NATIONAL ENVIRONMENTAL POLICY ACT DECISION

AND

FINDING OF NO SIGNIFICANT IMPACT

Monsanto Company

MON-87427 Maize

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 genetically engineered MON 87427 corn that expresses a tissue-selective *cp4 epsps* gene, the subject of a petition request (APHIS Number 10-281-01) by Monsanto Company (hereafter referred to as Monsanto). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment that may result from approving the petition seeking nonregulated status for MON 87427 corn. The EA assesses alternatives to a determination of nonregulated status of MON 87427 corn 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 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 provision 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 agriculture and the environment.

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). 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. 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 foods.

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 Cosmetics 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.

In 2010, Monsanto submitted information to the Environmental Protection Agency (EPA) requesting herbicide label changes to reflect the new use patterns of glyphosate that this product would require (Monsanto 2010), in order to increase tolerance levels for glyphosate. On May 11, 2011, EPA published its approval of this request (76 FR pp. 27268-27271), increasing tolerance levels in or on field or forage corn, to 13 ppm, based on a scientific review of the data.

Monsanto initiated a nutritional and safety consultation on MON 87427 corn with the Food and Drug Administration (FDA) (Monsanto 2010). On April 12, 2012, FDA stated that they had no further questions regarding food and feed derived from MON 87427 corn (BNF No. 000126).

Regulated Organisms

The APHIS Biotechnology Regulatory Services' (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 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 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 risk 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 risk 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 87427 corn. 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 no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

The Monsanto Company of St. Louis, MO submitted petition 10-281-01 to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in October 2010 seeking a determination of nonregulated status of maize (hereafter the term 'corn' will be used) event MON 87427 that exhibits a tissue-selective glyphosate resistant phenotype. MON 87427 corn is currently regulated under 7 CFR part 340.

MON 87427 Corn

MON 87427 corn is genetically engineered (GE) with tissue-selective glyphosate resistance in order to facilitate the production of hybrid seed. This technology results in more efficient corn hybrid seed production compared to mechanical and hand detasseling, or the use of cytoplasmic male sterility (CMS). Modern hybrid corn seed production is based on the use of two corn inbred parents, one designated as a female parent and one as a male parent. Hybrid seed production is accomplished through the combining of genetic material from one inbred parent with that of the other inbred parent. Specifically, pollen from the tassel (male flower) of the male parent is used to fertilize the ear (female flower) of the female parent. When used as a female inbred parent and sprayed with glyphosate during late vegetative development, MON 87427 corn is unable to produce viable pollen and self-fertilize. This phenotype precludes the need for first mechanical then hand detasseling of MON 87427 corn, facilitating greater efficiency of production and eliminating yield penalties generally associated with mechanical detasseling.

Glyphosate applications to MON 87427 that will result in the male sterile phenotype through tissue-selective glyphosate resistance will take place at approximate corn vegetative growth stages ranging from V8 to V13. The two glyphosate applications would take place during an approximate 14 day window within these growth stages, a much longer time period compared to an average 3 – 4 day window between tassel emergence and pollen shed and silk emergence. This timing accounts for significantly improved flexibility in hybrid seed production.

If the petition is approved, the nonregulated status for MON 87427 corn would include MON 87427 corn, any progeny derived from crosses between MON 87427 corn and conventional corn, and crosses of event MON 87427 corn with other biotechnology-derived corn that has been deregulated pursuant to Part 340 and the Plant Protection Act. Because many of the inbred lines that are employed in seed corn production do not have glyphosate resistance, glyphosate for weed control is not used. If MON 87427 corn is deregulated, developers and seed corn producers would have a trait useful for both improvements in seed production and also glyphosate resistance for weed management. Thus, these producers are expected to see economic benefits from herbicide resistance similar to most other conventional corn growers, through increased crop yield, and increased efficiencies in seed corn production.

Event MON 87427 corn is currently regulated under 7 CFR part 340. Interstate movements and field trials of MON 87427 corn have been conducted under notifications and permits acknowledged by APHIS since 2005. These field trials were conducted in typical corn production regions within the U.S., ranging from Arkansas to Wisconsin. Details regarding and data resulting from these field trials are described in the MON 87427 petition for nonregulated status (Monsanto, 2010); field trial data was analyzed for plant pest risk potential in the APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2012).

