NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

Monsanto Company
Corn Rootworm-Protected and Glyphosate-Tolerant MON 87411 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 Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS No. 13-290-01p) by Monsanto Company, St. Louis, Missouri (referred to as "Monsanto" in this document) for Monsanto 87411 Maize (referenced in this document as "MON 87411 Maize"), genetically engineered for resistance[1] to the herbicide, glyphosate, and to control corn rootworms.

[1] "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 by (HRAC. 2013. Guideline to the management of herbicide resistance. Herbicide Resistance Action Committee (HRAC) 2013. http://www.hracglobal.com/pages/ManagementofHerbicideResistance.aspx) as 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 EA, and this 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) used in the EA and this FONSI.

MON 87411 Maize[2] contains three GE modes-of-actions (MOAs): two for insect pest protection; one for resistance to the herbicide, glyphosate. The insect protection mechanisms are designed to control corn rootworms (CRWs), a major pest of maize in the United States.

MON 87411 Maize contains two transgenes to control CRW. The *Cry3Bb1* gene protects against CRW larval feeding by promoting expression of an insecticidal crystalline (Cry) protein, Cry3Bb1. The *Cry3Bb1* gene is a modified form of a gene derived from the soil bacterium *Bacillus thuringiensis* subsp. *kumamotoensis*, also known as *Bt* (Monsanto, 2013). Crops producing Cry proteins are also known as *Bt* crops. Another transgene in MON 87411 Maize promotes expression of an interference RNA (RNAi). The RNAi expressed in MON 87411 Maize mediates a gene silencing mechanism that stops expression of a gene in western corn rootworm (WCR: *Diabrotica virgifera virgifera*) (Monsanto, 2013). When expression of the *Snf7* gene is suppressed by RNAi in WCR, production of the protein is suppressed. This results in WCR death (Bolognesi et al., 2012). This additional mechanism was developed and incorporated into MON 87411 Maize because some CRW populations, especially western corn rootworms (WCR) populations, have become resistant to the insecticidal Cry protein expressed by other *Bt* corn crops (Tabashnik et al., 2013; US-EPA, 2013; Gassmann et al., 2014).

MON 87411 Maize also contains the *epsps* gene coding sequence from an *Agrobacterium* sp. (strain CP4) that encodes the EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) protein that confers resistance to glyphosate (Monsanto, 2013). The CP4 EPSPS protein in MON 87411 Maize is identical to the CP4 EPSPS protein present in several other commercially available crops that are no longer regulated following USDA reviews (e.g., glyphosate resistant [GR] varieties of soybean, maize, cotton, sugar beet, canola, and alfalfa). Expression of this glyphosate resistance trait in MON 87411 Maize allows growers to make post-emergent applications of herbicide products containing glyphosate as the active ingredient (a.i.) for broad-spectrum weed control.

The EA was prepared to specifically evaluate the impacts on the quality of the human environment[3] that may result from a determination of nonregulated status of MON 87411 Maize. The EA assessed alternatives related to a determination of nonregulated status of MON 87411 Maize, and analyzed the potential environmental and socioeconomic impacts that may result from the proposed action and the alternatives.

Regulatory Authority

[2] The terms, "maize" and "corn" are used interchangeably throughout this document for crops and products derived from *Zea mays.*

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

"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 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 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 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 potential plant pests under the plant pest provisions of the Plant Protection Act 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 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 plant-incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act (FFDCA) and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). The EPA is responsible for regulating the sale, distribution and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology.

Regulated Organisms

The 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 Plant Protection Act (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 Plant Protection Act 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 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 87411 Maize. When a petition for nonregulated status is submitted, APHIS must determine if the GE organism of concern 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 87411 Maize

MON 87411 Maize is currently regulated under 7 CFR part 340. Interstate movement and confined field releases of MON 87411 Maize were conducted under notifications acknowledged by APHIS, since 2010. These trials were conducted in diverse growing regions within the United States that include Arkansas, California, Colorado, Georgia, Hawaii, Iowa, Illinois, Indiana, Kansas, Louisiana, Michigan, Minnesota, Missouri, Mississippi, Nebraska, North Carolina, Ohio, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, and Wisconsin. Details about and data resulting from these field trials are described in the MON 87411 Maize petition (Monsanto, 2013), and were analyzed for plant pest risk in a preliminary Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2014).

Coordinated Framework Review

Food and Drug Administration

Mon 87411 Maize is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced by genetic engineering. It is genetically engineered for resistance to glyphosate and control of corn rootworms. 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). These recommendation 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 completed its submission of its safety and nutritional assessment of food and feed derived from MON 87411 Maize to FDA on March 14, 2014. All materials relevant to this notification were placed in a file designated as BNF 000145 by FDA. Based on the information Monsanto submitted, FDA acknowledged in a letter on October 17, 2014 that it had no further questions concerning food and feed derived from MON 87411 Maize.

Environmental Protection Agency

EPA has authority under FIFRA to establish pesticide use restrictions. These are listed on pesticide labels which are prepared during the pesticide registration process. Mon 87411 Maize is similar to currently available glyphosate-resistant (GR) maize varieties. Monsanto indicates that there will be no change in the use pattern for glyphosate on this glyphosate-resistant variety. APHIS used the current glyphosate labels relevant to applications for corn production as the basis for its evaluation of the potential impacts associated with the use of and exposure to glyphosate. EPA also regulates plants that express Bt proteins, as part of its authority to oversee plant-incorporated protectants (PIP), and the protein expressed by Mon 87411 has already been commercialized with extensive field use. Mon 87411 Maize incorporates an additional PIP DvSnf7 RNA that is expressed in the plant and specifically targets corn rootworm. EPA has produced an Environmental Risk Assessment for a FIFRA Section 3 Limited Seed Increase (US-EPA, 2015), based on Monsanto's submitted results required by provisions of the ecological impact assessment method used for other PIPSs. However, this will not necessarily be the same analysis used for future products. As EPA notes, "because of uncertainties associated with the potential for unexpected effects related to exposure to dsRNA, EPA raised questions to the SAP (Science Advisory Panel) regarding the applicability of the above approach to dsRNA PIPs. The SAP found that this approach was not sufficient to determine risks to nontarget organisms, and suggested an alternative framework (see pages 61-64 of the SAP minutes), which EPA is currently evaluating" (US-EPA, 2015). EPA plans to initially provide a limited acreage seed increase permit for two years to the product. EPA has also asked Monsanto for additional details about data and observations already supplied to EPA by Monsanto which will become part of the data package needed for the EPA permit for commercial use on Mon 87411 (US-EPA, 2015).Scope of the Environmental Analysis.

Although a determination of nonregulated status of Mon 87411 Maize would allow for new plantings of Mon 87411 Maize anywhere in the United States, APHIS primarily focused the environmental analysis on those geographic areas that currently support corn production. A

determination of nonregulated status of Mon 87411 Maize 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. To identify areas in the United States where corn is produced, APHIS used data from the National Agricultural Statistics Service (NASS, 2014).

Public Involvement

In a *Federal Register* notice (79 FR 13035-6) on March 7, 2014, APHIS announced the availability of the petition for public review and comment (Docket No. APHIS-2014-0007). The 60-day public comment period closed on May 7, 2014. APHIS received 423 comments during the period the petition was available for public review. Comments are available for public review in the docket file at:

http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0007

On June 1, 2015, APHIS published a notice in the *Federal Register* (77 FR 13258-13260, Docket No. APHIS-2011-0129) announcing the availability of the MON 87411 Maize draft EA and preliminary PPRA for public review and comment. The comment period closed on July 1, 2015. APHIS received 12 comments during this review process. Responses to these comments are included in an addendum to this FONSI.

