

**NATIONAL ENVIRONMENTAL POLICY ACT DECISION  
AND  
PRELIMINARY FINDING OF NO SIGNIFICANT IMPACT**

**Monsanto Company  
Dicamba- and Glufosinate-Tolerant MON 87419 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 (CEQ) regulations implementing NEPA, and the USDA-APHIS NEPA-implementing regulations and procedures (7 Code of Federal Regulations (CFR) part 372). This NEPA decision document, a preliminary 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 a draft 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 No. 15-113-01p) by Monsanto Company, St. Louis, Missouri (referred to as "Monsanto" in this document), for corn referred to as 87419 corn (referenced in this document as "MON 87419 corn"), genetically engineered for resistance<sup>1</sup> to the herbicides dicamba and glufosinate (Monsanto 2015a).

MON 87419 corn<sup>2</sup> was genetically engineered to be resistant to dicamba by expressing a mono-oxygenase gene (*dmo*) from *Stenotrophomonas maltophilia* that rapidly demethylates dicamba, rendering it inactive. The same DMO protein is found in MON 87708 soybean and MON 88701

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<sup>1</sup> "Resistance" to herbicides is defined by the Herbicide Resistance Action Committee (HRAC) as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type. Several technologies are available that can be used to develop herbicide resistance in plants including classical breeding, tissue culture, mutagenesis and genetic engineering. "Tolerance" is distinguished from resistance and defined as HRAC. (2013). "Guideline to the management of herbicide resistance." from <http://www.hracglobal.com/pages/ManagementofHerbicideResistance.aspx>. the inherent ability of a plant to survive and reproduce following exposure to an herbicide treatment. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. Throughout the draft EA, and this preliminary FONSI, USDA-APHIS has used the terms "resistance" and "tolerance" consistent with the definitions of the HRAC. It should be noted however, that different terms for the same concept may be used interchangeably in some instances. In its petition to USDA-APHIS, Monsanto used the term "herbicide tolerant" throughout its documentation. This terminology can be considered synonymous with "herbicide-resistant" (HR) as used in the draft EA and this preliminary FONSI.

<sup>2</sup> The terms, "maize" and "corn" are used interchangeably throughout this document for crops and products derived from *Zea mays*.

cotton, both of which have been deregulated by USDA-APHIS (USDA-APHIS 2014a) and completed food safety consultations with the Food and Drug Administration (FDA; FDA BNF 000125 and BNF 000135, respectively) (FDA 2011, FDA 2013b). Additionally, MON 87419 corn contains the phosphinothricin N-acetyltransferase (*pat*) gene from *Streptomyces viridochromogenes* that expresses the PAT protein and provides resistance to the herbicide glufosinate. The PAT protein is produced in numerous deregulated commercial soybean, canola, and corn products; and the safety of PAT proteins present in biotechnology-derived crops has been extensively assessed. Expression of the dicamba and glufosinate resistance traits in MON 87419 corn allows growers to make post-emergent applications of herbicide products containing dicamba and glufosinate as the active ingredients (a.i.) for broad-spectrum weed control (Monsanto 2015a).

The draft EA was prepared to specifically evaluate the impacts on the quality of the human environment<sup>3</sup> that may result from a determination of nonregulated status of MON 87419 corn. The draft EA assessed alternatives related to a determination of nonregulated status of MON 87419 corn and analyzed the potential environmental and socioeconomic impacts that may result from the proposed action and the alternatives.

### **Regulatory Authority**

“Protecting American Agriculture” is the basic mission 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 public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of GE varieties) can increase farm income, and provide benefits to the environment and consumers.

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 (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 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 required 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 APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

APHIS is authorized to regulate GE organisms that are plant pests or are potential plant pests

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<sup>3</sup> Under NEPA regulations, the “human environment” includes “the natural and physical environment and the relationship of people with that environment” (40 CFR §508.14).

under the plant pest provisions of the Plant Protection Act (PPA) of 2000, as amended (7 USC §§ 7701 *et seq.*), to ensure that they do not pose a plant pest risk as defined in 7 CFR part 340.

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 foods for human consumption and animal feeds, including those that are genetically engineered or contain components and/or ingredients derived using genetic engineering. 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). 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 GE foods.