Coordinated Framework Review

Food and Drug Administration

MON 87427 corn is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced by genetic engineering. In June 2006, FDA published recommendations in "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use" (US-FDA, 2011) for establishing voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

The information provided in the Monsanto petition indicates that the CP4 EPSPS protein is not expected to be allergenic, toxic, or pathogenic in mammals (Monsanto, 2010). Monsanto initiated a nutritional and safety consultation on MON 87427 corn with the Food and Drug Administration (FDA) (Monsanto, 2010). On April 12, 2012, FDA stated that they had no further questions regarding food and feed derived from MON 87427 corn (BNF No. 000126).

Environmental Protection Agency

As described in Subsection 2.4, Human Health, under FIFRA, all pesticides (including herbicides) sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2011a).

Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. All pesticides registered prior to November 1, 1984, such as glyphosate, must also be reregistered to ensure that they meet the current, more stringent standards and should have a reregistration review every 15 years (US-EPA, 2011a). The latest reregistration decision for glyphosate was issued in 1993 and the reregistration review was started in July 2009 (US-EPA, 2009b); (US-EPA, 2009a). Before a pesticide can be used on a food or feed crop, the EPA must establish the tolerance value, which is the maximum amount of pesticide residue that can remain on the crop or in foods or feed processed from that crop (US-EPA, 2011c). Glyphosate currently has established tolerances for residues, including established residue concentrations for glyphosate in field corn for forage, grain, and stover (US-EPA, 2011b). Pesticide tolerance levels for glyphosate have been established for corn and are published in the *Federal Register*, CFR, and the *Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities* (US-EPA, 2011b). The glyphosate tolerance level established for field corn intended for forage was 6.0 ppm and for grain corn was 5.0 ppm (40 CFR §180.364). Monsanto petitioned EPA to increase the glyphosate tolerance level to 13.0 ppm, which was approved by EPA in May 2011 (76 FR pp.27268-27271).

Scope of the Environmental Analysis

Although the preferred alternative would allow for new plantings of MON 87427 corn anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas that currently support hybrid corn seed production. A determination of nonregulated status of MON 87427 corn is not expected to increase hybrid corn seed production, either by its availability alone or accompanied by other factors, or cause an increase in overall GE corn acreage. The hybrid seed production sites are principally located in some of the major Corn Belt states of Nebraska, Iowa, Illinois, and Indiana where rainfall or irrigation is optimal for corn production, and the transport distance to purchasers is not distant (Monsanto, 2010). To determine the larger area of commodity corn production in the US, APHIS used data from the National Agricultural Statistics Service (USDA-NASS, 2010). The majority of commercial corn acres are found in Iowa, Illinois, Nebraska, and Minnesota, and parts of Indiana, South Dakota, Kansas, Ohio, Wisconsin, and Missouri. These ten states comprised approximately 73 percent of the nation's corn production in 2011 (USDA-NASS, 2012a; USDA-NASS, 2012b).

Public Involvement

On July 13, 2012, APHIS published a notice in the Federal Register (77 FR 41359-41361, Docket no. APHIS-2012-0027) announcing the availability of the Monsanto petition for a 60-day public review and comment period. Comments were required to be received on or before September 11, 2012. All comments were carefully analyzed to identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in the evaluation of the petition. A total of 23,698 comments were received from individuals during the comment period[1], of which 23,604 were form letters. The issues that were raised in the public comments which were related to the MON 87427 corn petition included:

[1] Comment documents may be viewed at:
http://www.regulations.gov/#!searchResults;rpp=50;so=ASC;sb=docId;po=0;s=APHIS-2012-0027

- As another glyphosate resistant corn, additional use of glyphosate will increase glyphosate resistant weeds, requiring use of other herbicides, and weeds will develop resistance to these as well.
- Should not deregulate MON 87427 until the provider has obtained authorizations from key foreign markets prior to deregulation.
- More glyphosate use will increase herbicide levels in air and water sources and affect biological organisms. Herbicides such as glyphosate increase soil pathogens and lead to diseases including *Fusarium* wilt.
- Gene flow of the resistance trait from cultivated plants to wild/weedy/feral relatives may occur.
- Cultivation of this crop may reduce organic production of corn, because cross-pollination will affect sensitive markets for organic growers.
- Concerns that GE plants cause adverse health effects on humans and animals

In the EA, APHIS evaluated these comments and other documents submitted and has included a discussion of these and other related issues with relevant documentation and citations where appropriate.

