

Record of Decision

Monsanto Petitions (10-188-01p and 12-185-01p) for Determination of Nonregulated Status for Dicamba-Resistant Soybean and Cotton Varieties

OVERVIEW

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) completed and published a Final Environmental Impact Statement (FEIS) after receiving two petitions submitted by Monsanto Company of St. Louis, Missouri (Monsanto), seeking determinations of nonregulated status for soybean and cotton cultivars genetically engineered to be resistant to certain herbicides. The first petition, APHIS Petition Number 10-188-01p (Monsanto, 2012a), seeks a determination of nonregulated status for soybean (*Glycine max*) designated as event MON 87708. This soybean event has been genetically engineered for increased resistance to the broadleaf herbicide dicamba (3,6-dichloro-2-methoxybenzoic acid). The second petition, APHIS Petition Number 12-185-01p (Monsanto, 2012b), seeks a determination of nonregulated status for cotton (*Gossypium hirsutum*) designated as event MON 88701. This cotton event has been genetically engineered for resistance to the broadleaf herbicide dicamba and the nonselective herbicide glufosinate.

The petitions state that these articles are unlikely to pose a plant pest risk and, therefore, should not be regulated under APHIS' regulations in 7 Code of Federal Regulations (CFR) part 340. These Part 340 regulations are authorized by the Plant Protection Act to prevent the introduction or dissemination of plant pests and the decision on whether or not to approve the petitions is based on this authority.

APHIS prepared the FEIS to examine the potential environmental impacts of MON 87708 soybean and MON 88701 cotton and the potential interrelated socioeconomic impacts associated with determinations of nonregulated status of these genetically engineered (GE) soybean and cotton events. APHIS examined four alternatives in the FEIS:

- Alternative 1: No Action;
- Alternative 2: Determination of Nonregulated Status of MON 87708 Soybean and MON 88701 Cotton;
- Alternative 3: Determination of Nonregulated Status of MON 88701 Cotton, Only; and
- Alternative 4: Determination of Nonregulated Status of MON 87708 Soybean, Only.

In this Record of Decision for the published FEIS, APHIS is announcing the agency's environmental decision on the alternatives examined in the FEIS. In accordance with its statutory authority and following the publication of its FEIS, APHIS is choosing Alternative 2.

Additionally, APHIS' regulatory determinations of nonregulated status of MON 87708 soybean and MON 88701 cotton pursuant to the Part 340 regulations will become effective upon publication in the *Federal Register*. APHIS' two regulatory determinations are entitled:

- Determination of Nonregulated Status for Monsanto Company MON 87708 Soybean; and
- Determination of Nonregulated Status for Monsanto Company MON 88701 Cotton.

BACKGROUND

Coordinated Framework

APHIS is one of the Federal agencies with regulatory responsibilities as described in the 1986 Federal Coordinated Framework for the Regulation of Biotechnology (hereafter Coordinated Framework) published by the Office of Science and Technology Policy, Executive Office of the President. The Coordinated Framework is a Federal policy statement that “describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products.” The Coordinated Framework explains the proper allocation and coordination of oversight responsibilities under the relevant Federal statutes and among the relevant Federal agencies.

The Coordinated Framework thus addresses who shall have oversight authority in each instance, but does not address how that authority should be exercised in the frequent situations in which a statute leaves the implementing agency latitude for discretion. To that end, the Office of Science and Technology Policy published a notice of Federal policy in the *Federal Register* in 1992 in which it set forth “the proper basis for agencies’ exercise of oversight authority within the scope of discretion afforded by statute.”

The notice describes:

“a risk-based, scientifically sound approach to the oversight of planned introductions of biotechnology products into the environment that focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created. Exercise of oversight in the scope of discretion afforded by statute should be based on the risk posed by the introduction and should not turn on the fact that an organism has been modified by a particular process or technique.”

The policy statement of 1992 states further:

“In order to ensure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable, that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed. The extent and type of oversight measure(s) will thus be commensurate with the gravity and type of risk being addressed, the costs of alternative oversight options, and the effect of additional oversight on existing safety incentives.”