Major Issues Addressed in the EA

Issues discussed in the EA were identified by considering public concerns and issues described in public comments for the petition for nonregulated status of MON 87411 Maize and other environmental assessments of GE organisms. Issues identified in lawsuits, and those submitted by various stakeholders were also discussed. These issues, including those regarding the agricultural production of corn using various production methods, and the environmental food/feed safety of GE plants, were addressed to analyze the potential environmental impacts of MON 87411 Maize.

The 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 Maize Production
- Agronomic Practices
- Organic Maize Farming 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 EA analyzes the potential environmental consequences of a determination of nonregulated status of MON 87477 Maize. To respond favorably to a petition for nonregulated status, USDA-APHIS must determine that MON 87411 Maize is unlikely to pose a plant pest risk. Based on its PPRA (USDA- APHIS, 2014), USDA-APHIS made a determination that MON 87411 Maize is unlikely to pose a plant pest risk. Therefore, APHIS must determine that MON 87411 Maize is no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of MON 87411 Maize. APHIS has assessed the potential for environmental impacts for each alternative in the "Environmental Consequences" section of the EA.

<u>No Action</u>: Continuation as a Regulated Article

Under the No Action Alternative, USDA-APHIS would deny the petition. MON 87411 Maize and progeny derived from MON 87411 Maize 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 87411 Maize 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 87411 Maize.

This alternative is not the Preferred Alternative because APHIS concluded through its PPRA that MON 87411 Maize is unlikely to pose a plant pest risk (USDA- APHIS, 2014). 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 87411 Maize Is No Longer a Regulated Article

Under this alternative, MON 87411 Maize and progeny derived from this event would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87411 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2014b). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87411 Maize and progeny derived from this event.

This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the Agency's authority under the plant pest provisions of the PPA. Based on the Agency's conclusion that MON 87411 Maize is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87411 Maize 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 87411 Maize and progeny derived from this event if the developer decides to commercialize MON 87411 Maize.

Alternatives Considered but Rejected From Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 87411 Maize. 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 87411 Maize. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below with the specific reasons for rejecting each.

Prohibit Any MON 87411 Maize 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 87411 Maize, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate because MON 87411 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2014).

In enacting the PPA, Congress found that:

> . . . "decisions affecting imports, exports, and interstate movement of products regulated under this title [i.e., the PPA] 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:

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

Based on its PPRA (USDA-APHIS, 2014) and the scientific data evaluated therein, USDA-APHIS concluded that MON 87411 Maize is not likely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87411 Maize.

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 s described in a petition. Because USDA-APHIS has concluded that MON 87411 Maize 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 87411 Maize 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 87411 Maize from non-GE maize production. However, because APHIS has concluded that MON 87411 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2014b), 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 87411 Maize based on the location of production of non-GE maize 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 PPRA for MON 87411 Maize, there are no geographic differences associated with any identifiable plant pest risks for MON 87411 Maize (USDA- APHIS, 2014). Therefore, to be consistent with this determination, this alternative was rejected and not analyzed in detail. APHIS has concluded that MON 87411 Maize does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area (USDA-APHIS, 2014). 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 Plant Protection Act. Nevertheless, APHIS is not expecting significant impacts. However, individuals might choose on their own to geographically isolate their non-GE maize productions systems from MON 87411 Maize 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 hybrid stacks based on MON 87411 Maize is available from Association of Official Seed Certifying Agencies (AOSCA, 2011).

Requirement of Testing for MON 87411 Maize

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. Such a requirement would be extremely difficult to implement and maintain. Because MON 87411 Maize also does not pose a plant pest risk (USDA-APHIS, 2014), 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 87411 Maize 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 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.

Table 1. Summary of Potential Impacts and Consequences of Alternatives.

Attribute/ Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose, Need and Objectives:	**No**	**Yes**
Unlikely to pose a plant pest risk:	Satisfied by regulated field trials.	Satisfied by risk assessment (USDA-APHIS, 2014)
Management Practices		
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.	Areas and acreage devoted to corn production are not expected to change.
Herbicide Use and Weed Management 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	Populations of weeds resistant to glyphosate and other herbicides will increase. Growers will continue to use herbicides in addition to glyphosate along with herbicide mixtures to control and avoid new resistant weed populations. Because MON 87411 is also resistant to glyphosate, it will be replacing other GR varieties and little or no change will accompany adoption of nonregulated MON 87411 Maize.
Insecticide Use:	EPA approves and labels uses of herbicides on corn and PIPs in GE corn. Chemical insecticide use has declined since the introduction of IR corn varieties.	Insecticide use likely to be unchanged or minimally changed (possibly reduced) compared to No Action Alternative (Coupe and Capel, 2015).

Attribute/ Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Organic Farming:	An extremely small amount (0.25%) of corn production is certified organic and some may be grown outside major GE corn-growing sites.	Planting of organic corn is unlikely to change.
Specialty Corn Including Seed Production:	The U.S. specialty corn crop is small (5%) compared to total U.S. corn production.	Planting of specialty corn is unlikely to change.
Physical Environment		
Land Use:	Current trends in acreage and areas of production are likely to continue to be driven by market conditions for corn and corn products, by ethanol, animal feed needs and by Federal policy.	Current trends in acreage and production are likely to continue to be driven by market use and Federal policy.
Soil Quality:	Herbicide use in conjunction with HR corn has promoted conservation tillage; IR corn reduces reliance on chemical insecticides. Both tend to preserve or enhance soil quality.	Herbicide use with HR corn will continue to promote conservation tillage. MON 84711 is not expected to change the composition or structure of microbial communities.
Water Resources:	Agricultural NPS pollution sources (e.g., increased sedimentation from soil erosion; fertilizer and chemical pesticide residues) have declined as agronomic practices such as conservation tillage that mitigate runoff have been adopted for corn production.	Beneficial consequences of continued use of conservation tillage will remain the same as the No Action Alternative.

Attribute/ Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Air Quality:	Pollution from agricultural sources (dust from tilling; drift/diffusion/volatilization of farm chemicals; exhaust emissions from mechanized farm equipment) have declined as mitigating agronomic practices such as conservation tillage have increased in conjunction with the introduction of GE corn	Pollution from agricultural sources will continue to decline.
Climate Change:	Agriculture-related activities that are sources of GHGs (e.g., exhaust from mechanized farm equipment; soil disturbance from tillage; fertilizer applications) have declined with the introduction of GE corn.	GHGs would continue to decline with determination of non-regulated status of MON84711.
Biological Resources		
Animal Communities:	Currently available insect resistant corn varieties do not impact populations of vertebrate and most invertebrate animals other than target pest species (e.g., European corn borer; CRWs). Non-target invertebrates are generally more abundant in *Bt*-corn fields than in fields of non- GE corn.	Expected to be the same as under the No Action Alternative. Studies have shown no adverse effects on vertebrate or invertebrate animals from diet containing the MON 84711 product or the dsRNA sequences that are produced by it. EPA regulates PIPs in IR corn and herbicides applied to HR corn, and determines whether specific PIPs including the RNAi PIP that is a subject of the EA, pose an unacceptable risk or impact on non-target organisms