The EA, PPRA, Preliminary FONSI and Preliminary Determination were made available for public comment during a 30-day review period beginning on July 25, 2013. During this second review period, APHIS received 20 comments.

Two comments supported approving the petition for determination of nonregulated status for MON 87427. They were submitted by corn growers' associations and noted that seed production "technology can benefit the entire agricultural biotechnology industry."

Eighteen commenters expressed general objection to all GE crops, including MON 87427. A few commenters described specific issues that might result from approving the petition for nonregulated status for MON 87427, but mostly without identifying scientific data or other documentation of issues that were not addressed in the EA. Some objected to additional use of glyphosate on another glyphosate resistant corn. The general objection to GE crops is outside the scope of the analysis, and the use of glyphosate is regulated by EPA. Some commenters propose that levels of glyphosate and formaldehyde should have been assessed in the product because of their supposed high concentrations in corn: "There MUST be a test to prove that there is no glyphosate (linked to autism, allergies, autoimmune diseases, asthma, alzheimers and more) and no formeldyhyde which is lethal." Another commenter was concerned that "examples of other glyphosate resistant corn varieties having higher levels of aflatoxin than is permitted by regulation exist, and this crop should be considered a plant pest compared to conventional maize." He notes that some glyphosate resistant corn had been shown to have higher *Aspergillus flavus* (a fungus) and aflatoxin levels than "conventional corn," citing Reddy et al. (2007). Another commenter noted, "I also request that there is thorough risk assessment as to the effects to native pollinators." Another commenter said, "I am concerned how an average person stands a chance at commenting on such a regulation, when all the language used is

particular to the industry and not really in layperson terms." APHIS responses to those issues are included in the addendum to this FONSI.

Major Issues Addressed in the EA

Issues discussed in the EA were developed by considering typical 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 food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of MON 87427 corn.

The resource areas considered were developed by APHIS through experience in considering public concerns and issues raised in public comments submitted for other EAs of GE organisms. Within each resource area, concerns raised in previous and unrelated lawsuits were considered, as well as issues that have been raised by various stakeholders in the past. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25). These resource areas can be categorized as follows:

Agricultural Production Considerations:

- Acreage and Range of Commercial Corn Production
- Agronomic Practices of Commercial Corn Production
- Hybrid Corn Seed Production: Pollen Control
- Organic Corn Production

Physical Environment and Biological Resource Considerations:

- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Gene Flow and Weediness
- Microorganisms
- Biodiversity

Human Health Considerations:

- Public Health
- Worker Safety

Animal Feed Considerations:

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 87427 corn. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87427 corn is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2012), APHIS has concluded that MON 87427 corn is unlikely to pose a plant pest risk. Therefore, APHIS must determine that MON 87427 corn 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 87427 corn. 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 87427 corn and progeny derived from MON 87427 corn would continue to be regulated articles under the regulations at 7 CFR part 340. Permits or notifications acknowledged by APHIS would still be required for introductions of MON 87427 corn and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MON 87427 corn.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment that MON 87427 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012). 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 87427 Corn is No Longer a Regulated Article

Under this alternative, MON 87427 corn and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87427 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87427 corn and progeny derived from this event. The Preferred Alternative, i.e., a determination of nonregulated status of MON 87427 corn, is expected to provide increased efficiency in production of hybrid seed corn as it is integrated into corn inbred lines. The trait is not expected to increase corn or seed corn production, either by its availability alone or associated with other factors, or result in an increase in overall acreage of GE seed corn. Potential impacts would be similar to the No Action

Alternative. 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 87427 corn is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87427 corn is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Alternatives Considered but Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 87427 corn. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for MON 87427 corn. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

1. Prohibit any MON 87427 Corn from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of MON 87427 corn, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MON 87427 corn is unlikely to pose a plant health risk

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 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 mandate of each agency"

Based on the PPRA (USDA-APHIS, 2012), and the scientific data evaluated therein, APHIS concluded that MON 87427 corn is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87427 corn.

