NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

MONSANTO COMPANY
EVENT MON 87460 CORN

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has developed this decision document to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) regulations implementing NEPA, and the USDA APHIS' NEPA implementing regulations and procedures. This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS Number 09-055-01p) by Monsanto Company (Monsanto) for their genetically engineered MON 87460 drought tolerant (DT) corn (hereafter referred to as MON 87460). MON 87460 is designed to mitigate grain yield loss under water-limited conditions. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from a determination of nonregulated status of MON 87460. The EA assesses alternatives to a determination of nonregulated status of MON 87460 and analyzes the potential environmental and social effects that result from the proposed action and the alternatives.

Regulatory Authority

"Protecting American agriculture" is the basic charge of 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, organic, or the use of genetically engineered (GE) varieties) 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

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §508.14).

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 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 provisions 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). EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act (FFDCA) and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). The 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.

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.

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 who request a determination of the regulated status of GE organisms, including GE plants such as MON 87460. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE 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.

Monsanto has submitted a petition (APHIS Number 09-055-01p) to APHIS seeking a determination that their genetically engineered MON 87460 drought tolerant corn is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

Monsanto Event MON 87460 Corn

MON 87460 is designed to mitigate grain yield loss under water-limited conditions. As detailed in the Monsanto 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* (Monsanto, 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 (Monsanto, 2010).

Drought is one of the major limiting factors in corn that prevents realization of optimum grain yield worldwide (Boyer, 1982). 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).

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 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).

Scope of the Environmental Analysis
The scope of analysis includes any land in the U.S. currently producing corn, any land that is currently producing crops that could incorporate a corn rotation, as well as land that could be converted from inactive cropland to active cropland, and land currently in the Conservation Reserve Program (CRP) that could be removed from the program and farmed. Conversion of grassland, forest, or other land types to cropland as a result of a determination of nonregulated status of 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 the EA. Furthermore, as described in Chapter 4 of the EA, 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.

Public Involvement
On May 11, 2011, APHIS published a notice in the Federal Register (76 FR 27303-27304, Docket no. APHIS-2011-0023) announcing the availability of the Monsanto petition, and the APHIS PPRA and draft EA for a 60-day public review and comment period. Public comments were initially solicited for a 60-day public comment period ending July 11, 2011; however, APHIS extended the public comment period for an additional 30 days (76 FR 44892-44893, docket number APHIS-2011-0023). Comments were required to be received on or before August 12, 2011. A total of 250 comments were received from various groups and individuals during the 90 day comment period. The majority of the comments (229) opposed the development and use of genetically engineered foods and/or MON87460 corn, while 21 comments supported a determination of nonregulated status of MON87460 corn. Three of the comments opposing a determination of nonregulated status included submitted electronic attachments that consisted either of: a) a single letter signed by numerous people (6,335

signatures); b) many letters containing identical material (16,742 letters); or c) a consolidated document of comments (22,500). Public comments included individual submissions, form letters, and various electronic media encompassing both the peer-reviewed and non-peer-reviewed literature. Comment documents may be viewed at http://www.regulations.gov/#!searchResults:dct=PS;rpp=10;po=0;s=APHIS-2011-0023. All comments were carefully analyzed to identify new issues, alternatives, or information. Responses to substantive comments are included as an attachment to this Finding of No Significant Impact.

Major Issues Addressed in the EA

The issues considered in the EA were developed based on APHIS' determination that certain genetically engineered organisms are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status of MON 87460. Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments of genetically engineered 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 genetically engineered plants were addressed to analyze the potential environmental impacts of MON 87460.

The EA describes the alternatives considered and evaluated using the identified issues. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25):

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
- Gene movement

Human health considerations:

- Public health
- Worker safety
- Livestock feed

Socioeconomic considerations:

- Domestic economic environment
- Trade economic environment

Alternatives that were fully analyzed
The EA analyzes the potential environmental consequences of a determination of nonregulated status of MON 87460. 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 were evaluated in the 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 of the EA.

No Action: 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.

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.

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.

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 has concluded that MON 87460 is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON87460.

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.

Isolation distance between MON 87460 and non-GE corn 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 corn 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 2009).

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.

Environmental Consequences of APHIS' Selected Action

The EA contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

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		

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

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

Finding of No Significant Impact
The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I agree with this conclusion and therefore find that an EIS need not be prepared. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27):

Context – The term "context" recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action has potential to affect conventional and organic corn production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; and foreign and domestic commodity markets. Corn grain is commercially produced in all U.S. states except Alaska (USDA, 2009). 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. with 86 percent of all corn planted in 2010 representing a GE variety (USDA-ERS, 2010; USDA-ERS, 2010a). Of the 13.1 billion bushels, 11.1 billion bushels entered the domestic market and 2 billion bushels were exported (USDA-ERS, 2011). 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, 2010a, 2011).

As described in Chapter 4 of the EA, MON 87460 would be cultivated in areas that already support economically viable corn production. MON 87460 does not exhibit traits that would allow it to establish outside the agricultural environment. 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. As a result, MON 87460 could be grown on 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 that could be removed from the program and farmed. Conversion of grassland, forest, or other land types to cropland as a result of a determination of nonregulated status of MON 87460 would be less likely because these types of conversions have not been notable contributors to cropland over the past 18 years. A determination of nonregulated status of MON 87460 is not expected to directly cause an increase in agricultural acreage devoted to corn production beyond projected USDA-ERS increases and is not anticipated to change the availability of GE and non-GE corn varieties on the market. 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.

Intensity – Intensity is a measure of the degree or severity of an impact based upon the ten factors. The following factors were used as a basis for this decision:

1. *Impacts that may be both beneficial and adverse.*
   A determination of nonregulated status of MON 87460 will have no significant environmental impact in relation to the availability of GE, conventional, organic or specialty corn varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 87460 is not expected to directly cause an increase in agricultural acreage devoted to corn production beyond projected USDA-ERS increases. The availability of MON 87460 will not change cultivation areas or cropping practices

for corn production. MON 87460 would be cultivated in areas that already support economically viable corn production. MON 87460 does not exhibit traits that would allow it to establish outside the agricultural environment. Minimum moisture requirements are similar between MON 87360 and conventional corn. 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. A determination of nonregulated status of MON 87460 could add another GE corn variety to the conventional corn market and is not expected to change the availability of GE and non-GE corn varieties on the market. 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. Corn-related farm incomes could increase in areas that adopt MON 87460. The impact of such an increase in returns would be greater for states where farms represent a greater share of state gross domestic product and where corn represents a greater share of crop acreage. Impacts on overall farm household incomes due to a determination of nonregulated status of MON 87460 are expected to be negligible. Growers will likely experience less yield loss with MON 87460 than those incurred by planting non-drought tolerant corn varieties. MON 87460 is designed to provide increased yield security in current corn-producing areas that are subject to moderate drought stress and is expected to reduce yield loss by six percent or more under water-limited conditions compared to conventional corn (Monsanto, 2010). 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. Therefore, the impacts of a determination of nonregulated status of MON 87460 would not likely be different from the corn seed options that currently exist. 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 a determination of nonregulated status 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.

2. *The degree to which the proposed action affects public health or safety.*

A determination of nonregulated status of MON 87460 would have no significant impacts on human or animal health. The food/feed nutritional and safety assessment for MON 87460 has been reviewed by the FDA. 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 on December 19, 2008. Based on the information provided by Monsanto, FDA completed their consultation on MON 87460 on December 10, 2010 and had no further questions concerning MON 87460 drought tolerant corn (FDA, 2010). 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 a determination of nonregulated status of MON 87460 would have no adverse impacts on human or animal health.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.*

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of MON 87460. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property; do not cause any alterations of property, wildlife habitat, or landscapes; and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of MON 87460. The product will be deployed on agricultural land currently suitable for production of corn, will replace existing varieties, and is not expected to increase the acreage of corn production. Progeny of this variety that express the identified traits of the MON 87460 will be retained by Monsanto or licensed users. 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. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of MON 87460, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to corn production sites.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

The effects on the quality of the human environment from a determination of nonregulated status of MON 87460 are not highly controversial. Although there is some opposition to a determination of nonregulated status of MON 87460, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 87460 is not expected to directly cause an increase in agricultural acreage devoted to corn production, or those corn acres devoted to GE corn cultivation. The availability of MON 87460 will not change cultivation areas for corn production in the U.S. and there are no anticipated changes to the availability of GE and non-GE corn varieties on the market. MON 87460 is not expected to directly cause an increase in agricultural acreage devoted to corn production beyond projected USDA-ERS increases. A determination of nonregulated status of MON 87460 will not result in changes in the current practices of crop rotation, tillage, and herbicide and pesticide use. MON 87460 exhibits similar agronomic and growth characteristics to conventional corn, with the exception of reduced grain yield loss under water-limiting conditions. Physiological evidence and recorded measures of moisture depletion strongly indicate that water use (uptake of water by the plant) is not different between MON 87460 and conventional corn (Monsanto, 2010). The effect of MON 87460 on wildlife or biodiversity is no different than that of other GE or non-GE corn produced in conventional agriculture in the U.S. During the public comment period, APHIS received comments opposing a determination of nonregulated status of MON 87460. Many of these public comments expressed a general opposition to genetically modified organisms (GMOs) or GE crops and the domestic regulatory process surrounding GE plants; perceived negative effects on public and animal health, biodiversity, and the environment; and a lack of consideration regarding organic production systems and the public right to choose non-GE containing food products. The majority of these public comments did not explain or identify elements in the MON87460 corn PPRA or EA that were perceived to be inadequate or provide any supporting evidence for their claims. However, several specific issues related to the MON87460 EA were identified. APHIS has addressed these concerns in the response to public comments document attached to this FONSI based on scientific evidence found in peer-reviewed, scholarly, and scientific journals.

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*

Based on the analysis documented in the EA the possible effects on the human environment are well understood. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 87460 is not expected to directly cause an increase in agricultural acreage devoted to corn production, or those corn acres devoted to GE corn cultivation. The availability of MON 87460 will not change cultivation areas for corn production in the U.S. and there are no anticipated changes to the availability of GE and non-GE corn varieties on the market. MON 87460 is not expected to directly cause an increase in agricultural acreage devoted to corn production beyond projected USDA-ERS increases. A determination of nonregulated status of MON 87460 will not result in changes in the current practices of crop rotation, tillage, and herbicide and pesticide use. MON 87460 exhibits similar agronomic and growth characteristics to conventional corn, with the exception of reduced grain yield loss under water-limiting conditions. Physiological evidence and recorded measures of moisture depletion strongly indicate that water use (uptake of water by the plant) is not different between MON 87460 and conventional corn (Monsanto, 2010). The effect of MON 87460 on wildlife or biodiversity is no different than that of other GE or non-GE corn produced in conventional agriculture in the U.S. As described in Chapters 2 and 4 of the EA, well established management practices, production controls, and production practices (GE, conventional, and organic) are currently being used in corn production systems (commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce conventional corn (GE and non-GE varieties), MON 87460, or produce corn using organic methods or specialty systems, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural corn production. Additionally, most of the corn acreage in the U.S. is planted to GE corn. 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. with 86 percent of all corn planted in 2010 representing a GE variety (USDA-ERS, 2010; USDA-ERS, 2010a). GE corn varieties represent a progressively increasing proportion of total U.S. corn planted, ranging from a low of 25% in 2000 to 86% in 2010 (USDA-ERS, 2010). Based upon historic trends, conventional production practices that use GE varieties will likely continue to dominate in terms of acreage with or without a determination of nonregulated status of MON 87460. Given the extensive experience that APHIS, stakeholders, and growers have in dealing with the use of GE corn products, the possible effects to the human environment from the release of a an additional GE corn product are already well known and understood. Therefore the impacts are not highly uncertain, and do not involve unique or unknown risks.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*
A determination of nonregulated status of MON 87460 would not establish a precedent for future actions with significant effects or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based upon an independent determination on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and undergoes this independent review to determine if the regulated article poses a plant pest risk. 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 who request a determination of the regulated status of GE organisms, including GE plants such as MON 87460. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment 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 regulations at 7 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 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.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*
No significant cumulative effects were identified through this assessment. The EA discussed cumulative effects on corn management practices, human and animal health, and the environment and concluded that such impacts were not significant. In Chapter 5 of the EA, a cumulative effects analysis is included for each environmental issue analyzed in the EA. In the event of a determination of nonregulated status, MON 87460 may be stacked (combined) with non-GE and GE corn varieties by traditional breeding techniques, resulting in a plant that, for example, may also be insect resistant or herbicide tolerant. There is no guarantee that MON 87460 will be stacked with any particular GE variety that has previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, as company plans and market demands play a significant role in those business decisions. Moreover, MON 87460 could even be combined with non-GE corn varieties. Thus, predicting all potential combinations of stacked varieties that could be created using both GE corn varieties that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act and also non-GE corn varieties is hypothetical and purely speculative. In the event of a determination of nonregulated status of MON 87460, APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of MON 87460 when added to other past, present, and reasonably foreseeable future actions.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.*
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. A determination of nonregulated status of MON 87460 would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of nonregulated status of MON 87460. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of MON 87460 is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is

that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the corn production regions. The cultivation of MON 87460 does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

9. *The degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*
As described in Chapter 6 of the EA, APHIS has analyzed the potential for effects from cultivation of MON 87460 and its progeny on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of MON 87460, 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.

10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*
The proposed action would be in compliance with all federal, state, and local laws. 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. 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 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). There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting Alternative 2 (Determination that MON 87460 is No Longer a Regulated Article). This alternative meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the Plant Protection Act.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with MON 87460, the continued regulated status of MON 87460 would be inconsistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of MON 87460 will not have any significant environmental effects.

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
U.S. Department of Agriculture

Date: 11/30/2011

Literature Cited:

AOSCA. (2009). Seed Certification Handbook: Including Genetic and Crop Standards, Procedures, and AOSCA Service Programs.

Barker, T., Campos, H., Cooper, M., Dolan, D., Edmeades, G., Habben, J., Schussler, J., Wright, D., & Zinselmeier, C. (2005). Improving drought tolerance in maize. In J. Janick (Ed.), *Plant Breeding Reviews* (Vol. 25): John Wiley and Sons, Inc

Boyer, J. S. (1982). Plant productivity and environment. *Science, 218*(4571), 443.

FDA. (2010). List of Completed Consultations on Bioengineered Foods. United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, Maryland, January 2011, from http://www.fda.gov/Food/Biotechnology/Submissions/default.htm

Monsanto (2010). Petition for the Determination of Nonregulated Status for MON 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. The Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

USDA-APHIS. (2010). Plant Pest Risk Assessment for MON 87460 Corn. (Biotechnology Regulatory Service). Riverdale, MD: APHIS - Animal and Plant Health Inspection Service.

USDA-ERS. (2010). Adoption of Genetically Engineered Crops in the U.S.: Corn Varieties Retrieved Aug. 11 2010, from http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable1.htm

USDA-ERS. (2010a). Agricultural Projections to 2019.

USDA-ERS. (2011). USDA Agricultural Projections to 2020.

USDA. (2009). *2007 Census of Agriculture: United States Summary and State Data.*

Yu and Babcock, B. (2010). Are U.S. Corn and Soybeans Becoming more Drought Tolerant? *Staff General Research Papers*: Iowa State University.

Finding of No Significant Impact
Response to Comments
Petition 09-055-01p

On May 11, 2011, APHIS published a notice in the Federal Register (76 FR 27303-27304, Docket no. APHIS-2011-0023) announcing the availability of the Monsanto petition, and the APHIS PPRA and draft EA for a 60-day public review and comment period. Public comments were initially solicited for a 60-day public comment period ending July 11, 2011; however, APHIS extended the public comment period for an additional 30 days (76 FR 44892-44893, docket number APHIS-2011-0023). Comments were required to be received on or before August 12, 2011.

APHIS received a total of 250 comments from various individuals and groups on the MON87460 corn petition, PPRA, and draft EA. The majority of the comments (229) opposed the development and use of genetically engineered foods and/or MON87460 corn, while 21 comments supported a determination of nonregulated status of MON87460 corn. Public comments included individual submissions, form letters, and various electronic media encompassing both the peer-reviewed and non-peer-reviewed literature.

Twenty-one public comments supporting a determination of nonregulated status of MON87460 corn were submitted from private citizens, farmers routinely affected by drought, agribusiness associations, corn grower associations, and state agriculture departments. Those individuals cited several salient points regarding the potential benefits of MON 87460 corn, including: 1) a capacity to alleviate the risk of reduced corn grain yields in areas susceptible to drought; 2) increased economic benefit for consumers, processers, and growers due to more stable corn grain yields; and 3) the utilization of another tool for American corn growers to meet an increasing global demand for corn grain.

Those 229 public comments received opposing a determination of nonregulated status of MON87460 corn were submitted by individuals and Non-Government Organizations (NGO). Of these NGOs, three submitted electronic attachments that consisted either of: a) a single letter signed by numerous people (6,335 signatures); b) many letters containing identical material (16,742 letters); or c) a consolidated document of comments (22,500). Many of these public comments expressed a general opposition to genetically modified organisms (GMOs) or GE crops and the domestic regulatory process surrounding GE plants; perceived negative effects on public and animal health, biodiversity, and the environment; and a lack of consideration regarding organic production systems and the public right to choose non-GE containing food products. The majority of these public comments did not explain or identify elements in the MON87460 corn PPRA or EA that were perceived to be inadequate or provide any supporting evidence for their claims. Several specific issues related to the MON87460 EA were, however, identified from the collective pool of public comments and form letter submissions. These were organized into categories and addressed below.

Public comments and Responses

Comment 1: Several commenters expressed a general disapproval of GE plants for non-cited reasons related to health and the environment; additionally, several comments voiced concern that an Environmental Assessment (EA) was insufficient for MON87460 corn and that an Environmental Impact Statement (EIS) should be prepared to inform any decision regarding a determination of nonregulated status of MON87460 corn. Concerns were also raised in response to a perceived APHIS reliance on Monsanto data throughout the MON87460 EA. Several commenters voiced support for a moratorium on GE plants by the agency.

Response 1: APHIS recognizes that some citizens are opposed to genetic engineering of food crops. As discussed in Chapter 1 of the EA, the basic charge of APHIS is to protect American agriculture through improvements in agricultural productivity and competitiveness, and contributions to the national economy and the public health. APHIS asserts that all methods of agricultural production (conventional, organic, or the use of genetically engineered (GE) varieties) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States government has regulated GE organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (51 FR 23302, 57 FR 22984) (Chapters 1.1; 1.2; and 1.6 of the EA). As described in Chapter 1.2 of the EA, APHIS regulates the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340. 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. Based on scientific information and analysis provided in both the PPRA (USDA-APHIS, 2010) and EA, APHIS has concluded that MON 87460 does not pose a plant pest risk and will not significantly impact the quality of the human environment, respectively. Due to the lack of significant impacts as presented in the FONSI, an EIS for a determination of nonregulated status of MON87460 corn is not necessary.

APHIS relied on a variety of sources to support its analysis of the potential impacts of a determination of nonregulated status of MON87460 including those pertaining to health and the environment. These sources included, but are not limited to the Monsanto petition, Federal agencies (e.g., USDA-ERS, USDA-NASS, and FDA), academic datasets (http://www.prism.oregonstate.edu), and peer-reviewed literature. The analyses in the EA utilized a variety of sources in addition to the MON87460 petition. A complete list of references used to support development of the EA can be viewed in the bibliography located in Chapter 8 of the EA.

APHIS rejects the proposal for a moratorium on the commercialization of MON87460 and GE plants in general. Such an approach would contradict the national policy as described in the Coordinated Framework for the Regulation of Biotechnology (51 FR 23302, 57 FR 22984), which states that the mere fact of using genetically engineering to modify an organism does not mean that the organism necessarily poses a greater risk. Rather, the regulatory approach focuses on the characteristics of the organism or product, and how the organism or product is to be used.

References

USDA-APHIS (2010) Plant Pest Risk Assessment for Mon 87460 Corn. Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html

Comment 2: Several commenters claimed that APHIS failed to consider geographic isolation as an Alternative, since the target range of MON87460 corn is the western dryland Great Plains region. Additionally, several commenters claimed that APHIS generally failed to consider the benefits of organic corn or biodynamic production systems as an Alternative in the EA.

Response 2: The EA was been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from a determination of nonregulated status of MON87460 corn. APHIS assembled a list of alternatives that might be considered for MON87460. 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 MON87460. As described in Chapters 3.1 and 3.2 of the EA, APHIS evaluated two alternatives; (1) no action and (2) determination of nonregulated status of MON87460 in the environmental consequences section of the EA (Chapter 4). In addition, APHIS rejected several other alternatives. These alternatives are discussed briefly in Chapter 3.3 of the EA along with the specific reasons for rejecting each.

As described in Chapter 3.3.3 of the EA, Geographic Restriction was rejected as an Alternative and not analyzed in detail because APHIS concluded that MON87460 does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Consequently, a Geographic Restriction 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; furthermore, the imposition of 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.

APHIS did not consider the general nature of organic agriculture and similar systems as an alternative in the EA because the nature or use of organic agriculture is not within the scope of analysis of this EA or APHIS regulatory decision in response to Monsanto's petition request for MON87460 corn. The EA was been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from a determination of nonregulated status of MON87460 corn. The potential impacts of APHIS' regulatory decision with respect to non-GE, organic and specialty corn production systems are presented in Chapters 2.1.2 and 4.3 of the EA.

Comment 3: Several commenters suggested that the Cumulative Impacts Analysis of the MON87460 EA was inadequate in that the stacking of GE traits was not discussed.

Response 3: APHIS disagrees that the Cumulative Impacts sections in the EA was inadequate. However, in order to further organize and clarify the Cumulative Impacts analysis in the EA, individual Cumulative Impact sections that were presented in Chapter 4 of the draft EA have been consolidated and rewritten as Chapter 5 in the final EA. APHIS directs readers and commenters to Chapter 5 of the EA for any further discussion.

Comment 4: Several comments expressed concern regarding the potential rejection of MON87460 corn produced in the U.S. by certain foreign markets that have not approved MON87460 corn for import.

Response 4: Key nations and governments that import U.S. corn include Japan, Canada, Mexico, and the European Union (EU). Import requirements for the major U.S. corn-importing nations are listed in Chapter 2.6.1 and Chapter 4.8.2 of the EA. As stated in the Monsanto petition (Chapter X.C.1.4) and Chapter 4.8.2.2 of the EA, the Monsanto Company does not intend to enter MON87460 corn into commercial production within the U.S. until all major U.S. corn-importing nations and governments with functioning regulatory systems also grant approval of MON87460 corn (Monsanto, 2010b). Some nations and governments are not presently major importers of U.S. corn, though some are steadily increasing import of U.S. corn (e.g., China) (USDA-ERS, 2011). Of the many GE varieties of corn currently grown by farmers, many are approved for import into other countries, but not all have been approved to all countries (e.g., China). When farmers choose to grow a GE variety of corn, the approval status in foreign countries should be of major concern (NCGA, 2011). The importance of this issue is well known to farmers, distributors, and exporters, because trade disruptions over non approved varieties have been experienced by the industry (Marvier and Acker, 2005). Corn growers associations, such as the National Corn Growers Association (NCGA) provides guidance for GE corn grain production of events that are not approved in certain countries. In short, this guidance suggests that individual growers 1) feed livestock on their own operations with the unapproved events; 2) find domestic livestock feeding channels; and 3) identify grain elevators that accept corn grain varieties that are not approved by other countries and nations (NCGA, 2011). Monsanto is committed to product stewardship, and for its current line of Genuity corn products, notes that "This product has been approved for import into key export markets with functioning regulatory systems. Any crop or material produced from this product can only be exported to, or used, processed or sold in countries where all necessary regulatory approvals have been granted...Growers should talk to their grain handler or product purchaser to confirm their buying position for this product" (Monsanto, 2010a, 2011).

Corn purchasing and processing facilities employ quality control processes to assure buyers that the products produced using specialty corn will be usable for specific end products and destinations. Before commercialization, Monsanto has agreed to make available a detection method for MON87460 corn to grain producers, processors, and buyers in order to control the adventitious presence of non-approved GE traits (Monsanto, 2010b). A determination of nonregulated status of MON87460 corn is unlikely to significantly impact these mechanisms.

References

Marvier M and Acker RCV. (2005) Can Crop Transgenes Be Kept on a Leash? *Frontiers in Ecology and the Environment, 3*(2), 99-106.

Monsanto (2010a) Monsanto Technology/Stewardship Agreement. The Monsanto Company.

Monsanto (2010b) Petition for the Determination of Nonregulated Status for Mon 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. The Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

Monsanto (2011) Genuity Corn and Soybean Trait Products Lineup Expanded for 2011. The Monsanto Company. Retrieved November, 2011 from http://monsanto.mediaroom.com/2011-genuity-corn-soybean-product-lineup

NCGA (2011) Know before You Grow. National Corn Growers Association. Retrieved October, 2011 from http://www.ncga.com/know-before-you-grow/

USDA-ERS. (2011) Feed Grains Database - Custom Query. Retrieved October, 2011 from United States Department of Agriculture - Economic Research Service http://www.ers.usda.gov/data/feedgrains/CustomQuery/Default.aspx

Comment 5: Several commenters claimed that the drought-tolerance of MON87460 corn is unsupported by field trials, emphasizing that MON87460 yield was 9 percent lower than the control under water-limited conditions in its target range and that the MON87460 trait reduced grain yield by ten percent under well-watered conditions. Additionally, several comments also claimed that APHIS did not discuss conflicting reports from independent sources regarding the poor performance of MON87460 under well-watered conditions. A single comment also claimed that Monsanto did not publish its experimental method.

Response 5: APHIS does not agree that the drought-tolerance of MON87460 is unsubstantiated. As mentioned in Chapter 4.3.2.2 of the EA, MON87460 is not intended to eliminate or reduce the need for irrigation over the cultivation period of corn; rather, it is intended to provide a buffer against yield loss during periods of drought stress. While the yield of MON87460 under suitable water-limited conditions does not exceed that of the reference variety range, yield is generally improved relative to its control variety. For example, MON87460 yields were significantly higher than its respective control in combined-site analysis of 2006/2007 Chilean field studies. Under water-limited conditions, both 2007 split plot and strip plot studies demonstrate that MON87460 possessed higher grain yield than its respective control (7.5 and 35.2 percent greater yield, respectively) (Table R1). Both of these sites, while not statistically significant, demonstrated a general increased yield trend of MON87460 corn relative to its respective control corn variety under water-limited conditions and a not a 9 percent decrease.

Table R1. Comparison of grain yield between MON87460 corn and its control in Great Plain states.

	Design	Site	Year	Yield (bushels/acre)	% difference in MON87460 yield
Water-Limited					
MON87460[1]	Split Plot	TX	2007	186	+ 7.5
Control[1]	Split Plot	TX	2007	173.1	
MON87460[2]	Strip plot	TX	2007	228.3	+ 35.2
Control[2]	Strip plot	TX	2007	168.8	
Water-sufficient					
MON87460[3]	Split Plot	TX	2007	215.4	- 1.69
Control[3]	Split Plot	TX	2007	219.1	
MON87460[4]	RCB	KS+NE	2006	164.1	- 6.7
Control[4]	RCB	KS+NE	2006	175.9	
MON87460[5]	RCB	NE	2007	156.4	-0.07
Control[5]	RCB	NE	2007	156.5	
MON87460[6]	Strip plot	KS+NE+TX	2007	192.3	+ 3.05
Control[6]	Strip plot	KS+NE+TX	2007	186.6	

1 Table F-19 of the MON87460 petition.
2 Table VIII-11 of the MON87460 petition.
3 Table F-18 of the MON87460 petition.
4 Table F-14 of the MON87460 petition.
5 Table F-15 of the MON87460 petition.
6 Table F20 of the MON87460 petition.

APHIS also disagrees that MON87460 corn yielded 10 percent less grain than its respective controls under well-watered conditions in Great Plains states. It should be noted that the commenter did not describe how the 10 percent value was calculated. In Table R1, while the 2007-TX split plot and the 2006-KS and NE randomized complete block (RCB) studies showed a decreased MON87460 grain yield relative to its control (-1.69 and -6.7 percent, respectively), other studies demonstrated that grain yields of MON87460 corn are near identical (2007-NE RCB study: - 0.07 percent) or greater (2007-KS, NE, and TX strip plot study: 3.05 percent) than its respective control in the tested Great Plains states. Despite the direction of these differences, the magnitude of differences was not statistically significant. Thus, across time and site locations, MON87460 corn grain yield is comparable to its respective control under water-sufficient conditions in the Great Plains states.

Additionally, with respect to the claim that APHIS did not review independent sources regarding the performance of MON87460 corn under conditions of normal precipitation, APHIS is unable to find any independent reviews of MON87460 in the literature. Even the example provided by the commenter cannot confirm that it is MON87460 that is being discussed ("He stated: —The flaw is a profound one. It amounts to shifting the yield losses experienced in dry seasons onto the good years. While it is not clear from the article whether that variety is the same event as MON 87460…").

With regard to the claim that Monsanto did not publish its experimental design, this is explained in Chapter VIII of the MON87460 petition.

References

Monsanto (2010) Petition for the Determination of Nonregulated Status for MON 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. The Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html)

Comment 6: Several commenters expressed concern that a determination of nonregulatory status of MON87460 corn and other GE crops allows for the creation of corporate food monopolies.

Response 6: APHIS acknowledges the comments. Although APHIS recognizes that new technologies developed and owned by a private firm have the potential to lead to increased market concentration when introduced in the market, introduction of new technologies or increased market concentration do not in themselves lead to unfair competition. Fair competition and business practices are enforced through United States anti-trust laws and institutions and are beyond the scope of this EA.

Comment 7: Several comments expressed concern regarding the plant pest risk of MON87460 corn, including the potential to hybridize with sexually-compatible relatives to produce progeny plants with weedy characteristics. Additionally, a specific reference was made to the root lodging of MON87460 corn in one field trial location and its implication with increased plant weediness.

Response 7: MON 87460 corn was produced by transformation of corn tissue using *Agrobacterium tumefaciens* to introduce the *nptII* (neomycin phosphotransferase II) and *cspB* (cold shock protein B) genes (as described in Appendix A of the EA). Consequently, MON87460 corn was considered a regulated article under APHIS regulations at 7 CFR part 340. Part 340 regulates, among other things, the introduction of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe plant pests. Under 7 CFR part 340 and in response to the Monsanto Company MON87460 petition, APHIS prepared a Plant Pest Risk Assessment (PPRA) and published it in conjunction with the MON87460 Environmental Assessment (EA). APHIS concluded that MON87460 does not pose a plant pest risk and is unlikely to be any more invasive than currently available varieties of corn (USDA-APHIS, 2010).

The Monsanto Company collected agronomic data from numerous MON87460 studies (field, greenhouse, and laboratory) with respect to composition; 14 plant growth and development characteristics, five seed germination parameters, two pollen characteristics; plant response to abiotic stressors; and several observations on plant-insect and plant-disease interactions (Monsanto, 2010). No significant and consistent differences were observed between MON87460 corn and its control with regard to seed germination and pollen characteristics, response to abiotic stresses, and plant-insect/disease responses. From six field studies totaling 31 sites across two years, very few unexpected statistically significant differences were observed in combined site analyses with regard to phenotypic characteristics (i.e., 14 plant growth/development characters and five seed germination characters) indicative of increased weediness between MON87460 corn and control plants. A statistically significant measurement increase in root lodging was observed in one year (Table VIII-4 of the MON87460 petition) and was not observed in other years (Monsanto, 2010). This observation, along with other statistically significant measurements were always within the reference range of other corn varieties, strongly suggesting that the observed measurements were typical variations for corn behavior in the same field trials and not increased plant weediness.

APHIS also evaluated the potential for introgression to occur from MON87460 to sexually compatible wild relatives and considered whether introgression, if it were to occur, would result in increased weediness in the MON87460 PPRA. Cultivated corn (MON87460 included) is sexually compatible with several members of the genus *Zea* (e.g., teosinte), and to a much lesser degree, members of the genus *Tripsacum*. As described in the Chapter 4.5.4 of the EA, the likelihood of gene flow between MON87460 and teosinte due to differences in flowering phenology, current and expected geographic separation, and genetically based cross-incompatibility systems (Baltazar et al., 2005; Doebley, 1990a, 1990b; Ellstrand et al., 2007; Galinat, 1988; Kermicle and Evans, 2005). Additionally, hybridization between corn and *Tripsacum* is not likely in the absence of specialized hybridization techniques in controlled conditions, strongly suggesting that hybridization is unlikely in typical field conditions (Galinat, 1988; Mangelsdorf, 1974; Russell and Hallauer, 1980). Furthermore, none of the sexually compatible relatives of corn in the U.S. are considered to be weeds in the U.S. (Holm et al., 1979). Therefore, even in those instances of accidental gene flow between MON 87460 corn and wild relatives, the transgenes of MON 87460 corn are unlikely to transform corn wild relatives into more weedy species.

References

Baltazar B, de Jesus Sanchez-Gonzalez J, de la Cruz-Larios L, and Schoper J. (2005) Pollination between Maize and Teosinte: An Important Determinant of Gene Flow in Mexico. *TAG Theoretical and Applied Genetics, 110*(3), 519-526.

Doebley J. (1990a) Molecular Evidence for Gene Flow among *Zea* Species. *BioScience, 40*(6), 443-448.

Doebley J. (1990b) Molecular Systematic of *Zea* (Gramineae). *Maydica, 35*, 143-150.

Ellstrand NC, Garner LC, Hegde S, Guadagnuolo R, and Blancas L. (2007) Spontaneous Hybridization between Maize and Teosinte. *Journal of Heredity, 98*(2), 183.

Galinat W. (1988) The Origin of Corn. In GF Sprague and JW Dudley (Eds.), *Corn and Corn Improvement* (pp. 1-27). Madison, WI: American Society of Agronomy, Inc., Crop Soil Science Society of America, Inc., and the Soil Science Society of America, Inc.

Holm L, Pancho J, Herberger V, and Plucknett DL. (1979) A Geographical Atlas of World Weeds. 471-04393.

Kermicle J and Evans M. (2005) Pollen–Pistil Barriers to Crossing in Maize and Teosinte Result from Incongruity Rather Than Active Rejection. *Sexual Plant Reproduction, 18*(4), 187-194.

Mangelsdorf PC. (1974) *Corn: Its Origin, Evolution, and Improvement.* Harvard University Press Cambridge, MA.

Monsanto (2010) Petition for the Determination of Nonregulated Status for Mon 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. The Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).
Russell WA and Hallauer AR. (1980) Corn. In WR Fehr and HH Hadley (Eds.), *Hybridization of Crop Plants* (pp. 302). Madison, WI: American Society of Agronomy and Crop Science Society of America.
USDA-APHIS (2010) Plant Pest Risk Assessment for Mon 87460 Corn. Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html

Comment 8: Several commenters expressed concern regarding a 22 nucleotide deletion at the plant/insert junction of the T-DNA cassette. Additionally, concern was also raised regarding any residual *Agrobacterium tumefaciens* in MON87460 following transformation.

Response 8: With regard to the 22 nucleotide deletion at the plant/inset junction of the T-DNA cassette in MON87460, the commenters did not state the reasoning behind this concern. The potential for small localized deletions at the site of T-DNA integration following *Agrobacterium*-mediated transformation is well a known-phenomena and is only detrimental if a negative phenotype is produced (Bundock and Hooykaas, 1996). In spite of this 22 nucleotide deletion, genetic stability of the insert was not negatively affected; furthermore, agronomic, forage, or grain compositional analysis was not negatively affected, suggesting that this 22 nucleotide deletion did not disrupt an essential gene required by corn (USDA-APHIS, 2010).

Additionally, APHIS concluded that no residual *A. tumefaciens* remained in MON87460 corn, as the use of carbenicillin (Monsanto, 2010) during the corn callus regeneration process effectively eliminates *A. tumefaciens* (Opabode, 2006).

References

Bundock P and Hooykaas PJJ. (1996) Integration of Agrobacterium Tumefaciens T-DNA in the Saccharomyces Cerevisiae Genome by Illegitimate□Recombination. *Proceedings of the National Academy of Sciences, 93*(26), 15272-15275.
Monsanto (2010) Petition for the Determination of Nonregulated Status for Mon 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. The Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).
Opabode J. (2006) Agrobacterium-Mediated Transformation of Plants: Emerging Factors That Influence Efficiency. *Biotechnology and Molecular Biology Reviews, 1*(1), 12-20.
USDA-APHIS (2010) Plant Pest Risk Assessment for Mon 87460 Corn. Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html

Comment 9: A comment expressed concern regarding honey bee Colony Collapse Disorder (CCD) and genetically engineered crops like MON87460 corn.

Response 9: Honey bees (*Apis mellifera*), the only bee species commercially maintained in the U.S. function as vital pollinators of a variety of agricultural crops. First observed on the eastern

U.S. coast in the second half of 2006, honey bee Colony Collapse Disorder accounted for a decline of approximately 36 percent of the honey bee population (Johnson, 2010). In contrast to other previous bee colony losses, CCD can be distinguished by several unusual attributes, including: 1) failure of adult worker bees to return to the hive, despite the presence of a brood and queen remaining in the hive; 2) relatively wide-spread and rapid colony loss throughout the entire year (i.e., not seasonal); and 3) that the mechanisms of the loss still remain unknown. Possible causes of CCD include pathogens, parasites, environmental stresses, and bee management stresses (e.g., poor nutrition); however, recent evidence suggests that CCD may represent a syndrome caused by a suite of factors interacting synergistically to produce rapid and wide-spread colony collapse (USDA, 2009). Potential biotic and abiotic stresses correlated with CCD include, but may not be limited to: the single-celled parasite *Nosema ceranae*; Israeli acute paralysis virus (IAPV) and its potential vector, the Varroa mite; or neonicotinoid, a synthetic insecticide derived from nicotine (Johnson, 2010). Indeed, a recent publication demonstrated increased honey bee mortality due to the synergistic interaction between *N. ceranae* infection and sublethal exposure to the insecticides fipronil or thiacloprid (Vidau et al., 2011). It is prudent to observe, however, that correlation does not equal causation; consequently, while several factors have been observed to be strongly correlated with CCD, it is not known whether any one of these products is the cause of CCD.

A consultation with FDA with successfully completed for both NPTII and CSPB proteins in MON87460 corn (Appendix A of the EA), demonstrating a lack of atoxicity and allergenicity for human and animal consumption. MON87460 corn, like all corn cultivars, does not produce nectar. Thus, foraging honey bees would only collect corn pollen. Mon87460 expresses both *nptII* and *cspb* in a variety of plant tissues, pollen included. As discussed in Chapter 4.5.1.2 and Chapter 4.6.1.2 of the EA, both NPTII and CSPB are not expected to have any negative effect on non-target organisms. The safety of NPTII has been addressed in multiple publications and has been granted an exemption from the requirement of tolerance for use as a selectable marker in raw agricultural commodities (40 CFR Part 180.1134) (EFSA, 2004; Fuchs et al., 1993a; Fuchs et al., 1993b; Nap et al., 1992). In regard to CSPB, it is not expected to affect non-target organisms through toxicity. The donor organism for CSPB, *Bacillus subtilis*, is not pathogenic, has a history of safe use, and its enzyme preparations (containing CSPB) are generally recognized as safe by the Food and Drug Administration (FDA) (FDA, 1999, 2010).

References

EFSA. (2004) Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants. Scientific Opinion of the Panel on Genetically Modified Organisms (Gmo) and the Panel of Biological Hazards (Biohaz). *EFSA Journal*(4), 1-18.