Attribute/ Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Plant Communities:	Corn growers will continue to use accepted practices to control weeds. Because glyphosate will continue to be used in corn production, increased populations of glyphosate resistant weeds are expected. High intensity agriculture will have some impact on plant communities near corn agricultural fields	MON 87411 is not a potential plant pest because it does not compete with native plant species, does not hybridize with relatives, and will not affect natural plant communities. Continued development of HR weeds is likely to continue, including the potential for development of weeds with resistance to multiple modes of action. Because MON 87411 is GR, replacing other GR varieties with this trait will have no new impacts. Corn growers use production practices to manage weeds in and around fields. EPA regulates herbicides applied to HR corn and PIPS, and determines whether they, including the RNAi PIP that is the subject of this final EA, pose an unacceptable risk or impact on non-target organisms including plants.
Soil Microorganisms:	Soil microbial communities will provide valuable resources to growers in the form of soil stability and quality, while responding to the transient impacts of common agricultural production practices.	Because MON 84711 has not been shown to impact soil microbial communities, determination of nonregulated status will not be expected to change microbial composition or structure.
Biological Diversity:	Currently available *Bt*-corn crops may increase non-target abundance compared to those treated with broad-spectrum insecticides. There is no evidence of landscape-level impacts from currently available IR HR corn varieties.	Field testing of MON 87411 in three countries has not shown any impacts on arthropod diversity when compared with fields planted to non-RNAi expressing varieties. MON 87411is not expected to alter biological diversity. EPA regulates impacts on biological diversity based on unacceptable risk or impact to non-target organisms

Attribute/ Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Gene Movement:	Cultivated corn varieties can cross pollinate. Growers and seed-corn producers use various management practices to eliminate undesired cross pollination.	Current practices to maintain genetic purity of corn stocks are effective (Ireland, 2006). MON 84711 will not change these practices.
Public Health		
Human Health:	All corn varieties are associated with the same risks deriving from agricultural practices. Allergenicity to corn will continue to affect a small percentage of the population.	Neither the products of the RNAi mechanism associated with subject of this final EA (dsDvSnf7), nor the Cry proteins of *Bt*-corn products, nor the EPSPS protein are toxic to humans, and there are no known allergenic properties for humans.
Worker Safety:	EPA regulates herbicides applied to HR corn. Workers that routinely handle glyphosate may be exposed during spray operations. Because of low acute toxicity of glyphosate and absence of evidence of carcinogenicity and other toxicological concerns, occupational exposure data is not required for reregistration. However, EPA has classified	There are no effects of MON 87411 and its expressed RNAi dsDvSnf7 sequence on human health and no expectations of adverse worker exposure to the MON 87411 variety with its expressed Bt and EPSPS protein or exposure to the herbicide glyphosate.
Animal Feed:	Corn products will continue to be used in livestock feed.	Neither the products of the RNAi –based MON 87411 (expressing the dsDvSnf7) , the Cry proteins of this *Bt*-corn variety nor the EPSPS protein are known to be toxic to animal species fed corn products aside from targeted insects.
Socioeconomic Environment		

Attribute/ Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Domestic Economic Environment:	The US will continue to produce both GE and conventional corn varieties.	Farm income is positively impacted by currently available *Bt* and HR corn by reducing production costs or increasing revenues. Pest-resistant corn generally has a positive impact on farm income because of cost savings from reduced pesticide use.
Trade Economic Environment:	The primary US corn export destinations are to the largest world importers of corn and do not have barriers for importing food or feed commodities produced from transgenic crops including those with insect resistance traits. Nevertheless, import of each specific trait	Export of MON 84711 will require applications and approvals by the importing country, and Monsanto has begun to seek those approvals.
Other Regulatory Approvals		
U.S. Agencies:	On March 31, 2004, the EPA established a permanent exemption from the requirement of a tolerance for the PIP, *Bacillus thuringiensis* Cry3Bb1 protein, and the genetic material necessary for its production in food and feed commodities of field corn, sweet corn and popcorn (40 CFR § 180.1214).	In a letter dated October 17, 2014 (Appendix A of this final EA), FDA confirmed completion of a consultation for a food/feed safety and nutritional assessment for Monsanto's 87411 corn. A summary of findings was submitted to FDA in November 2013.
Compliance with Other Laws		
CAA, CWA, EOs:	Fully compliant	Fully compliant

[1]Unchanged–the current conditions will not change as a result of the selection of this alternative;

[2]Minimal–the current conditions may change slightly as a result of the selection of this alternative, but the changes, if any, are negligible.

Finding of No Significant Impact

APHIS' analysis in the 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. I agree with this conclusion and therefore find that an Environmental Impact Statement is not required. 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 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 highest concentration of production is located in the central United States (USDA-ERS, 2013a; USDA-NASS, 2013). The two states with the most production are Iowa and Illinois. They account for slightly more than a third of the United States (USDA-ERS, 2014c).

During the past two decades, corn acreage has increased. In 2000, 25% of U.S. corn production was from GE varieties (USDA-ERS, 2013b). In 2002, stacked hybrids were introduced. This led to a further increase in acreage of GE corn (Fernandez-Cornejo et al., 2014). By 2009, GE corn acreage exceeded 70% of the total in all major corn-growing states except Ohio (67%) (Fernandez-Cornejo et al., 2014). By 2013, 90% of the 87.6-million-acre U.S. crop was produced from GE corn.

In the period, 2006-2012, acreage of corn planted annually in the United States increased because market prices favored the planting of corn over alternative crops. In addition to the demand for feed grain, strong demand for ethanol production resulted in higher corn prices, which corresponded to an incentive to growers to increase acreage (USDA-ERS, 2013a). The increase in acreage involved all varieties of corn and occurred throughout the corn growing areas (USDA-ERS, 2010). In many cases, farmers increased corn acreage by adjusting crop rotations. Other sources of land for increased corn plantings were conversion from pasture and fallow land, acreage returned to production from expiring Conservation Reserve Program contracts, and shifts from other crops, such as soybean and cotton (USDA-ERS, 2014). A determination of nonregulated status of MON 87411 Maize is not expected to directly affect these influences on production trends, nor cause an increase in agricultural acreage devoted to corn production in general and that devoted to GE-corn cultivation. The availability of MON 87411 Maize will not change cultivation areas for corn production in the United States, and there are no anticipated changes to the availability of GE- and non-GE corn varieties on the market.

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 87411 Maize will have no significant environmental impact on the availability of GE, conventional or organic corn varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of Mon 87411 Maize is expected to neither directly result in an increase in overall U.S. acreage of corn production, nor acreage of GE-corn. The availability of MON 87411 Maize will not change the areas of cultivation for corn production in the United States, and there are no anticipated changes in the availability of GE and non-GE corn varieties on the market. A determination of nonregulated status of Mon 87411 Maize will 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 87411 (Monsanto 2013) andhas concluded in the EA that the availability of Mon 87411 Maize will not alter the agronomic practices, locations of corn production, nor the production methods and quality characteristics of conventional and GE corn seed production. The introduction of Mon 87411 Maize provides an alternative corn variety with traits that control CRW and the continuing sustainability of *Bt* proteins that are currently used for CRW control. The trait for resistance to glyphosate is similar to that of many current varieties of commercial corn, and would result in no new changes in development of weed resistance to glyphosate.

