or life forms in an area, is highly managed in agricultural systems. Farmers typically plant crops that are genetically adapted to grow well in a specific area of cultivation and have been bred for a specific market. In the case of corn agriculture, varieties have been developed for food processing needs (e.g., waxy corn), consumer qualities (e.g., blue corn or white corn), or for use as a vegetable (e.g. sweet corn). In conventional agriculture, farmers want to encourage high yields from their corn crop, and will intensively manage the 'plant communities,' or weeds, found in corn crops through chemical, cultural, or mechanical means. Animals, particularly insect and other pest species, will also be managed through chemical and cultural controls to protect the crop from damage by certain animal pests. Therefore, the biological diversity in agricultural systems (the agro-ecosystem) is highly managed and may be lower than in the surrounding habitats. Biodiversity in an agro-ecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agro-ecosystem; 2) permanence of various crops within the system; 3) intensity of management, including selection and use of insecticides and herbicides; and 4) extent of isolation of the agro-ecosystem from natural vegetation (Southwood and Way, 1970).

4.5.3.1 No Action Alternative: Biodiversity

Under the No Action Alternative, environmental releases of MON 87460 would be under APHIS regulation. Animal and plant species that typically inhabit seed corn and commercial production systems will be continue to be affected by the management plan of typical conventional corn production, which includes the use of mechanical, cultural, and chemical control methods.

4.5.3.2 Preferred Alternative: Biodiversity

As discussed above in Plant and Animal Communities (of Environmental Consequences section) the Preferred Alternative is expected to have no impact on animal and plant species (including threatened and endangered species and critical habitat) for areas where the adoption of MON 87460 would not convert CRP land to MON 87460 production. It is not expected that use of MON 87460 in existing corn field would result in any changes in herbicide or pesticide application. Cultivation of MON 87460 seed requires the same agronomic practices as conventional corn production. Animal and plant species that typically inhabit seed-corn production systems will be managed as in conventional corn production, likely with the use of mechanical, cultural, and chemical control methods. Potential overall impacts from the introduction of MON 87460 into existing cornfields that would not require a change in herbicide or pesticide use would be similar to the No Action Alternative. Therefore, there would be no impact to biodiversity under this scenario of the Preferred Alternative.

For actions where: 1) MON 87460 would replace another crop; 2) land would be converted from inactive cropland to active cropland using MON 87460; 3) planting MON 87460 would require an increase in pesticide or herbicide use; or 4) CRP lands would be converted to MON 87460 production, the impact to biodiversity would be considered minor based on the following discussion.

The replacement of a different crop (such as soybeans) to MON 87460 may likely result in a shift in biodiversity (different animals and plants might be present). However, as previously stated, biodiversity in any agricultural system is highly managed, and rotating from one crop to MON 87460 would not be likely to affect the overall species richness or abundance.

If farmers substituted organic corn cultivation with MON 87460 cultivation, local biodiversity could decline. Bengtsson et al. (2005) analyzed the effects of organic farming on species richness and abundance using meta-analysis of literature published before December 2002. Their results indicated that, compared to conventional farming systems, organic farming often has positive effects on species richness and abundance, but that its effects are likely to differ between organism groups and landscapes. For example, the Bengtsson et al. (2005) review showed that, on average, organisms were 50 percent more abundant in organic farming systems than conventional systems, but the results were highly variable between studies and organism groups. Birds, predatory insects, soil organisms, and plants responded positively to organic farming, while non-predatory insects and pests did not. The authors suggest that positive effects of organic farming on species richness can be expected in intensively managed agricultural landscapes, but not in small-scale landscapes comprised of many other habitat types (Bengtsson et al., 2005).

The biodiversity in agricultural systems is highly managed and is likely lower than in the surrounding habitats. Therefore, the conversion of inactive cropland or CRP land to MON 87460 production and use of pesticides and herbicides likely may result in a loss of local biodiversity. The level of impact would depend on the amount of inactive cropland and CRP land converted to agriculture and the types of herbicides or pesticides used. APHIS cannot predict the amount of inactive cropland and CRP land that may be converted to MON 87460 production. As noted earlier, if all converted CRP land were used to grow corn, the impacts would represent only 3 percent of all existing corn planting. In addition, USDA- ERS expects that total CRP lands will change little between 2011 and 2020 (USDA-ERS 2011; see also Environmental Scope, Section 4.1). Consequently, no notable impacts on animal and plant populations are expected to occur at the regional level. Finally, cropland in the U.S. has been declining, as more cropland has been converted to other types of land than other types of land have been converted to cropland (NRCS, 2011).

4.5.3.3 Cumulative Effects: Animal and Plant Communities and Biodiversity

No direct or indirect impacts of MON 87460 on plants were determined because MON 87460 does not possess weedy characteristics, and is unlikely to introgress into wild plants or to corn agriculture. Consequently, no cumulative impacts would be expected.

There may be some potential for certain foreseeable actions to contribute to cumulative impacts in conjunction with adoption of MON 87460. One action could include industry stacking together multiple drought tolerant corn varieties with additional traits such as insect resistance, and herbicide tolerance. Non-regulated GE traits may be stacked with MON 87460 would also have been evaluated by USDA, EPA and FDA, and will be as safe as the non-transgenic corn varieties. Continued conversion of inactive cropland and CRP lands to croplands that could be planted to MON 87460 may lead to a decrease in biodiversity (because of increased used of herbicides, pesticides and the general effects of agriculture) and displacement of plants and animals. However, as shown previously, USDA does not expect large scale conversion of CRP acres to corn production. In CRP land that is converted to corn acreage, adoption of MON 87460 would not result in any cumulative impact on animal and plant communities because corn cropping practices, including pesticide application, is not anticipated to be significantly different from conventional corn.

If MON 87460 corn were grown without additional traits, different herbicides would be used than those typically used in herbicide-tolerant crops, but as demonstrated in the Preferred Alternative analysis under Cropping Practices, no change to total pesticide application area of corn would be expected, though shifts in pesticide product use may occur. However, also as discussed in Cropping Practices Section (4.3.2.2 Preferred Alternative), any shift of specific pesticide product use would likely be mitigated by hybridization of MON 87460 with other deregulated herbicide-tolerant or insecticide traits that are likely to be already present in the area.

4.5.4 Gene Flow

4.5.4.1 No Action Alternative: Gene Flow

Under the No Action Alternative, environmental releases of MON 87460 would be under APHIS regulation. Horizontal gene flow from corn to other organisms would be unlikely to occur. Gene flow to other GE and conventional crops, to the extent that it occurs will continue to occur, with little impact on marketing and sales of corn seed and corn for processing.

4.5.4.2 Preferred Alternative: Gene Flow

Pollen- or seed-mediated gene flow would represent potential direct impacts of MON 87460 but are not expected to pose a greater impact than that of currently cultivated corn varieties. Besides the ability to exhibit a reduced yield phenotype when subject to water-limiting conditions, MON 87460 does not notably differ from other corn varieties. Under well-watered conditions, MON 87460 did not notably differ from non-GE comparable varieties (Reeves, 2010). No evidence of changes to pollen attributes or seed attributes were observed (Reeves, 2010). Gene flow will therefore be determined by the factors discussed above, including differences in flowering time between hybrid GE lines and inbred lines (such as some organic crops), distance between a pollen source and recipient plants, and the impact of environmental factors such as wind, temperature, and humidity on viability and dispersal of corn pollen.

To review, pollen-mediated gene flow from MON 87460 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 less 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. a very minor impact.

Based on the information detailed in the sections above, pollen-mediated gene flow between corn crop fields planted with MON 87460 and neighboring corn fields is not expected to be substantially different from pollen-mediated gene flow between any other two corn varieties. As reviewed by Sanvido et al., 2008, pollen-mediated gene flow decreases rapidly with increasing distance from source crop fields, regardless of corn cultivar or variety. As such, the pollen-mediated gene flow from MON 87460 will not be substantially different and represents a minimal impact. Section 2.1.2 describes the cropping practices corn farmers use to maintain seed purity between corn varieties. Because there were no identified differences in traits (besides drought tolerance) between conventional and MON 87460, there is no reason to expect that cropping practices utilized to maintain genetic purity of corn varieties (AOSCA, 2009) would be any less effective for cultivation of MON 87460. Because MON 87460 exhibits decreased yield loss under water-limiting conditions (Reeves, 2010), it can be suggested that drought conditions may increase the risk of pollen-mediated gene flow due to less pollen abortion or changes in floral phenology. However, no evidence for changes in pollen structure, function, abundance, or dispersal was reported in MON 87460 under water-limiting conditions (Reeves, 2010). Under conditions of drought, corn plants (conventional, organic, or GE) can continue to produce pollen, but the window of fertilization is shortened because of the delaying effects of drought on deployment of female reproductive structures (silks) and reductions in pollen viability (R. C. Hall and Twidwell, 2002). Therefore, pollen-mediated gene flow from MON 87460 under drought conditions would not be expected to differ from conventional corn and would be limited, in part, because of shortened pollen viability as a result of dry conditions and a reduced window for fertilization on silks of adjacent corn fields.

Seed-mediated gene flow is of minimal concern due to the lack of seed dispersal and feral traits in corn. As described in Section 2.1.2.2 all corn seed producers (including organic seed producers) use standard procedures to assure seed quality. In research conducted to evaluate MON 87460 (Reeves, 2010), the expression of the *cspB* conveys a drought resistance trait that decreases yield loss when subject to reduced water conditions. If MON 87460 seeds were able to successfully disperse out of crop fields by natural mechanisms (e.g., extreme weather) or human-mediated mechanisms (e.g., transport), persistence of the corn could not be expected to produce a feral population because the shatter and dispersal attributes of MON 87460 are not reported to be different from conventional corn. The only phenotypic difference between MON 87460 and conventional corn varieties is tolerance of mild drought conditions. Therefore, the ability to establish and persist as a feral weed would be extremely low and certainly not likely to be any greater than other varieties of corn. The drought tolerant modification would not allow feral corn seeds to colonize new habitats or become a greater weed, because the trait confers reduced yield loss and does not alter any other corn traits.

4.5.4.3. Cumulative Effects: Gene Flow

MON 87460 is not likely to increase the impact of gene flow to an extent greater than that of other corn varieties and would also not likely do so when combined with other GE traits that have themselves been evaluated as having no traits that would increase potential gene flow. Additionally, no deregulated GE variety of corn has resulted in a change in the properties associated with pollen-mediated or seed-mediated gene flow from corn. Therefore, there are no expected cumulative impacts.

4.6 Human Health

This section focuses on whether the proposed action affects overall public health and worker safety. For MON 87460, the evaluation of human health impacts involves the potential effects of the two inserted genes – cold shock protein B (*cspB*) and neomycin phosphotransferase (*nptII*) – and the expressed proteins (CSPB and NPTII). Public health concerns relating to MON 87460 center on food and product safety, including allergenicity, toxicity, and nutritional changes (Section 4.6.1). Indirect health effects to workers, such as from changes in pesticide use, related to the farming of MON 87460 are considered (Section 4.6.2). Also, indirect food-safety issues from livestock feed, such as consumption of animal products from livestock, are addressed (Section 4.6.3).

4.6.1 Public Health

Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from MON 87460 must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Monsanto consulted with FDA about food and feed derived from MON 87460 and provided a comprehensive assessment of food and feed safety data on the CSPB and NPTII proteins in MON 87460. The FDA has determined Monsanto’s submission to be complete (FDA, 2010). MON 87460 does not contain a biotechnology-derived plant-incorporated protectant or a biological control organism, and therefore is not regulated by the EPA.

4.6.1.1 No Action: Public Health

Under the No Action Alternative, MON 87460 would continue to be a regulated article. Human exposure to this product would be limited to those individuals involved in cultivation under regulated conditions. Exposure to existing traditional and GE corn would not change under this alternative. The status of Monsanto's consultation with FDA on the CSPB and NPTII proteins in MON 87460 would not change under the No Action Alternative.