2. Approve the petition in part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that MON 87427 corn is unlikely to pose a plant pest risk, (USDA-APHIS, 2012) and it is the only event in the petition, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3. Isolation Distance between MON 87427 Corn and Non-GE Corn Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating MON 87427 corn from conventional or specialty corn production. APHIS also considered geographically restricting the production of MON 87427 corn based on the location of production of non-GE corn in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants.

Establishing appropriate isolation distances is generally part of the hybrid corn seed production process. Hybrid corn seed producers typically isolate production plots physically from neighboring corn seed or grain production fields to avoid cross-pollination during the flowering stage by wind-borne pollen. The isolation distance from other corn is regulated by seed certification standards, and is typically at least 660 feet from other corn (AOSCA, 2009). Isolation is often enhanced with male parent inbred border rows around the perimeter of the seed production plots, which increases desirable pollen shed from the male parent inbred during the silking period of the female parent inbred and reduces the potential for cross-pollination from external pollen sources. Official seed certification regulations often allow isolation distances between seed production fields to be reduced as the number of border rows increases (Agrawal et al., 1998)

As presented in APHIS' plant pest risk assessment for MON 87427 corn, there are no geographic differences that might alter identifiable plant pest risks for MON 87427 corn (USDA-APHIS, 2012). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87427 corn does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. However, individuals might choose on their own to geographically isolate their non-GE corn production systems from MON 87427 corn or to use isolation distances and other management practices to minimize gene movement between MON

87427 corn and non-GE corn fields. Information to assist growers in making informed management decisions for MON 87427 corn is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

Because APHIS has concluded that MON 87427 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012), 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.

4. Requirement of Testing for MON 87427 Corn

During the comment periods for other petitions for nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. APHIS notes that 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 87427 corn does not pose a plant pest risk (USDA-APHIS, 2012), 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 87427 corn 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.

Summary of Issues of Potential Impacts and Consequences of Alternatives		
Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied—risk assessment (USDA-APHIS, 2012)
Management Practices		
Acreage and Areas	Yearly fluctuation but no or small net increase of acreage	Unchanged from No Action

Summary of Issues of Potential Impacts and Consequences of Alternatives		
of Corn Production	and no new regions of corn planted	Alternative
Agronomic Practices	Seed production practices will continue to depend on mechanical and hand detasseling	Use of glyphosate to sterilize male tissue and prevent pollination. May see some reductions in use of mechanical and hand detasseling
Pesticide Use	Herbicide use patterns on GE and non-GE corn will continue with present rates.	Glyphosate use in seed corn production may increase slightly
Corn Seed Production	Fluctuates yearly somewhat; foreign seed production used to respond to specific needs	Unchanged
Organic Corn Production	Yearly production not affected by conventional corn production	Unchanged
Environment		
Land Use	Seed corn acreage may range from 0.5 to one million acres	MON 87427 corn is not expected to have any effect on land use
Water Resources	Herbicides in water fluctuate with weather, climate and usage	MON 87427 corn is not expected to have any effect on water
Soil	Glyphosate in soil has a short half-life. Conservation tillage may be increasing slightly	MON 87427 corn is not expected to increase tillage or substantially change glyphosate use
Air Quality	Air quality (particulates) affected by tillage and weather	MON 87427 corn is not expected to have any effect on air quality
Climate Change	Climate changes affected by land use, tillage and greenhouse gases	MON 87427 corn is not expected to change land use, tillage practices or greenhouse gases.
Animals and Plants		
Animals	Vertebrates interact infrequently with corn agriculture; impacts on invertebrates from corn	MON 87427 corn and glyphosate is not expected to have any effect on vertebrate animals or most invertebrate animals Unchanged from the No