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

A determination of nonregulated status of MON 87411 Maize would have no significant impacts on human or animal health. Compositional tests conducted by the petitioner indicate that MON 87411 Maize is compositionally similar to other commercially available GE corn varieties (Monsanto 2013). Monsanto initiated a consultation process with FDA for the commercial distribution of MON 87411 Maize and submitted a safety and nutritional assessment of food and feed derived from MON 87411 Maize to the FDA. In a letter dated October 17, 2014, FDA confirmed completion of this consultation. Based on the information Monsanto submitted, FDA confirmed that it had no further questions regarding MON 87411 Maize. Based on the FDA's consultation, laboratory data and scientific literature provided by Monsanto (Monsanto 2013), and safety data available on other Bt-expressing and herbicide-resistant products, APHIS has concluded that MON 87411 Maize 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 be adversely impacted by a determination of nonregulated status for MON 87411 Maize. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance, nor 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 87411 Maize. 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 87411 Maize including the use of EPA-registered pesticides. The 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 87411 Maize, 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 following a USDA determination of nonregulated status for MON 87411 Maize 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 87411 Maize, this action is not likely to be 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 in general, nor acreage devoted to GE corn cultivation. The availability of MON 87411 Maize 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 87411 Maize 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 87411 Maize 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 effect of MON 87411 Maize 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. EPA will provide initially for only a seed increase permit for two years and on limited acreage, and has requested additional information about observations conducted to study arthropod biodiversity already supplied by Monsanto (US-EPA, 2015).

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

   From the analysis documented in the EA, the possible effects on the human environment are understood, although as EPA acknowledged some "uncertainties associated with the potential for unexpected effects related to exposure to dsRNA" had to be considered by the Science Advisory Panel that offered advisement on the issues (US-EPA, 2015). However, EPA has produced an Environmental Risk Assessment for a FlFRA Section 3 Limited Seed Increase (US-EPA, 2015), based on the previous ecological impact assessment method used for other PIPSs (US-EPA, 2015). 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.

As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 87411 Maize 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 87411 Maize 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 effect of MON 87411 Maize 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 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 87411 Maize. Given the extensive experience that APHIS, stakeholders, and growers have with the use of GE corn products, the possible effects to the human environment from the release 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 87411 Maize would not establish a precedent for future actions with significant effects, nor would it represent a decision in principle about a future decision. While the request to EPA for an Experimental Use Permit for MON 87411 represents a request for a new trait with a target dissimilar to any others already permitted (interference RNA to control an insect pest), EPA is using its current ecological risk assessment approach for PIPs that was developed primarily from experience with *Bt*-derived Cry and Vip proteins (US-EPA, 2015). However, this will not necessarily be the same analysis used for future products. As EPA notes, "because of uncertainties associated with the potential for unexpected effects related to exposure to dsRNA, EPA raised questions to the SAP [Science Advisory Panel) regarding the applicability of the above approach to dsRNA PIPs. The SAP found that this approach was not sufficient to determine risks to nontarget organisms, and suggested an alternative framework (see pages 61-64 of the SAP minutes), which EPA is currently evaluating" (US-EPA, 2015).

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 87411 Maize. 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 effects were identified during 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. In the event APHIS reaches a determination of nonregulated status of MON 87411 Maize, APHIS would no longer have regulatory authority over it and would no longer regulate it. In the event of a determination of nonregulated status of MON 87411 Maize, 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 87411 Maize 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 87411 Maize 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 87411 Maize 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 87411 Maize. 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 87411 Maize 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 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. These cultivation practices are also being conducted currently throughout the corn production regions. The cultivation of MON 87411 Maize 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 EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of MON 87411 Maize 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 of a determination of nonregulated status of MON 87411 Maize, APHIS has concluded that a determination of nonregulated status of MON 87411 Maize 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. EPA regulates all plant incorporated products, including both traits that express either the Bt protein, or the dsRNA for DvSnf7. EPA in an Environmental Risk Assessment has determined that "the activity of the Cry3Bbl protein expressed in MON 88017 was also determined to be biochemically and functionally equivalent to Cry3Bbl expressed in MON 863 maize, and both were determined to have no unreasonable adverse effects on nontarget organisms (US-EPA, 2015). EPA has also concluded, "Based on the data and rationale presented, adverse effects to nontarget organisms are not expected as a result of the proposed seed increase registration of DvSnf7 expressed in MON 874 11 corn.

    Because APHIS has concluded that MON 87411 Maize is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87411 Maize 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. Monsanto initiated the consultation process with FDA for the commercial distribution of MON 87411 Maize and submitted a safety and nutritional assessment of food and feed derived from MON 87411 Maize to the FDA (Monsanto 2013). Based on the information Monsanto submitted, FDA confirmed on October 17, 2014 that it had no further questions regarding MON 87411 Maize. MON 87411 Maize is compositionally similar to currently available corn on the market. 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 87411 Maize 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; (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with Mon 87411 Maize, the continued regulated status of MON 87411 Maize 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 87411 Maize will not have any significant environmental effects.

10/23/2015

Michael J. Firko, Ph.D.

Date

APHIS Deputy Administrator

Biotechnology Regulatory Services

Animal and Plant Health Inspection Service

U.S. Department of Agriculture

Response to Public Comments on Monsanto 87411 Maize

In a *Federal Register* notice (79 FR 13035-6) on March 7, 2014, APHIS announced the availability of the petition for public review and comment (Docket No. APHIS-2014-0007). The 60-day public comment period closed on May 7, 2014. APHIS received 423 comments during the period the petition was available for public review. Comments are available for public review in the docket file:

http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0007

Issues identified in comments submitted for the petition were considered by APHIS as part of its environmental analysis process and responses were incorporated into the EA.

On March 6, 2015, APHIS published a notice in the Federal Register (77 FR 13035-13036, Docket No. APHIS- 2014-0007) announcing the availability of the draft Environmental Assessment (EA) and preliminary plant pest risk assessment (PPRA) for a 60-day public review period. On June 1, 2015 the comment period was reopened for an additional 30 days (80 FR 30997-30998) Docket No. APHIS-2014-0007). APHIS received a total of 12 comments: two supported a decision of nonregulated status for MON 87411 Maize; nine were opposed. Comments can be reviewed in the docket file at:

http://www.regulations.gov/#!documentDetail;D=APHIS-2014-0007-0002.

Most of the comments expressing opposition to nonregulatory status for MON 87411 Maize expressed general opposition to genetically engineered (GE) food, the belief that GE crops harm the environment, or the belief that GE crops are not beneficial to farmers. Several specific issues related to the Monsanto CRW-protected and GR maize EA were identified by the public. All comments received were evaluated on the basis of whether they addressed the issues in question, whether they were based on valid science, and whether they were reasonable and practicable.

One opposing comment included 67 attachments of documents and published articles. APHIS has extensively reviewed the relevant articles submitted with this comment. Thirty-one of these attachments were relevant to Monsanto's petition and the EA; 63 either were not relevant to issues and topics considered in the EA, or were general review papers that did not provide any new information that had not been included in the EA.

Issues expressed in opposing comments related to Monsanto CRW-protected and GR maize EA were organized into categories. Substantive issues were identified and are addressed in the responses that follow. Some comments included more than one issue. Therefore, the number of issues that follow, and the Agency response to each of them, does not correspond to the number of opposing comments that were submitted for the EA.

Issue 1: The EA is based on incomplete and inadequate science and analyses, and lacks critical data and vital risk assessments.

Response 1: APHIS disagrees. The Agency reviewed all available information and performed a rigorous analysis of the consequences and uncertainties in its EA before making a decision. The CEQ requires that an EA must be based on the best-available information. It does not require that new studies be commissioned or that new data be developed to support a NEPA document and decision.

APHIS identified reasonable alternatives and analyzed them using available information from various sources, including the data provided by Monsanto (Monsanto, 2013) and that available in the peer-reviewed, scientific literature to make an informed regulatory decision regarding the possible plant pest risks that may be associated with MON 87411 CRW-protected and GR maize. The Agency concluded that this product is unlikely to pose a plant pest risk.

