NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

Bayer CropScience
Petition (16-235-01p) for Extension of Determination of Non-regulated Status for Male Sterile, Glufosinate-Ammonium Resistant MS11 Canola (*Brassica napus*)

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 on Environmental Quality (CEQ) NEPA implementing regulations (7 CFR parts 1500-1508), and USDA-APHIS NEPA implementing regulations (7 CFR part 372). This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale.

Bayer CropScience of Research Triangle Park, N.C. (hereafter referred to as Bayer) submitted a petition (16-235-01p, amended as 16-235-01p-a1[1]) to APHIS in September 2016 requesting an extension of non-regulated status for MS11 canola, which has been genetically engineered (GE) for male sterility and resistance to the herbicide active ingredient glufosinate-ammonium (Weeks et al. 2016). Bayer requests that an APHIS determination of non-regulated status for InVigor® Hybrid Canola MS8, issued by APHIS in 1999,[2] be extended to MS11 canola. Bayer has requested that APHIS extend non-regulated status to MS11 canola based on its similarity to MS8 canola; both have been genetically engineered (GE) for male sterility and resistance to the herbicide active ingredient, glufosinate-ammonium.[3] In the event APHIS extends a determination of non-regulated status, the non-regulated status would include MS11 canola and any progeny derived from crosses of MS11 canola and conventional canola, including crosses with other GE

[1] The amended petition corrects the year of publication of one reference cited in the petition and provides longer exposures of two photographs in the petition in order to clearly visualize positive controls.

[2] 64 Federal Register, No. 61, Wednesday, March 31, 1999, p. 15337: Notice - AgrEvo USA Co.; Availability of Determination of Nonregulated Status for Canola Genetically Engineered for Male Sterility, Fertility Restoration, and Glufosinate Herbicide Tolerance [https://www.gpo.gov/fdsys/pkg/FR-1999-03-31/pdf/99-7803.pdf]

[3] "Resistance" to herbicides is defined by the Weed Science Society of America (WSSA) as the inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type. In a plant, resistance may be naturally occurring, induced by such techniques as genetic engineering, or by tissue culture or mutagenesis. "Tolerance" is distinguished from resistance and defined by WSSA as the inherent ability of a plant to survive and reproduce following exposure to an herbicide. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. In its request to APHIS, Bayer references MS11 canola as herbicide "tolerant" and used the terms "tolerance" and "tolerant" throughout its documentation to describe MS11 canola. In this EA, APHIS has used the term "resistance" when referring to MS11 canola to be consistent with the WSSA definition. For the purposes of this EA, Bayer's use of the term "herbicide-tolerant" can be considered synonymous with "herbicide-resistant" (HR), as used in this EA.

canola varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or under the authority of the Plant Protection Act (PPA). As part of the evaluation of Bayer's extension request, APHIS completed an Environmental Assessment (EA) to determine if there are any significant environmental impacts that could derive from approval of the extension request.

APHIS Regulatory Authority

"Protecting American agriculture" is the basic mission of APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of GE varieties) can provide benefits to the environment, consumers, and farm income. APHIS' authority to regulate GE organisms derives from the plant pest provisions in the PPA of 2000, as amended (7 USC §7701 *et seq*.). APHIS regulates GE organisms to ensure that they do not pose a plant pest risk based on requirements in 7 CFR part 340.

APHIS' Response to a Request for Extension of Non-regulated Status

As required by 7 CFR § 340.6, APHIS must respond to petitioners who request a determination of regulatory status for GE organisms subject to 7 CFR part 340. APHIS reviewed Bayer's extension request (Weeks et al. 2016) and based on a Plant Pest Risk Similarity Assessment (PPRSA) and other relevant information has concluded that MS11 canola is no more likely to pose a plant pest risk than the previously deregulated MS8 canola (USDA-APHIS 2016). APHIS has also conducted an EA to determine if there are any significant impacts on the human environment that could derive from an extension of non-regulated status to MS11 canola. APHIS conducted an EA for the prior petition (98-278-01p) and issued a FONSI for its determination of non-regulated for MS8 and RF3 canola in 1999.[4] APHIS has considered the NEPA documentation for petition 98-278-01p, and, due to the time that has elapsed since issuance of the prior FONSI, has conducted a new EA for Bayer's MS11 canola petition (16-235-01p).

MS11 Canola

MS11 canola is genetically engineered for male sterility and resistance to the herbicide active ingredient glufosinate-ammonium. MS11 canola was produced by insertion of the bar gene from *Streptomyces hygroscopicus*, and the barstar and barnase genes from *Bacillus amyloliquefaciens*, using *Agrobacterium*-mediated transformation. The bar gene encodes for the enzyme phosphinothricin N-acetyltransferase (PAT), which confers resistance to glufosinate-ammonium.[5] The barnase gene renders the plant male sterile through production of the enzyme barnase. The barstar gene in MS11 improves transformation efficiency; it has no effect on the male sterile, glufosinate-ammonium resistant phenotype. Based on field trials and molecular

[4] USDA-APHIS Petitions for Determination of Nonregulated Status: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status

[5] Glufosinate is described under the EPA Substance Registry System as: Butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, (CAS. No. 51276-47-2). The International Union of Pure and Applied Chemistry (IUPAC) identifies glufosinate as: (2RS)-2-amino-4-[hydroxy(methyl)phosphinoyl]butyric acid, or 2-Amino-4-[hydroxy(methyl)phosphoryl]butanoic acid. When we refer to glufosinate we mean this compound and its salts.

characterization studies, MS11 canola is agronomically and phenotypically similar to its antecedent, MS8 canola (Weeks et al. 2016).

The purpose of MS11 canola is to eventually replace Bayer's current MS8 canola line, which is used as breeding stock in the production of GE herbicide-resistant (HR) canola crop seed. The current crop seed production system is comprised of two GE canola lines. The first, MS8 canola, is a male sterile, glufosinate-ammonium resistant canola line, which is conferred by the barnase and bar genes, respectively. The second, RF3 canola, is also glufosinate-ammonium resistant (bar gene), and provides fertility restoration via the barstar gene. When MS8 and RF3 canola are crossbred (denoted as MS8 × RF3), the resultant hybrid crop seed is both fertile and glufosinate-ammonium resistant.