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).

EPA Regulation of Biotechnology

The EPA is responsible for regulating the sale, distribution, and use of pesticides, including those that are expressed by an organism modified using techniques of modern biotechnology, identified as plant-incorporated protectants (PIPs).¹ The EPA regulates these PIPs under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S. Code (U.S.C.) 136, *et seq.*) and certain biological control organisms under the Toxic Substances Control Act (15 U.S.C. 53, *et seq.*). Before planting a crop containing a PIP, a company must seek an experimental use permit from the EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 Registration with the EPA. Before the EPA can register a pesticide there must be sufficient data demonstrating that it will not pose unreasonable risks to human health or the environment when used according to label directions. When assessing the potential risks of genetically engineered PIPs, the EPA requires extensive studies examining numerous factors, such as risks to human health, nontarget organisms and the environment, potential for gene flow, and the need for insect resistance management plans.

FDA Regulation of Biotechnology

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, on May 29, 1992 (57 FR 22984). Under this policy, the FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of food derived from GE products.²

APHIS Regulation of Biotechnology

In 1987, APHIS promulgated its biotechnology regulations (7 CFR part 340) under the authority of the Federal Plant Pest Act and the Plant Quarantine Act³ to address potential risks that certain

¹ A list of EPA Current and Previously Registered Section 3 PIP Registrations can be found here: http://www.epa.gov/pesticides/biopesticides/pips/pip_list.htm.

² A list of all completed Biotechnology consultations on Genetically Engineered foods evaluated under FDA's 1992 Statement of Policy: Foods Derived from New Plant Varieties can be found here: <http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon>.

³ The Federal Plant Pest Act and Plant Quarantine Act were consolidated along with other statutory authorities into the Plant Protection Act of 2000, in which Congress found that: "it is the responsibility of the Secretary to facilitate exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests . . . in ways that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests . . . ; decisions affecting imports, exports, and interstate movement of products regulated under this title shall be based on sound science . . ."

The Plant Protection Act of 2000 defines a plant pest as:

PLANT PEST—The term "plant pest" means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:

- (A) A protozoan.
- (B) A nonhuman animal.
- (C) A parasitic plant.
- (D) A bacterium.
- (E) A fungus.
- (F) A virus or viroid.

Record of Decision

GE organisms might pose as plant pests. The regulations refer to such GE organisms as “regulated articles.”⁴

The APHIS regulations codified at 7 CFR part 340 were amended in 1993 to provide a procedure for the deregulation (i.e., a petition for nonregulated status) of such GE plants that are unlikely to present a plant pest risk and, therefore, should no longer be regulated. 7 CFR 340.6 describes the process for submitting petitions for nonregulated status, the data requirements, and actions that the APHIS Administrator may take on the petition. It is under this procedure that APHIS received petition requests from Monsanto seeking determinations of nonregulated status of MON 87708 soybean and MON 88701 cotton. Petition 10-188-01p for MON 87708 soybean was received on July 6, 2010, and Petition 12-185-01p for MON 88701 cotton was received on July 2, 2012. *Federal Register* notices sought public comments on Petition 10-188-01p (MON 87708 soybean) and Petition 12-185-01p (MON 88701 cotton) on July 13, 2012 (77 FR 41356), and February 27, 2013 (78 FR 13308), respectively.

In response to the receipt of the two Monsanto petitions, APHIS prepared plant pest risk assessments (PPRAs) to assess the plant pest risk for each plant variety pursuant to the Plant Protection Act (USDA-APHIS, 2014a; 2014b). APHIS also examined the environmental impacts of its potential regulatory decisions for nonregulated status of MON 87708 soybean and MON 88701 cotton pursuant to the National Environmental Policy Act (NEPA) with this publication of the FEIS.

