NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

Monsanto Company
Increased Ear Biomass Corn MON 87403 Maize

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

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

In accordance with APHIS procedures implementing NEPA (7 CFR Part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS Number 14-213-01p) by Monsanto Company (hereinafter referred to as "Monsanto") for their transgenic corn, event MON 87403, which is genetically engineered to increase ear biomass. MON 87403 maize was developed using *Agrobacterium*-mediated transformation to stably incorporate the *ATHB17* gene from *Arabidopsis thaliana* into corn. The transformation results in the production of the ATHB17Δ113 protein that likely modulates HD-Zip regulated pathways in the ear, which leads to increased ear growth at an early reproductive stage (Monsanto, 2014; Rice *et al.*, 2014). Larger ear biomass at early reproductive stages is associated with increased grain yield at harvest. This EA has been prepared in order to specifically evaluate the impacts on the quality of the human environment[1] that may result from a determination of nonregulated status of MON 87403 maize. The EA assesses alternatives to a determination of nonregulated status of MON 87403 maize and analyzes the potential environmental and socioeconomic impacts that result from the proposed action and the alternatives.

Regulatory Authority

"Protecting American agriculture" is the basic mission of APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, and the use of

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

genetically engineered (GE) varieties) can provide benefits to the environment, consumers, and farm income.

In 1986, the White House Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology (CF), which outlined a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The CF sought to achieve a balance between regulation adequate to ensure the protection of health and the environment while maintaining sufficient regulatory flexibility to avoid impeding innovation. In 1992, OSTP issued an update to the CF that sets forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment (57 FR 6753; February 27, 1992). The update affirmed that Federal oversight should focus on the characteristics of the product, the environment into which it is being introduced, and the intended use of the product, rather than the process by which the product is created.

The Coordinated Framework explains the regulatory roles and authorities of the three primary Federal agencies that have oversight responsibilities for the products of biotechnology: USDA's APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

APHIS has authority to regulate GE organisms and plants under the plant pest provisions in the Plant Protection Act of 2000, as amended (7 USC § 7701 *et seq.*). APHIS regulates GE organisms and plants to ensure that they do not pose a plant pest risk based on requirements in 7 CFR Part 340.

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act. The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, the FDA encourages them to participate in a voluntary consultation process. All food and feed derived from GE crops currently on the market in the United States have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, the FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food.

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

Regulated Organisms

The APHIS Biotechnology Regulatory Service's (BRS) mission is to protect and enhance U.S. agricultural and natural resources using a science- and risk-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which are promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act or the regulations at 7 CFR 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS' Response to Petition for Nonregulated Status

Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR Part 340, APHIS has issued authorizations for the safe introduction of regulated GE organisms. As required by 7 CFR 340.6, APHIS responds to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as MON 87403 maize. When a petition for nonregulated status is submitted, APHIS determines if the GE organism poses 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 the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

Monsanto has submitted a petition (APHIS Number 14-213-01p) to APHIS seeking a determination that their transgenic corn, MON 87403 maize, is unlikely to pose a plant pest risk and, therefore, should no longer be regulated by APHIS pursuant to 7 CFR Part 340.

MON 87403 Maize

MON 87403 maize is genetically engineered to have increased ear biomass at the early reproductive stage (R1) compared to conventional corn. Ear biomass, which is set during early reproductive stages, is considered an important determinant of reproductive success and a larger ear biomass at early reproductive stages is associated with increased grain yield at harvest.

MON 87403 maize was produced by insertion of *ATHB17* gene from *Arabidopsis thaliana* through *Agrobacterium*-mediated transformation. ATHB17 is a member of the HD-Zip family of

plant transcription factors, which are proteins that bind to specific deoxyribonucleic acid (DNA) sequences and regulate gene expression (Monsanto, 2014). HD-Zip proteins have been shown to play an important role in the modulation of plant growth and development. In MON 87403 maize, maize-specific splicing of the *ATHB17* transcript results in a truncated protein, ATHB17Δ113, which is missing the first 113 N-terminal amino acids that are expressed in *Arabidopsis thaliana*. The ATHB17Δ113 protein retains the ability to bind to target DNA sequences like the full-length protein. However, ATHB17Δ113 is unable to function as a transcriptional repressor because the protein lacks a functional repression domain (Monsanto, 2014). The ATHB17Δ113 protein likely modulates HD-Zip regulated pathways in the ear, which leads to increased ear growth at the early reproductive stage (Monsanto, 2014; Rice *et al.*, 2014). Larger ear biomass at early reproductive stages is associated with increased grain yield at harvest. Consistent with this, multiple years of field testing showed that MON 87403 maize out-yielded its comparators at a majority of locations tested (Leibman *et al.*, 2014; Monsanto, 2014).

