NATIONAL ENVIRONMENTAL POLICY ACT DECISION

FINDING OF NO SIGNIFICANT IMPACT

Monsanto Company
Insect Resistant MON 88702 Cotton

OECD Unique Identifier: MON-887Ø2-4

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) NEPA implementing regulations, and APHIS NEPA implementing regulations and procedures (7 CFR 372). This FONSI sets forth APHIS' NEPA decision with respect to potential impacts on the human environment that could derive from a determination of nonregulated status for Monsanto Company insect resistant MON 88702 cotton.

Monsanto Company (hereinafter referred to as "Monsanto") submitted a petition (19-091-01p) to APHIS requesting that genetically engineered (GE) MON 88702 Cotton, and any progeny derived from it, no longer be considered regulated under Title 7 of the Code of Federal Regulations part 340 (7 CFR 340). An organism developed using genetic engineering is no longer subject to the requirements of 7 CFR part 340 if APHIS determines that it is unlikely to pose a plant pest risk. MON 88702 Cotton is currently regulated by APHIS.

Monsanto genetically engineered MON 88702 Cotton for resistance to certain economically important cotton insect pests. It is intended to provide growers with a better alternative for the management of these pests than is currently available.

As part of its evaluation of Monsanto's petition, APHIS conducted an Environmental Assessment (EA) to inform APHIS decision regarding the regulatory status of MON 88702 Cotton. The EA evaluates the potential impacts of APHIS' regulatory decision on the quality of the human environment.[1] The EA did not identify any significant impacts that will result from either approval or denial of the action requested by the petitioner. Therefore, the Agency has prepared this FONSI, pursuant to 40 CFR §1508.13, which provides a summary of the EA, and the reasons why APHIS concluded that a determination of nonregulated status for MON 88702 Cotton will not have a significant impact on the human environment.

APHIS Regulatory Authority and the Coordinated Framework

In 1986, the Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework), which describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products.[2] Since 1986, the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and USDA have regulated organisms developed using genetic engineering consistent with this framework. On January 4, 2017, the USDA, EPA, and FDA released a 2017 update to the Coordinated Framework (USDA-APHIS 2018), and an accompanying

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR § 1508.14).
[2] An *Update to the Coordinated Framework for Regulation of Biotechnology* was released on January 4, 2017. See https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/update-coordinated-framework-regulation-biotechnology

National Strategy for Modernizing the Regulatory System for Biotechnology Products (ETIPCC 2017). The authorities and regulatory roles for USDA–APHIS, the EPA, and FDA are briefly summarized below.

USDA-APHIS

Protecting animal and plant health is among APHIS' primary strategic goals. APHIS provides leadership in ensuring the health and care of plants and animals. The agency's strategic goals help improve agricultural productivity and competitiveness, and contributes to the national economy and the public health. The USDA asserts that all methods of agricultural production (conventional, organic, or the use of varieties developed using genetic engineering) can provide benefits to the environment, consumers, and farm income.

APHIS regulates organisms developed using genetic engineering to ensure that they do not pose a plant pest risk pursuant to the Plant Protection Act (PPA) of 2000, as amended (7 USC §§ 7701 et seq.) and APHIS implementing regulations at 7 CFR part 340. APHIS regulations at 7 CFR part 340 govern the importation, interstate movement, and environmental release of organisms developed using genetic engineering that may pose a plant pest risk. An organism developed using genetic engineering is no longer subject to the PPA or to the requirements of 7 CFR part 340 when APHIS determines that the organism is unlikely to pose a plant pest risk.

FDA

The FDA regulates organisms developed using genetic engineering under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Food Safety Modernization Act (FSMA). The FDA is responsible for ensuring the safety and proper labeling of all foods and feeds, including plants developed using genetic engineering. The FDA policy statement concerning regulation of products derived from new plant varieties, including those developed using genetic engineering, was published in 1992 (57 FR 22984-23005). Pursuant to this policy, the FDA uses what is termed a voluntary consultation process between producers and FDA to ensure that human food and animal feed safety issues and other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of foods derived from crops developed using genetic engineering. To help developers of food and feed derived from plants developed using genetic engineering comply with their obligations under federal food safety laws, the FDA encourages them to participate in a voluntary consultation process.