4.6.1.2 Preferred Alternative: Public Health

Under the Preferred Alternative, it is expected that members of the public would primarily come in contact with the introduced transgenes (i.e., *cspB* and *nptII*) and CSPB and NPTII proteins through dietary exposure to food and products derived from MON 87460. Generally, proteins containing cold shock domains are ubiquitous in nature, being present in many plants and common bacteria, including species that are normally present in gastrointestinal flora. Cold shock proteins have no known toxicity and are not associated with pathogenicity. Based on the evidence provided (Reeves, 2010), the CSPB and NPTII proteins are anticipated to present no potential adverse effects to exposed organisms, including humans, in the environment. The following paragraphs summarize the supporting information from the safety assessment performed for CSPB and NPTII proteins found in MON 87460.

Acute oral toxicity studies for the CSPB and NPTII proteins conducted on mice did not result in any observed adverse effects, even at the highest tested dose levels (Smedley, 2008). A dietary safety assessment was performed to evaluate the potential risks to humans and animals from CSPB and NPTII proteins present in the foods and feeds derived from MON 87460. The ratio of the no observable effect level (NOEL) for CSPB and NPTII to the estimated dietary intake, also called the margin of exposure (MOE), was estimated to be greater than or equal to 26,700 and 454,000,000 for the U.S. population, respectively. In general, MOEs of more than about 1,000 to 3,000 are considered an adequate margin of safety (GAO, 2001). For children aged 1 through 6 years, representing the age group with the highest corn to body weight ratio (i.e., most sensitivity), the MOE was greater than or equal to 11,400 and 208,000,000 for CSPB and NPTII, respectively.

Based on assessments performed with bioinformatic tools, such as the FASTA algorithm and the PROTEIN and TOXIN6 databases, CSPB and NPTII were shown not to share any amino acid sequence similarities with known allergens, gliadins, glutenins, or protein toxins which have adverse effects on mammals (Burzio et al., 2008; Tu, 2009).

The donor organism of the CSPB protein, *B. subtilis*, has been shown to be not pathogenic. Additionally, it has been frequently used as a food additive and is found in many fermented foods which have been safely consumed by humans for a long time. Enzyme preparations from this organism have been designated by the FDA as generally recognized as safe (GRAS) since 1999 (FDA, 1999b).

The CSPB protein shares a high percent of identity with CSPs present in other bacterial species widely used by the food industry and with CSD-containing proteins in plant species used as food.

The CSPB protein is homologous to the CSP proteins found in the genera *Lactobacillus*, *Lactococcus*, *Bifidobacterium*, and *E. coli*, which are normally present in gastrointestinal flora and, therefore, considered to be safe. The strains of lactic acid bacteria, *Bifidobacterium* and *Lactobacillus*, are the most common type of bacteria used in the dairy industry for preparation of probiotic products containing live bacterial cultures. In addition, *Bacillus*, *Lactobacillus*, and *Lactococcus* species containing CSPs are utilized in many food fermentation processes of milk, meats, cereals, and vegetables.

Digestive fate experiments conducted with the CSPB protein demonstrated that the full-length protein is rapidly digested in simulated gastrointestinal fluid, a characteristic shared among many proteins with a history of safe consumption. Proteins that are rapidly digestible in mammalian gastrointestinal systems are unlikely to be allergens when consumed. Additionally, the CSPB protein represents no more than 0.00007 percent of the total protein in the grain of MON 87460.

The safety of NPTII has been addressed in multiple publications (EFSA, 2004; Fuchs et al., 1993a; Fuchs et al., 1993b; Nap et al., 1992). Several products containing NPTII have been approved by regulatory agencies on a global basis. EPA established an exemption from the requirement of a tolerance for NPTII for use as a selectable marker in raw agricultural commodities (40 CFR Part 180.1134). In 2007, the European Food Safety Authority (EFSA) affirmed its conclusion that the presence of *nptII* does not pose a threat to human health or the environment. Moreover, the USDA previously evaluated the safety of NPTII in several biotechnology-derived commercial crops that have undergone previous safety assessments (e.g., so far NPTII was used as a selectable marker in 28 petitions deregulated by APHIS BRS; http://www.isb.vt.edu/cfdocs/biopetitions1.cfm), including corn.

Compositional comparisons between MON 87460 and conventional corn presented by Monsanto showed no biologically meaningful differences for grain and forage compositions either for major nutrients or for secondary metabolites (Reeves, 2010). Therefore, based on this data, it is reasonable to assume that the foods and feeds derived from MON 87460 can be considered compositionally equivalent to those derived from conventional corn.

Based on the assessment of laboratory data provided by Monsanto in the submitted petition and an analysis of the scientific literature (USDA-APHIS, 2010), along with the completion of the consultation process with FDA regarding the CSPB and NPTII proteins of MON 87460, APHIS has concluded that under the Preferred Alternative, a determination of nonregulated status of MON 87460 would have no expected impacts on public health.

4.6.1.3 Cumulative Effects: Public Health

There are no expected impacts on human health related to the Preferred Alternative. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to affect public health. Therefore, there are no cumulative effects identified for this issue.

4.6.2 Worker Safety

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.

4.6.2.1 No Action: Worker Safety

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, exposure to these agricultural chemicals during corn production would remain the same as under current conditions.

4.6.2.2 Preferred Alternative: Worker Safety

Agricultural production with MON 87460 does not require any change to the agronomic practices or chemicals currently used (i.e., pesticides) for conventional corn. Therefore, worker safety issues associated with the agricultural production of MON 87460 would remain the same as those under the No Action Alternative.

4.6.2.3 Cumulative Effects: Worker Safety

Worker safety issues related to agronomic practices and the use of pesticides during agricultural production of MON 87460 would remain the same under both alternatives. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to impact worker health and safety. Therefore, there are no cumulative effects identified for this issue.

4.7 Livestock Feed

As with human health, livestock ingestion of inserted genes and proteins in MON 87460, with subsequent human ingestion of livestock food products, is considered one of the primary concerns in MON 87460. In addition, horizontal transfer of genetic material to gastrointestinal bacteria is a concern. This section addresses the use of MON 87460 as animal feed, and the potential effects of this use on livestock health, especially as it pertains to any effects on human health from ingestion of or other exposure to livestock products such as meat and milk.

4.7.1 No Action: Livestock Feed

Under the No Action Alternative, APHIS would not deregulate MON 87460, and its use would continue to be limited to areas APHIS has approved for regulated releases. Thus, there would be no additional risks or benefits to livestock feed safety from MON 87460.

4.7.2 Preferred Alternative: Livestock Feed

As discussed in Sections 4.6.1 an extensive safety evaluation of the inserted genes (*cspB* and *nptII*) and proteins (CSPB and NPTII) expressed in MON 87460 indicated that they are not expected to be allergenic, toxic, or pathogenic in mammals. Additionally, no gene transfer to gastrointestinal flora is expected. Both CSBP and NPII proteins have a history of safe consumption in the context of other food and feeds (FDA, 2010).

Compositional analyses of forage and grain tissues from MON 87460 confirmed that the corn grain and forage derived from MON 87460, and the intended foods and feeds derived from MON 87460, can be considered compositionally and nutritionally equivalent to conventional corn hybrids that have a history of safe consumption that are currently in commerce. Therefore, any food, such as meat and milk, derived from animals that are fed MON 87460 are not expected to differ from food derived from animals fed conventional corn.

The results of a dietary safety assessment indicate that animals exposed to CSPB and NPTII present in the foods and feeds derived from MON 87460 will be low, with chickens, swine, and dairy cows consuming only nanogram quantities of each protein per kilogram of body weight (Reeves, 2010).

The FDA has evaluated horizontal gene transfer from the use of antibiotic resistance marker genes. The FDA has concluded that the likelihood of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans, animals, or the environment, is remote (http://vm.cfsan.fda.gov/~dms/opa-armg.html).

Based on the assessment of data provided by the applicant and review of additional literature, the Preferred Alternative is not anticipated to have any adverse effects on livestock feed and, consequently, humans.

4.7.3 Cumulative Effects: Livestock Feed

There are no expected impacts on human or livestock health related to the Preferred Alternative. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to affect livestock feed. Therefore, there are no cumulative effects identified for this issue.

4.8 Socioeconomics

The CEQ and NEPA define effects on the human environment broadly to include economic and social impacts in addition to physical impacts, although economic or social impacts, by themselves, would not trigger the need for an Environmental Impact Statement (EIS) (40 CFR 1508.8, 1508.14).

4.8.1 Domestic Economic Environment

Domestic demand for corn in the U.S. comes from its domestic use for feed, ethanol production, food, and seed, and totaled 11.1 billion bushels in the 2009/10 marketing year (USDA-ERS, 2011b). Exports added another 2 billion bushels to total U.S. corn use. Demand is satisfied almost entirely by domestic supply, with few imports, the U.S. being largely a net exporter of corn. The U.S. produced 13 billion bushels of corn in the 2009/10 marketing year and corn occupied the most acreage of any crop in the country (USDA-ERS, 2011b). In the 2009/10 marketing year, feed was approximately 40 percent of U.S. corn production, ethanol production was about 35 percent of U.S. corn use, food, seed, and industrial uses were approximately 45 percent, and exports the remaining 15 percent (USDA-ERS, 2011b). Seeds constituted approximately 1.7 percent of domestic corn production, with 5.6 percent being used for high fructose corn syrup, glucose and dextrose, and corn starch (USDA-ERS, 2010c).

Ethanol production from corn represented a much smaller share of demand before 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 (Westcott, 2007). 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 percent and the share of exports to grow to 16 to 17 percent. Prices are projected to remain historically high. According to the USDA, acreage is projected to increase to 92 million by 2020 from 88 million in 2010, approximately a 4.5 percent increase, at the expense of other crop acreage (USDA-ERS, 2011b).

U.S. corn production benefits from various Federal programs, including crop insurance, counter-cyclical payments, marketing loans, and the Average Crop Revenue Election program. Additionally, ethanol imports are discouraged through an import tariff of 54 cents per gallon. Corn is grown in all of the continental U.S., but more than 90 percent is grown in the top 18 producing states, mostly in the Midwest and Great Plains. The states with the most harvested acres of corn for grains and silage in the 2007 Agricultural Census were Iowa, Illinois, Nebraska, Minnesota, and Indiana (USDA, 2009).

Because MON 87460 is expected to reduce yield loss under water-limited conditions compared to conventional corn, it would most likely be adopted in areas subject to frequent moderate water deficit. It is also possible that irrigated corn-producing areas would benefit if adoption of MON 87460 would allow reduction of irrigation costs with net returns. These two conditions may be found in Western drylands. Areas that currently do not produce corn are less likely to benefit because they reveal fewer competitive advantages for corn production, although the possibility of expansion of corn acreage has been assessed earlier.

Corn production requires a steady supply of moisture totaling approximately 20 inches during the growing season to achieve maximum yields. Many U.S. states have average annual precipitation below 20 inches per year. Among those states, those with most non-irrigated acreage of corn harvested are North Dakota, Colorado, Montana, New Mexico, and Wyoming. States with average annual precipitation between 20 and 30 inches per year could also benefit from MON 87460, given variations in precipitation throughout the year and from one year to another. Among those states, those with most non-irrigated acreage of corn harvested are Minnesota, South Dakota, Nebraska, Kansas, and Texas (NOAA, 2010; USDA, 2009). States with annual precipitation of more than 30 inches per year also could also benefit. However, the increase in expected yields from adoption of MON 87460 would be less during times of higher annual average precipitation and of lower variation of precipitation throughout the year (and in between years). Therefore, there would be fewer incentives for adoption of MON 87460 in states with higher average annual precipitation. Of the 10 states identified above, all except Minnesota are in the Great Plains area of corn production, with Minnesota bordering this area in the Midwest.