According to documentation provided by the developer, MON 87403 maize will be combined with other deregulated biotechnology-derived traits through traditional breeding methods to create commercial products with increased yield as well as protection against corn pests and resistance to multiple herbicides (Monsanto, 2014).

Coordinated Framework Review

Food and Drug Administration
MON 87403 maize falls within the scope of the 1992 FDA policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (US-FDA, 1992). In compliance with the FDA policy, in October 2014, Monsanto submitted a safety and nutritional assessment summary document to the FDA to initiate a consultation on the food and feed safety and compositional assessment of MON 87403 maize. Monsanto received a completed consultation letter from the FDA on June 19, 2015. FDA concluded: "food and feed derived from MON 87403 maize are not materially different in composition, safety, and other relevant parameters from cornseed-derived food and feed currently on the market, and that genetically engineered MON 87403 maize does not raise issues that would require premarket review or approval by FDA" (US-FDA, 2015) .

Environmental Protection Agency
The EPA regulates plant-incorporated protectants under the 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 FFDCA and regulates certain biological control organisms under the TSCA. MON 87403 maize does not produce a plant-incorporated protectant, does not provide herbicide resistance, and is not a biological control organism. Therefore, EPA has no authority to regulate or review MON 87403 maize.

Scope of the Environmental Analysis

Although a determination of nonregulated status of MON 87403 maize would not restrict new plantings of MON 87403 maize to occur anywhere in the United States, APHIS limited the environmental analysis to those geographic areas that currently support corn production. To determine areas of corn production, APHIS used data from various official USDA sources. A

determination of nonregulated status of MON 87403 maize is not expected to increase corn production, or result in an increase in overall GE corn acreage or cultivation in new regions. In the United States, corn is generally cultivated where there is sufficient moisture (natural or irrigated) and frost-free days to reach maturity. Approximately 80% of annual U.S. corn production is concentrated in the Corn Belt, an area of the midwest and central plains (USDA-NASS, 2014a).

Relationship to Other Environmental Documents

USDA-APHIS prepared a draft EA for the nonregulated status of MON 87403 maize. APHIS published a notice in the *Federal Register* (80 FR 43053-5, Docket No. APHIS-2014-0097) announcing the availability of the MON 87403 Maize draft EA and preliminary PPRA for public review and comment.

Public Involvement

The petition was accepted as complete by APHIS on September 30, 2014. In a *Federal Register* notice (80 FR 2674-5) on January 20, 2015, the Agency announced the availability of the petition for public review and comment (Docket No. APHIS-2014-0097). The 60-day public comment period closed on March 23, 2015. APHIS received 20 comments during the period the petition was available for public review. All comments were carefully analyzed to identify new issues, alternatives, or information. One comment from a large corn growers association provided support of the EA's preferred alternative and 19 comments were in opposition.

On July 21, 2015, APHIS published a notice in the *Federal Register* (80 FR 43053-5), Docket No. APHIS-2014-0097) announcing the availability of the MON 87403 maize draft EA and preliminary PPRA for public review and comment. The comment period closed on August 20, 2015. APHIS received 4 comments during this review process, of which one supported a decision of nonregulated status for MON 87403 maize; two were opposed, and one was in support of nonregulated status but wanted APHIS to require continued oversight during the commercialization process. Responses to these comments are included in an addendum to this FONSI. Comment documents on the petition, EA and preliminary PPRA may be viewed at http://www.regulations.gov for Docket No. APHIS-2014-0097. No new issues, alternatives or substantive information new to USDA were identified in any of the EA comments received by APHIS.

Major Issues Addressed in the EA

The issues considered in the EA were developed based on APHIS' determination that certain GE organisms are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status of MON 87403 maize. Issues discussed in the EA were developed by considering public comments as well as issues raised in public comments submitted for other environmental assessments of GE organisms, concerns raised in lawsuits, as well as those raised by various stakeholders. Issues raised in these public comments on the petition were focused on general safety, potential for increased weediness, and the potential for gene flow to other corn varieties. Issues raised in favor of the petition for nonregulated status were received from an

association of corn growers. These included the benefits to growers from increased yields, and the need to increase per acre production in order to feed the world population now and in the future.