Summary of Issues of Potential Impacts and Consequences of Alternatives		
	production similar to impacts from any other agricultural production	Action Alternative
Plants	Natural vegetation highly reduced near farms; herbicide resistant weeds increasing	Unchanged from No Action alternative
Gene Movement	No gene flow to wild plants; gene flow to other corn controlled by grower needs. Horizontal gene flow not observed	MON 87427 corn used in seed production will allow pollination to be more directed but not expected to have any effect on vertical or horizontal gene flow
Soil Microorganisms	Microorganisms affected by tillage, agronomic activity and pesticides	Unchanged from No Action alternative
Biological Diversity	Contemporary agriculture already impacts diversity	Unchanged from No Action alternative
Human and Animal Health		
Risk to Human Health	EPA rates glyphosate impacts from glyphosate resistant corn as having no reasonable certainty of harm	MON 87427 corn does not have any adverse human health effects. Unchanged from No Action
Risk to Animal Feed	Corn is a major feed protein for animal nutrition; quality is unchanging and adequate to animal needs	MON 87427 corn will be used for seed, but no effects expected on animal nutrition
Socioeconomic		
Domestic and Economic Environment	Corn seed with various traits has a competitive market in the US, with four major seed suppliers and over a hundred smaller ones	MON 87427 corn would be deployed in inbreds for hybrid corn production, replacing mechanical and cytoplasmic sterility in the domestic seed corn production business; some gradual decline expected in summer temporary worker hiring
Trade Economic Environment	Corn export levels decreased by 23% from 2010 to 2012 in the	MON 87427 corn not likely to change corn production

Summary of Issues of Potential Impacts and Consequences of Alternatives		
	US	
Other Regulatory Approvals	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted
Compliance with Other Laws		
CWA, CAA, Eos	Fully compliant	Fully compliant

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.

The glyphosate sensitive trait in MON 87427 corn would be used in hybrid seed production, and corn bearing the trait is expected to be planted on a small percentage of acres compared to corn destined for grain and feed production. Corn planted for purposes of hybrid seed production have historically been restricted to small amounts of land, about 0.5 million acres annually (Jugenheimer, 1976), an area that is not expected to change with the introduction of MON 87427 corn. Over the last 35 years, the volume of hybrid corn seed planted in the U.S. has changed very little, with 20.10 million bushels (MBu) harvested in 1975 and 22.9 MBu harvested in 2009 (USDA-ERS, 2011g). Grain yields have increased significantly over this same period. The total retail value of corn seed sales in the US exceeds $7 billion (assuming $85/acre seed for160 Bu/acre expected yield, corn following soybean, IA (Duffy, 2012) and considering recent acreage). Corn seed suppliers in the US include a total of 173 independently owned companies (Monsanto, undated), and the petitioner is one of the four largest). Additional production of U.S. seed is contracted by U.S. seed companies among South American growers as needed for flexibility and speed (Leidy, 2009; Woodall, 2012) which also may reduce the need to expand acreage in the US for seed corn production.

Currently, only a small part of the world corn seed for planting originates in the US, as US exports of seed are less than 0.04% of total US corn seed production and less than

0.06% of world corn seed needs[2] (USDA-FAS, 2012) (USDA-FAS, 2013). Corn seed for planting in 2012 was purchased by Canada, several South American countries, Mexico and 40 other countries. Corn for commodity use is cultivated worldwide, including Argentina, South Africa, Brazil, Canada, China, and the former Soviet Union States, including the Ukraine (USDA-OCE, 2011). Egypt, the EU, Japan, Mexico, Southeast Asia, and South Korea are net importers of corn (USDA-OCE, 2011). Approximately 15 to 20% of the U.S. corn production is exported (USDA-OCE, 2011). In 2009, the U.S. produced 40% of the total world supply of corn (USDA-OCE, 2011).

The gene incorporated into MON 87427 corn codes for the same gene as that in currently available Monsanto glyphosate resistant corn, but with a different promoter and intron combination. Consequently, this promoter/gene combination would also be found in new hybrid seed when the MON 87427 trait is incorporated into inbred lines for seed production. Approximately 88% of corn fields were planted with transgenic corn in 2011 of which most was glyphosate-resistant (USDA-NASS, 2011). Introduction of additional herbicide-resistant corn varieties has not significantly affected corn acreage. APHIS concludes that a determination of nonregulated status of this glyphosate resistant MON 87427 corn is not expected to directly cause an increase in agricultural acreage devoted to seed corn or commodity corn production. The availability of glyphosate resistant MON 87427 corn will not change areas of cultivation 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.