Carbohydrase and Protease Enzyme Preparations Derived from *Bacillus Subtilis* or *Bacillus Amyloliquefaciens*; Affirmation of Gras Status as Direct Food Ingredients, FDA.

FDA (2010) List of Completed Consultations on Bioengineered Foods. United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, Maryland. United States Food and Drug Administration. Retrieved January 2011 from http://www.fda.gov/Food/Biotechnology/Submissions/default.htm

Fuchs R, Heeren R, Gustafson M, Rogan G, Bartnicki D, Leimgruber R, Finn R, Hershman A, and Berberich S. (1993a) Purification and Characterization of Microbially Expressed

Neomycin Phosphotransferase Ii (Nptii) Protein and Its Equivalence to the Plant Expressed Protein. *Nature Biotechnology, 11*(12), 1537-1542.
Fuchs RL, Ream JE, Hammond BG, Naylor MW, Leimgruber RM, and Berberich SA. (1993b) Safety Assessment of the Neomycin Phosphotransferase Ii (Nptii) Protein. *Nature Biotechnology, 11*(12), 1543-1547.
Johnson R (2010) Honey Bee Colony Collapse Disorder. Congressional Research Service. Retrieved April 2011, from http://books.google.com/books?id=SxaJTt3KgoEC&lpg=PP1&dq=Honey%20bee%20colony%20collapse%20disorder&pg=PP1#v=onepage&q&f=false.
Nap J-P, Bijvoet J, and Stiekema W. (1992) Biosafety of Kanamycin-Resistant Transgenic Plants. *Transgenic Research, 1*(6), 239-249.
USDA (2009) Colony Collapse Disorder Progress Report. CCD Steering Committee. Retrieved March 2011, from http://www.ars.usda.gov/is/br/ccd/ccdprogressreport.pdf
Vidau C, Diogon M, Aufauvre J, Fontbonne R, Viguès B, Brunet J-L, Texier C, Biron DG, Blot N, El Alaoui H, Belzunces LP, and Delbac F. (2011) Exposure to Sublethal Doses of Fipronil and Thiacloprid Highly Increases Mortality of Honeybees Previously Infected by Nosema Ceranae. *PLoS One, 6*(6), e21550.

Comment 10: A commenter claimed that APHIS failed to comply with the Endangered Species Act (ESA) by not consulting other Federal agencies on impacts to Threatened and Endangered Species.

Response 10: 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. 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. APHIS follows USFWS procedures required by the agency, and those specifically agreed upon by USFWS for APHIS to follow, thus fulfilling their obligations and responsibilities under Section 7 of the ESA for permit- and petition-related regulatory actions. APHIS disagrees with the claim that APHIS failed to comply with the ESA. As detailed in Chapter 6 of the EA, APHIS concluded after an environmental review that a determination of nonregulated status of MON87460 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, because of this conclusion, consultation with the United States Fish and Wildlife Service (USFWS) or National Marines Fisheries Service (NMFS) was not required for that action.

Comment 11: Several commenters claimed that a determination of nonregulated status of MON87460 corn would directly lead to a significant increase in U.S. corn acreage, negatively impacting enrollment of land in the Conservation Reserve Program (CRP). Additionally, a commenter claimed that APHIS failed to look at regional impacts of the conversion of CRP land to intensive corn production, citing a study by Brooke et al (2009) examining the Prairie Pothole Region as an example of this difference.

Response 11: APHIS acknowledges that there will be a small increase in domestic corn cultivation acreage, as this increase is supported by existing land-use decisions for agricultural commodities and projected trends for U.S. corn production (USDA-ERS, 2011a, 2011b). However, APHIS disagrees that a determination of nonregulated status of MON87460 corn will directly increase U.S. corn acreage. Additionally, APHIS also disagrees with the contention that a determination of nonregulated status of MON87460 corn will reduce enrollment of land in the CRP.

It is well established that market forces and government policies are the two primary factors associated with increased U.S. corn production (Claassen and Tegene, 1999; Plantinga et al., 2001; Secchi et al., 2011; USDA-ERS, 2011a). Increased domestic demand for corn ethanol and increased international demand for livestock feed represent two existing and continuing economic forces stimulating corn production (Secchi et al., 2009; USDA-ERS, 2009; USDA, 2009b). Additionally, ethanol tax credits (e.g., Ethanol Excise Tax Credit [VEETC]), increased funding for federal land-use programs (e.g., Working-Land Conservation Programs), and decreased funding for conservation programs (e.g., the decrease of the overall CRP land enrollment) (Brooke et al., 2009; USDA-ERS, 2011a; USDA-FAS, 2011) represent government policies enacted to satisfy current and projected demand for U.S. agricultural commodities such as corn grain. Collectively, these external market forces and federal policy decisions incentivize corn cultivation, leading to baseline increases in corn grain production as concluded by academic studies (Donner and Kucharik, 2008; Solomon et al., 2007), government reports (USDA-ERS, 2011a, 2011b; USDA, 2009a), and even the commenter him/herself ("Recently, government incentives for ethanol production have led to dramatic increases in corn production;" "This has led to an increase in both corn demand and prices;" "High corn prices...The primary reason farmers take their land out of CRP is economic"). It is worth noting, however, that despite these synergistic factors that facilitate and sustain increased domestic corn production, the majority of land for increased corn cultivation is derived from other crops, such as wheat and soybean, and not at the expense of novel land conversion (USDA-ERS, 2011b). It is also worth noting that these existing factors, directly responsible for recent trends in increased corn production, occurred independently of the regulatory status of MON87460 corn. In order for a determination of nonregulated status of MON87460 corn to discourage CRP land enrollment/reenrollment and increase net corn acreage beyond baseline rates/projections based on the current agricultural and economic environment, MON87460 corn would have to provide a farmer with some incentive beyond those already available with conventional corn varieties. Incentives include corn attributes that enable cultivation on marginal land, decrease farm cost typically associated with corn cultivation, or significantly increase grain yield beyond currently-available and commercialized corn hybrid varieties. As demonstrated in the Monsanto petition and APHIS analysis, MON87460 corn requires similar management conditions and does not possess increased salt, heat, and cold tolerances, thus precluding any reasonable expectation that it is more likely to be cultivated on CRP or marginal lands or result in reduced operating costs relative to conventional corn varieties. Additionally, while MON87460 corn is designed to exhibit a reduced yield-loss phenotype relative to its nontransgenic parent variety under water-limiting condition, the magnitude of the MON87460 phenotype is within the natural range of variation of commercial corn hybrids under both water-sufficient/limited conditions, strongly suggesting that cultivation of MON87460 corn is unlikely to provide grain yield benefits beyond what is already available with currently-commercialized corn varieties. This EA was not written to assess the general causes of increased corn cultivation or speculate on general trends related to CRP land enrollment; it was written to determine if a determination of nonregulated status of MON87460 would significantly impact the quality of the human environment, such as enabling the expansion of corn acreage beyond what is already available with current corn varieties. As illustrated above, the primary factors directing U.S. corn production occurred and are occurring independently of the regulated status of MON87460 corn. Additionally, MON87460 is not any more likely to be cultivated on CRP/marginal land than conventional corn varieties, nor does its agronomic performance deviate beyond the range of natural variation currently present in commercial corn hybrids. What MON87460 does provide is reduced grain loss relative to its comparator under water-limiting conditions. Thus, based on these two conclusions, a determination of nonregulated status of MON87460 is unlikely significantly increase corn acreage or decrease CRP enrollment beyond what is already occurring. Chapters 2.1.1, 4.3.1.1, 4.3.1.2, and 4.5.1.2 of the EA have been rewritten to better illustrate this relationship between existing trends in corn acreage, external market forces, and government policies that directly affect agricultural commodities. Furthermore, those chapters of the EA have been rewritten to clarify APHIS' analysis that a determination of nonregulated status of MON87460 corn is unlikely to significantly impact U.S. corn acreage and CRP land enrollment. APHIS directs readers and commenters to those rewritten sections for discussions of these two issues.

APHIS disagrees with the comment that claimed a failure of APHIS to analyze both regional and national impacts on CRP land conversion following a determination of nonregulated status of MON87460, and the implication that these impacts would differ significantly on the regional and national scales. Firstly, APHIS disagrees with the commenter contention that the study by Brooke et al. (2009) reports a significant environmental impact resulting from the conversion of CRP land into corn production in the Prairie Pothole Region. As undertaken in Brooke et al. (2009), the land-use change [change index] metric is calculated from corn acreage, CRP enrollment, and conversion of grassland into agricultural production (when data was available). Thus, any observed effect is due to those three factors collectively. For the commenter to attribute any impact solely to CRP land conversion is erroneous, as the metric consists of three factors and not one. Furthermore, the land-use change metric and its effects may be overestimated because it takes into account net corn acreage but does not attempt to separate out the effect of crop shifting, effectively equating shifts away from soybean/wheat on agricultural land with conversion of novel land into agricultural production (Brooke et al., 2009). This is particularly relevant, as it is known that the majority of additional corn acreage comes at the expense of other crops (USDA-ERS, 2011a, 2011b). Secondly, the commenter assumes that any national/regional CRP impact will be determined by the availability of a product (i.e., MON87460 corn), once again citing the Prairie Pothole Region as an example. This contention is false; as described in Chapters 2.1.1, 4.3.1.1, 4.3.1.2 of the EA, and Brooke et al. (2009), CRP enrollment on both national and regional levels is ultimately influenced by economic forces and government policy. However, if this were true, then CRP acreage trends would differ on national and regional scales. As seen in Figure R1, national and regional CRP trends generally mirror each other. Also in Figure R1, it can be observed that general increases/decreases in CRP acreage on both national and regional scales follow CRP enrollment changes dictated by successive Farm Bills (increase in 1990; decrease in1996; increase in 2002; and decrease in 2008), providing an example of how government policy and not a particular corn variety affects CRP acreage. Additionally, if this commenter assumption were true, then national/regional trends in CRP and corn acreage would bear an inverse relationship, where an increase in corn acreage caused a decrease in CRP acreage. However, acreage trends from Figures R1 and R2 demonstrate that this is not the case on both the national and regional scale; in the U.S. and the Prairie Pothole Region, corn and CRP acreage generally mirror each other (a trend also observed in Figure 5 of the EA). These trends suggest that increases in corn acreage do not come at the expense of CRP land, but rather from other crops. This is confirmed by USDA-ERS data, where only 2 percent of corn-soybean farms converted land from CRP after a period of increased corn production, with the rest derived from other crops (USDA-ERS, 2011a). This latter point can be additionally observed in Figures R2 and R3, where national/regional increases in corn acreage coincide with national/regional decreases in wheat (though corn is not planted only at the expense of wheat).

Issues of impacts on threatened and endangered species were analyzed by species (in their specific regions of occurrence) and no impact was concluded.

Figure R1. US and Prairie Pothole Region CRP acreage

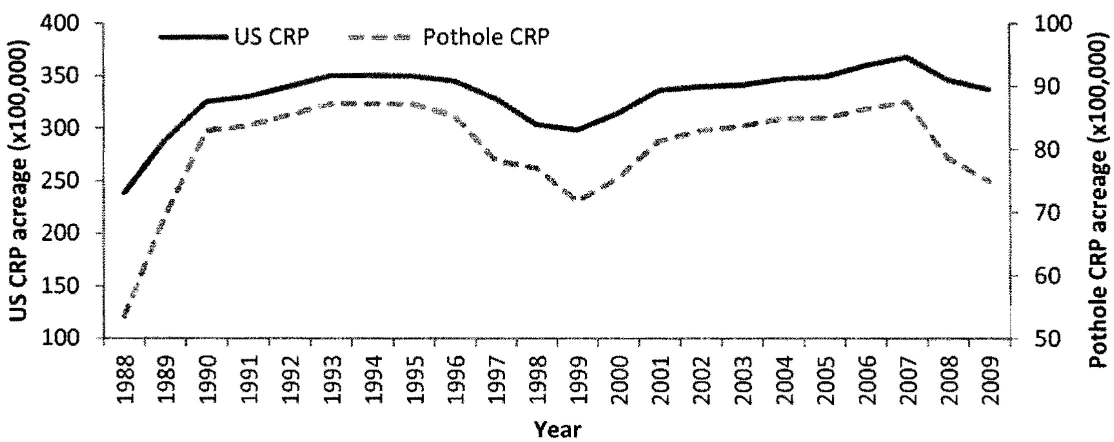


Figure R2. US and Prairie Pothole Region Corn Acreage

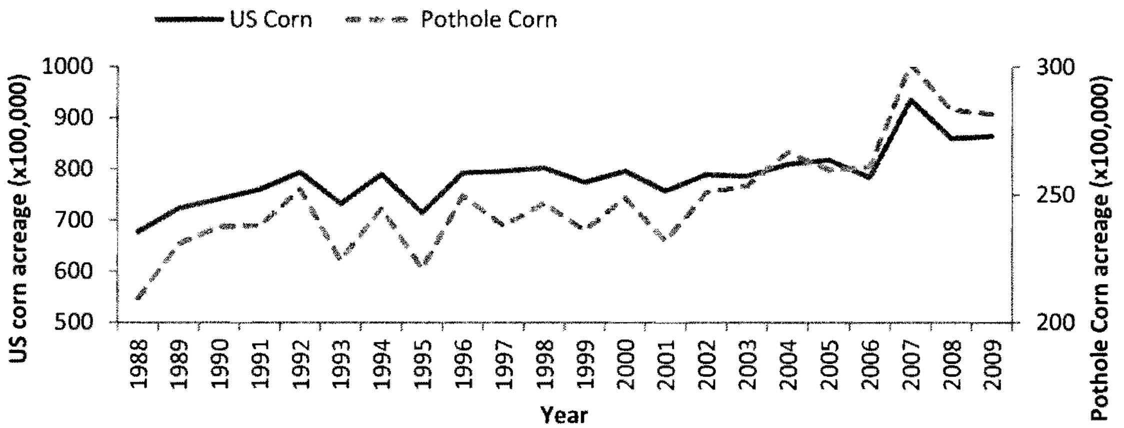
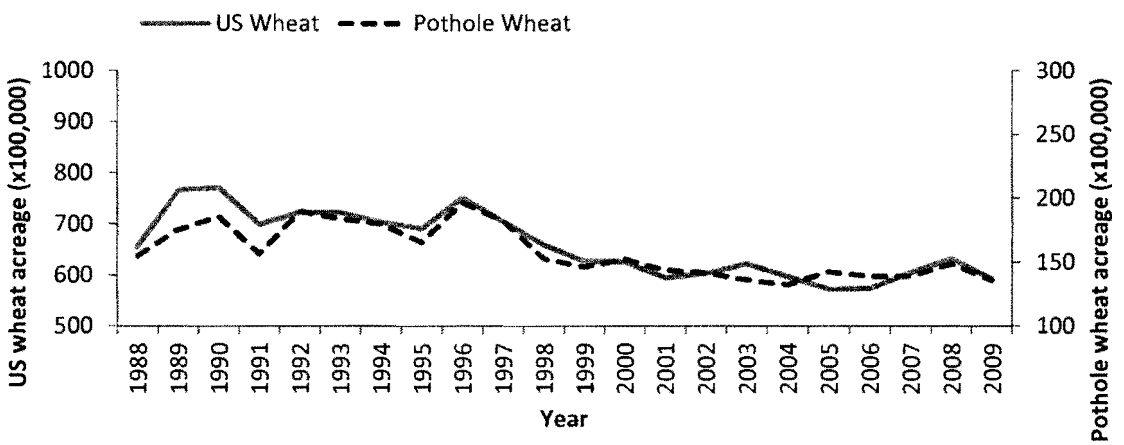


Figure R3. US and Prairie Pothole Region Wheat Acreage



(USDA-FSA, 2011; USDA-NASS, 2011)

References

Brooke R, Fogel G, Glaser A, Griffin E, and Johnson K (2009) Corn Ethanol and Wildlife: How Increases in Corn Plantings Are Affecting Habitat and Wildlife in the Prairie Pothole Region. National Wildlife Federation.

Claassen R and Tegene A. (1999) Agricultural Land Use Choice: A Discrete Choice Approach. *Agricultural and Resource Economics Review, 28*(1), 26-35.

Donner SD and Kucharik CJ. (2008) Corn-Based Ethanol Production Compromises Goal of Reducing Nitrogen Export by the Mississippi River. *Proceedings of the National Academy of Sciences, 105*(11), 4513-4518.

Plantinga AJ, Alig R, and Cheng Ht. (2001) The Supply of Land for Conservation Uses: Evidence from the Conservation Reserve Program. *Resources, Conservation and Recycling, 31*(3), 199-215.

Secchi S, Gassman P, Williams J, and Babcock B. (2009) Corn-Based Ethanol Production and Environmental Quality: A Case of Iowa and the Conservation Reserve Program. *Environmental Management, 44*(4), 732-744.
Secchi S, Kurkalova L, Gassman PW, and Hart C. (2011) Land Use Change in a Biofuels Hotspot: The Case of Iowa, USA. *Biomass and Bioenergy, 35*(6), 2391-2400.
Solomon BD, Barnes JR, and Halvorsen KE. (2007) Grain and Cellulosic Ethanol: History, Economics, and Energy Policy. *Biomass and Bioenergy, 31*(6), 416-425.
USDA-ERS (2009) Briefing Rooms. Corn: Trade. United States Department of Agriculture - Economic Research Service. Retrieved January, 2011 from http://www.ers.usda.gov/Briefing/corn/trade.htm
USDA-ERS (2011a) The Ethanol Decade: An Expansion of U.S. Corn Production, 2000-09. EIB-79. United States Department of Agriculture, Economic Research Service. Retrieved September, 2011 from http://www.ers.usda.gov/Publications/EIB79/EIB79.pdf
USDA-ERS (2011b) Usda Agricultural Projections to 2020. United States Department of Agriculture - Economic Research Service. Retrieved March, 2011 from http://www.ers.usda.gov/Publications/OCE111/OCE111.pdf
USDA-FAS (2011) Conservation Programs. United States Department of Agriculture - Farm Service Agency. Retrieved 2011, October from http://www.fsa.usda.gov/FSA/webapp?area=home&subject=copr&topic=crp-st
USDA-FSA (2011) Crp Enrollment and Rental Payments by State. United States Department of Agriculture - Farm Service Agency. Retrieved October, 2011 from http://www.fsa.usda.gov/FSA/webapp?area=home&subject=copr&topic=rns-css
USDA-NASS (2011) Quickstats 1.0. United Stated Department of Agriculture - National Agricultural Statistics Service. Retrieved October, 2011 from http://www.nass.usda.gov/QuickStats/Create_Federal_All.jsp
USDA. (2009a).2007 Census of Agriculture: United States Summary and State Data. Last accessed from
USDA (2009b) Summary Report: 2007 National Resources Inventory. Natural Resources Conservation Service
Center for Survey Statistics and Methodology. Retrieved from http://www.nrcs.usda.gov/technical/NRI/2007/2007_NRI_Summary.pdf

Comment 12: Several commenters asserted that the MON87460 EA did not sufficiently address the relationship between conservation tillage (thus facilitated by GE crops, like MON87460 corn), carbon sequestration, and global climate change. Additionally, several commenters also asserted that the MON87460 EA did not examine the influence of conservation tillage strategies on emission of nitrous oxide, a potent greenhouse gas (GHG), potentially offsetting any gains achieved through a potential increase in carbon sequestration and reduced carbon dioxide emission.

Response 12: In regard to global climate change, APHIS recognizes and understands that agricultural activities (including, but not limited to tillage and other management strategies) contribute to the release of GHG emissions that may affect global climate change. However, the EA was written in response to the Monsanto Company's petition for determination of nonregulated status of MON87460 corn and not to address the effects of agriculture or genetically engineered crop production systems on global climate change. It is prudent to mention, however, that management practices between MON87460 corn and currently available corn varieties are unlikely to be dissimilar, considering the likelihood of stacking MON87460 corn with other corn events that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (as described in Chapter 4.10 of the EA) and the almost universal adoption of genetically engineered corn production systems in the U.S. Chapter 2.2.4 of the EA was rewritten in recognition of the relationship between agricultural activities such as conservation tillage, GHG emissions, and global climate change. A conventional paradigm generalizing the relationship between conservation tillage strategies and GHG emissions is dependent on a number of factors, including geographic location, soil structure, moisture availability, and agronomic management practices. Given the variability of these parameters, tillage impacts may be beneficial, neutral, or detrimental.

Comment 13: Several commenters claimed that the EA failed to discuss the relationship between increased pesticide application (associated with conservation tillage) and climate change if MON87460 corn were granted a determination of nonregulated status.

Response 13: As stated in Chapter 4.10 of the EA and the MON87460 petition, MON87460 is likely to be stacked with GE traits that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, such as readily available glyphosate tolerant and Bt traits, and very unlikely to be grown as a standalone corn variety (Monsanto, 2010). As an example, a corn variety containing MON87460 and glyphosate tolerance may be cultivated in place of a corn variety containing only glyphosate tolerance. Also, as discussed in Chapters 2.1.1, 4.3.1.1, 4.3.1.2 of the EA, MON87460 is unlikely to increase corn acreage beyond projected values. Thus, any increase in pesticide usage beyond that associated with projected corn acreage increases (USDA-ERS, 2011) due to MON87460 is unlikely, because any variety containing MON87460 can be viewed as a replacement product for corn varieties that already require similar pesticide application strategies and that expectation that MON87460 itself is unlikely to increase corn acreage.

In regard to climate change, APHIS recognizes and understands that agricultural activities contribute to the release of GHG emissions that may act as affecters of global climate change. However, the EA was written in response to the Monsanto Company's petition for determination of nonregulated status of MON87460 corn and not to address the specific effects of agriculture or genetically engineered crop production systems on global climate change. APHIS directs readers to Chapter 2.2.4 of the EA for a discussion of climate change and agriculture.

References

Monsanto (2010) Petition for the Determination of Nonregulated Status for Mon 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. The Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

USDA-ERS (2011) Usda Agricultural Projections to 2020. United States Department of Agriculture - Economic Research Service. Retrieved March, 2011 from http://www.ers.usda.gov/Publications/OCE111/OCE111.pdf

Comment 14: A commenter claimed that the MON87460 EA failed to examine the displacement of less environmentally friendly crops, such as wheat, soybeans, and sorghum by MON87460 corn.

Response 14: Farm-level land-use decisions on U.S. farms are often dependent on both market forces and government policies on the local, regional, and national level. It is unlikely that a determination of nonregulated status of MON87460 corn would significantly impact current and future corn production trends, as described in Chapter 4.3 of the EA. Historical data collected by United States Department of Agriculture – National Agricultural Statics Service (USDA-NASS) shows that planted corn acreage has generally increased over time as a result of increased production efficiency, improved hybrid corn varieties, and a net increase in harvested acreage; consequently, other crops such as sorghum, cotton, and wheat generally show decreases in planted acreage over the same time frame (USDA-NASS, 2011). This trend in increased corn acreage is readily apparent between 2000 and 2009, where an approximate 10 percent increase in harvested corn acreage coincided with domestic bioenergy policy and an increased demand for ethanol and its corn grain feedstock (USDA-ERS, 2011a). In general, increased demand for corn grain has resulted in U.S. farmers generally shifting agricultural acreage away from other crops, such as soybean and wheat, into corn production for both the present and future outlooks (USDA-ERS, 2011b). An examination of aggregate (national, state, and county) and farm-level data within this period (2006 – 2008, when acreage peaked) by United States Department of Agriculture – Economic Research Service (USDA-ERS) revealed that both corn and soybean acreage increased at the expense of other crops in both the short run (2006-2008) and the long run (2000-2009) (USDA-ERS, 2011a). Additionally, further examination of farm-level data to provide finer detail on how harvested corn acreage may have expanded (i.e., conversion of previously uncultivated or fallowed land to agricultural production) revealed that the observed increase in corn production resulted primarily at the expense of cultivated crop acreage (e.g., soybean, cotton, wheat) and with a smaller proportion coming from uncultivated/fallowed land (30 percent) (USDA-ERS, 2011a). The primary source of this uncultivated land/fallowed land, however, was hay and grazing land, as only two percent of corn and soybean farms brought Conservation Reserve Program (CRP) land into production in 2007, following the peak in domestic corn acreage (USDA-ERS, 2011a).

Thus, the current trend of increasing corn acreage primarily at the expense of other crop acreage has been occurring independent of any regulatory decision on MON87460 corn. Consequently, current and future market forces affecting corn price and a variety of government policies are likely to continue affecting farm-level land-use decisions. A determination of nonregulated status of MON87460 corn is unlikely to disrupt this trend, due to the relatively small proportion of domestic corn production it is likely to represent and the incidence of current corn production trends already occurring without the commercialization of MON87460.

References

USDA-ERS (2011a) The Ethanol Decade: An Expansion of U.S. Corn Production, 2000-09. EIB-79. United States Department of Agriculture, Economic Research Service. Retrieved September, 2011 from http://www.ers.usda.gov/Publications/EIB79/EIB79.pdf

USDA-ERS (2011b) Usda Agricultural Projections to 2020. United States Department of Agriculture - Economic Research Service. Retrieved March, 2011 from http://www.ers.usda.gov/Publications/OCE111/OCE111.pdf

USDA-NASS. (2011) Corn, Cotton, Sorghum, Soybean, and Wheat Planted Acreage (1985 - 2010). Retrieved September, 2011 from United States Department of Agriculture, National Agricultural Statistics Service http://www.nass.usda.gov/QuickStats/Create_Federal_All.jsp

Comment 15: Several commenters asserted that GE crops, like MON87460 corn, increases the frequency of animal and human diseases/pathogens, and cited the letter to Agriculture Secretary Vilsack from retired Professor Don Huber as support for this contention.

Response 15: Professor Huber's letter alleges that either the gene to produce glyphosate tolerant crops or the use of glyphosate (Roundup) is either a promoter or cofactor that facilitates a pathogen capable of infecting soybean, corn, their products, various livestock and "probably human beings." The letter claims evidence for the pathogen in electron micrographs (which are not published) and alleges animal infertility (anecdotes, none published, with no general corroboration), and a claim for escalating frequency of Goss' wilt in corn, and sudden death syndrome in soybean (no data to support the claims). Where animal abortions were noted, an inference was made that animals consumed a wheat product, on which glyphosate may have been used indirectly. While these hypotheses are certainly remarkable, there has been no evidence provided for most of these statements. Until Prof. Huber publishes his methods, results and conclusions, scientists have no basis for evaluating these claims.

Comment 16: Several commenters expressed concern that both NPTII and CSPB (the two introduced proteins in MON87460) are not sufficiently examined in the MON87460 EA, citing a lack of objective or peer-reviewed evidence with regard to NPTII and CSPB.

Response 16: NPTII, which serves as a selectable marker in MON87460 corn, is a well characterized and equally well established protein product in plant biotechnology. The toxicity of NPTII has been evaluated in both the peer-reviewed literature (Flavell et al., 1992; Fuchs et al., 1993a; Fuchs et al., 1993b; Nap et al., 1992) and by government in different countries (EFSA, 2007; FDA, 1998; OGRT, 2009). CSPB, originally derived from *Bacillus subtilis*, is responsible for the MON87460 corn reduced yield loss phenotype under water-limited conditions. CSPB does not possess any homology to any known toxin or allergen (Burzio et al., 2008) and is well studied in the peer-reviewed literature (Graumann and Marahiel, 1994; Graumann et al., 1996; Willimsky et al., 1992). As described in Chapter 4.5.1.2 and Chapter 4.6 of the EA, the donor organism of CSPB, *B. subtilis*, is not pathogenic and is frequently found in fermented foods that have been consumed by humans frequently and for a long time. Additionally, the peer-reviewed literature demonstrates that enzyme preparations from *B. subtilis* are not toxic to animals and thus would not be expected to be toxic to humans (Hong et al., 2008; Simon M, 2011). A search of the published literature by Food Safety Australia New Zealand (FSANZ) did not identify any journal articles relating to the allergenicity of any of the bacterial cold shock proteins (FSANZ, 2010). Additionally, government regulators from both the U.S. Food and Drug Administration (FDA) and FSANZ have determined that *B. subtilis* does not pose any specific risk to human health, with the FDA designating enzyme preparations from *B. subtilis* as generally recognized as safe (GRAS) (FDA, 1999, 2010; FSANZ, 2010). Furthermore, FSANZ has already determined that MON87460 corn does not pose any public health or safety issues, and considers MON87460 corn as safe and wholesome as food derived from other commercial corn varieties (FSANZ, 2010).

References

Burzio LA, McClain JS, and Silvanovich A. (2008). *Bioinformatics Evaluation of the Cspb Protein Utilizing the Ad8, Toxin6 and Protein Databases.* Monsanto Company.

EFSA (2007) Efsa Review of Statistical Analyses Conducted for the Assessment of the Mon863 90-Day Rat Feeding Study. European Food Safety Authority.

FDA (1998) Guidance for Industry: Use of Antibiotic Resistance Marker Genes in Transgenic Plants. U.S. Food and Drug Administration. Retrieved September, 2011 from http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/biotechnology/ucm096135.htm

Carbohydrase and Protease Enzyme Preparations Derived from *Bacillus Subtilis* or *Bacillus Amyloliquefaciens*; Affirmation of Gras Status as Direct Food Ingredients, FDA.

FDA (2010) List of Completed Consultations on Bioengineered Foods. United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, Maryland. United States Food and Drug Administration. Retrieved January 2011 from http://www.fda.gov/Food/Biotechnology/Submissions/default.htm

Flavell RB, Dart E, Fuchs RL, and Fraley RT. (1992) Selectable Marker Genes: Safe for Plants? *Biotechnology*(10), 141-144.

FSANZ (2010) Supporting Document 1: Application A1029 Food Derived from Drought-Tolerant Corn Line Mon87460 Approval Report. Food Standards Australia New Zealand.

Fuchs R, Heeren R, Gustafson M, Rogan G, Bartnicki D, Leimgruber R, Finn R, Hershman A, and Berberich S. (1993a) Purification and Characterization of Microbially Expressed Neomycin Phosphotransferase Ii (Nptii) Protein and Its Equivalence to the Plant Expressed Protein. *Nature Biotechnology, 11*(12), 1537-1542.

Fuchs RL, Ream JE, Hammond BG, Naylor MW, Leimgruber RM, and Berberich SA. (1993b) Safety Assessment of the Neomycin Phosphotransferase Ii (Nptii) Protein. *Nature Biotechnology, 11*(12), 1543-1547.

Graumann P and Marahiel MA. (1994) The Major Cold Shock Protein of Bacillus Subtilis Cspb Binds with High Affinity to the Attgg- and Ccaat Sequences in Single Stranded Oligonucleotides. *FEBS Letters, 338*(2), 157-160.

Graumann P, Schroder K, Schmid R, and Marahiel M. (1996) Cold Shock Stress-Induced Proteins in Bacillus Subtilis. *J. Bacteriol., 178*(15), 4611-4619.

Hong HA, Huang JM, Khaneja R, Hiep LV, Urdaci MC, and Cutting SM. (2008) The Safety of Bacillus Subtilis and Bacillus Indicus as Food Probiotics. *Journal of Applied Microbiology, 105*(2), 510-520.

Nap J-P, Bijvoet J, and Stiekema W. (1992) Biosafety of Kanamycin-Resistant Transgenic Plants. *Transgenic Research, 1*(6), 239-249.
OGRT (2009) Risk Assessment and Risk Management Plan for Dir 95 – Limited and Controlled Release of Sugar Cane Genetically Modified for Altered Plant Growth, Enhanced Drought Tolerance, Enhanced Nitrogen Use Efficiency, Altered Sucrose Accumulation, and Improved Cellulosic Ethanol Production From. Australian Government, Department of Health and Ageing, Office of the Gene Technology Regulator.
Simon M C. (2011) Bacillus Probiotics. *Food Microbiology, 28*(2), 214-220.
Willimsky G, Bang H, Fischer G, and Marahiel MA. (1992) Characterization of Cspb, a Bacillus Subtilis Inducible Cold Shock Gene Affecting Cell Viability at Low Temperatures. *J. Bacteriol., 174*(20), 6326-6335.

Comment 17: Several commenters expressed concern regarding horizontal and vertical gene transfer from MON87460 corn, noting specifically that: a) Genetic material inserted into GE soy transfers into the DNA of bacteria living inside human intestines; b) Gene transfer between MON87460 and other plants may lead to the generation of herbicide resistant weeds; and c) That gene flow between corn and teosinte may reduce the genetic diversity of teosinte, creating problems for farmers that use teosinte for breeding improved corn.

Responses 17: As mentioned in Chapter 4.7.2 of the EA, the Food and Drug Administration (FDA) has previously concluded that the likelihood of horizontal gene transfer from plant genomes to microorganisms in the gastrointestinal tract of humans, animals, or the environment is remote (FDA, 1998). In regard to the claim that genetic material transfers from human-consumed GE soy into the DNA of human gastrointestinal tract bacteria, this appears to be a misrepresentation of the results from the peer-reviewed journal article entitled "Assessing the survival of transgenic plant DNA in the human gastrointestinal tract" by Netherwood et al. In the original publication, low-frequency gene transfer from GE soy to the microflora of the small bowel occurred in three out of seven human ileostomists (Netherwood et al., 2004). Ileostomists, however, represent an artificial system where the end of the small intestine is separated from the large intestine and connected to collection receptacle; thus, ingested material does not normally proceed through the complete human digestive system, where it normally remain in the large intestine for approximately 16 hours. Furthermore, when the experiment was repeated in the absence of ileostomists (i.e., complete gastrointestinal passage that is more representative of true human digestive physiology), the authors concluded that the transgene contained within the GE soy did not survive passage through human subjects with intact gastrointestinal tracts and that horizontal gene transfer did not occur during this feeding experiment (Netherwood et al., 2004).

Additionally, it is unlikely that vertical gene transfer (i.e., gene flow) from MON87460 to sexually compatible relatives will lead to the production of herbicide resistant weeds or a reduction in the genetic diversity of teosinte, the wild progenitor of domesticated corn. As discussed in Chapter 4.5.4 of the EA, MON87460 does not differ from currently available corn varieties with regard to pollen or seed attributes; thus, MON87460 is not any more likely to hybridize with sexually compatible relatives than any currently available corn variety. Sexually compatible relatives in the U.S. include *Tripsacum dactyloides*, *Tripsacum floridanum*, and teosinte. As discussed in Chapter 4.5.2 of the EA, due to the absence of reproductive differences between MON87460 and commercially-available corn, MON87460 is unlikely to successfully hybridize with *Tripsacum dactyloides* and *Tripsacum floridanum* under normal field conditions due to various sterility mechanisms, chromosomal mismatch, and significantly reduced offspring fitness (Mangelsdorf, 1974). Consequently, although MON87460 may be stacked with herbicide tolerant traits events that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, it is unlikely that gene flow will between corn and sexually compatible relatives will lead to the formation of herbicide resistant weeds. Also, as discussed in Chapter 4.5.2 and Chapter 4.5.4 of the EA, MON87460 is unlikely to successfully hybridize with teosinte (e.g., *Zea Mexicana* and *Z. perennis*) in the U.S. due to the limited distribution of teosinte, and differences in flowering time and reproductive compatibiity (Galinat, 1988). Thus, due to unlikely nature of introgression of genetic material from MON87460 to teosinte, it is also unlikely that MON87460 will erode the genetic diversity of teosinte in the U.S.

References

FDA (1998) Guidance for Industry: Use of Antibiotic Resistance Marker Genes in Transgenic Plants. U.S. Food and Drug Administration. Retrieved September, 2011 from http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/biotechnology/ucm096135.htm

Galinat W. (1988) The Origin of Corn. In GF Sprague and JW Dudley (Eds.), *Corn and Corn Improvement* (pp. 1-27). Madison, WI: American Society of Agronomy, Inc., Crop Soil Science Society of America, Inc., and the Soil Science Society of America, Inc.

Mangelsdorf PC. (1974) *Corn: Its Origin, Evolution, and Improvement.* Harvard University Press Cambridge, MA.

Netherwood T, Martín-Orúe S, O'Donnell A, Gockling S, Graham J, Mathers J, and Gilbert H. (2004) Assessing the Survival of Transgenic Plant DNA in the Human Gastrointestinal Tract. *Nature Biotechnology, 22*(2), 204-209.

Comment 18: Several commenters asserted that genetically engineered (GE) commodities and respective agricultural practices have been proven to have adverse effects on human and livestock health, including generalized statements suggesting that GE plants are associated with increased organ failure, inflammatory bowel disease, reduced fecundity/fertility, asthma, lung damage, digestive problems, celiac' s disease, obesity, Morgellon's Disease, autoimmune disorders, autism, and increased endocrine system damage. One commenter suggested that the increased prevalence of GE crops is responsible for the increase of many serious diseases in the U.S. Furthermore, one comment alluded to studies by Dr. Irina Ermakova and a separate study from the Baylor college of medicine as evidence that GE crops were detrimental to human health; additionally, another commenter cited a study undertaken by Vendomois et al (2009) in hamsters and rats (2009) as evidence that GE plants contribute to birth defects, high informant mortality rates, and sterility in humans.

Response 18: As described in Chapter 1.1 and Chapter 1.6 of the EA, the U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety of all food and feed derived from GE plants. No U.S. agency has made an assertion linking GE crops to the presence or increased prevalence of any disease. Furthermore, following a report from the European Commission (2011) examining the risk of GE crops, it was stated that "The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not *per se* more risky than e.g. conventional plant breeding technologies".

Following a consultation between FDA and the Monsanto Company, FDA determined that MON87460 corn is not materially different from currently-available corn varieties, thus concluding that MON87460 does not pose any increased risk with regard to food and feed safety relative to currently-available corn varieties (FDA, 2010). Additionally, description of *in silico* analysis of the two inserted, fully functional, genetic elements (NPTII and CSPB) in Chapter 4.6.1.2 of the EA state that neither NPTII nor CSPB share any amino acid sequence similarities with known allergens, gliadins, glutenins, or protein toxins which have adverse effects on mammals. NPTII is the most common selectable marker utilized in GE plants, and has been utilized in 28 petitions that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act; additionally, the general safety of NPTII has been described by both the EPA (through the granting of an exemption of tolerance) and the European Food Safety Authority (EFSA). Also as described in Chapter 4.6.1.2 of the EA, CSPB has been shown to: 1) be rapidly digested in simulated gastrointestinal fluid, a characteristic shared among many proteins with a history of safe consumption; 2) share 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; and 3) be one component of an enzyme preparation that is generally recognized as safe (GRAS) by the FDA from *Bacillus subtilis*, the ubiquitous microorganism from which CSPB is derived and is found in many fermented foods that are frequently consumed by humans. Compositional analysis of MON87460 corn described by the Monsanto Company Petition (Monsanto, 2010) demonstrated that neither NPTII or CSBP expression or activity results in any meaningful differences for grain and forage compositions either for major nutrients or secondary metabolites. Collectively, these data strongly suggest that the no meaningful changes, aside from the reduced yield loss phenotype under water-limited conditions, are derived from the transformation event itself.

MON87460 corn does not contain any plant incorporated protectants (PIPs) that may confer an insect resistance phenotype or herbicide resistance traits. However, as examined in the EA, it is foreseeable that MON87460 may be conventionally crossed with corn varieties containing GE traits that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Thus, progeny of MON 87460 corn may potentially contain a stack of traits, including drought tolerance, insect resistance, or herbicide tolerance. It is important to note that any trait foreseeably stacked with MON87460 that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, will represent a trait that has been previously shown to neither pose a plant pest risk nor present a significant impact on the human health.