EPA

The EPA regulates pesticide use, including plant-incorporated protectants (PIPs), pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA also establishes maximum residue limits, commonly referred to as tolerances, for pesticide residue on and in food and animal feed or establishes an exemption from the requirement for a tolerance under the FFDCA. It also regulates certain GE microorganisms under the Toxic Substances Control Act (TSCA). The EPA is responsible for regulating the sale, distribution, and use of pesticides, including those pesticides that are produced by an organism modified through techniques of modern biotechnology.

APHIS' Response to Petitions for Nonregulated Status

APHIS regulations at 7 CFR part 340 govern the movement (e.g., transport, environmental release) of organisms developed using genetic engineering that may pose a plant pest risk. An organism developed using genetic engineering is no longer subject to the requirements of 7 CFR part 340 or the plant pest provisions of the PPA if APHIS determines through conduct of a Plant Pest Risk Assessment (PPRA) that it is unlikely to pose a plant pest risk.

Public Involvement

On September 26, 2019, APHIS announced in the *Federal Register* that it was making Monsanto's petition available for public review and comment to help identify potential environmental and interrelated economic

impacts that APHIS should consider in evaluating Monsanto's petition request[3]. APHIS accepted written comments about the petition for a period of 60 days (until midnight November 25, 2019). The Agency received 35 comments during the comment period. All comments were reviewed carefully to identify new issues, alternatives, or information. Those relevant to the assessment of plant health risks or environmental effects were analyzed in the PPRA and EA respectively.

On October 16, 2020, APHIS published a notice in the *Federal Register* announcing availability of the draft EA and draft PPRA for a 30-day public comment period. Comments were due on or before November 16, 2020[4]. Fourteen comments were received. Most were supportive of Monsanto's petition request; three were opposed. None of the comments identified new issues or information that needed to be addressed, but were not analyzed in the draft EA. All comments submitted for the draft EA are available for public review at www.regulations.gov (Docket ID: APHIS-2019-0050).

Major Issues Addressed in the EA

APHIS prepared the EA 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 topics for consideration in the EA based on issues identified in prior EAs for regulated cotton varieties, public comments submitted on the petition for MON 88702 Cotton, other EAs and environmental impact statements (EISs) evaluating petitions for nonregulated status, the scientific literature on agricultural biotechnology, and issues identified by APHIS specific to wild and cultivated cotton (*Gossypium* spp.). As part of the scoping requirements for NEPA (40 CFR § 1508.25), the following topics were identified as relevant for analysis:

Agricultural Production

- Acreage and Areas of Cotton Production
- Agronomic Practices in Cotton Production

Environmental Considerations

- Water Resources
- Soil Quality
- Air Quality
- Animal Communities
- Plant Communities
- Soil Microorganisms
- Biodiversity
- Gene Flow and Weediness
- Weed Management and Herbicide Resistant Weed Management

Human Health

- Human Health and Worker Safety

Animal Health

[3] Federal Register, / Vol. 84, No. 187 / Thursday, September 26, 2019, p. 50818 Monsanto Company; Availability of Petition for Determination of Nonregulated Status of Cotton Genetically Engineered for Insect Resistance
[Docket No. APHIS–2019–0050]. Available at https://www.aphis.usda.gov/brs/fedregister/BRS_20190926.pdf

[4] Federal Register / Vol. 85, No. 201 / Friday, October 16, 2020 / Notices / p. 65789: Monsanto Company Availability of a Draft Plant Pest Risk Assessment and Draft Environmental Assessment for Determination of Nonregulated Status of Cotton Genetically Engineered for Insect Resistance.
[Docket No. APHIS–2019–0050]. Available at https://www.govinfo.gov/content/pkg/FR-2020-10-16/pdf/2020-22917.pdf

- Animal Health and Welfare

Socioeconomics
- Domestic Socioeconomic Environment
- International Trade Economic Environment

Threatened and Endangered Species
- Threatened and Endangered Plant Species and Critical Habitat
- Threatened and Endangered Animal Species

Alternatives Evaluated in the EA

The EA considered two alternatives in response to the petition request: either deny or approve Monsanto's request for nonregulated status for MON 88702 Cotton. APHIS analyzed the potential environmental, human health, and socioeconomic impacts that may result if it selected either of those two alternatives.