The EPA regulates pesticides, including plant-incorporated protectants, under the Federal Insecticide, Fungicide, and Rodenticide Act. 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 FFDCA and regulates certain biological control organisms under the Toxic Substances Control Act. 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 mission of APHIS Biotechnology Regulatory Services (BRS) is to protect America's agriculture and environment using a dynamic, science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 CFR part 340 were promulgated pursuant to authority under the Federal Plant Pest Act. This authority has since been replaced by the plant pest provisions of the PPA of 2000, as amended (7 United States Code (U.S.C.) 7701-7772), which allows the Agency to 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 under 7 CFR part 340 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 7 CFR part 340 if the Administrator determines the GE organism is a plant pest or has reason to believe is a plant pest. An individual may petition APHIS for a determination 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 PPA or the regulations at 7 CFR part 340. Under §340.6(c) (4), petitioners are required to provide information 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 PPA 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 PPA 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 87419 corn. When a petition for nonregulated status is submitted, APHIS must determine if the GE organism is likely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment (PPRA), that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to regulation under 7 CFR part 340.

### **MON 87419 Corn**

MON 87419 corn is currently regulated under 7 CFR part 340. Interstate movement and confined field releases of MON 87419 corn were conducted under APHIS authorizations since 2011. Field releases were conducted in diverse growing regions within the United States that include Alabama, Arizona, Arkansas, California, Hawaii, Iowa, Illinois, Indiana, Kansas, Louisiana, Michigan, Missouri, Mississippi, Nebraska, North Carolina, Ohio, Pennsylvania, Puerto Rico, South Dakota, and Wisconsin (Monsanto 2015a). Details about and data resulting from these field trials are described in the MON 87419 corn petition (Monsanto 2015a), and were analyzed for plant pest risk in a PPRA (USDA-APHIS 2015b).

### **Coordinated Framework Review**

#### ***Food and Drug Administration***

MON 87419 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 (FDA 1992). It is genetically engineered for resistance to the herbicides dicamba and glufosinate. 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" (FDA 2006). These recommendations established voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties, including GE plants, intended for use as food. Early food safety evaluations are designed to ensure that potential food safety issues related to a new protein in a new plant variety are addressed early in development.

Monsanto submitted a food/feed safety and nutritional assessment summary document to FDA on May 22, 2015 (Monsanto 2015b). At this time, Monsanto has not yet received a completed consultation letter from the FDA. The DMO and PAT proteins (both naturally occurring in the environment) expressed in MON 87419 corn have been previously reviewed and approved for commercial use by the FDA and USDA (FDA 2011, FDA 2013b, FDA 2013a, FDA 2013c, FDA 2014, USDA-APHIS 2014c, USDA-APHIS 2014d).

#### ***Environmental Protection Agency***

Prior to registration for a new use for a new or previously registered pesticide, EPA must determine through a comprehensive risk analysis that the pesticide does not cause unreasonable adverse effects on humans, the environment, and nontarget species when used in accordance

with label instructions. EPA must also approve the language used on the pesticide label in accordance with Data Requirements for Pesticides (40 CFR part 158).

Dicamba was first registered in 1967 and glufosinate in 1994 for use as pesticides (herbicides) in the United States (EPA 2009b, BASF 2010). The EPA completed the reregistration process for dicamba and a Registration Eligibility Decision (RED) was issued in 2006. It was subsequently amended in 2008 and 2009 (EPA 2009a). The EPA assessed the safety of using glufosinate (as an active ingredient) to control broadleaf weeds in a 2008 risk assessment (EPA 2008). EPA's human health and ecological risk assessments for the registration review of glufosinate is currently underway [Federal Register Volume 78, Number 44 (Wednesday, March 6, 2013)]. Both pesticides, when used as required by label specifications, have been determined to not pose unreasonable adverse effects on the environment and a reasonable certainty of no harm to humans.

Dicamba is currently labeled for preplant and postemergence use on corn, with less than 7 percent of maize acreage in 2014 treated with dicamba (USDA-NASS 2015b). To allow for a wider window of application of dicamba on MON 87419 maize, Monsanto will petition EPA to change the maximum use rate of dicamba in corn from 0.5 lbs to 1.0 lbs acid equivalent (a.e.) per acre for preemergence applications and up to two applications of 0.5 lbs a.e. of dicamba per acre for postemergence applications through the V8 growth stage (i.e., collar of eighth leaf visible) or corn height of 30 inches, whichever comes first (Monsanto 2015b). The combined maximum annual application rate of dicamba on MON 87419 would be 2.0 lbs a.e. dicamba per acre per year (Monsanto 2015b). EPA's assessment will analyze risks to nontarget organisms to determine if the label is sufficient to meet EPA's standards for registration: "reasonable certainty of no harm to humans" and "no unreasonable adverse effects on the environment." If these standards are not met, EPA will apply appropriate risk mitigation strategies and propose label modifications to address the specific concerns, if practicable.