The majority of health effects claims were not substantiated without any references from the peer-reviewed literature. Thus, APHIS finds it difficult to address these claims directly; in lieu of provided references, APHIS directs commenters to the sections of the EA mentioned above and the preceding paragraphs discussing the health and safety of MON87460 corn and its introduced proteins. In regard to study by Irina Ermakova on GE soy and rat health, it is prudent to mention that the data from this study was neither peer-reviewed nor published in the peer-reviewed literature (Marshall, 2007); consequently, APHIS cannot address these claims directly. Following an moderated interview feature in Nature Biotechnology, however, several experts discovered flaws in the experimental design of Ermakova's study that make it very difficult to conclude any relationship between GE soy and rat health (Chassy et al., 2007). Additionally, in the study alluded to by the Baylor College of Medicine, the commenters' claim is without much warrant, as the original authors of the paper make no mention of GE corn in the journal article (Markaverich et al., 2001).

In the referenced study of Vendomois et al (2009), it was concluded that several sex- and dose-dependent effects (e.g., organ weights and blood chemistry) observed in rats were linked with GE corn consumption. Several independent scientific groups and regulatory agencies have reviewed and refuted this study, including the French High Council on Biotechnology (HCB), Food Standards Australia New Zealand (FSANZ), and the European Food Safety Authority (EFSA) S(EFSA, 2007; FSANZ, 2009; HCB, 2009). The three scientific groups or regulatory agencies agreed that the conclusions presented by Vendomois et al. (2009) rely primarily on statistical analysis and fail to interpret these differences within a biological or toxicological context. Normal background variability between animals fed with different diets was ignored. Additionally, HCB, FSANZ, and the EFSA concluded, based on the data published in Vendomois et al. (2009), that no new evidence was provided about the general safety of these GE plants, and that there was no reason to reconsider the safety assessments previously completed for NK603, MON810, and MON863 corn (EFSA, 2010; FSANZ, 2009; HCB, 2010; Monsanto, 2010).

References

Chassy B, Moses V, McHughen A, and Giddings V. (2007) Response to Gm Soybeans - Revisiting a Controversial Format. *Nature Biotechnology, 25*(12), 1356-1358.

EFSA (2007) Efsa Review of Statistical Analyses Conducted for the Assessment of the Mon863 90-Day Rat Feeding Study. European Food Safety Authority.

FDA (2010) List of Completed Consultations on Bioengineered Foods. United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, Maryland. United States Food and Drug Administration. Retrieved January 2011 from http://www.fda.gov/Food/Biotechnology/Submissions/default.htm

FSANZ (2009) Fsanz Response to a Comparison of the Effects of Three Gm Corn Varieties on Mammalian Health. Food Standards Australia and New Zealand. Retrieved September, 2011 from

http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets2009/fsanzresponsetoseral4647.cfm.
HCB (2009) Opinion Relating to the Deposition of 15 December 2009 by the Member of Parliment, Froncois Grosdidier, as to the Conclusions of the Study Entitled "a Comparison of the Effects of Three Gm Corn Varieties on Mammalian Health" by J. Spiroux De Vendomois, F. Roullier, D. Cellier, and G.E. Seralini, Int. J. Biol. Sci: 5(7): 706-726. High Council of Biotechnologies.
Markaverich B, Mani S, Alejandro M, Mitchell A, Markaverich D, Brown T, Velez-Trippe C, Murchison C, O'Malley B, and Faith R. (2001) A Novel Endocrine-Disrupting Agent in Corn with Mitogenic Activity in Human Breast and Prostatic Cancer Cells. *Environmental Health Perspectives, 110*(2), 169-177.
Marshall A. (2007) Gm Soybeans and Health Safety - a Controversy Reexamined. *Nat Biotech, 25*(9), 981-987.
Monsanto (2010) Petition for the Determination of Nonregulated Status for Mon 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. The Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).
UC (2011) A Decade of Eu-Funded Gmo Research. Brussels, Belgium: European Commission - Directorate General for Research and Innovation Biotechnologies, Agriculture, Food.

Comment 19: Several commenters expressed concern regarding a study by Aris and Leblanc (2011) describing the detection of the Cry1ab protein in maternal blood serum (non-pregnant and pregnant women) and fetal blood serum (human fetuses). Several commenters also raised concern with regard to a study by Benachour and Seralini (2009) entitled "Glyphosate formulations induce apoptosis and necrosis in human umbilical, embryonic, and placental cells." Additionally, several commenters generally stated that more long-term human studies were needed for GE crops, including MON87460.

Responses 19: In the study by Aris and Leblanc (2011), the Cry1ab protein (a common insecticidal protein introduced into GE crops, such as corn) was detected in 93 percent of maternal blood, 80 percent of fetal blood, and 69 percent of blood from non-pregnant women. The subjects of this study all resided in Sherbrooke, an urban area of Eastern Townships of Quebec, Canada. MON87460 does not contain any Bt traits; however, these traits may be introduced through conventional breeding, as described in Chapter 5 of the EA.

While Aris and Leblanc (2011) detected the Cry1ab protein in the majority of blood samples tested, the authors did not make any effort to determine the origin of the Cry1ab protein, only assuming that the source of Cry1ab must be through the consumption of GE crops, "given the widespread use of GM [GE] foods in the local daily diet (soybeans, corn, potatoes...), it is conceivable that the majority of the population is exposed through their daily diet." However, the authors neglect to mention that *Bacillus thuringiensis*, a bacterium from which Cry1ab is derived and produced, is commonly used in organic farming (either as proteins sprays or sprays of the *B. thuringiensis* itself) (Aroian, 2011; EPA, 2005). In previous studies, naturally-occurring *B. thuringiensis* has been detected in fresh fruits and vegetables (Frederiksen et al., 2006); milk, ice cream, and green-tea samples (Zhou et al., 2008); and human nasal samples following aerial sprays to control gypsy moth populations (Valadares de Amorim et al., 2001).

Additionally, Aris and Leblanc (2011) made no effort to eliminate the possibility of detecting false positives through the ELISA-based screening kit (DAS ELISA kit for Bt-Cry1ab/1Ac protein, Agdia). The detection limit for the DAS ELISA kit for Bt-Cry1ab/1Ac protein is reported to be 1 ng/ml (Paul et al., 2008); however, Aris and Leblanc detected the Cry1ab protein at averaged levels of approximately 0.18 ng/ml in the blood serum of pregnant women, 0.12 ng/ml in the blood serum of non-pregnant women, and 0.05 ng/ml in the blood serum of human fetuses. The 1 ng/ml detection limit of the ELISA kit and the levels detected in the study is problematic, as the detection limit of a kit is generally regarded as the lowest possible for which a user may reliably detect a compound. Unfortunately, no additional Cry1ab protein detection method was cited in the Aris and Leblanc (2011) study to corroborate and verify that these very low detection levels did not consist of false positives, as would be standard practice. With regard to the ELISA kit itself, it was not validated for its suitability to measure Cry1ab in human blood; rather, it was designed to detect Cry1ab from plant tissues (Agdia, 2011; FSANZ, 2011).

APHIS also disagrees with the implication that Bt proteins (Cry family proteins) are inherently dangerous to human health. APHIS directs commenters to previous EAs (USDA-APHIS, 2011) that have examined the risk of human exposure to Bt proteins and determined that Bt proteins pose little risk to human health.

With regard to Benachour and Seralini (2009), the entire study was conducted *in vitro*, meaning that the study was conducted in an artificial environment outside of a living organism. Such studies are useful for screening and prioritization purposes (e.g., designing *in vivo* studies), but they have the major limitation of requiring extrapolation of the *in vitro* result to an *in vivo* situation to reach the commenters' conclusion, especially in cases such has glyphosate where *in vivo* tests have already been conducted and have demonstrated relatively low levels of overall toxicity. In *in vivo* studies, the chemical form and dose can change in the intestine during digestion, uptake, metabolism, and excretion, and be mediated by adsorbed proteins, detoxification processes, and various immune and other protective responses, all of which affect the dose and form of the chemical that ultimately comes in contact with the cell. An affected cell in turn is then subject to possible repair and other protective mechanisms before the potential for adverse health effects is realized. Also, aside from *in vitro* glyphosate application, this study also used glyphosate formulations, which include surfactants and other ingredients. These raise the question about what chemical is actually being studied and causing the effects. Furthermore, applying these formulations directly to cell lines is a very different situation for the cells in terms of the types and concentrations of chemicals compared to what the cells would be exposed to after oral, inhalation, or dermal uptake, metabolism, etc.

In summary, APHIS believes that the study of Aris and Leblanc (2011) possesses several short-comings that bring its conclusions about the detection of the Cry1ab protein into doubt. These include issues surrounding the source of the Cry1ab detected, problems with the assay method used to detect the Cry1ab protein, and the implication that Cry1ab poses any significant risk to human health. Additionally, APHIS also believes that the limitations of *in vitro* glyphosate toxicity studies cannot be overlooked, and that it should be taken in context of *in vivo* studies that have already been performed that suggests a relatively low overall toxicity of the compound (Williams et al., 2000).

With regard to commenter claims that more long-term studies are required for MON87460 corn, APHIS concluded that there were no short-term impacts from MON87460 and its engineered proteins (e.g., NPTII and CSPB) on human and animal health (Chapters 2.3.1; 2.4; and 2.5 of the EA). Because no short-term impacts were not noted, there is no reason to continue looking for long-term impacts.

References

Agdia (2011) Das Elisa for the Detection of Bt-Cry1ab/1ac Proteins. Agdia. Retrieved October, 2011 from https://orders.agdia.com/Documents/m172.pdf

Aris A and Leblanc S. (2011) Maternal and Fetal Exposure to Pesticides Associated to Genetically Modified Foods in Eastern Townships of Quebec, Canada. *Reproductive Toxicology, 31*(4), 528-533.

Aroian R (2011) Bacillus Thuringiensis - Organic Farming. University of California San Diego. Retrieved October, 2011 from http://www.bt.ucsd.edu/organic_farming.html

Benachour N and Seralini G. (2009) Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical, Embryonic, and Placental Cells. *Chemical Research in Toxicology, 22*(1), 97-105.

EPA (2005) Bacillus Thuringiensis Cry3bb1 Protein and the Genetic Material Necessary for Its Production (Vector Zmir13l) in Event Mon 863 Corn & Bacillus Thuringiensis Cry1ab Delta Endotoxin and the Genetic Material Necessary for Its Production in Corn (006430, 006484) Fact Sheet Enviromental Protection Agency. Retrieved October, 2011 from http://www.epa.gov/pesticides/biopesticides/ingredients/factsheets/factsheet_006430-006484.htm

Frederiksen K, Rosenquist H, Jorgensen K, and Wilcks A. (2006) Occurrence of Natural Bacillus Thuringiensis Contaminants and Residues of Bacillus Thuringiensis-Based Insecticides on Fresh Fruits and Vegetables. *Appl. Environ. Microbiol., 72*(5), 3435-3440.

FSANZ (2011) Fsanz Response to Study Linking Cry1ab Protein in Blood to Gm Foods. Food Standards Australia and New Zealand. Retrieved October, 2011 from http://www.foodstandards.gov.au/consumerinformation/gmfoods/fsanzresponsetostudy5185.cfm

Paul V, Steinke K, and Meyer HHD. (2008) Development and Validation of a Sensitive Enzyme Immunoassay for Surveillance of Cry1ab Toxin in Bovine Blood Plasma of Cows Fed Bt-Maize (Mon810). *Analytica Chimica Acta, 607*(1), 106-113.

USDA-APHIS (2011) Petitions for Nonregulated Status Granted or Pending by Aphis. United States Department of Agriculture - Animal and Plant Health Inspection Service. Retrieved September, 2011 from http://www.aphis.usda.gov/biotechnology/not_reg.html

Valadares de Amorim G, Whittome B, Shore B, and Levin DB. (2001) Identification of Bacillus Thuringiensis Subsp. Kurstaki Strain Hd1-Like Bacteria from Environmental and Human Samples after Aerial Spraying of Victoria, British Columbia, Canada, with Foray 48b. *Appl. Environ. Microbiol., 67*(3), 1035-1043.

Williams GM, Kroes R, and Munro IC. (2000) Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans. *Regulatory Toxicology and Pharmacology, 31*(2), 117-165.

Zhou G, Yan J, Dasheng Z, Zhou X, and Yuan Z. (2008) The Residual Occurrences of Bacillus Thuringiensis Biopesticides in Food and Beverages. *International Journal of Food Microbiology, 127*(1-2), 68-72.

Comment 20: Several comments suggested that APHIS failed to adequately analyze the impact of a determination of nonregulated status of MON87460 on the public's right to choose non-GE foods, citing a 2010 National Public Radio (NPR) poll indicating that "an overwhelming number of Americans are wary of GE crop production in the U.S." Additionally, several comments endorsed the labeling of GE foods or foods containing GE ingredients, citing a "recent opinion poll that up to 90 percent of Americans support the labeling of GE ingredients" and a poll released by ABC news.

Response 20: APHIS acknowledges that the public has a right to choose non-GE foods (Anderson, 2008). Recent comments by Secretary Vilsack demonstrate USDA's goal to "ensure that all forms of agriculture thrive so that food can remain abundant, affordable, and safe" and thereby promoting an individual's choice to purchase or grow food produced by either conventional, GE, or organic methods. To fulfill its commitment to NEPA, APHIS has conducted an environmental assessment analyzing the potential impacts of MON87460 corn on all forms of agriculture. Based on the analysis provided in Chapter 4.3, 4.5 and 4.8 of the EA, APHIS concluded that there is no evidence for significant environmental impact on conventional or organic agriculture.

However, APHIS disagrees with the conclusion that an overwhelming number of Americans are wary of GE crop production in the U.S., based on the cited and misrepresented 2010 NPR poll. Firstly, while the word "wary" is used in reference to GE salmon in the NPR article describing this poll, "wary" is not used anywhere in the survey questions regarding genetically engineered foods (Hensley, 2010; NPR, 2010). Secondly, only 15 percent of the 3,025 people surveyed believed that GE foods were not safe; an additional 64 percent was unsure about the safety of GE foods, while 21 percent believed the GE foods were safe (NPR, 2010). Thirdly, a majority (60%) of those polled indicated that they were willing to eat GE vegetables, fruits, and grains, thus dispelling any notion that an overwhelming proportion of the population is wary about U.S. GE crop production (NPR, 2010). What this poll did show, however, was that 93 percent of those polled believed that foods should be labeled to indicate that they have been genetically engineered or contain genetically engineered ingredients (Hensley, 2010; NPR, 2010). Additionally, a poll conducted by ABC news also supports this number (ABC News, 2003). While these poll numbers supports another cited poll that states "recent opinion polls indicate that up to 90 percent of Americans support labeling of GE ingredients," this does not indicate that labeling is entirely related to a desire to avoid GE foods. Examining the study in further detail, the conclusion drawn by the writers of the report state that: "Though it appears that most Americans want GM foods labeled, it is possible that their stated preference for such a label could stem from a more general desire for more information about the foods they eat." In order to test this, the developers asked the participants to rate how important it was that food labels indicate certain information (Hallman et al., 2004). The conclusions from that test indicated that the information rated as most important to put on a label was "whether pesticides were used in the process of growing the food." Next in importance was information concerning "whether the food contains GE ingredients" and "if the food was grown or raised organically," which were rated as equally important. These results imply that consumers want a variety of additional information on food labels and as concluded by the writers, "the support of such labels may be more an issue of 'consumer sovereignty' rather than simple avoidance" (Hallman et al., 2004).

APHIS is responsible for regulating GE organisms and plants under the plant pest provisions in the Plant Protection Act of 2000 (PPA), as amended (7 USC § 7701 *et seq.*) to ensure that they do not pose a plant pest risk to the environment. The PPA does not grant APHIS authority to label foods. As described in the EA, the Coordinated Framework for the Regulation of Biotechnology indicates that three Federal agencies, APHIS, FDA and EPA, are responsible for regulating biotechnology in the US. FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act. 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 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.

References

ABC News (2003) Modified Foods Gives Consumers Pause. ABC News. Retrieved October, 2011 from http://abcnews.go.com/images/pdf/930a1FoodSafety.pdf

Anderson G. (2008) Lake County Votes to Ban Gmo Crops. *The Press Democrat.*

Hallman W, Hebden W, Cuite C, Aquino H, and Lang J (2004) Americans and Gm Food: Knowledge, Opinion, and Interest in 2004. RR-1104-007. New Brunswick, New Jersey: Food Policy Institute. Retrieved September, 2011 from http://www.foodprocessing.com/Media/MediaManager/RutgersGMFoodStudy.pdf

Hensley S (2010) Americans Are Way of Genetically Engineered Foods. National Public Radio. Retrieved September, 2011 from http://www.npr.org/blogs/health/2011/06/07/131270519/americans-are-wary-about-genetically-engineered-foods

NPR (2010) National Survey of Healthcare Consumers: Genetically Engineered Foods. Thomson Reuters. Retrieved September, 2011 from http://www.factsforhealthcare.com/pressroom/NPR_report_GeneticEngineeredFood.pdf

Comment 21: Several commenters expressed concern that pollen-mediated gene flow, the lack of a proposed isolation distance by APHIS, and the possibility of seed mixture between MON87460 (or genetically engineered [GE] corn in general) and organic corn would result in the adventitious presence of GE material in organic corn. These comments referenced Star Link corn and Liberty Link Rice as evidence to support their claims that mixing of GE and organic seed is inevitable. Consequently, several commenters suggested that the

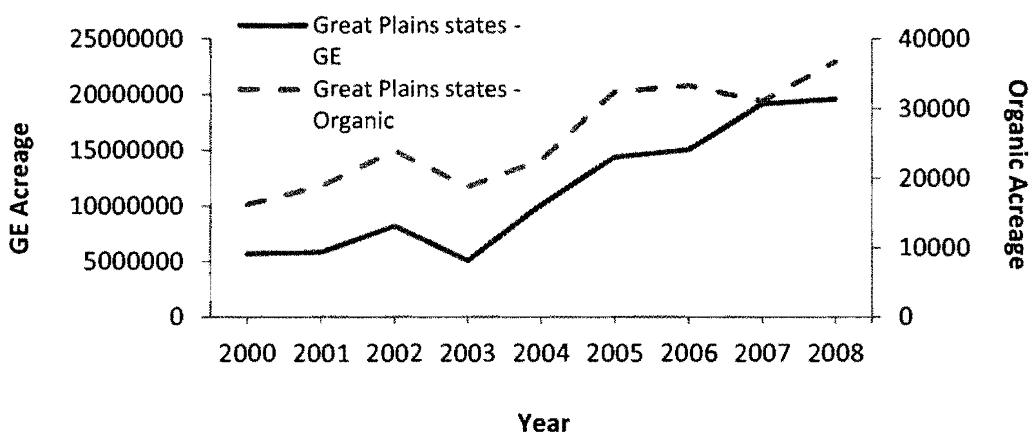
EA failed to examine how the adventitious presence of MON87460 corn (or any other variety of GE corn) may impact the U.S. organic market.

Response 21: In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS-NOP, 2011). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced. Consequently, USDA-certified organic labeling requires that growers develop and submit an organic production plan in order to outline the steps taken to avoid contact or mixing with the products of excluded methods (e.g., non-approved synthetic pesticides or fertilizers). In accordance with NOP regulations, organic operators are required to manage the potential exposure of organic commodities with other substances not approved for use in organic production systems, whether from the non-organic portion of a split operation or from neighboring farms. The use of GE products is specifically prohibited in organic production and handling; however, the inadvertent presence of GE material in organic products is not sufficient to preclude USDA-certified organic labeling if the organic producer followed his/her submitted organic production plan (USDA-AMS, 2011). Implementation of procedures to maintain seed and commodity integrity within the context of an individual organic system plan required for NOP certification has proven effective in preventing the presence of excluded materials in certified organic products.

Growers have, for decades, been successfully growing crops bearing different traits and often on adjoining fields despite the method by which traits were introduced (conventional breeding or recombinant DNA technology). Growers have always had the choice of what crops to grow, and have had to contend with commingling, admixtures, and other contaminants in their crops (Ronald and Fouche, 2006). Studies of coexistence of major GE and non-GE crops in North America and the European Union (EU) have demonstrated that there has been no significant introgression of GE genes, and that GE and non-GE crops are coexisting with minimal economic effects (Brookes and Barfoot, 2004a; Brookes and Barfoot, 2004b; Gealy et al., 2007). Ultimately, under NOP regulations, organic producers are obligated to manage their operations to avoid unintentional contact with excluded methods. As described in Chapter 2.1.2.2 and Chapter 4.3.3 of the EA, isolation distances, reproductive isolation (e.g., staggering planting dates or growing corn with differential maturity times), and farmer communication can be successfully used to minimize the effects of pollen-mediated gene flow from MON87460 corn into organic corn. Growers can obtain the Association of Official Seed Certifying Agencies' (AOSCA) reference material which describes the isolation distance requirements for the certification of corn seed (AOSCA, 2003, 2009). Additionally, organic growers may also choose to plant border rows to mitigate the movement of pollen derived from GE corn and use seed from a known, non-GE stock (Krueger, 2007; Kuepper, 2002; NCAT, 2003).

Methods for limiting gene flow between GE and organic corn are well understood and are in place not only in farms using organic production methods, but also those systems producing specialty corn varieties, such as waxy, sweet, and high amylopectin corn. As noted by Ronald and Fouche (2006), "While 100% purity (zero tolerance for any undesired components) is very difficult to attain for any agricultural commodity, standard procedures involving spatial separation, border rows, planting dates, maturity dates, cleaning of equipment, and post-harvest handling have traditionally been able to provide products that meet diverse market requirements." The same mechanisms are used to mitigate gene flow between GE and organic corn systems (Thomison, 2011). The NOP specifically discusses buffer zones and defines them as areas located between a certified organic production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact with prohibited substances applied to adjacent land areas and the organic grower can incur costs associated with the establishment of these buffer zones. Despite any potential economic harm resulting from gene flow that organic producers in the target introduction area (Great Plains states) of MON87460 may encounter, it is clear that organic corn acreage is increasingly steadily in spite of concurrent increases and overwhelming adoption of GE corn production, suggesting that current methods to limit corn gene flow are sufficient and that the large presence of GE corn has not stopped the cultivation of corn by organic methods (Figure R1). As discussed in Chapter 4.5.2 of the EA and the MON87460 corn PPRA (USDA-APHIS, 2010), MON87460 corn does not differ in reproductive characteristics from conventional corn; consequently, established methods that have been proven successful in mitigating gene flow between corn varieties are likely to be as effective if MON87460 were cultivated.

Figure R4. Acreage of corn produced by GE or organic production methods in the Great Plains States*, 2000 – 2008.



* Great Plains states evaluated included Kansas, Nebraska, North Dakota, South Dakota, and Texas. GE corn adoption data for other Great Plains states were unavailable from USDA-ERS (J. Moore, personal communication). Data collected from (USDA-ERS, 2010a, 2010b; USDA-NASS, 2011b).

The possible cost to organic producers resulting from proximity to GE-based agriculture is dependent upon the acceptable level of GE material that may be inadvertently present and on consumers' expectations and perceptions. The NOP identifies four levels of product composition for organic agriculture certification (7 CFR 205.301): 1) 100 percent organic; 2) 95 percent or more organic; 3) 70 to 95 percent organic; and 4) less than 70 percent organic. A third party organic certification system based on thresholds is also in place to reassure organic customers (Non-GMO-Project, 2010). If there is a negative public perception of the adventitious presence of GE material in organically-produced products, profitability of an organic enterprise may be diminished through the loss of price premiums earned by these products. Survey evidence presented in the Brookes and Barfoot (2004a) study showed that the vast majority (92 percent) of U.S. organic farmers had not incurred any direct additional costs or incurred losses due to GE crops having been grown near their crops. According to the report, four percent had experienced lost organic sales or downgrading of produce as a result of GE organism presence and the remaining four percent of farmers had incurred small additional costs only for testing. However, as observed in Apted and Mazur (2007), the Brookes and Barfoot (Brookes and Barfoot, 2004a) study was not able to quantify the impact of measures undertaken by organic producers to avoid GE material coming into contact with organic crops. Nonetheless, there is data to indicate that farmers using organic production systems are being compensated for the unidentified costs associated with meeting any contractual obligations and NOP standards for corn produced through organic systems. For example, in 2008, conventional corn averaged $4.06/bushel (USDA-NASS, 2011a), whereas organic corn averaged $9.69/bushel in the same time period (USDA-ERS, 2011).

There are millions of acres planted to corn and other crops throughout the U.S. each year, and yet instances such as those mentioned by the commenter (e.g., StarLink), are rare relative to the number of regulated GE plants in confined field tests. Therefore, it is reasonable to assume that coexistence practices can be sufficient to maintain the integrity of a crop and the purity of seed, especially if there are economic/market motivations to implement coexistence practices, e.g., for organic farmers who receive higher price premiums for their crop (Ronald and Fouche, 2006). In terms of purity, for example, a bag of "pure" seed corn will cost $100 per bag, whereas one that exceeds the 5% tolerance is worth $2 per bag (Fernandez and Polansky, 2006).

References

AOSCA (2003) Aosca: 99% Non-Gmo Corn Grain Program Requirements. American Association of Seed Certifying Agenicies. Retrieved March 2011, from http://www.identitypreserved.com/handbook/aosca-nongmocorn.htm

AOSCA. (2009) Seed Certification Handbook: Including Genetic and Crop Standards, Procedures, and Aosca Service Programs.

Apted S and Mazur K (2007) Potential Impacts from the Introduciton of Gm Canola on Organic Farming in Australia, Abare Research Report 07.11. Prepared for the Australian Government Department of Agriculture, Fisheries and Forestry. Retrieved October, 2011 from http://adl.brs.gov.au/data/warehouse/pe_abare99001362/organic_farming.pdf

Brookes G and Barfoot P (2004a) Co-Existence in North American Agriculture: Can Gm Crops Be Grown with Conventional and Organic Crops? Dorchester, UK: PG Economics Ltd.

Brookes G and Barfoot P. (2004b) Coexistence of Gm and Non-Gm Crops: Case Study of Maize Grown in Spain. Dorchester, Uk: Pg Economics Ltd.

Fernandez M and Polansky A. (2006). Presented at Peaceful Coexistence Among Growers of: Genetically Engineered, Conventional, and Organic Crops. Summary of a Multi-Stakeholder Workshop, Boulder, CO.

Gealy D, Bradford K, Hall L, Hellmich R, Raybould A, Wolt J, and Zilberman D (2007) Implications of Gene Flow in the Scale-up and Commercial Use of Biotechnology-Derived Crops: Economic and Policy Considerations. Council for Agricultural Science and Technology (CAST).

Krueger JE (2007) If Your Farm Is Organic, Must It Be Gmo-Free? . Farmers' Legal Action Group, Inc. Retrieved from http://www.flaginc.org/topics/pubs/arts/OrganicsAndGMOs2007.pdf

Kuepper G (2002) Organic Field Corn Production. National Sustainable Agricultural Information Service. ATTRA. Retrieved from http://attra.ncat.org/attra-pub/PDF/fieldcorn.pdf

NCAT (2003) Ncat's Organic Crops Workbook: A Guide to Sustainable and Allowed Practices. Retrieved from http://attra.ncat.org/attra-pub/PDF/cropsworkbook.pdf

Non-GMO-Project (2010) Non-Gmo Project. Retrieved July 31, 2010, from http://www.nongmoproject.org/

Ronald P and Fouche B (2006) Genetic Engineering and Organic Production Systems. University of California, Agriculture and Natural Resources. Retrieved September 2011, from http://ucanr.org/freepubs/docs/8188.pdf

Thomison P (2011) Managing "Pollen" Drift to Minimize Contamination of Non-Gmo Corn, Agf-153. Retrieved October, 2011 from http://ohioline.osu.edu/agf-fact/0153.html

USDA-AMS-NOP (2011) What Is Organic? United States Department of Agriculture, Agricultural Marketing Services, National Organic Program. Retrieved October, 2011 from http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateC&navID=NationalOrganicProgram&leftNav=NationalOrganicProgram&page=NOPConsumers&description=Consumers&acct=nopgeninfo

USDA-AMS (2011) Policy Memorandum. Washington DC: United States Department of Agriculture, Agricultural Marketing Services, National Organics Program.

USDA-APHIS (2010) Plant Pest Risk Assessment for Mon 87460 Corn. Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html

USDA-ERS (2010a) Adoption of Genetically Engineered Crops in the U.S.: Corn Varieties. Retrieved Aug. 11 2010, from http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable1.htm

USDA-ERS (2010b) Organic Production. Retrieved February 2011, from http://www.ers.usda.gov/Data/Organic/

USDA-ERS (2011) Organic Prices. United States Department of Agriculture, Economic Research Service. Retrieved October, 2011 from http://www.ers.usda.gov/data/OrganicPrices/

USDA-NASS (2011a) Crop Values - 2010 Summary. 1449-0372. United States Department of Agriculture, National Agricultural Statistics Service. Retrieved October, 2011 from http://usda.mannlib.cornell.edu/usda/current/CropValuSu/CropValuSu-02-16-2011.pdf

USDA-NASS. (2011b) Quick Stats 2.0. Retrieved October, 2011 from United States Department of Agriculture, National Agricultural Statistics Service http://quickstats.nass.usda.gov/

Comment 22: Several commenters expressed concern that the adventitious presence of GE traits has deterred farmers from producing corn through organic methods, thus reducing the capacity of the organic industry from growing due to supply issues. As justification for this, one commenter quoted an organic grain handler explaining that they are unable to supply organic corn because of unreliable separation between organic and GE corn production.

Response 22: APHIS supports all forms of agricultural production, whether it is organic, conventional, or GE production methods. Additionally, as stated in the EA, APHIS acknowledges that there may be a lag between supply and demand of organic corn. However, assigning the presence of GE corn as the major or only factor preventing further organic corn production is not consistent with observations about the economic and market successes of organic crops. Even the same commenter suggests GE corn production may prevent organic corn adoption concedes that "it is unclear why more U.S. farmers are not growing organic corn." Just as demonstrated for several other organic commodities, such as coffee or nuts, short supplies have been noted, although many of these do not have any commercialized GE varieties (Greene et al., 2009).

As stated in Chapter 4.3.3.2 of the EA, organic corn production continues to increase in the U.S. despite the presence of corn produced through excluded methods. This trend demonstrates the capacity of current organic system plans to avoid the use of excluded methods and the efficacy of these plans to increasingly produce organic agricultural commodities for target markets. Additionally, the same organic grain handler cited by the commenters is also cited as providing other reasons for the tight supply of organic agricultural commodities, including: 1) the three-year transition requirement for organic production; 2) fewer organic marketing outlets; 3) the need for on-farm storage; 4) the lack of third-party contractors for organic pest and nutrient management; 4) heavy and intensive production requirements; 5) fear of criticism from neighbors; 6) unknown risks; 7) an absence of supporting government infrastructure; 8) and subsidies for ethanol that increase demand for conventional production and supply (Greene et al., 2009). Furthermore, Brookes and Barfoot (2004) also noted in an examination of trends in the planting of GE and organic crops that the growth of the crop area used for GE plants has not impeded the development of the organic sector in North America. The U.S. had under a million acres of certified organic farmland when Congress passed the Organic Foods Production Act of 1990. By the time USDA implemented national organic standards in 2002, certified organic farmland had doubled, and doubled again between 2002 and 2005 (USDA-ERS, 2010). The U.S. total number of certified organic producers in 2000 was 6,592; this number increased to 10,159 in 2007 (USDA-ERS, 2010). Thus, due to the presence of all these possible preventative factors and the concurrent growth of both organic and GE corn sectors, it is unlikely that a determination of nonregulated status of MON87460 will not have any impact on the growth of the organic corn industry.

References

Brookes G and Barfoot P (2004) Co-Existence in North American Agriculture: Can Gm Crops Be Grown with Conventional and Organic Crops? Dorchester, UK: PG Economics Ltd.

Greene C, Dimitri C, Lin B-H, McBride W, Oberholter L, and Smith T (2009) Emerging Issues in the U.S. Organic Industry. USDA-ORS. Retrieved October 2011, from http://www.ers.usda.gov/publications/eib55/eib55.pdf
USDA-ERS (2010) Organic Production. Retrieved February 2011, from http://www.ers.usda.gov/Data/Organic/

Comment 23: Several commenters expressed concern that cultivation of MON87460 corn, either alone or stacked with other commercially-available GE traits, would lead to a general increase pesticide application. Additionally, several commenters also expressed concern that the presence of a GE corn variety stacked with MON87460 and glyphosate-tolerance traits will lead to an increase in incidents of glyphosate-resistant weeds.

Responses 23: While it was stated that Chapter 4.3.2.2 of the EA that cultivation of MON87460 may result in a shift away from glyphosate use, it was also stated that this shifts is likely to be limited through stacking of the MON87460 trait with commercially-available herbicide-tolerant traits (USDA-APHIS, 2011). In fact, Monsanto does not plan on marketing MON87460 as a stand-alone product, suggesting that stacking of MON87460 with GE herbicide-tolerant traits is very likely (Monsanto, 2010). The Cumulative Impacts section (Chapter 5) of the EA has been rewritten to further clarify this point and address commenter concern that the stacking of traits will lead to an increase in pesticide application. Due to similar management strategies between any stacked hybrid progeny and their parent varieties (e.g., hybrid progeny and one of the parent varieties will possess herbicide tolerance), overall pesticide application will remain relatively unchanged and is not likely to increase beyond that which can be expected from projected increases in corn cultivation. Other agricultural inputs, such as fertilizer application, will likely slightly increase as well.

Weed management is an important part of any agricultural system. The commercialization of corn varieties stacked with glyphosate-tolerant and the MON87460 traits would permit existing and widely-adopted management strategies to continue. Relying on glyphosate alone as the only weed-removal strategy may influence the number of weed species that may become glyphosate-resistant. However, as this same commenter concedes, "These specific risks are not unique to MON87460" and may be influenced by a number of other factors involved in the evolution of glyphosate resistance in weeds. A variety of genetic, biological/ecological, and operational factors contribute to the evolution of herbicide resistance in weeds. Genetic factors include the frequency of genes in a particular weed species that promotes resistance to a particular herbicide, the mechanism of resistance and the capacity of genes to facilitate this resistance, how resistance is inherited, and the fitness of the weed in the presence and absence of the herbicide (Georghiou and Taylor, 1986; Neve, 2008). Biological/ecological factors include the method of weed reproduction, seed production capacity, seed bank turnover, and the amount and frequency of gene flow between weed populations (Jasieniuk et al., 1996; Maxwell and Mortimer, 1994). Collectively, these issues illustrate that different plant species may present different risks of resistance. Operational factors influencing development of weed resistance include farm-level management practices such as the chemistry of the applied herbicide and its respective mechanism of action, and the application rates/frequency of herbicide application (Georghiou and Taylor, 1986; Jasieniuk et al., 1996).

Currently, there are no concrete data, information, or models that provide a prescriptive determination on the evolution of herbicide resistance in specific weeds or the efficacy of a particular management strategy to prevent the evolution of resistance to glyphosate. APHIS is not aware of any models that simulate the evolution of weed resistance to glyphosate in herbicide-tolerant agricultural systems. What can be generally observed, however, is the influence a management strategy exerts in the evolution of herbicide resistance in weeds. With regard corn varieties stacked with MON87460 and glyphosate resistance, it is unlikely that this GE hybrid corn variety would alter any baseline influence of established management strategies that are currently practiced in GE corn cultivation systems. Thus, it is unlikely that any GE corn hybrid variety stacked with MON87460 would increase the incidence of glyphosate resistant weeds, as the factors resulting in of glyphosate resistance in weeds would remain unchanged. Chemistry of the applied herbicide (e.g., glyphosate) and the frequency and rate of application would remain unchanged, as any progeny GE corn variety containing both MON87460 and glyphosate-tolerant traits would possess the same glyphosate-tolerant trait as its parent variety, and thus, require similar weed management.

References

Georghiou G and Taylor C. (1986) Factors Influencing the Evolution of Resistance *Pesticide Resistance: Strategies and Tactics for Management* (pp. 157-169). Washington DC: National Academy Press.

Jasieniuk M, Brûlé-Babel AL, and Morrison IN. (1996) The Evolution and Genetics of Herbicide Resistance in Weeds. *Weed Science, 44*(1), 176-193.

Maxwell B and Mortimer A. (1994) Selection for Herbicide Resistance. In S Powles and J Holtrum (Eds.), *Herbicide Resistance in Plants: Biology and Biochemistry* (pp. 1-25). Baco Raton, FL: CRC Press.

Monsanto (2010) Petition for the Determination of Nonregulated Status for Mon 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. The Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

Neve P. (2008) Simulation Modeling to Understand the Evolution and Management of Glyphosate Resistance in Weeds. *Pest Management Science, 64*, 392-401.

USDA-APHIS (2011) Petitions for Nonregulated Status Granted or Pending by Aphis. United States Department of Agriculture - Animal and Plant Health Inspection Service. Retrieved September, 2011 from http://www.aphis.usda.gov/biotechnology/not_reg.html

Comment 24: Concern was expressed by commenters that MON87460 corn would generally harm soil microorganisms and that soil and water quality would suffer if MON87460 corn were stacked with commercially-available GE corn varieties that possess insect resistance (Bt protein production) and/or herbicide-tolerance (e.g., glyphosate-tolerance) traits.

Response 24: APHIS disagrees that MON87460 would harm soil organisms. As detailed in Chapter 4.4.2.2 of the EA, microbial soil populations may encounter the NPTII and CSPB proteins produced by MON87460 corn through degrading plant material in the field or the *in situ* root system. Both expressed proteins in MON87460 corn (NPTII and CSPB) have been shown to be safe for the environment (Monsanto, 2010). In particular, the NPTII protein has been used in a variety of GE crops without any adverse effect on the environment. APHIS refers any commenter to the EA and response #16 of this FONSI for further discussion about the relative safety of MON87460 corn and its expressed proteins. Additionally, compositional analysis of MON87460 corn reveals that it is similar to conventional corn, with no meaningful biological differences (USDA-APHIS, 2010), thus suggesting that there would not be any differences in availability of nitrogen or other nutrients following the degradation of plant material in the field.