No Action: Continuation as Regulated

One of the alternatives that must be considered by APHIS is a "No Action Alternative," pursuant to CEQ regulations at 40 CFR part 1502.14. No Action in this instance means no change in regulatory status. Under the No Action Alternative, APHIS would deny the petition request for nonregulated status and MON 88702 Cotton. It would remain regulated under 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would be required for the introduction of DP202216 corn. Because APHIS concluded in its PPRA that MON 88702 Cotton is unlikely to pose a plant pest risk, this is not the preferred alternative (USDA-APHIS 2020). Choosing this alternative would not be an appropriate response to the petition for nonregulated status, nor satisfactorily meet the purpose and need for making a regulatory status decision pursuant to the requirements of 7 CFR part 340.

Preferred Alternative: Determination of nonregulated status for MON 88702 Cotton

Under this alternative, MON 88702 Cotton and progeny derived from it would no longer be subject to 7 CFR 340 because it was determined that, based on the scientific evidence available to the Agency, MON 88702 Cotton is unlikely to pose a plant pest risk. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 88702 Cotton or its progeny. Under this alternative, growers may have future access to MON 88702 Cotton and progeny derived from it if the developer decides to commercialize MON 88702 Cotton. This alternative best satisfies the purpose and need to respond appropriately to the petition pursuant to the requirements of 7 CFR part 340.6, the Agency's statutory authority under the PPA, and the biotechnology regulatory policies described for the Coordinated Framework.

Alternatives Considered but Dismissed from Detailed Analysis in the EA

APHIS evaluated several alternatives for consideration in the EA in light of the Agency's statutory authority under the PPA and APHIS implementing regulations at 7 CFR part 340, but dismissed these alternatives from detailed analysis in the EA. The alternatives considered are described in the EA along with the reasons for dismissal from detailed analysis.

Environmental Consequences of APHIS' Selected Action

The EA provides analyses of the alternatives APHIS considered, to which the reader is referred for specific details. The following table briefly summarizes the potential environmental consequences of the alternatives evaluated in the EA.

Summary of Potential Impacts of the Alternatives Considered		
Attribute/Measure	**No Action Alternative: Continue to Regulate MON 88702 Cotton**	**Preferred Alternative: Approve the Petition for Nonregulated Status for MON 88702 Cotton**
Meets Purpose and Need, and Objectives	No	Yes
Agricultural Production		
Acreage and Areas of Cotton Production	Denial of the petition would have no effect on the areas or acreage utilized for cotton production. Fluctuations in production areas and acreage would be relative to weed, insect pest, and disease pressures, and market demand for cotton commodities. Regulated field trials would be conducted on lands allocated for this purpose.	MON 88702 Cotton will be introduced into new insect resistant (IR) cotton varieties based on farmer demand. Cultivation of MON 88702 Cotton and stacked-trait progeny would be on lands used for agricultural field experiments, crop production, crop seed production, and new variety plant development. These lands are regularly used for agricultural purposes.
Agronomic Practices and Inputs	Agronomic practices and inputs used in cotton crop production, to include regulated field trials, would remain unchanged.	The agronomic practices and inputs used for MON 88702 Cotton hybrid production would be the same as for other varieties of IR cotton. Relative to non-IR cotton varieties, MON 88702 Cotton could require less insecticide use; an average of 1.2 fewer insecticide applications per crop cycle
Production of Cotton developed using genetic engineering	Denial of the petition would have no effect on the use of existing varieties of IR cotton. Varieties of cotton containing either herbicide resistance (HR), IR, or a combination of traits comprised about 98% of all cotton planted in the United States in 2019.	Approval of the petition would provide for production of stacked-trait HR/IR cotton varieties that are resistant to economically important Lepidoptera, Hemiptera, and Thysanoptera insect pests.
Physical Environment		
Soil Quality	Agronomic practices and inputs associated with cotton crop production	The agronomic practices and inputs used for MON 88702 Cotton production that can