MON 87419 corn is similar to currently available glufosinate-resistant corn varieties. In 2014, glufosinate was used on 2 percent of corn acres (USDA-NASS 2015a). Monsanto indicates that there will be no change in the current labeled use pattern of glufosinate on MON 87419 corn (Monsanto 2015a).

### **Scope of the Environmental Analysis**

Determination of nonregulated status of MON 87419 corn would allow for new plantings of MON 87419 corn anywhere in the United States, however, APHIS primarily focused the environmental analysis on those geographic areas that currently support corn production. A determination of nonregulated status of MON 87419 corn is not expected to increase corn production by its availability alone, or when accompanied by other factors, nor should it cause an increase in overall GE-corn acreage (USDA-APHIS 2015a). In the United States, corn is cultivated in all states to some extent, with over 90.6 million acres of corn planted in 2014 (USDA-NASS 2015b). The majority of production occurs in the Corn Belt, generally defined as including Illinois, Iowa, Indiana, southern and western Minnesota, eastern South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri. The leading corn-producing states of Illinois, Iowa, and Nebraska account for approximately 40 percent of the annual U.S. harvest (USDA-NASS 2015b). Acreage used for U.S. corn production is

expected to remain steady over the next decade, at approximately 89 million acres annually (Westcott and Hansen 2015).

### **Relationship to Other Environmental Documents**

USDA-APHIS prepared a Final EIS (FEIS) for the nonregulated status of dicamba-resistant MON 87708 soybean and dicamba-resistant MON 87701 cotton (USDA-APHIS 2014a). APHIS published a notice (79 FR 73890) advising the public of the determinations of nonregulated status and availability of the Record of Decision (ROD) on December 12, 2014. The draft EA is tiered to that FEIS. Pertinent and current information available in the FEIS has been incorporated by reference into the draft EA and this decision document.

USDA-APHIS prepared a Final FEIS for the nonregulated status of 2,4-D- and ACCase inhibitor-resistant DAS 40278-9 corn; 2,4-D- and glufosinate-resistant DAS 68416-4 soybean; and 2,4-D-, glufosinate- and glyphosate-resistant DAS 44406-6 soybean (USDA-APHIS 2014b). APHIS published a notice (79 FR 56555-56557) advising the public of the determinations of nonregulated status and availability of the ROD on September 22, 2014. The draft EA is tiered to that FEIS. Pertinent and current information available in the FEIS has been incorporated by reference into the draft EA and this decision document.

### **Public Involvement**

On August 13, 2015, APHIS published a notice in the *Federal Register*, (80 FR 48489-90, Docket No. APHIS-2015-0048) announcing the availability of the MON 87419 corn petition for a 60-day public review and comment period. Comments were required to be received on or before October 13, 2015. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 21 comment responses were received from various groups and individuals during the comment period. Some of the submissions to the docket contained multiple attached comments gathered by organizations from their members. Contained within the 21 submissions was a single public comment with a total of 23,867 signatures against the petition. The majority of the comments expressed a general disapproval of the planting and use of GE crops. The submitted comments may be viewed in the regulations.gov APHIS docket:

<http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0048>

No new issues, alternatives, or substantive information new to USDA were identified in any of the comments received by APHIS.

### **Major Issues Addressed in the Draft EA**

Issues discussed in the draft EA were identified by considering public concerns and issues described in public comments for the petition for nonregulated status of MON 87419 corn and other environmental assessments of GE organisms. Issues identified in lawsuits, and those submitted by various stakeholders were also considered. These issues, including those regarding the agricultural production of corn using various production methods, including conventional and organic; the development of and costs associated with managing herbicide-resistant weeds; obtaining authorizations from key foreign markets prior to deregulation; and the food/feed safety of GE plants, were addressed to analyze the potential environmental impacts of MON

87419 corn. The draft EA describes the alternatives considered and evaluated using the issues identified. The alternatives encompassed the following topics that were identified as important to the scope of the analysis (40 CFR 1508.25):

**Agricultural Production:**

- Areas and Acreage of Corn Production
- Agronomic Practices
- Organic and Specialty Corn Production