As discussed in Chapter 5 of the EA, MON87460 will likely be stacked with commercially-available GE corn traits. The two most common GE corn traits include glyphosate tolerance and insect resistance. The glyphosate-tolerant phenotype permits the application of the herbicide glyphosate in order to control weeds. Glyphosate adsorbs strongly to soil, does not generally move vertically below six inches through the soil, and typically possesses a half-life of less than 60 days (Giesy et al., 2000). Glyphosate can also either inhibit or mobilize various elements, including Al, Fe, Cu, Zn, Ni, P, Si, and As in soil, depending on various factors such as the amount of clay or organic matter (Barrett and McBride, 2006). Soil microbial populations readily degrade glyphosate into aminomethylphosphonic acid (AMPA), a degradation product. Observed AMPA concentrations in glyphosate-treated areas are many times lower than levels with potentially adverse effects (Gimsing et al., 2004; USDA, 2003). While some data has indicated that many microorganisms produce aromatic amino acids through the same metabolic pathway that glyphosate inhibits in plants, there is little empirical evidence to support the conclusion that glyphosate can negatively impact soil microbes; on the contrary, some field studies have shown an increase in microbial activity (USDA-FS, 2003). Thus, the application of glyphosate itself is unlikely to significantly impact soil microbial populations and their respective activities that influence soil quality. In addition to glyphosate tolerance, MON87460 may also be stacked with various commercially-available Bt proteins that confer specific insect-resistant phenotypes. Bt proteins are a family of proteins produced by *Bacillus thuringiensis* that exhibit specificity for either Lepidopteran or Coleopteran pests of corn. Soil organisms may be exposed to Bt through decaying plant material from or the root system of Bt-expressing plants. Evidence shows that Bt proteins have no measurable effect on soil microbial populations, of either bacteria, actinomycetes, fungi, protozoa, algae, or nematodes (Mendelsohn et al., 2003). APHIS agrees that weed management strategies can impact soil and water quality, such as tillage affecting runoff and soil loss. The majority of corn cultivated in the U.S. is managed using glyphosate tolerant varieties, and these have been shown to have ecological advantages over those not managed predominantly with glyphosate (Fernandez-Cornejo et al., 2009). As discussed in Chapter 5 of the EA, no direct impact on current corn pest management practices is likely to result from hybrid corn progeny stacked with MON87460 and/or herbicide-tolerant and/or insect-resistant traits. MON87460 expressing these GE hybrid corn traits would require similar management strategies as the parent varieties. Stacked corn varieties with MON87460 are intended to be replacement products for GE corn varieties possessing herbicide tolerance and/or insect resistance in its target range; thus, no increase or shift in pesticide application is expected, nor is any alteration anticipated in tillage. These two factors may influence soil and water quality and will remain unchanged from current practices if stacked corn varieties with MON87460 were cultivated. Furthermore, compositional analysis of both MON87460 and commercially-available GE corn varieties demonstrated that they are not dissimilar (USDA-APHIS, 2010, 2011); consequently, any progeny derived from these varieties and MON87460 is unlikely to be compositionally different from its respective parent varieties and unlikely to significantly impact soil organisms through degradation of plant tissue in the field.

In summary, no significant impact to soil and water quality is expected from the stacking of MON87460 with herbicide-tolerant and/or insect resistant traits, as there is no reason to expect that this GE hybrid corn would be compositionally different from currently-available corn varieties. MON87460 corn would require similar management conditions already in place in conventional corn production systems. Evidence in the literature demonstrates no toxicity for either glyphosate or Bt proteins on soil microorganisms.

References

Barrett KA and McBride MB. (2006) Trace Element Mobilization in Soils by Glyphosate. *Soil Science Society of America, 70*(6), 1882-1888.

Fernandez-Cornejo J, Nehring R, Sinha EN, Grube A, and Vialou A. (2009) *Assessing Recent Trends in Pesticide Use in U. S. Agriculture*. Paper presented at the Meeting of the AAEA, Milwaukee, WI.

Giesy J, Dobson S, and Solomon K. (2000) Ecotoxicological Risk Assessment for Roundup Herbicide. *Reviews of Environmental Contaminaton and Toxicology* (167), 35-120.

Gimsing AL, Borggaard OK, Jacobsen OS, Aamand J, and Sørensen J. (2004) Chemical and Microbiological Soil Characteristics Controlling Glyphosate Mineralisation in Danish Surface Soils. *Applied Soil Ecology, 27*(3), 233-242.

Mendelsohn M, Kough J, Vaituzis Z, and Matthews K. (2003) Are Bt Crops Safe? *Nature Biotechnology, 21*(9), 1003-1009.

Monsanto (2010) Petition for the Determination of Nonregulated Status for Mon 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. The Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

USDA-APHIS (2010) Plant Pest Risk Assessment for Mon 87460 Corn. Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html

USDA-APHIS (2011) Petitions for Nonregulated Status Granted or Pending by Aphis. United States Department of Agriculture - Animal and Plant Health Inspection Service. Retrieved September, 2011 from http://www.aphis.usda.gov/biotechnology/not_reg.html

USDA-FS (2003) Glyphosate - Human Health and Ecological Risk Assessment: Final Report. United States Department of Agriculture Forest Service. Retrieved October, 2011 from http://teamarundo.org/control_manage/docs/04a03_glyphosate.pdf

USDA (2003) Glyphosate Human Health and Ecological Risk Assessment Final Report. Prepared by Syracuse Environmental Research Associated, Inc for Usda, Forest Service Health Protection. United States Department of Agriculture.

PLANT PEST RISK ASSESSMENT FOR MON 87460 CORN

Monsanto Company has petitioned the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture for a determination that genetically engineered (GE) corn (*Zea mays*) event MON 87460 (APHIS number 09-055-01p-a1) is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under APHIS' regulations at 7 CFR part 340. APHIS administers 7 CFR part 340 under the authority of the plant pest provisions of the Plant Protection Act of 2000[1]. This plant pest risk assessment was conducted to determine whether MON 87460 corn is unlikely to pose a plant pest risk.

History of Development of MON 87460 Drought-Tolerant Corn

Corn is the second major food and feed crop in world. Recently corn is also considered as a major biofuel crop in the U.S.; therefore, it is expected that U.S. corn cultivation may continue to increase in the coming years (USDA 2007). Conventional breeding methods have made enormous progress in corn crop improvement (Sprague and Dudley 1988). Despite those improvements the demand for corn far exceeds the current production level, leading to a worldwide grain shortage.

As with many high yielding modern crop plants, drought is one of the major limiting factors in corn that prevents realization of optimum grain yield (Heisey and Edmeades 1999), and that problem may become a frequent feature across U.S. farmlands and elsewhere in the future. Abiotic stress is the primary cause of crop loss worldwide, reducing average yields for most major crop plants by more than 50% (Boyer 1982; Bray et al. 2000). In North America alone, it is estimated that 40% of annual crop losses are due to sub-optimal water availability (Boyer 1982). Although some of the recent corn cultivars are bred to exhibit some degree of drought tolerance (Byrne et al. 1995; Tollenaar and Wu 1999; Bängiger et al. 2006), the current corn gene pool and conventional breeding techniques may not be able to bring a significant improvement for drought tolerance in future corn cultivars. In this regard, new biotechniques combined with conventional breeding methods offer potential new tools and avenues to harness drought tolerant gene from different sources to increase corn yield stability under water-limited conditions (Bänziger and Araus 2007).

Drought conditions vary in nature, severity, and impact (Jacobsen and Shaw 1989; Close et al. 1993; Campos et al. 2006). While extreme drought conditions prevent normal growth and development of plants leading to complete crop failure, suboptimal soil water at key plant growth stages can also substantially reduce crop yield. Drought tolerant crops are designed to escape water limitation through both genetic and agronomic manipulations. The strength of drought tolerance is a relative quantification measured over existing cultivars, which varies greatly among crop plants. Under no circumstances, however, it is likely that crop improvement alone can mitigate all economic losses under water-limited conditions; rather it has the potential to play a key role in minimizing crop loss in drought-prone areas (Heisey and Morris 2006).

---

[1] Section 403 (14) of the Plant Protection Act (7USC Sec 7702(14)) defines plant pest as:
"Plant Pest - The term "plant pest" means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan. (B) A nonhuman animal. (C) A parasitic plant. (D) A bacterium. (E) A fungus. (F) A virus or viroid. (G) An infectious agent or other pathogen. (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs."

Monsanto has developed MON 87460 corn event (hereafter referred to as MON 87460) that is expected to reduce yield loss under water-limited conditions compared to conventional corn. The ability to withstand the water limitation in MON 87460 comes from an introduced gene called cold shock protein B (CSPB) derived from the bacterium *Bacillus subtilis*. The CSPB is a RNA chaperone. RNA chaperones are ubiquitous and abundant proteins found in all living organisms and viruses. RNA tends to be kinetically trapped in misfolded forms, and RNA binding proteins, acting as chaperones, can resolve these structures, ensuring accessibility for its biological function. In bacteria, RNA chaperones are believed to play a general role in sustaining growth by favoring active transcription, translation, and/or ribosome assembly (Castiglioni et al. 2008). In bacteria, the CSPB protein helps preserve normal cellular functions during certain stresses by binding cellular RNA and unfolding nontranslatable secondary structures affecting RNA stability and translation. As in bacteria, the CSPB protein in MON 87460 binds RNA and appears to help maintain plant cellular functions.

Data submitted by Monsanto suggest that MON 87460 reduces yield loss, primarily through increased kernel number per ear, under water-limited conditions by minimizing the effect of water limitation on photosynthesis, stomatal conductance, and carbon fixation. On a plant level, corn yield losses associated with drought stress occur as a result of reduced synchrony between anthesis and silking, embryo loss, and/or reduced grain filling in viable kernels (Claassen and Shaw 1970; Boyer and Westgate 2004; Campos et al. 2006). Studies on conventional germplasm with enhanced drought tolerance show that yield improvements are attained through improvements in all of these endpoints (Bolanos et al. 1993: Bolanos and Edmeads 1996: Barker et al. 2005). Therefore, the enhanced yield stability of MON 87460 under water-limited conditions, conferred by the expressed CSPB protein, appears to be the result of improvements in the natural stress response mechanisms over conventional corn.

MON 87460 corn has been field tested under APHIS regulations since 2002 and Monsanto provided data in the petition for field trials completed prior to the petition submission. Because MON 87460 reduces yield loss under water-limited conditions, Monsanto designed field studies to collect relevant data across a broad range of soil moisture (well watered and water-limited conditions) and environmental conditions relevant to where commercial production would be expected. Data submitted by Monsanto shows that under well-watered conditions, grain yield for MON 87460 is not significantly different from conventional corn, yet MON87460 experienced reduced yield loss when water stress was around 20% less than normal. However, like conventional corn, MON 87460 is still subject to yield loss under severe water-limited conditions, particularly during flowering and grainfill periods when corn yield potential is most sensitive to water stress. In the following paragraphs APHIS BRS summarizes its plant pest risks assessment of MON 87460 because of inserted genetic elements and/or their products.

Description of the Inserted Genetic Material

MON 87460 was developed through a plant pathogenic bacterium *Agrobacterium tumefaciens* mediated transformation of corn line LH59 embryos (Armstrong and Phillips 1988). However, the *A. tumefaciens* strain, ABI, that was used to develop MON 87460, was made non pathogenic by removing the pathogenic sequences present in Ti (tumor inducing) plasmid originally present in *A. tumefaciens* (Koncz and Schell 1986). The disarmed *A. tumefaciens* harbors a binary plasmid vector PV-ZMAP595 (Monsanto 2010, Figure III-1, p. 97). This vector was approximately 9.4 kb and contained a single T-DNA delineated by left and right border regions with in which there were two expression cassettes: a *cspB* gene expression cassette, which contained coding sequence for CSPB protein, and a neomycin phosphotransferase II (*nptII*) expression cassette, which contained coding sequence for the NPTII protein.

The *cspB* expression cassette consisted of the following genetic elements (Monsanto 2010, Table IV-1, p. 100):

- Promoter, leader, and intron from the rice (*Oryza sativa*) actin gene, *Ract1* (McElroy et al. 1990).
- Full length coding sequences of Cold Shock Protein B (*cspB*) gene from the bacterium, *Bacillus subtilis* (Willimsky et al. 1992).
- 3' nontranslated terminator sequence of the *transcript* 7 gene from *Agrobacterium tumefaciens* that directs polyadenylation (Dhaese et al. 1983).

The *nptII* expression cassette consisted of the following genetic elements (Monsanto 2010, Table IV-1, p. 100):

- *loxP* sequence from *Bacteriophage P1* for the recombination site recognized by Cre recombinase (Russell et al. 1992). Cre-Lox recombination provides a way to knockout genes.
- P-*35S* promoter for the 35S RNA of the Cauliflower mosaic virus (Odell et al. 1985).
- CS-*nptII* coding sequence from *Tn5* (Beck et al. 1982) in *Escherichia coli* encoding neomycin and kanamycin resistance (Fraley et al. 1983) that was used as a selectable marker during transformation selection.
- T-*nos* 3' nontranslated sequence of the *nopaline synthase* (NOS) gene from *A. tumefaciens.* This sequence terminates gene expression by a polyadenylation site (Depicker et al. 1982).
- *loxP* sequence from *Bacteriophage P1* for the recombination site recognized by Cre recombinase (Russell et al. 1992). The *loxP* sites were inserted to facilitate the potential excision of the *nptII* cassette using CRE recombinase.

In addition to the above-mentioned genetic elements, the insert also contained noncoding intervening sequences of 1-73 base pair length and right and left border sequences that were used during DNA cloning.

Monsanto provided evidence demonstrating that:

- the final product does not contain any of the backbone sequences outside of the T-DNA borders from the transformation vector, PV-ZMAp595 (Monsanto 2010, Figure V-5, p. 117; Figure V-15, p. 134),
- the DNA inserted into the corn genome is present at a single locus and contains one functional copy of *cspB* and *nptII* genes (Monsanto 2010, Figure V-4, p. 116; Figure V-14, p. 133),

- the sequence and organization of inserted genes in MON 87460 are identical to their original sequences and arrangements in the donor plasmid PV-ZMAp595 (based on DNA sequence analysis),
- no novel open reading frames were created that spanned either the 5′ or 3′ junctions between the T-DNA and corn genomic sequences, and
- the stability of introduced genes was demonstrated by the presence of introduced genes via Southern blot fingerprint of MON 87460 (Monsanto 2010, Figures V-14 and V-15, p. 133-134) for seven generations tested (Monsanto 2010, Figure V-13, p. 132) in the breeding history. The stability was further confirmed by the Mendelian inheritance of the T-DNA in MON 87460 (Monsanto 2010, Table V-3, p. 136).

Two minor changes occurred during the MON 87460 transformation event; one in the inserted genetic element and one to the adjacent corn genomic DNA. A part (733 base pairs) of the promoter, rice actin gene (*Ract1*), did not get incorporated into the transformed plant. According to Monsanto, this rearrangement probably resulted from double-strand break repair mechanisms in the plant during the *Agrobacterium*-mediated transformation process (Salomon and Puchta 1998). Furthermore, analysis of the T-DNA insertion site indicated that a 22 base pair length of genomic DNA got deleted at the insert-to-plant DNA junction in MON 87460. Despite these minor genetic sequence modifications in MON 87460, neither the stability analysis of the inserted genetic elements over seven generations (Monsanto 2010, Figures V-14 and V-15, p. 133-134; Monsanto 2010, Table V-3, p. 136), nor the forage and grain compositional assessment (p. 151-174 in Monsanto 2010) showed any biologically meaningful differences between MON 87460 and conventional corn control except for the drought tolerance traits.

PLANT PEST RISK ASSESSMENT

MON 87460 corn was produced by transformation of corn tissue using *A. tumefaciens* to introduce two genes: a gene (*cspB*) that confers drought tolerance and a gene (*nptII*) that facilitates selection of transformed plants. Because *A. tumefaciens* is a plant pest and some of the regulatory sequences (35S Promoter sequence from Cauliflower mosaic virus and nopaline synthase terminator sequence from *A. tumefaciens*) used to facilitate expression of these genes in corn were derived from plant pests, the engineered corn has been considered a regulated article under APHIS regulations at 7 CFR part 340.

Potential impacts to be addressed in this risk assessment are those that pertain to the use of MON 87460 corn and its progeny in the absence of confinement. APHIS utilizes data and information submitted by the applicant, in addition to current literature, to determine if MON 87460 is unlikely to pose a plant pest risk. If APHIS determines that a GE organism is unlikely to pose a plant pest risk, then APHIS has no regulatory authority over that organism.

Of the information requested by APHIS for submission of a petition for nonregulated status (§ 340.6(c)(4)), APHIS examined information submitted by the applicant related to plant pest risk characteristics, expression of the gene product, changes to plant metabolism, disease and pest susceptibilities, impacts on the weediness of any other plant with which it can interbreed, weediness of the regulated article, and impacts on nontarget organisms. Issues related to agricultural or cultivation practices are discussed in the Environmental Assessment prepared by APHIS for MON 87460 corn.

Potential Impacts of Genetic Modifications on Altered Disease and Pest Susceptibilities

USDA-APHIS assessed whether MON 87460 corn is likely to have significantly increased disease and pest susceptibility. This assessment encompasses a thorough consideration of introduced traits, their impact on agronomic traits and plant composition, and interactions with pests and diseases.

Introduced Traits

MON 87460 contains drought tolerance traits from the introduced gene product CSPB protein and a selectable marker gene product NPTII protein. The CSPB protein in MON 87460 belongs to the cold-shock protein (CSP) family and is identical in amino acid sequence to the native CSPB protein produced in *B. subtilis* (Willimsky et al., 1992) with the exception of one amino acid change in the second position from leucine to valine. This amino acid change was implemented by Monsanto to facilitate the assembly of the plasmid vector PV-ZMAP595 for plant transformation. The structure of CSPB is well characterized (Schindelin et al. 1993; Schindelin et al. 1994) and in bacteria CSPs are composed of 67-73 amino acids (Graumann et al. 1997). The CSPB protein in MON 87460 consists of 66 amino acids (Monsanto 2010, Figure IV-1, p. 102). Although Figure IV-1 shows 67 amino acids for the CSPB protein in MON 87460, which were predicted based on *cspB* coding sequence, following translation, however, the N-terminal methionine is cleaved by methionine aminopeptidase leaving 66 amino acids in the final CSPB protein in MON 87460 (Monsanto 2010, Appendix B, p. 283-284). CSPs are a group of small proteins that contain a highly conserved RNA-binding sequence identified as a cold shock domain (CSD). Under environmental stress, bacterial CSD-containing proteins have been shown to bind many types of RNA (Cristofari and Darlix, 2002), leading to sustainable translation, maintenance of mRNA levels, and improved cellular function. Similar to bacteria, CSD-containing proteins in plants also bind RNA, unfold RNA secondary structures caused by environmental stress, and help maintain cellular functions under stress. These plant CSD proteins share a high level of similarity to the bacterial CSPs and have been shown to share *in vitro* and *in vivo* functions with bacterial CSPs (Karlson and Imai 2003; Kim et al. 2007; Nakaminami et al. 2005 and 2006; Chaikam and Karlson 2008; Fusaro et al. 2007). As with bacterial and other plant CSD-containing proteins, the CSPB protein from *B.subtilis*, which is expressed in MON 87460, binds RNA, unfolds RNA secondary structures, and accumulates in actively growing tissues (Monsanto 2010, Figures I-7 – I-9). CSPB accumulation is highest in rapidly growing areas of the leaf and seedling and tends to decline as the tissue matures. CSPB concentrations tend to increase over time in developing ears and decline over time in silks. Likewise, CSPB concentrations increase over time in immature tassels and either remain the same or decline in pollen. Taken together, the data on RNA binding, CSPB accumulation and CSPB localization in MON 87460 are consistent with the pattern of RNA binding, accumulation, localization, and functions described for plant CSD-containing proteins (Fusaro et al. 2007; Sasaki et al. 2007; Chaikam and Karlson 2008).

Monsanto did not observe any abnormal or altered mechanisms of plant response to drought stress in transgenic CSPB-containing corn plants. Greenhouse experiments were conducted with CSPB events that are genetically and phenotypically similar to MON 87460 to evaluate if these characteristics had been altered when compared with controls. The plants containing CSPB protein show broadly the same relative water content (Monsanto 2010, Table I-4), leaf water potential (Monsanto 2010, Figure I-22), and leaf osmotic potential (Monsanto 2010, Figure I-23) as the control plants. CSPB-containing plants accumulate similar levels of abscisic acid (ABA) (Monsanto 2010, Figure I-24) and osmotically active solutes (sucrose, fructose, glucose, choline, proline, glycine betaine) as observed in controls (Monsanto 2010, Figures I-25 - 28). Results from these experiments suggest that common mechanisms of plant response to drought stress are not altered in transgenic CSPB-containing corn plants. Thus, like endogenous CSD proteins found in plants, the CSPB protein in MON 87460 interacts with RNA, accumulates, and localizes to rapidly growing tissues and in developing reproductive organs, thereby helping to maintain normal cellular function in those tissues critical to yield under water-limited conditions. Monsanto observed that the major component contributing to the improved yield of MON 87460 under water-limited conditions was the increased number of kernels per plant (Monsanto 2010, Tables I-1 & I-2, p. 46-47), which is consistent with the current understanding of the effect of drought stress on corn yield potential (Barker et al. 2005).

NPTII protein is well characterized (Fuchs et al. 1993), and in MON 87460 NPTII protein consists of 264 amino acids (Monsanto 2010, Figure IV-2, p. 102). The NPTII protein in MON 87460 confers resistance to kanamycin, so as to facilitate the selection of transformed plants (Bevan et al. 1983). The effect of NPTII protein on plant growth and development has been extensively evaluated through several lines of experimental evidence, and several products containing NPTII have been approved by regulatory agencies on a global basis(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). NPTII is the most commonly used antibiotic resistance marker in several commercially grown biotechnology-derived crops including YieldGard® Rootworm corn (MON 863), Bollgard® cotton (MON 531), Bollgard®II cotton (MON 15985), and Roundup Ready cotton (MON 1445). NPTII protein was never found to facilitate plant pest characteristics to plants. Based on the known functions and mechanisms of these proteins (summarized in Monsanto 2010), neither of these proteins are expected to directly alter susceptibility to plant pathogens.

Compositional Analysis

Compositional comparisons between MON 87460 and a conventional control were performed using the principles and analytes outlined in the OECD consensus documents for corn composition (OECD 2002 and 2006). The control substance was a conventional corn hybrid with genetic background similar to MON 87460. The investigation also included 15 other conventional commercial corn hybrids (Monsanto 2010, Appendix Tables E-1 and E-2, p. 311). The commercial reference hybrids selected by Monsanto for each study were adapted to the geographic region in which they were grown with selections based on agronomic characteristics such as relative maturity and drought tolerance ratings. The rationale for the use of commercial references in various experiments was to provide data for the development of a 99% tolerance interval for each variable analyzed. This interval is expected to contain, with 95% confidence, 99% of the values obtained from the population of commercial corn highlighting the existing natural variability in the commercial corn under cultivation. The knowledge of existing natural variability was used to draw biological meanings into those statistically significant differences between MON 87460 and controls. This comparative evaluation also considered natural ranges in corn component levels published in the literature or in the International Life Sciences Institute Crop Composition Database (ILSI 2006).

Monsanto's compositional analyses of MON 87460 were based on forage and grain harvested from two different growing seasons, the first during 2006 in the U.S. conducted under typical agronomic practices and water conditions, and the second during 2006/2007 in Chile under well-watered and water-limited conditions. Components evaluated in samples harvested from both studies included (1) moisture, protein, carbohydrates by calculation, fat, fiber, and ash in a proximate analysis, (2) essential macro- and micro-nutrients in a nutritional analysis, and (3) known endogenous toxicants and anti-nutrients. A supplementary analysis of secondary metabolites associated with stress tolerance was also conducted by Monsanto for samples from Chile in 2006 and 2007 (see Appendix E for details). In total, there were 434 comparisons made for compositional analyses (7 sets of comparisons x 53 components from grain) + (7 sets of comparisons x 9 components from forage).

Overall, a comprehensive evaluation of MON 87460 and the control showed no biologically meaningful differences for grain and forage compositions either for major nutrients (Monsanto 2010, Table VII-2, p. 157-158; Table VII-3, p. 164; Table VII-5, p. 168) or for secondary metabolites (Monsanto 2010, Table VII-6, p. 171; Monsanto 2010, Table VII-7, p. 173). The few detected differences were either exceedingly small in magnitude or the mean component values of MON 87460 and the control were within the 99% tolerance interval. Therefore, based on the data presented by Monsanto on forage and grain, 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.

Agronomic Properties

Monsanto evaluated phenotypic and agronomic characteristics of MON 87460 in a comparative manner to assess plant pest potential (OECD, 1993). These assessments included 14 plant growth and development characteristics, five seed germination parameters, two pollen characteristics, several observations on plant-insect and plant-disease interactions, and plant responses to abiotic stressors (Monsanto 2010, Table VIII-1, p. 178). Monsanto provided phenotypic and agronomic data (see Section VIII. Phenotypic, Agronomic, and Environmental Interactions Assessment, p. 176-231) supporting their claims that MON 87460 is similar to unmodified control corn cultivar except for the intended drought tolerant trait and that MON 87460 does not possess characteristics that would confer a plant pest risk compared to conventional corn. Detailed agronomic and phenotypic characteristics are discussed further in relevant sections of this document, while the observed disease and pest susceptibility of MON 87460 is discussed in the following paragraph.

Monsanto used well-established qualitative or quantitative techniques to measure field trials for damage due to diseases (Anthracnose, Ear rot, Kernel rot, Eyespot, *Fusarium*, Gray leaf spot, Gray mold, Leaf blight, Maize dwarf mosaic virus, Northern leaf spot, *Pythium*, Rust, Seedling blight, Smut, Southern leaf blight, Stalk rot, Stewarts wilt, and Yellow leaf blight), insect pests (Aphids, Leafhoppers, Armyworms, Corn earworms, European corn borers, Southwestern corn borers, Grasshoppers, Corn rootworms, Flea beetles, Japanese beetles, Grape colaspis, Wireworms, White grubs, Spider mites, Seedcorn maggots) for two years conducted across different agroecological conditions. The data submitted by Monsanto indicated no meaningful differences between MON 87460 corn and the non-transgenic counterparts for diseases (Monsanto 2010, Table H-2, p. 432), or insect pests (Monsanto 2010, Tables H-3 to H-7, p. 433-441; Table H-4, p. 434: Tables H-5 to H-6, p. p. 435-438). Thus MON 87460 corn is expected to be susceptible to the same plant pathogens and insect pests as conventional corn.

Monsanto's aforementioned data (description of the inserted genetic elements, expression of the gene product, compositional analysis, and agronomic and phenotypic observations) indicates that MON 87460 corn is not biologically different from conventional corn (with the exception of the CSPB3 and NPTII proteins), and MON87460 is no more susceptible to pests and diseases compared to conventional corn cultivars.

Potential Impacts from Outcrossing (Gene Flow) to Sexually-compatible Wild Relatives

Gene flow is a natural biological process with significant evolutionary importance. A number of angiosperm taxa are believed to be derived from hybridization or introgression between closely related taxa (Grant 1981; Soltis and Soltis 1993; Rieseberg 1997; Hegde et al. 2006), and even in the existing floras, the occurrence of hybridization or introgression is reported to be widespread (Stace 1987; Rieseberg and Wendel 1993; Peterson et al. 2002). It has been a common practice by plant breeders to artificially introgress traits from wild relatives into crop plants to develop new cultivars. However, gene flow from crops to wild relatives is also thought of as having a potential to enhance the weediness of wild relatives, as observed in rice, sorghum, sunflower and few other crops (see Table 1 in Ellstrand et al. 1999).

Corn is a monoecious species with separate male and female inflorescences that enable cross pollination. Corn is predominantly a wind pollinated outcrosser with occasional bee visitation for pollen. Bees rarely visit female inflorescences (silk). Researchers recognize that: (i) the percent gene flow will vary by population, hybrid or inbred, (ii) the level of gene flow decreases with greater distance between the source and recipient plants; (iii) environmental factors affect the level of gene flow, (iv) corn pollen is viable for a relatively short period of time under field conditions, (v) corn produces ample pollen over an extended period of time, and (vi) corn is not pollinated by insects (pollinating insects, especially bees, are occasional visitors to the tassels but rarely visit silks of corn) (Jemison and Vayda, 2000; Luna et al., 2001).

APHIS evaluated the potential for gene introgression to occur from MON 87460 corn to sexually compatible wild relatives and considered whether such introgression would result in increased weediness. Cultivated corn, or maize, *Zea mays* L. subsp. *mays*, is sexually compatible with several members of the genus *Zea*, and to a much lesser degree with members of the genus *Tripsacum* (OECD 2003; Monsanto 2010, Table II-1, p. 82). Wild diploid and tetraploid members of *Zea,* collectively referred to as teosinte, are normally confined to the tropical and subtropical regions of Mexico, Guatemala, and Nicaragua (Wilkes 1967; Matsuoke et al. 2002; Fukunaga et al. 2005). Corn and annual teosinte (*Zea mays* subsp. *mexicana*) are genetically compatible, wind-pollinated, and may hybridize when in close proximity to each other, e.g., in areas of Mexico and Guatemala. While some teosinte may be considered weeds in certain instances, they are also used by some farmers for breeding improved maize (Sánchez and Ruiz 1997 and references therein). Teosinte is described as being susceptible to many of the same pests and diseases that attack cultivated corn (Sánchez and Corral 1997). In the wild, introgressive hybridization from corn to teosinte is currently limited, in part, by several factors including geographic isolation, differing degrees of genetic incompatibility, differences in flowering time in some cases, developmental morphology and timing of the reproductive structures, dissemination, and dormancy (Doebley 1990a and 1990b; Galinat 1988; Ellstrand 2007). Genetically based cross-incompatibility mechanisms are known to reduce hybrids between corn and teosinte when corn is the pollen source (Baltazar et al. 2005; Kermicle and Evans 2005), which thus acts as a significant constraint to introgression.

Teosinte is not present in the U.S. other than as an occasional botanical garden specimen and a few small feral populations of *Zea mexicana* in Florida, Alabama, and Maryland and *Zea perennis* in South Carolina (http://plants.usda.gov). Introgression of genes from corn into teosinte or *Tripsacum* species has not been described to occur in nature in the U.S. Furthermore, MON 87460 is unlikely to outcross with sexually compatible species in the U.S. as differences in factors such as flowering time, geographical separation, and development factors make natural crosses in the U.S. highly unlikely.

Corn is also distantly related to the species in the genus *Tripsacum,* which contains up to 16 recognized species (Monsanto 2010, Table II-1, p. 82), most of which are native to Mexico, Central and South America, but three (*T. dactyloides, T. floridatum*, and *T. lanceolatum*) exist as wild and/or cultivated species in the continental U.S (OECD 2003); and two taxa (*T. fasciculatum* and *T. latifolium*) also occur in Puerto Rico (http://plants.usda.gov). In contrast with corn and teosinte which easily hybridize under certain conditions, special techniques are required to hybridize corn and *Tripsacum* and the offspring of the cross show varying levels of sterility (Galinat 1988; Mangelsdorf 1974; Russell and Hallauer 1980). Furthermore, none of the sexually compatible relatives of corn in the U.S. are considered to be weeds in the U.S. (Holm et. al. 1979). Therefore, even in those instances of accidental gene flow between MON 87460 corn and wild relatives, the transgenes of MON 87460 corn are unlikely to transform corn wild relatives into more weedy species. Based on the data presented in the petition, MON 87460 corn does not exhibit characteristics that cause it to be any weedier than other cultivated corn (see the section "Potential Impacts Based on the Relative Weediness of MON 87460 Corn" below). Moreover, its potential impact due to the extremely limited potential for gene introgression into teosinte is not expected to be any different than that of other cultivated corn varieties. Based on the above considerations, MON 87460 corn is unlikely to adversely impact sexually compatible wild relatives or their weediness characters.

Potential Impacts Based on the Relative Weediness of MON 87460 Corn

In the U.S., corn is not listed as a weed (Crockett 1977; Holm et al. 1979; Muenscher 1980), nor is it present on the Federal Noxious Weed List (7 CFR part 360; http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/weedlist2006.pdf). 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 (Baker 1965; Keeler 1989; Galinat 1988). 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 suit of traits that are characteristics of successful weeds (Baker 1965; Keeler 1989).

APHIS assessed whether MON 87460 corn 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 corn evaluated under field conditions, including potential weedines 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. 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 agroecological regions 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 (Monsanto 2010, Table VIII-2, p. 189). 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.

For the majority of the traits assessed, there were no statistically significant differences between MON 87460 and nontransgenic control (Monsanto 2010, Tables VIII-4 to VIII-12, p. 192-204; Tables VIII-14 to VIII-16, p. 208-210). 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 (Monsanto 2010, Table VIII-14, p. 208). No differences were detected in pollen morphology or viability between MON 87460 and the control (Monsanto 2010, Table VIII-15 & VIII-16, p. 209-210). 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, with the exception of drought. Development of deep root system is typically one of the agronomic traits that has 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.

Based on the agronomic field data and literature survey concerning corn's weediness potential, MON 87460 corn is unlikely to persist as a troublesome weed or to impact on current weed management practices. Furthermore, extensive post-harvest monitoring of field trial plots planted with MON 87460 under USDA-APHIS notifications (Monsanto 2010, Appendix N, p. 519-523) did not reveal any differences in survivability or persistence relative to other corn. These data suggest that MON 87460 is no more likely to become a weed than conventional corn.

Potential Impacts on Nontarget Organisms, Including Beneficial Organisms

Monsanto is in consultation with FDA about food and feed derived from corn event MON 87460 and has submitted a comprehensive assessment of food and feed safety data on CSPB and NPTII proteins of MON 87460 to FDA. Monsanto considered the following factors to establish food and feed safety of introduced gene products.

- The donor organism of the CSPB protein, *B. subtilis*, is not pathogenic, is oftenused as a food additive, is present in many fermented foods, and has a history of safe consumption. In 1999, FDA designated enzyme preparations from this organism as GRAS (generally recognized as safe, FDA, 1999).
- The *B. subtilis* CSPB shares a high percent of identity with CSPs present in other bacterial species broadly used by the food industry and with CSD-containing proteins in plant species used as a food. Many foods prepared with the help of *B. subtilis* have been consumed for a long time with no documented history of any adverse effects to human health. CSPB protein present in MON 87460 shares amino acid identity to other naturally occurring CSD-containing proteins found in food and feed products. The amino acid identity of CSPB ranges from 35% to 98.5% across different plant and bacterial species. 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.
- A dietary safety assessment conducted to evaluate the risks to humans and animals from the CSPB and NPTII proteins present in the foods and feeds derived from MON 87460 did not cause any observed adverse effects even at the highest tested dose levels.
- CSPB protein represents no more than 0.00007% of the total protein in the grain of MON 87460. Digestive fate experiments conducted with the CSPB protein demonstrated that the full-length protein is rapidly digested in simulated gastric 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.
- CSPB and NPTII proteins do not share any amino acid sequence similarities with known allergens, gliadins, glutenins, or protein toxins which have adverse effects to mammals.
- The safety of the NPTII protein and its donor organism, *E. coli*, have been recognized by regulatory agencies and well documented. All existing data suggest that the NPTII protein represents a negligible hazard to human health and is safe for consumption.

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 mentioned earlier, MON 87460 is found to be safe for human and animal consumption. Therefore, Monsanto assessed the nontarget impact of MON 87460 on all those exposed organisms (e.g. pests, diseases, and beneficial arthropods) in the corn agroecosystem.

During the U.S. and Chile phenotypic field studies at 31 locations in 2006 and 2007, each field site was rated at four time intervals during the season for specific insects (pest and non-pests), and diseases (Monsanto 2010, Section VIII.F.1, p. 211-212) to evaluate whether the plant-disease or plant-insect interactions of MON 87460 were altered compared to commercial corn. Out of nearly 388 pest and non-pest arthropod evaluations, only two differences were observed between MON 87460 and the control. Grasshopper damage was lower for MON 87460 compared to the control and European corn borer damage was higher for MON 87460 compared to the control. These differences were within the range of the references observed for corn cultivars. Likewise, out of the more than 425 disease stressor observations, no differences were detected between MON 87460 and the control. These results support the conclusion that no biologically meaningful interactions were observed with the species exposed to MON 87460 and that MON 87460 is not different in its environmental interactions relative to other corn.

Potential Impacts from Transferring Genetic Information from MON 87460 Corn to Organisms with which It cannot Interbreed

APHIS examined the potential for the new genetic material inserted into MON 87460 corn to be horizontally transferred to other organisms without sexual reproduction and whether such an event could lead directly or indirectly to disease, damage, injury or harm to plants, including the creation of more virulent pathogens. The horizontal gene transfer between unrelated organisms is one of the most intensively studied fields since 1940, and the issue gained extra attention with the release of transgenic plants into the environment (Droge et al. 1998). Horizontal gene transfer has been implicated as a major contributor to the spread of antibiotic resistance amongst pathogenic bacteria and the emergence of increased virulence in bacteria, eukaryotes, and viruses; and has contributed to major transitions in evolution.

Potential for Horizontal Gene Transfer to Bacteria, Fungi, OR Viruses

The MON 87460 contains two genes and two noncoding regulatory sequences from bacteria. Horizontal gene transfer and expression of DNA from a plant species to other bacterial species is unlikely to occur based on the following observations. Although there are many opportunities for plants to directly interact with fungi and bacteria (e.g. as commensals, symbionts, parasites, pathogens, decomposers, or in the guts of herbivores), so far there are no reports of horizontal gene transfer to bacteria from eukaryotes or from plants to fungi (as reviewed in Keese 2008). The only genes likely to be transferred successfully from genetically engineered plants to bacteria are other bacterial genes. Horizontal transfer from and expression in bacteria of the foreign DNA inserted into the nuclear genome of MON 87460 corn is unlikely to occur. First, many genomes (or parts thereof) have been sequenced from bacteria that are closely associated with plants including *Agrobacterium* and *Rhizobium* (Kaneko et al. 2000; Kaneko et al. 2002; Wood et al. 2001). There is no evidence that these organisms contain genes derived from plants. Second, in cases where review of sequence data implied that horizontal gene transfer occurred, these events are inferred to occur on an evolutionary time scale on the order of millions of years (Koonin et al. 2001; Brown 2003). Third, the FDA has evaluated horizontal gene transfer from the use of antibiotic resistance marker genes and concluded that the likelihood of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals, or in the environment, is remote (http://vm.cfsan.fda.gov/~dms/opa-armg.html). APHIS also considered whether horizontal transfer of DNA from MON 87460 corn to plant viruses was likely to occur and would lead to the creation or selection of a more virulent plant pathogen through recombination with other plant viruses. This issue has been considered before by other science review panels and government regulatory bodies (for a general review of the issue see Keese 2008). There are two noncoding regulatory sequences (35S and *LoxP*) from virus present in MON 87460 corn. These two sequences have not been implicated in viral recombination raising safety concerns (Hull et al. 2000). Therefore, APHIS concludes that horizontal gene transfer is unlikely to occur and thus poses no significant environmental or plant pest risk.

Conclusion

APHIS has reviewed and conducted a plant pest risk assessment on MON 87460 corn. Due to the lack of plant pest risk from the inserted genetic material, the lack of atypical responses to disease or plant pests in the field, the lack of weediness characteristics of MON 87460 corn, the lack of deleterious effects on non-targets or beneficial organisms in the agro-ecosystem, and the lack of horizontal gene transfer, APHIS concludes that MON 87460 corn is unlikely to pose a plant pest risk.

References

Armstrong, C.L., and Phillips, R. L.. 1988. Genetic and cytogenetic variation in plants regenerated from organogenic and friable, embryogenic tissue cultures of maize. Crop Science 28: 363-369.

Baker, H. B. 1965. Characteristics and modes of origin of weeds. Pp. 147-169 *in* H. G. Baker and G. L. Stebbins (eds.), The genetics of colonizing species. Academic Press, London.

Baltazar, B. M., Sánchez González, J. J., de la Cruz-Larios, L., and Schoper, J. B. 2005. Pollination between maize and teosinte: an important determinant of gene flow in Mexico. Theoretical and Applied Genetics 110: 519–526.

Bänziger, M., and Araus, J. 2007. Recent advances in breeding maize for drought and salinity stress tolerance. PP 587-601*in* M.A. Jenks and P.M. Hasegawa and S.M. Jain (eds.), Advances in Molecular Breeding Toward Drought and Salt Tolerant Crops. Springer, Dordretch, Netherlands.