Summary of Potential Impacts of the Alternatives Considered		
	potentially impacting soils, to include regulated field trials, would continue consistent with current trends.	potentially impact soil quality would be the same as those currently used, apart from reductions in insecticide use with MON 88702 Cotton hybrids, as compared to non-IR varieties.
Water Resources	Denial of the petition, which would preclude commercial production of MON 88702 Cotton, would have no effect on water resources in the United States. Regulated field trials are limited on a spatial-temporal scale, and present negligible risks to water resources.	Because the agronomic practices and inputs utilized for MON 88702 Cotton production would be the same as those currently used, and MON 88702 Cotton would not entail any increase in acreage or alter the areas of cotton production, sources of potential impacts on water resources, (i.e., NPS pollutants in agricultural run-off), would not be expected to substantially differ from those of the No Action Alternative. However, runoff from MON 88702 Cotton/progeny production fields may include lesser quantities of insecticide residues than what is associated with the No Action Alternative, so potential risks to surface waters and groundwater may be reduced.
Air Quality	Emission sources, (i.e., tillage and machinery combusting fossil fuels), and the level of emissions associated with cotton crop production, to include regulated field trials, would be unaffected by denial of the petition.	Because the agronomic practices and inputs used for MON 88702 Cotton would remain unchanged, no changes to emission sources are expected. As an IR crop, there could be reductions in insecticide use compared to current cotton production practices, which would reduce use of fossil fuels in the machinery used for application, and thereby the quantity of related emissions. There would also be commensurate reductions in

Summary of Potential Impacts of the Alternatives Considered		
		insecticide drift and volatilization associated with MON 88702 Cotton/stacked-trait progeny crops.
Biological Resources		
Soil Biota	Potential impacts of cotton crop production, to include field trials, on soil biota would be unaffected by denial of the petition.	The agronomic practices and inputs used for MON 88702 Cotton production that can impact soil biota would be no different from those currently used. The insecticidal mCry51Aa2 protein, derived from naturally occurring soil bacterium, *B. thuringiensis*, is unlikely to present a significant risk to populations of soil biota and their ecological interactions (US-EPA 2018a).
Animal Communities	Regulated field trials of MON 88702 Cotton would present negligible risk to animal communities.	There are no hazards to vertebrate taxa associated with exposure to mCry51Aa2 protein (Koch et al. 2015; US-EPA 2018b). Adverse effects on non-target insects (e.g., ladybird beetles, rove beetles, parasitic wasps, bees) as a result of exposure to mCry51Aa2 are not expected
Plant Communities	Regulated field trials of MON 88702 Cotton would present negligible risks to plant communities.	Because the agronomic practices and inputs that will be used for MON 88702 Cotton production are the same as those for other cotton varieties (apart from reduced insecticide use), the potential impacts on vegetation next to cotton fields would not substantially differ from the No Action Alternative.
Gene Flow and Weediness	Under the No Action Alternative MON 88702 Cotton could be grown under APHIS regulatory authority. Any potential for gene flow from MON 88702	MON 88702 Cotton, if grown for commercial purposes, would be cultivated as are current cotton varieties and present the same potential for gene flow, specifically the