**Environmental Resources:**

- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Soil Microorganisms
- Biological Diversity
- Gene Movement

**Human Health:**

- Public Health
- Worker Health and Safety

**Animal Health:**

- Animal Feed
- Livestock Health

**Socioeconomics:**

- Domestic Economic Environment
- Trade Economic Environment

**Alternatives that Were Fully Analyzed**

The draft EA analyzes the potential environmental consequences of a determination of nonregulated status of MON 87419 corn. To respond favorably to a petition for nonregulated status, USDA-APHIS must determine that MON 87419 corn is unlikely to pose a plant pest risk. Based on its preliminary PPRA (USDA-APHIS 2015b), USDA-APHIS made a determination that MON 87419 corn is unlikely to pose a plant pest risk. APHIS determined that MON 87419 corn is no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA. Two alternatives were evaluated in the draft EA: (1) no action and (2) a determination of nonregulated status of MON 87419 corn. APHIS has assessed the potential for environmental impacts for each alternative in the “Environmental Consequences” section of the draft EA.

**No Action: Continuation as a Regulated Article**

Under the No Action Alternative, USDA-APHIS would deny the petition. MON 87419 corn and progeny derived from MON 87419 corn 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 87419 corn and measures to ensure physical and reproductive confinement would continue to be applied. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MON 87419 corn.

This alternative is not the Preferred Alternative because APHIS concluded through its preliminary PPRA that MON 87419 corn is unlikely to pose a plant pest risk (USDA-APHIS 2015b). 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 87419 Corn Is No Longer a Regulated Article**

Under this alternative, MON 87419 corn and progeny derived from this event would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87419 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2015). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87419 corn and progeny derived from this event.

Based on the Agency's conclusion that MON 87419 corn is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87419 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 of the Coordinated Framework. Under this alternative, growers may have future access to MON 87419 corn and progeny derived from this event if the developer decides to commercialize MON 87419 corn. 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 PPA.

### **Alternatives Considered but Rejected from Further Consideration**

APHIS assembled a list of alternatives that might be considered for MON 87419 corn. APHIS evaluated these alternatives according to the Agency's authority under the plant pest provisions of the PPA, 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 87419 corn. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below with the specific reasons for rejecting each.

#### **Prohibit Any MON 87419 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 87419 corn, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate because MON 87419 corn is unlikely to pose a plant pest risk (USDA-APHIS 2015b).



In enacting the Plant Protection Act, Congress found that (7 U.S. C. §7701(4)): "decisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science".

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: "Decisions 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 its preliminary PPRA (USDA-APHIS 2015b) and the scientific data evaluated therein, USDA-APHIS concluded that MON 87419 corn is not likely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87419 corn.

#### Approve the Petition in Part

The regulations at 7 CFR part 340.6(d)(3)(i) state that USDA-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 events described in a petition. Because USDA-APHIS has concluded that MON 87419 corn is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the petition only in part.

#### Isolation Distance between MON 87419 Corn and Non-GE Maize 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 87419 corn from non-GE maize production. However, because APHIS has concluded that MON 87419 corn is unlikely to pose a plant pest risk (USDA-APHIS 2015b), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of MON 87419 corn based on the location of production of non-GE corn in organic production systems in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in the Agency's preliminary PPRA for MON 87419 corn, there are no geographic differences associated with any identifiable plant pest risks for MON 87419 corn (USDA-APHIS 2015b). Therefore, to be consistent with this determination, this alternative was rejected and not analyzed in detail. APHIS has concluded that MON 87419 corn does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area (USDA-APHIS 2015b). Therefore, such an alternative would not be consistent with the APHIS statutory authority under the plant pest provisions of the PPA, the regulations in 7 CFR part 340 and the biotechnology regulatory policies described 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 PPA. However, individuals might choose on their own to geographically isolate their non-GE corn production systems from MON 87419 corn or to use isolation distances and other management practices to minimize gene movement between cornfields. Information to assist growers in making informed management decisions for on MON 87419 corn, including hybrid stacks, is available from Association of Official Seed Certifying Agencies (AOSCA 2015).

#### Requirement of Testing for MON 87419 Corn

During 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. USDA-APHIS notes that there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Because MON 87419 corn also does not pose a plant pest risk (USDA-APHIS 2015b), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR part 340, and the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for MON 87419 corn would not meet the USDA-APHIS purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

#### Environmental Consequences of APHIS' Selected Action

The draft 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 draft EA.