It is anticipated that MS8 will be gradually phased out during the next ten years and replaced by MS11 canola. Hence, rather than MS8 canola, MS11 canola will be used in the production of glufosinate-ammonium resistant crop seed. Fundamentally, there is no difference between the intended purpose and rational for the use of MS11 and MS8 canola lines. MS11 hybrid seed will be used for commercial canola crop production, the same as the current MS8 hybrid seed. Crops derived from planting these seeds will be used for the production of canola oil and canola meal, the latter of which is primarily used for animal feed.

Coordinated Framework

In 1986, the Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology (CF), which describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology products (51 FR 23302, 1986). Since 1986, the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and USDA has regulated GE organisms consistent with this framework. The CF 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 should focus on the characteristics and risks of the biotechnology product, not the process by which it is created; and, (3) agencies should exercise oversight of biotechnology products only when there is evidence of "unreasonable" risk.

In 2015, the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the United States Department of Agriculture (USDA) began an effort to modernize the regulatory system for biotechnology products to accomplish three tasks: (1) clarify the current roles and responsibilities of the EPA, FDA, and USDA in the regulatory process; (2) develop a long-term strategy to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, of the future products of biotechnology; and (3) commission an expert analysis of the future landscape of biotechnology products. The *Update to the Coordinated Framework for the Regulation of Biotechnology* was released on January 4, 2017,[6] representing the first time in 30 years that the federal government has produced a comprehensive summary of the roles and responsibilities of the three principal regulatory agencies with respect to regulating biotechnology products. This update offers the public a complete picture of a robust

[6] See https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/update-coordinated-framework-regulation-biotechnology

and flexible regulatory structure that provides appropriate oversight for all products of modern biotechnology. Within that regulatory structure the federal agencies maintain high standards that, based on the best available science, protect health and the environment, while also establishing transparent, coordinated, predictable and efficient regulatory practices. The authorities and regulatory roles for APHIS, the EPA, and FDA are briefly summarized below.

USDA-APHIS

As described above, APHIS regulates GE organisms to ensure that they do not pose a plant pest risk pursuant to the PPA of 2000 and APHIS implementing regulations at 7 CFR part 340. As part of regulatory review for MS11 canola, APHIS conducted a PPRSA and the EA subject of this FONSI.

FDA

The FDA regulates GE organisms pursuant to the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations pursuant 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.[7] Pursuant to 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 are resolved prior to commercial distribution of bioengineered foods. If Bayer intendeds to market MS11 canola for food or feed purposes, Bayer may consult with the FDA on the food and feed safety of canola oil and meal derived from MS11 canola hybrid seed.

EPA

The EPA regulates pesticides, including plant-incorporated protectants pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Specifically, the EPA sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, pursuant to FFDCA, and regulates certain biological control organisms pursuant to 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.

Glufosinate (also called phosphinothricin), the herbicide active ingredient to which MS11 canola is resistant, was first registered by the EPA in 1993, and is currently registered for use on a variety of crops. The EPA reviews each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration. The EPA is currently reviewing glufosinate (US-EPA 2016) and issued an updated ecological risk assessment in 2014 (US-EPA 2014).

The Environmental Assessment and Scope of Analysis

[7] Available at U.S. FDA: Statement of Policy - Foods Derived from New Plant Varieties; http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm

The EA was prepared consistent with the CEQ regulations (40 CFR parts 1500-1508) and USDA-APHIS NEPA implementing regulations (7 CFR part 372). APHIS developed a list of resource areas for consideration in the EA based on issues identified in the EA for InVigor® Hybrid Canola MS8 and RF3, public comments submitted for other EAs and EISs evaluating petitions for non-regulated status, the scientific literature on agricultural biotechnology, and issues identified by APHIS specific to wild and cultivated *Brassica* species. The following topics were identified as relevant to the scope of analysis (40 CFR § 1508.25):

Agricultural Production

- Acreage and Areas of Canola Production
- Agronomic Practices and Inputs

Environmental Considerations

- Soil Quality
- Water Resources
- Air Quality
- Soil Biota
- Animal and Plant Communities
- Herbicide Resistant Weeds
- Gene Flow and Weediness of Canola
- Biodiversity
- Climate Change

Human Health

- Consumer Health and Worker Safety

Animal Health

- Animal Feed/Livestock Health

Socioeconomics

- Domestic Economic Environment and International Trade

In addition to evaluation of potential direct and indirect impacts, potential cumulative impacts relative to these topics were also considered, potential impacts on threatened and endangered species, as wells as adherence of the proposed action to executive orders, and environmental laws and regulations to which the regulatory status decision may be subject.

Public Involvement

On April 12, 2017, APHIS announced in the *Federal Register* it was making available its draft EA, preliminary regulatory determination, preliminary FONSI, and preliminary PPRSA for public review and comment (82 FR No. 69, April 12, 2017, pp. 17625-17626). On May 10, 2017, APHIS announced in the *Federal Register* that the comment period for the notice published on April 12, 2017 would be extended to May 30, 2017 (82 FR, No. 89, May 10, 2017, p. 21790). At the end of the comment period APHIS had received 5 comments. The Agency expresses thanks to all those who participated in the public involvement process by reviewing these documents for the MS11 canola petition request and providing comments. APHIS welcomes public involvement and considers public perspectives and input in its decision-making process.

APHIS evaluated the comments received and determined that no new, substantive information was provided that required changes to the analyses presented in these documents or the Agency's preliminary regulatory status determination. Hence, APHIS prepared a final EA, FONSI, and PPRSA, and issued a final decision to extend non-regulated status to MS11 canola. All of these documents are available to the public on the APHIS-BRS website (Petition 16-235-01p).[8] All comments received on the draft EA remain available for public review at www.regulations.gov, Docket ID: APHIS-2017-0015.[9] APHIS provides a more detailed response to comments in the last section of this FONSI.