Summary of Potential Impacts of the Alternatives Considered		
	Cotton permitted testing sites would be evaluated on a case-by-case basis relevant to the site-specific containment conditions imposed to prevent gene flow.	propensity and frequency of gene flow associated with current cotton varieties. Available evidence indicates that there is a low potential for introgression of transgenic material from MON 88702 Cotton into wild or feral relative species (USDA-APHIS 2020), and even if gene flow occurred, no increased plant pest risk harms are expected
Biodiversity	Denial of the petition, and further regulated field trials of MON 88702 Cotton, would present negligible risks to biodiversity in an around MON 88702 Cotton crops.	The production of MON 88702 Cotton would be expected to affect biodiversity in and around MON 88702 Cotton hybrid crops similar to other IR cotton cropping systems, with minor transient differences in the targeted insect populations affected (thrips, lygus bugs [tarnished plant bugs], bollworms, tobacco budworm, and armyworm), and predator-prey relationships. While IR crops may have increased biodiversity in comparison to non-IR crops due to reduced use of pesticides, the difference is not significant because of the highly managed nature of the agricultural system and already decreased biodiversity in this environment. Indirect effects of IR crops on agricultural ecosystems due to multi-trophic exposure, loss of prey, or reduction of prey quality, are generally negligible compared with the direct effects of the significant environmental manipulations associated with current

Summary of Potential Impacts of the Alternatives Considered		
		standard agricultural practices (Storer et al. 2008).
Human and Animal Health		
Human Health and Worker Safety	Denial of the petition would have no direct or indirect effects on human health or welfare. MON 88702 Cotton would remain regulated and would not be available for food, feed, or fiber uses.	Approval of the petition would not be expected to present any risks to public health. Monsanto consulted with FDA on MON 88702 Cotton (BNF 000160) in September 2018. The FDA did not identify any safety or regulatory issues under the FDCA that would require further evaluation at this time for MON 88702 Cotton (US-FDA 2019). The EPA concluded that there are no unreasonable adverse effects and there is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to the mCry51Aa2 protein and the genetic material necessary for its production in MON 88702 Cotton (US-EPA 2018a). The EPA issued an exemption from the requirement of a tolerance for residues of Cry51Aa2.834_16 protein in or on cotton (US-EPA 2018b). MON 88702 Cotton could potentially reduce the overall pesticide inputs compared to non-IR cotton. These reductions could have potential beneficial impacts by reducing human exposure to pesticides, however these will likely be minimal since growers are required to use pesticides according to the label directions minimizing harmful exposure and the EPA WPS will continue to provide

Summary of Potential Impacts of the Alternatives Considered		
		the same level of protection as is currently available.
Animal Health and Welfare	Denial of the petition would have no effect on the quality or availability of animal feed or on animal health and welfare.	Stacked-trait IR varieties produced using MON 88702 Cotton would provide for animal feed products (e.g., oil, meal, whole seed). As discussed for human health, Monsanto consulted with FDA, which did not identify any safety or regulatory issues under the FDCA that would require further evaluation at this time for MON 88702 Cotton (US-FDA 2019).
Socioeconomic		
Domestic Economy and International Trade	Cotton commodity markets would be unaffected by denial of the petition.	Approval of the petition and eventual production of MON 88702 Cotton progeny would have no impacts on cotton commodities markets, or trade of cotton commodities. Approval of the petition and eventual production of MON 88702 Cotton would have no impacts on domestic cotton commodities markets. Since most U.S. cotton production is of varieties developed using genetic engineering, MON 88702 Cotton is unlikely to impact domestic GE sensitive markets. The foreign trade impacts associated with a determination of nonregulated status of MON 88702 Cotton is anticipated to be similar to the No Action alternative however, import of each specific trait requires separate application and approval by the importing country.
Cumulative Impacts		
Agriculture, Physical and Biological Resources, Public Health, Socioeconomic	There are no cumulative impacts on any aspect of the human environment evaluated that would be	MON 88702 Cotton/progeny production would entail the use of pesticides and fertilizers, and to some extent tillage, which will contribute

Summary of Potential Impacts of the Alternatives Considered		
	derived from denial of the petition.	to potential cumulative impacts on water, soil, and air quality, the same as current cotton production methods. If MON 88702 Cotton stacked-trait IR varieties are adopted by growers, this could potentially contribute in a cumulative manner to a reduction in insecticide runoff from agricultural sites. As with all uses of Bt Cry based insecticides, insect resistant management will be an inherent aspect of production of MON 88702 Cotton and its progeny.
Coordinated Framework		
U.S. Regulatory Agencies	Denial of the petition would have no effect on FDA and EPA oversight of MON 88702 Cotton. Introductions of MON 88702 Cotton would be regulated by USDA.	Monsanto has consulted with FDA as to the food/feed safety of MON 88702 Cotton, and obtained appropriate registrations and established tolerances for mCry51Aa2 from EPA.
Regulatory and Policy Compliance		
ESA, CWA, CAA, SDWA, NHPA, EOs	Compliant	Compliant