APHIS also carefully reviewed the information provided by the petitioner and all available other sources and considered the possible environmental effects of regulating MON 87411 Maize (no-action alternative) or not regulating it (preferred alternative). Using the best-available relevant scientific information, APHIS analyzed possible effects of MON 87411 Maize on the environment, and concluded in its EA that these effects would not cause significant impacts.

Issue 2: The broad geographical range and the widespread importance of corn as a major cropping system in the United States requires preparation of an environmental impact statement (EIS).

Response 2: APHIS notes that neither the geographical extent nor economic importance of a crop, such as corn, is primary requirements for initiating an EIS. NEPA regulations determined by CEQ clarify that the threshold establishing the need for an EIS is the identification of one or more significant environmental impacts by an agency during its analysis for completing an EA. APHIS prepared its EA to consider all possible environmental effects of the proposed action and the reasonable alternatives to that action, consistent with NEPA requirements (40 CFR parts 1500-1508, 7 CFR 1b, and 7 CFR part 372).

The EA specifically evaluated the possible effects on the quality of the human environment that may result from a determination of the regulated status of Monsanto CRW-protected and GR maize. APHIS assembled a list of alternatives and evaluated these alternatives consistent with the Agency's statutory authority under the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340, and NEPA requirements (40 CFR parts 1500-1508, 7 CFR 1b, and 7 CFR part 372). It considered environmental safety, efficacy, and practicality to identify which alternatives were the appropriate ones to evaluate before making its decision. As described in the EA, APHIS evaluated two alternatives; (1) no action and (2) a determination of nonregulated status for Monsanto's rootworm-protected and glyphosate resistance maize. APHIS concluded that the determination of nonregulated status would not cause significant impacts on the environment. Therefore, APHIS does not need to prepare an EIS before making a regulatory decision about to MON 87411 Maize.

Issue 3: MON 87411 Maize is unique because it incorporates an "animal" gene:

Response 3: The SvSbf7 gene in MON 87411 Maize is based on the partial coding sequence of the Snf7 gene from the corn rootworm, a Coleopteran insect (Monsanto, 2013). Data indicate

that the gene product is very specific, and is known to target only the corn rootworm, but not other insects even within the same family. There is no protein produced from the SvSbf7 gene, but rather only dsRNA. APHIS has experience evaluating numerous GE plants which utilize RNAi technology. In addition, APHIS has experience evaluating a variety of GE plants which contain genes from divergent sources including plants, bacteria, and viruses, and marine invertebrates. Thus, MON 87411 Maize utilizes familiar technology and does not present unique risks that have not been considered in other GE plants.

Issue 4: The commenter claims that potentially significant impacts on cultural development were not addressed in the petition, PPRA and EA.

Response 4: APHIS notes that the term, "cultural development" is not defined in the guidelines for responding to NEPA established by CEQ nor by the APHIS-implementing regulations for NEPA. The Agency also notes that the petitioner is not required to address "cultural development" in a petition for nonregulatory status.

If cultural development issues are included as components of the domestic economic environment and the trade economic environment, then APHIS addressed these in its EA, and determined that neither the preferred alternative nor the no action alternative will cause significant impacts on the domestic or trade economic environment.

Issue 5: A simple risk assessment based on safety to humans or the environment is inadequate to evaluate potentially significant cultural reactions to DvSnf7 RNA, such as not accepting the presence in food containing novel genes expressed in the plant.

Response 5: APHIS did not evaluate consumer preferences with regard to GE food in its EA because it is not within the scope of its NEPA requirement, APHIS regulatory authority, or the policies of the Federal government for products produced using recombinant DNA techniques as set forth in the Coordinated Framework for regulating biotechnology. FDA, not USDA, has authority over food safety and nutritional equivalencies of products derived from crops, whether genetically engineered or derived otherwise.

FDA responsibilities in reference to food products derived from GE crops are defined in the Coordinated Framework and Monsanto addressed those by engaging FDA in a consultation process.

Issue 6: "APHIS should consider all 'reasonably foreseeable' environmental impacts of the proposed deregulation of MON 84711, taking a programmatic approach to consider the use of RNAi technology on other crops and against other pests that will likely follow the deregulation of MON 84711."

Response 6: EPA, not USDA, has the authority to regulate the PIPs (plant-incorporated protectants: (*Bt* and RNAi) in MON 84711 Maize. EPA will continue to analyze environmental effects of this and other similar RNAi products which may impact nontarget animals beginning with a "White Paper," convening a Science Advisory Panel and following with a summary document of the Panel's findings. EPA has not fully completed a programmatic response to this type of product to allow for full registration. For MON 87411 Maize, EPA will require as

much data from Monsanto as needed to make a decision about the registration of this product and the required conditions for its use (pesticide labeling requirements), if any. In addition, current approaches for data needed to establish safety for other PIPs are being used in the EPA evaluation. Additional assessments will be made if new issues and risks are identified in the course of a proposed EPA permit for seed increase on limited acreage.

An EPA commitment for a programmatic approach to additional RNAi products has been made, which includes establishing new requirements for tests and observations. The requirements will be constructed after continued assessment of recent data requests of Monsanto, as well as any further field and lab data offered by Monsanto. An EPA Science Advisory Panel has already been convened in January 2015, and this has provided EPA with advice for the future development of regulation of future RNAi products. Finally, interactions with the company on an ongoing basis will also provide information sufficient for analysis of potential risks of future related products. When the regulatory protocols for these similar products are established, APHIS will use these to inform and confirm its future NEPA assessments.

Issue 7: **APHIS must assess the impacts associated with this novel technology which is in the early phases of its development in an EIS, and new information about host-induced gene silencing is only now being revealed.**

Response 7: Although RNAi technologies are not new, APHIS agrees new research continues to add to our understanding of the RNAi mechanism, however, much is known and APHIS has sufficient information on the phenotype and spectrum of activity of MON 87411 to perform a risk assessment. The commenter pointed out recent findings by Ivashuta et al. (2015), which show that long dsRNAs from corn may produce many 21 nucleotide (nt) siRNAs that correspond with western corn rootworm transcripts and are routinely formed in relatively high abundance. However, these do not affect the insect transcriptome, since most of these siRNAs derived from the host plant are formed from plant dsRNA by the insect in low copy number. While this is not a surprising finding, the conclusion that the authors could find no impact of plant-originated siRNAs on WCR RNA transcripts was important. The authors also found that while beetles were capable of cellular uptake and incorporation of environmental RNA (env-RNA), in a lepidopteran insect no plant-sourced siRNAs (one type of an env-RNA) were found. Feeding of whole animals with high concentrations of RNA isolated from corn or soy did not cause any changes of development or in weight gain. It appears that sequence identity of plant-produced RNAs is not alone sufficient to change transcription or host development, but that high copy numbers of the dsRNA are also required. This molecular analysis provides a mechanism for exclusion of potentially impacted nontarget organisms, confirming that such impacts on RNA insensitive insects such as Lepidoptera are unlikely. While new information about host induced gene silencing is valuable, the major issues about its mechanism are relevant, but the potential for impacts and under what circumstances they are important are

known from experimental observations and experience. Because EPA concludes that there are sufficient observations about these impacts, and that safety concerns have been satisfied by these observations, then EPA will provide conditional approval of two-year limited acreage seed increases. New details about underlying mechanisms elucidated by continuing research are also useful, and will be considered by USDA as future RNAi products are assessed for environmental impacts.