Corn is the most widely cultivated feed grain, accounting for more than 95% of total value and production of feed grains (USDA-ERS, 2011). In the U.S. for the 2012 production year, corn was cultivated on over 96 million acres, a 5% increase in corn acreage from 2011 (USDA-NASS, 2012a). Within the 2010 acreage, corn for silage was cultivated on approximately 5.6 million acres, or approximately 6% of the total corn production area (USDA-NASS, 2012b). Corn production in 2010 was estimated at 12.4 billion bushels, valued at an estimated $5.18 per bushel in 2010 and $6.20 in 2011 (USDA-NASS, 2012a), (USDA-NASS, 2012c). GE herbicide-resistant corn comprised approximately 21% of the total corn acreage in the U.S., insect-resistant varieties comprised 15% of the acreage, and stacked varieties which include herbicide resistant traits comprised 52% of the total corn acreage (USDA-NASS, 2012a). The costs for GE corn seed are higher than that for conventional seed. Growers pay a premium for GE seed, with growers in 2008 paying as much as 50% more for GE corn seed than conventional seed (NRC, 2010). This seed premium includes a technology fee for the cultivation of the seed (NRC, 2010).

Results of the agronomic and morphologic assessments conducted by Monsanto indicate that the introduced herbicide resistance trait does not confer any competitive advantage in terms of

[2] Using 169.6 million world hectares corn planted annually, assuming 25# corn planted per acre, US corn seed exports are 42 million kgs,

weediness (USDA-APHIS, 2012). Monsanto asserts that MON 87427 corn will be incorporated into inbred lines used for hybrid seed production, and these inbreds will have the new trait that is useful for both efficient hybrid production and weed control. A need for new acreage for seed production is not expected to accompany the cultivation of MON 87427 corn and a more efficient hybridization system (Monsanto, 2010); hybrid corn seed needs will not increase. The glyphosate resistant trait, already in commercial use for fifteen years, is not expected to extend the typical areas of seed production for MON 87427 corn outside of the present areas of seed corn cultivation (Monsanto, 2010) nor will the ability to control pollination with non-mechanical technology alter that cultivation area.

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.*
   In the past 30 years, the public's consumption of corn-based products has more than doubled. Per capita consumption of corn products rose from 12.9 pounds annually per capita in 1980 to 33 pounds in 2008; and corn sweeteners increased from 35.3 pounds annually per capita to 69.2 pounds during that period (USCB, 2011). As of 2012, 88% of the corn cultivated is GE (USDA-NASS, 2012a)). Public health concerns associated with the use of GE corn, such as MON 87427 corn, and GE corn products focus primarily on human and animal (livestock) consumption of GE food and feed commodities.

   A determination of nonregulated status of MON 87427 corn will have no significant environmental impact in relation to the availability of GE, conventional, and organic corn varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 87427 corn is not expected to directly cause an increase in agricultural acreage devoted to hybrid seed corn or commercial corn production, or those corn acres devoted to GE corn cultivation. The availability of MON 87427 corn will not change the cultivation areas for hybrid seed corn or commercial corn production in the U.S. and there are no anticipated changes in the availability of GE and non-GE corn seed or conventional corn varieties on the market or corn produced using organic methods. A determination of nonregulated status of MON 87427 corn will encourage replacement of non-herbicide resistant inbred corn lines for hybrid seed production with the MON 87427 glyphosate resistance trait so that glyphosate applications can be used both for sterilization of male tissues on female inbreds and also managing weeds. Properties of MON 87427 corn are otherwise comparable to properties and expressed genes of existing GE glyphosate resistant corn. Based on the data provided by Monsanto for MON 87427 corn (Monsanto, 2010), APHIS has concluded that the availability of MON 87427 corn would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE corn seed production (USDA-APHIS, 2011). A determination of nonregulated status of MON 87427 corn will not result in an environmentally significant impact on agricultural production, although some increased

efficiency in hybrid seed production practices is expected, and possibly fewer vehicular activities may be needed on seed production fields. Some decrease in summer employment may occur among in-school and part time employees who have been paid for hand detasseling, an activity which will be decreased by adoption of this trait, but any change is likely to occur gradually.