For most petitions for a determination of nonregulated status of GE organisms that APHIS has evaluated previously, it has prepared an environmental assessment to provide the APHIS decisionmaker with an environmental review and analysis that identifies whether there may be any significant environmental impacts. If the Agency makes a finding of no significant impact (FONSI), the NEPA process stops and a FONSI decision is issued. If significant environmental impacts are identified, the process continues with the preparation of an environmental impact statement (EIS) before a determination is made. For MON 87708 soybean and MON 88701 cotton, the decision to prepare the EIS was discretionary on the part of APHIS based on public concerns about the potential environmental impacts associated with the increased use of certain herbicides and possible selection for⁵ and spread of weeds resistant to the herbicide dicamba

(G) An infectious agent or other pathogen.

(H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

(7 U.S.C. §7702(14))

⁴ A “regulated article” is defined as: “Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.” (7 Code of Federal Regulations (CFR) 340.0)

⁵ Populations exhibit natural variations in genetic traits. As part of the natural selection process, conditions or selection pressures may favor the survival of genotypes with certain traits over those without that trait. The surviving population reproduces and, over time, the population exhibiting the favorable trait may increase. In the same way, weed populations may contain genotypes that exhibit natural resistance to herbicide. Herbicides can act

alone or to dicamba and other herbicides with different modes of action (multiple resistance). Because of the likely socioeconomic impacts that would result in the event that dicamba-resistant weeds would be selected for from the potential increased use of dicamba, APHIS concluded these impacts were at minimum uncertain and perhaps potentially significant in certain areas under certain conditions. Therefore, APHIS decided that, for MON 87708 soybean and MON 88701 cotton, an EIS would be prepared to further analyze the potential for selection of dicamba-resistant weeds and other potential environmental impacts that might occur from making regulatory determinations of nonregulated status for these varieties. APHIS decided that it was appropriate to use one EIS to evaluate the potential environmental impacts of the two similar Monsanto events. Accordingly, as part of the scoping process, APHIS published a Notice of Intent in the *Federal Register* to prepare the EIS for the two petitions (78 FR 28796) and sought public input during a comment period from May 16 to July 17, 2013.

APHIS issued the PPRAs and the draft EIS (DEIS) for the petitions for determination of nonregulated status for MON 87708 soybean (Petition 10-188-01p) and MON 88701 cotton (Petition 12-185-01p) for review and public comment. Availability of the DEIS was announced through publication of a Notice of Availability in the *Federal Register* (79 FR 46799) on August 11, 2014. The DEIS, PPRAs, and supporting documents were made available to the public on the regulations.gov docket (APHIS 2013-0043) and on APHIS' webpage.⁶ Initially, the public was given 45 days, from August 11 through September 25, 2014, to submit their comments to the docket, but the comment period was further extended to October 10, 2014, for a total of 61 days.

APHIS received 4,693 public submissions to the DEIS docket. Of these comments, 935 opposed and 3,708 supported regulatory determinations of nonregulated status for MON 87708 soybean and MON 88701 cotton. Some of the submissions in support or opposition were petitions with signatures, letters with multiple signatures, or batches of nearly identical letters. In addition, APHIS held a virtual public meeting September 11, 2014, at which a total of 16 participants provided verbal comments. From the virtual meeting, APHIS received 11 comments supportive of deregulation, all from farmers. Similar to some of the submitted written comments, supporters of deregulation cited the need for additional weed management tools. Those opposed to deregulation cited herbicide drift potential, persistence of dicamba in the environment, toxicity of dicamba, herbicide misapplication, and risks to organic crop certifications as concerns.

APHIS reviewed and evaluated all of the public comments received on the DEIS for MON 87708 soybean and MON 88701 cotton and prepared formal responses to them as part of the FEIS (see Appendix 11). On December 12, 2014, a Notice in the *Federal Register* (79 FR 73890) announced the availability of the FEIS to the public. Additionally, APHIS distributed the FEIS to all interested individuals who had specifically requested a copy of the FEIS and also posted it on its website.⁷

as a selection pressure, killing susceptible weeds while resistant weeds survive and reproduce. Repeated use of the same herbicide may result in the selection for weeds resistant to the herbicide.

⁶ http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml.

⁷ The FEIS can be viewed at http://www.aphis.usda.gov/brs/aphisdocs/dicamba_feis.pdf or under docket number APHIS-2013-0043 at regulations.gov.