The states with the most irrigated acreage of corn harvested are Nebraska, Kansas, Texas, Colorado, and California (USDA, 2009). Of these, all but California are in the Great Plains area of corn production. In Texas and Colorado, the share of total irrigated crop acres (not just corn acres) that had diminished yields due to irrigation interruption in 2008 was more than a quarter of the total (USDA, 2008).

Most of this section focuses on the states where MON 87460 adoption would be expected to result in more impacts on local yields and crop-related farm income. The geographic borders of the analyzed region are a simplification intended to facilitate analysis and should not be interpreted rigidly; some states included in this region have portions with considerably higher annual average precipitation than others and portion of states not included in this regional focus also might have corn production under non-irrigated areas routinely subject to water shortages. In addition, climate change could impact areas of greater or lesser annual precipitation in the future. This regional focus, however, is intended to emphasize the potential for regionally differentiated impacts, noting that impacts on other corn-producing areas could be similar, but arguably of a lesser degree.

There is no geographical difference in the U.S. among the areas of production of GE corn and areas of production of organic and non-GE corn. Although the demand for different types of corn depends on varietal traits that are often independent of the corn's GE or non-GE quality, there is a niche market for non-GE food and feed in the U.S., as evidenced by private labeling initiatives (e.g., Non-GMO Project) that offer third-party product verification and labeling for non-GMO products (Non-GMO-Project, 2010). There also is a growing niche market for organic products in the U.S. Sales of organic products have been growing quickly, having grown from $1 billion in 1990 to $24.8 billion in 2009 and 5.1 percent between 2008 and 2009 (OTA, 2010). To satisfy the demand for either organic or non-GE corn, producers have had to adopt specific production practices that have been widely used in the U.S. for more than a decade. However, in the case of organic corn production, there is some evidence that supply might be lagging behind demand (Greene, et al., 2009).

Corn seed production in the U.S. follows standards of varietal purity. The AOSCA offers a standard for production of non-GE corn seeds that allows for 1 percent presence of GE content (AOSCA, 2003).

The affected domestic environment is defined as any land in the U.S. that is currently producing crops that could incorporate a corn rotation, as well as land that could be converted from inactive cropland to active cropland, and land currently in the CRP that could be removed from the program and farmed. Within this affected environment, adoption of MON 87460 would be more likely in some geographic areas than in others. Therefore, the domestic economic environment most likely affected by deregulating MON 87460 would be the area of its adoption. To the extent MON 87460 adoption allows for increased returns from corn production, MON 87460 deregulation could increase the supply of corn and corn-related farm income.

Because MON 87460 is expected to decrease yield loss in water-limited conditions, deregulation of MON 87460 could impact total domestic corn production and corn acreage. Because it is a GE crop, the potential for unintended presence in non-GE corn fields could impact marketing non-GE and organic corn.

4.8.1.1 No Action: Domestic Economic Environment

Under the No Action Alternative, any potential increase in corn production due to the decreased yield loss under water-limited conditions offered by MON 87460 would not be realized. It should be noted that demand for U.S. corn is projected to remain strong due mostly to the increases in global demand (exports) and the maintenance of incentives for use of ethanol.

4.8.1.2 Preferred Alternative: Domestic Economic Environment

Varieties of Drought Tolerant Corn Available

Deregulating MON 87460 would allow the commercialization of a GE corn variety that is expected to reduce yield loss by six percent or more under water-limited conditions compared to conventional corn (Reeves, 2010). There appears to be two types of drought tolerant corn seed available: the incrementally improving hybrids and some that are more advanced, which are just making an appearance in the marketplace. Regionally marketed conventional traits apparently have similar drought tolerant properties to those offered by MON 87460. To some extent, all U.S. corn varieties have been becoming more drought resistant over time (Yu and Babcock, 2010), but others have been specially selected for drought tolerance. A current offering of seed might include 22% of the options with a high drought tolerance rating (for maturities 79-119) (DeKalb, 2011). Some companies currently offer corn seed that expresses exceptional drought tolerant characteristics, which are generated without using transgenic techniques (e.g., Optimum Aquamax, 5% yield advantage under water stress, limited availability in 2011 season) (Pioneer-Hi-Bred, 2010, 2011a, 2011b). The impacts of deregulating MON 87460 would likely not be different from these other existing seed options.

Analysis of Increases in Corn Acreage

Beyond increased expected yields in areas currently producing corn and subject to water-limited conditions, an increase in corn acreage (without expansion necessarily to new agricultural areas) is theoretically possible due to the increased expected returns to corn production. An estimate depends on the expectations regarding rainfall, decreased yields in conventional corn during water-limited conditions, decreased yield loss provided by MON 87460 during water-limited conditions, the impact of yields on returns, the elasticity of corn acreage to increased returns, and the extent of adoption of MON 87460. Because of uncertainties regarding each of these factors, a reliable estimate is not possible. However, for illustrative purposes, a numerical exercise is provided below for a hypothetical scenario. The variables assumed in this exercise should not be considered to be those APHIS expects to actually occur, but rather reasonable assumptions, given the illustrative purpose of this exercise and current available information.

Assumptions:

1. Yields of conventional varieties are expected to be 15 percent lower during water-limited conditions, as the minimum assumed in the Monsanto variety trials (Reeves, 2010) (i.e., yield under water-limited conditions would be 85% of the yield under adequate water conditions).

2. MON 87460 is expected to provide a 6 percent reduction in yield losses under those circumstances (Reeves, 2010).

3. Farmers perceived a 50 percent chance of water shortages (i.e., half the planted corn is subjected to water-limited conditions and half is under adequate water conditions)

Expected yield returns in corn farming would increase as estimated below:

Expected yield with conventional variety $= Yh \times 0.5 + Yl \times 0.5$

$= Yh \times 0.5 + 0.85Yh \times 0.5$

$= 1.85Yh \times 0.5 = 0.925Yh$

Expected yield with DT Corn $= Yh \times 0.5 + Yl \times 1.06 \times 0.5$

$= Yh \times 0.5 + 0.85Yh \times 1.06 \times 0.5$

$= 1.901Yh \times 0.5 = 0.9505Yh$

Increased expected yield with DT Corn =

$$\frac{\text{(Expected yield with DT corn- Expected yield with conventional variety)}}{\text{(Expected yield with conventional variety)}}$$

$= (0.9505Yh - 0.925Yh) / 0.925Yh$

$= (0.9505 - 0.925)Yh / 0.925Yh = 2.76\%$

Where:

Yh - yield under adequate water conditions; and

Yl - yield under water shortage (Yl = 0.85Yh).

Based on the above calculations, the expected yield increase using MON 87460 corn would be 2.76%. Based on USDA (USDA-ERS, 2010b) production cost and return estimates, a 2.76 percent increase in yields would translate to an approximate 5.5 percent increase in net returns (i.e., from USDA data, yield/net returns = 0.5, then assuming the same ratio or 0.5 = (2.76)/(% increase in net returns), a 2.76 percent increase in yields corresponds to 5.5 percent increase in net returns). Available estimates of elasticity of corn acreage to expected returns are up to 0.48 for the U.S plains (FAPRI, 2004), suggesting a 5.5 percent increase in returns would translate to a 2.6 percent increase in corn acreage (i.e., percent increase in corn acreage = 0.48 x 5.5 percent increase in net returns) in those areas where returns from adoption of MON 87460 are expected to increase. Taking non-irrigated harvest corn acreage from the 2007 Agricultural Census of the 10 previously mentioned states most likely to benefit from MON 87460 adoption as a basis, a 2.6 percent increase in corn acreage would result in 572 thousand acres of added corn fields (2.6 percent x 22 million acres), or approximately 0.65 percent of the current corn acreage in the U.S. Because available estimates of the elasticity of agricultural land use to increased returns in agriculture are very low (Barr et al., 2010), this increase in acreage would be almost entirely observed on land converted from other crop production, rather than from land currently not in agricultural use (including CRP land). Because the areas of corn expansion would be presumably areas subject to yield loss under water shortages, a 0.65 percent increase in corn acreage would likely have a less than proportional impact on corn production.

Again, the above numerical exercise should not be interpreted as an estimate, but rather as an illustration of the magnitude of the potential impact, given the assumptions. If the number of farms potentially benefiting from MON 87460 adoption is substantially larger, for example, the impact on corn acreage also could be larger. However, given the magnitude of impacts illustrated by the exercise above, the impact of MON 87460 deregulation on corn acreage is expected to be minor.

Locations of Increased Farm Income

Corn-related farm incomes could increase in areas that adopt MON 87460. For example, using the same hypothetical scenario described above and based on USDA (2010b) production cost and return estimates, a possible 2.76 percent increase in yields would translate to an approximate 5.5 percent increase in net returns. The impact of such an increase in returns would be greater for states where farms represent a greater share of state GDP and where corn represents a greater share of crop acreage, such as Nebraska and South Dakota.

Impacts on Overall Farm Income

Increases in corn-related farm incomes would have a less than proportional impact on farm household incomes because of the importance of other sources of income for corn-farm households. An analysis of the USDA 2001 Agricultural Resource Management Survey suggests that almost all the income of rural residence corn farmers and most of the income of intermediate corn farmers (those with less than $250,000 in annual farm sales) was from off-farm sources. Only on commercial corn farms (those with more than $250,000 in annual farm sales) was crop-related farm income most of total income, a large share also being from direct government payments. In all cases, corn-related income was a very small (typically negative) share of the total income of corn-farm households (McBride, 2005). Based on this information, impacts on overall farm income due to the deregulation of MON 87460 are expected to be negligible.

Impacts on Irrigation and Water Use with MON 87460

Regarding the impact of MON 87460 on water use in irrigated corn, no data has been provided or is available to assess the extent of savings in water costs that might be stimulated following the adoption of MON 87460. Indeed, the observations presented in the petition indicate that expected maximum yield in the variety depends on attaining sufficient water (Reeves, 2010). MON 87460 would be used to provide a safeguard against unexpected interruptions in water for irrigation, but would certainly be used by growers if reductions in irrigation proven possible or that MON87460 was otherwise useful in some circumstances to reduce use of irrigation water. At present, irrigation sparing capacity of MON 87460 has not been demonstrated, and expectations for savings on irrigation are not consistent with current experimental observations provided by the applicant (Reeves, 2010).

Additional Impacts

The greatest impact of the product will likely be that growers experience yield losses with MON 87460 that are less than those incurred by planting non-drought tolerant corn varieties. Another possible impact is the possible reduction of crop insurance costs, since better potential yield in drought could be purchased by growers especially if growing MON 87460 might be specifically stipulated by an insurance contract (as for example, a "Biotech Yield Endorsement" that is offered by insurance providers (Iowa State, 2007)). An increase in land values as a result of planting MON 87460 is also possible, although there is not enough information to assess these potential impacts.

Impacts on Organic and non-GE Corn Producers by MON 87460

Non-GE, organic, and GE corn are currently grown in generally the same areas. Although the unintended presence of GE content in organic farming does not necessarily lead to the loss of organic certification, a cost to both organic and non-GE corn farmers may include testing for the presence of GE material that is required by some discriminating buyers. However, there is no reason to believe that gene flow from MON 87460 would be any more likely than gene flow from currently available GE varieties for reasons previously described. To the extent deregulation of MON 87460 would contribute to increased GE corn acreage, the likelihood of proximity of organic and non-GE corn farmers to GE corn could potentially increase as well. However, as previously analyzed, current projections for increases in corn acreage under the No Action Alternative are about 4.5 percent between 2009 and 2020. As demonstrated by the numerical exercise above, the magnitude of impact of MON 87460 deregulation on corn acreage could be substantially less than that of other current factors that encourage planting of other GE varieties and for them to affect increases in corn acreage.

An estimate of the increase in corn production would depend on the degree of adoption, on the actual impact of MON 87460 to yields under water-limited conditions, and the degree of water shortage in any given year. The overall impact of MON 87460 deregulation on U.S. corn production is expected to be minor.