Bängiger, M., Setimela, P. S., Hodson, D., and Vivek, B. 2006. Breeding for improved drought tolerance in maize adapted to southern Africa. Agricultural Water Management 80: 212-224.

Barker, T., Campos, H., Cooper, M. Dolan, D. Edmeades, G. O., Habben, J. Schussler, J. Wright, D., and Zinselmeoer, C. 2005. Improving drought tolerance in maize. Plant Breeding Review 25: 173-253.

Beck, E., Ludwig, G., Auerswald, E. A., Reiss, B. and Schaller, H. 1982. Nucleotide sequence and exact localization of the neomycin phosphotransferase gene from transposon *Tn5*. Gene 19: 327-336.

Bevan, M.W, Flavell, R. B., and Chilton, M.D. 1983. A chimeric antibiotic resistance gene as a selectable marker for plant cell transformation. Nature 304: 184-187.

Bolanos, J., and Edmeades, G. O. 1996. The importance of the anthesis-silking interval in breeding for drought tolerance in tropical maize. Field Crops Research 48: 65-80.

Bolanos, J., Edmeades, G. O., and Martinez, L. 1993. Eight cycles of selection for drought tolerance in tropical maize. III. Responses in drought-adaptive physiological and morphological traits. Field Crops Research 31: 269-286.

Boyer, J. S. 1982. Plant productivity and environment. Science 218: 443–448.

Boyer, J. S., and Westgate, M. E. 2004. Grain yields with limited water. Journal of Experimental Botany 55: 2385-2394.

Bray, E.A. Bailey-Serres, J., and Weretilnyk, E. 2000. Responses to abiotic stresses. Pp. 1158-1249 *in* W. Gruissem, B. Buchannan and R. Jones (eds.) Biochemistry and Molecular Biology of Plants. American Society of Plant Physiologists, Rockville, MD.

Brown, J. R. 2003. Ancient horizontal gene transfer. Genetics 4: 121-132.

Bruce, W.B., Edmeades, G. O., and Barker, T. C. 2002. Molecular and physiological approaches to maize improvement for drought tolerance. Journal of Experimental Botany 53: 13-25.

Byrne, P.F., Bolanos, J., Edmeades, G. O. and Eaton, D. L. 1995. Gains from selection under drought versus multilocus testing in related tropical maize populations. Crop Science 35: 63-69.

Campos, H., Cooper, M., Edmeades, G. O., Loffler, C., Schussler, J. R. and Ibanez. M. 2006. Changes in drought tolerance in maize associated with fifty years of breeding for yield in the U.S. Corn Belt. Maydica 51: 369-381.

Castiglioni, P., Warner, D., Bensen, R. J., Anstrom, D. C., Harrison, J., Stoecker, M., Abad, M., Kumar, G., Salvador, S., Ordine, R. D., Navarro, S., Back, S., Fernandes, M., Targolli, J., Dasgupta, S., Bonin, C., Luethy, M. H., and Heard, J. E. 2008. Bacterial RNA chaperones confer abiotic stress tolerance in plants and improved grain yield in maize under water-limited conditions. Plant Physiology 147: 446-455.

Chaikam, V., and Karlson, D. 2008. Functional characterization of two cold shock domain proteins from *Oryza sativa*. Plant Cell and Environment 31: 995-1006.

Claassen, M. M., and Shaw, R. H. . 1970. Water deficit effects on corn. II. Grain components. Agronomy Journal 62: 652-655.

Close, T. J., Fenton, R. D., Yang, A., Asghar, R., DeMason, D. A., Crone, D. E., Meyer, N. C., and Moonan, F. 1993. Dehydrin: the protein. Current Topics in Plant Physiology 10: 104-118.

Cristofari, G., and Darlix, J. L. 2002. The ubiquitous nature of RNA chaperone proteins. Progress in Nucleic Acid Research and Molecular Biology 72: 223-268.

Crockett, L. 1977. Wildly Successful Plants: North American Weeds. University of Hawaii Press, Hawaii.

Depicker, A., Stachel, S., Dhaese, P., Zambryski, P., and Goodman, H. M. 1982. Nopaline synthase: transcript mapping and DNA sequence. Journal of Molecular and Applied Genetics 1: 561-573.

Dhaese, P., De Greve, H., D., Gielen, J., Seurinck, L., Van Montague , M. and Schell, J. 1983. Identification of sequences involved in polyadenylation of higher plant nuclear transcripts using *Agrobacterium* T-DNA genes as models. EMBO Journal . 2: 419-426.

Doebley, J. 1990a. Molecular evidence for gene flow among *Zea* species. BioScience 40: 443- 448.

Doebley, J. 1990b. Molecular systematics of *Zea* (Gramineae). Maydica 35:143-50.

Dröge, M., Puhler, A., and Selbitschka, W. 1998. Horizontal gene transfer as a biosafety issue: A natural phenomenon of public concern. Journal of Biotechnology 64: 75-90.

Ellstrand, N. C., Prentice, H. C., and Hancock, J. F. 1999. Gene flow and introgression from domesticated plants into their wild relatives. Annual Review of Ecology and Systematics 30: 539-563.

Ellstrand, N.C., Garner, L. C., Hegde, S., Guadagnuolo, R., and Blancas, L. 2007. Spontaneous hybridization between maize and teosinte. Journal of Heredity 98: 183-187.

FDA (Food and Drug Administration). 1999. Carbohydrase and protease enzyme preparations derived from *Bacillus subtilis* or *Bacillus amyloliquefaciens*; affirmation of GRAS status as direct food ingredients, Final Rule. Federal Register 64:19887-19895, U.S. Food and Drug Administration, Washington, D.C.

Fraley, R.T., Rogers, S.. G., Horsch, R. B., Sanders, P. R., Flick, J. S., Adams, S. P., Bittner, M. L., Brand, L. A., Fink, C. L., Fry, J. S., Galluppi, G. R., Goldberg, S. B., Hoffmann, N. L., and Woo, S. C. 1983. Expression of bacterial genes in plant cells. Proceedings of the National Academy of Sciences (USA) 80: 4803-4807.

Fuchs, R.L., R.A. Heeren, M.E. Gustafson, G.J. Rogan, D.E. Bartnicki, R.M. Leimgruber, R.F. Finn, A. Hershman, and S.A. Berberich. 1993. Purification and characterization of microbially expressed neomycin phosphotransferase II (NPTII) protein and its equivalence to the plant expressed protein. BioTechnology 11: 1537-1542.

Fukunaga, K., Hill, J., Vigouroux, Y., Matsuoka, Y., Sanchez, J. S., Liu, K., Buckler, E. S., and Doebley, J. 2005. Genetics 169: 2241–2255.

Fusaro, A.F., Bocca, S.N, Ramos, R.L.B., Barroca, R.M., Magioli, C., Jorge, V.C., Coutinho, T.C., Rangel-Lima, C.M., De Rycke, R., Inze, D., Engler, G., and Sachetto-Martins, G. 2007. AtGRP2, a Cold-induced Nucleo-cytoplasmic RNAbinding Protein, has a role in flower and seed development. Planta. 225: 1339-1351

Galinat, W.C. 1988. The origin of corn. Pp.1-31 *in* Sprague, G.F. and J.W. Dudley (eds.) Corn and Corn Improvement. 3rd ed., American Society of Agronomy, Crop Science Society of America, and Soil Science Society of America, Madison, WI.

Grant, V. 1981. Plant speciation. Columbia University Press, New York.

Graumann, P., T.M. Wendrich, M.H.W. Weber, K. Schroder, and M.A. Marahiel. 1997. A family of cold shock proteins in *Bacillus subtilis* is essential for cellular growth and for efficient protein synthesis at optimal and low temperatures. Molecular Microbiology 25: 741-756.

Hegde, S.G., Nason, J. D., Clegg, J. M., and Ellstrand, N. C. 2006. The evolution of California's wild radish has resulted in the extinction of its progenitors. Evolution 60:1187-1197.

Heisey, P. W., and Edmeades, G. O. 1999. Maize production in drought-stressed environments: Technical options and research resource allocation. Part I of CIMMYT 1997/1998 World Facts and Trends: Maize Production in Drought-Stressed Environments: Technical Options and Research resource Allocation. Mexico, D. F.: CIMMYT.

Heisey, P.W., and Morris, M.L. 2006. Economic impact of water limited conditions on cereal grain production. Pp. 17-48 *in* J.M. Ribaut (ed.) Drought Adaptation in Cereals. Haworth Press Inc., Binghamton.

Holm, L., Pancho, J. V., Herbarger, J. P., and Plucknett, D. L. 1979. A Geographical Atlas of World Weeds. John Wiley and Sons, New York.

Hull, R., Covey, S. N., and Dale, P. 2000. Genetically modified plants and the 35S promoter: assessing the risks and enhancing the debate. Microbial Ecology in Health and Disease 12: 1-5.

ILSI (International Life Sciences Institute). 2006. International Life Sciences Institute Crop Composition Database, version 3.0. http://www.cropcomposition.org/ (Last modified: 10/1/2008)

Jacobson, J. V., Shaw, D. C. 1989. Heat-stable protein and abscisic acid action in barley aleurone cells. Plant Physiology 91: 1520-1526.

Jemison, J.M., and Vayda, M. 2000. Pollen transport from genetically modified corn. Page 145 in 2000 Agronomy Abstracts. American Society of Agronomy (ASA), Madison, Wisconsin.

Kaneko, T., Nakamura, Y., Sato, S., Asamizu, E., Kato, T., Sasamoto, S., Watanabe, A., Idesawa, K., Ishikawa, A., Kawashima, K., Kimura, T., Kishida, Y., Kiyokawa, C., Kohara, M., Matsumoto, M., Matsuno, A., Mochizuki, Y., Nakayama, S., Nakazaki, N., Shimpo, S., Sugimoto, M., Takeuchi, C., Yamada, M., and Tabata, S. 2000. Complete genome structure of the nitrogen-fixing symbiotic bacterium *Mesorhizobium loti*. DNA Research 7: 331-338.

Kaneko, T., Nakamura, Y., Sato, S., Minamisawa, K., Uchiumi, T., Sasamoto, S., Watanabe, A., Idesawa, K., Iriguchi, M., Kawashima, K., Kohara, M., Matsumoto, M., Shimpo, S., Tsuruoka, H., Wada, T., Yamada, M., and Tabata, S. 2002. Complete genomic sequence of nitrogen-fixing symbiotic bacterium *Bradyrhizobium japonicum* USDA110. DNA Research 9: 189-197.

Karlson, D., and Imai, R. 2003. Conservation of the cold shock domain protein family in plants. Plant Physiology 131: 12-15

Kermicle, J. L., and Evans, M. M. S. 2005. Pollen-pistil barriers to crossing in maize and teosinte result from incongruity rather than active rejection. Sexual Plant Reproduction 18: 187–194.

Keeler, K. 1989. Can genetically engineered crops become weeds? Bio/Technology 7: 1134-1139.

Keese, P. 2008. Review Article: Risks from GMOs due to horizontal gene transfer. Environmental Biosafety Research 7: 123-149.

Kim, J.Y., Park, S. J., Jang, B. S., Jung, C. H., Ahn, S. J., Goh, C. H., Cho, K., Han, O., and Kang, H. S. 2007. Functional characterization of a glycine-rich RNA-binding protein 2 in *Arabidopsis thaliana* under abiotic stress conditions. Plant Journal 50: 439-451.

Koncz, C., and Schell, J. 1986. The promoter of Tl-DNA gene 5 controls the tissue specific expression of chimeric genes carried by a novel type of Agrobacterium binary vector. Molecular and General Genetics 204: 383-396.

Koonin, E. V., Makarova,K. S., and Aravind, L. 2001. Horizontal gene transfer in prokaryotes: quantification and classification. Annual Review of Microbiology 55: 709-742.

Luna, S.V., Figueroa, J. M., Baltazar,B. M., Gomez, R. L., Townsend, R., and Schoper, J. B. 2001. Maize pollen longevity and distance isolation requirement for effective pollen control. Crop Science 41: 1551-1557.

Mangelsdorf, P.C. 1974. Corn: its Origin, Evolution, and Improvement. Harvard University Press, Cambridge, MA.

Matsuoka, Y., Vigouroux, Y., Goodman, M. M., Sanchez, J., Buckler, E., and Doebley, J. 2002. Proceedings of National Academy of Sciences (USA) 99: 6080–6084.

McElroy, D., Zhang, W., Cao, J., and Wu, R. 1990. Isolation of an efficient actin promoter for use in rice transformation. Plant Cell 2: 163-171.

Messmer, R., Fracheboud, Y., Banziger, M., Vargas, M., Stamp, P., and Ribaut, J-M. 2009. Drought stress and tropical maize: QTL-by-environment interactions and stability of QTLs across environments for yield components and secondary traits. Theoretical and Applied Genetics 119: 913–930.

Monsanto (2010). Petition for the Determination of Nonregulated Status for MON 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

Muenscher, W. C. 1980. Weeds. 2nd Edition. Cornell University Press, New York.

Nakaminami, K., Karlson, D.T., and Imai, R. 2006. Functional conservation of cold shock domains in bacteria and higher plants. Proceedings of the National Academy of Sciences (USA) 103: 10122-10127

Nakaminami, K., Sasaki, K., Kajita, S., Takeda, H., Karlson, D., Ohgi, K., and Imai, R. 2005. Heat stable ssDNA/RNA-binding activity of a wheat cold shock domain protein. FEBS Letters 579: 4887-4891.

OECD (Organization for Economic Co-operation and Development). 1993. Safety considerations for biotechnology: Scale-up of crop plants. Organization for Economic Co-operation and Development, Paris, France.

OECD (Organization for Economic Co-operation and Development). 2002. Consensus document on compositional considerations for new varieties of maize (*Zea mays*): key food and feed nutrients, antinutrients and secondary plant metabolites. Organisation for Economic Co-operation and Development. Paris, France.

OECD (Organization for Economic Co-operation and Development). 2003a. Consensus document on the biology of *Zea mays* subsp. *mays* (maize). Series on Harmonisation of Regulatory Oversight in Biotechnology, No. 27, OECD, Paris.

OECD (Organization for Economic Co-operation and Development). 2003b. Considerations for the safety assessment of animal feedstuffs derived from genetically modified plants. Series on the Safety of Novel Foods and Feeds. Paris, France

OECD (Organization for Economic Co-operation and Development). 2006. An Introduction to the Food/Feed Safety Consensus Documents of the Task Force. Organisation for Economic Co-operation and Development, Paris, France.

Odell, J.T., Nagy, F., and Chua, N-H. 1985. Identification of DNA sequences required for activity of the cauliflower mosaic virus 35S promoter. Nature 313: 810-812.

Peterson, C.D., Pearman, D. A., and Dines, T. D. 2002. New Atlas of the British flora. Oxford University Press, London, U.K.

Rieseberg, L. H. 1997. Hybrid origins of plant species. Annual Review of Ecology and Systematics 28: 359-389.

Rieseberg, L.H., and Wendel, J. F. 1993. Introgression and its consequences in plants. Pp. 70–109 i*n* R.G. Harrison (ed.) Hybrid Zones and the Evolutionary Process. Oxford University Press, Oxford, U.K.

Russell, W.A., and Hallauer, A. R. 1980. Corn. Pp. 299-312 *in* W. R. Fehr and H.H. Hadley (eds.) Hybridization of Crop Plants. American Society of Agronomy and Crop Science Society of America, Madison, Wisconsin.

Russell, S.H., Hoopes, J. L., and Odell, J. T. 1992. Directed excision of a transgene from the plant genome. Molecular and General Genetics 234: 49-59.

Sánchez, G. J. J. and Ruiz, C. J. A. 1997. Teosinte distribution in Mexico. Pp 18-39 *in* J. A. Serratos, M. C. Willcox, and F. Castillo-Gonzalez (eds.) Gene Flow among Maize Landraces, Improved Maize Varieties, and Teosinte: Implications for Transgenic Maize. CIMMYT, Mexico, D.F.

Sasaki, K., Kim, M. H., and Imai, R. 2007. Arabidopsis cold shock domain protein 2 is a RNA chaperone that is regulated by cold and developmental signals. Biochemical and Biophysical Research Communications 364: 633-638.

Schindelin, H., Marahiel, M. A., and Heinemann, U. 1993. Universal nucleic acid-binding domain revealed by crystal structure of the *B. subtilis* major cold-shock protein. Nature. 364:164-168.

Schindelin, H., Jiang, W., Inouye, M. and Heinemann, U. 1994. Crystal structure of CspA, the major cold shock protein of *Escherichia coli*. Proceedings of the National Academy of Sciences (USA) 91: 5119-5123.

Salomon, S. and Puchta, H. 1998. Capture of genomic and T-DNA sequences during double-strand break repair in somatic plant cells. EMBO Journal 17: 6086-6095.

Sprague, G. F. and Dudley, J. F. (editors). 1988. Corn and Corn Improvement, 3rd Edition. ASA-CSSA-SSSA, Madison, WI.

Soltis, D.E., and Soltis, P. S. 1993. Molecular data and the dynamic nature of polyploidy. Critical Reviews in Plant Sciences 12: 243–273.

Stace, C.A. 1987. Hybridization and the plant species. Pp. 115–127 *in* K.M. Urbanska (ed.) Differentiation Patterns in Higher Plants. Academic Press, New York.

Tollenaar, M., and Wu, J. 1999. Yield improvement in tropical maize is attributable to greater stress tolerance. Crop Science 39: 1597-1604.USDA-APHIS. 2000.

USDA (U.S. Department of Agriculture). 2007. USDA Agricultural Projections to 2016 Office of the Chief Economist, Washington, DC.

Wilkes, H. G. 1967. Teosinte: The closest relative of maize. The Bussey Institute, Harvard University, Cambridge, MA.

Willimsky, G., H. Bang, G. Fischer and M.A. Marahiel. 1992. Characterization of *cspB*, a

Bacillus subtilis inducible cold shock gene affecting cell viability at low temperatures. Journal of Bacteriology 174: 6326-6335.

Wood, D. W., Setubal, J. C., Kaul, K., Monks, D. E., Kitajima, J. P., Okura, V. K., Zhou, Y., Chen, L., Wood, G. E., Almeida Jr., N. F., Woo, L., Chen, Y., Paulsen, I. T., J. Eisen, J. A., Karp, P. D., Bovee Sr., D., Chapman, P., Clendenning, J., Deatherage, G., Gillet, W., Grant, C., Kutyavin, T., Levy, R., Li, M.-J., McClelland, E., Palmieri, A., Raymond, C., Rouse, G., Saenphimmachak, C., Wu, Z., Romero, P., Gordon, D., Zhang, S., Yoo, H., Tao, Y., Biddle, P., Jung, M., Krespan, W., Perry, M., Gordon-Kamm, B., Liao, L., Kim, S., Hendrick, C., Zhao, Z-Y., Dolan, M., Chumley, F., Tingey, S. V., Tomb, J-F., Gordon, M. P., Olson, M. V., and Nester, E. W. 2001. The genome of the natural genetic engineer *Agrobacterium tumefaciens* C58. Science 294: 2317-2323.

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

OECD Unique Identifier:
MON 87460-4

Final Environmental Assessment

November 2011

Agency Contact
Cindy Eck
Biotechnology Regulatory Services
USDA, APHIS
4700 River Road
Riverdale, MD 20737
Fax: (301) 734-8669

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACRONYMNS 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
EQIP	The Environmental Quality Incentives Program
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
VOC	volatile organic compound
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 provisions 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). EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act (FFDCA) and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). The 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: MON87460 Drought Tolerant Corn

The Monsanto Company of St. Louis, MO, submitted a petition to APHIS in 2010 for determination of nonregulated status of Event MON87460 drought tolerant (DT) corn (hereafter referred to as MON87460) (Monsanto, 2010). In the event of a determination of nonregulated status, the nonregulated status of MON87460 would include MON87460, and any progeny derived from crosses between MON87460 and conventional corn and crosses of MON87460 with other biotechnology-derived corn that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Event MON87460 is currently regulated under 7 CFR Part 340. Interstate movements and field trials of MON87460 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 (Monsanto, 2010).

1.4 Purpose of Product

MON87460 is designed to mitigate grain yield loss under water-limited conditions. As detailed in the Monsanto Company petition, the enhanced drought tolerance of MON87460 results from the introduction and controlled expression of cold shock protein B (*cspB*), a native ribonucleic acid (RNA) chaperone derived from *Bacillus subtilis* (Monsanto, 2010). The enhanced drought tolerant phenotype of MON87460 manifests primarily as reduced yield loss relative to conventional corn when subjected to water-limiting conditions. When MON87460 was subjected to well-watered conditions, grain yield for MON87460 was not notably different than conventional corn. Data provided by the Monsanto Company demonstrates that MON87460 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 (Monsanto, 2010).

Drought is one of the major limiting factors in corn that prevents realization of optimum grain yield worldwide (Boyer, 1982). 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 MON87460 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 a determination of nonregulated status of MON87460 corn.

[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)

1.6 Coordinated Framework Review

MON87460 does not contain a biotechnology-derived PIP nor is it a biological control organism; thus, EPA does not regulate MON87460. MON87460 is within the scope of the FDA 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 MON87460, and submitted a safety and nutritional assessment of food and feed derived from MON87460 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 MON87460 drought tolerant corn (FDA, 2010).

1.7 Public Involvement

APHIS routinely seeks public comment on environmental assessments prepared in response to petitions seeking a determination of nonregulated status of GE organisms. APHIS does this through a notice published in the Federal Register. The issues discussed in this EA were developed by considering 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 MON87460.

This EA, the petition submitted by the Monsanto Company (Monsanto, 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 MON87460 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 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.

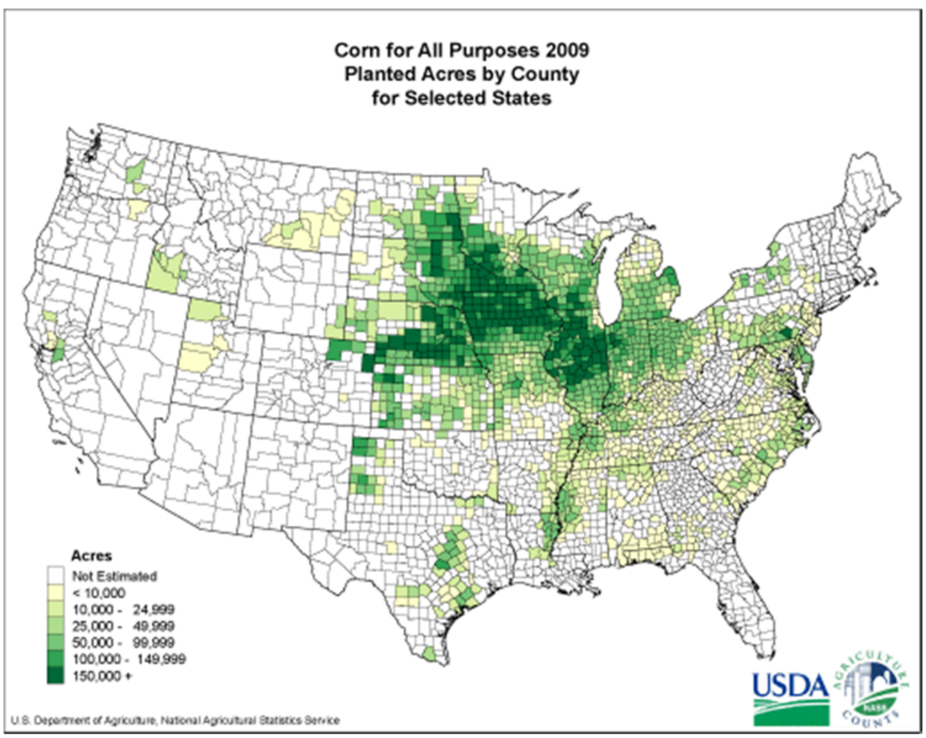
2 AFFECTED ENVIRONMENT

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 in 2009.



Source: (USDA-NASS 2010c).

The U.S. is the world's largest producer and exporter of corn. In 2009, the U.S. produced approximately 40 percent of the world's total corn harvest (FAOSTAT, 2008). During the 2009 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, 2011c). This ten-year projection reflects an increased domestic and international demand for U.S. corn, and will be enabled by improvements in plant genetics, agronomic practices, and government policy on both the national and state level (Claassen and Tegene, 1999; USDA-ERS, 2010e). Arable land for increased corn planting acreage will result primarily from a combination of grower shifts away from other crops and the minor return of idle farmland, such as Conservation Reserve Program (CRP) land, back into corn production (USDA-ERS, 2011c). The CRP program encourages the environmental protection of highly erodible, privately owned land through voluntary, time-dependent contracts between individual land owners and the USDA. Conditions of these contracts and their renewals are dependent on statutory and regulatory provisions built into the CRP program (Watson, 1994). In particular, land-use decisions regarding CRP land enrollment/reenrollment is strongly influenced by agriculture commodity market forces (e.g., crop commodity price) and Federal policy governing land subsidies (as there is a reluctance to directly regulate private property) (Claassen and Tegene, 1999; Heisel, 1998; Plantinga et al., 2001; Secchi et al., 2009). For example, the Food, Conservation, and Energy Act of 2008 has already stipulated a reduction in CRP land enrollment from 39.2 million acres to 32 million acres in order to provide additional cropland to meet future agricultural demands (Food Conservation and Energy Act, 2008). This previously established reduction in CRP land enrollment, combined with increased funding for Working-Land Conservation Programs, such as The Environmental Quality Incentives Program (EQIP), are already providing farmers economic incentives to continue farming arable land in order to boost agricultural production while also encouraging the adoption and implementation of a wide range of conservation practices (Food Conservation and Energy Act, 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 GE varieties that no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Growers can choose from a large number of corn hybrids produced from traditional breeding or genetic engineering systems. Adoption of GE corn in the U.S. has significantly increased since 2000 on both the state and national level, with 88 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 GE corn varieties by major U.S. corn production states, 2000-2010.

	GE Corn Varieties (percent of all corn planted)										
State	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Illinois	16	22	28	33	36	55	74	80	84	84	86
Indiana	12	13	16	21	26	40	59	78	79	79	85
Iowa	32	41	45	54	60	64	78	84	86	86	90
Kansas	38	43	47	54	63	68	82	90	91	91	92
Michigan	17	22	35	33	40	44	60	72	75	75	87
Minnesota	36	44	53	63	66	73	86	88	88	88	93
Missouri	32	34	42	49	55	59	62	70	77	77	85
Nebraska	34	46	52	60	69	76	79	86	91	91	93
North Dakota	-	-	-	-	75	83	88	89	93	93	97
Ohio	11	9	9	13	18	26	41	66	67	67	74
South Dakota	47	66	75	79	83	86	93	95	96	96	96
Texas	-	-	-	-	72	77	79	78	84	84	88
Wisconsin	18	26	32	38	46	50	64	75	77	77	86
Other States	20	27	36	46	44	55	67	74	78	78	86
U.S. total	26	34	40	47	52	61	73	80	85	85	88

Source: (USDA-ERS, 2010a; USDA-NASS, 2011a)

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). 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; 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 order to maximize corn grain yield (Paulson and Babcock, 2010; Sheriff, 2006). 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) most routinely applied (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; Day et al., 1999; 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). Crops used in rotation with corn vary regionally, but there has been an increase in the number of fields that have adopted a corn-to-corn rotation. Decisions about crop sequences are guided by many factors, including economic return from differences in input cost, yield potential, and commodity prices. Reflecting these agricultural and market forces, the recent trend in the adoption of corn-to-corn rotation in conventional and GE production systems has been primarily attributed to rising corn prices and increased market demand for corn across all consumer sectors (Hart, 2006; Stockton et al., 2007). However, in spite of these market forces, the benefits of crop rotation in terms of pest and disease management strategies provide an incentive for growers to choose corn-alternative crop rotations and remain one factor among many that contribute to overall land-use decisions by individual farmers.

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). 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. Excluded methods, as defined by the USDA-NOP, may include the use of synthetic pesticides, fertilizers, and recombinant DNA technology found in GE crops. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods.

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

In 2007, 93.5 million acres of corn were planted in the U.S., yielding 13 billion bushels of corn (USDA-NASS, 2010b). 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 68 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	11,909	11,459
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 one 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. 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, and facilitate 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 structure, 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, 2010c; 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, 2010d). 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, 2010a). Greenhouse gas (GHG) emissions from agriculture (crops and livestock) are mainly in the form of methane and nitrous oxide (EPA, 2010c). 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 global climate conditions, including shifts in the frequency of extreme weather, that may be measured across time and space (Cook et al., 2008; Karl et al., 2008). Production of agricultural commodities is interrelated with climate change on several different levels, with agricultural activities recognized as both direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) sources of GHG emissions (Dale, 1997; EPA, 2010b; Fargione et al., 2008; Gutowski et al., 2008; Piñeiro et al., 2009; Rosenzweig and Parry, 1994). Greenhouse gases, including carbon dioxide (CO_2), methane (CH_4), and nitrous oxide (N_2O), function as retainers of solar radiation. GHGs are derived from agricultural activities, such as combustion of fossil fuels in mechanized farm equipment, fertilizer application, and decomposition of agricultural waste products (Aneja et al., 2009; EPA, 2010b). 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, 2010b).

Agricultural crop commodities may also affect dynamic geophysical soil processes, such as carbon turnover and sequestration, through tillage and land management practices (Smith and Conen, 2004). In general, conservation tillage strategies (including no- and reduced-tillage practices) are associated with more stable and increased carbon sequestration due to a net reduction in carbon dioxide emissions (Lal and Bruce, 1999; West and Marland, 2002). Recent literature, however, suggests that the relationship between conservation tillage and increased carbon sequestration require more study, as soil depth level and seasonal sampling bias may have inadvertently affected measurements (Angers et al., 1997; Baker et al., 2007; Oorts et al., 2007; Potter et al., 1998; Wanniarachchi et al., 1999; West and Marland, 2002). However, the relationship between different GHG emissions, such as carbon dioxide and the more potent nitrous oxide may influence paradigms related to tillage strategies and global climate change (Gregorich et al., 2005). For example, increased nitrous oxide emissions as a result of conservation tillage strategies may offset any gains achieved through increased carbon sequestration and reduced carbon dioxide emissions. Like the relationship between conservation tillage strategies and carbon sequestration, a broad generalization regarding the impact of tillage strategy and nitrous oxide emissions is difficult, as numerous factors influence soil nitrification cycles, including geographic location, soil structure, moisture, and farm-level management practices (including, but not limited to fertilizer and pesticide application) (Almaraz et al., 2009; Ball et al., 2008; Campbell, 2003; Del Grosso et al., 2008; Elmi et al., 2003; Farahbakhshazad et al., 2008; Grandy et al., 2006; Gregorich et al., 2006; Gregorich et al., 2005; Halvorson et al., 2008; Linn and Doran, 1984; MacKenzie et al., 1998; Metay et al., 2007; Palma et al., 1997; Philippe, 2008; Poirier et al., 2009; Rochette et al., 2008; Ruser et al., 2006; Six et al., 2004; Smith and Conen, 2004; Smith et al., 2002; Steinbach and Alvarez, 2006; Tan et al., 2009; Ussiri et al., 2009; Venterea et al., 2005).

Global climate change may also affect agricultural crop production (CCSP, 2008). 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 a determination of nonregulated status. 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 Animal 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 row crop fields include, among others, blackbirds (e.g., red-winged blackbirds (*Agelaius phoeniceus*)), horned larks (*Eremophila alpestris*), brown-headed cowbirds (*Molothrus ater*), and vesper sparrows (*Pooecetes gramineus*) (Best and Gionfriddo, 1991). Specific bird species can act as beneficial or detrimental members in the agro-environment. For example, red-winged blackbird are often initially attracted to corn fields to feed on insect pests, but then also feed on the corn. Studies have shown that red-winged blackbirds can destroy more than 360,000 tons of field corn and substantial amounts of sweet corn annually (Dolbeer, 1990). Although many birds visit row-crop fields such as corn, numbers are low and few nest there, likely due to overlap between nesting phenology and mechanized harvest (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 (Smith, 2005). The thirteen-lined ground squirrel feeds primarily on seeds of weeds and available crops, such as corn and wheat (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).

<u>Weediness</u>

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 (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 (Baker, 1965; Keeler, 1989).

APHIS assessed whether MON87460 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 MON87460 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). The Monsanto Company 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 data from four field trials from Chile (Monsanto, 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 enhanced weediness potential in MON87460.

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 (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; Pioneer, 2009; Romeis et al., 2006; Torres and Ruberson, 2005; 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; Hawes et al., 2003; Roy et al.). 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 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 (Mallory-Smith and Zapiola, 2008; Rieger et al., 2002). 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. Unlike other grass species in the U.S. (Watrud et al., 2004; Wipff and Fricker, 2002), 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 (Pioneer, 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 (Eastham and Sweet, 2002).

A variety of plant properties, environmental conditions, and imposed conditions can affect movement of genes between corn cultivars (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 (Mallory-Smith and Zapiola, 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). 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).

<u>Pollen-mediated gene flow and mitigation</u>

As noted, a primary spatial mechanism to maintain corn genetic purity is isolation distance. Although corn pollen is dispersed by wind and gravity, in contrast to the pollen of other grass species, corn pollen is much larger (Thomison, 2011). The majority of corn pollen generally falls within a short distance of the originating corn plant, though under certain atmospheric conditions, corn pollen may travel farther (Eastham and Sweet, 2002). 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; 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.

<u>Seed-mediated gene flow and mitigation</u>

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).

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

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

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 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

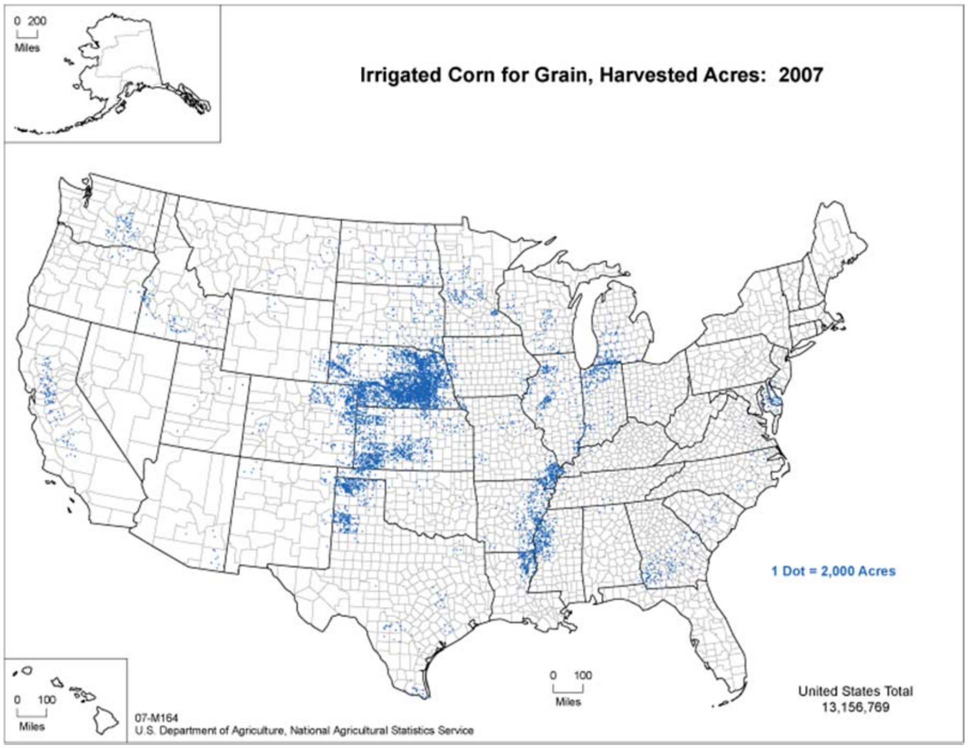
2.6.1 Domestic and Trade Economic Environment

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, 2011c). Exports added another 2 billion bushels to total U.S. corn use. Demand is satisfied almost entirely by domestic supply, with 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, 2011c). In the 2009/10 marketing year, feed was approximately 40 percent of U.S. corn production, food, seed, and industrial uses were approximately 45 percent, and exports the remaining 15 percent (USDA-ERS, 2011c). 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 Arkansas (USDA, 2009). 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 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 presence 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 (Pioneer, 2009).

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.

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, 2011c). 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, 2011c).

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. In Japan, 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, 2008a). South Korea has similar approval processes as Japan and requires labeling for GE animal feed (USDA-FAS, 2008b). 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 a determination of nonregulated status of MON87460 would be those countries who import 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 MON87460 corn. To respond favorably to a petition for nonregulated status, APHIS must determine that MON87460 is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2010) APHIS has concluded that MON87460 is unlikely to pose a plant pest risk. Therefore APHIS must determine that MON87460 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 MON87460. 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. MON87460 and progeny derived from MON87460 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 MON87460 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 MON87460.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRA (USDA-APHIS, 2010) that MON87460 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 MON87460 corn is No Longer a Regulated Article

Under this alternative, MON87460 and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR Part 340. MON87460 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 MON87460 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 MON87460 is unlikely to pose a plant pest risk, a determination of nonregulated status of MON87460 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 MON87460 and progeny derived from this event if the developer decides to commercialize MON87460.

3.3 Alternatives Considered but Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON87460. 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 MON87460. 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 MON87460 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 MON87460, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MON87460 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 MON87460 is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON87460.

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 MON87460 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 MON87460 and Non-GE Corn Production and Geographic Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating MON87460 from conventional or specialty corn production. However, because APHIS has concluded that MON87460 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 MON87460 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 MON87460 (USDA-APHIS, 2010). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON87460 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 corn productions systems from MON87460 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 MON87460 is available from AOSCA (AOSCA 2004).

3.3.4 Requirement of Testing for MON87460

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 MON87460 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 MON87460 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 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 Flow	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		
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 MON87460 does not pose a plant pest risk and therefore should no longer be regulated under 7 CFR 340. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON87460 are described in detail throughout this section. A cumulative impacts analysis is presented in Chapter 5. 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 a determination of nonregulated status of MON87460 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, MON87460 is unlikely to significantly increase future corn acreage beyond USDA-ERS projected expansion in irrigated U.S. corn production regions. The MON87460 trait is intended to increase grain yield security under conditions of moderate water stress. Minimum moisture requirements are similar between MON87460 and conventional corn and therefore MON87460 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 MON87460 phenotype presented in the Monsanto 87460 Petition for Determination of Nonregulated Status. In summary, MON87460 does not exhibit improved grain yield relative to the near-isogenic control corn variety when subject to well-watered conditions. When other indicators of MON87460 agronomic performance are compared to a variety of regionally-adapted corn reference hybrids and the near-isogenic control variety, MON87460 neither significantly nor consistently performs beyond the observed range of variation, further reinforcing the lack of increased agronomic performance in MON87460 under well-watered conditions (Monsanto, 2010).

When subject to water-limited conditions ($\leq$50 percent field capacity), MON87460 displays significantly less yield loss relative to the near-isogenic control corn variety. However, other measures of the MON87460 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 MON87460 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 MON87460 under water-limited conditions confirms its single and predicted phenotype (Monsanto, 2010). These data provide multiple lines of evidence indicating that CSPB protein modulates the 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 (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 approximately 86.5 million acres in 2009/10 to 92 million acres in 2020/21 (USDA-ERS, 2011c). 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 88 percent in 2010 (USDA-ERS, 2010a; USDA-NASS, 2011a). 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 2009/2010 market year, 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).