Issue 8: **APHIS cannot base claims of "no impact" for MON 87411 on previous examples of gene silencing in GE crops such as GE papaya, summer squash, plum or genes of the plant itself (GE potato, apple, altered oil soybean) because their targets are completely different.**

Response 8: While APHIS believes that the experience gained using other plants that use RNAi technology is relevant, we agree that each case is different and thus we continue to evaluate each on a case-by-case basis.

In this case, APHIS reviewed information which indicated that the activity spectrum of DvSnf7 RNA has been shown to be highly specific to corn rootworms. Bioassays were performed using representative insect species having close taxonomic relatedness to corn rootworm. In total 14 representative insect species from 10 Families and 4 Orders (Hemiptera, Hymenoptera, Lepidoptera, and Coleoptera) were tested. In these bioassays activity was found only in the subfamily Galerucinae in the family Chrysomelidae within the order Coleoptera. Specifically, only the western corn rootworm and the southern corn rootworm were affected. the Colorado potato beetle, which is in another subfamily (Chrysomelinae) of Chrysomelidae,is known to be sensitive to certain ingested dsRNAs; however, it was not affected by DvSnf7 RNA.

In addition, data indicated no effect of DvSnf7 RNA on any of the other nontarget species tested including the following which are often considered beneficial to agriculture: the spotted ladybird beetle, ground beetle, honeybee, insidious flower bug, and earthworm. This, together with the results from the study using the 14 species described above and the sequence specific nature of RNAi support a conclusion that it is unlikely that DvSnf7 RNA will have an effect on nontarget organisms.

APHIS also considered many other aspects of the observed phenotype in agronomic settings as described in the petition. . The totality of this information allowed APHIS to reach a Finding of No Significant Impact (FONSI).

Issue 9: Off-target effects of RNAi silencing are common – so common in fact that they constitute major obstacles to the use of gene silencing, for example in human therapy as noted by Haussecker and Kay, 2015, the production of RNAi pesticides as described by Palli, 2014, and the agronomic improvement of crops cited by Saurabh et al., 2014."

Response 9: The writer cites Saurabh et al., (2014) as suggesting that off-target effects are a "major obstacle" to commercial usages, but these authors note that one of the benefits of RNAi for gene silencing is that it is "precise—no off-target effects." While the issues for potential

human impacts of RNAi are noted by Haussecker and Kay (2015), these concerns are not directed towards environmental RNA, which would be the mode of human exposure to RNAi from the MON 87411 Maize product. Rather, additional but different modes of human exposure are the focus in this paper.

The first modality cited by Haussecker and Kay (2015) includes RNAi expressed by transformed human cells (that is, using a "genetic template") that produce dsRNA. The impacts of this usage would be on those internal cellular processes normally mediated by microRNAs. Second, these authors note the alternative strategy for providing an effective dosage of human RNAi is through administering oligonucleotides directly. This requires use of a specific 'delivery option' to protect introduced dsRNA from the mechanisms by which these RNAs are easily degraded in humans. As noted in the Environmental Consequences Human Impacts section, RNA is not stable in human digestive tracts or circulatory system and is rapidly degraded. The third author cited by the commenter, Palli (2014), recognizes the potential issue of off-target activity of either plant-expressed or applied (externally sprayed) RNAi, but he notes the study of Bachmann et al. (2013) which showed the specificity of the DvSnf7 and its lack of effects on the insects of 10 families. Spraying of RNAi in agricultural situations has potential for impacts but he notes that 90% of DvSnf7 is degraded in 36 hours (Dubelman et al., 2014), and was not detectable after two days. Palli (2014) cites the authors conclusion that DvSnf7 was not likely to accumulate in the environment, so is unavailable for uptake and thus unlikely to cause off-target effects.

Issue 10: Corn rootworms are likely to develop resistance to the RNA-interference-based mechanism for several likely reasons.

Issue 10 A. Several commenters addressed the possibility that corn rootworms would develop resistance to the RNAi component of MON 87411 Maize because each component, the Bt protein as well as the RNAi mechanism results in mortality consistent with a "low dose" strategy of plant protection.

Response 10 A: The development of resistance to any insecticidal mechanism should be managed and then averted if possible. However, given the available rootworm products such as various *Bts*, and now this product, the extremely high mortality that might be most desirable is not commercially available. Taking account of this limitation, multiple overlapping toxins are the best strategy to avoid a rapid selection for resistance (Storer et al., 2012). Critical to the usefulness of this is that first, the multiple toxins act independently of one another through different modes of action, so cross resistance isn't possible. As recently affirmed by Levine et al. (2015), the Cry protein, 3Bb1, currently used in field protection from damage caused by corn rootworm acts completely independently of DvSnf7 for toxicity to southern corn rootworm. Second, as noted by the commenter, the target insect should not be resistant to one of the multiple toxins used in the strategy. In the case of growers who have known or

suspected rootworm resistance to Cry3Bb1, these would be advised on Monsanto's and on independent websites, by field seed dealers and state extension personnel not to plant MON 87411 Maize combined with this *Bt* trait in their affected corn production fields. Grower perception of CRW resistance is considerable. About 23% of growers in Iowa in 2012 perceived that resistance to a *Bt* trait had occurred in their fields (Hodgson et al., 2013), and over half were able to confirm the suspicion with either direct root surveys or observations of corn plant goosenecking. APHIS concludes that growers will respond correctly to the advice of consultants to avoid planting the MON 87411 variety when a field location already is suggestive of susceptibility of CRW to Cry3bb1. Use of a seed combination of the MON 87411 trait along with *Bt*s to which the CRW were not previously resistant would be a robust strategy to protect the future use of *Bt*s, and also delay resistance to MON 87411.

Issue 10 B: Evidence for variable mortality responses to one RNAi-based pest control strategy are already described, and therefore resistance to the strategy may occur quickly (Chu et al., 2014).

Response 10 B: APHIS disagrees with Chu et al. (2014) who indicate that resistance to MON 87411 Maize will quickly appear in rootworm populations. From observations made by Chu et al. (2014) the authors conclude that RNAi silencing for insect control should be chosen so that the sequences used do not cause variable effects on different populations of the same species. APHIS agrees that differential susceptibility would potentially lead to early selection of populations for resistance to the introduced dsRNA sequence. In the case of the sequences that were assayed by Chu et al. (2014), the authors knew before beginning their observations that the genes were expressed at different levels in the three populations on which mortality would be assessed. Since it is known that pest populations with variable susceptibility to a particular RNAi based control method are likely to rapidly give rise to a largely resistant population. APHIS expects that any future products will be chosen which are broadly effective against the entire population when possible, thus delaying the possible selection of resistant pests.

Issue 10 C: Because the mechanism of cellular viral response to degrade virus impacts employs the same machinery as used by RNAi strategies for pest control, changes in viral susceptibility could alter the RNAi susceptibility as well.

Response 10 C: Multiple mechanisms are often involved in the development of insect resistance to external chemicals, and a mechanism that may change the RNAi machinery and allow susceptibility to the Snf7 dsRNAi sequence is possible (Swevers et al., 2013). As for this potential development in insects, and the consequences for other insect populations, APHIS does not disagree with the conclusion. No actual occurrences of this damage to silencing capacity in a cell have been demonstrated, neither to processing of an insect dsRNA, miRNA, nor siRNA. Some insect families may not have the capacity initially to process dsRNAs, but

these would be the native condition and for which an RNAi strategy would not be developed. APHIS estimates that if a population of pest insect became more susceptible to viruses (by inactivity of the Dicer/RISC) because they were tolerant of silencing dsRNA, populations of CRW could disappear. In contrast, if defenses against viruses were sharpened because the Dicer/RISC complex became more selective, discriminating between virus sequences for which siRNA was produced and which destroyed virus development and dsRNA against CRW which it failed to silence, infected insects as a source of a persist virus may be possible but of no consequence to insects other than the targeted pest species. It is clear that the capacity of many invertebrates to respond to virus infection is based on an RNAi mechanism, and may be indispensable for the protection afforded.