4.8.1.3 Cumulative Effects: Domestic Economic Environment

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. These policies are expected to continue in the foreseeable future and add to the incentive for corn production that would follow MON 87460 deregulation.

Corn acreage is expected to increase, but 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, 2.6 million acres below the 2008 enrollment (Farm Bill, 2008). To the extent that some of this land is converted to agricultural use, existing corn acreage could increase and add to the incentive for corn production. The conversion of CRP acres would be independent of adoption of MON 87460 corn.

Other Federal policies such as Federal crop insurance, marketing loans, direct and counter-cyclical 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 that would follow MON 87460 deregulation.

4.8.2 Trade Economic Environment

The U.S. is the largest world exporter of corn. This section describes potential impacts on U.S. trade flows from deregulating of MON 87460.

In the 2008/9 marketing year, corn exports accounted for approximately 15 percent of the total U.S. corn use behind feed, ethanol production, and food and seed (USDA-ERS, 2011b). Because exports are a relatively small share of U.S. corn use but the U.S. is the largest exporter of corn, U.S. domestic markets have a large influence on international corn prices (USDA ERS 2009b). In 2009, total exports of corn valued approximately $9 billion, with less than 2.5 percent of this being for seed. The primary countries of destination for U.S. corn exports in 2009 were Japan, Mexico, South Korea, Taiwan, Canada, and Egypt, with more than 75 percent of the total (USDA-FAS, 2010a). The primary seed export destinations are Canada and Mexico.

The U.S. is by far a net exporter of corn with imports in 2009 valued less than $300 million, almost 90 percent of this coming from Chile, Argentina, and Canada (USDA FAS 2010a, code 1005 of the Harmonized System).

About 60 percent of the world trade in coarse grains (corn, barley, sorghum, rye, oats, millet, and mixed grains) is for feed and 75 percent of the coarse grains trade is corn. Trade in feed for livestock has been a driver of trade in corn (USDA-ERS, 2011b). Japan is the world's largest corn importer, typically followed by South Korea, Mexico, Egypt, and Taiwan (USDA-FAS, 2010b). Between the trade years (October through September) of 2003/4 through 2007/8, the U.S. share of world corn exports averaged 60 percent, the second largest exporter being Argentina, with China's exports being occasionally important yet unpredictable, and largely a function of internal policies(USDA, 2009).

The primary U.S. corn export destinations are also the largest world importers of corn and do not seem to have major barriers for importing GE products. In Japan there are no restrictions for import of genetically engineered varieties that have been approved for commercialization in Japan. In the case of genetically engineered varieties not yet approved in Japan a 1 percent presence in feed is still allowed, as long as it has been approved by an exporting country with safety assessments equivalent to Japan's. There is no restriction after approval. Labeling is mandatory for GE food when the GE content can be detected and if the GE ingredient is one of the first three ingredients of a product and accounts for more than 5 percent of its total weight (Greuere, 2006). Mexico imports and consumes regularly existing varieties of GE corn (USDA-FAS, 2008b). South Korea has similar approval processes as Japan and requires labeling for GE animal feed (USDA-FAS, 2008). Taiwan requires labeling for products containing more than 5 percent GE content (USDA-FAS, 2008c). Egypt is a large consumer of GE crops, including corn, soybeans, and vegetable oils (USDA-FAS, 2006).

While detailed data are not readily available for U.S. organic crop exports, the USDA Foreign Agricultural Service estimates that exports of all organic products in 2009 totaled $1.7 billion (USDA-ERS, 2011a; USDA-FAS, 2011). Official U.S. data are currently limited by the lack of international trade codes for organic products; thus far, only Canada and the U.S. have established trade codes for organic products (USDA-FAS, 2011). However, given the large demand for non-organic grain corn on the international market, it is likely that U.S. organic trade is a small contributor to total corn trade.

The affected trade economic is defined as those countries with which the U.S. engages in corn feed, seed and food trade. Therefore, the trade economic environment most likely affected by deregulating MON 87460 would be those countries who import MON 87460 feed, seed, and food.

4.8.2.1 No Action: Trade Economic Environment

The USDA provides projections for the agricultural sector through 2020 (USDA-ERS, 2011b). World trade in corn is projected to increase 30 percent between the 2008/9 trade year and the 2019/20 trade year. The U.S. share of that trade is projected to remain slightly below 60 percent, with U.S. corn exports therefore increasing at a rate also close to 30 percent. Although, many countries are investing in biofuel production capacity, several feedstocks are used in addition to corn, such as sugarcane for ethanol and rapeseed and soybean oil for biodiesel. Feed for livestock is projected to remain the main driver of corn trade.

Under the No Action Alternative, any potential increase in corn seed exports with deregulation of MON 87460 in the U.S. would not be realized.

4.8.2.2 Preferred Alternative: Trade Economic Environment

Although the primary U.S. corn export destinations do not present major barriers to trade in GE products, Monsanto would need to obtain MON 87460 approval in destination countries before commercialization to avoid adversely affecting current trade flows. Monsanto recognizes this in its petition and states its intention to seek approval for MON 87460 in primary U.S. export destinations with functioning regulatory systems before commercialization in the U.S. (Reeves, 2010). Requests for approvals have been submitted to several markets, and Canada had approved the product for food, feed and cultivation, and Australia and New Zealand have approved it for food use.

MON 87460 seed could be of particular interest to parts of the world where corn production suffers from water-limited conditions. To the extent this interest translates to demand for U.S. MON 87460 seed as a result of the deregulation of MON 87460, there could be a potential for increased corn seed exports. Because corn seed exports are a small share of total U.S. corn exports, this impact is expected to be minor or negligible. Corn from this foreign production could potentially enhance production in drought stressed locations in other countries.

4.8.2.3 Cumulative Effects: Trade Economic Environment

APHIS identified a potential minor or negligible impact to trade economic environment as a result of the Preferred Alternative, which could contribute to a cumulative impact by another foreseeable action. MON 87460 seed may be marketed abroad, potentially stacked with existing corn germplasm that exhibits similar traits; depending upon how much increase in corn production the variety may encourage, there may be incremental changes to foreign corn production. MON 87460 could have impacts of unknown size on U.S. trade following MON 87460 deregulation in the U.S and abroad. Currently, requests for approvals for all purposes including planting have been submitted to Mexico and Canada but only Canada has approved the product for cultivation so far.

4.9 International Impacts Analysis

4.9.1 Transboundary Impacts

The CEQ guidance on NEPA analyses for transboundary impacts (CEQ 1997) requires Federal officials to consider reasonably foreseeable transboundary effects in the environmental analysis of proposed actions occurring in the U.S. Potential transboundary impacts on Mexico and Canada are addressed below.

As discussed in the Animal and Plant Communities Affected Environment section, APHIS evaluated the potential for gene flow to occur from MON 87460 to sexually compatible wild relatives. As stated previously, cultivated corn 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; Wilkes, 1967). Corn and teosinte are genetically compatible, wind-pollinated, and can hybridize when close to each other, but hybridization would only be likely to occur in Mexico and Guatemala because teosinte is not present in the U.S., except for a few small feral populations of *Zea mexicana* in Alabama, Florida, Maryland (USDA-NRCS, 2010), and *Zea perennis* in South Carolina (USDA-NRCS, 2011). *Tripsacum* species have one less chromosome than corn but can hybridize with corn, although it is very difficult and requires special techniques, and the hybrids have a high degree of sterility and are genetically unstable (Mangelsdorf, 1974). Crosses between corn and *Tripsacum dactyloides* can be made, but only through human intervention and, even then, it is extremely difficult (CFIA, 1994).

MON 87460 is not likely to hybridize with sexually compatible species in the United States because of differences in factors such as flowering time, geographical separation, and development factors (Doebley, 1990a, 1990b; Ellstrand, et al., 2007; Galinat, 1988). Further, *Tripsacum dactyloides* and *Tripsacum floridanum* would not be affected by MON 87460 because of the difficulty of hybridizing with these species. The potential impact of gene flow into teosinte is not expected to be any different than that of other currently available cultivated corn varieties. Based on these considerations, and in particular geographic separation, APHIS anticipates no potential direct, indirect or cumulative transboundary gene flow impacts into teosinte found in Mexico.

No known sexually compatible species were identified in Canada, and APHIS has identified no potential direct, indirect or cumulative transboundary gene flow impacts in relation to Canada following from the deregulation of MON 87460.

5 THREATENED AND ENDANGERED SPECIES

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

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

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

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

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or critical habitat. This process is used by APHIS to assist the program in fulfilling their obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

As part the environmental review process, APHIS thoroughly reviews GE product information and data to inform the ESA effects analysis and, if necessary, the biological assessment. For each transgene(s)/transgenic plant the following information, data, and questions are considered by APHIS:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;

- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant); and
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.

APHIS analyzed the potential for effects from cultivation of MON 87460 on Federally listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the ESA. Direct effects are analyzed by considering the response that TES could have if exposed to MON 87460. Indirect effects are those that could result from the use of MON 87460 in corn production, would occur later in time, but are still reasonably certain to occur. Consideration is given for the potential of MON 87460 to change the baseline habitat of TES including critical habitat.

MON 87460 will be grown on agricultural acres managed by growers in a manner similar to conventionally bred corn. MON 87460 is not genetically engineered to produce a toxin or pesticide, and is not genetically engineered to be tolerant to an herbicide. Corn is an annual, wind-pollinated crop which lacks sexually compatible wild relatives (including threatened or endangered plant species) in the U.S., except for an occasional botanical garden specimen or small feral populations of *Zea mexicana* in Florida, Alabama and Maryland or *Zea perennis* in South Carolina (http://plants.usda.gov). Because corn itself is not sexually compatible with any listed plant species, there is no potential for a direct effect of MON 87460 on TES plants. Because corn cannot naturalize and would not affect pollinators, there are no expected indirect effects of MON 87460 on TES plants.

Corn exhibits extremely limited seed dormancy, has no weedy characteristics, and volunteers are easily controlled. It is not capable of establishing persistent populations in unmanaged environments. As discussed previously, the presence of the CSPB protein in no way alters the weediness potential or gene flow potential of MON 87460. Therefore, it is highly unlikely that MON 87460 poses any more of a risk to threatened or endangered plant species than conventionally bred corn.

Corn is a feed commonly provided to many livestock and consumed by wildlife (e.g., birds, deer, and rodents). The data presented in the petition suggests there is no difference in compositional and nutritional quality of MON 87460 compared to conventional corn, apart from the presence of the CSPB and NPTII proteins. Based on the nature of the proteins, their known activity, and the characteristics of the donor organisms, the CSPB and NPTII proteins have a history of safety to organisms exposed at levels found in MON 87460. Because there is no toxicity or allergenicity potential with MON 87460, there would be no direct or indirect toxicity or allergenicity impacts on wildlife species that feed on corn or the associated biological food chain of organisms. A consultation with FDA was successfully completed for CSPB and NPTII proteins of MON 87460 (Appendix A), which demonstrated a lack of toxicity and allergenicity of MON 87460 for human and animal consumption. Therefore, it is unlikely that MON 87460 would affect threatened and endangered animal species, including animals such as insects, bats or birds that may be pollinators of TES plants.

APHIS has considered whether approval of MON 87460 will result in additional lands being converted to corn acreage, and consequently have possible impacts on T&E species. APHIS evaluates that corn acreage may well increase through 2020, but much of the land used will be at the expense of acreage planted to other crops on existing agricultural lands. Another source of additional lands are those in federal set aside programs, such as the Conservation Reserve Program. This program safeguards environmentally sensitive lands by planting native plants or long-term, resource-conserving cover crops that would control soil erosion, improve water and air quality, and enhance wildlife habitat. By taking land out of production under long term contracts, growers are given annual rental payments and cost-share assistance to promote these federal and state goals. The native and introduced vegetation provides habitat to wildlife, most notably birds (Delisle and Savidge, 1997; McCoy et al., 2001). Animals, including threatened and endangered species that could be affected by conversion of CRP land to MON 87460 production, use CRP land for food or cover. The animals that could be present in CRP areas would vary depending on the region and type of habitat. APHIS has concluded that although corn acreage could increase through 2020, no net increase in conversion of CRP lands for the reduced yield loss corn will likely occur. Some acreage may move in and out of CRP lands, but overall, APHIS has evaluated in this EA that neither this crop nor other corn crops will directly contribute to large-scale conversion of these reserved lands to agricultural lands.