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

Under the No Action Alternative, MON87460 and its progeny would remain subject to the regulatory requirements of 7 CFR part 340. Existing trends related to the cultivation and proportion of crop acreage planted with GE corn varieties are expected to continue, incrementally increasing due to broad domestic adoption of commercially-available GE corn varieties (USDA-ERS, 2010a, 2011c). With respect to corn cultivation range, corn will continue to be commercially cultivated in 49 U.S. states, with the majority of production centered in the Midwestern U.S. Corn Belt states.

External market forces across all consumer sectors are anticipated to continue dictating increases in corn production under the No Action Alternative. Increased demand for animal feed in the livestock industry and favorable net returns for corn ethanol production is likely to sustain this growing demand for U.S. corn. In response to these domestic and international market forces, U.S. farmers are planting additional corn acreage primarily at the expense of other crops and agricultural commodities (e.g., wheat, soybean, and hay), with net corn acreage projected to increase to 92 million acres in 2020 from 88 million planted acres in 2010 (USDA-ERS, 2011a, 2011c). Additionally, under the No Action Alternative, government policies have and will continue enabling U.S. farmers to meet corn production targets by providing economic incentive to retain arable land in agricultural production. For example, as stipulated in the Food, Conservation, and Energy Act of 2008, a net reduction in CRP land enrollment from 39.2 to 32 million acres in combination with increased funding for Working-Land Conservation Programs (e.g., EQIP), represents two Federal policy tools to increase the amount of arable land for agricultural production while also encouraging farmers to adopt and implement environmentally-friendly practices to maintain agricultural productivity (Food Conservation and Energy Act, 2008).

External market forces leading to a growing demand for U.S. corn production, reactive government policy designed to increase domestic production of agricultural commodities while maintaining the productivity of arable land, and responsive individual land-use decisions to meet corn production targets by primarily implementing acreage shifts away from other agricultural commodities (e.g., wheat, soybean, and hay) reflect economic conditions and trends that have occurred independently of the regulatory status of MON87460. Thus, under the No Action Alternative, there is no reason to assume that these market conditions and trends will not continue.

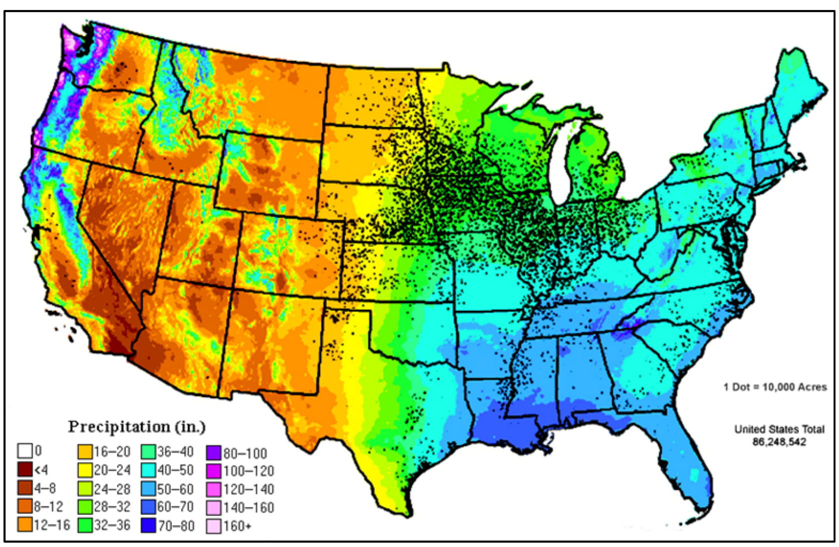
4.3.1.2 Preferred Alternative: Current Acreage and U.S. Cultivation Range

Under the Preferred Alternative, MON87460 would no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Due to previous trends regarding domestic GE corn adoption (USDA-ERS, 2010a), a determination of nonregulated status of MON87460 is unlikely to significantly impact this trend due to the current availability of numerous GE corn hybrid varieties.

As previously discussed, both external market forces and government policies have affected domestic land-use decisions on the farm level, eventually leading to corn production increases to meet growing domestic and international demand for U.S. corn (Chapter 4.3.1.1). Increasing domestic corn production can be accomplished by improving efficiency of grain production per acre or by increasing the amount of corn cultivation acreage. MON87460 produces a reduced yield loss phenotype under conditions of moderate water stress. Under the Preferred Alternative, MON87460 may permit farmers to improve grain yield efficiency in areas subject to drought, such as the targeted dryland Great Plains Region of corn production. Under this same Preferred Alternative, MON87460 is unlikely to significantly expand corn cultivation acreage into novel areas or beyond projected values based on physiology of the plant and existing agricultural and corn production trends.

In general, MON87460 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 PPRA of MON87460, the MON87460 trait only confers a reduced yield-loss phenotype under water-limited conditions. When subject to water-sufficient conditions, MON87460 displays similar measures of growth, development, and agronomic performance compared to conventional corn (USDA-APHIS, 2010). Additionally, MON87460 does not possess traits, such as increased water uptake or increased abiotic stress tolerances (e.g., salt, cold, and heat tolerances), that increases its likelihood of establishment in non-agricultural areas (USDA-APHIS, 2010). Minimum moisture requirements are similar between MON87460 and conventional corn. When grown in water-limited field and greenhouse conditions, MON87460 exhibits classic drought sensitivity symptoms, including reductions in plant height, ear height, seedling vigor, and expected changes in chlorophyll content and leaf roll (USDA-APHIS, 2010). The magnitude of these drought-induced changes in MON87460 is similar to that of water-limited conventional corn, with increasing water deficit producing more severe developmental symptoms. Collectively, these data provide strong evidence that the negative effects of abiotic stress in MON87460 are not eliminated and demonstrate that the cultivation range of MON87460 is limited to arable land, similar to that of currently-available corn varieties. Despite sharing a cultivation range with commercially-available corn varieties, however, MON87460 does not provide improved agronomic performance relative to conventional corn when subject to water-sufficient conditions (Monsanto, 2010). Consequently, MON87460 is unlikely to be adopted in geographic areas that receive sufficient precipitation ($\geq$ 30 inches) to routinely support high levels of corn production due to an absence of grower benefit (Figure 3). These non-irrigated geographic regions, such as the Midwestern Corn Belt, account for approximately 85 percent of U.S. corn production and does not represent the intended area of introduction, as described elsewhere in this EA and the Monsanto petition (Monsanto, 2010; USDA-NASS, 2007, 2010b).

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



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

Existing and projected agricultural trends also provide evidence that MON87460 will not directly cause an expansion of corn acreage. As previously discussed in Chapter 2.1.1 and Chapter 4.3.1.1 of this EA, domestic corn acreage is projected to increase from 88 million acres in 2010 to 92 million acres in 2020 (USDA-ERS, 2010e, 2011c). This projection reflects recent demand for corn grain and encompasses previous observation that any increase in corn acreage is primarily taken at the expense of other crops, such as wheat, soybean, and hay (Table 5) (USDA-ERS, 2011a, 2011c). Additionally, this projection also takes into consideration government policies, such as net reductions to CRP land enrollment and an increase in funding for Work-Land Conservation Programs (Food Conservation and Energy Act, 2008), that were previously implemented to retain arable land in agricultural productivity. Despite numerous potential sources of land, recent data indicates that the overwhelming majority of corn and soybean farms (98 percent) are increasing corn acreage through crop shifting and not expansion into conservation land (USDA-ERS, 2011a). The current economic outlook for corn demand, reactive government policy to address this demand for U.S. agricultural production, and responsive crop-shifting by U.S. farmers to increase corn acreage was driven by external market forces and not the presence of any particular biotechnology-derived corn variety.

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

	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

Additionally, it is prudent to acknowledge that the reduced yield-loss phenotype of MON 87360 does not exceed the natural variation observed in regionally-adapted varieties of conventional corn (representing different genetic backgrounds) (Monsanto, 2010). Thus, equally drought resistant corn varieties produced through conventional breeding techniques are readily available and may be cultivated in lieu of MON87460 under the Preferred Alternative. However, despite the presence of these comparable corn varieties, crop shifts away from other crops (i.e., wheat, soybean, and hay) remain the primary sources of land for additional corn acreage and not expansion of cultivation into land not managed for agricultural productivity (e.g., CRP acreage). This is best detailed in recent data from the Agricultural Resource Management Survey, where farm-level production practices and operator financial statuses are collected. Following a period of significant increases in corn acreage (2006 – 2007), only 2 percent of corn and soybean farms returned CRP acreage back into agricultural production in 2008, providing farm-level evidence that crop-shifts by farmers are supplying the majority of land to support increased corn production (USDA-ERS, 2011a).

In summary, under the Preferred Alternative, MON87460 may provide an additional tool for U.S. farmers to increase corn grain production efficiency in areas subject to water stress, such as the western Dryland Great Plains corn production regions. However, MON87460 is unlikely to directly expand corn acreage under the Preferred Alternative because: 1) it is unlikely to be adopted in the majority of corn production regions due to an absence of grower benefit; 2) it is unlikely to permit corn cultivation in novel areas not previously managed for economically-viable corn production due to similarities in growth, development, and other aspects of physiology with currently-available corn varieties; and 3) it is unlikely to affect current market forces and responsive government policy that are already enabling previous and projected corn acreage trends. These three factors are made even more poignant when one considers that the reduced yield-loss phenotype of MON87460 does not exceed the natural variation observed in currently-available corn varieties (Monsanto, 2010; USDA-APHIS, 2010). Thus, equally drought resistant varieties produced through conventional breeding techniques are readily available in irrigated corn production regions. Despite the availability of comparable corn varieties in U.S. markets, however, drought tolerance of the magnitude observed in MON87460 has not been described as a significant factor influencing market conditions, government policy, or observed crop shifts on U.S. farms.

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 (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, MON87460 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 MON87460 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; Paulson and Babcock, 2010). 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 fertilizer, 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 strongly influencing corn rotation practices.

4.3.2.2 Preferred Alternative: Cropping Practices

Under the Preferred Alternative, a determination of nonregulated status of MON87460 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 MON87460 due to the low likelihood of adoption.

A determination of nonregulated status of MON87460 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. MON87460 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 MON87460 will significantly differ from conventional corn in responding to fertilizer or moisture application. In particular, MON87460 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 MON87460 and conventionally-produced drought tolerant corn varieties will not differ. With regard to cropping practices in regions targeted by MON87460, many management strategies are already focused on land management practices that increase water retention characteristics of the soil (reduced till and no-till strategies) and appropriate management practices that reflect the cultivated crop (adapted cultivars and weed control methods). These strategies are available and already employed by farmers regardless of production method. Thus, a determination of nonregulated status of MON87460 is unlikely to affect the agronomic practices, as it encourages adoption of management practices related to fertilization and irrigation already in place by corn farmers.

Additionally, MON87460 is not expected to alter corn rotation strategies. Recent trends in crop rotation strategies already favor corn and are most strongly influenced by market forces and government policy; likewise, these trends are often independent of available corn varieties (GE, conventional, or organic) at that time (Wu and Brorsen, 1995). This is best demonstrated by the sharp increase in corn acreage between 2006 and 2007, paralleling increases in corn price and demand (USDA-NASS, 2010b).

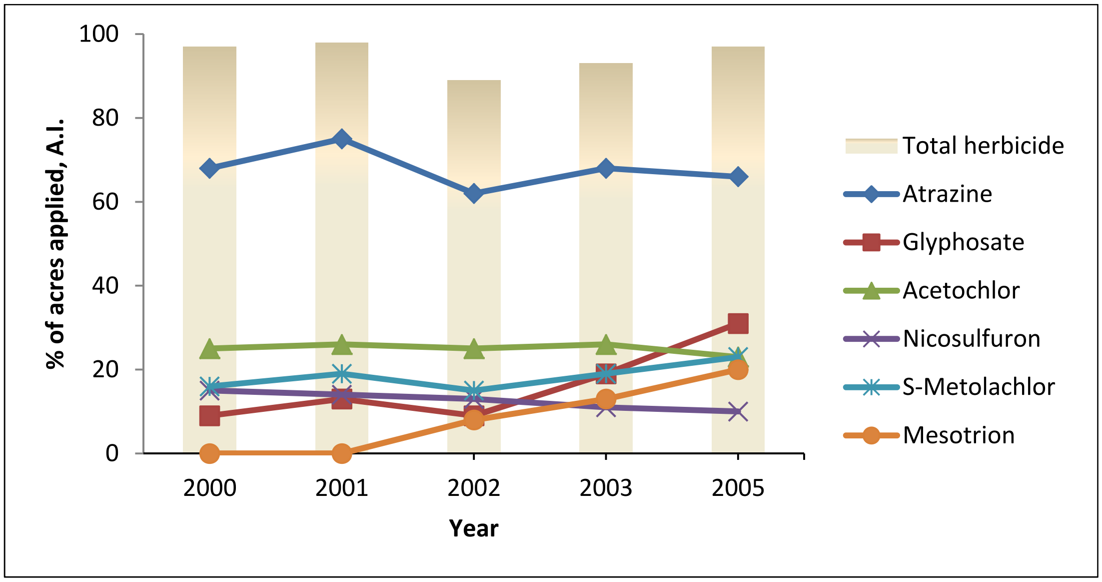
MON87460 is designed to constitutively express the *E. coli cspB* RNA chaperone. No pesticide (e.g., glyphosate tolerance or *Bt* protein production) traits are co-engineered into the MON87460 event. Despite the absence of herbicide-tolerant or insect-resistant traits in MON87460, pesticide use is not 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 4). However, MON87460 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 4). If MON87460 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 MON87460. Given typical corn offerings, corn hybrid varieties produced with MON87460 will likely be stacked with insect resistant and herbicide tolerant events that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, because trait stacks represent a growing proportion of commercially-available corn varieties (Table 6 and Chapter 5). 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 4. 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)

4.3.3 Organic

Certified organic corn represented approximately 0.2 percent (172,112 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 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 (NCAT, 2003). Organic plans should also include mechanisms to monitor the risk of GE pollen or seed co-mingling with the organic crop (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 unwanted gene flow 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, MON87460 and its progeny would continue to be regulated articles under the regulations at 7 CFR part 340. This however, will not change the ready availability of other corn hybrid varieties produced through GE methods. GE corn will continue to represent a large majority of corn production acreage, with GE corn totaling 88 percent of all corn production in the U.S. in 2007 (USDA-ERS, 2010a). Trends of conventional and organic commercial corn production will not change and will remain the same under the No Action Alternative. Planting and production of GE corn varieties and organic corn have both increased due to market demands over the last ten years, and these markets are likely to continue to increase under the No Action Alternative.

4.3.3.2 Preferred Alternative: Organic

A determination of nonregulated status of MON87460 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 (≥ 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 MON87460, 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

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
Louisiana	726,897	100	0	0
Maine	28,703	98.631	393	1.369
Maryland	533,903	99.733	1,427	0.267
Massachusetts	21,575	99.754	53	0.246
Michigan	2,658,538	99.465	14,231	0.535
Minnesota	8,352,731	99.726	22,864	0.274
Mississippi	888,049	100	0	0
Missouri	3,332,832	99.898	3,410	0.102
Montana	83,344	99.996	3	0.004
Nebraska	9,438,807	99.903	9,200	0.097
Nevada	6,006	100	0	0
New Hampshire	14,611	99.966	5	0.034
New Jersey	100,766	99.991	9	0.009
New Mexico	136,008	99.512	664	0.488
New York	1,099,413	98.754	13,703	1.246
North Carolina	1,028,533	99.933	689	0.067
North Dakota	2,528,921	99.953	1,189	0.047
Ohio	3,834,164	99.767	8,926	0.233
Oklahoma	301,443	99.999	3	0.001
Oregon	88,692	95.407	4,074	4.593
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)

4.4 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. MON87460 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 MON87460 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 MON87460 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 MON87460 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 MON87460 is not enabled by increased water uptake, as demonstrated by several lines of evidence. Firstly, patterns of shoot and root fresh/dry weight between MON87460 and conventional corn are not significantly different under well-watered or water-limited conditions (Monsanto, 2010). If water uptake were increased in MON87460, it is plausible that shoot/root fresh weight would be increased in MON87460 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 MON87460. 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 MON87460 and conventional corn (Monsanto, 2010). Taken in total, the physiological evidence and recorded measures of moisture depletion strongly indicate that MON87460 does not inherently transport more water than conventional corn. Consequently, MON87460 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 MON87460. 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. MON87460 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 MON87460 is unlikely to cause changes in current water quality trends associated with corn production practices.

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, MON87460 use would be limited to areas APHIS has approved it 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, MON87460 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 MON87460, 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 MON87460 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 MON87460, the neomycin phosphotransferase II and cold shock protein B have been shown to be safe for the environment (Monsanto, 2010). In particular, the NPTII protein has regularly been used in the selection of many transgenic crop varieties that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, further demonstrating the safety of this protein. Because of the similarities in composition between MON87460 and conventional corn, and the examined safety of the MON87460 gene products, it is not anticipated that degradation of MON87460 plant tissue following grain harvest will significantly impact microbial and arthropod soil populations compared to conventional corn.

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 (Baker et al., 2005). Emissions released from agricultural practices include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (EPA, 2010c). 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, MON87460 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 MON87460 and conventional corn. Thus, a determination of nonregulated status of MON87460 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 MON87460 is similar to that of conventional corn, except under water-limiting conditions. When subject to water-limiting conditions, MON87460 exhibits a reduced yield phenotype. Accordingly, the physical impact of MON87460 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 MON87460 and conventional corn.

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, MON87460 use would be limited to areas APHIS has approved it for regulated releases. Agronomic management practices and phenotypic characteristics regarding MON87460 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 MON87460 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 MON87460 and conventional corn. In particular, due to the continued availability of herbicide choice in MON87460 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 MON87460 is not significantly different from conventional corn, with the exception of reduced yield loss under water-limiting conditions. Accordingly, the physical impact of MON87460 on climate change is not anticipated to be significantly different from that of conventional corn because MON87460 requires similar management conditions. 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 MON87460 and conventional corn. Additionally, due to the scale of projection time related to climate change (CCSP, 2009), an accurate description of effects is difficult and will not likely be unique to MON87460.

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 in Chapter 5.

4.5.1.1 No Action Alternative: Animal Communities

Under the No Action Alternative, environmental releases of MON87460 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 MON87460 (Appendix A), which demonstrated a lack of toxicity and allergenicity of MON87460 for human and animal consumption. Based upon the FDA consultation, APHIS supports Monsanto's conclusions that MON87460 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, MON87460 would no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. The agronomic practices used to produce MON87460 are similar to those used to produce conventionally grown corn. The introduced gene products of MON87460 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 MON87460 focuses solely on the nontarget impacts from MON87460, especially the introduced proteins, CSPB and NPTII. APHIS analyzed the potential impacts of MON87460 on animal species including (1) exposure from directly contacting or consuming MON87460, (2) exposure from increased use of pesticides or herbicides, and (3) conversion of CRP land to MON87460 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 MON87460 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 (Monsanto, 2010). No differences between MON87460 and non-drought-tolerant corn were noted except for the intended drought-tolerant trait.

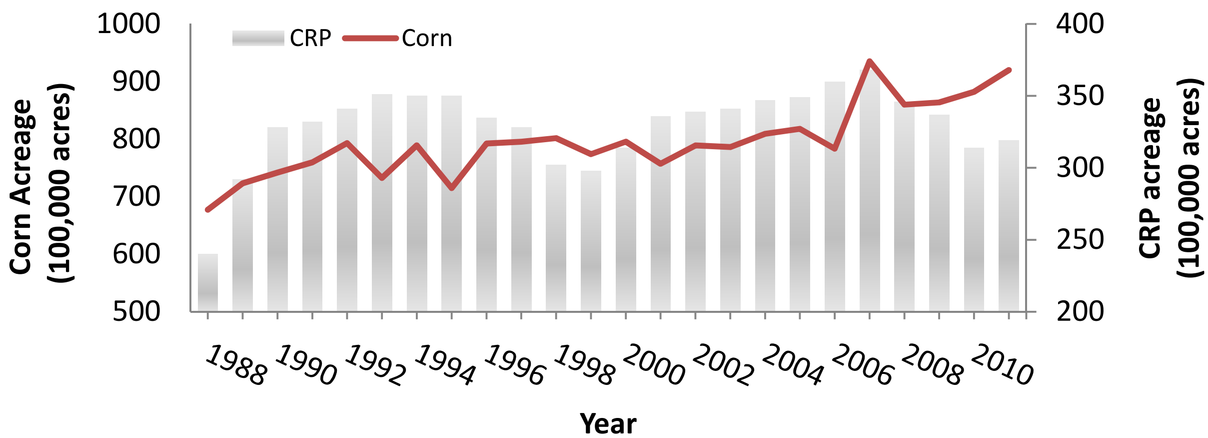
CSPB is not known to exert any effects on pest and non-pest organisms. Arthropod (pest and beneficial) abundance was assessed and indicated no significant impact on non-target organisms. APHIS concludes that no species exposed to MON87460 showed adverse consequences and that MON87460 is not different in its environmental interactions relative to conventional corn. Because no differences in physical traits or characteristics were observed between MON87460 and conventional corn, it is not expected that MON87460 would impact the behavior of arthropods found in or around corn fields.

The transgene proteins in MON87460 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, 2010). The petitioner assessed the risks to animals from the transgene proteins present in the foods and feeds derived from MON87460, and the results indicated no adverse effects, even at the highest tested dose levels (Monsanto, 2010). Furthermore, the CSPB protein represents no more than 0.00007 percent of the total protein in the grain of MON87460, 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 MON87460, 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 MON87460 (Appendix A), which demonstrated a lack of toxicity and allergenicity of MON87460 for human and animal consumption.

MON87460 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 MON87460 and a control from several locations were evaluated for major nutrients and secondary metabolites (Monsanto, 2010). The results indicate that MON87460 is compositionally and nutritionally equivalent to conventional corn except for the expression of the transgene proteins (CSPB and NPTII).

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 grassland birds and waterfowl use CRP land, though the animals present would ultimately be dependent on the region and habitat type (Johnson, 2005). Former CRP land returned into agricultural production may also provide land for additional corn acreage, although this contribution is likely to be minimal based on projections and farmer surveys (USDA-ERS, 2011a, 2011c). Following a period of prolific corn production (2006-2007), only a small proportion of farms (2 percent) brought CRP land back into corn production, further suggesting that crop shifting and not expansion into CRP land is primarily responsible for recent increases in domestic corn production (USDA-ERS, 2011a). Interestingly, total CRP acreage often mirrors that of corn acreage, further suggesting that CRP land does not generally return to corn cultivation (Figure 5). In the event that farmers convert current CRP land to MON87460 production, some birds and mammals that use CRP land for food and/or cover may be displaced to nearby areas of similar habitat. Under the Preferred Alternative, however, MON87460 is not expected to significantly affect animal communities in CRP land, as the conversion of CRP land to corn production occurs as relatively low levels.

Figure 5. U.S. corn and CRP acreage between 1988 and 2010 (USDA-FSA, 2009; USDA-NASS, 2011b).



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 MON87460 (Appendix A). No major impacts on animals, either directly or indirectly, are expected from a determination of nonregulated status of MON87460; 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 native plant species found in the U.S.

4.5.2.1 No Action Alternative: Plant Communities

Under the No Action Alternative, environmental releases of MON87460 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

MON87460 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 (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.

Possible Weediness of MON87460

For the majority of the agronomic traits assessed, there were no statistically significant differences between MON87460 and nontransgenic control (Monsanto, 2010). No biologically meaningful differences were detected in the germination and dormancy of seed from MON87460. In particular, the absence of hard seed supports a conclusion of no increased weediness potential of MON87460 compared to conventional corn for germination and dormancy characteristics (Monsanto, 2010). No differences were detected in pollen morphology or viability between MON87460 and the control (Monsanto, 2010). Results from the genotype-environmental interaction assessments also support the conclusion that MON87460 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). Consistent with this observation, soil moisture depletion studies between MON87460 and its respective control demonstrate that water depletion rates are similar between both MON87460 and its respective control (Monsanto, 2010). Finally, MON87460 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 MON87460 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 MON87460 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.

Possible Weediness of MON87460 if Hybridized with Other Plants

MON87460 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 MON87460 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). MON87460 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 (Galinat, 1988). *Tripsacum dactyloides* and *Tripsacum floridanum* would not be affected by MON87460 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, MON87460 would pose no direct or indirect impacts on sexually compatible wild relatives.

Other Possible Impacts

The introduced gene products of MON87460 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), MON87460 does not contain any herbicide tolerant or insect resistant traits, and adoption of MON87460 is not anticipated to change current corn agricultural practices.

Minor impacts on plant populations could occur if farmers converted current CRP land to MON87460 production. The extent of impacts depends on the amount of CRP land converted to agriculture. However, the USDA (USDA-ERS, 2011c) projects minor increases 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 a determination of nonregulated status of MON87460; 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. 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 MON87460 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 MON87460 would not convert CRP land to MON87460 production. It is not expected that use of MON87460 in existing corn fields would result in any changes in herbicide or pesticide application. Cultivation of MON87460 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 MON87460 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) MON87460 would replace another crop; 2) land would be converted from inactive cropland to active cropland using MON87460; 3) planting MON87460 would require an increase in pesticide or herbicide use; or 4) CRP lands would be converted to MON87460 production, the impact to biodiversity would be considered minor based on the following discussion.

The replacement of a different crop (such as soybeans) with MON87460 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 MON87460 would not be likely to affect the overall species richness or abundance.

If farmers substituted organic corn cultivation with MON87460 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 MON87460 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 MON87460 production. As noted earlier, if all converted CRP land were used to grow corn, the impacts would affect 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 2011b; 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).

4.5.4 Gene Flow

4.5.4.1 No Action Alternative: Gene Flow

Under the No Action Alternative, environmental releases of MON87460 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 MON87460 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, MON87460 does not notably differ from other corn varieties. Under well-watered conditions, MON87460 did not notably differ from non-GE comparable varieties (Monsanto, 2010). No evidence of changes to pollen attributes or seed attributes were observed (Monsanto, 2010). Horizontal gene flow from MON87460 (or any other GE plant) to soil-borne microorganisms is unlikely, as no evidence has produced under field conditions, suggesting that horizontal gene transfer did not occur at detectable levels or that its potential impacts are negligible in field conditions (Badosa et al., 2004; de Vries and Wackernagel, 2005; Demanèche et al., 2008; Gebhard and Smalla, 1999; Paget et al., 1998). Gene flow between plants 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 MON87460 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 MON87460 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 MON87460 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 MON87460, 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 MON87460. Because MON87460 exhibits decreased yield loss under water-limiting conditions (Monsanto, 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 MON87460 under water-limiting conditions (Monsanto, 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 (Hall and Twidwell, 2002). Therefore, pollen-mediated gene flow from MON87460 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 MON87460 (Monsanto, 2010), the expression of the *cspB* conveys a drought resistance trait that decreases yield loss when subject to reduced water conditions. If MON87460 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 MON87460 are not reported to be different from conventional corn. The only phenotypic difference between MON87460 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.

4.6 Human Health

This section focuses on whether the proposed action affects overall public health and worker safety. For MON87460, 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 MON87460 include food and product safety, 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

MON87460 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 MON87460 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 MON87460 and provided a comprehensive assessment of food and feed safety data on the CSPB and NPTII proteins in MON87460. The FDA has determined Monsanto's submission to be complete (FDA, 2010). MON87460 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 Alternative: Public Health

Under the No Action Alternative, MON87460 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 MON87460 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 MON87460. 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 (Monsanto, 2010), the NPTII and CSPB proteins are anticipated to present no potential adverse effects to exposed organisms, including humans, in the environment (Fuchs et al., 1993a; Fuchs et al., 1993b). The following paragraphs summarize the supporting information from the safety assessment performed for NPTII and CSPB proteins found in MON87460.

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 that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act; http://www.isb.vt.edu/cfdocs/biopetitions1.cfm), including corn.

Based on assessments performed with bioinformatic tools, such as the FASTA algorithm and the PROTEIN and TOXIN6 databases, NPTII and CSPB 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).

Acute oral toxicity studies for the CSPB 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 MON87460. 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.

The donor organism of the CSPB protein, *B. subtilis*, has been shown to be non-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, 1999, 2010).

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 MON87460.Compositional comparisons between MON87460 and conventional corn presented by Monsanto showed no biologically meaningful differences for grain and forage compositions either for major nutrients, antinutrients, secondary metabolites related to normal growth and development or drought stress responses (Monsanto, 2010). Therefore, based on this data, it is reasonable to assume that the foods and feeds derived from MON87460 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 MON87460, APHIS has concluded that under the Preferred Alternative, a determination of nonregulated status of MON87460 would have no expected impacts on public health.

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 Alternative: 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 MON87460 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 MON87460 would remain the same as those under the No Action Alternative.

4.7 Livestock Feed

This section addresses the use of MON87460 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 Alternative: Livestock Feed

Under the No Action Alternative, MON87460 would continue to be limited to areas APHIS has approved it for regulated releases. Thus, there would be no additional risks or benefits to livestock feed safety from MON87460.

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 MON87460 indicated that they are not expected to be allergenic, toxic, or pathogenic in mammals. Monsanto consulted with FDA about food and feed derived from MON87460 and provided a comprehensive assessment of food and feed safety data on the CSPB and NPTII proteins in MON87460. The FDA has determined Monsanto's submission to be complete (FDA, 2010). 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 (Burzio et al., 2008; Tu, 2009).

Compositional analyses of forage and grain tissues from MON87460 confirmed that the corn grain and forage derived from MON87460, and the intended foods and feeds derived from MON87460, 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 MON87460 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 MON87460 will be low, with chickens, swine, and dairy cows consuming only nanogram quantities of each protein per kilogram of body weight (Monsanto, 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 (FDA, 1998).

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.

4.8 Socioeconomic

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, 2011c). 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, 2011c). In the 2009/10 marketing year, feed was approximately 40 percent of U.S. corn production, food, seed, and industrial uses were approximately 45 percent, and exports the remaining 15 percent (USDA-ERS, 2011c). 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, 2011c).

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 MON87460 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 MON87460 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 MON87460, 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 MON87460 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 MON87460 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 MON87460 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 MON87460 would be more likely in some geographic areas than in others. Therefore, the domestic economic environment most likely affected by a determination of nonregulated status of MON87460 would be the area of its adoption. To the extent MON87460 adoption allows for increased returns from corn production, a determination of nonregulated status of MON87460 could increase the supply of corn and corn-related farm income.

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 Alternative: 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 MON87460 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

<u>Varieties of Drought Tolerant Corn Available</u>

A determination of nonregulated status of MON87460 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 (Monsanto, 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 MON87460. 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) (Asgrow and 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, 2010, 2011a, 2011b). The impacts of a determination of nonregulated status of MON87460 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 MON87460 during water-limited conditions, the impact of yields on returns, the elasticity of corn acreage to increased returns, and the extent of adoption of MON87460. 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 (Monsanto, 2010) (i.e., yield under water-limited conditions would be 85% of the yield under adequate water conditions).

2. MON87460 is expected to provide a 6 percent reduction in yield losses under those circumstances (Monsanto, 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 = $Yh \times 0.5 + Yl \times 0.5$

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

$$= 1.85Yh \times 0.5 = 0.925Yh$$

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

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

$$= 1.901Yh \times 0.5 = 0.9505Yh$$

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 MON87460 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 MON87460 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 MON87460 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 MON87460 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 a determination of nonregulated status of MON87460 on corn acreage is expected to be minor.

Locations of Increased Farm Income

Corn-related farm incomes could increase in areas that adopt MON87460. 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 a determination of nonregulated status of MON87460 are expected to be negligible.

Impacts on Irrigation and Water Use with MON87460

Regarding the impact of MON87460 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 MON87460. Indeed, the observations presented in the petition indicate that expected maximum yield in the variety depends on attaining sufficient water (Monsanto, 2010). MON87460 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 prove possible or that MON87460 was otherwise useful in some circumstances to reduce use of irrigation water. At present, irrigation sparing capacity of MON87460 has not been demonstrated, and expectations for savings on irrigation are not consistent with current experimental observations provided by the applicant (Monsanto, 2010).

Additional Impacts

The largest impact of the product will likely be that growers experience reduced yield losses with MON87460 in some years that are less than those incurred by planting non-drought tolerant corn varieties. Another impact is that crop insurance costs may be reduced if growing MON87460, since the Federal Crop Insurance Corporation has historically offered growers who purchased certain biotech varieties with lower rates (USDA, 2011a, 2011b). If indeed better drought performance was accomplished by this product, federal crop insurance underwriters could have reason to offer a future policy endorsement. An increase in land values as a result of planting MON87460 is also possible, although there is not enough information to assess these potential impacts.

Impacts on Organic and non-GE Corn Producers by MON87460

Non-GE, organic, and GE corn are currently grown in generally the same areas. Incurred economic impacts on organic farming from conventional GE farming have been suggested to include those on process, on sales potential, and on inferred salability. APHIS concludes that overall economic impacts of GE corn on organic corn production are likely inconsequential for the following reasons:

- The unintended presence of a small percentage of GE content in crops produced under organic farming does not lead to the loss of organic certification of the organic operation or property (see 2.1.2.3 Organic Corn Production Systems; 4.3.3.2 Preferred Alternative: Organic).

- USDA-APHIS acknowledges that some organic buyers or seed or of produce may require the grower to assay seed for the presence of transgenes. Financial costs to both organic and non-GE corn farmers thus may include testing for the presence of GE material. As is clear from organic production in general, there are many sources of additional input for organic crops compared to conventional ones, but the increased wholesale and retail cost of organic products should adequately compensate for additional costs to the organic grower (McBride, 2008).

- Some growers cite concerns that buyers of organic seed or produce may avoid purchase of their agricultural output if the grower's production farm is too close to conventional agricultural farms, even if actual admixture is not detected. As noted earlier in this EA (4.3.3.2 Preferred Alternative: Organic), organic agriculture has continued to expand, responding to increasing demand for more products, and in the case of organic corn, supply may considerably lag behind demand (see 2.6.1 Domestic and Trade Economic Environment). Criteria for description as organic has been regularized by third-party product verification and labeling (Non-GMO-Project, 2010) so that acceptable thresholds of unintentional admixture of GE can be identified, and exact standards agreed by producers and buyers. Consequently, the incidental presence of small amounts of GE in organic products is not a disqualifying attribute for many organic buyers.

Additionally, gene flow from MON87460 resulting in admixture into organic or non-GE crops would not be any more likely than gene flow from currently available GE varieties especially given the prevalence of so many other GE traits in the corn seed marketplace. To the extent that a determination of nonregulated status of MON87460 would contribute to increased GE corn acreage, the likelihood of proximity of either organic or non-GE corn farms to GE corn farms 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 a determination of nonregulated status of MON87460 on corn acreage could be substantially less than that of other current factors (such as higher prices for corn commodities) that encourage planting of many other GE varieties. Thus, these other factors are more likely to result in increases of corn acreage.

An accurate estimate of the increase in U.S. corn production would depend on determining the degree of adoption, on the actual impact of MON87460 to yields under water-limited conditions, and the degree of water shortage in any given year. However, USDA-APHIS assesses that these three factors will be low, so that the overall impact of a determination of nonregulated status of MON87460 on U.S. corn production is expected to be minor.

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 a determination of nonregulated status of MON87460.

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, 2011c). 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, 2011c). 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, 2008a). South Korea has similar approval processes as Japan and requires labeling for GE animal feed (USDA-FAS, 2008b). 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, 2011b; 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 a determination of nonregulated status of MON87460 would be those countries who import MON87460 feed, seed, and food.

4.8.2.1 No Action Alternative: Trade Economic Environment

The USDA provides projections for the agricultural sector through 2020 (USDA-ERS, 2011c). 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 a determination of nonregulated status of MON87460 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 MON87460 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 MON87460 in primary U.S. export destinations with functioning regulatory systems before commercialization in the U.S. (Monsanto, 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.

MON87460 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. MON87460 seed as a result of a determination of nonregulated status of MON87460, 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.

5 CUMULATIVE IMPACTS

5.1 Assumptions used for Cumulative Impacts

A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions.

Cultivation of stacked varieties, those crop varieties that may contain more than one trait, are currently found in the marketplace and in agricultural production. In the event APHIS reaches a determination of nonregulated status, MON87460 may be combined with non-GE and GE corn varieties by traditional breeding techniques. APHIS' regulations at 7 CFR Part 340 do not provide for Agency oversight of GE corn varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, nor over stacked varieties combining GE varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 unless it can be positively shown that such stacked varieties were to pose a likely plant pest risk.

There is no guarantee that MON87460 will be stacked with any particular non-GE or GE corn varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, as company plans and market demands play a significant role in those business decisions. Predicting all potential combinations of stacked varieties that could be created using both non-GE and GE corn varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 is hypothetical and purely speculative.

GE corn varieties are planted on the majority of corn acres in the U.S. (88 percent of acreage in 2011) (USDA-ERS, 2010a; USDA-NASS, 2011a). Several states in the target range for MON87460 also demonstrate this trend, where adoption rates range from 87 percent to 97 percent of all corn varieties planted in surveyed states (USDA-NASS, 2011a). These GE corn varieties were previously determined to pose no significant impact on the human environment, and are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. These GE corn varieties include herbicide tolerant (e.g., glyphosate tolerant), insect resistant (e.g., Bt protein), or stacked varieties (e.g., glyphosate tolerant and Bt protein) (USDA-APHIS, 2011). Based on information detailed in the Monsanto petition (Monsanto, 2010) and increasing adoption of GE corn varieties with stacked traits on both national and regional scales (USDA-ERS, 2010a), it is reasonable to foresee that MON87460 will be stacked with herbicide-tolerant and/or insect-resistant traits. Consequently, USDA-APHIS will assume that MON87460 will be stacked with commercially available GE traits in this cumulative impacts analysis.

5.2 Cumulative Impacts: Current Acreage and U.S. Cultivation Range

Stacked corn varieties with the MON87460 trait are unlikely to significantly impact current agricultural corn production strategies. With regard to projected increases in domestic corn production (USDA-ERS, 2011c), acreage shifts away from other crops (USDA-ERS, 2010b, 2011c) are likely to continue providing primary sources of additional land for corn cultivation, rather than the conversion of non-arable or conservation land (USDA-ERS, 2011a). As previously discussed, farm-level decisions to increase corn production reflect a sustained increase in corn demand and reactive government policies on agricultural commodity production (Claassen and Tegene, 1999; Plantinga et al., 2001). These external market forces and government policies strongly influence farmer land-use decisions and will likely continue excerpting a strong influence independently of any particular GE corn variety (e.g., MON87460 stacked variety). Additionally, stacked corn varieties with the MON87460 trait are also unlikely to enable cultivation of corn in novel and non-arable areas based on the influence of biotechnology-derived traits on corn physiology. With regard to corn growth, development, and abiotic stress responses (heat, cold, and salt stress responses), MON87460 is not significantly different from currently-available corn varieties under both water-sufficient and water-limited conditions (USDA-APHIS, 2010). The magnitude of drought tolerance in MON87460 is observed in other regionally adapted, drought tolerant corn varieties (Monsanto, 2010). Commercialized GE corn varieties and their progeny were also determined to be similar to conventional corn varieties with respect to growth and development (USDA-APHIS, 2011). Thus, the breeding of MON87460 with other GE herbicide-tolerant and/or insect-resistant varieties is unlikely to produce a corn plant with a significantly different cultivation range, as these individual corn varieties did not in themselves possess traits that would enable an increased cultivation range.