Alternatives Evaluated in the EA

The EA considered two alternatives in responding to the extensions request, to either deny or approve the request for extension of non-regulated status, and analyzed the potential environmental and socioeconomic impacts that may result from the alternatives.

No Action: Continuation as a Regulated Article

One of the alternatives that must be considered by APHIS is a "No Action Alternative," pursuant to CEQ regulations at 40 CFR § 1502.14. Under the No Action Alternative, APHIS would deny the petition. MS11 canola and progeny derived from MS11 canola would continue to be regulated articles under the regulations at 7 CFR part 340. Authorizations by APHIS would continue to be required for introductions of MS11 canola 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 MS11 canola.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRSA that MS11 canola is unlikely to pose a plant pest risk (USDA-APHIS 2016). 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 non-regulated status.

Preferred Alternative: Determination of Non-regulated Status for MS11 Canola

Under the Preferred Alternative, MS11 canola and progeny derived from it would no longer be regulated articles under the regulations at 7 CFR part 340. APHIS has conducted a science-based PPRSA and evaluated the plant pest risks associated with MS11 canola (USDA-APHIS 2016). Based upon this analysis, APHIS believes that MS11 is unlikely to pose a plant pest risk. APHIS would no longer require authorizations for introductions of MS11 canola 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. Because the agency has concluded that MS11 canola is unlikely to poise a plant pest risk, a determination of non-regulated status of MS11 canola is the response that is consistent with the plant pest provisions of the PPA, the

[8] USDA-APHIS-BRS, Petitions for Determination of Nonregulated Status: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status

[9] https://www.regulations.gov/docket?D=APHIS-2017-0015

regulations codified in 7 CFR part 340, and the biotechnology regulatory policies described for the Coordinated Framework.

Under this alternative, growers may have future access to MS11 canola and progeny derived from this event if the developer decides to commercialize MS11 canola.

Alternatives Considered but Dismissed from Detailed Analysis in the EA

APHIS assembled a list of alternatives that might be considered for MS11 canola. The Agency evaluated these alternatives in light of 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 MS11 canola. Based on this evaluation, APHIS rejected several alternatives. These alternatives are summarized below along with the specific reasons why they were rejected.

Prohibit the Release of MS11 Canola

APHIS considered prohibiting the environmental release of MS11 canola, including denying permits for field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MS11 canola is unlikely to pose a plant pest risk (USDA-APHIS 2016).

In enacting the Plant Protection Act (PPA) of 2000, Congress included findings that:

"decisions affecting imports, exports, and interstate movement of products regulated under [the PPA] shall be based on sound science;…" (7 U.S. C. § 7701(4)) and that "The Secretary's determination on the petition shall be based on sound science" (§ 7711(3)(c)).

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

"Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency"

MS8 canola is no longer regulated by APHIS. It has been in commercial production for over 10 years. Over this time, APHIS is not aware of MS8 canola being a plant pest or presenting a plant pest risk. In addition, MS11 canola has been field tested under APHIS permits. Based on the PPRSA for MS11 canola (USDA-APHIS 2016), experience with MS8 canola, MS11 field tests, and additional scientific information, APHIS concluded that MS11 canola is unlikely to pose a plant pest risk. Accordingly, there is no scientific or legal basis for prohibiting the release of MS11 canola. Consequently, an alternative that would prohibit the environmental release of MS11 was dismissed.

Approve the Request for Extension 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 non-regulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. APHIS has previously concluded that MS8 and RF3 canola lines should no longer be regulated. APHIS has also concluded that MS11 canola is unlikely to pose a plant pest risk (USDA-APHIS 2016). Therefore, it would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340 to consider approval of the petition only in part. Consequently, this alternative was dismissed for detailed analysis in this EA.

Isolation Distance of MS11 Canola and Non-GE Canola Production Systems or Geographic Restriction

In the past, APHIS has received public comments expressing concerns regarding gene movement between GE and non-GE plants. APHIS considered requiring isolation distances for separation of MS11 canola from non-GE canola cropping systems. APHIS also considered geographically restricting the production of MS11 canola based on the location of production of non-GE canola in organic production systems or production systems for GE-sensitive markets. However, because APHIS has concluded that MS11 canola is not likely to pose a plant pest risk (USDA-APHIS 2016), prescribing isolation distances or geographic restrictions on production would be inconsistent with APHIS' statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340. In addition, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to the request for extension of non-regulated status based on the requirements in 7 CFR part 340 and the Agency's authority under the plant pest provisions of the PPA. Consequently, this alternative was dismissed. However, this would not prevent individuals from voluntarily choosing to isolate or geographically restrict their non-GE canola production systems from MS11 canola or to use other management practices to minimize gene movement between canola fields.

Requirements for Testing MS11 Canola

During comment periods for other petitions for non-regulated status, certain commenters requested that the USDA require and provide testing for the presence of GE material in non-GE production systems. Because there are no federal regulations describing testing criteria or quantitative thresholds for GE material in non-GE cropping systems or crop products, nationwide testing and monitoring would be extremely difficult to implement. Additionally, because MS11 canola is unlikely to pose a plant pest risk (USDA-APHIS 2016), the imposition of any type of testing requirements for MS11 canola would be inconsistent with the PPA, 7 CFR part 340, and federal regulatory policies embodied in the Coordinated Framework. Consequently, this alternative was dismissed.

Environmental Consequences of APHIS' Selected Action

The EA provides a thorough analysis of the alternatives considered to which the reader is referred for specific details. The following table briefly summarizes the results for each of the issues analyzed in the EA.

Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MS11 Canola as a Plant Pest**	**Preferred Alternative: Extension of Non-regulated Status to MS11 Canola**
Meets Purpose and Need	No	Yes
Unlikely to pose a plant pest risk	Addressed by the use of regulated field trials.	Determined by the plant pest risk similarity assessment (USDA-APHIS 2016).
Agricultural Production		
Acreage and Areas of Canola Production	Denial of the petition would have no effect on the location or acreage of canola production. There may be fluctuations in production areas and acreage relative to market demand for canola products.	Extension of non-regulated status to MS11 canola, and the eventual replacement of MS8 with MS11 canola, is not expected to alter the location or acreage of canola production.
Agronomic Practices and Inputs	Agronomic practices or inputs used in canola crop production would remain unchanged.	Because MS11 canola is phenotypically and agronomically similar to currently cultivated MS8 canola, agronomic practices and inputs would be the same.
Physical Environment		
Soils	Agronomic practices, inputs, or other factors that impact soils would be unaffected by denial of the petition. Growers will continue or adopt management practices, such as crop rotation, tillage, and pest and weed management strategies that maximize crop yield, avoid the development of herbicide resistance, preserve soil quality, and avoid erosion. Growers may experience more efficient weed control using HR canola over non HR varieties. This may reduce the need for certain weed control practices such as tillage. A reduction in tillage may reduce soil erosion in some areas.	Because MS11 canola is phenotypically similar to currently cultivated MS8 canola, and agronomic management practices and inputs are the same for both MS11 and MS8 canola, potential impacts to soils would be unchanged.
Water Resources	Agronomic practices and inputs, such as irrigation needs and pesticide use, or other factors that may impact water resources would be unaffected. Soil erosion and runoff are a significant form of non-point source (NPS) water pollution. This NPS can introduce sediments, fertilizer, pesticides, and other types of pollution into aquatic ecosystems. It is expected that growers will continue or adopt management practices to mitigate erosion, run-off, and other adverse impacts on water quality. Growers may experience more efficient weed control using HR canola over non HR varieties. This may reduce the need for certain weed control practices such as tillage. A reduction in tillage may reduce erosion in some areas. The EPA regulates pesticides applied to GE	Because MS11 canola is phenotypically and agronomically similar to currently cultivated MS8 canola, an extension of non-regulated status to MS11 canola is not expected to alter potential impacts on water resources.

Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MS11 Canola as a Plant Pest**	**Preferred Alternative: Extension of Non-regulated Status to MS11 Canola**
	HR canola and determines whether pesticides, including those that contain glufosinate, pose an unacceptable risk to non-target organisms, including aquatic organisms.	
Air Quality	Emission sources and the level of emissions associated with canola production would be unaffected by denial of the petition.	Potential impacts on air quality would be the same as under the No Action Alternative.
Biological Resources		
Soil Biota	Potential impacts on soil biota would be unaffected by denial of the petition. The EPA regulates pesticides applied to GE HR canola and determines whether pesticides pose an unacceptable risk to soil biota.	Commercial production of MS11 canola and MS11 hybrid crops is unlikely to affect soil biota any differently than cropping systems based on MS8 hybrid canola.
Animal Communities	Potential impacts on animal communities would be unaffected by denial of the petition. Canola fields can contain several animal species. Some species (such as insect crop pests) may need to be controlled using a range of tools. These tools may be deployed within integrated pest management strategies. The EPA regulates pesticides and determines whether they pose an unacceptable risk to animal communities. It is violation of federal law to use a pesticide in a manner that is not in strict accordance with the instructions on its EPA-approved label.	Potential impacts on animal communities would the same as that under the No Action Alternative.
Plant Communities	Potential impacts on plant communities would be unaffected by denial of the petition. Plants (other than crop plants) in canola fields are considered weeds as they can impact crop yield and quality. Weeds are managed using a range of tools, including mechanical control methods such as tillage and herbicides. Growers may be able to more efficiently control weeds when they use HR canola varieties compared to when they use non-HR varieties. This may reduce the need for certain weed control practices such as tillage and the use of additional herbicides. The EPA regulates and determines how pesticides can be used. EPA pesticide use requirements are intended to be protective of non-target plant communities and other plants, such as those in adjacent fields.	Potential impacts on plant communities would the same as that for the No Action Alternative.
Herbicide Resistant Weeds	The over-reliance on a weed control method, such as using a single herbicide, can impose a selection pressure on weed	Because the agronomic management practices used in cultivation of MS11 canola are the same as those currently used in

Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MS11 Canola as a Plant Pest**	**Preferred Alternative: Extension of Non-regulated Status to MS11 Canola**
	communities adjacent to or within production systems. Over time, this can lead to the development of weed populations that are resistant to that control method. Although the use of glufosinate could result in development of resistant weed populations, there are several strategies that greatly reduce the chances that this will occur. The EPA issued updated guidance for glufosinate resistance management in 2016. This is supported by technical information from the Weed Science Society of America (WSSA), information developed and disseminated by the USDA, universities, and others. It is violation of federal law to use a pesticide in a manner that is not in strict accordance with the instructions on its EPA-approved label. It is expected that herbicides registered for use on canola will be used per EPA requirements, within an overall strategy that reduces the development and spread of glufosinate resistant weed populations.	cultivation of MS8 canola, an extension of non-regulated status to MS11 canola is not expected to increase the propensity for, or the rate or extent of development of, glufosinate resistant weed populations as compared to the No Action Alternative.
Gene Flow and Weediness	Pollen may flow from GE HR canola to sexually-compatible wild relatives i.e., *Brassica* spp. The progeny of this gene flow (e.g., seeds) could spread populations to other areas and lead to the establishment of additional feral hybrid populations. Because of the general ecological requirements of *Brassica* spp., the establishment of feral hybrid populations is more likely in sites that are subject to frequent disturbances. Pollen dispersal is most likely to areas 300 feet or less from pollen sources. Rarely, outcrosses may occur at distances up to 2 miles away. APHIS recognizes interspecific and intraspecific hybridization will occur, although probably at a low frequencies. Gene flow is most likely to occur among *B. napus* crops grown in adjacent areas, and *B. napus* crops and wild relative *B. rapa* species.	An extension of non-regulated status for MS11 canola would not be expected to increase or decrease the risk for gene flow to wild relative species as compared MS8 canola. Likewise, the risk for occurrence and persistence of feral MS11 canola hybrids and volunteers would not be expected to be any different from MS8 canola. Based on the PPRSA, APHIS concluded that is unlikely that gene introgression from MS11 event to other organism with which it can interbreed will increase their weediness (USDA-APHIS 2016). Consequently, the Preferred Alternative is not expected to substantially differ from the No Action Alternative in regard to the potential environmental impacts associated with gene flow and weediness.
Biodiversity	Under the No Action Alternative, MS11 canola and its progeny would continue to be regulated by APHIS under 7 CFR part 340, and it could be grown in field trial settings under permit or notification. Because of the relatively small acreages and short periods required for field trials compared to that of commercial-scale crop seed production, it is	Because MS11 canola is phenotypically and agronomically similar to currently cultivated MS8 canola, potential impacts on biodiversity would be the same as under the No Action Alternative.

Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MS11 Canola as a Plant Pest**	**Preferred Alternative: Extension of Non-regulated Status to MS11 Canola**
	unlikely that MS11 field trials would impact biodiversity.	
Human and Animal Health		
Human Health	The FDA regulates food and feed safety and, in 1998, consulted with AgrEvo (acquired by Bayer CropScience in 2001) on MS8 and RF3 canola. The bar, barnase, and barstar genes and their expression products have been evaluated by the FDA, naturally occur in soils worldwide, and present negligible risk to human health. MS8 canola has been on the commercial market for over a decade. The EPA regulates use of glufosinate. The EPA concluded on glufosinate registration review that the current tolerances are accurate and protective of human health. The EPA pesticide registration review for glufosinate includes the development of use restrictions that, when followed, have been determined to be protective of worker health. It is violation of federal law to use a pesticide in a manner that is not in strict accordance with the instructions on its label.	An extension of non-regulated status for MS11 canola would present negligible risk to human health, to include worker safety. MS11 canola is equivalent to currently cultivated MS8 canola, which has been used for production canola oil and canola meal in the United States for more than a decade. An extension of non-regulated status would not be expected to have any effect on glufosinate use, EPA regulation of glufosinate, or worker protection standards.
Animal Health and Welfare	The FDA consulted with AgrEvo on MS8 and RF3 canola and had no concerns regarding feed derived from these canola cultivars. Under the No Action Alternative, MS11 canola will remain a regulated article, will not be available as an animal feed, and current canola based feed for livestock will remain unchanged.	The PAT, barstar, and barnase proteins present negligible risk to animals. Extension of non-regulated status to MS11 canola would not result in any novel exposure of livestock to these proteins, given they are currently present in commercial GE HR canola used for production of canola meal, as well as in soils. Under both the Preferred and No Action Alternative animal health and welfare would be expected to be supported by canola based feed, to include canola meal derived from MS8 canola hybrids and MS11 canola hybrids.
Socioeconomic Effects		
Domestic Economic Environment	MS11 canola would continue to be regulated by APHIS and would not be used for commercial purposes. MS8 canola hybrids would continue to be cultivated, relative to grower preference for this GE HR canola variety. Accordingly, there would be no impact on the U.S. domestic canola oil, meal, or biodiesel markets on a decision to deny the extension request. Production of organic canola is currently limited; any increase will be commensurate with market demand for organic canola oil, and perhaps organic canola meal for feed.	It is expected that MS11 canola would, over time, supplant MS8 canola. While there could be some efficiencies gained in the production of MS11 hybrid crop seed compared to the current MS8 based cropping systems, the potential domestic economic impacts associated with the introduction of MS11 canola into commerce would not be different than those currently observed for MS8 hybrid canola.

Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate MS11 Canola as a Plant Pest**	**Preferred Alternative: Extension of Non-regulated Status to MS11 Canola**
	Certified organic foods are produced according to federal standards set by the USDA National Organic Program. Under these standards, the use of GE crops is prohibited in organic products.	
International Trade	MS8 canola hybrid seed would be exported subject to market demand. There would be no impacts on trade under the No Action Alternative.	U.S. canola imports and exports would be unaffected by an extension of non-regulated status to MS11 canola. Bayer will seek international regulatory approvals in Australia and Canada.
Cumulative Impacts		
Agriculture, Physical and Biological Resources, Public Health, Socioeconomic	No significant cumulative impacts on agronomic practices and inputs, the acreage and areas of canola production, the physical environment and biological resources, development of pest and weed resistance, gene flow and weediness, human and animal health, domestic markets, or international trade were identified.	There are no reasonably foreseeable adverse cumulative effects on any aspect of the human environment that would derive from MS11 canola, or any hybrid progeny derived from it (e.g., insect and disease resistant canola). It is highly unlikely an extension of non-regulated status for MS11 canola would contribute to any adverse cumulative impacts.
Climate Change	All agricultural cropping systems, to include canola, contribute to climate change. A cumulative impact associated with canola production is its contribution to global greenhouse gas emissions, such as N_2O and CO_2. Based on current data, GE HR canola has in part contributed to reductions in GHG emissions from canola cropping systems over the last two decades. These contributions to N_2O and CO_2 emissions reductions, relative to canola production in the 1990s and prior decades, would be expected to continue.	Unchanged from No Action Alternative
Coordinated Framework Review		
U.S. Regulatory Agencies	Voluntary consultation with the FDA and changes to the EPA registration of glufosinate based herbicides would be unnecessary.	Bayer may undergo voluntary consultation with the FDA on the food and feed safety and MS11 canola and hybrids derived from it. The EPA will determine the uses of herbicides that contain glufosinate on MS11 canola.
Regulatory and Policy Compliance		
ESA, CWA, CAA, SDWA, NHPA, EOs	Fully compliant	Fully compliant

Finding of No Significant Impact

Based on the analysis of potential impacts presented in the EA, an extension of non-regulated status for MS11 canola will not have a significant impact, individually or cumulatively, on the quality of the human environment. Assessment of significant impacts, as required by NEPA

regulations (40 CFR § 1508.27), entails the consideration of both the context and intensity of potential impacts. The EA considered and this FONSI is based upon, in part, the following factors.