MON 87460 is a corn variety that may reduce yield loss from drought, and displays no agronomic characteristics substantially different from existing commercial corn, and therefore is not weedy, nor likely to contribute to weediness of corn. Aside from expression of a common bacterial protein, no differences have been shown from similar corn varieties. Because no traits of MON 87460 corn have been shown to be different from commodity corn, it is highly unlikely that MON 87460 will have impacts different from other commodity corn varieties. Neither are impacts likely when MON 87460 corn is combined through traditional breeding methods with APHIS- or EPA-approved insect-protected or herbicide tolerant traits. No direct or indirect adverse impacts were identified that would result from producing this corn, and APHIS concluded that there were also no cumulative impacts on any resources in agricultural or non-agricultural environment.

After reviewing possible effects of a determination of nonregulated status of MON 87460 corn, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. As a result, a detailed exposure analysis for individual species is not necessary.

APHIS has considered the effect of MON 87460 production on designated critical habitat or habitat proposed for designation and could identify no difference from effects that would occur from the production of other corn varieties. Additionally, cornfields are not designated critical habitat for any Federally threatened and endangered animal species listed under the ESA (USFWS 2010). As discussed, APHIS has concluded that the deregulation of this MON 87460 corn is unlikely to lead to large scale conversion of CRP land and consequent significant impacts on some CRP land that could become agricultural.

Based on the above information, APHIS has concluded that a determination of nonregulated status of MON 87460 would have no effect on Federally listed threatened or endangered species or species proposed for listing, nor would it affect designated critical habitat or habitat proposed for designation. Consequently, consultation with the USFWS or NMFS is not required for this action.

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

6.1.1 Executive Orders with Domestic Implications

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

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

CEQ guidance for implementation of EO 12898 in the context of NEPA (*Environmental Justice. Guidance Under the National Environmental Policy Act*, December 10, 1997) identifies a minority population as an affected area where over 50 percent of the population belongs to a minority group or where the percentage presence of minority groups is meaningfully greater than in the general population. Geographically disperse groups with common conditions of environmental exposure may also be considered as a community subject to analysis for percentage presence of minority groups (e.g. agricultural workers).

Table 8 shows minority presence in the U.S. and in the states where MON 87460 would likely be adopted to reduce the potential yield loss from water shortages. African Americans are represented in Texas at 11.4%, the highest percentage of all the affected states, while Hispanic Americans are represented at the highest in New Mexico at 44.9% and Texas at 36.5%. Although in New Mexico and Texas minorities are more than 50 percent of the population, in the ten states as a whole, minorities constitute only a slightly higher share of the total population than in the U.S. In all ten analyzed states, Hispanics and Native Americans are the minority groups whose presence surpasses their presence in the country as a whole: in both cases, their share in the ten analyzed states is approximately 1.7 times their share in the U.S.

Table 8. Minority populations in states where MON 87460 may be adopted, 2008.

		Percent of Total Population								
Location	Total Population	White	Black or African American	Alaska Native or American Indian	Asian	Native Hawaiian & Other Pacific Islander	Some Other Race	Two or More Races	Hispanic or Latino[a]	Total Minorities[b]
U.S.	304,059,728	75.05%	12.36%	0.80%	4.41%	0.14%	4.93%	2.31%	15.42%	34.57%
Colorado	4,939,456	84.74%	3.80%	0.97%	2.55%	0.11%	4.75%	3.08%	20.19%	29.22%
Kansas	2,802,134	86.25%	5.62%	0.73%	2.14%	0.07%	2.48%	2.70%	9.08%	19.78%
Minnesota	5,220,393	88.14%	4.42%	1.05%	3.52%	0.01%	1.07%	1.80%	4.13%	14.69%
Montana	967,440	89.62%	0.54%	6.05%	0.67%	0.07%	0.64%	2.41%	2.82%	12.14%

Table 8. Minority populations in states where MON 87460 may be adopted, 2008.

Location	Total Population	Percent of Total Population								
		White	Black or African American	Alaska Native or American Indian	Asian	Native Hawaiian & Other Pacific Islander	Some Other Race	Two or More Races	Hispanic or Latino[a]	Total Minorities[b]
Nebraska	1,783,432	88.91%	3.99%	0.76%	1.50%	0.05%	2.61%	2.18%	7.84%	15.82%
New Mexico	1,984,356	73.45%	2.28%	9.22%	1.35%	0.04%	10.48%	3.19%	44.90%	58.45%
North Dakota	641,481	91.00%	0.95%	5.30%	0.84%	0.04%	0.56%	1.30%	2.02%	10.21%
South Dakota	804,194	87.10%	0.94%	8.17%	0.82%	0.03%	0.77%	2.17%	2.36%	13.96%
Texas	24,326,974	73.87%	11.43%	0.50%	3.46%	0.08%	8.71%	1.95%	36.46%	52.78%
Wyoming	532,668	91.87%	1.06%	2.04%	0.70%	0.03%	1.52%	2.77%	7.73%	13.34%
Total of 10 States	44,002,528	79.22%	7.95%	1.39%	2.92%	0.07%	6.27%	2.19%	26.06%	39.57%

Source: U.S. Census Bureau, American Community Survey 2008 (USCB 2008).

[a] Individuals who identify themselves as Hispanic, Latino, or Spanish might be of any race; the sum of the other percentages under the "Percent of Total Population" columns plus the "Hispanic or Latino" column therefore does not equal 100 percent.

[b] The total minority population, for the purposes of this analysis, is the total population minus the non-Latino/Spanish/Hispanic white population.

Table 9: Minority farmer populations in states where MON 87460 may be adopted, 2007.

Location	Total farmer population	Hispanic or Latino	Percent of Total	Alaska Native or American Indian	Percent of Total
U.S.	3,337,450	82,462	2.47%	55,889	1. 7%
Colorado	60,684	2,610	4.30%	619	1.0%
Kansas	97,150	780	0.80%	508	0.5%
Minnesota	119,650	507	0.42%	413	0.4%
Montana	46,903	345	0.74%	2,013	4.4%
Nebraska	71,924	288	0.40%	63	0.1%
New Mexico	32,109	8,904	27.73%	6,611	21.2%
North Dakota	45,114	142	0.31%	503	1.1%
South Dakota	46,710	196	0.42%	1,150	2.5%
Texas	372,563	28,921	7.76%	3,604	1.0%
Wyoming	18,522	256	1.38%	324	1.8%
Total of 10 States	911,329	42,949	4.71%	15,808	1.7%

Source: 2007 Census of Agriculture – State Data (USDA-NASS 2007b)

To the extent that impacts of MON 87460 deregulation affect primarily farm households, Table 9 shows the presence of Hispanics and American Indians among farm operators (those who run the farm: owners or other). The highest percentage of Hispanic farmers is found in New Mexico at 27.7% and in Texas at 7.8% and the highest percentage of American Indian farmers is in New Mexico at 20.6% (Table 9). Although Hispanic operators are considerably more highly represented in the ten state region than in the country as a whole (1.9 times more), both Hispanics and American Indian operators comprise a much smaller share of farm operators than they are of the total population in the 10-state region: 4.7 percent of operators are Hispanics and 1.7 percent are American Indian.

A large percentage of agricultural workers in the U.S. are born in Mexico – 75 percent in the 2001/02 fiscal year (USDOL-(United-States-Department-of-Labor), 2005). A relatively small share, 14 percent, of all agricultural workers had a field crop as their primary crop in 2001/02, most agricultural workers being employed in fruit, vegetable, and horticultural crops (USDOL-(United-States-Department-of-Labor), 2005). However, any impacts on agricultural workers would likely affect a considerably larger share of Hispanics than the share of Hispanics in the total population.

CEQ guidance for implementation of EO 12898 in the context of NEPA (*Environmental Justice. Guidance Under the National Environmental Policy Act*, December 10, 1997) suggests an analysis based upon U.S. Census Bureau Current Population Reports, Series P-60 on Income and Poverty for identification of low-income populations. This data is derived from the American Community Survey done annually through a representative household sample. Table 10, below, shows that the share of population in poverty in the ten state region is only slightly higher than the share of the population in poverty in the country as a whole.

Table 10: Low-income presence, 2008.

Location	Total[a]	Low-Income	Low-Income Share of Total
U.S.	296,184,480	39,108,422	13.20%
Colorado	4,835,406	552,889	11.43%
Kansas	2,716,652	307,478	11.32%
Minnesota	5,090,468	490,911	9.64%
Montana	942,874	139,707	14.82%
Nebraska	1,727,276	186,727	10.81%
New Mexico	1,941,428	332,769	17.14%
North Dakota	615,412	73,622	11.96%
South Dakota	774,737	96,490	12.45%
Texas	23,727,821	3,760,431	15.85%
Wyoming	518,368	48,776	9.41%
Total of 10 States	42,890,442	5,989,800	13.97%

Source: U.S. Census Bureau, American Community Survey 2008 (UCSB 2008).
[a]Universe is population for whom poverty status is determined

With respect to farm households, in 2003, 11 percent of the U.S. population was below the U.S. Census Bureau poverty line, while 14 percent of farm households were poor. Offutt and Gundersen (2005) argue that the U.S. Census Bureau poverty line might not adequately capture poverty in farm households, given that it does not capture the volatility of farm income and the greater asset holdings of farm households. Under the USDA alternative concept of Limited Resource Farmer, 11 percent of farm households would fall under that category in 2003, while under the USDA ERS Low Income/Low Wealth concept, only 5 percent of farm households would be classified as such in that same year.

The possibility of disproportionately high and adverse human health and environmental effects depends on the existence in the affected area of minority or low-income populations and on the existence of significant impacts of a proposed alternative. If, for example, differential patterns of consumption of water or subsistence consumption of indigenous fish, vegetation, or wildlife are important to minority populations, low-income populations, or Indian tribes in the affected area, and some adverse impact existed on these resources, then these differential patterns of consumption could also lead to disproportionately high and adverse impacts.

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

MON 87460 has been shown to be no difference in compositional and nutritional quality compared to conventional corn, apart from the presence of the CSPB and NPTII proteins. The inserted genes (*cspB* and *nptII*) and proteins (CSPB and NPTII) expressed in MON 87460 are not expected to be allergenic, toxic, or pathogenic in mammals. Both CSBP and NPII proteins have a history of safe consumption in the context of other food and feeds (FDA, 2010). This information establishes the safety of MON 87460 and its products to humans, including minorities and low income populations who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken.

None of the impacts on agricultural practices expected to be associated with deregulation of MON 87460 are expected to have a disproportionate adverse effect on minorities and low income populations. MON 87460 is not genetically engineered to produce a toxin or pesticide, and is not genetically engineered to be tolerant to a herbicide. Due to the lack of pesticidal and herbicidal traits in MON 87460, corn hybrid varieties may be produced with MON 87460 and other nonregulated corn hybrids containing herbicide tolerant and/or pesticide traits. Thus, pesticide application practices and usage associated with deregulation of MON 87460 are not expected to change from the current trends for existing nonregulated GE corn.

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

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

MON 87460 has been shown to be no difference in compositional and nutritional quality compared to conventional corn, apart from the presence of the CSPB and NPTII proteins. The inserted genes (*cspB* and *nptII*) and proteins (CSPB and NPTII) expressed in MON 87460 are not expected to be allergenic, toxic, or pathogenic in mammals. Both CSBP and NPII proteins have a history of safe consumption in the context of other food and feeds (FDA, 2010). This information establishes the safety of MON 87460 and its products to humans, including children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken.