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

Agricultural Production of Corn

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

Environmental Considerations

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

Human Health

- Public Health
- Worker Safety

Livestock Health

- Animal Feed/Livestock Health

Socioeconomic

- Domestic Economics
- Trade Economics

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of MON 87403 maize. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87403 maize is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2015), APHIS has concluded that MON 87403 maize is unlikely to pose a plant pest risk. Therefore, APHIS must determine that MON 87403 maize is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of MON 87403 maize. APHIS has assessed the potential for environmental impacts for each alternative in the "Environmental Consequences" section of the EA.

No Action: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. MON 87403 maize and progeny derived from MON 87403 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 87403 maize and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MON 87403 maize.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRA (USDA-APHIS, 2015) that MON 87403 maize is unlikely to pose a plant pest risk. Therefore, choosing this alternative would not meet the purpose and need to respond appropriately to a petition for nonregulated status and would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act, the regulations codified in 7 CFR Part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Preferred Alternative: Determination that MON 87403 Maize is No Longer a Regulated Article

Under this alternative, MON 87403 maize and progeny derived from it would no longer be regulated articles under the regulations at 7 CFR Part 340. MON 87403 maize is unlikely to pose a plant pest risk (USDA-APHIS, 2015). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87403 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 Plant Protection Act. Because the agency has concluded that MON 87403 maize is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87403 maize is a response that is consistent with the plant pest provisions of the Plant Protection Act, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. Under this alternative, growers may have future access to MON 87403 maize and progeny derived from this event if the developer decides to commercialize MON 87403 maize.

Alternatives Considered but Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 87403 maize. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for MON 87403 maize. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

Prohibit any MON 87403 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 MON 87403 maize, including denying

any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MON 87403 maize is unlikely to pose a plant pest risk (USDA-APHIS, 2015).

In enacting the Plant Protection Act, Congress found that:

> [D]ecisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science... § 402(4).

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation of policies for oversight of emerging technologies (such as genetic engineering) at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principle, among others, to the extent permitted by law, when regulating emerging technologies:

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

Based on our PPRA (USDA-APHIS, 2015) and the scientific data evaluated therein, APHIS has concluded that MON 87403 maize is unlikely to pose a plant pest risk. Accordingly, there is no risk-based justification for prohibiting the release of MON 87403 maize.

Approve the petition in part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all events described in a petition. Because MON 87403 is the only event for which the petition was submitted, and because APHIS has concluded that MON 87403 maize is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

Require Isolation distance between MON 87403 maize and non-GE corn and geographical restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating MON 87403 maize from non-GE corn production. However, because APHIS has concluded that MON 87403 maize is unlikely to pose a plant pest risk (USDA-APHIS, 2015), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of MON 87403 maize based on the location of production of non-GE corn in organic production systems in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as

presented in APHIS' PPRA for MON 87403 maize, there are no geographic differences associated with any identifiable plant pest risks for MON 87403 maize (USDA-APHIS, 2015). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87403 maize does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act, the regulations codified in 7 CFR Part 340, and the biotechnology regulatory policies 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 corn productions systems from MON 87403 maize or to use isolation distances and other management practices to minimize gene movement between corn fields.

Requirement of Testing for MON 87403 maize

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing to identify GE products in non-GE production systems. APHIS notes there are no nationally-established regulations requiring testing, criteria, or limits of GE material in non-GE systems. Additionally, because MON 87403 maize does not pose a plant pest risk (DAS, 2013; USDA-APHIS, 2014; 2015), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR Part 340, and the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for MON 87403 maize would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

Environmental Consequences of APHIS' Selected Action

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

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials.	Satisfied—risk assessment (USDA-APHIS, 2015)
Management Practices		
Acreage and Areas of	Corn acreage declined 4 percent	Unchanged from No Action