## Summary of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
<b>Meets Purpose, Need and Objectives:</b>	<b>No</b>	<b>Yes</b>
Unlikely to pose a plant pest risk:	Satisfied by regulated field trials.	Satisfied by risk assessment (USDA-APHIS 2015b).
<b>Management Practices</b>		
Areas and Acreage of Corn Production:	90% of U.S. corn is GE; 70% is stacked with HR and IR traits. Market economics is the primary factor influencing U.S. corn acreage and areas of production.	Acreage of plantings likely unchanged. The nonregulated varieties might replace other corn varieties currently grown in the United States. Locations of corn production are expected to remain unchanged.
Agronomic Practices:	Weeds resistant to glyphosate and other herbicides will continue to increase. As HR weeds become more prevalent, growers are expected to shift to more costly weed control measures or other HR crops that are economically viable. Some potential exists for use of increased conventional tillage or reduced conservation tillage. Growers of corn not resistant to herbicides) are likely to continue the use of herbicides.	Use of dicamba and glufosinate in corn cropping systems is expected to increase, but changes in dicamba use are contingent on EPA's decision to approve the new uses of dicamba on these crop varieties. More efficient weed control is expected to reduce the need for more complex herbicide combinations to control resistant weeds.  Conventional growers are likely to continue use of herbicides and retain conservation tillage practices if resistant weeds do not develop over time.
Organic Farming:	Planting of organic corn is not likely to change.	Planting of organic corn is unlikely to change.
Use of GE Crops	Planting of existing varieties of GE HR crops is likely already at a maximum, because the percentage of these crops has not been changing in recent years.	Planting of new GE HR corn will likely remain the same or increase only slightly as multiply-resistant weeds increase.
<b>Physical Environment</b>		
Soil Quality:	One strategy for dealing with herbicide-resistant weeds is to increase tillage and cultivation, which can disrupt conservation tillage patterns.	A new option, dicamba resistant corn, would provide growers an additional strategy for weed control.

<b>Attribute/Measure</b>	<b>Alternative A: No Action</b>	<b>Alternative B: Determination of Nonregulated Status</b>
Water Resources:	Increased tillage to manage HR weeds may be one option in corn in some regions of the U.S. This could increase evaporative water loss and demand for water resources by irrigation, and cause increased soil erosion accompanied by diminished water quality from sedimentation.	MON 87419 corn will support continued or increased use of current conservation tillage practices in the short term.  In the long term, development of more HR weeds may be accompanied by increased tillage with negative impacts (as described in the No Action Alternative).
Air Quality:	Increased use of herbicides may occur to manage HR weeds. This would increase drift from herbicides that would reduce air quality.  Increased tillage to manage HR weeds is one option in the SE regions of the United States for cropping systems that include corn. This could reduce air quality from increased air particulates and exhaust from farm equipment.	Overall use of herbicides will remain the same or be reduced by better management of HR weeds. Drift from herbicides will remain the same or be reduced, resulting in no change or improved air quality.  Use of MON 87419 corn is expected to stabilize current tillage. This will be accompanied by a reduction in airborne particulates and exhaust emissions, which will increase air quality.
Climate Change:	Increased tillage to manage HR weeds (as in a limited portion of the United States) is an option in cropping systems that include corn. This would increase the release of greenhouse gases (primarily carbon dioxide and methane).	Use of MON 87419 corn is expected to stabilize current conservation tillage. This will be accompanied by averting the release of additional greenhouse gases (primarily carbon dioxide and methane).
<b>Biological Resources</b>		
Animal Communities:	Cultivated corn currently provides limited food and habitat for wildlife in regular cropping situations.	Expected to be the same as No Action because toxicological studies and studies of allergenicity of the added traits did not reveal any impacts on animals.