Issue 10 D: Defenses of insects against dsRNAs may be dispensable traits, and if so, this would allow new mechanisms of resistance to arise against the RNAi strategy.

Response 10 D: APHIS agrees that a variety of genetic adaptations could be used by CRW to overcome an RNAi-based defensive mechanism expressed by plants. As noted by Swevers et al. (2013), "as for every method for insect control, however, the rise of insecticide resistance is always a major issue." Speculation about these mechanisms is certainly justified as the commenter reports. Selective loss of the Dicer/RISC based defenses against viruses (the mechanism that is used by the RNAi expression) would be a highly tenuous insect strategy inasmuch as there would need to be simultaneous development of an alternative means to control viruses as noted by Shabalina and Koonin (2008). The most important issue is not that CRW may be unintentionally selected for susceptibility to RNAi, but that appropriate strategies should be developed and executed by growers to effectively delay the potential for new resistance. Increasingly corn growers recognize that they must detect and respond to new incidents of corn rootworm resistance in their managed fields (Hodgson et al., 2013). These growers are well aware of recently arising CRW resistance in corn with one of the available *Bt* traits (and possibly another), and are incorporating additional strategies beyond reliance on seed technology to protect current resources used to defend corn from rootworm-inflicted losses of yield (Hodgson et al., 2013). Growers will also likely defend future resources by choosing good insect management practices for MON 87411.

Issue 10 E: In the nematode *C. elegans*, persistent viral infections and deficiency of RNAi s are correlated in some existing strains, and the underlying mechanism for the observation although not known, could become a mechanism of resistance in CRW if environmental RNA never accumulated in some populations of insect pests.

Response 10 E: The potential for disruption of the siRNA mechanism by virus infection is suggested by Swevers et al. (2013) who find evidence for several such mechanisms, including

some in insects. These mechanisms are those directed by the virus to inhibit a component of the Dicer/RISC based system that responds to virus infections (to the detriment of the virus). The question posed by Swevers et al. (2013) is whether deployment of an RNAi based technique can demonstrate whether latent or chronic viral infections might be a successful mechanism for resistance to a commercial gene silencing mechanism. Again, APHIS asserts that mechanisms for resistance to any insect control strategy may well develop in an environment which exerts a consistent selecting pressure against an insect, but the focus for growers who plant this variety should be one of stewardship in which users attempt to delay that result by using appropriate pest management techniques.

Issue 10 F: APHIS concludes that the likelihood of CRW developing resistance to DvSnf7 RNAi is decreased by the presence of CRW-targeted Bt protein, but susceptibility of the insect to new mechanisms of resistance to the RNAi could reduce the ability of sustainable use of the Bt proteins which it would otherwise be supporting.

Response 10 F: As noted earlier in these Responses to Comments, APHIS does not disagree that resistance mechanisms to RNAi have been proposed, and that some may be potentially efficacious for developing resistance if selected for by exposure of CRW to RNAi. In the EA, APHIS has recognized the current status of corn rootworm resistance to *Bt*s (Section 5.3.1) and does not speculate on the future usefulness of those CRW *Bt*s to which resistance has not yet developed. However, APHIS asserts that the combination of multiple CRW toxins is a more effective strategy than either of these alone, either RNAi or specific *Bt* traits. Monsanto plans to stack commercial varieties with both MON 87411 toxins, and thus, seed production will not be pursued with the RNAi trait alone to resist CRW, which may not be a sustainable approach to provide sustained defenses against CRW.

Issue 11: APHIS ignored substantial uncertainties and data gaps in its EA analysis and based its analysis on very recent studies of Monsanto itself.

Response 11: The uncertainties about potential for impacts on the environment have been identified by EPA's Scientific Advisory Panel, convened in January, 2014, and acknowledged in EPA's summary of the record (US-EPA, 2014). Several authors who have reviewed the potential for impacts from RNAi use have also described some of the means by which these products might be assessed; these means may reduce the uncertainties of granting EPA permits and if adopted by EPA, further encourage their deployment on a commercial scale. EPA recently requested additional data from Monsanto supplementing the permit application, to further investigate the safety of MON 87411 Maize (personal communication, US-EPA). EPA subsequently received the data from Monsanto which EPA accepted but is also requesting clarification of some of the completed experiments and their conditions (US-EPA, 2015). The initial EPA and human effects and environmental effects analyses have been released for public

comment, and these represent the primary federal analysis of risks to the environment from MON 87411 (US-EPA, 2015). EPA has regulatory authority over pesticides and Plant-Incorporated Protectants (PIPs) and employs that authority to issue permits for this and other PIPs.

EPA has determined that it would primarily assess the potential impacts of DvSnf7 dsRNA using criteria and testing protocols developed for other plant incorporated protectants (US-EPA, 2015). EPA has concluded that the types of barriers within nontarget organisms for environmental RNA were sufficient to prevent environmental impacts (US-EPA, 2015), and although certain types of genomic and transcriptional details in these nontarget organisms might be of interest (US-EPA, 2014), an empirical approach was more likely to be adequate for analysis of the impact possibilities.

Although APHIS analyzed possible effects of MON 87411 Maize in its EA, USDA defers to the regulatory authority of EPA consistent with its findings and conclusions, regarding risks that may be associated with MON 87411 Maize. Some of these are uncertain because although possible impacts have been proposed, currently available data neither confirm nor refute these possibilities.

USDA used the best available data to prepare its EA, which is the requirement of NEPA, and made its conclusion based on the preponderance of evidence that MON 87411 Maize would not cause any significant environmental impacts if it were no longer regulated as a plant pest.

Issue 12: To carefully weigh the risks associated with RNAi to express a pesticide trait, USDA should work with the EPA to design a new risk assessment framework that can adequately capture the unintended consequences of the introduction of dsRNA molecules before any crops containing the technology are approved.

Response 12: As noted in previous responses, the approach that EPA is taking for future products is development of a risk assessment framework, which by following the pattern of previous permit processes, will prescribe specific types of tests and most likely, expected designs for field trials. As EPA announced for MON 87411 Maize, the assessment will include a permit for only a limited spatial release (15,000 acres) for the purpose of producing seed and potentially extending existing Monsanto observations and data, during a limited temporal release (for two years). Additional information about existing data will be used by EPA to make a final decision (US-EPA, 2015). This period of conditional and limited approval of a permit for the novel PIP (RNAi) in MON 87411 Maize will allow Monsanto to provide additional support for this RNAi product.

Issue 13: USDA must look at the literature surrounding this technology and evaluate the specific safety concerns for a method with so many associated risks.

Response 13: Since the publication of the Science Advisory Panel Minutes and discussion offered within the EPA white paper on RNA Interference (US-EPA, 2014), more details of the fate of dsRNA in the environment have been determined, and their conclusions published. Fate in agricultural soils established that the dsRNA from MON 87411 does not persist for any but a short time (Dubelman et al., 2014). As discussed in the EA, all evidence shows that persistence of RNAs in water is highly unlikely. No controversy exists to show that environmental persistence of DvSnf7 is at issue.

Issue 14: Many studies have shown that RNAi can actually suppress unintended genes that are similar to the target gene. These unintended effects may also be heritable through reproduction, which could have serious ramifications for plant and animal populations.