None of the impacts on agricultural practices expected to be associated with deregulation of MON 87460 are expected to have a disproportionate adverse effect on children. MON 87460 is not genetically engineered to produce a toxin or pesticide, and is not genetically engineered to be tolerant to a herbicide. Due to the lack of pesticidal and herbicidal traits in MON 87460, corn hybrid varieties may be produced with MON 87460 and other nonregulated corn hybrids containing herbicide tolerant and/or pesticide traits. Thus, pesticide application practices and usage associated with deregulation of MON 87460 are not expected to change from the current trends for existing nonregulated GE corn.

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

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

All corn varieties, including MON 87460, require human assistance to persist beyond a first generation of corn plants that may arise from spilled seed; they do not establish self-propagating populations. Corn does not possess traits that are characteristic of invasive species (Baker 1965, Keeler 1989, Galinat 1988).

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

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

Data submitted by the applicant has shown no difference in compositional and nutritional quality of MON 87460 compared with other GE corn or non-GE corn, apart from the presence of the CSPB and NPTII proteins. MON 87460 not expected to be allergenic, toxic, or pathogenic in mammals. Both CSBP and NPII proteins have a history of safe consumption in the context of other food and feeds (FDA, 2010). Additionally, the FDA has completed its food safety consultation on MON 87460. Based on APHIS' assessment of MON 87460, it is unlikely that a determination of nonregulated status of MON 87460 will have a negative effect on migratory bird populations.

6.1.2 International Implications

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

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of MON 87460. All existing national and international regulatory authorities, and phytosanitary regimes that currently apply to introductions of new corn cultivars internationally apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR Part 340.

Any international trade of MON 87460 subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC, 2010). The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

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

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

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

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the Organization for Economic Cooperation and Development (OECD). NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures (RSPM) No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO, 2009).

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

6.1.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the changes in corn production due to the unrestricted use of MON 87460. Cultivation of MON 87460 is not expected to lead to the increased production of corn in U.S. agriculture.

There is no expected change in water use and quality due to the cultivation of MON 87460 compared with current corn production. Also, there is no expected change in air quality associated with the cultivation of MON 87460.

Based on this review, APHIS concludes that the cultivation of MON 87460 would comply with the Clean Water Act and the Clean Air Act.

6.1.4 Impacts on Unique Characteristics of Geographic Areas

A determination of nonregulated status of MON 87460 is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

The common agricultural practices that would be carried out in the cultivation of MON 87460 are not expected to deviate from current practices. The product is expected to be deployed on agricultural land currently suitable for production of corn and replace existing varieties, and is not expected to increase the acreage of corn production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of MON 87460. This action would not convert land use to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87460, including the use of EPA registered pesticides.

6.1.5 National Historic Preservation Act (NHPA) of 1966 as Amended

The NHPA of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

APHIS' proposed action, a determination of nonregulated status of MON 87460 is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

APHIS' Preferred Alternative would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources.

APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment close to such sites. Nevertheless, it is expected that this noise would only be temporary and short-term. The cultivation of MON 87460 is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

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APPENDIX A. FDA BIOTECHNOLOGY CONSULTATION NOTE TO THE FILE (BNF NO. 000116)

BIOTECHNOLOGY CONSULTATION - NOTE TO THE FILE
BIOTECHNOLOGY NOTIFICATION FILE BNF NO. 000119

DATE
December 9, 2010

Subject
MON 87460, drought tolerant corn

Keywords
Maize; corn; *Zea mays* L.; drought tolerance; MON 87460; OECD unique identifier MON-8746Ø-4; cold shock protein B (CSPB) from *Bacillus subtilis*; neomycin phosphotransferase II (NPTII) from *Escherichia coli*, Monsanto

Purpose
This document summarizes our evaluation of Biotechnology Notification File (BNF) No. 000116. In a submission dated December 19, 2008, the Monsanto Company (Monsanto) submitted a safety and nutritional assessment of the bioengineered corn MON 87460. Monsanto provided additional information in submissions dated April 9, May 1, June 1, June 29, July 7, August 10, September 10, November 2, 2009, and August 3, 2010. Monsanto is voluntarily consulting with the agency as discussed in the agency's 1997 Guidance on Consultation Procedures for Foods Derived from New Plant Varieties. Here we discuss the outcome of the consultation, but do not intend to restate the information provided in the final consultation in its entirety.

Intended Effects
The intended effect of the modification in corn event MON 87460 is to reduce yield loss under water-limited conditions compared to conventional corn. To accomplish this objective, Monsanto introduced the gene (cspB) for cold shock protein B (CSPB) from B. subtilis. CSPB confers tolerance to water-limited conditions. Monsanto also introduced the gene (nptII) for neomycin phosphotransferase II (NPTII) protein from E. coli. NPTII was used as a selectable marker in the development of corn event MON 87460. The NPTII protein does not confer tolerance to water-limited conditions.

Regulatory Considerations
The purpose of this evaluation is to assess whether the developer has introduced a substance requiring premarket approval as a food additive or has unintentionally adulterated the food with respect to the Federal Food, Drug and Cosmetic Act (FFDCA).

Genetic Modification and Characterization
Parental Variety
Monsanto transformed the recipient LH59 (a non-transgenic conventional corn variety) callus tissue to obtain MON 87460.

Transformation Plasmid and Method
Monsanto described the development of corn event MON 87460 using Agrobacterium tumefaciens-mediated transformation of corn embryo-derived tissue. The A. tumefaciens strain harbored the transformation vector PV-ZMAP595. The transforming vector carried a transfer DNA sequence comprised of both cspB and nptII expression cassettes. Following transformation, the corn tissue was

transferred to medium containing the antibiotics carbenicillin to eliminate A. tumefaciens, and paromomycin (related to neomycin) to eliminate cells that were not transformed.

Characteristics, Inheritance, and Stability of the Introduced DNA
Monsanto provided genomic DNA blot (Southern) analyses to demonstrate that corn event MON 87460 has one intact copy of the transfer DNA region comprised of tandem cspB and nptII expression cassettes inserted in its genome. Monsanto provided genomic DNA blot analyses and polymerase chain reaction analyses in conjunction with DNA sequencing to verify the integrity of the integrated cspB and nptII genes along with their associated regulatory elements. Monsanto used genomic DNA blot analyses to demonstrate that MON 87460 does not contain any detectable DNA from the transformation vector, other than the transfer DNA region.

Monsanto presented genomic DNA blot analyses to demonstrate the stability of the inserted cspB and nptII expression cassettes across multiple generations of corn event MON 87460. Monsanto presented Chi-square analyses of the segregation patterns across multiple generations of corn event MON 87460 to demonstrate the stable Mendelian inheritance of the transfer DNA region containing both the cspB and the nptII cassettes.

Monsanto assessed the inserted DNA sequence for any potential unintended open reading frames (ORFs) that might encode proteins. Monsanto identified several putative polypeptides of at least eight amino acids that could be expressed. Monsanto performed bioinformatic analyses to compare sequences within these putative polypeptides to those of known toxins and allergens in standard toxin, allergen and protein databases. Monsanto found no similarity to any known allergen or toxin.

Protein Characterization
Function and expression levels of introduced proteins
Monsanto describes the CSPB protein produced in corn event MON 87460 as identical to the native CSPB protein produced in B. subtilis except for one amino acid introduced for cloning purposes. Bacterial cold shock proteins (CSP) are hypothesized to function by binding to RNA secondary structures, thus reducing the free energy required for unfolding misfolded RNA. CSPs are classified as RNA chaperones. Monsanto notes that similar cold shock domain-containing proteins are also present in plants where they appear to play a role in conferring stress tolerance.

Monsanto describes the function of the NPTII protein as being a selectable marker used in the development of corn event MON 87460. NPTII phosphorylates neomycin and related antibiotics, thus inactivating them.

Monsanto estimated the levels of CSPB and NPTII proteins in corn event MON 87460 from both well-watered (i.e., received adequate water throughout the growing season) and water-limited plants grown in the field. Monsanto noted that given the genetic construct of the transferred DNA, both CSPB and NPTII proteins would be expected to be present in all tissues. Using standard biochemical techniques, Monsanto reports CSPB protein being present in all tissues tested. Monsanto reports NPTII protein also being present in all tissues tested, with the exception of mature grain where it was below the detection method's limit of quantitation (where the limit of quantitation is 0.0047 micrograms per gram of tissue on a fresh weight basis).

Potential Toxicity of the Introduced Proteins
Monsanto assessed the potential for toxicity for both CSPB and NPTII proteins. Regarding CSPB, Monsanto noted that the source of the cspB gene is B. subtilis, a microorganism used as the donor organism for several enzyme preparations used in food manufacturing applications. In support of the safety of B. subtilis used in such food applications, Monsanto cited several published studies as well as

the opinions of expert scientific bodies. In support of the safety of the CSPB protein, Monsanto noted that it is homologous to several proteins from microbial and plant sources present in the human diet. Using the CSPB protein sequence, Monsanto performed bioinformatic analyses to look for similarities between CSPB and proteins known to be toxic or bioactive and found no such similarities. Monsanto also conducted an acute oral toxicity study in mice (single dose of 4.7 milligrams/kilogram) using E. coli-produced CSPB protein. Monsanto noted no treatment-related adverse effects. Given the totality of the evidence, Monsanto concluded that the CSPB protein from corn event MON 87460 is unlikely to exhibit toxic effects when incorporated into food or feed.

Regarding NPTII, Monsanto stated that the source of the nptII gene is E. coli K-12. NPTII, also referred to as APH(3')II, is regulated as a food additive under 21 CFR 173.170 and 21 CFR 573.130 for use as a processing aid in the development of new varieties of tomato, oilseed rape and cotton. Scientific studies and evaluations regarding the use of NPTII in new plant development have been performed since FDA filed the food additive petition for these uses. In reviewing NPTII, FDA concluded that NPTII does not have any properties that would distinguish it toxicologically from any other phosphorylating enzymes in the food supply. Using the NPTII protein sequence, Monsanto performed bioinformatic analyses, which found no similarities between NPTII and proteins known to be toxic or bioactive and provided additional citations supporting its safety. Given the totality of the evidence, Monsanto concluded that the NPTII protein from corn event MON 87460 is unlikely to exhibit toxic effects when consumed in food or feed.

Assessment of the Potential for Allergenicity of the Introduced Proteins
Monsanto evaluated the potential for allergenicity of CSPB and NPTII proteins. For CSPB and NPTII proteins, bioinformatics analyses of sequence similarities using standard methods, including the allergen database in conjunction with the FASTA sequence alignment tool, and an eight-amino acid sliding window search (ALLERGENSEARCH) revealed no significant homology to known allergens. For the CSPB protein, in vitro gastric and intestinal digestibility studies using standard methods did not identify significant resistance to proteolysis. For the NPTII protein, Monsanto cites an FDA draft guidance document to support its conclusion that the NPTII protein poses no allergenic risk [Guidance for Industry: Use of Antibiotic Resistance Marker Genes in Transgenic Plants (Draft Guidance, issued September 4, 1998)]. In this draft guidance, FDA states that NPTII protein is known to be rapidly degraded under simulated gastric conditions, is neither glycosylated nor heat-resistant and lacks homology to known food allergens using several databases. FDA concludes that there are no allergenicity concerns.

Food & Feed Use
Corn (Zea mays L.) originated in Mexico and was grown as a food crop as early as 2700 B.C. Today, corn is grown worldwide for food, feed, and industrial uses. Corn grain is used in food primarily in the form of processed products, such as high fructose corn syrup, cereals, oil, meal, flour, starch, and grits. Corn is a source of nutritionally important amino acids (methionine and cystine), carotenoids, and vitamin E. Corn oil is rich in polyunsaturated fatty acids and is used mainly as a salad and cooking oil and in margarine production.

Corn is also used in animal feed. Corn grain is primarily fed to cattle, poultry, and swine either as intact or processed grain or as dry or wet milling byproducts, but may be a component of most animal feeds. Corn silage (entire above ground portion of the corn plant that is harvested prior to maturation) is primarily fed to ruminants.