<b>Attribute/Measure</b>	<b>Alternative A: No Action</b>	<b>Alternative B: Determination of Nonregulated Status</b>
Plant Communities:	The most important plant communities interacting with corn production are competing weeds. Production practices including herbicides are used to manage weeds. Under the No Action Alternative, selection for herbicide-resistant weeds will continue, some with resistance against multiple herbicides that are used.	<p>Selection pressure to develop dicamba and glufosinate resistance in weed populations will increase, including the potential for development of weeds with multiple resistance to more than one herbicide mode of action.</p> <p>MON 87419 corn is not a potential plant pest because it does not compete with native plant species and lacks the potential to do so, so will not adversely impact natural plant communities.</p>
Gene Movement and Weediness:	Gene flow from corn to wild plants does not occur; Volunteers can easily be controlled with herbicides.	Many herbicide options exist for control of various HR volunteer corn varieties including MON 87419 corn.
Soil Microorganisms:	Soil organisms provide for organic material breakdown, nutrient transformations, soil structure, and supporting or inhibiting plant pathogens.	Traits of GE corn have not consistently been shown to support changes in soil microbial diversity or abundance.
Biological Diversity:	<p>Cropping systems generally are not expected to change, so biodiversity in regions where corn is produced will not change.</p> <p>Herbicide use may decrease weed prevalence or modify the weed species complex in some regions. These changes could modify the species complex of organisms that rely on these weeds as a food source or habitat.</p>	<p>Crop biodiversity is not expected to substantially change relative to the No Action Alternative.</p> <p>Use of MON 87419 corn will allow for stable levels of conservation tillage in areas with weeds resistant to herbicides such as glyphosate, which will not decrease biodiversity and might increase it.</p> <p>Use of MON 87419 corn will likely not require increased overall herbicide use, which will not reduce biodiversity and might increase it. Selection pressure for dicamba and glufosinate resistance in weed populations may modify the weed species complex in some regions, which might modify the species complex of organisms that rely on these weeds as a food source or habitat.</p> <p>Selection pressure for dicamba and glufosinate resistance in weed populations may modify the weed species complex in some regions, which might modify the species</p>
<b>Human and Animal Health</b>		

<b>Attribute/Measure</b>	<b>Alternative A: No Action</b>	<b>Alternative B: Determination of Nonregulated Status</b>
Risk to Human Health:	<p>Corn varieties are associated with all the normal risks of agricultural production.</p> <p>The EPA label use restrictions are designed to protect humans during herbicide use in corn cropping systems to achieve a standard of a “reasonable certainty of no harm”.</p>	<p>MON 87419 corn does not present any additional risks to workers.</p> <p>The revised EPA label use restrictions for corn herbicides will be designed to achieve the same level of human health and safety as those that currently exist for herbicide use with non-GE varieties.</p>
Risk to Animal Feed:	Risks of new gene expression in GE crops are assessed through FDA biotechnology consultations; EPA provides tolerances for genes and pesticides in crops and their derivative commodities.	The DMO protein is not allergenic, has no toxicity, and an orthologue has been assessed for safety by FDA. The PAT protein has already received a tolerance in several other GE crops.
<b>Socioeconomic Environment</b>		
Domestic Economic Environment:	The percentage of GE varieties in the market is not expected to change.	MON 87419 corn is not expected to change the overall percentage of GE varieties in the market; other auxinic class herbicide-resistant corn varieties will also be available, as will corn varieties resistant to several other herbicides.
Trade Economic Environment:	The U.S. will continue to be an exporter of GE corn.	Monsanto has submitted or is planning to submit requests for regulatory approvals in the main export markets for these varieties of corn. The U.S. will continue to be an exporter of GE corn. MON 87419 corn is not substantially different from those varieties already in commerce.
<b>Other Regulatory Approvals</b>		
FDA	All products of biotechnology that are offered in the US have undergone a consultation with the FDA.	Monsanto submitted a food and feed safety document to FDA as part of a biotech consultation.
EPA	EPA must approve all uses of herbicides and all pesticide residues on food and feed.	Application of glufosinate and dicamba on corn is already a use registered by EPA. Approval of an increase in the maximum application rate of dicamba on corn is being sought.
<b>Compliance with Other Laws</b>		
CAA, CWA, EOs:	All presently commercialized GE corn varieties have complied with existing EOs.	MON 87419 corn will be in compliance with existing EOs.

## **Finding of No Significant Impact**

APHIS' analysis in the draft EA indicates that there will not be any significant impacts, individually or cumulatively, on the quality of the human environment as a result of this action. This NEPA determination is based on the following context and intensity factors as required by NEPA regulations (40 CFR 1508.27).

*Context* - The term "context" identifies potentially affected resources, the locations, and the specific circumstances and conditions in which the environmental impacts may occur. This action has the 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 is grown in all 48 states of the conterminous continental United States. The majority of production occurs in the Corn Belt, generally defined as including Illinois, Iowa, Indiana, southern and western Minnesota, eastern South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri. The leading corn-producing states of Illinois, Iowa, and Nebraska account for approximately 40 percent of the annual U.S. harvest (USDA-NASS 2015b).