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Corn Production	from 2013 to 91.6 million acres in 2014. Corn acreage is likely to remain steady for the foreseeable future.	Alternative
Agronomic Practices	General cropping practices such as crop rotation, tillage, pest and disease management, and crop nutrition will remain the same as current practices for commercial corn production.	Unchanged from No Action Alternative
Organic Corn Production	Specialty crop growers employ practices and standards for production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops. Certified organic corn acreage is a small but increasing percentage of overall corn production. Organic corn production consisted of about 0.21 percent of total U.S. corn production.	Unchanged from No Action Alternative
Physical Environment		
Soil Quality	Agronomic practices such as crop type, tillage, and pest management can affect soil quality. Growers currently use best management practices to address their specific needs in producing corn.	Unchanged from No Action Alternative
Water Resources	The primary cause of agricultural non-point source pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as crop nutrient management, pest management, and conservation buffers help protect water quality from	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	agricultural runoff.	
Air Quality	Agricultural activities such as burning, tilling, harvesting, spraying pesticides, and fertilizing, including the emissions from farm equipment, can directly affect air quality. Aerial application of herbicides may impact air quality from drift, diffusion, and volatilization of the chemicals, as well as motor vehicle emissions from airplanes or helicopters.	Unchanged from No Action Alternative
Climate Change	Agriculture-related activities are recognized as both direct sources of GHG (e.g., exhaust from motorized equipment) and indirect sources (e.g., soil disturbance from tillage, fertilizer production).	Unchanged from No Action Alternative
Biological Resources		
Animal Communities	Corn fields may be host to many animal and insect species. Many of these animals are typically considered pests and may be controlled by the use of integrated pest management strategies.	Unchanged from the No Action Alternative
Plant Communities	Corn fields can be bordered by other agricultural fields, woodlands, or pasture and grasslands. The most agronomically important members of a surrounding plant community are those that behave as weeds. Corn growers use production practices to manage weeds in and around fields.	Unchanged from No Action Alternative
Gene Flow and Weediness	Cultivated corn varieties can cross pollinate. Growers use various production practices to limit undesired cross pollination.	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Microorganisms	Microorganisms are affected by tillage, agronomic activity and pesticides.	Unchanged from No Action Alternative
Biodiversity	The biological diversity in corn fields is highly managed and may be lower than in surrounding habitats.	Unchanged from No Action Alternative
Human and Animal Health		
Risk to Human Health	Corn has a known history of safe consumption and use. The EPA's WPS; (40 CFR part 170.1, *Scope and Purpose*) requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.	Unchanged from No Action Alternative. A comprehensive assessment of MON 87403 maize demonstrated that the proteins in MON 87403 maize are nontoxic to mammals and unlikely to be a food allergen and that MON 87403 maize is compositionally equivalent to commercially available corn varieties. Agricultural production of MON 87403 maize does not require any changes to the agronomic practices currently used for conventional corn. Therefore, worker safety issues associated with the agricultural production of MON 87403 maize would remain the same as those under the No Action Alternative
Risk to Animal Feed	Corn is a major feed protein for animal nutrition. It is the responsibility of food and feed manufacturers to ensure that the products they market are safe and labeled properly.	Unchanged from No Action Alternative. A compositional analysis concluded that MON 87403 maize is compositionally equivalent to conventional corn varieties.
Socioeconomic		
Domestic Economic Environment	Corn is the primary U.S. crop. The majority of corn (61.7 percent) is grown for animal feed. Corn production in 2013 had an estimated value of $62.7 billion. Crop values vary over time in	Unchanged from No Action Alternative. Corn will continue to be the primary crop produced in the U.S. Growers of MON 87403 maize may realize some financial benefits as a result of the potential

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	response to market conditions.	increased yield opportunity.
Trade Economic Environment	In 2013, the United States exported approximately $9.3 billion in corn products. The United States produced approximately 36% of the work corn supply. The United States is the leading exporter of corn. U.S. corn and corn products will continue to play a role in global corn production, and the United States will continue to be a supplier in the international market.	The trade economic impacts associated with a determination of nonregulated status of MON 87403 maize are anticipated to be similar to the No Action Alternative because Monsanto does not intend to globally launch MON 87403 maize until the proper regulatory approvals have been obtained.
Other Regulatory Approvals		
U.S.	Monsanto submitted a safety and nutritional assessment of food and feed derived from MON 87403 maize to FDA in October 2014 (USDA-APHIS, 2015). FDA consultation completed on June 19, 2015 (US-FDA, 2015).	Monsanto submitted a safety and nutritional assessment of food and feed derived from MON 87403 maize to FDA in October 2014 (USDA-APHIS, 2015). FDA consultation completed on June 19, 2015 (US-FDA, 2015).
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

Finding of No Significant Impact

The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. APHIS agrees with this conclusion and therefore finds that an EIS need not be prepared. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27):

Context – The term "context" recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action has potential to affect conventional and organic corn production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; and foreign and domestic commodity markets.