Composition
Scope of Analysis
Monsanto analyzed the composition of forage and grain from the MON 87460 corn and compared it with its near isogenic parental line (a non-transgenic corn variety with a similar genetic background to MON

87460, hereafter referred to as the comparator control line). Two field studies were summarized in Monsanto's submission (United States (U.S.) and Chilean studies).

- In the U.S. study, Monsanto evaluated the composition of forage and grain from MON 87460, its comparator control line, and from a total of eighteen commercial non-transgenic corn varieties.
- In the Chilean study, Monsanto evaluated the composition of forage and grain from MON 87460, its comparator control line, and sixteen commercial non-transgenic corn varieties grown under water-limited or irrigation conditions.

Monsanto used the data derived from the reference varieties to generate a 99% tolerance1 interval for each component. Monsanto states that these data illustrate the natural variability in commercially grown corn varieties grown under similar field conditions.

Study Design - Compositional Analyses
As described by Monsanto, corn event MON 87460 and the comparator control line were grown at six replicated field sites in corn production regions in the U.S. during the 2006 growing season. At the same sites, three unique conventional commercial hybrid lines were also grown at each of the six sites, thus providing a total of 18 commercial references for compositional analyses of forage and grain tissue samples. Plants in all six sites were grown under commercially acceptable agronomic practices typical for the area, with four sites being rain-fed and two receiving supplemental irrigation. At each field site, seed was planted in a randomized block design with three replicates per block. Forage and grain samples were collected from corn event MON 87460 and the comparator control line from all three blocks. Forage and grain samples were collected from the three conventional commercial hybrid lines from a single block. Samples of forage at the early dent plant growth state and grain at physiological maturity were collected from all plots and analyzed for nutritional components, toxicants, and anti-nutrients. Monsanto measured and evaluated seven components in forage and 68 in grain. Compositional analyses of the forage samples included measurement of moisture, crude fat, crude protein, ash, carbohydrates by calculation, acid detergent fiber (ADF), neutral detergent fiber (NDF), calcium, and phosphorus. Compositional analyses of the grain samples included measurement of moisture, crude fat, crude protein, ash, carbohydrates by calculation, ADF, NDF, total dietary fiber (TDF), amino acids (18), fatty acids (C8-C22), minerals (calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium, and zinc), vitamins (vitamin B1, vitamin B2, vitamin B6, vitamin E, niacin, and folic acid), and key secondary metabolites (furfural, p-coumaric acid, and ferulic acid), anti-nutrients (raffinose and phytic acid).

Monsanto also described field trials from the 2006-2007 growing season in commercial corn production regions of Chile. According to Monsanto, these four sites are well-suited to growing corn, but typically do not receive any rainfall so crops receive water only through controlled irrigation. Monsanto planted corn event MON 87460, the comparator control line, and four unique commercial conventional hybrid corn lines per site, providing a total of 16 commercial references for compositional analyses of forage and grain samples. At the Chilean sites, Monsanto used a strip plot design with three replicates per site with the water level treatment (either well-watered for optimal growth using irrigation or water-limited to impose a drought stress during a critical stage of growth) as the whole plot and substance type as the subplot to allow for a comparison of plants grown under the two different water level treatments. Monsanto described the whole plot factor as arranged as a randomized complete block design and the split-plot factor consisting of corn event MON 87460, the comparator control line, and the conventional commercial hybrid lines. Monsanto collected forage (early dent stage) and grain samples (at physiological maturity) from corn event MON 87460 and the comparator control line from all three blocks for each treatment and forage and grain samples from the four conventional commercial hybrid lines from a single block for each irrigation treatment.

For the U.S. study, statistical assessments of the compositional data were conducted using mixed model analysis of variance on each individual site and a comparison across all sites, referred to as the combined site analysis. For the Chilean field trials, Monsanto described statistical considerations to assess the effects of the two irrigation treatments. As described by Monsanto, for a site to be considered in the combined-site analysis, the commercial conventional hybrid lines must have exhibited a phenotypic response indicative of the treatment. For the water-limited plants, this response was defined as a minimum of a 15 percent reduction in yield. In summary, for the Chilean field trials, there were four sets of statistical analyses made for each treatment, three used data from each of the field sites and the fourth used data from a combined-site analysis

Statistical differences at the 5 percent level ($P<0.05$) were declared to be significant. Where statistically significant differences between corn event MON 87460 and the comparator control line were observed, Monsanto notes that all mean component values of the test and control substances were within the 99 percent tolerance interval established from the commercial references.

Results of analyses:
Monsanto made the following observations and conclusions regarding the results of the levels of components measured in forage and grain from corn event MON 87460. For the U.S. field trials, 77 different analytical components were measured, 15 had more than 50 percent of the observations below the assay limit of quantitation. These components are known to be present at low levels in corn grain. Noted below are statistically significant differences detected for the combined-site analysis only. Similarly, for the Chilean well-watered field trials, of the 77 different analytical components measured, 16 had more than 50 percent of the observations below the assay limit of quantization.

Compositional analysis of corn forage
Monsanto reported no statistically significant differences in moisture, crude fat, crude protein, ash, carbohydrates by calculation, ADF, NDF, calcium, and phosphorus levels between MON 87460 and the comparator control line in the U.S study. Similarly, there were no statistically significant differences in moisture, crude fat, crude protein, ash, ADF, NDF, calcium, and phosphorus levels in the water-supplemented treatment in Chile. Carbohydrates by calculation was higher in forage obtained from MON 87460 when compared to the comparator control line in corn grown under water-supplemented treatment, but the values for MON 87460 and the comparator control line fell within the 99 percent tolerance interval for conventional varieties grown under similar conditions. Total fat was higher in forage obtained from MON 87460 when compared to the comparator control line in corn grown under water-limited conditions, but the values for MON 87460 and the comparator control line fell within the 99 percent tolerance interval for conventional varieties grown under similar conditions.

Compositional analysis of corn grain
U.S. Study:
Monsanto reported no statistically significant differences in moisture, crude fat, crude protein, carbohydrates by calculation, ADF, NDF, TDF, minerals (calcium, copper, iron, magnesium, manganese, phosphorus, potassium, and zinc), all 18 amino acids, 7 fatty acids (palmitic, palmitoleic, oleic, linoleic, linolenic, arachidic, and behenic acids), 6 vitamins, phytic acid, raffinose, ferulic acid, and p-coumaric acid between MON 87460 and the comparator control line. Ash and stearic fatty acid contents were statistically higher in MON 87460 than the comparator control line, but the MON 87460 and comparator control line values fell within the 99% tolerance interval for conventional varieties grown under similar conditions. Eicosenoic fatty acid content was statistically lower in MON 87460 when compared to the comparator control line and both of these values were slightly lower than the lowest value for the 99% tolerance interval.

Chilean Water-Supplemented Sub-plot:
Monsanto reported no statistically significant differences in moisture, crude protein, ash, carbohydrates by calculation, ADF, NDF, TDF, minerals (except for magnesium), all 18 amino acids, the 8 detectable fatty acids, 6 vitamins, phytic acid, raffinose, ferulic acid, and p-coumaric acid between MON 87460 and comparator control line. Ash and magnesium contents were statistically higher in MON 87460 than the comparator control line, but the values for MON 87460 and the comparator control line fell within the 99% tolerance interval for conventional varieties grown under similar conditions.

Chilean Water-Limited Sub-plot:
Monsanto reported no statistically significant differences in moisture, crude fat, crude protein, ash, carbohydrates by calculation, ADF, NDF, TDF, 8 minerals, 18 amino acids, fatty acids (except eicosenoic acid), 6 vitamins, phytic acid, raffinose, ferulic acid, and p-coumaric acid between MON 87460 and comparator control line. Although the values for eicosenoic acids were statistically different, the values were numerically (at two decimal points) the same and these values fell within the 99 percent tolerance interval for conventional varieties grown under similar conditions.

Summary of Compositional Analyses
As noted above, in Monsanto's combined site analyses, a few statistically significant differences were found in the comparisons of corn event MON 87460 and the comparator control line. Of the statistically significant differences detected, all mean component values were within the 99 percent tolerance level established from the commercial references. In addition, the mean levels for each of these components were within the range of values reported in either the International Life Science Institute (ILSI) Crop Composition Database (ILSI 2006), the OECD consensus document (OECD, 2002), or both. Monsanto concluded that the differences were within the natural variability of corn.

Conclusion
FDA evaluated Monsanto's submission to determine whether the developer's product raises any safety issues with respect to the intended modification or with respect to the food itself, as discussed in the agency's 1992 Policy Statement on New Plant Varieties. Based on the information provided by the company and other information available to the agency, FDA did not identify any issues under Sections 402 and 409 of the Federal Food, Drug and Cosmetic Act that would require further evaluation at this time.

Monsanto has concluded that its drought tolerant corn variety, corn event MON 87460 (MON-8746Ø-4) and the foods and feeds derived from it are as safe as conventional corn varieties and with the exception of the drought tolerance trait, are not materially different in composition or any other relevant parameter from other corn varieties now grown, marketed, and consumed in the U.S. At this time, based on Monsanto's data and information, the agency considers Monsanto's consultation on MON 87460 corn to be complete

Susan Carlson

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[1]A 99 percent tolerance interval represents, with 95 percent confidence, 99 percent of the values contained in the population of commercial conventional corn varieties

APPENDIX B. POLLEN- AND GENE-MEDIATED GENE FLOW

B.1. Gene Flow among Corn Cultivars

As reviewed by Zapiola and Mallory-Smith (2008), several factors are necessary for and can affect levels of pollen-mediated and seed-mediated gene flow between plant populations. Table B-1 lists and describes the many factors that affect gene flow.

Table B-1: Factors that contribute to gene flow due to pollen and seed

Pollen mediated gene flow	Seed mediated gene flow
Requires: • Coexistence of pollen donor and receptors • Overlapping flowering phenology • Successful pollination and fertilization • Establishment	**Requires:** • Dispersal – weather, animals, humans
Factors that increases pollen gene flow: • Feral crop populations and volunteers • Sexually compatible wild relatives • Out-crossing • Self-incompatibility • Large pollen source • Large pollen production • Strong winds (wind pollination) • Lightweight pollen • Insect populations (insect pollination) • Long pollen viability • Favorable weather conditions for pollen viability (low temp and high humidity)	**Factors that increase seed gene flow:** • Feral crop populations and volunteers • Small seeds • Lightweight seeds • High seed production • Seed shattering • Seed dormancy • Use of commingled seed • Seed transport • Improperly cleaned machinery
Factors that decrease pollen gene flow: • Isolation of populations • Non-synchronous flowering time • Border rows • Volunteer control	**Factors that decrease seed gene flow:** • Certified seed • Proper machine cleaning between fields • Proper transport of seeds • Correct product labeling • Volunteer control

Source: Adapted from Zapiola and Mallory-Smith 2008.