In 2014, 89 percent of the 87.6-million-acre U.S. corn crop was produced with GE herbicide-resistant corn and 80 percent with insect-resistant corn varieties (Fernandez-Cornejo, Wechsler et al. 2014). Stacked-trait varieties with both IR and HR traits accounted for 76 percent of the 2014 crop (USDA-ERS 2015). A determination of nonregulated status of MON 87419 corn is not expected to directly affect production trends or cause an increase in the agricultural acreage devoted to corn production in the United States because it is not substantially different from existing corn, and will not likely cause changes in the economic costs of that production. Consequently, there are no anticipated changes in the availability of GE- and non-GE corn varieties on the market.

Although a determination of nonregulated status of MON 87419 corn would allow for new plantings of MON 87419 corn to occur anywhere in the United States, APHIS' environmental analysis included the geographic areas that currently support corn production. A determination of nonregulated status of MON 87419 corn is not expected to increase corn production, or result in an increase in overall GE corn acreage or cultivation in new regions.

*Intensity* – Intensity is a measure of the degree or severity of an impact based upon 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 87419 corn will have no significant environmental impact on the availability of GE, conventional or organic corn varieties. As discussed in Chapter 4 of the draft EA, a determination of nonregulated status of MON 87419 corn is not expected to directly result in an increase in the overall U.S. acreage devoted to corn production or the acreage of GE-corn. The availability of MON 87419 corn will not change the areas in the United States where corn is cultivated, and there are no anticipated changes in the availability of GE and non-GE corn varieties in the market. A determination of nonregulated status of MON 87419 corn would add another GE corn variety to the corn market, but is not expected to change the market demands for GE corn or corn produced using organic methods.

APHIS analyzed the data provided by Monsanto for MON 87419 corn (Monsanto 2015a) and has concluded in the draft EA that the availability of MON 87419 corn will not alter the agronomic practices, locations of corn production, or the production methods and quality characteristics of conventional and GE corn seed production. The introduction of MON 87419 corn provides an alternative corn variety with resistance to the herbicides dicamba and glufosinate.

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

A determination of nonregulated status of MON 87419 corn would have no significant impacts on human or animal health. Compositional tests conducted by the petitioner indicate that MON 87419 corn is compositionally similar to other commercially available GE corn varieties (Monsanto 2015a). Monsanto initiated a consultation process with FDA for the commercial distribution of MON 87419 corn and submitted a safety and nutritional assessment of food and feed derived from MON 87419 corn to the FDA (Monsanto 2015b). At this time, Monsanto has not yet received a completed consultation letter from the FDA. However, the DMO and PAT proteins (both naturally occurring in the environment) expressed in MON 87419 corn have been previously reviewed and approved for commercial use by the FDA and USDA, and have a history of safe use in several commercially available soybean, canola, cotton, and corn products. Prior agency reviews of the DMO and PAT proteins, based on research from scientific literature, concluded that consumption of the PAT and DMO proteins pose negligible risk to human or animal health (FDA 2011, FDA 2013b, FDA 2013a, FDA 2013c, FDA 2014, USDA-APHIS 2014c, USDA-APHIS 2014d). Based on FDA's previous consultations on these proteins, laboratory data and scientific literature provided by Monsanto (Monsanto 2015a), and safety data available on other similar herbicide-resistant products, APHIS has concluded that MON 87419 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, which would be adversely impacted by a determination of nonregulated status for MON 87419 corn. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance or 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 87419 corn. The product will be planted on agricultural land currently suitable for production of corn, will replace existing varieties, and is not expected to increase the acreage of corn production. This action would not convert nonagricultural land 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 87419 corn, including the use of EPA-registered pesticides. The applicant's adherence to EPA label use restrictions for the pesticides used will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of MON 87419 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 impacts on the quality of the human environment following a USDA determination of nonregulated status for MON 87419 corn are not highly contested by scientists or those who may be in a position to supply substantive information. Although APHIS received public comments opposed to a determination of nonregulated status of MON 87419 corn, this action is not likely to be highly controversial in terms of size, nature or impacts on the natural or physical environment. As discussed in Chapter 4 of the draft EA, a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to corn production in general, nor acreage devoted to GE corn cultivation. The availability of MON 87419 corn will not change cultivation areas for corn production in the United States, and there are no anticipated changes to the availability of non-GE- and GE-corn varieties on the market. A determination of nonregulated status of MON 87419 corn would add another GE-corn variety to the conventional corn market and is not expected to change the market demands for GE corn or corn produced using organic methods. A determination of nonregulated status of MON 87419 corn will not change current practices for planting, tillage, fertilizer application or use, cultivation, pesticide application or use, or volunteer control. Management practices and seed standards for production of certified corn seed would not change. The impacts of MON 87419 corn on wildlife or biodiversity is no different than that of other GE corn currently used in agriculture, or other GE or non-GE corn produced in conventional agriculture in the United States. During the public comments period, APHIS received comments opposing a determination of nonregulated status of MON 87419 corn. No new issues, alternatives or substantive new information were identified in any of the comments received. APHIS has addressed the substantive comments in the response to public comments document attached to this preliminary 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 draft EA, the possible impacts on the human environment are well understood. The effects of the proposed determination of nonregulated status are based on the preponderance of evidence provided by Monsanto and by USDA's assessment of potential risk through consideration of experimental evidence and factual information in the scientific literature. USDA does not conclude that risks to the natural or physical environment are substantive ones. The effects on the natural and physical environment of the proposed activities are not highly uncertain and do not involve unique or unknown risks. As discussed in Chapter 4 of the draft EA, a determination of nonregulated status of MON 87419 corn is expected to neither directly cause an increase in agricultural acreage devoted to corn production nor increase acreage devoted to GE-corn cultivation. A determination of nonregulated status of MON 87419 corn will not result in changes in the current practices of planting, tillage, fertilizer application/use, pesticide application/use or volunteer control. Management practices and seed standards for production of certified corn seed would not change. The impacts of MON 87419 corn on wildlife or biodiversity is neither different from that of other GE crops currently used in agriculture, nor that of other GE or non-GE corn produced in conventional agriculture in the United States. As described in Chapter 2 of the draft EA, well-established management practices, production controls, and production practices (GE, conventional, and organic) are