Finding of No Significant Impact

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

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

The EA identified the areas in which cotton is grown and may be cultivated in the United States, and those aspects of the human environment potentially affected by the Agency's regulatory decision. This action has the potential to affect biotech and non-biotech cotton cropping systems; environments adjacent to and associated with MON 88702 Cotton cropping systems; cotton fiber and seed oil post-harvest processing systems; and domestic and foreign commodity markets. In 2017, cotton was planted on approximately 12.6 million acres in the United States (USDA-ERS 2017a). According to USDA-NASS data, cotton has been planted on approximately 10 to 12 million acres over the last several years (USDA-NASS 2015). Varieties of cotton

developed using genetic engineering, containing either herbicide resistance, insect resistance, or both traits, comprised 96 percent of all cotton planted in 2017 (USDA-ERS 2017b). Cotton is grown in 17 states across the southern United States. These states include Alabama, Arizona, Arkansas, California, Florida, Georgia, Kansas, Louisiana, Mississippi, Missouri, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia (USDA-NASS 2015).

A determination of nonregulated status for MON 88702 Cotton is not expected to result in any increase in agricultural acreage utilized for cotton production, or change in the areas where cotton is grown, because it is not substantially different, phenotypically and agronomically, from existing cotton, and will be used to provide the same cotton commodities, fiber and oil, as non-GE varieties.

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

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

   The EA evaluated the all potential impacts of approval and denial of the petition, including those that would be potentially adverse and those beneficial. These are summarized below.

   Potentially Beneficial: Approval of the petition would likely result in availability of MON 88702 Cotton, a variety that may expand the range of options available to growers for better management insect pests of cotton than currently available.

   Monsanto could cross MON 88702 Cotton with cotton lines that are herbicide resistant. MON 88702 Cotton may also be crossed with IR varieties expressing other Cry proteins (e.g., Cry1Ab, Cry2Ae, and Vip3Aa19) to breed in resistance to additional pests (e.g., lepidopteran pests) . The availability of such stacked-trait varieties that combine the IR trait of MON 88702 Cotton with IR/HR traits of other varieties could help growers effectively manage both agricultural weeds and other insect pests of cotton that are not affected by the IR trait of MON 88702 Cotton.

   Potentially Adverse: Reliance on IR MON 88702 Cotton could result in the selection of insect populations that are resistant to the IR trait of MON 88702 Cotton, so are no longer controlled by it.

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

   Approval of the petition would have no impact on public health or safety. MON 88702 Cotton does not differ compositionally from other cotton varieties currently in production.

   The EPA conducts human health and environmental risk assessments for pesticide active ingredients, including plant-incorporated protectants (PIPs) expressed in some varieties of plants developed using genetic engineering. EPA has evaluated the Cry protein expressed by MON 88702. EPA has determined that it does not have unacceptable adverse human and environmental health risk, and has issued a tolerance exemption for the Cry protein expressed by MON 88702 Cotton. Monsanto consulted with FDA on MON 88702 Cotton (BNF 000160) in September 2018. The FDA concluded their review with no further questions (US-FDA 2019).

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.*

The EA concluded that 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 approval of the petition. Cotton volunteers may occur in areas where MON 88702 Cotton is cultivated and due to spilling of seed during transport. However, invasion of park lands, wetlands, wild and scenic areas, or ecologically critical areas by MON 88702 Cotton or feral hybrids is considered unlikely. APHIS conducted a PPRA and concluded that it is unlikely that MON 88702 Cotton will become weedy or invasive (USDA-APHIS 2020).