Response 14: APHIS agrees that silencing specific RNAi sequences of a target organism may also silence unintended sequences of nontarget organisms. Identical sequences in another organism which might be exposed, or possibly even some that were nearly identical or similar, may potentially be targeted. First, it is becoming clear that there are multiple reasons why environmental dsRNA might not be sufficient to silence genes. One is that the quantity of the environmental dsRNAi to which an organism is exposed is important. In those observations where copy number is low, such as transcripts produced by the natural RNA output of a host plant with similar 21nt sequences to those found in animal targets, recipients may take up these RNAs, but there still may be no impact at all on host incorporated transcripts; these observation have been made in honeybees (Snow et al., 2013). Two is that effective copy number may be insufficient for gene silencing because of inacessible subcellular location of the transcripts in addition to low sequence copy number (Wittwer and Hirschi, 2004). In fact, among miRNAs, only 60% of those detected in tissues may have any "discernable activity" (Mullokandov et al., 2012). Second, as noted earlier in previous responses to comments here, genomic repetition number of a 21 nt (nucleotide) sequence empirically distinguishes whether or not an organism will respond to exogenous dsRNAs (such as from diet or a plant). In beetles there must be a minimum number of three of these dvSnf7 sequences in sensitive species (Bachman et al., 2013). Clearly the frequency of these repeated sequences decreases with decreasing phylogenetic relationship of the target organism (Bachman et al., 2013). Too few repeats will not trigger an appropriate RNAi impact on target sequences.

As described, not all organisms are sensitive to environmental RNAi, degrading it before it can be taken up by cells; gene silencing following exposure to env-RNAi in humans and vertebrates is not likely, a consensus clear from the EPA's 2014 Science Advisory Panel (US-EPA, 2014). Off target effects, in which target sequences do not precisely correspond with the RNAi sequences silenced may also be a potential issue. Evidence of silencing of non-identical sequences from the insect *Plutella xylostella* is that these occur when the supplied environmental RNA populations are extremely high (see Section 5.4.1 of the EA and (Bautista

et al., 2009)), the nature of the host, the type of exposure, duration of exposure, the endogenous defensive mechanisms as well as the total cellular exposure are all relevant to any silencing response at all. Finally, it should be noted that the use of environmental RNA, through the use of dsRNA in insect diets, cannot be inherited because there is no cellular machinery in animal cells to form DNA from RNA sequences.

Issue 15: APHIS ignores impacts of glyphosate and makes outdated conclusions about herbicide use.

Response 15: The EA includes thorough documentation in support of the fact that MON 87411 Maize will only replace other corn varieties that express the GR trait and that this will not result in an increase /expansion of U.S. corn acreage planted in GR varieties. Therefore, the glyphosate use on corn in the United States is not expected to change, so any effects associated with its use will not change if MON Maize 87411 is no longer regulated as a plant pest.

The general uses of glyphosate are outside the scope of the EA. EPA is responsible for reviewing and analyzing the uses and toxicity of pesticides such as glyphosate, and establishing through its registration and labeling process restrictions on uses that have provide an acceptable margin of safety. While one organization (WHO) has made allegations of new hazards from exposure to glyphosate, US-EPA has no credible evidence to affirm the conclusion.

Issue 16: APHIS failed to consider impacts on monarch butterflies.

Response 16: Brower et al. (2012) analyzed the decrease in population abundance of monarch butterflies in Mexico, which is an overwintering area for some populations of monarchs. While the paper suggests that the potential decrease in habitat for the monarch's host plant, milkweed, may be due in part to the increased spraying of glyphosate on GR crops and, subsequently, may be responsible for decreased monarch population levels, the study showed a statistically significant difference in monarch population levels over a period of several years, but did not contain any data or present any experiments which demonstrated that GE crop adoption is, in fact, responsible for any decrease in population.

Brower et al. (2012) also mentioned other potential causes of monarch population decline, such as extreme weather occurrences, and forest degradation. Furthermore, Brower et al. (2012) has been questioned by other researchers, including Davis et al. (2012), who performed a statistical analysis of monarch population levels of colonies in New Jersey and Michigan, and found that that population levels were not decreasing, but were, in fact, stable over a long period of time.

Chapter 4 of the EA provides a general review of the possible effects of GE crops on nontarget organisms. There are many variables that may affect population levels of nontarget organisms. These include cropping practices (e.g., strip or contour cropping, crop rotation), soil conservation practices that maintain grass strips, windbreaks and shelterbelts and the like, tillage, and the application of agrochemicals. The rotation of crops and strip contour cropping provide varied habitat that can benefit biodiversity. Crop production in general impacts

biodiversity at the landscape scale by potentially converting natural lands that have greater animal and plant species diversity to more monocultural landscapes. Glyphosate was found by the EPA to be no more than slightly toxic to birds, moderately toxic to practically nontoxic to fish, and practically nontoxic to aquatic invertebrates and honeybees (US-EPA, 1993).

The EA also includes thorough documentation in support of the fact that MON 87411 Maize will only replace other corn varieties that express the GR trait and that this will not result in an increase or expansion of U.S. corn acreage planted in GR varieties. Therefore, current glyphosate use on corn in the United States is not expected to change, so any effects associated with it use on monarch butterflies or other non-target organism is unlikely to change. The general uses of glyphosate are outside the scope of the EA. EPA is responsible for reviewing and analyzing the uses and toxicity of pesticides such as glyphosate to non-target organisms, and establishing through its registration and labeling process restrictions on uses that mitigate effects on non-target organisms.

Issue 17: APHIS did not adequately assess potential migratory bird impacts or those on threatened and endangered (T&E) species. One commenter also stated that APHIS failed to consider that the novel trait of MON 87411 Maize combined with the BT trait will result in expansion of corn acreage into natural areas.

Response 17: APHIS disagrees. The EA contains a section that reviewed the Agency's obligations under EO 13186 (US-NARA, 2010), *"Responsibilities of Federal Agencies to Protect Migratory Birds*, and the potential for MON 87411 Maize to impact migratory birds. APHIS concluded that there is no reason to expect impacts to migratory birds.

As required under Section 7 of the ESA, APHIS considered the potential for effects from the proposed determination of nonregulated status for MON 87411 Maize on federally listed threatened and endangered species and species proposed for listing, as well as effects on designated critical habitat and habitat proposed for designation. APHIS considered possible effects on all listed species and on all species proposed for listing. It also considered all designated critical habitat and habitat proposed for designation in States where corn is commercially grown. Species information was obtained from the USFWS Environmental Conservation Online System (ECOS; as accessed January 20, 2015 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp) (USDA-APHIS, 2015a), (USDA-APHIS, 2015b). After analyzing the potential for any effect, APHIS could not identify any stressor that would affect the reproduction, numbers, or distribution of any species, or affect their critical habitat. Based on this analysis, APHIS concluded that the determination of nonregulated status for MON 87411 Maize will have no effect on any federally listed T&E species or species proposed for listing, nor will it affect any designated critical habitat or habitat proposed for designation. This no effect determination eliminates a need for a consultation with, or the concurrence of, the USFWS and/or NMFS, consistent with ESA requirements.

Prior to performing its effects analysis on T&E species, APHIS considered the potential for MON 87411 Maize to expand corn production into natural areas. As reported in the EA, the conclusion from this analysis was that MON 87411 Maize is only expected to replace existing GE corn varieties in areas where corn is currently grown. It is not expected to increase total

U.S. corn acreage, nor is it likely to shift any existing corn acreage from where it is now grown into natural areas.

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