2. *The degree to which the proposed action affects public health or safety.*
Non-GE corn varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for human food or animal feed safety prior to release in the market. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and labeled properly. As a GE product, however, food and feed derived from MON 87427 corn must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who have wished to commercialize a GE variety that would be included in the food supply have completed a consultation with the FDA. In such consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. This process includes: 1) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; 2) an assessment of the protein's potential for digestion; and 3) an evaluation of the history of safe use in food (Hammond and Jez, 2011). FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Several international agencies also review food safety associated with GE-derived food items, including the European Food Safety Agency (EFSA) and the Australia and New Zealand Food Standards Agency (ANZFS). Monsanto has provided the FDA with information on the identity, function, and characterization of the genes for MON 87427 corn, including expression of the gene products. The FDA has completed its early food safety evaluation, and has completed its food and nutrition Biotechnology Consultation (BNF 000126).

   A determination of nonregulated status of MON 87427 corn would have no significant impacts on human or animal health. MON 87427 corn is compositionally similar to currently available corn on the market including others with the introduced trait for glyphosate resistance, having only a differing promoter and intron combination (which themselves result in no new protein production). Based on the FDA's consultation, laboratory data and scientific literature provided by Monsanto (Monsanto, 2010), APHIS has concluded that MON 87427 corn would have no significant 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 adversely impacted by a determination of nonregulated status of MON 87427 corn. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property, 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 87427 corn. MON 87427 corn will be deployed on agricultural land currently suitable for production of seed corn, will replace existing inbred varieties without the glyphosate resistant trait, and is not expected to increase the acreage of corn production. This action would not be likely to encourage land conversion 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 87427 corn 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 87427 corn, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to corn production sites.

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 87427 corn are not highly controversial. Although APHIS received comments opposed to a determination of nonregulated status of MON 87427 corn, 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 is not expected to directly cause an increase in agricultural acreage devoted to corn production, or those acres devoted to GE corn cultivation. The availability of MON 87427 corn 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. A determination of nonregulated status of MON 87427 corn would be another GE corn variety focused on the specialized seed corn market, and is not expected to change the market demands for GE corn seed or corn seed produced using organic methods. A determination of nonregulated status of MON 87427 corn will not result in changes in the current practices of planting, tillage, fertilizer application/use, cultivation, pesticide application use/volunteer control. However, greater efficiency in

seed production would be facilitated by the availability of MON 87427 corn. Management practices and seed standards for production of certified corn seed would not change. The effect of MON 87427 corn on wildlife or biodiversity is not different than that of other glyphosate-resistant crops currently used in agriculture, or other GE or non-GE corn produced in conventional agriculture in the U.S.

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 87427 corn is not expected to directly cause any considerable changes in seed corn production, other than the intended change of removing the need for mechanical and hand detasseling. No increase in agricultural acreage devoted to seed corn production, or those acres devoted to GE corn cultivation is expected. A determination of nonregulated status of MON 87427 corn will not result in large changes in the current practices of planting, tillage, fertilizer application/use, and volunteer control, but some seed corn acres will be managed using practices resembling the majority of conventional GE corn acres. These acres may see greater efficiencies in production of hybrid seed corn. Although cost of seed production could decline, the costs of seed to growers are not expected to decline. Management practices and seed standards for production of certified corn seed would not change. The effect of MON 87427 corn on wildlife or biodiversity is no different than that of other glyphosate-resistant crops currently used in agriculture, or other GE or non-GE corn produced in conventional agriculture in the U.S. As described in Chapter 2 of the EA, well established management practices, production controls, and production practices (GE, conventional, and organic) are currently being used in seed corn production systems (commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce seed corn (GE and non-GE varieties), MON 87427 corn, or produce seed corn using organic methods, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural seed corn production. Additionally, GE corn currently is planted on the majority of corn acres (88% of acreage in 2010) (USDA-NASS, 2012a). Based upon historic trends, conventional seed production practices for GE varieties will likely continue to dominate in terms of acreage with or without a determination of nonregulated status of MON 87427 corn. Given the extensive experience that APHIS, stakeholders, and growers have in dealing with the use of GE corn products and glyphosate-resistant agricultural crops, the possible effects to the human environment from the release of an additional GE corn product with one additional feature for the specialty seed production market are already