In terms of acreage, corn ranks first among crops cultivated in the United States (USDA-NASS, 2014a). From 1994 to 2014, acreage planted with corn increased from approximately 78.9 million acres to about 90.9 million acres. The geographic range of corn production in the United

States is primarily concentrated in the Corn Belt, an area that represents approximately 80 percent of annual U.S. corn production and includes Iowa, Illinois, Nebraska, and Minnesota, and parts of Indiana, South Dakota, Kansas, Ohio, Wisconsin, and Missouri (USDA-NASS, 2014b). Iowa and Illinois, the two top corn-producing states, typically account for one-third of the total U.S. corn crop (USDA-NASS, 2014a). As of 2014, it was estimated that approximately 13 percent of the crop was GE herbicide-resistant only, 4 percent was GE insect-resistant only, 76 percent was a stacked gene variety (likely both herbicide resistant and insect resistant), and 93 percent of the total U.S. corn crop was planted in some GE variety (USDA-NASS, 2014a).

A determination of nonregulated status of MON 87403 maize is not expected to directly cause an increase in agricultural acreage devoted to corn production or those corn acres devoted to GE corn cultivation. The availability of MON 87403 maize is not expected to change cultivation areas for corn production in the United States, because it is not substantially different from existing corn, and will not likely cause changes in the economic costs of that production. Consequently there are no anticipated changes to the availability of GE and non-GE corn varieties on the market.

Although a determination of nonregulated status of MON 87403 maize would allow for new plantings of MON 87403 maize to occur anywhere in the United States, APHIS limited the environmental analysis to those geographic areas that currently support corn production. A determination of nonregulated status of MON 87403 maize is not expected to increase corn production, or result in an increase in overall GE corn acreage or cultivation in new regions.

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

1. *Impacts that may be both beneficial and adverse.*
   A determination of nonregulated status of MON 87403 maize will have no significant environmental impact in relation to the availability of GE, conventional or organic corn varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 87403 maize is not expected to directly cause an increase in agricultural acreage devoted to corn production or those corn acres devoted to GE corn cultivation. The availability of MON 87403 maize is not expected to change regional cultivation patterns for corn production in the United States. There are no anticipated changes to the availability of GE and non-GE corn varieties now on the market.

   A determination of nonregulated status of MON 87403 maize will add another GE corn variety to the conventional corn market, but is not expected to change the market demands for GE corn or corn produced using organic methods. The acreage devoted to organic corn is expected to remain small regardless of whether new varieties of GE or non-GE corn varieties, including MON 87403 maize, become available for commercial corn production. In 2008, USDA Economic Research Services (USDA-ERS) reported that 194,637 acres out of a total 93.5 million (0.21 percent) planted corn acres were certified organic (USDA-ERS, 2010). Wisconsin, Iowa, Minnesota, Michigan, New York, Texas, and Nebraska each had more than 10,000 acres of certified organic corn, totaling approximately 68 percent of all certified organic acreage in the U.S. Generally, acreage increased from 2007 to 2008, although, in some instances, certain

states showed a decrease in the number of certified organic corn acres. The most recent survey showed that total acres of organic corn have declined from earlier surveys, although a few states have shown increased acreage. Organic corn was produced on 134,877 acres in 2011 and yielded 14.2 million bushels, equal to approximately 0.1 percent of U.S. corn production (USDA-NASS, 2012). MON 87403 maize would not present any new or different issues and impacts for organic corn producers and consumers. Based on demonstrated agronomic characteristics and cultivation practices, the market share of organic corn varieties is unlikely to change by the introduction of MON 87403 maize. APHIS has determined that there are no past, present, or reasonably foreseeable changes from the commercial production of MON 87403 maize that would impact organic corn producers and consumers.

As discussed in Chapter 4 of the EA, studies demonstrate MON 87403 maize is essentially indistinguishable from other corn varieties used in terms of agronomic characteristics and cultivation practices. Monsanto did not identify any differences between MON 87403 maize and conventional in dormancy, germination potential, disease or insect response, seedling vigor, or plant maturity (Monsanto, 2014; USDA-APHIS, 2015). MON 87403 maize is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterparts (Monsanto, 2014; USDA-APHIS, 2015). Consistent with the lack of difference in agronomic properties, MON 87403 maize is not expected to have an increased ability to cross pollinate other corn varieties. Changes in the agronomic practices and locations for corn seed production using MON 87403 maize are not expected. Additionally, MON 87403 maize does not show increased susceptibility to microbial or insect pests, suggesting that management practices would not differ between it and other corn varieties, including pesticide use (Monsanto, 2014; USDA-APHIS, 2015). Weed management practices in the production of MON 87403 maize are anticipated to be substantially the same as current corn production practices (Monsanto, 2014). MON 87403 maize is essentially indistinguishable from other currently cultivated corn varieties in terms of agronomic characteristics, cultivation practices, and disease susceptibility (Monsanto, 2014; USDA-APHIS, 2015). The absence of variety differences will make unlikely any new impacts deriving from management practices in corn production.