Context

The term "context" means identification of the locations and resources that could potentially be affected by the Agency's action. The EA identified the areas in which canola is and may be cultivated in the United States, inclusive of GE and non-GE canola, and those aspects of the human environment potentially affected by the Agency's regulatory status decision, as summarized above in the scope of analysis. This action has the potential to affect conventional and organic canola cropping systems; environments adjacent to and associated with MS11 canola cropping systems; canola oil and meal post-harvest processing systems; and domestic and foreign commodity markets. The areas affected by the regulatory status determination are localized to those of commercial canola production, canola seed processing – namely crushing facilities, and the transport routes associated with planting and harvested seed distribution. In the United States, canola is currently produced in 34 states, and canola croplands comprise around 1.7 million acres (USDA-ERS 2016; USDA-NASS 2016). Around 80% to 90% of U.S. canola production occurs in North Dakota (depending on the year), with significantly less production occurring in other states. Canola production is largely concentrated in the Northwestern United States, where a cooler climate is more amenable to optimizing yields (ideal temperature for canola is between 53° and 86° F).

GE glufosinate-ammonium resistant canola varieties have been cultivated in the United States for over 10 years. Currently, around 90% of U.S. canola acreage is comprised of GE HR varieties. A small percentage of canola crops are comprised of non-GE cultivars. As of 2015, there were only 2 certified or exempt organic canola farms in the United States, one in North Dakota, the other in Pennsylvania. Canola production, to some extent, may increase in areas outside of North Dakota as there are regional reports of increasing production in the Southeastern United States. The number of farmers growing winter canola in Alabama, Tennessee, North Carolina, Georgia, and Kentucky is reportedly expanding.

Intensity

Within the context of the potential impacts considered, intensity means the degree or severity of potential impacts. As recommended by CEQ (40 CFR § 1508.27), the following were considered in evaluating intensity, and making this NEPA determination.

1. *Impacts that may be both beneficial and adverse.*

   The potentially beneficial and adverse impacts of this decision are addressed in Chapters 4 through 6 of the EA. It is expected that MS11 hybrid canola, if adopted for commercial production, would supplant existing MS8 hybrid canola. This would not entail in any direct, indirect, or cumulative manner an increase in the acreage of canola crops, or affect the areas where canola is produced. Canola acreage may expand over time, but that expansion would be in response to market demand for canola oil, canola meal, and perhaps biofuels. There are no significant impacts on the acreage, or influence on the areas where canola is produced, that would likely derive from denial or approval of the petition.

Because MS8 canola hybrids have been in production in the United States for over 10 years, and MS11 canola is agronomically and phenotypically equivalent to, and intended to replace, MS8 canola (Weeks et al. 2016), changes to the agronomic practices and inputs used in the commercial production of MS11 hybrids are not expected. Hence, the potential beneficial and adverse impacts on soils, air quality, water quality, and biological resources, as well as socioeconomic impacts, as a result of cultivation of MS11 hybrid canola would be unaffected. U.S. growers would use the same agronomic practices and inputs associated with these canola varieties under either alternative. These include the use of herbicides, insecticides, fungicides, and fertilizers, as well as tillage, seeding, and harvesting practices.

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

   As described in Sections 4.6 and 5.7 of the EA, which address human health, there are no potential direct, indirect, or cumulative adverse impacts on human health associated with the consumption of canola oil produced from MS11 canola hybrids, or from the cultivation of MS11 canola. The EPA considers the potential effects of pesticides on human health as part of their registration and registration review processes, and in establishment of label use instructions. The EPA also establishes residue tolerance limits for pesticides on food and feed crops, to include canola. APHIS assumes that applications of herbicides containing glufosinate, and any other pesticides that may be used in conjunction with MS11 canola and MS11 canola progeny, will be done so consistent with EPA approved labels.

   Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Bayer may undergo a voluntary consultation process with the FDA prior to release of MS11 canola to the commercial market to identify and discuss relevant safety, nutritional, or other regulatory issues regarding food and feed products derived from MS11 canola.

   Considering these factors, it is highly unlikely an extension of non-regulated status for MS11 canola would present any risk to human health, to include worker safety.

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.*

   It is unlikely that historic or cultural resources, park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas would be significantly impacted by an extension of non-regulated status to MS11 canola. MS11 hybrid canola is expected to supplant existing MS8 hybrid canola, and commercial cultivation limited to those agricultural lands suitable for canola production. Feral populations of GE HR canola will likely persist along transport routes and in environments proximate to GE HR canola crop fields, as they currently do. However, invasion of park lands, wetlands, wild and scenic areas, or ecologically critical areas by GE HR canola is considered unlikely.

   APHIS conducted a PPRSA and concluded that it is unlikely that MS11 canola will become a weed, and that it is similarly unlikely that gene introgression from MS11 to

other organism with which it can interbreed will increase their weediness (USDA-APHIS 2016). Hence, an extension of non-regulated status to MS11 canola is not expected to have significant impacts on historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

   From public comments on prior EAs and EISs, APHIS understands that some stakeholders are opposed to determinations of non-regulated status for GE crops. Although APHIS has received public comments opposing GE crops, extension of non-regulated status for MS11 canola and its progeny is not an action considered highly controversial in nature. MS8 canola has been in commercial production for over a decade. The availability of MS11 canola, which is agronomically and phenotypically similar to MS8 canola (USDA-APHIS 2016), and intended to replace MS8 canola, will not change the acreage or areas for canola production nor have any significant impacts on domestic or international markets. An extension of non-regulated status for MS11 canola will not result in changes to the agricultural practices and inputs used for GE HR canola production, to include GE HR volunteer canola control and herbicide resistance weed management. The potential impacts of MS11 canola production on physical and biological resources is no different than that of currently cultivated MS8 canola. Consequently, there are no novel or unique impacts related to the extension of non-regulated status that are considered highly controversial.