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

Approval of the petition for nonregulated status for MON 88702 Cotton and its progeny is not an action considered highly controversial in nature. The EA concluded that there would be no significant changes to the agricultural practices and inputs used for cotton production, nor the potential impacts of these practices and inputs on the human environment. The potential sources of impacts of MON 88702 Cotton production, and the nature of the potential impacts on physical and biological resources are no different than that of currently cultivated cotton varieties. There are no novel or unique impacts on the human environment, nor any considered controversial, that would derive from approval of the petition.

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

There are no unique or unknown impacts associated with MON 88702 Cotton. A transgene expressing a modified insecticidal protein (mCry51Aa2) derived from *Bacillus thuringiensis* (Bt), which was used to develop MON 88702 Cotton, is a naturally occurring soil bacterium. Since 1995, APHIS has evaluated eight IRcotton varieties that express Cry proteins.

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.*

Approval of Monsanto's petition would not establish a precedent for future actions that would result in significant impacts on the human environment, nor would it represent a decision in principle about a future decision. Approval of the petition is based upon an independent determination of whether MON 88702 Cotton is unlikely to pose a plant pest risk (USDA-APHIS 2020) pursuant to 7 CFR part 340, and an EA consistent with NEPA and CEQ implementing regulations. APHIS has reviewed and approved petitions for nonregulated status since 1992. Each was reviewed independently, and determinations of regulatory status were issued in part based on plant pest risk assessments and relevant NEPA analyses specific for the organism developed with genetic engineering. Each petition that APHIS receives is specific for a particular organism/trait combination and undergoes an independent review to determine if the regulated organism may pose a plant pest risk. The requirements for petitions for nonregulated status, applicable to both APHIS and the petitioner, are described in 7 CFR part 340. These requirements have been reviewed above under the sections summarizing APHIS' regulatory authority, and APHIS' requirements to respond to petitions for nonregulated status.

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

The EA included a review and analysis of potential cumulative impacts on agricultural practices and inputs, human and animal health, physical and biological resources, and on the selection pressure for the

development of resistant insect pest populations. Impacts from the cultivation of MON 88702 Cotton would not be considered cumulatively significant nor greater than that which occurs with currently cultivated cotton varieties.

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.*

The EA concluded that approval of the petition 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 cause any loss or destruction of significant scientific, cultural, or historic resources. MON 88702 Cotton would be cultivated on lands zoned for agricultural uses. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of cotton would be used in cultivation of MON 88702 Cotton. The crop production practices used in the cultivation of cotton 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 a 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 an 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 MON 88702 Cotton on threatened and endangered species and critical habitat in Chapter 6 of the EA. APHIS concluded that approval of the petition for nonregulated status for MON 88702 Cotton, and any subsequent commercial production of it, will have no effect on listed species or species proposed for listing, nor would it affect designated habitat or habitat proposed for designation. Because of this no-effect determination, neither consultation under Section 7(a)(2) of the Act nor the concurrences of the U.S. Fish and Wildlife Service and National Marine Fisheries Services are required.

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

The EA evaluated the federal, state, and local laws and regulations, executive orders, and policy related to Monsanto's petition. The EA concluded that approval of the petition request would not present a risk to violation of federal and state laws and regulations governing environmental and human health protections. The EPA will regulate the use of pesticides on MON 88702 Cotton, and Monsanto has consulted with the FDA as to the food and feed safety of products derived from MON 88702 Cotton.

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 of nonregulated status for MON 88702 Cotton). This alternative meets APHIS' purpose and need to allow the safe development and use of organisms developed using genetic engineering consistent with the plant pest provisions of the PPA.

As stated in 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 organisms developed using genetic engineering; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with MON 88702 Cotton, the continued status of MON 88702 Cotton as regulated would be inconsistent with the plant pest provisions of the PPA, APHIS regulations at 7 CFR 340, and the biotechnology regulatory policies of the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status for MON 88702 Cotton will not have any significant environmental impacts.

BERNADETTE JUAREZ

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Date: 2021.01.12 09:38:15 -05'00'

Bernadette R. Juarez
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
U.S. Department of Agriculture

Date:

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