5.3 Cumulative Impacts: Cropping Practices

With respect to corn cropping practices, stacked corn varieties with MON87460 are unlikely to pose a significant cumulative impact on corn management strategies related to tillage, irrigation, and pesticide/fertilizer application, and crop rotation. Corn management strategies are generally dependent on the corn variety cultivated; consequently, due to the large adoption of GE corn varieties on both a national and regional scale (e.g., Great Plains dryland region) (USDA-NASS, 2011a), the majority of these management strategies reflect those that are suitable for herbicide-tolerant or insect-resistant corn varieties. The presence of any herbicide-tolerant trait will continue to encourage conservation tillage strategies that are already adopted as an integral part of corn cultivation practices. Additionally, established methods of irrigation and fertilizer application are unlikely to change in the presence of stacked corn varieties with the MON87460 trait, as this corn hybrid is likely to require these similar moisture and nutritional requirements as its parent varieties. Stacked corn varieties with MON87460 are likely to mitigate any potential shifts in pesticide use (detailed in Chapter 4.3.2 of this EA), as commonly-adopted pesticide application strategies is likely to be applicable to any stacked corn variety with MON87460 due to the presence of existing herbicide-tolerant and/or insect-resistant traits. In its target range of the Great Plains dryland region, stacked corn varieties with MON87460 will likely represent a replacement product rather than a supplemental product; thus, as a replacement product for currently cultivated corn varieties possessing herbicide-tolerant and/or insect resistant traits, no significant increases in fertilizer/pesticide/irrigation beyond that associated with additional corn production (USDA-ERS, 2011c) is anticipated, due to the adoption of cropping practices already in use. With respect to rotational strategy, shifts toward corn-corn rotations are already occurring due to farm profitability associated with increased international and domestic corn demand; corn varieties stacked with MON87460 are unlikely to significantly influence these external market forces, and thus, will unlikely change the increasing trend toward corn-corn rotation in the foreseeable future (USDA-ERS, 2011a).

5.4 Cumulative Impacts: Organic

Organic corn production is unlikely to experience a significant cumulative impact due to the presence of stacked corn varieties with MON87460. Production of GE corn and organic corn has increased in the recent past and will likely continue into the foreseeable future, reflecting an increasing demand for corn derived from both production strategies. Organic corn production and acreage has increased in spite of concurrent adoption in GE corn production methods (USDA-ERS, 2010a, 2010d), suggesting that current methods of isolation and identity preservation (Kuepper, 2002; Kuepper et al., 2007) are sufficient to limit gene flow between GE and organic corn. Stacked corn varieties with MON87460 is intended as a replacement product for other stacked corn varieties in its intended target region; thus, GE corn acreage is not anticipated to significantly increase corn acreage beyond projected values, as it will replace and not supplement hybrid GE corn varieties already cultivated. Furthermore, reproductive characteristics of MON87460 does not differ from commercially-available corn varieties (USDA-APHIS, 2010); additionally, the reproductive characteristics of GE corn varieties that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act also do not differ from commercially-available varieties (USDA-APHIS, 2011). Thus, any stacked corn variety containing MON87460 is also unlikely to display any significant differences in pollen viability or pollen number, further suggesting that current methods of isolation and identity preservation are likely to be sufficient to limit gene flow between GE and organic corn. The presence of inadvertent GE material in organic corn does not preclude USDA organic certification, as it is a processed-based system (USDA-AMS, 2011). Additionally, third-party verification of organic corn based on a threshold presence of GE material is already practiced for the benefit of organic retailers (Non-GMO-Project, 2010) and is unlikely to be impacted by any corn variety stacked with MON87460.

5.5 Cumulative Impacts: Water Usage and Water Quality

With regard to water usage and water quality, stacked corn varieties with MON87460 is not anticipated to pose any significant cumulative impact. MON87460 has been determined to share similar moisture requirements with conventional corn varieties; in addition, the mechanism of drought tolerance in MON87460 has been attributed to improvements in water use efficiency rather than increased water uptake (USDA-APHIS, 2010). There is no reason to suspect that commercially-available GE corn varieties require more moisture or possess increased water uptake than conventional corn varieties, as these GE corn varieties were engineered to tolerate herbicide application or resist insect herbivory. Thus, water usage is not anticipated to be significantly different in hybrid corn varieties possessing MON87460 and other commercially-available GE traits.

As discussed in Chapter 5.3 of this EA, stacked corn varieties with MON87460 will permit the continued use of established and common corn agronomic practices. This includes the continued use of conservation tillage strategies that are widely-practiced in U.S. corn production systems. The relationship between conservation tillage and reduced soil erosion is well documented, as is the correlation between reduced soil erosion and reduced agricultural NPS pollution. Stacked corn varieties with MON87460 will enable the continued use of conservation strategies, thus making it unlikely that this stacked corn variety with MON87460 will significantly change soil quality and the NPS pollution that directly influences water quality.

5.6 Cumulative Impacts: Soil

The soil environment in and around corn fields is complex, and rich in microorganisms and arthropods. 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. As discussed in Chapter 5.3 of this EA, the stacking of MON87460 with herbicide-tolerant/insect-resistant traits would represent a replacement product for GE corn varieties that possess the same herbicide-tolerant/insect-resistant traits, due to similarities in management practices. Due to similar management practices between corn varieties stacked with MON87460 and current commercially-available corn hybrids, it is unlikely that a cumulative impact on soil quality would occur following a determination of nonregulated status of MON87460.

5.7 Cumulative Impacts: 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). As discussed in Chapter 5.3 of this EA, the stacking of MON87460 with herbicide-tolerant/insect-resistant traits would represent a replacement product for current GE corn varieties that possess the same herbicide-tolerant/insect-resistant traits, due to similarities in management practices. Due to similar management practices in agricultural practices between currently-available GE corn varieties and corn varieties stacked with MON87460, it is unlikely that any significant cumulative impact on air quality would occur following a determination of nonregulated status of MON87460.

5.8 Cumulative Impacts: Climate Change

U.S. agricultural activities can directly contribute to the emission of GHG through the combustion of fossil fuels. Additionally, agricultural input strategies and management practices can affect soil quality and disturbance, and the degradation of agricultural residues in the field. As discussed in Chapter 5.3 of this EA, the stacking of MON87460 with herbicide-tolerant/insect-resistant traits would represent a replacement product for current GE corn varieties that possess the same herbicide-tolerant/insect-resistant traits, due to similarities in management practices. Due to similar management practices in agricultural practices between currently-available GE corn varieties and corn varieties stacked with MON87460, it is unlikely that any significant cumulative impact on climate change will occur, as agricultural practices that affect climate change will be similar between corn varieties stacked with MON87460 and the majority of corn that is currently cultivated.

It is possible that climate change may affect corn cultivation areas in the U.S. For example, as projected by the U.S. Global Change Research Program (2009), the northern regions of the Great Plains may become wetter while the southern regions may become drier. However, these shifts are unlikely to uniquely affect stacked corn varieties with MON87460, as there is no reasonable expectation that this corn hybrid would require less moisture or possess a cultivation range that is significantly different than conventional corn. Additionally, climate change projections are often made on a large scale (e.g., 80-90 years), which makes an accurate determination of its effects difficult and uncertain.

5.9 Cumulative Impacts: Animal Communities

As discussed in Chapter 4.5.1 and 4.6 of this EA, both NPTII and CSPB do not represent proteins that can elicit a toxic or allergic response from animals. There is no reason to anticipate molecular changes to these proteins following the hybridization of MON87460 with commercially-available corn varieties. Additionally, there is also no reason to expect a significant cumulative impact from this stacked corn variety with MON87460, as it would contain common traits that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (USDA-APHIS, 2011). As discussed in Chapter 5.3 of this EA, stacked corn varieties with MON87460 would represent replacement products to currently available GE corn varieties that contain herbicide-tolerant and insect-resistant traits. Consequently, management practices will remain similar between stacked corn varieties containing MON87460 and current GE corn varieties, indicating that there will be no increase in the application of herbicides and pesticides beyond the current baseline.

5.10 Cumulative Impact: Plant Communities

Neither MON87460 nor previous GE corn varieties pose a plant pest risk; thus the progeny of MON87460 and commercially-available GE corn varieties is unlikely to possess weedy characteristics or introgress into wild relatives (USDA-APHIS, 2010, 2011). This stacked corn variety with MON87460 is not expected to be invasive in natural environments, compete with native vegetation, or have any different effect on habitat than conventional corn. No biological differences are anticipated in reproductive characteristics as well, including pollen viability and morphology. This corn variety stacked with MON87460 is not expected to significantly differ from conventional corn varieties with regard to hybridization with wild relatives, as the same barriers between conventional corn and sexually compatible relatives will persist, such as differences in flowering time, geographical separation, and development factors (Galinat, 1988). Consequently, no cumulative impacts are anticipated on plant communities resulting from the stacking of MON87460 and commercially-available GE corn varieties, as both parent corn varieties and progeny are expected to not possess any plant pest risk.

5.11 Cumulative Impacts: Biodiversity

While biodiversity may decrease following the general return of CRP land back into corn production, a stacked corn variety containing MON87460 is unlikely to increase the low conversion that already exists, as described in Chapter 4.3 of this EA. Farm-level land-use decisions are complex and strongly influenced by external market forces and existing government policies/subsidies (Claassen and Tegene, 1999; Plantinga et al., 2001) that exist independently of any particular biotechnology-derived corn variety. Stacked corn varieties with MON87460 are unlikely to significantly impact these economic forces and government policies related to corn grain production; thus, stacked corn varieties with MON87460 is unlikely to significantly impact biodiversity. Interestingly, net CRP acreage often mirrored that of total corn acreage from 1988 – 2010 (Figure 5), further suggesting a disconnect between corn production and CRP acreage. Additionally, stacked corn varieties with MON87460 are unlikely to significantly affect biodiversity, as biotechnology-derived proteins from both parent varieties (MON87460 and proteins related to herbicide-tolerance and/or insect resistance) are generally thought of as safe, with very little toxic effect on non-target organisms (USDA-APHIS, 2011).

5.12 Cumulative Impacts: Gene Flow

As described in the USDA-APHIS PPRA for MON87460, no significant differences are observed in pollen viability, pollen morphology, or seed dormancy (USDA-APHIS, 2010). Additionally, the GE corn varieties that MON87460 are likely to be stacked with (i.e., herbicide-tolerant or insect-resistant traits) have been previously analyzed by USDA-APHIS and found to share similar reproductive characteristics with conventional corn (USDA-APHIS, 2011). The stacking of MON87460 and corn varieties no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act would not be anticipated to significantly alter reproductive characteristics relative to those of conventional corn varieties. Consequently, the barriers that exist between different corn varieties and sexually-compatible wild relatives would likely be shared with stacked corn varieties with MON87460, such as differences in flowering time, geographical separation, and development factors (Galinat, 1988).

5.13 Cumulative Impacts: Public Health

Stacked corn varieties with MON87460 are unlikely to significantly affect public health. As previously discussed in Chapter 4.6 and 4.7 of this EA, the NPTII and CSPB proteins in MON87460 are not likely to negatively affect public health. Additionally, the GE traits most prevalent in commercially-available corn varieties, such as herbicide-tolerance and insect resistance (Bt protein production), are also not likely to negatively affect public health, worker safety, and animal health (USDA-APHIS, 2011; USDA-BRS, 2006). Stacking these commercially-available traits with MON87460 to produce a new hybrid corn variety is not anticipated to negatively affect public health. Additionally, with respect to GE herbicide-tolerance traits, glyphosate and glufosinate tolerance are the most prevalent traits in herbicide-tolerant corn varieties. These two herbicides are generally considered safe, with low toxicity to humans, animals, and other non-target organisms. Application strategies of these two herbicides, or any other herbicide utilized in corn production, is unlikely to change in the presence of a stacked corn variety with MON87460. Furthermore, herbicide application is unlikely to show a net increase beyond that which can be expected with baseline increases in corn production, as any stacked corn variety with MON87460 is intended to be a replacement product rather than a supplemental product. Accordingly, herbicide application is unlikely to increase in areas growing a GE hybrid corn variety containing the MON87460 and herbicide-tolerant traits, as this particular variety is likely to replace herbicide-tolerant corn varieties that were already present, thus maintaining worker exposure to herbicide at present levels.

5.14 Cumulative Impacts: Livestock Health

Stacked corn varieties with MON87460 are unlikely to negatively impact livestock health through its use as animal feed. As discussed in Chapters 4.6 and 4.7 of this EA, both NPTII and CSPB do not represent toxic proteins or proteins that are capable of eliciting an allergic reaction; additionally, previous GE corn varieties (e.g., herbicide tolerance or insect resistance) that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act contain proteins that also are not toxic or elicit allergic reactions. Additionally, both MON87460 and current GE corn varieties are compositionally similar to conventional corn (USDA-APHIS, 2010, 2011). Consequently, stacking of MON87460 with herbicide-tolerant or insect-resistant traits is not expected to produce any novel proteins and only produce those proteins native to corn or those proteins that were determined to not pose any significant risk to livestock health. Any food, such as meat and milk, derived from animals that are fed corn varieties stacked with MON87460 are not expected to differ from food derived from animals fed conventional corn.

5.15 Cumulative Impact: 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 a determination of nonregulated status of MON87460. 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 a determination of nonregulated status of MON87460. These patterns occurred independently of a determination of nonregulatory status of MON87460 or any other GE corn variety, and it is unlikely that any cumulative impact would result from a stacked product consisting of MON87460 and other readily-available GE trait.

5.16 Cumulative Impact: 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. MON87460 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. MON87460 could have impacts of unknown size on U.S. trade following a determination of nonregulated status of MON87460 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. However, according to the Monsanto petition, no product containing MON87460 will be commercialized until regulatory approval has been granted from all major U.S. corn-importing countries.

6 THREATENED AND ENDANGERED SPECIES

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

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

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

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

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action “may affect” listed species or critical habitat. 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 MON87460 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 MON87460. Indirect effects are those that could result from the use of MON87460 in corn production, would occur later in time, but are still reasonably certain to occur. Consideration is given for the potential of MON87460 to change the baseline habitat of TES including critical habitat.

MON87460 will be grown on agricultural acres managed by growers in a manner similar to conventionally bred corn. MON87460 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 MON87460 on TES plants. Because corn cannot naturalize and would not affect pollinators, there are no expected indirect effects of MON87460 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 MON87460. Therefore, it is highly unlikely that MON87460 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 MON87460 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 MON87460. Because there is no toxicity or allergenicity potential with MON87460, 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 MON87460 (Appendix A), which demonstrated a lack of toxicity and allergenicity of MON87460 for human and animal consumption. Therefore, it is unlikely that MON87460 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 MON87460 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; Johnson, 2005). Animals, including threatened and endangered species that could be affected by conversion of CRP land to MON87460 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.

MON87460 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 MON87460 corn have been shown to be different from commodity corn, it is highly unlikely that MON87460 will have impacts different from other commodity corn varieties. Neither are impacts likely when MON87460 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 MON87460 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 MON87460 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 a determination of nonregulated status of MON87460 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 MON87460 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.

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

7.1 Executive Orders with Domestic Implications

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

- ***Executive Order (EO) 12898 (US-NARA, 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 that minority presence in the U.S. and in the states where MON87460 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 MON87460 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%

Table 8. Minority populations in states where MON87460 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]
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%
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 MON87460 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 a determination of nonregulated status of MON87460 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.

MON87460 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 MON87460 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 MON87460 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 a determination of nonregulated status of MON87460 are expected to have a disproportionate adverse effect on minorities and low income populations. MON87460 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 MON87460, corn hybrid varieties may be produced with MON87460 and other nonregulated corn hybrids containing herbicide tolerant and/or pesticide traits. Thus, pesticide application practices and usage associated a determination of nonregulated status of MON87460 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.

None of the impacts on agricultural practices expected to be associated with a determination of nonregulated status of MON87460 are expected to have a disproportionate adverse effect on children. MON87460 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 MON87460, corn hybrid varieties may be produced with MON87460 and other nonregulated corn hybrids containing herbicide tolerant and/or pesticide traits. Thus, pesticide application practices and usage associated with a determination of nonregulated status of MON87460 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 MON87460, 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 MON87460 compared with other GE corn or non-GE corn, apart from the presence of the CSPB and NPTII proteins. MON87460 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 MON87460. Based on APHIS' assessment of MON87460, it is unlikely that a determination of nonregulated status of MON87460 will have a negative effect on migratory bird populations.

7.2 International Implications

EO 12114 (US-NARA, 2010), "Environmental Effects Abroad of Major Federal Actions" requires federal officials to take into consideration any potential environmental effects outside the 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 MON87460. 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 MON87460 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.

7.3 Compliance with the Clean Water Act and Clean Air Act

This EA evaluated the changes in corn production due to the unrestricted use of MON87460. Cultivation of MON87460 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 MON87460 compared with current corn production. Also, there is no expected change in air quality associated with the cultivation of MON87460.

Based on this review, APHIS concludes that the cultivation of MON87460 would comply with the Clean Water Act and the Clean Air Act.

7.4 Impacts on Unique Characteristics of Geographic Areas

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of MON87460.

The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property; do not cause any alterations of property, wildlife habitat, or landscapes; and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of MON87460. The product will be deployed on agricultural land currently suitable for production of corn, will replace existing varieties, and is not expected to increase the acreage of corn production. Progeny of this variety that express the identified traits of the MON87460 will be retained by Monsanto or licensed users. 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 MON87460 including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of MON87460, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to corn production sites.

7.5 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 MON87460 is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

A determination of nonregulated status of MON87460 would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of nonregulated status of MON87460. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of MON87460 is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the corn production regions. The cultivation of MON87460 does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

7.6 International Impacts Analysis

7.6.1 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 MON87460 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).

MON87460 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 (Galinat, 1988). Further, *Tripsacum dactyloides* and *Tripsacum floridanum* would not be affected by MON87460 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 a determination of nonregulated status of MON87460.

8 REFERENCES

Almaraz JJ, Mabood F, Zhou X, Madramootoo C, Rochette P, Ma B-L, and Smith DL. (2009) Carbon Dioxide and Nitrous Oxide Fluxes in Corn Grown under Two Tillage Systems in Southwestern Quebec. *Soil Science Society of America, 73*(1), 113-119.

Aneja VP, Schlesinger WH, and Erisman JW. (2009) Effects of Agriculture upon the Air Quality and Climate: Research, Policy, and Regulations. *Environmental Science & Technology, 43*(12), 4234-4240.

Angers DA, Bolinder MA, Carter MR, Gregorich EG, Drury CF, Liang BC, Voroney RP, Simard RR, Donald RG, Beyaert RP, and Martel J. (1997) Impact of tillage practices on organic carbon and nitrogen storage in cool, humid soils of eastern Canada. *Soil and Tillage Research, 41*(3-4), 191-201.

AOSCA (2003) AOSCA: 99% Non-GMO Corn Grain Program Requirements. American Association of Seed Certifying Agenicies. Retrieved March 2011, from http://www.identitypreserved.com/handbook/aosca-nongmocorn.htm

AOSCA. (2009) Seed Certification Handbook: Including Genetic and Crop Standards, Procedures, and AOSCA Service Programs.

Asgrow and DeKalb (2011). 2011 Seed Resource Guide. Submitted by Registration Manager. (See Table https://www.asgrowanddekalb.com/products/Documents/2011_seed_resource_guide_north.pdf).

Badosa E, Moreno C, and Montesinos E. (2004) Lack of detection of ampicillin resistance gene transfer from Bt176 transgenic corn to culturable bacteria under field conditions. *FEMS Microbiology Ecology, 48*(2), 169-178.

Bais HP, Weir TL, Perry LG, Gilroy S, and Vivanco JM. (2006) The role of root exudates in rhizosphere interactions with plants and other organisms. *Annual Review of Plant Biology, 57*(1), 233-266.

Baker HG. (1965) Characteristics and modes of origin of weeds. In HG Baker and GL Stebbins (Eds.), *The Genetics of Colonizing Species* (pp. 147-168). Berkeley, CA: Department of Botany, University of California, Berkeley, USA.

Baker JB, Southard RJ, and Mitchell JP. (2005) Agricultural Dust Production in Standard and Conservation Tillage Systems in the San Joaquin Valley. *Journal of Environmental Quality, 34*(4), 1260-1269.

Baker JM, Ochsner TE, Venterea RT, and Griffis TJ. (2007) Tillage and soil carbon sequestration—What do we really know? *Agriculture, Ecosystems & Environment, 118*(1-4), 1-5.

Ball BC, Crichton I, and Horgan GW. (2008) Dynamics of upward and downward N2O and CO2 fluxes in ploughed or no-tilled soils in relation to water-filled pore space, compaction and crop presence. *Soil and Tillage Research, 101*(1-2), 20-30.

Barker T, Campos H, Cooper M, Dolan D, Edmeades G, Habben J, Schussler J, Wright D, and Zinselmeier C. (2005) Improving drought tolerance in maize. In J Janick (Ed.), *Plant Breeding Reviews*): John Wiley and Sons, Inc

Barr KJ, Babcock BA, Carriquiry M, Nasser A, and Harfuch L (2010) Agricultural Land Elasticities in the United States and Brazil. Center for Agricultural and Rural Development, Iowa State University. Retrieved from http://ageconsearch.umn.edu/bitstream/58047/2/10-WP_505.pdf

Beasley JC and Rhodes Jr. OE. (2008) Relationship between raccoon abundance and crop damage. *Human-Wildlife Conflicts, 2*(2), 248-259.

Benbrook C (2009) Crops on Pesticide Use in the United States: The First Thirteen Years. The Organic Center. Retrieved from http://www.organic-center.org/reportfiles/GE13YearsReport.pdf

Bengtsson J, Ahnström J, and Weibull A. (2005) The effects of organic agriculture on biodiversity and abundance: a meta-analysis. *Journal of Applied Ecology, 42*(2), 261-269.

Best LB and Gionfriddo JP. (1991) Characterization of Grit Use by Cornfield Birds. *The Wilson Bulletin by the Wilson Ornithological Society, 103*(1), 68-82.

Bosnic AC and Swanton CJ. (1997) Influence of barnyardgrass (*Echinochloa crusgalli*) time of emergence and density on corn (*Zea mays*). *Weed Science, 45*(2), 276-282.

Boyer JS. (1982) Plant productivity and environment. *Science, 218*(4571), 443.

Brookes G and Barfoot P (2010) GM crops: global socio-economic and environmental impacts 1996-2008. PG Economics Ltd, Dorchester, UK. Retrieved from http://www.pgeconomics.co.uk/

Brooks DR, Bohan DA, Champion GT, Haughton AJ, Hawes C, Heard MS, Clark SJ, Dewar AM, Firbank LG, Perry JN, Rothery P, Scott RJ, Woiwod IP, Birchall C, Skellern MP, Walker JH, Baker P, Bell D, Browne EL, Dewar AJG, Fairfax CM, Garner BH, Haylock LA, Horne SL, Hulmes SE, Mason NS, Norton LR, Nuttall P, Randle Z, Rossall MJ, Sands RJN, Singer EJ, and Walker MJ. (2003) Invertebrate responses to the management of genetically modified herbicide–tolerant and conventional spring crops. I. Soil-surface-active invertebrates. *Philosophical Transactions of the Royal Society of London. Series B: Biological Sciences, 358*(1439), 1847-1862.

Bruce WB, Edmeades GO, and Barker TC. (2002) Molecular and physiological approaches to maize improvement for drought tolerance. *Journal of Experimental Botany, 53*(366), 13-25.

Burzio LA, McClain JS, and Silvanovich A. (2008). *Bioinformatics evaluation of the CSPB protein utilizing the AD8, TOXIN6 and PROTEIN databases.* Monsanto Company.

Campbell S. (2003) Insuring best management practices. *Journal of Soil and Water Conservation, 58*(6), 116A-117A.

CBD (2010) The Cartegena Protocol on Biosafety. Convention on Biological Diversity. Retrieved March 30, 2010 from http://www.cbd.int/biosafety/

CCSP (2008) The Effects of Climate Change on Agriculture, Land Resources, Water Resources, and Biodiversity in the United States (U.S. Climate Change Science Program Synthesis and Assessment Product 4.3). The U.S. Climate Change Science Program. Retrieved October, 2011 from http://www.climatescience.gov/Library/sap/sap4-3/final-report/Synthesis_SAP_4.3.pdf

CCSP (2009) Global Climate Change Impacts in the United States. U.S. Global Change Research Program.

Cerrato ME and Blackmer AM. (1990) Comparison of models for describing corn yield response to nitrogen fertilizer. *Agronomy Journal, 82*(1), 138-143.

CFIA. (1994).The biology of *Zea mays* (L.) (Maize). Plant Biosafety Office, Last accessed August 23, 2010, from http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9411e.pdf

Chen M, Zhao J-Z, Collins HL, Earle ED, Cao J, and Shelton AM. (2008) A critical assessment of the effects of Bt transgenic plants on parasitoids. *PLoS One, 3*(5), e2284.

Childs D (1996) Top Ten Weeds. Purdue Plant Pest and Diagnostic Laboratory, Purdue University. Retrieved March 2011, from http://www.ppdl.purdue.edu/ppdl/expert/Top_Ten_Weeds.html

Christensen LA. (2002) Soil, nutrient, and water management systems used in U. S. corn production. *Agriculture Information Bulletin, 774*.

Claassen R and Tegene A. (1999) Agricultural Land Use Choice: A Discrete Choice Approach. *Agricultural and Resource Economics Review, 28*(1), 26-35.

Cook E, Bartlein P, Diffenbaugh N, Seager R, Shuman B, Webb R, Williams J, and Woodhouse C (2008) Hydrological Variability and Change. The U.S. Climate Change Science Program.

Crockett L. (1977) *Wildly successful plants: a handbook of North American weeds*. Macmillan.

Dale VH. (1997) The Relationship Between Land-Use Change and Climate Change. *Ecological applications, 7*(3), 753-769.

Day J, Hallahan C, Sandretto C, and Lindamood W. (1999) Pesticide use in U.S. corn production: Does conservation tillage make a difference. *Journal of Soil and Water Conservation, 54*(2), 477-484.

de Vries J and Wackernagel W. (2005) Microbial horizontal gene transfer and the DNA release from transgenic crop plants. *Plant and Soil, 266*(1), 91-104.

Del Grosso SJ, Halvorson AD, and Parton WJ. (2008) Testing DAYCENT Model Simulations of Corn Yields and Nitrous Oxide Emissions in Irrigated Tillage Systems in Colorado. *Journal of Environmental Quality, 37*(4), 1383-1389.

Delisle JM and Savidge JA. (1997) Avian use and vegetation characteristics of Conservation Reserve Program fields. *Journal of Wildlife Management, 61*, 318-325.

Demanèche S, Sanguin H, Poté J, Navarro E, Bernillon D, Mavingui P, Wildi W, Vogel TM, and Simonet P. (2008) Antibiotic-resistant soil bacteria in transgenic plant fields. *Proceedings of the National Academy of Sciences, 105*(10), 3957-3962.

Dolbeer RA. (1990) Ornithology and integrated pest management: red-winged blackbirds *Agleaius phoeniceus* and corn. *The International Journal of Avian Science, 132*, 309-322.

Eastham K and Sweet J (2002) Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer. European Environment Agency.

EFSA. (2004) Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants. Scientific Opinion of the Panel on Genetically Modified Organisms (GMO) and the Panel of Biological Hazards (BIOHAZ). *EFSA Journal*(4), 1-18.

Elbehri A. (2007) The changing face of the US grain system. *Economic Research Report No. ERR-35, Economic Research Service, USDA*.

Elmi A, Madramootoo C, Hamel C, and Liu A. (2003) Denitrification and nitrous oxide to nitrous oxide plus dinitrogen ratios in the soil profile under three tillage systems. *Biology and Fertility of Soils, 38*(6), 340-348.

EPA. (2005) Protecting Water Quality for Agricultural Runoff. (EPA 841-F-05-001).

EPA (2009) Soil Preparation. Environmental Protection Agency. Retrieved March 2011, from http://www.epa.gov/agriculture/ag101/cropsoil.html

EPA (2010a) Basic Information - Air Emission Sources. Retrieved March 2011, from http://www.epa.gov/air/emissions/basic.htm

EPA. (2010b).Climate change indicators in the United States. Environmental Protection Agency, Washington DC. Last accessed from http://www.epa.gov/climatechange/indicators/pdfs/ClimateIndicators_full.pdf

EPA (2010c) Inventory of U.S. greenhouse gas emissions and sinks: 1990-2008. Retrieved March 2011, from http://www.epa.gov/climatechange/emissions/downloads10/US-GHG-Inventory-2010_Report.pdf

EPA (2010d) National Ambient Air Quality Standards (NAAQS). Retrieved March 2011, from http://www.epa.gov/air/criteria.html

FAOSTAT (2008) Food and agricultural commodities production. . Retrieved March 2011, from http://faostat.fao.org/site/339/default.aspx

FAPRI (2004) Documentation of the FAPRI Modeling System. Food and Agricultural Policy Research Institute. Retrieved from http://www.fapri.missouri.edu/outreach/publications/2004/FAPRI_UMC_Report_12_04.pdf

Farahbakhshazad N, Dinnes DL, Li C, Jaynes DB, and Salas W. (2008) Modeling biogeochemical impacts of alternative management practices for a row-crop field in Iowa. *Agriculture, Ecosystems & Environment, 123*(1-3), 30-48.

Fargione J, Hill J, Tilman D, Polasky S, and Hawthorne P. (2008) Land Clearing and the Biofuel Carbon Debt. *Science, 319*(5867), 1235-1238.

Fausey JC, James JK, Swinton SM, and Renner KA. (1997) Giant Foxtail (Setaria faberi) interference in nonirrigated corn (*Zea mays*). *Weed Science, 45*(2), 256-260.

Faust MJ. (2002) New feeds from genetically modified plants: the US approach to safety for animals and the food chain. *Livestock Production Science, 74*(3), 239-254.

Fawcett R and Caruana S (2001) Better soil, better yields: A guidebook to improving soil organic matter and infiltration. CTIC. Retrieved from http://www.ctic.purdue.edu/media/pdf/Better%20Soil%20Better%20Yields.pdf

FDA (1998) Guidance for Industry: Use of Antibiotic Resistance Marker Genes in Transgenic Plants. U.S. Food and Drug Administration. Retrieved September, 2011 from http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/biotechnology/ucm096135.htm

Carbohydrase and protease enzyme preparations derived from *Bacillus subtilis* or *Bacillus amyloliquefaciens*; affirmation of GRAS status as direct food ingredients, FDA.

FDA (2010) List of Completed Consultations on Bioengineered Foods. United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, Maryland. United States Food and Drug Administration. Retrieved January 2011 from http://www.fda.gov/Food/Biotechnology/Submissions/default.htm

Fernandez-Cornejo J, Nehring R, Sinha EN, Grube A, and Vialou A. (2009) *Assessing recent trends in pesticide use in U. S. agriculture*. Paper presented at the Meeting of the AAEA, Milwaukee, WI.

Flachowsky G, Chesson A, and Aulrich K. (2005) Animal nutrition with feeds from genetically modified plants. *Archives of Animal Nutrition, 59*(1), 1-40.

Food Conservation and Energy Act. (2008).

Fuchs R, Heeren R, Gustafson M, Rogan G, Bartnicki D, Leimgruber R, Finn R, Hershman A, and Berberich S. (1993a) Purification and Characterization of Microbially Expressed Neomycin Phosphotransferase II (NPTII) Protein and its Equivalence to the Plant Expressed Protein. *Nature Biotechnology, 11*(12), 1537-1542.

Fuchs RL, Ream JE, Hammond BG, Naylor MW, Leimgruber RM, and Berberich SA. (1993b) Safety Assessment of the Neomycin Phosphotransferase II (NPTII) Protein. *Nature Biotechnology, 11*(12), 1543-1547.

Galinat W. (1988) The origin of corn. In GF Sprague and JW Dudley (Eds.), *Corn and Corn Improvement* (pp. 1-27). Madison, WI: American Society of Agronomy, Inc., Crop Soil Science Society of America, Inc., and the Soil Science Society of America, Inc.

GAO. (2001) Chemical risk assessment: Selected Federal agencies' procedures, assumptions, and policies. United States General Accounting Office Report to Congressional Requesters. August 2001. GAO-01-810

Gebhard F and Smalla K. (1999) Monitoring field releases of genetically modified sugar beets for persistence of transgenic plant DNA and horizontal gene transfer. *FEMS Microbiology Ecology, 28*(3), 261-272.

Giannessi LP. (2005) Economic and herbicide use impacts of glyphosate-resistant crops. *Pest Management Science, 61*, 241-245.

Giles D, Downey D, and Thompson J (2006) In Field Assessments of Dust Generation of Harvesting Equipment. Workshop on Agricultural Air Quality. Retrieved from http://www.ncsu.edu/airworkshop/Emissions_Crop.pdf

Gould F. (1968) *Grass Systematics*. New York, New York: McGraw Hill, NJ.

Grandy AS, Loecke TD, Parr S, and Robertson GP. (2006) Long-Term Trends in Nitrous Oxide Emissions, Soil Nitrogen, and Crop Yields of Till and No-Till Cropping Systems. *Journal of Enviromental Quality*, *35*(4), 1487-1495.

Greene C, Dimitri C, Lin B-H, McBride W, Oberholter L, and Smith T (2009) Emerging issues in the U.S. organic industry. USDA-ORS. Retrieved October 2011, from http://www.ers.usda.gov/publications/eib55/eib55.pdf

Gregorich EG, Rochette P, Hopkins DW, McKim UF, and St-Georges P. (2006) Tillage-induced environmental conditions in soil and substrate limitation determine biogenic gas production. *Soil Biology and Biochemistry, 38*(9), 2614-2628.

Gregorich EG, Rochette P, VandenBygaart AJ, and Angers DA. (2005) Greenhouse gas contributions of agricultural soils and potential mitigation practices in Eastern Canada. *Soil and Tillage Research, 83*(1), 53-72.

Greuere GP (2006) An analysis of trade related international regulations of genetically modified food and their effects on developing countries. International Food Policy Research Institute. Retrieved from http://www.ifpri.org/publication/analysis-trade-related-international-regulations-genetically-modified-food-and-their-eff

Griffiths BS, Caul S, Thompson J, Birch ANE, Cortet J, Andersen MN, and Krogh PH. (2007a) Microbial and microfaunal community structure in cropping systems with genetically modified plants. *Pedobiologia, 51*(3), 195-206.

Griffiths BS, Heckmann LH, Caul S, Thompson J, Scrimgeour C, and Krogh PH. (2007b) Varietal effects of eight paired lines of transgenic Bt maize and near-isogenic non-Bt maize on soil microbial and nematode community structure. *Plant Biotechnology Journal, 5*(1), 60-68.

Gutowski W, Hergerl G, Holland G, Knutson T, Mearns L, Stouffer R, Webster P, Wehner M, Zwiers F, Brooks H, Emanuel K, Komar P, Kossin J, Kunkel K, McDonald R, Meehl G, and Trapp R (2008) Causes of Observed Changes in Extremes and Projections of Future Changes. The U.S. Climate Change Science Program. Retrieved October, 2011 from http://www.climatescience.gov/Library/sap/sap3-3/final-report/sap3-3-final-Chapter3.pdf

Hall M, Swanton C, and Anderson G. (1992) The Critical Period of Weed Control in Grain Corn (*Zea mays*). *Weed Science, 40*(3), 441-447.

Hall RC and Twidwell EK (2002) Effects of drought stress on corn production. Cooperative Extension Service. Retrieved from http://www.sdstate.edu/sdces/store/Publications/pub-details.cfm?customel_datapageid_858688=872114

Halvorson AD, Del Grosso SJ, and Reule CA. (2008) Nitrogen, Tillage, and Crop Rotation Effects on Nitrous Oxide Emissions from Irrigated Cropping Systems. *Journal of Enviromental Quality, 37*(4), 1337-1344.

Hart CE. (2006) Feeding the Ethanol Boom: Where will the Corn come from? *Iowa Agricultural Review, 12*, 3-5.

Hawes C, Haughton AJ, Osborne JL, Roy DB, Clark SJ, Perry JN, Rothery P, Bohan DA, Brooks DR, Champion GT, Dewar AM, Heard MS, Woiwod IP, Daniels RE, Young MW, Parish AM, Scott RJ, Firbank LG, and Squire GR. (2003) Responses of plants and invertebrate trophic groups to contrasting herbicide regimes in the Farm Scale Evaluations of genetically modified herbicide–tolerant crops. *Philosophical Transactions of the Royal Society of London. Series B: Biological Sciences, 358*(1439), 1899-1913.

Heap IM (2008) International Survey of Herbicide Resistant Weeds. . Retrieved 1, from www.weedscience.com.

Heisel E (1998) Biodiversity and Federal Land Ownership: Mapping a Strategy for the Future. Ecology Law Quarterly.

Henry C, Morgan D, Weekes R, Daniels R, and Boffey C (2003) Farm scale evaluations of GM crops: monitoring gene flow from GM crops to non-GM equivalent crops in the vicinity (contract reference EPG 1/5/138). Part I: Forage Maize. DEFRA. Retrieved from http://www.cib.org.br/estudos/estudos_cientificos_alimentar_14.pdf

Utilizing Drought-Damaged Corn, 1-4 (1990).

Hoeft R, Nafziger E, Johnson R, and Aldrich S. (2000) *Modern corn and soybean production.* Savoy, IL: MCSP Publications.

Holm L, Pancho J, Herberger V, and Plucknett DL. (1979) A geographical atlas of world weeds. 471-04393.

Holmén B, Miller D, Hiscox A, Yang W, Wang J, Sammis T, and Bottoms R. (2006) *Aerosol Emissions from Field Planting Operations*

Howell TA, Tolk JA, Schneider AD, and Evett SR. (1998) Evapotranspiration, yield, and water use efficiency of corn hybrids differing in maturity. *Agronomy Journal, 90*(1), 3-9.

Humberg L, DeVault T, MacGowan B, Beasley J, and Rhodes Jr O. (2007) *Crop depredation by wildlife in northcentral Indiana*

IPPC (2007). Climate Change 2007: The Physical Science. Submitted by S Solomon, D. Qin, M. Manning, Registration Manager. Cambridge University Press (See Table

IPPC (2010) Official web site for the International Plant Protection Convention: International Phytosanitary Portal International Plant Protection Convention. Retrieved March 30, 2010 from https://www.ippc.int/IPP/En/default.jsp

Ireland D, Wilson Jr D, Westgate M, Burris J, and Lauer M. (2006) Managing reproductive isolation in hybrid seed corn production. *Crop Science, 46*(4), 1445.

Johnson DH. (2000) Grassland bird use of Conservation Reserve Program Fields in the Great Plains. In WL Hohman and DJ Halloum (Eds.), *A Comprehensive Review of Farm Bill Contributions to Wildlife Conservation, 1985-2000* (pp. 19-34).

Johnson DH. (2005) Grassland bird use of Conservation Reserve Program fields in the Great Plains: 2000-2005 Update. In JB Haufler (Ed.), *Fish and Wildlife Benefits of Farm Bill Programs: 2000-2005 Update*). Bethesda, MD: Wildlife Society.

Karl T, Meehl G, Miller C, Hassol S, Waple A, and Murray W (2008) Weather and Climate Extremes in a Changing Climate - Regions of Focus: North America, Hawaii, Caribbean, and U.S. Pacific Islands. The U.S. Climate Change Science Program. Retrieved October, 2011 from http://www.climatescience.gov/Library/sap/sap3-3/final-report/

Keeler KH. (1989) Can genetically engineered crops become weeds? *Biotechnology, 7*(11), 1134-1139.