PURPOSE AND NEED FOR AGENCY ACTION

In both the DEIS and the FEIS, APHIS identified a purpose and need to respond to the Monsanto petitions for MON 87708 soybean (Petition 10-188-01p) and MON 88701 cotton (Petition 12-185-01p) for determinations of nonregulated status in accordance with its current regulatory authority. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of a GE organism, including GE plants such as MON 87708 soybean and MON 88701 cotton, and must make a regulatory determination on whether the GE organism is likely to pose a plant pest risk. If APHIS determines, based on its PPRA, that the GE organism is unlikely to pose a plant pest risk, APHIS has no legal basis to continue to regulate that GE organism and must deregulate the GE organism. Once APHIS does deregulate a GE organism, the GE organism is no longer subject to the plant pest provisions of the Plant Protection Act of 2000 and 7 CFR part 340. In summary, the purpose and need of this project is to make a decision on these petitions that is consistent with APHIS's statutory authority under the PPA and 7 CFR part 340.

PLANT PEST RISK ASSESSMENT

The PPRA characterizes the potential plant pest risks associated with the GE product (crop) that is the subject of the petition for nonregulated status relative to its conventional varieties. It is based on information supplied in the petition for determination of nonregulated status together with other relevant publically available scientific data.

APHIS concluded from its PPRA that MON 87708 soybean and MON 88701 cotton are unlikely to pose a plant pest risk. APHIS found no evidence of MON 87708 soybean and MON 88701 cotton posing plant pest risks or other risks based on the following reasons:

- (1) No plant pest risk was identified from the transformed process, the insertion and/or expression of new genetic material, or from changes in metabolism in MON 87708 soybean and MON 88701 cotton.
- (2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in MON 87708 soybean and MON 88701 cotton compared to their nontransgenic counterparts or other comparators in field trials conducted in growing regions representative of where MON 87708 soybean and MON 88701 cotton are expected to be grown. Observed agronomic traits also did not reveal any significant differences that would indirectly indicate that MON 87708 soybean and MON 88701 cotton are more susceptible to pests or diseases. Therefore, no plant pest effects are expected based on these or other agricultural products and no impacts are expected to APHIS pest control programs.
- (3) Based on an evaluation of the gene products (DMO protein in MON 87708 soybean; DMO and PAT proteins in MON 88701 cotton) donor organisms, chemical composition of MON 87708 soybean and MON 88701 cotton plants, and arthropod abundance in field trials of MON 87708 soybean and MON 88701 cotton, exposure to and/or consumption of MON 87708 soybean and MON 88701 cotton are unlikely to adversely impact nontarget organisms beneficial to agriculture.

(4) MON 87708 soybean and MON 88701 cotton are no more likely to become weedier or more difficult to control as a weed than conventional varieties of these crops based on their observed agronomic characteristics, weediness potential of the crops and current management practices available to control MON 87708 soybean and MON 88701 cotton as weeds.

(5) MON 87708 soybean and MON 88701 cotton are not likely to increase the weed risk potential of other species with which they can interbreed in the United States or its territories. Gene flow, hybridization and/or introgression of inserted genes from MON 87708 soybean to other sexually compatible relatives with which they can interbreed are not likely to occur. For MON 88701 cotton, gene flow, hybridization and/or introgression of inserted genes from the cotton event to other sexually compatible relatives with which it can interbreed may occur.⁸ These compatible relatives are not considered weedy or invasive. The new phenotype(s) conferred by genetic engineering is not likely to increase the weediness of these compatible relatives or affect the current ability to control these relatives should they become weedy or invasive.

(6) Significant changes in agricultural or cultivation practices (e.g. pesticide applications, tillage, irrigation, harvesting, etc.) from adoption of MON 87708 soybean and MON 88701 cotton are expected, but are not likely to increase plant diseases or pests or compromise their management.

(7) Horizontal gene transfer of the new genetic material inserted into MON 87708 soybean and MON 88701 cotton to other organisms is highly unlikely, and is not expected to lead directly or indirectly to disease, damage, injury or harm to plants, including the creation of new or more virulent pests, pathogens, or parasitic plants.

