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 — 11/30/2011

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

Date:

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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

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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.

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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).

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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).

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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

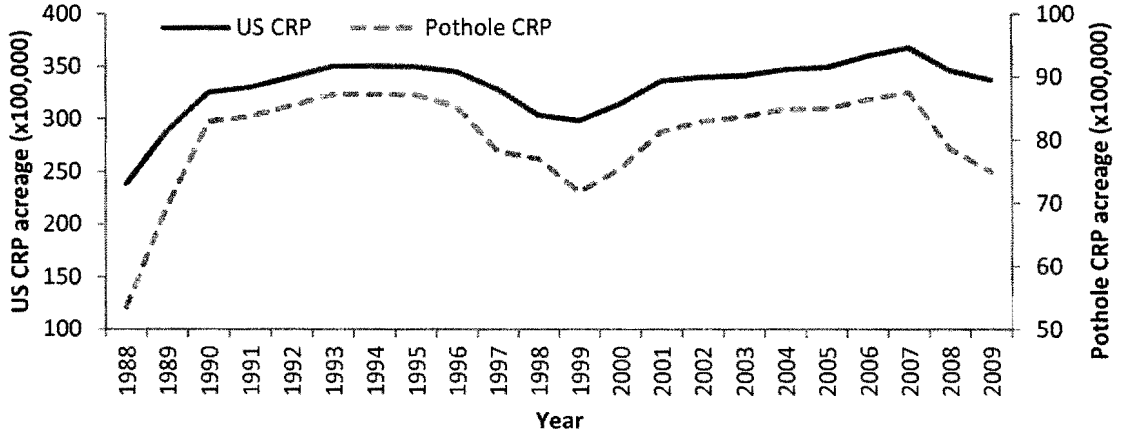


Figure R2. US and Prairie Pothole Region Corn Acreage

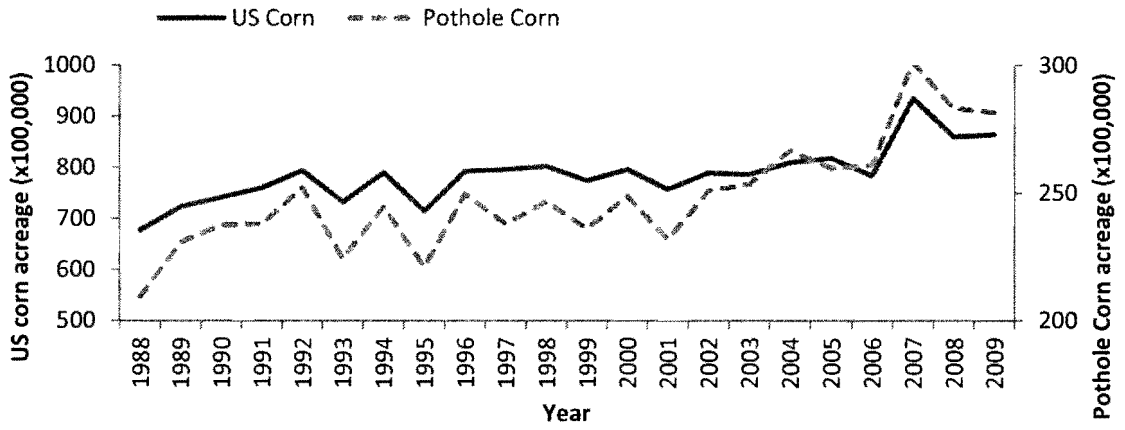
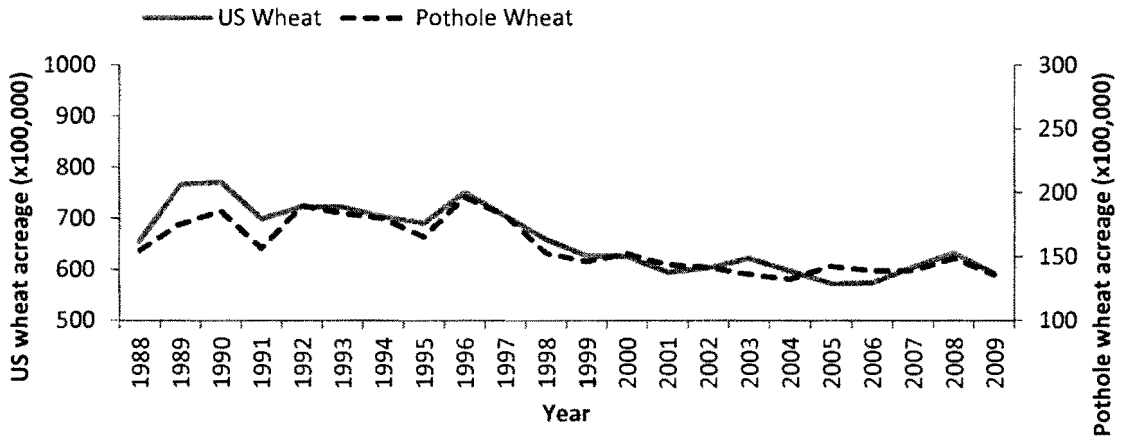


Figure R3. US and Prairie Pothole Region Wheat Acreage



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

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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.

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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.

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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).

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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.

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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).

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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 shortcomings 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.

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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.

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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.

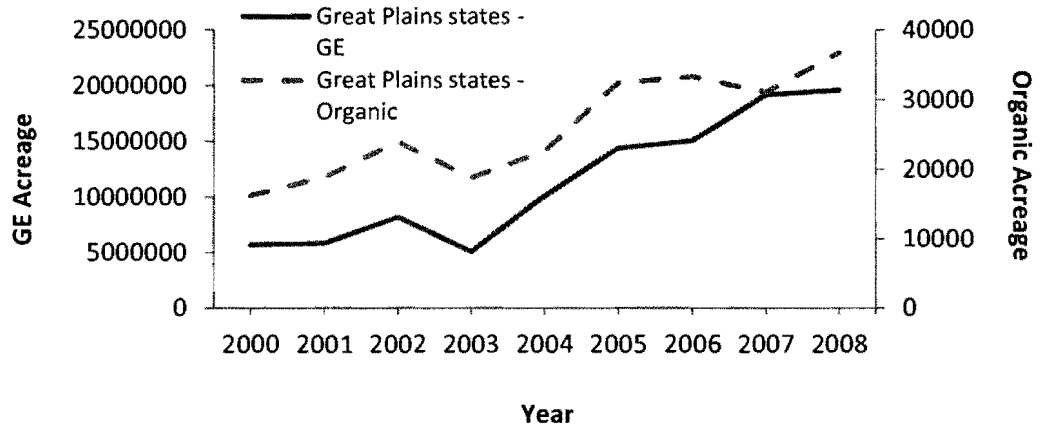
Response 21: In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS-NOP, 2011). Organic certification is a process-based 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).

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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.

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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.

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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.

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