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

   The potential impacts of MS11 canola on the human environment do not involve a high degree of uncertainty, nor does MS11 canola present unique or unknown impacts. Currently, around 90% of the canola grown in the United States is GE HR canola. The antecedent, MS8 canola, has been used in commercial canola production in the United States for over 10 years. Considering the data and information evaluated in the EA and PPRSA, the similarity of MS11 and MS8 canola (USDA-APHIS 2016), and the extensive experience that APHIS, GE HR canola developers, and growers have in the use of GE HR canola, the potential impacts on the human environment that may derive from the cultivation of MS11 canola are well understood. There are no highly uncertain, nor unique or unknown impacts, associated with the commercial cultivation of MS11 canola.

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.*

   An extension of non-regulated status to MS11 canola and its progeny would not establish a precedent for future actions with significant impacts, nor would it represent a decision in principle about a future decision. Similar to past extension requests reviewed and approved by APHIS, an extension of non-regulated status to MS11 canola is based upon an independent determination of whether MS11 canola is unlikely to pose a plant pest risk pursuant to 7 CFR part 340. APHIS has reviewed and approved requests for extensions of non-regulated status since 1994, each of these requests reviewed independent of the other, and determinations of regulatory status issued in part based on plant pest risk

assessments specific for the GE organism subject of the extension request. Each extension request that APHIS receives is specific to a particular GE organism and undergoes an independent review to determine if the regulated article may pose a plant pest risk. The requirements for extension requests, applicable to both APHIS and the petitioner, are described in the PPA and 7 CFR part 340. These requirements have been reviewed above under the sections summarizing APHIS' regulatory authority, and APHIS' requirements to respond to extension requests for non-regulated status.

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

   The EA concluded it is unlikely that cultivation of MS11 canola would contribute to any potential cumulative impacts. A cumulative impacts analysis is included for the acreage and areas of canola production, agronomic practices, physical environment, biological resources (to include herbicide resistant weeds and gene flow and weediness), human and animal health, domestic and international markets, and climate change. No significant cumulative impacts were identified.

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.*

   An extension of non-regulated status to MS11 canola is not an action that would directly or indirectly alter the character or use of properties protected under the National Historic Preservation Act. It 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 the extension cause any loss or destruction of significant scientific, cultural, or historic resources. MS11 hybrid canola would be cultivated on croplands currently used for canola production. In general, the crop production practices used in the cultivation of canola do not introduce significant visual impairments, or noise, in a manner that would impact the use and enjoyment of historic properties. Any farming activities that may be undertaken on tribal lands are only conducted under the tribe's approval; tribes have control over any potential conflict with cultural resources on tribal properties.

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.*

   APHIS analyzed the potential effects of MS11 canola on threatened and endangered species and critical habitat in Chapter 6 of the EA. APHIS concluded that approval of a petition for non-regulated status for MS11 canola, and the corresponding environmental release of this canola variety, will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the U.S. Fish and Wildlife Service and National Marine Fisheries Services are not required.

10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*

    In Chapter 7, the EA evaluated compliance with federal and state laws and regulations, executive orders, and policy related to the petition. An extension of non-regulated status would be in compliance with all federal, state, and local laws providing environmental protections. Because APHIS concluded that MS11 canola is unlikely to pose a plant pest risk, an extension of non-regulated status to MS11 canola is consistent with the plant pest provisions of the PPA, APHIS implementing regulations in 7 CFR part 340, and the biotechnology regulatory policies of the Coordinated Framework. The EPA will regulate the use of glufosinate on MS11 canola, and Bayer may choose to consult with the FDA as to the food and feed safety of canola oil and canola meal derived from MS11 canola or its progeny. There are no further federal, state, or local requirements or permits that are needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA for this FONSI. Based on APHIS' conclusion that MS11 canola encompasses the same scope of environmental analysis and regulatory decision as MS8 canola; that is, a determination of nonregulated status pursuant to 7 CFR part 340, I conclude the issues identified and analyzed in EA for MS8 canola, as updated and supplemented are relevant to this regulatory action and best addressed by extending a determination of non-regulated status to MS11 canola. This regulatory action meets APHIS' purpose and need to allow the safe development and use of GE organisms consistent with the plant pest provisions of the PPA and pursuant to 7 CFR part 340.

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, the Preferred Alternative is selected because (1) it allows APHIS to fulfill its statutory mission to protect the health and value of American agriculture and natural resources using a science-based regulatory framework that allows for the safe development and use of GE organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with MS11 canola, the continued status of MS11 canola as a regulated article would be inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR part 340, and the biotechnology regulatory policies of the Coordinated Framework. For the reasons stated above, I have determined that a determination of non-regulated status for MS11 canola will not have any significant environmental impacts.

M. J. Firko

Michael J. Firko, Ph.D.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service

26 July 2017

Date

U.S. Department of Agriculture

Summary of Comments Received from the Public on the Draft Environmental Assessment

APHIS received 5 public comments on the EA, a full record of each comment received for the draft EA is available for public review at www.regualtions.gov.[10] The Agency expresses thanks to all those who participated in the public involvement process by reviewing the draft EA for the MS11 canola petition request and providing comments. APHIS welcomes public involvement and considers the perspectives and input from individuals and organizations in its decision-making process. APHIS evaluated all comments received; the majority of comments were opposed to an extension of non-regulated status for MS11 canola. In review of the comments APHIS determined that none provided substantive, new information that improved or required revision of the environmental or plant pest risk analyses. However, APHIS provides a response below to certain comments received for matters of clarification.

Comment ID: APHIS-2017-0015-0009: To what extent is herbicide treatment of this canola increased beyond that of regular canola? (For example, from no treatment with herbicide to which the canola is now resistant to possible multiple herbicide applications during the growing season).

As discussed in EA Section 1.3.2 – the Environmental Protection Agency, the use of glufosinate on MS11 hybrid canola would be subject to the EPA registration and label use requirements – these are legal requirements. The EPA regulates the sale, distribution, and use of pesticides, to include annual use applications.

Comment ID: APHIS-2017-0015-0009: Does the APHIS review consider negative impacts to other organisms with which we share our environment? To what extent? How will this increased herbicide use impact other organisms? For instance, loss of milkweed due to increased herbicide use on GE crops has negatively impacted the monarch butterfly, which is an obvious and iconic species.