2. *The degree to which the proposed action affects public health or safety.*
A determination of nonregulated status of MON 87403 maize would have no significant impacts on human or animal health. Monsanto's intention in developing MON 87403 maize is to increase yields. There is no pesticide aspect associated with MON 87403 maize, so there is no need for an EPA registration or establishment of residue tolerances.

FDA has no questions about the food safety of MON 87403 maize. On June 19, 2015, the FDA completed its consultation on MON 87403 maize and has concluded that the product is not materially different in any respect relevant to food safety compared to corn varieties currently on the market, has no further questions about food and feed derived from this corn variety (US-FDA, 2015). Accordingly, MON 87403 maize is anticipated to be safe for human and animal consumption with reference to the *ATHB17* gene. Based on the FDA's consultation, our analysis of field and laboratory data and

scientific literature provided by Monsanto (Monsanto, 2014) and safety data available on other GE corn varieties, APHIS has concluded that a determination of nonregulated status of MON 87403 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 of MON 87403 maize. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property; do not cause any new alterations of property, wildlife habitat, or landscapes; and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of MON 87403 maize. The product will be deployed on agricultural land currently suitable for production of corn and is not expected to increase the acreage of corn production. This action would not convert land use to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87403 maize, including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of MON 87403 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.*

As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 87403 maize is not expected to directly cause an increase in agricultural acreage devoted to corn production or those corn acres devoted to GE corn cultivation. The availability of MON 87403 maize is not expected to 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. MON 87403 maize is not expected to result in changes in the current corn cropping practices. MON 87403 maize is genetically engineered to increase yields. Monsanto acknowledges that prior to commercialization, MON 87403 maize will be crossed with other non-regulated commercial varieties that possess herbicide and insect resistance. This resistance to herbicides and insect pests will be accomplished by traditional breeding (Monsanto, 2014). The impact of MON 87403 maize on wildlife or biodiversity is no different than that of other GE or non-GE corn produced in conventional agriculture in the U.S. Cultivation of MON 87403 maize is highly unlikely to have direct toxic effects on non-target organisms and is likely to be neutral to biodiversity compared with conventionally managed GE and non-GE corn.

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

Based on the analysis documented in the EA, the possible impacts on the human environment are well understood. The impacts of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 87403 maize is not expected to directly cause an increase in agricultural acreage devoted to all corn production or those corn acres devoted to GE corn cultivation. A determination of nonregulated status of MON 87403 maize is not expected to result in changes in the current corn cropping practices, including pesticide use. As discussed in Chapter 4 of the EA, studies demonstrate MON 87403 maize is essentially indistinguishable from other corn varieties used in terms of agronomic characteristics and cultivation practices (Monsanto, 2014). Monsanto did not identify any differences between MON 87403 maize and conventional corn in seed dormancy and germination, pollen morphology, plant phenotypic observations and environmental interaction evaluations (Monsanto, 2014). The effect of MON 87403 maize on wildlife or biodiversity is no different than that of other GE or non-GE corn produced in conventional agriculture in the United States. Cultivation of MON 87403 maize is highly unlikely to have direct toxic effects on non-target organisms and is likely to be neutral to biodiversity compared with conventionally managed GE and non-GE corn. As described in Chapter 4 of the EA, well established management practices, production controls, and production practices (GE, conventional and organic) are currently being used in corn production systems (commercial and seed production) in the United States. Therefore, it is reasonable to assume that farmers, who produce conventional corn (GE and non-GE varieties), MON 87403 maize, or produce corn using organic methods, will continue to use these reasonable and commonly accepted best management practices for their chosen systems and varieties during agricultural corn production. MON 87403 maize will be added to existing corn varieties through traditional breeding and is not expected to change the market demands for GE corn or corn produced using organic methods. Cultivation of MON 87403 maize as a new GE corn variety would not present any new or different issues and impacts for organic corn producers and consumers. Based on demonstrated agronomic characteristics and cultivation practices, and because the market share of organic corn varieties is unlikely to change by the introduction of MON 87403 maize, APHIS has determined that there are no past, present, or reasonably foreseeable changes that would impact organic corn producers and consumers. Additionally, most of the corn acreage in the United States is planted to GE corn. Currently 96 percent of the corn grown in the United States is genetically engineered, an increase of 61% since 2000 (USDA-ERS, 2014). Based upon historic trends, conventional production practices that use GE varieties will likely continue to dominate in terms of acreage with or without a determination of nonregulated status of MON 87403 maize. Given the extensive experience that APHIS, stakeholders, and growers have in dealing with the use of GE corn products and organic corn varieties, the possible impacts to the human environment from the release of an additional GE corn product are already known and understood. Therefore the impacts are not highly uncertain, and do not involve unique or unknown risks.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*
A determination of nonregulated status of MON 87403 maize would not establish a precedent for future actions with significant impacts or represent a decision in principle about a future decision. Each petition that APHIS receives is for a specific GE organism and undergoes a specific review to determine if the regulated article poses a plant pest risk. Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR Part 340, APHIS has issued authorizations for the introduction of regulated 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 87403 maize. When a petition for nonregulated status is submitted, APHIS must make a determination whether the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its PPRA 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 Plant Protection Act and 7 CFR Part 340. APHIS regulations at 7 CFR Part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, should no longer be regulated under the plant pest provisions of the Plant Protection Act or the regulations at 7 CFR 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*
No significant cumulative impacts were identified through this assessment. The EA discussed cumulative impacts on corn management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative impacts analysis is included for each environmental issue analyzed in Chapter 4 of the EA. In the event of a determination of nonregulated status, MON 87403 maize may be stacked (combined) with non-GE and GE corn traits by traditional breeding techniques, resulting in a plant that, for example, may also be resistant to herbicides, but may also have progeny with no transgenes at all. There is no assurance that MON 87403 maize will be stacked with any particular non-GE or GE corn traits that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR Part 340, as company plans and market demands play a significant role in those business decisions. Extensively foreseeing all potential combinations of stacked varieties that could be created using both