Kegley SE, Hill BR, Orme S, and Choi AH (2010) PAN Pesticide Database. Pesticide Action Network: North America. Retrieved March 2011, from http://www.pesticideinfo.org/

Kermicle JL and Evans MMS. (2010) The *Zea mays* sexual compatibility gene ga2: naturally occurring alleles, their distribution, and role in reproductive isolation. *Journal of Heredity, 101*, 737-749.

Koele B (2008) Wildlife Damage Abatement and Claims Program, 2008. USDA. Retrieved from http://dnr.wi.gov/org/land/wildlife/damage/progreport.pdf

König A, Cockburn A, Crevel RWR, Debruyne E, Grafstroem R, Hammerling U, Kimber I, Knudsen I, Kuiper HA, Peijnenburg AACM, Penninks AH, Poulsen M, Schauzu M, and Wal JM. (2004) Assessment of the safety of foods derived from genetically modified (GM) crops. *Food and Chemical Toxicology, 42*(7), 1047-1088.

Krueger JE (2007) If your farm is organic, must it be GMO-free? . Farmers' Legal Action Group, Inc. Retrieved from http://www.flaginc.org/topics/pubs/arts/OrganicsAndGMOs2007.pdf

Krupa S, Booker F, Bowersox V, and Grantz D. (2006) *Uncertainties in the Current Knowledge of Atmospheric Trace Gases Associated with Cropping Systems in the US*

Kuepper G (2002) Organic field corn production. National Sustainable Agricultural Information Service. ATTRA. Retrieved from http://attra.ncat.org/attra-pub/PDF/fieldcorn.pdf

Kuepper G, Born H, and Gegner L (2007) Organic System Plan (OSP) Templates for Certifiers

ATTRA. Retrieved from http://attra.ncat.org/attra-pub/PDF/OSPtemplates.pdf

KyCGA (2011) Feed Corn and distiller's grains promotion. Kentucky Corn Growers Association. Retrieved March 2011, from

Lal R and Bruce J. (1999) The potential of world cropland soils to sequester C and mitigate the greenhouse effect. *Environmental Science & Policy, 2*(2), 177-185.

Levine E. (1991) Management of Diabroticite Rootworms in Corn. *Annual Review of Entomology, 36*, 229-255.

Lew A (2004) GEOGRAPHY: USA Retrieved Aug. 18, 2010, from http://www.geog.nau.edu/courses/alew/ggr346/text/chapters/ch8.html

Linn DM and Doran JW. (1984) Effect of Water-Filled Pore Space on Carbon Dioxide and Nitrous Oxide Production in Tilled and Nontilled Soils1. *Soil Science Society of America, 48*(6), 1267-1272.

MacKenzie A, Fan M, and Cadrin F. (1998) Nitrous Oxide Emission in Three years as Affected by Tillage, Corn-Soybean-Alfalfa Rotations, and Nitrogen Fertilization. *Journal of environmental quality, 27*(3), 698-703.

Mallory-Smith C and Zapiola M. (2008) Gene flow from glyphosate-resistant crops. *Pest management science, 64*(4), 428-440.

Mangelsdorf PC. (1974) *Corn: Its origin, evolution, and improvement*. Harvard University Press Cambridge, MA.

Marvier M, McCreedy C, Regetz J, and Kareiva P. (2007) A meta-analysis of effects of Bt cotton and maize on nontarget invertebrates. *Science, 316*(5830), 1475-1477.

McBride W (2005) Farm Income Less Important to Most Corn Farm Households. United States Department of Agriculture-Economic Research Service. Retrieved from http://www.ers.usda.gov/AmberWaves/February05/Findings/FarmIncomeLess.htm

McBride W. (2008) *The Profitability of Organic Soybean Production*. Paper presented at the American Agriculture Economics Association Annual Meeting, Orlando, FL.

McWilliams D (2002) Drought Strategies for Corn and Grain Sorghum. Retrieved March 2011, from http://cahedev.nmsu.edu/pubs/_circulars/CR-580.pdf

Messmer R, Fracheboud Y, Bänziger M, Vargas M, Stamp P, and Ribaut J-M. (2009) Drought stress and tropical maize: QTL-by-environment interactions and stability of QTLs across environments for yield components and secondary traits. *TAG Theoretical and Applied Genetics, 119*(5), 913-930.

Metay A, Oliver R, Scopel E, Douzet J-M, Aloisio Alves Moreira J, Maraux F, Feigl BJ, and Feller C. (2007) N2O and CH4 emissions from soils under conventional and no-till management practices in Goiânia (Cerrados, Brazil). *Geoderma, 141*(1-2), 78-88.

Monsanto (2010) Petition for the Determination of Nonregulated Status for MON 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. The Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

Morris M and Hill A (1998) Overview of the world maize economy. Retrieved from

Muenscher W. (1980) *Weeds, Reprinted*. Cornell University Press, Ithaca, New York.

Nap J-P, Bijvoet J, and Stiekema W. (1992) Biosafety of kanamycin-resistant transgenic plants. *Transgenic Research, 1*(6), 239-249.

NAPPO (2009) NAPPO approved standards. North American Plant Protection Organization. Retrieved April 22, 2010 from http://www.nappo.org/Standards/Std-e.html

NBII (2010) United States Regulatory Agencies Unified Biotechnology Website. United States National Biological Information Infrastructure, Center for Biological Informatics Geological Survey. Retrieved March 30, 2010 from http://usbiotechreg.nbii.gov/

NCAT (2003) NCAT's organic crops workbook: a guide to sustainable and allowed practices. Retrieved from http://attra.ncat.org/attra-pub/PDF/cropsworkbook.pdf

NCGA (2007) Truths about water use, corn, and ethanol. Retrieved Febraury 2011, from

Neild RE and Newman JE. (1990) Growing Season Characteristics and Requirements in the Corn Belt. In RF Dale, DG Hanway, RE Carlson, GO Benson, RE Felch, CM Sakamoto, EA Runge, RM Castleberry, MW Seeley, RH Shaw, DR Hicks and RL Nielsen (Eds.), *National Corn Belt*).

Neilsen B (1995) Symptoms of deer corn damage. Purdue Plant and Pest Diagnostic Laboratory. Purdue University. Retrieved March 2011, from http://www.ppdl.purdue.edu/PPDL/weeklypics/1-10-05.html

NOAA (2010) Total Precipitation in Inches by Month. Climatology by State based on Climate Division Data: 1971-2000. Retrieved March 2011, from http://www.esrl.noaa.gov/psd/data/usclimate/pcp.state.19712000.climo

Non-GMO-Project (2010) Non-GMO Project. Retrieved July 31, 2010, from http://www.nongmoproject.org/

NRC. (2004) Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. The National Academies Press:Washington, D.C.

NRC. (2010) Impact of Genetically Engineered Crops on Farm Sustainability in the United States. The National Academies Press:Washington, DC.

NRCS (2011) National Resources Inventory. Unisted States Department of Agriculture Natural Resources Conservation Service. Retrieved March 2011, from http://www.nrcs.usda.gov/technical/NRI/

OECD (2003) Consensus document on the biology of *Zea mays* subsp. mays (maize). Organization for Economic Co-operation and Development Retrieved from http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO(2003)11&doclanguage=en

Olson RA and Sander DH. (1988) Corn Production. In GF Sprague and JW Dudley (Eds.), *Corn and Corn Improvement* (pp. 639-686): American Society of Agronomy-Crop Science Society of America-Soil Science Society of America.

Oorts K, Merckx R, Gréhan E, Labreuche J, and Nicolardot B. (2007) Determinants of annual fluxes of CO2 and N2O in long-term no-tillage and conventional tillage systems in northern France. *Soil and Tillage Research, 95*(1-2), 133-148.

OTA (2010) Industry Statistics and Projected Growth. Organic Trade Association. Retrieved February 2011, from http://www.ota.com/organic/mt/business.html

Paget E, Lebrun M, Freyssinet G, and Simonet P. (1998) The fate of recombinant plant DNA in soil. *European Journal of Soil Biology, 34*(2), 81-88.

Palma RM, Rímolo M, Saubidet MI, and Conti ME. (1997) Influence of tillage system on denitrification in maize-cropped soils. *Biology and Fertility of Soils, 25*(2), 142-146.

Patterson MP and Best LB. (1996) Bird abundance and nesting success in Iowa CRP fields: The importance of vegetation structure and composition. *American Midland Naturalist, 135*(1), 153-167.

Paulson N and Babcock B. (2010) Readdressing the Fertilizer Problem. *Journal of Agricultural and Resource Economics, 35*(3), 368-384.

Philippe R. (2008) No-till only increases N2O emissions in poorly-aerated soils. *Soil and Tillage Research, 101*(1-2), 97-100.

Piñeiro G, Jobbágy EG, Baker J, Murray BC, and Jackson RB. (2009) Set-asides can be better climate investment than corn ethanol. *Ecological applications, 19*(2), 277-282.

Pioneer (2009) Petition for the Determination of Nonregulated Satus for Maize 32138 SPT Maintainer Used in the Pioneer Seed Production Technology (SPT) Process. Submitted by Natalie Weber, Regulatory Affairs Manager. Pioneer Hi-Bred International, Inc. (See Table

Pioneer (2010) Pioneer Research to Develop Drought Tolerant Corn Hybrids. Retrieved from http://www.pioneer.com/CMRoot/pioneer/us/agronomy/agronomy_research_summary/2010/low_water_environments/2010_drought_tolerant_corn_hybrids.pdf

Pioneer (2011a) Introducing Optimum Aquamax Hybrids. Retrieved 3-9-11, from http://www.pioneer.com/CMRoot/pioneer/us/products/seed_trait_technology/optimum_aquamax/aquamax_product_info_brochure.pdf

Pioneer (2011b) Optimum AQUAmax hybrids. Retrieved from http://www.pioneer.com/home/site/us/products/corn/seed-traits-technologies-corn/optimum-aquamax-hybrids/

Plantinga AJ, Alig R, and Cheng Ht. (2001) The supply of land for conservation uses: evidence from the conservation reserve program. *Resources, Conservation and Recycling, 31*(3), 199-215.

Poirier V, Angers DA, Rochette P, Chantigny MH, Ziadi N, Tremblay G, and Fortin J. (2009) Interactive Effects of Tillage and Mineral Fertilization on Soil Carbon Profiles. *Soil Science Society of America, 73*(1), 255-261.

Ponsard S, Gutierrez AP, and Mills NJ. (2002) Effect of Bt-toxin (Cry1Ac) in transgenic cotton on the adult longevity of four Heteropteran predators. *Environmental Entomology, 31*, 1197-1205.

Potter KN, Torbert HA, Jones OR, Matocha JE, Morrison Jr JE, and Unger PW. (1998) Distribution and amount of soil organic C in long-term management systems in Texas. *Soil and Tillage Research, 47*(3-4), 309-321.

Rieger MA, Lamond M, Preston C, Powles SB, and Roush RT. (2002) Pollen-Mediated Movement of Herbicide Resistance Between Commercial Canola Fields. *Science, 296*(5577), 2386-2388.

Rochette P, Angers DA, Chantigny MH, and Bertrand N. (2008) Nitrous Oxide Emissions Respond Differently to No-Till in a Loam and a Heavy Clay Soil. *Soil Science Society of America, 72*(5), 1363-1369.

Romeis J, Meissle M, and Bigler F. (2006) Transgenic crops expressing *Bacillus thuringiensis* toxins and biological control. *Nature Biotechnology, 24*(1), 63-71.

Rosenzweig C, Iglesias A, Yang XB, Epstein PR, and Chivian E. (2001) Climate change and extreme weather events: Implications for food production, plant diseases, and pests. *Global Change and Human Health, 2*(2), 90-104.

Rosenzweig C and Parry ML. (1994) Potential impact of climate change on world food supply. *Nature, 367*(6459), 133-138.

Roy DB, Bohan DA, Haughton AJ, Hill MO, Osborne JL, Clark SJ, Perry JN, Rothery P, Scott RJ, Brooks DR, Champion GT, Hawes C, Heard MS, and Firbank LG. Invertebrates and vegetation of field margins adjacent to crops subject to contrasting herbicide regimes in the Farm Scale Evaluations of genetically modified herbicide-tolerant crops. *Philosophical Transactions of the Royal Society of London. Series B: Biological Sciences, 358*(1439), 1879-1898.

Ruser R, Flessa H, Russow R, Schmidt G, Buegger F, and Munch JC. (2006) Emission of N2O, N2 and CO2 from soil fertilized with nitrate: effect of compaction, soil moisture and rewetting. *Soil Biology and Biochemistry, 38*(2), 263-274.

Russell WA and Hallauer AR. (1980) Corn. In WR Fehr and HH Hadley (Eds.), *Hybridization of crop plants* (pp. 302). Madison, WI: American Society of Agronomy and Crop Science Society of America.

Ruth L. (2003) Tailoring thresholds for GMO testing. *Analytical chemistry, 75*(17), 392-396.

Sanvido O, Widmer F, Winzeler M, Streit B, Szerencsits E, and Bigler F. (2008) Definition and feasibility of isolation distances for transgenic maize cultivation. *Transgenic research, 17*(3), 317-335.

Schmidhuber J and Tubiello FN. (2007) Global food security under climate change. *Proceedings of the National Academy of Sciences, 104*(50), 19703-19708.

Secchi S, Gassman P, Williams J, and Babcock B. (2009) Corn-Based Ethanol Production and Environmental Quality: A Case of Iowa and the Conservation Reserve Program. *Environmental Management, 44*(4), 732-744.

Sheriff G. (2006) Efficient waste - Why farmers over-apply nutrients and the implications for policy design *Review of Agricultural Economics, 27*(4), 542-557.

Six J, Ogle SM, Jay breidt F, Conant RT, Mosier AR, and Paustian K. (2004) The potential to mitigate global warming with no-tillage management is only realized when practised in the long term. *Global Change Biology, 10*(2), 155-160.

Smedley JW (2008) An acute toxicity study of cold shock protein B administered by the oral (gavage) route to mice.

Smika D and Wicks G. (1968) Soil water storage during fallow in the Central Great Plains as influenced by tillage and herbicide treatments. *Soil Science Society of America Journal, 32*(4), 591.

Smith D and White D. (1988) Diseases of Corn. In GF Sprague and JW Dudley (Eds.), *Corn and Corn Improvement* (pp. 687-749). Madison, WI: American Society of Agronomy.

Smith J (2005) Small Mammals and Agriculture - A study of Effects and Responses. St. Olaf College. Retrieved March 2011, from http://www.stolaf.edu/depts/environmental-studies/courses/es-399%20home/es-399-05/Projects/Jared's%20Senior%20Seminar%20Research%20Page/index.htm

Smith KA and Conen F. (2004) Impacts of land management on fluxes of trace greenhouse gases. *Soil Use and Management, 20*(2), 255-263.

Smith W, Desjardins R, Grant B, and Lemke R. (2002) *Estimated N20 Emissions as Influenced by Agricultural Practices in Canada*. Paper presented at the 12th ISCO Conference, Beijing.

Southwood TRE and Way MJ. (1970) Ecological background to pest management *Concepts of Pest Management* (pp. 7-28). Raleigh: N.C. State University.

Stallman HR and Best LB. (1996) Small-mammal use of an experimental strip intercropping system in northeastern Iowa. *American Midland Naturalist, 135*(2), 266-273.

Steinbach HS and Alvarez R. (2006) Changes in Soil Organic Carbon Contents and Nitrous Oxide Emissions after Introduction of No-Till in Pampean Agroecosystems. *Journal of Enviromental Quality, 35*(1), 3-13.

Sterner RT, Petersen BE, Gaddis SE, Tope KL, and Poss DJ. (2003) Impacts of small mammals and birds on low-tillage, dryland crops. *Crop Protection, 22*(4), 595-602.

Stockton M, Wilson R, and Colburn F (2007) Continuous Corn or a Corn/Soybean Rotation? University of Nebraska - Lincoln Extension, Institute of Agricultureand Natural Resources. Retrieved from

Sundstrom F, Williams J, Van Deynze A, and Bradford K. (2002) *Identity preservation of agricultural commodities*. ANR Publications.

Tan IYS, van Es HM, Duxbury JM, Melkonian JJ, Schindelbeck RR, Geohring LD, Hively WD, and Moebius BN. (2009) Single-event nitrous oxide losses under maize production as affected by soil type, tillage, rotation, and fertilization. *Soil and Tillage Research, 102*(1), 19-26.

Thomison P (2011) Managing "Pollen" Drift to Minimize Contamination of Non-GMO Corn, AGF-153. Retrieved October, 2011 from http://ohioline.osu.edu/agf-fact/0153.html

Torres JB and Ruberson JR. (2005) Canopy- and Ground-Dwelling Predatory Arthropods in Commercial Bt and non-Bt Cotton Fields: Patterns and Mechanisms. *Environmental entomology, 34*(5), 1242-1256.

Tu H. (2009) Updated bioinforamtic evaluation of the NPTII protein utilising the AD 2009 and TOX 2009 databases.

US-NARA (2010) Executive Orders disposition tables index. United States National Archives and Records Administration. Retrieved March 11, 2010 from http://www.archives.gov/federal-register/executive-orders/disposition.html
USCB (2011) Per Capita Consumption of Major Food Commodities, 1980 - 2008. U.S. Census Bureau. Retrieved March 2011, from http://www.census.gov/compendia/statab/
USDA-AMS (2011) Policy Memorandum. Washington DC: United States Department of Agriculture, Agricultural Marketing Services, National Organics Program.
USDA-APHIS (2010) Plant Pest Risk Assessment for MON 87460 Corn. Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html
USDA-APHIS (2011) Petitions for Nonregulated Status Granted or Pending by APHIS. United States Department of Agriculture - Animal and Plant Health Inspection Service. Retrieved September, 2011 from http://www.aphis.usda.gov/biotechnology/not_reg.html
USDA-BRS (2006) Decision Tree on Whether Section 7 Consultation with FWS is Triggered for Petitions of Transgenic Plants. October 20, 2005. Revised July 11, 2006. Retrieved from http://www.aphis.usda.gov/brs/aphisdocs/04_30901r_ea.pdf
USDA-ERS (2010a) Adoption of Genetically Engineered Crops in the U.S.: Corn Varieties. Retrieved Aug. 11 2010, from http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable1.htm
USDA-ERS. (2010b) Agricultural Projections to 2019.
USDA-ERS (2010c) NEW Feed Grains Data: Yearbook Tables, Corn: Food, seed, and industrial use. Retrieved March 2011, from http://www.ers.usda.gov/data/FeedGrains/Table.asp?t=31
USDA-ERS (2010d) Organic Production. Retrieved February 2011, from http://www.ers.usda.gov/Data/Organic/
USDA-ERS (2010e) USDA Feed Grain Baseline, 2010-19. Retrieved January 2011, from http://www.ers.usda.gov/briefing/corn/2010baseline.htm
USDA-ERS (2011a) The Ethanol Decade: An Expansion of U.S. Corn Production, 2000-09. EIB-79. United States Department of Agriculture, Economic Research Service. Retrieved September, 2011 from http://www.ers.usda.gov/Publications/EIB79/EIB79.pdf
USDA-ERS (2011b) Organic agriculture: Organic trade. United States Department of Agriculture-Economic Research Service. Retrieved March 2011, from http://www.ers.usda.gov/briefing/organic/trade.htm
USDA-ERS (2011c) USDA Agricultural Projections to 2020. United States Department of Agriculture - Economic Research Service. Retrieved March, 2011 from http://www.ers.usda.gov/Publications/OCE111/OCE111.pdf
USDA-FAS (2006) Egypt. Biotechnology. Annual Agricultural Biotechnology Report 2006. Retrieved Aug. 22, 2010, from http://www.fas.usda.gov/gainfiles/200607/146208389.pdf
USDA-FAS (2008a) Mexico Biotechnology. GAIN Report. Retrieved Aug. 22, 2010 from http://www.fas.usda.gov/gainfiles/200807/146295179.pdf
USDA-FAS (2008b) Republic of Korea Agricultural Biotechnology Report 2008. Retrieved Aug. 22, 2010, from http://www.fas.usda.gov/gainfiles/200807/146295192.pdf
USDA-FAS (2008c) Taiwan Biotechnology, Annual 2008. GAIN Report. Retrieved Aug. 22, 2010 from http://www.fas.usda.gov/gainfiles/200810/146306245.pdf
USDA-FAS (2010a) Global Agricultural Trade System Online. Retrieved Aug. 21, 2010, from http://www.fas.usda.gov/gats/default.aspx

USDA-FAS (2010b) Grain: World Markets and Trade. Retrieved Aug. 21, 2010, from http://www.fas.usda.gov/grain/circular/2010/08-10/grainfull08-10.pdf

USDA-FAS (2011) U.S. organic exports continue to expand. United Stated Department of Agriculture-Foreign Agricultural Service. Retrieved March 2011, from http://www.fas.usda.gov/htp/organics/1-6-11%20Organics%20Summary.pdf

USDA-FSA (2009) Conservation Reserve Program: Summary and Enrollment Statistics.

USDA-NASS. (2006).Agricultural Chemical Usage 2005 Field Crops Summary. United States Department of Agriculture - National Agricultural Statistics Service, Last accessed from http://usda.mannlib.cornell.edu/usda/nass/AgriChemUsFC//2000s/2006/AgriChemUsFC-05-17-2006.pdf

USDA-NASS (2007) Irrigated Corn for Grain, Harvested Acres: 2007. . Retrieved Aug. 16, 2010, from http://www.nass.usda.gov/research/2007mapgallery/album/Crops_and_Plants/Field_Crops_Harvested/slides/Irrigated%20Corn%20for%20Grain,%20Harvested%20Acres.html

USDA-NASS (2010a) Crop Production 2009 Summary. Retrieved Aug. 16, 2010, from

USDA-NASS (2010b) National Statistics for Corn. Retrieved February 2011, from http://www.nass.usda.gov/Statistics_by_Subject/result.php?DAC4CC74-2AC5-3CB0-B975-89BE9E64EAF8&sector=CROPS&group=FIELD%20CROPS&comm=CORN

USDA-NASS (2011a) Acreage. 1949-1522. Retrieved October, 2011 from http://usda01.library.cornell.edu/usda/current/Acre/Acre-06-30-2011.pdf

USDA-NASS. (2011b) Corn, cotton, sorghum, soybean, and wheat planted acreage (1985 - 2010). Retrieved September, 2011 from United States Department of Agriculture, National Agricultural Statistics Service http://www.nass.usda.gov/QuickStats/Create_Federal_All.jsp

USDA-NRCS. (2010) Zea mexicana.

USDA-NRCS. (2011) Zea perrenis.

USDA (2008) Farm and Ranch Irrigation Survey. 2007 Census of Agriculture. . Retrieved Aug. 23, 2010, from http://www.agcensus.usda.gov/Publications/2007/Online_Highlights/Farm_and_Ranch_Irrigation_Survey/fris08.txt

USDA. (2009).2007 Census of Agriculture: United States Summary and State Data. Last accessed from

USDA (2011a) Crop Policies and Pilots - Biotechnology Endorsement. United States Department of Agriculture. Retrieved October, 2011 from http://www.rma.usda.gov/policies/bye.html

USDA (2011b) Federal Crop Insurance Corporation - Pilot Biotechnology Endorsement. United States Department of Agriculture.

USDOL-(United-States-Department-of-Labor). (2005) A Demographic and Employment Profile of United States Farm Workers. . *National Agricultural Workers Survey (NAWS) 2001-2002*.

USFWS (2010) United States Fish and Wildlife Service. Retrieved March 2011, from http://www.fws.gov/

USGC (2006) Value Enhanced Corn Report 2005/2006. U.S. Grains Council. Retrieved from http://www.agmrc.org/media/cms/USGC_Value_Enhanced_Corn_Report_200_08C7959C2B1E6.pdf

Ussiri DAN, Lal R, and Jarecki MK. (2009) Nitrous oxide and methane emissions from long-term tillage under a continuous corn cropping system in Ohio. *Soil and Tillage Research, 104*(2), 247-255.

Venterea RT, Burger M, and Spokas KA. (2005) Nitrogen Oxide and Methane Emissions under Varying Tillage and Fertilizer Management. *Journal of Enviromental Quality, 34*(5), 1467-1477.

Vercauteren KC and Hygnstrom SE. (1993) *White-tailed deer home range characteristics and impacts relative to field corn damage.* Presented at Great Plains Wildlife Damage Control Workshop Proceedings, University of Nebraska - Lincoln.

Vogel J, Majewski M, and Capel P. (2008) Pesticides in rain in four agricultural watersheds in the United States. *Journal of environmental quality, 37*(3), 1101.

Wanniarachchi SD, Voroney RP, Vyn TJ, Beyaert RP, and MacKenzie AF. (1999) Tillage effects on the dynamics of total and corn-residue-derived soil organic matter in two southern Ontario soils. *Canadian Journal of Soil Science, 79*(3), 473-480.

Watrud LS, Lee EH, Fairbrother A, Burdick C, Reichman JR, Bollman M, Storm M, King G, and Van de Water PK. (2004) Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker. *Proceedings of the National Academy of Sciences of the United States of America, 101*(40), 14533-14538.

Watson R (1994) Conservation Reserve Program: What Happens to the Land when the Contract Ends Northern Illinois University Law Review.

Weber WE, Bringezu T, Broer I, Eder J, and Holz F. (2007) Coexistence Between GM and Non-GM Maize Crops – Tested in 2004 at the Field Scale Level (Erprobungsanbau 2004). *Journal of Agronomy and Crop Science, 193*(2), 79-92.

West TO and Marland G. (2002) A synthesis of carbon sequestration, carbon emissions, and net carbon flux in agriculture: comparing tillage practices in the United States. *Agriculture, Ecosystems & Environment, 91*(1-3), 217-232.

Westcott P. (2007) US ethanol expansion driving changes throughout the agricultural sector. *Amber Waves, 5*(4), 10-15.

Westgate ME, Otegui ME, and Andrade FH. (2004) Physiology of the corn plant. In CW Smith, J Betran and ECA Runge (Eds.), *Corn: Origin, History, Technology, and Production*). Hoboken, NJ: John Wiley and Sons.

Wilkes H. (1967) Teosinte: the closest relative of maize. *Bussey Inst., Harvard Univ., Cambridge*.

Wipff J and Fricker C. (2002) Gene flow from transgenic creeping bentgrass (Agrostis stolonifera L) in the Willamette Valley, Oregon. *Australian Turfgrass Management 4.5*, 1-9.

Wolfenbarger L, Naranjo S, Lundgren J, Bitzer R, and Watrud L. (2008) Bt Crop Effects on Functional Guilds of Non-Target Arthropods: A Meta-Analysis. *PLoS One, 3*(5), e2118.

Wu J and Brorsen BW. (1995) The Impact of Government Programs and Land Characteristics on Cropping Patterns. *Canadian Journal of Agricultural Economics/Revue canadienne d'agroeconomie, 43*(1), 87-104.

Yu T and Babcock B (2010) Are U.S. Corn and Soybeans Becoming more Drought Tolerant? Iowa State University.

9 LIST OF PREPARERS

Biotechnology Regulatory Services	
David Reinhold Assistant Director, Environmental Risk Analysis Program	
Khamkeo Vongpaseuth, Ph.D. Environmental Protection Specialist	
Diane Sinkowski, Environmental Protection Specialist	
Craig Roseland, Ph.D Senior Environmental Protection Specialist	
Subray Hegde, Ph. D., Biotechnologist	
ICF International	
Christine Hartmann Project Manager, Technical Document Lead	Project Management Professional (PMP) Certification Professional Engineer (P.E.) Certification, Environmental Engineering M.E. Environmental Engineering, University of Maryland B.S. Environmental Engineering, University of Maryland 9 years of experience in environmental impact assessment, and 6 years of experience in managing and preparing NEPA documents

John Hansel Senior NEPA Advisor, Technical Document Lead	▪ J.D. Washington College of Law, American University ▪ B.A. Economics, University of Wisconsin ▪ 30 years of experience in environmental impact assessment and preparing NEPA documents
Michael Smith Senior NEPA Advisor	▪ Ph.D. Sociology, Utah State University ▪ M.A. Geography, University of Wyoming ▪ B.A. Environmental Studies, University of California, Santa Cruz ▪ 17 years of experience in environmental impact assessment
Ron Bass NEPA Compliance Review	▪ J.D. Washington College of Law, American University ▪ M.A. Environmental Planning, California State University Sacramento ▪ B.A. , Anthropology, Ohio State University ▪ 30 years of experience in environmental impact assessment and preparing NEPA documents
Rhey Solomon NEPA Compliance Review	▪ B.S. Watershed Management, University of Arizona ▪ M.S. Watershed Hydrology, University of Arizona ▪ 35 years of experience in environmental analysis and management
Steve Froggett Technical Document Lead	▪ Ph.D. Neuroscience and Behavior, University of Massachusetts ▪ M.S. Biology, University of North Carolina ▪ B.S. Biology and Psychology, Marietta College ▪ 9 years of experience working with government agencies, universities and the private sector on issues related to medical education, health care and food security
Erin Healy Technical Document Lead	▪ Professional Geologist (PG) Certification, New Hampshire ▪ M.Sc. Marine Science, University of South Carolina ▪ B.A. Colby College, Maine ▪ 18 years experience in environmental assessment and water resource evaluation

Audrey Ichida Technical Document Lead	▪ Ph.D. Plant Molecular Biology, University of California, San Diego ▪ B.A. Biology, Cornell College ▪ Graduate and post doctoral work in plant molecular biology and 13 years of experience in risk assessment
Kirsten Jaglo Technical Document Lead	▪ Ph.D. Crop and Soil Science, Plant Breeding and Genetics, Michigan State University ▪ B.A. Biology (minor in Chemistry), with honors, University of Minnesota ▪ 15 years of experience working with federal agencies, universities, and the private sector on issues related to genetic engineering
Dave Johnson Technical Document Lead	▪ B.S. Biology (minors in Chemistry and Geology), University of Minnesota ▪ 11 years experience in conducting aquatic resource delineations, habitat assessments, permitting assistance, and regulatory compliance
Jim Laurenson Technical Document Lead	▪ M.S. Environmental Health Management with Technical Specialty in Risk Assessment, Harvard University School of Public Health ▪ B.S. Animal Science and Pre-veterinary Medicine, University of Massachusetts ▪ 20 years of experience in conducting and managing environmental- and human health-related projects
Jason Londo Technical Document Lead	▪ Ph.D. Plant Biology, Washington University ▪ B.S. Molecular Biology, Florida Institute of Technology ▪ 3 years of experience in plant population biology and ecology, and 6 years of experience in plant population genetics
Meg McVey Senior Technical Review	▪ Ph.D. Animal Behavior and Ecology, The Rockefeller University ▪ B.S. Zoology, University of North Carolina ▪ 30 years of experience in human health and ecological risk assessment

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

---

[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 Mallory-Smith and Zapiola (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 Mallory-Smith and Zapiola 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 (Mallory-Smith and Zapiola, 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 (Mallory-Smith and Zapiola, 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]) (Ireland et al., 2006; Sanvido et al., 2008), 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). 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, 2002).

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 (Mallory-Smith and Zapiola, 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 (Mallory-Smith and Zapiola, 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; Galinat, 1988; Keeler, 1989). Corn is not present as a noxious weed on federal lists (Crockett, 1977; Holm et al., 1979; Muenscher, 1980; USDA-APHIS, 2010) 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 (Mallory-Smith and Zapiola, 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.

References

Baker HG. (1965) Characteristics and modes of origin of weeds. In HG Baker and GL Stebbins (Eds.), *The Genetics of Colonizing Species* (pp. 147-168). Berkeley, CA: Department of Botany, University of California, Berkeley, USA.

Bannert M. (2006) *Simulation of transgenic pollen dispersal by use of different grain colour maize.* Thesis. SWISS FEDERAL INSTITUTE OF TECHNOLOGY ZURICH.

Castillo G and Goodman M. (1997) Research on gene flow between improved maize and landraces.

Crockett L. (1977) *Wildly successful plants: a handbook of North American weeds*. Macmillan.

Cummings JL, Handley LW, Macbryde B, Tupper SK, Werner SJ, and Byram ZJ. (2008) Dispersal of viable row-crop seeds of commercial agriculture by farmland birds: implication for genetically modified crops. *Environ. Biosafety Res., 7*(4), 241-252.

Fernandez-Cornejo J. (2004).The seed industry in U.S. agriculture: An exploration of data and information on crop seed markets, regulation, industry structure, and research and development. United States Department of Agriculture, Economic Research Service, Washington, D.C. Last accessed Aug. 23, 2010, from http://www.ers.usda.gov/publications/aib786/aib786c.pdf

Galinat W. (1988) The origin of corn. In GF Sprague and JW Dudley (Eds.), *Corn and Corn Improvement* (pp. 1-27). Madison, WI: American Society of Agronomy, Inc., Crop Soil Science Society of America, Inc., and the Soil Science Society of America, Inc.

Goggi A, Lopez-Sanchez H, Caragea P, Westgate M, Arritt R, and Clark C. (2007) Gene flow in maize fields with different local pollen densities. *International Journal of Biometeorology, 51*(6), 493-503.

Gould F. (1968) *Grass Systematics*. New York, New York: McGraw Hill, NJ.

Guertler P, Lutz B, Kuehn R, Meyer H, Einspanier R, Killermann B, and Albrecht C. (2008) Fate of recombinant DNA and Cry1Ab protein after ingestion and dispersal of genetically modified maize in comparison to rapeseed by fallow deer (Dama dama). *European Journal of Wildlife Research, 54*(1), 36-43.

Hall RC and Twidwell EK (2002) Effects of drought stress on corn production. Cooperative Extension Service. Retrieved from http://www.sdstate.edu/sdces/store/Publications/pub-details.cfm?customel_datapageid_858688=872114

Halsey M, Remund K, Davis C, Qualls M, Eppard P, and Berberich S. (2005) Isolation of maize from pollen-mediated gene flow by time and distance. *Crop Science, 45*(6), 2172.

Holm L, Pancho J, Herberger V, and Plucknett DL. (1979) A geographical atlas of world weeds. 471-04393.

Ireland D, Wilson Jr D, Westgate M, Burris J, and Lauer M. (2006) Managing reproductive isolation in hybrid seed corn production. *Crop Science, 46*(4), 1445.

Jemison J and Vayda M. (2002) Cross pollination from genetically engineered corn: wind transport and seed source.

Jones M and Brooks J. (1950) Effectiveness of distance and border rows in preventing outcrossing in corn. *Oklahoma Agricultural Experiment Station Technical Bulletin No,* 3-18.

Keeler KH. (1989) Can genetically engineered crops become weeds? *Biotechnology, 7*(11), 1134-1139.

Kuparinen A, Schurr F, Tackenberg O, and O'Hara R. (2007) Air-mediated pollen flow from genetically modified to conventional crops. *Ecological applications, 17*(2), 431-440.

Luna V, Figueroa M, Baltazar M, Gomez L, Townsend R, and Schoper J. (2001) Maize Pollen Longevity and Distance Isolation Requirements for Effective Pollen Control. *Crop Science, 41*(5), 1551-1557.

Mallory-Smith C and Zapiola M. (2008) Gene flow from glyphosate-resistant crops. *Pest management science*, *64*(4), 428-440.

Muenscher W. (1980) *Weeds, Reprinted*. Cornell University Press, Ithaca, New York.

Sanvido O, Widmer F, Winzeler M, Streit B, Szerencsits E, and Bigler F. (2008) Definition and feasibility of isolation distances for transgenic maize cultivation. *Transgenic research, 17*(3), 317-335.

USDA-APHIS (2010) Plant Pest Risk Assessment for MON 87460 Corn. Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html

Weekes R, Allnutt T, Boffey C, Morgan S, Bilton M, Daniels R, and Henry C. (2007) A study of crop-to-crop gene flow using farm scale sites of fodder maize (Zea mays L.) in the UK. *Transgenic research*, *16*(2), 203-211.

Wiedemann S, Lutz B, Albrecht C, Kuehn R, Killermann B, Einspanier R, and Meyer H. (2009) Fate of genetically modified maize and conventional rapeseed, and endozoochory in wild boar (Sus scrofa). *Mammalian Biology-Zeitschrift fur Saugetierkunde, 74*(3), 191-197.

APPENDIX C. CHARACTERISTICS MEASURED FOR PHENOTYPIC, AGRONOMIC, AND ENVIROMENTAL 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

Characteristic	Characteristic Measured	Evaluation Timing	Evaluation Description (measurement endpoints
	Yield (bu/ac)	Harvest	Harvested weight of shelled grain, adjusted to 15.5% moisture
	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: (Monsanto, 2010)

References

Monsanto (2010) Petition for the Determination of Nonregulated Status for MON 87460. Submitted by W. R. Reeves, Regulatory Affairs Manager. The Monsanto Company (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

Determination of Nonregulated Status for MON 87460 Corn (*Zea mays* L.)

In response to petition 09-055-01p from Monsanto Company (hereafter referred to as Monsanto), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that MON 87460 corn and progeny derived from it are unlikely to pose plant pest risks and is no longer to be considered regulated article under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). Since APHIS has determined that MON 87460 corn is unlikely to pose plant pest risk, APHIS will approve the petition for nonregulated status of MON 87460 corn. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation under those regulations will no longer be required for MON 87460 corn and its progeny. Importation of MON 87460 corn seeds and other propagative material would still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and the Federal Seed Act regulations at 7 CFR part 201.

This determination for MON 87460 corn is based on APHIS' analyses of field and laboratory data submitted by Monsanto, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for MON 87460 corn.

The Plant Pest Risk Assessment conducted on MON 87460 corn concluded that it is unlikely to pose a plant pest risk and should no longer be subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 for the following reasons: (1) agronomic performance and disease and insect susceptibility of MON 87460 corn is similar to that of its non-genetically engineered corn counterpart and/or other corn cultivars grown in the U.S.; (2) the disarmed *Agrobacterium* transformation vector used to introduce the genetic material into MON 87460 corn was eliminated and neither the transformation vector nor the introduced genetic material or gene products are known to cause or promote disease, damage or injury to plants; (3) gene introgression from MON 87460 corn into wild relatives in the United States and its territories is unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely affect the genetic diversity of related plants any more than would cultivation of traditional or other corn varieties; (4) they exhibit no characteristics that would cause them to be weedier or more difficult to control as weeds than non-genetically engineered corn or any other cultivated corn; (5) the gene products (cold shock protein B and neomycin phosphotransferase II protein) have no known toxicity and are unlikely to pose any risks to non-target or beneficial organisms (6) horizontal gene transfer is unlikely to occur between MON 87460 corn and organisms with which they cannot interbreed.

In addition to our finding that MON 87460 corn is unlikely to pose a plant pest risk, APHIS has completed a Final Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action and has determined that a determination of nonregulated status for MON 87460 corn and its progeny would have no significant impacts, individually or collectively, on the quality of the human environment and will have no effect on federally listed threatened or endangered species, species proposed for listing, or their designated or proposed critical habitats (http://www.aphis.usda.gov/biotechnology/not_reg.html). APHIS also concludes in its PPRA that new varieties derived from MON 87460 corn are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for MON 87460 corn, or those observed for other corn varieties not considered regulated articles under 7 CFR part 340.

Based on my full and complete review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the PPRA, the Final EA, the agency's Response to Public Comments received in reference to the Draft EA, the FONSI, and my knowledge and experience as the Deputy Administrator of APHIS Biotechnology Regulatory Services, I have determined and decided that this determination of nonregulated status for MON 87460 corn is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire   11/30/2011

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date