well known and understood. While use of this technology would reduce the number of seasonal workers who mechanically detassel corn, the phase-in for the use of this technology would take place gradually, since replacement of inbreds could take between three to eight seasons, and adoption of the technology is not likely to be immediate for all sectors of this large and diverse industry. Efforts to successfully reduce hand labor have continued since the onset of the hybrid seed production industry (Leidy, 2009), . 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 for MON 87427 corn 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 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 87427 corn. 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 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 enough 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 part 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. A cumulative effects analysis is provided in Chapter 5 of the EA. One issue examined was whether this action combined with a previous petition approval for another non-mechanical detasseling process, Seed Production Technology corn (DuPont-Pioneer), would have impact on employment of detasseling crews. APHIS concluded that the integration of the technologies into the respective companies' hybrid seed processes would be a gradual one, likely each occurring in different locales, and the reduced hiring of temporary workers would not be significant. An impact to the considerably larger employment of permanent agricultural workers was also deemed unlikely. In the event APHIS reaches a determination of nonregulated status of MON 87427 corn, APHIS would no longer have regulatory authority over this corn. In the event of a determination of nonregulated status of MON 87427 corn, 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 87427 corn when added to 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 historic resources.*
   A determination of nonregulated status of MON 87427 corn will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on tribal lands are only conducted at the tribe's request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of MON 87427 corn would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historic resources. This action is limited to a determination of nonregulated status of MON 87427 corn. 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 87427 corn is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used. Such agricultural activities are not likely to result in effects on the use and enjoyment of a historic property when conducted under this action, and consequently do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could results 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 87427 corn 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 the 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 a determination of nonregulated status of MON 87427 corn 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 87427 corn, APHIS has determined that a determination of nonregulated status of MON 87427 corn would have no effect on Federally listed TES and species proposed for listing, or on 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 87427 corn is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87427 corn is a response that is

consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. 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 87427 corn 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 87427 corn, the continued regulated status of MON 87427 corn 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 87427 corn will not have any significant environmental effects.

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Biotechnology Regulatory Services

9/25/2013

Date

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Addendum I. Responses to Public Review Comments.

Issue 1—Constituents of GE compared to non-GE Corn

The constituents formaldehyde and glyphosate as well as others within GE corn ears derive from a data table in the unpublished report supplied by Profit Pro LLC, and is broadly cited by many internet sites. The results are inconsistent with what APHIS understands about corn constituents, and cannot be reconciled with any other findings (Folta, 2013); no experimental details of the analysis were presented. Formaldehyde has not been detected in any corn, and it is not legal to spray glyphosate so late in development that any residue would be found in corn ears. APHIS disagrees that there is any need to assess these constituents in corn. The agricultural nutrient company that released the table has deleted the report from their website.

Issue 2—GR corn and appearance of fungal toxins

That higher *Aspergillus flavus* (a fungus) propagules and aflatoxin levels are measured in glyphosate resistant corn than in "conventional corn," was not a conclusion made by Reddy et al. (2007). While in some years and some trials this result was obtained, the variability of the results allowed the authors to make no conclusions other than that "altered populations of *A. flavus* or higher aflatoxin concentrations in corn grain were due to indirect effects of the GR cropping system." APHIS disagrees that there is any evidence for consistent differences in GR corn with respect to adventitious fungal toxins or soil propagules of *Aspergillus.*

Issue 3. Pollinators and herbicide effects

Effects on pollinators should be assessed, and EPA does require toxicity testing on honeybees of herbicides and also of the proteins expressed in GE plants for herbicide resistance (EPA, 2011); however, there are no effects on honeybees (Giesy et al., 2000; Monsanto, 2010). Effects on honeybee pollinators should in general be indicative of effects on other pollinators. EPA

guidance documents assert that all data from university sources about pollinator impacts, including native pollinators, should be considered by the Registration Division when providing pesticide label requirements (EPA, 2011).

Issue 4. Use of plain and nontechnical language for NEPA documents

The language used in the EA certainly is focused on agricultural production and the terms of the industry but an attempt should be made to use language that is readable to those without technical backgrounds. APHIS doesn't disagree with the commenter, and will continue to use editors who will make an effort to assure that APHIS-BRS writing is comprehensible to the average reader.