non-GE and GE corn varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR Part 340 is hypothetical and purely speculative. In the event of a determination of nonregulated status of MON 87403 maize APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of MON 87403 maize when added to other past, present, and reasonably foreseeable future actions.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.*
A determination of nonregulated status of MON 87403 maize is not expected to adversely affect cultural resources on tribal properties. Any farming activities that may be undertaken 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 87403 maize would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of nonregulated status of MON 87403 maize. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87403 maize, including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential significant impacts to the human environment. A determination of nonregulated status of MON 87403 maize is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in impacts on the character or use of historic properties. For example, there is potential for audible impacts on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary impacts on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the corn production regions. The cultivation of MON 87403 maize does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

9. *The degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*
As described in Chapters 4 and 6 of the EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of MON 87403 maize on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section

7 of the Endangered Species Act. After reviewing possible impacts of a determination of nonregulated status of MON 87403 maize, APHIS has concluded that a determination of nonregulated status of MON 87403 maize would have no effect on federally listed threatened or endangered species and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*
The proposed action would be in compliance with all federal, state, and local laws. Because the agency has concluded that MON 87403 maize is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87403 maize is a response that is consistent with the plant pest provisions of the Plant Protection Act and the regulations codified in 7 CFR Part 340. MON 87403 maize falls within the scope of the 1992 FDA's policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (US-FDA, 1992). In compliance with this policy, Monsanto initiated a consultation with the FDA on the food and feed safety and nutritional assessment summary for MON 87403 maize. FDA agreed with Monsanto's safety assessment, and concluded that "MON 87403 maize, and food and feed derived from it are as safe as conventional corn varieties and are not materially different in composition or any other relevant parameter from other corn varieties now grown, marketed, and consumed in the United States." A copy of the completed FDA review can be found at FDA's website[2]. 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 87403 maize is No Longer a Regulated Article). This alternative meets APHIS' purpose and need to allow the development and use of genetically engineered organisms consistent with the plant pest provisions of the Plant Protection Act.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with MON 87403 maize, the continued regulated status of MON 87403 maize would be inconsistent with the plant pest provisions of the Plant Protection Act, the regulations codified at 7 CFR Part 340, and the principles and guidance in the Coordinated Framework. For the reasons stated above, I have determined that a

[2] http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/UCM427610

determination of nonregulated status of MON 87403 maize will not have any significant environmental impacts.