B.1.1 Pollen-mediated Gene Flow

Overview of gene flow

For gene flow to occur between corn cultivars or varieties, the pollen donor and pollen receptor plants must be sexually compatible, flowering phenology must overlap between source and sink populations, pollen transfer must occur, embryo/seeds must develop, and hybrid seed must disperse and establish. Corn is a monoecious (both male and female flowers on the same plant), 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 restricted between genetically modified, conventional, and organic corn. However, spatial and temporal isolation can be an effective barrier to gene exchange between corn crop cultivars (Zapiola and Mallory-

Smith 2008). In addition, current practices for maintaining the purity of hybrid seed production in corn are typically successful for maintaining 99 percent genetic purity (Ireland et al. 2006). The following are properties affecting pollen-mediated gene flow from corn:

- **Physical properties of corn plants:** The male and female reproductive structures of corn are physically separated and contribute to out-crossing. The male structure, the tassel, is at the top of the corn plant. The female structures, the silks, form at axillary buds lower on the plant at leaf junctions.
- **Properties of corn pollen:** Corn pollen is very large and heavy (in relation to other grass species) and, given its large size, pollen is primarily dispersed downwind from tassels into adjacent rows of planted corn. Once corn pollen is released, its viability depends on environmental conditions. Viability can be low when conditions are dry – only 1 to 4 hours (Bannert 2006) – or remain viable for up to 24 hours after shedding under conditions of cool temperature and high humidity (Luna et al. 2001).
- **Flower synchrony:** Because of the limited viability of corn pollen – 1 to 24 hours, as stated above – and short flowering period of corn plants, synchronization of pollen dispersal and flowering time is critical for the occurrence of pollen mediated-gene flow (Zapiola and Mallory-Smith 2008). Cross-pollination between neighboring corn fields can be effectively reduced, if not prevented, by desynchronizing flowering between fields by altering planting dates. Halsey et al. (2005) demonstrated that while gene flow could be detected at 0.01 percent at 1,640 feet (500 meters) from source populations when flowering time was synchronized, the farthest distance where this level of gene flow could be detected was 203 feet (62 meters) from source populations when flowering was desynchronized.
- **Insect pollination:** Insect pollinators (e.g., honeybees) often collect maize pollen from tassels for feeding and breeding of their larva, but because the female structures lack nectar production and other attractants, bees typically do not visit the silks. When bee populations are established before corn flowering, bees often avoid pollen collection from corn even when corn plants are close, because of bee preference for the flowers of other plant species. Therefore, insects, and honeybees in particular, do not usually contribute to fertilization and cross-pollination (Bannert 2006).
- **Wind pollination:** Wind pollination is the primary and most effective mechanism for fertilization and cross-pollination, or gene flow, between corn plants. Variation in flowering timing within corn crop fields can increase the flowering window of a given corn field. However, to maximize yield, most corn varieties have been selected to have a synchronous flowering time within the same field. Depending on genotypic and environmental factors, tassels typically shed pollen for 2 to 14 days (Bannert 2006). Pollen is typically released during dry and drying conditions, and often released in advance of changing atmospheric conditions (Bannert 2006). Tassel maturity and pollen release can occur on corn plants exposed to drought conditions, but silk deployment is delayed, reducing the fertilization and pollination window of drought-affected corn plants (Hall and Twidwell 2002). Rain is disadvantageous for pollen dispersal and frequent rainy weather can reduce fertilization in corn crops.

- **Pollen migration distance:** As stated above, corn pollen is very large and heavy (in relation to other grass species) and is primarily dispersed downwind from tassels into adjacent rows of planted corn. Thus, isolation distances can reduce movement of most of the pollen between two corn fields, but based on the evidence from these studies, complete confinement is not likely. Generally, most of the pollen moves within 9 to 49 feet (6 to 15 meters) of the donor plant, although wind can carry pollen for much greater distances. Numerous studies have examined the rate of pollen-mediated gene flow between corn populations (reviewed in Sanvido et al. 2008). Because of the multitude of different experimental designs results vary between studies, but most demonstrate that cross-fertilization rates drop below 1 percent within 33 feet (10 meters) of source plants, and levels of cross-fertilization (gene flow) was maintained below 0.5 percent within the first 164 feet (50 meters) (Sanvido et al. 2008). Early studies examining gene flow from corn demonstrated gene flow up to 1,650 feet [503 meters] from source fields (Jones and Brooks 1950), but many more recent studies suggest that gene flow distance follows an exponential decrease and diminishes greatly with increasing distance from source fields more than 656 feet [200 meters]) (Sanvido et al. 2008, Ireland et al. 2006), but limited instances of long-distance (more than 1,148 feet [350 meters]) low-level gene flow can occur when weather conditions, such as high winds, cool temperatures, and high humidity, contribute to increased pollen viability and dispersal (Bannert 2006).
- **Border rows and field size:** Planting of border rows at corn fields can contribute to reductions in gene flow, but cannot prevent it because turbulent wind currents can contribute to pollen dispersal beyond sink-field borders and some studies have demonstrated higher rates of gene flow from adjacent fields into field borders (Ireland et al. 2006). Luna et al. (2001) examined the effects of varied isolation distances between maize plants in Mexico, and found that low levels of cross-pollination occurred at 328 feet (100 meters) and that no pollination occurred at distances beyond 656 feet. Other researchers have shown that pollination can be as high as 60 percent between contiguous rows, but that from more remote rows it decreased with increasing distance such that no outcrosses were found 105 feet (32 meters) away from the pollen source (Castillo and Goodman 1997, Louette 1996). In large, field-based assessments of corn gene flow in the United Kingdom, Weekes et al. (2007) demonstrated that gene flow rates decreased rapidly with increasing distance from the GE source, but can be detected at distances up to and including 656 feet from the GE source. In addition, computer-based models predict that rates of gene flow can increase as the size of GE fields increase (Kuparinen et al. 2007).
- **Pollen competition:** A comparison of the risk of open-pollinated corn cultivation (non-hybrid) versus hybrid corn cultivation suggests that cross-fertilization rates are higher in open pollination production (Sanvido et al. 2008). However, research by Goggi et al. (2007) evaluated the effects of pollen competition (gene flow from a source into an established stand of corn) on gene flow between GE and non-GE corn. At distances of more than 328 feet (100 meters), the out-crossing frequency between GE corn and non-GE corn decreased to below 0.1 percent in fields with reduced pollen competition and below 0.03 percent in fields with normal pollen competition. These results indicate that when local pollen levels are low, incoming pollen has a competitive advantage, which results in a notably greater frequency of out-crossing than when the local pollen is

abundant. Accordingly, large corn donor fields can contribute to greater pollen flow into small recipient fields as a result of pollen competition (Jemison and Vayda 2001). Similarly, because of the low production of pollen in hybrid corn fields, low pollen competition could contribute to higher rates of cross-fertilization if temporal or spatial isolation is not observed (Zapiola and Mallory-Smith 2008).

B.1.2 Seed-mediated Gene Flow

Overview of seed dispersal

For gene flow to occur via seeds and result in feral populations of corn, seeds must disperse and establish in new habitats. Through thousands of years of selective breeding by humans, corn has been extensively modified to depend on human cultivation for survival. 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 crop species not equipped for survival without management (Gould 1968). 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, or husk (Zapiola and Mallory-Smith 2008). 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, because of the tightly bound nature of the corn seeds, competition between siblings can reduce fitness. The following are properties affecting seed-mediated gene flow from corn:

- **Human mediated seed dispersal:** Human-influenced seed-mediated gene flow in corn could occur as a result of seed mixing following improper cleaning of field machinery, and improper seed purity and certification methods. As described in Section 3.3.5, corn seed is almost exclusively produced as hybrid lines, with great care taken to maintain parental stock lines. However, in almost all current corn production, corn is planted as hybrid seed to reduce intra-field variation in plant height, flower synchrony, and harvest. Because of the nearly exclusive cultivation of hybrid lines that must be produced yearly by intentional hybridization between two different inbred lines, corn seed is not saved in the United States from previous harvests for replanting in subsequent years; instead, it purchased each year (Fernandez-Cornejo 2004). Feral corn plants can sometimes occur along roadsides as a result of seed spill during transport, but do not typically persist because of the same factors that reduce persistence in fields. Therefore, the purity of seed stocks purchased in each year would determine seed-mediated gene flow into corn fields.
- **Animal mediated seed dispersal:** Several different animal species (e.g., deer, wild boar, and waterfowl) will consume scattered corn if it is present, but dispersal of viable seeds is limited. Research by scientists in Germany has demonstrated that corn seeds do not survive digestion by deer, and survival of viable GE corn seeds through wild boar is extremely limited (0.009 percent) (Guertler et al. 2008, Wiedemann et al. 2009). In addition, research by Cummings et al. (2008) demonstrated that passage of viable corn seed does not occur through mallard ducks and rock pigeons.
- **Seed traits and weediness of corn:** The domestication history of corn has resulted in the production of a plant species that has a greatly reduced ability to persist and survive

outside of human cultivation. Lack of seed dormancy prevents accumulation of corn in weed seed banks, and lack of seed shatter and encasement within corn husks prevents dispersal of seeds. Therefore, corn is not suited to survive without human management and is not typically described as a weed (Baker 1965, Keeler 1989, Galinat 1988). Corn is not present as a noxious weed on federal lists ((USDA-APHIS 2010, Crockett 1977, Holm et al. 1979, Muenscher 1980) though the Southern Weed Science Society lists it as a weed (USDA-NRCS 2010). Volunteer corn can sometimes overwinter and occur in fields following cultivation and crop rotation, particularly with soybeans, but does not persist and can be controlled using mechanical or chemical measures. In addition, persistent populations of feral corn are not common along transportation routes or other weedy environments (see Zapiola and Mallory-Smith 2008). Based on the traits of modern corn and the factors necessary for corn to establish in new populations, it is not likely that gene flow will occur via seeds into new feral corn populations.

APPENDIX C. CHARACTERISTICS MEASURED FOR PHENOTYPIC, AGRONOMIC, AND ENVIRONMENTAL INTERACTIONS ASSESSMENT OF MON 87460

Characteristic	Characteristic Measured	Evaluation Timing	Evaluation Description (measurement endpoints
Plant phenotypic and agronomic characteristics	Dormancy, Germination	After 4, 7, and 12 days	Percent normally germinated, abnormally germinated, viable hard (dormant), dead, and viable firm swollen seed
	Seedling vigor	Stage V2–V4	Rated as: 1-3 = above average vigor, 7-9 = below average vigor (2007 scale) or, where 0 = dead, and 9 = above average vigor (2006 scale)
	Early stand count	Stage V2–V4	Number of emerged plants per plot
	Final stand count	Pre-harvest	Number of plants per plot
	Stay green	Maturity	Rated as: 1 = 90-100% green tissue, 5 = 50-59% green tissue, 9 = 0-19% green tissue (2007 rating scale) or, 0 = entire plant dried, and 9 = entire plant green (2006 rating scale)
	Ear height	Maturity	Distance from the soil surface at the base of the plant to the ear attachment node
	Plant height	Maturity	Distance from the soil surface at the base of the plant to the flag leaf collar
	Stalk lodged plants	Pre-harvest	Number of plants per plot broken below the ear
	Root lodged plants	Pre-harvest	Number of plants per plot leaning at the soil surface at >30° from the vertical
	Days to 50% pollen shed	Pollen shed	Days from planting until 50% of the plants have begun to shed pollen
	Days to 50% silking	Silking	Days from planting until 50% of the plants have silks exposed
	Pollen viability	Tasseling	Viable and nonviable pollen based on pollen grain staining characteristics
	Pollen morphology	Tasseling	Diameter of viable pollen grains
	Grain moisture	Harvest	Moisture percentage of harvested shelled grain
	Test weight (lb/bu)	Harvest	Test weight of harvested shelled grain
	Yield (bu/ac)	Harvest	Harvested weight of shelled grain, adjusted to 15.5% moisture

Characteristic	Characteristic Measured	Evaluation Timing	Evaluation Description (measurement endpoints
	Dropped ears	Pre-harvest	Number of mature ears dropped from plants
Plant environmental interactions	Insect, disease and abiotic stressors	Variable, from planting to harvest	Qualitative assessment of each plot, with rating on a 0-9 scale for plant-insect, plant-disease, and plant response to abiotic stressor interactions
	Abiotic stress tolerance to drought, cold, heat, and salt	Stage V2–V6	Conducted in greenhouse and growth chamber experiments. Measurements included plant height, growth stage, vigor, chlorophyll content, and biomass.
	Volunteer potential	After fall planting and following spring	Number of plants present as volunteer corn in plots
	Survival outside of cultivation	Variable, from planting to harvest	Variable, phenotypic assessments from planting to harvest that includes early and final stand counts, vigor ratings, plant height, and number of ears and seed per plot

Source: (Reeves, 2010)