currently being used in commercial corn crop and see production systems in the United States. Therefore, it is reasonable to assume that farmers who produce conventional corn (GE and non-GE varieties), or produce corn using organic methods, will continue to use these reasonable, commonly-accepted, best-management practices for their chosen systems and varieties during agricultural corn production. GE corn is also currently planted on the majority of U.S. corn acres. Based upon historic trends, conventional production practices that use GE varieties will likely continue to prevail in terms of acreage with or without a determination of nonregulated status of MON 87419 corn. Given the extensive experience that APHIS, stakeholders, and growers have with the use of GE corn products, the possible impacts to the human environment from the cultivation of 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 for MON 87419 corn would not establish a precedent for future actions with significant impacts, nor would it 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 PPA 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 87419 corn. When a petition for nonregulated status is submitted, APHIS must determine if the GE organism is unlikely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment, that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*

No significant cumulative impacts were identified through this assessment. The draft EA discussed cumulative impacts 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 draft EA. In the event APHIS reaches a determination of nonregulated status of MON 87419 corn, APHIS would no longer have regulatory authority over this corn and would no longer regulate it. APHIS has not identified any significant impact on the environment that may result from the incremental impact of a determination of nonregulated status of MON 87419 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 87419 corn will not adversely impact cultural resources on tribal properties. Any farming activities that may be used 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 87419 corn would not impact 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 87419 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. Adherence to EPA-label-use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of MON 87419 corn is a decision that will not directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act (NHPA). In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas where they are used that could result in impacts on the character or use of historic properties. For example, there is potential for audible impacts 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 impacts 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 impacts. These cultivation practices are also being conducted currently throughout the corn production regions. The cultivation of MON 87419 corn does not inherently change any of these agronomic practices in way that would cause any 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 draft EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of MON 87419 corn on federally-listed threatened and endangered species (TES), species proposed for listing, and designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. After reviewing possible effects on listed species and resources from exposure to MON 87419 corn, APHIS has concluded MON 87419 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 APHIS has concluded that MON 87419 corn is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87419 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 draft EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the draft EA are best addressed by selecting Alternative 2 (Determination that MON 87419 Corn is No Longer a Regulated Article). This alternative meets the APHIS purpose and need to allow the safe development and use of GE organisms consistent with the plant pest provisions of the PPA.

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 GE organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with MON 87419 corn, the continued regulated status of MON 87419 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 87419 corn will not have any significant environmental impacts.

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U.S. Department of Agriculture

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Date

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