M. J. Firko

11/17/2015

Michael J. Firko, Ph.D.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
U.S. Department of Agriculture

Date:

Response to Public Comments on Monsanto 87403 Corn

In a *Federal Register* notice (80 FR 2674-2675) on January 20, 2015, APHIS announced the availability of the petition for public review and comment (Docket No. APHIS-2014-0097). The 60-day public comment period closed on March 23, 2015. APHIS received 20 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/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2014-0097;refD=APHIS-2014-0097-0002

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 July 21, 2015, APHIS published a notice in the Federal Register (80 FR 43053-43055, Docket No. APHIS- 2014-0097) announcing the availability of the draft Environmental Assessment (EA) and preliminary plant pest risk assessment (PPRA) for a 60-day public review period. The comment period closed on August 20, 2015. APHIS received a total of 4 comments: one supported a decision of nonregulated status for MON 87403 maize; two were opposed, and one was in support of nonregulated status but wanted APHIS to require continued oversight during the commercialization process. Comments can be reviewed in the docket file at:

http://www.regulations.gov/#!documentDetail;D=APHIS-2014-0097-0023

The two comments expressing opposition to nonregulatory status for MON 87403 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. The comment in support of the petition was from a grower association citing the benefit of increased yields for farmers and the need to feed the world's population.

Issue 1. A commenter disagrees with APHIS's blanket statements in the socioeconomic impact discussion that a determination of nonregulated status for MON 87403 is not expected to adversely impact domestic commerce nor impact international corn markets. In support of this, the commenter pointed out that the draft environmental assessment is deficient in that it does not specify what Monsanto defines as "all key corn import markets with a functioning regulatory system." The commenter stated that the draft environmental assessment should be amended to identify and list the names of the specific countries for which Monsanto commits to obtain import authorization prior to commercializing MON 87403 in the United States, its projected timelines for obtaining such import authorizations, and steps regarding risk responsibility if such authorizations are not obtained. The commenter pointed to past problems with trade issues when developers provided seed to U.S. growers prior to having approvals in key nations that import the crop from the U.S.

APHIS disagrees with the statement that the socioeconomic impact findings in the EA are incorrect. Although trade issues have occurred in the past, there is no reason to believe that Monsanto will commercialize MON 87403 maize in the United States prior to obtaining approval with key trading partners. That said, it must be pointed out that Monsanto's plans and

efforts to seek approvals from foreign governments is beyond the APHIS' authority to regulate plants developed through genetic engineering. Requiring the applicant to identify which countries it is seeking regulatory approval from, and the timeframes of these approvals, would serve no regulatory purpose. The APHIS regulatory authority over GE organisms is limited to those GE organisms for which it has reason to believe might be a plant pest (7 CFR §340.1). After completing a PPRA, if APHIS determines that MON 87403 maize seeds, plants, or parts thereof do not pose a plant pest risk, then the article would no longer be subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that the article is no longer regulated. Once an article is no longer regulated, unless new information were to surface leading to the possibility of the article being a plant pest as defined in the Plant Protection Act, APHIS lacks regulatory authority over the article, including how developers market their products and work with foreign entities.

Issue 2. A commenter recommends that APHIS create and apply a different category of "deregulation" – namely *"conditional deregulation"* – expressly for MON 87403 and for other biotech-enhanced events that the agency determines do not present a plant pest or noxious weed risk, but which have not received approvals in significant U.S. export markets.

There are no provisions within APHIS' regulatory authority that allows for a "conditional deregulation" based on market approvals as suggested by the commenter, The APHIS regulatory authority over GE organisms is limited to those GE organisms for which it has reason to believe might be a plant pest (7 CFR §340.1). After completing a PPRA, if APHIS determines that MON 87403 maize seeds, plants, or parts thereof do not pose a plant pest risk, then the article would no longer be subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that the article is no longer regulated. Once an article is no longer regulated, unless new information were to surface leading to the possibility of the article being a plant pest as defined in the Plant Protection Act, APHIS lacks regulatory authority over the article.

Issue 3. A commenter encourages APHIS to work with other U.S. and foreign government entities and market stakeholders to develop and implement a U.S. policy that addresses the low-level presence (LLP) of biotech-enhanced events in both imports and exports that have been scientifically reviewed and approved as safe by a competent government authority in the country of export, but not yet by the importing country. The commenter pointed to organizations like the Biotechnology Industry Organization and CropLife International, which represent plant science and biotechnology companies, that have developed standards and policies for coexistence and stewardship. In these standards, technology owners are expected to communicate promptly, broadly and in a transparent manner with stakeholders.

APHIS has an LLP policy that applies to articles derived from plant biotechnology that are "regulated articles". As discussed under Issues 1 and 2, APHIS' regulatory authority over GE organisms is limited to those GE organisms for which it has reason to believe might be a plant pest (7 CFR §340.1). Although APHIS agrees that industry standards should be adopted and followed, APHIS does not have the authority to impose these standards on the industry for articles it no longer regulates. In addition, APHIS has no authority to hold companies responsible

for any disruption to agricultural markets that may occur as a result of how developers commercialize and market products.

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