APHIS examined potential adverse impacts on other organisms in the following sections and subsections of the EA. The commenter is referred to these sections for detailed information on potential impacts on other organisms with which we share our environment.

4.5 Biological Resources

4.5.1 Overview of Potential Effects on Non-Target Terrestrial and Aquatic Organisms

4.5.2 Soil Biota

4.5.3 Animal Communities

4.5.4 Plant Communities

4.5.4.1 Herbicide Resistant Weeds

4.5.5 Gene Flow and Weediness of Canola

4.5.6 Biodiversity

[10] MS11 canola comments are available at https://www.regulations.gov/docket?D=APHIS-2017-0015

5.5 Cumulative Impacts: Biological Resources

5.5.1 Pesticide Use

5.5.2 Pest and Weed Resistance

5.5.3 MS11 Canola Trait Genes

5.6 Cumulative Impacts: Gene Flow and Weediness

The decline of milkweed, is, in part, associated with the increased use of genetically modified herbicide-resistant crops, especially in the agricultural Midwest region of the United States.[11] However, recent research finds that a lack of milkweed is unlikely to be driving the monarch's population decline; rather, other factors are likely more significant in contributing to the observed decline in migratory monarch populations (Inamine et al. 2016). Due to the monarch population decline, the Natural Resources Conservation Service (NRCS) and others – including the United States Fish and Wildlife Service (USFWS) – have developed a collaborative landscape level partnership to benefit the monarch butterfly. The primary focus of the partnership is the design and application of selected NRCS conservation practice standards and enhancements to benefit the monarch butterfly. These conservation practice standards and enhancements are applied by NRCS when providing technical and financial assistance to eligible landowners using its Farm Bill authorities. Other actions implemented by the NRCS include the conversion of suitable monarch butterfly habitat types to other land uses, including crop production; and implementation of certain conservation practice standards and enhancements as part of the application of pesticides/herbicides to benefit the monarch butterfly, including but not limited to integrated pest management and herbaceous weed control.

Comment ID: APHIS-2017-0015-0009: Further, I am quite concerned about the male sterility trait - it is my understanding that this trait is meant to reduce the spread of the GE canola and/or to also eliminate the possibility that a farmer/producer could produce seed for use the next year.

This assumption is incorrect. As discussed in EA Section 1.2 – Petitioners Intended Use of MS11 Canola, and EA Subsection 4.5.1 – Overview of Potential Effects on Non-Target Terrestrial and Aquatic Organisms, the male sterility trait in MS11 canola is part of a hybrid plant breeding system comprised of MS11 canola and RF3 canola, which is used for continued generation of glufosinate-resistant MS11 x RF3 hybrid seed (crop seed). Potential benefits of this system are that MS11 x RF3 hybrids may potentially yield 20-25% more than open-pollinated varieties, and the uniformity of hybrids facilitates harvesting and marketing. There is no difference between the intended purpose and rational for the use of MS11 and MS8 canola, the latter having been commercially produced for over 15 years. GE MS11 canola will be used for the same purposes as MS8 canola, to produce glufosinate-ammonium resistant canola crop seed.

Comment ID: APHIS-2017-0015-0009: I am curious what environmental implications have been studied for the male sterility trait. Since MS11's cousin MS8 has been in production over the past 18 years, I am curious what we have learned.

[11] https://www.fws.gov/savethemonarch/pdfs/MonarchConferenceReport2016.pdf

As discussed in Sections 1.2 – Petitioners Intended Use of MS11 Canola, 4.6 – Human Health, and 5.5 – Cumulative Impacts: Biological Resources, the barnase and barstar proteins have a long history of safe use in MS8 and RF3 canola, which have been in commercial production for over 15 years. There are no known adverse impacts on wild Brassicaceae populations associated with the commercial cultivation of MS8, or MS8 x RF3 hybrids. A detailed discussion of the barnase, barstar, and bar traits is provided in EA Subsection 4.5.1 – Overview of Potential Effects on Non-Target Terrestrial and Aquatic Organisms. The environmental implications of these introduced traits is discussed in EA Section 4.5 – Biological Resources.

Comment ID: APHIS-2017-0015-0009: I am concerned that APHIS bases its decisions in large part on information provided by the company with the greatest financial interest in the GE canola. What safeguards are in place to make certain that the science presented for consideration is complete, factual, and of the highest ethical quality?

Safeguards in place include the conduct of plant pest risk assessments and environmental analyses, and the provision for public participation in the decision-making process. Petitions, notifications, and permit requests must submit the required scientific data to APHIS as specified in 7 CFR part 340 and APHIS guidance.[12] APHIS conducts an environmental analysis pursuant to NEPA (42 U.S.C. § 4321 et seq.), CEQ regulations (40 CFR parts 1500-1508), and the USDA and APHIS NEPA-implementing regulations and procedures (7 CFR part 1b, and 7 CFR part 372), as described in the EA. The environmental analysis also ensures compliance of Agency actions and decisions with other relevant laws and regulations protective of the environment (discussed in Chapter 6 and Chapter 7 of the EA). APHIS conducts a science-based plant pest risk assessment (PPRA) or plant pest risk similarity assessment (PPRSA) as part of its petition review process. APHIS regulations in 7 CFR 340.6(c) specify the information needed for consideration in a petition for non-regulated status.

APHIS provides references for the scientific studies and other sources of data and information considered the EA/EIS and PPRA/PPRSA, references anyone may access and review.

APHIS makes public its decision-making process and provides a public comment period on draft EAs/EISs, preliminary PPRAs, preliminary PPRSAs, preliminary Findings of No Significant Impacts (FONSIs), and preliminary regulatory status determinations, so that any oversight in these analyses, or new information, may be bought to light. Hence, provision of a public comment period facilitates public participation and transparency in the Agency's decision-making process. APHIS considers comments and new information that may be received on the analyses and regulatory status decisions, and revises its analyses and decisions as appropriate.

The USDA has established policy on Scientific Integrity in USDA Directive 1074-001 (issued May 10, 2013) that provides instruction and guidance to Departmental leadership, employees, and contractors to ensure the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes and analyses.

[12] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions

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