FINAL ENVIRONMENTAL IMPACT STATEMENT

APHIS prepared a FEIS to examine the potential impacts on the human environment from determinations of nonregulated status of MON 87708 soybean and MON 88701 cotton.⁹ APHIS evaluated potential environmental impacts in the FEIS associated with the regulatory decision to approve the two petitions requesting a determination of nonregulated status for MON 87708 soybean and MON 88701 cotton. A summary of the environmental analyses contained in the FEIS is set forth below, in the section entitled “Environmental Consequences Associated with the Determinations of Nonregulated Status under Alternative 2.”

Alternatives Considered in the FEIS

Alternative 1: No Action Alternative – Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the two petitions seeking a determination of nonregulated status of MON 87708 soybean and MON 88701 cotton. All interstate movements and environmental releases for MON 87708 soybean and MON 88701 cotton varieties would remain subject to the regulations in 7 CFR part 340. Notifications or permits

⁸ See APHIS’ PPRA for MON 88701 cotton for a detailed discussion (USDA-APHIS, 2014b).

⁹ The FEIS can be viewed at http://www.aphis.usda.gov/brs/aphisdocs/dicamba_feis.pdf or under docket number APHIS-2013-0043 at [regulations.gov](http://www.regulations.gov).

with conditions specified by APHIS would be required to move viable plant material and to plant it outdoors.

Alternative 2: Determination of Nonregulated Status of MON 87708 Soybean and MON 88701 Cotton

Under Alternative 2, if MON 87708 soybean and MON 88701 cotton varieties were determined unlikely to pose a plant pest risk and both events received nonregulated status, MON 87708 soybean and MON 88701 cotton varieties and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. APHIS Biotechnology Regulatory Services' (BRS) permits or notifications would no longer be required for introductions of soybean and cotton derived from MON 87708 soybean and MON 88701 cotton varieties.

Alternative 3: Determination of Nonregulated Status of MON 88701 Cotton, Only

Under Alternative 3, only MON 88701 cotton and progeny derived from its cultivation would be granted nonregulated status and no longer be subject to the regulations at 7 CFR part 340. MON 87708 soybean would continue to be regulated as described under Alternative 1. APHIS would no longer require BRS permits or notifications for introductions of MON 88701 cotton and progeny derived from this events. However, after conducting a plant pest analysis, APHIS made the determination that MON 87708 soybean and MON 88701 cotton varieties are unlikely to pose a plant pest risk to agricultural crops or other plants in the United States. Therefore, choosing this alternative would be inconsistent with the purpose and need of the project because it is inconsistent with the scientific evidence before APHIS regarding plant pest risk.

Alternative 4: Deregulation of MON 87708 Soybean, Only

Under Alternative 4, only MON 87708 soybean and progeny derived from its cultivation would be granted nonregulated status and no longer be subject to the regulations at 7 CFR part 340. MON 88701 cotton would continue to be regulated as described under Alternative 1. APHIS would no longer require BRS permits or notifications for introductions of MON 87708 soybean and progeny derived from this events. However, after conducting a plant pest analysis, APHIS made the determination that MON 87708 soybean and MON 88701 cotton varieties are unlikely to pose a plant pest risk to agricultural crops or other plants in the United States. Therefore, choosing this alternative would be inconsistent with the purpose and need of the project because it is inconsistent with the scientific evidence before APHIS regarding plant pest risk.

Major Issues Addressed in the FEIS

The FEIS described the four alternatives considered and assessed the potential impacts of the deregulation of MON 87708 soybean and MON 88701 cotton on the human environment. APHIS sought input from members of the public on issues and alternatives the Agency should consider in preparation of the EIS related to determinations of nonregulated status of MON 87708 soybean and MON 88701 cotton. The resource areas considered in the FEIS were developed based upon the relevant concerns and issues identified in the Notice of Intent to prepare an EIS that APHIS published in the *Federal Register* on May 16, 2013 (78 FR 28796). The following resource areas were assessed and evaluated by APHIS in the FEIS:

- Land use and acreage

Record of Decision

- Socioeconomic impacts
 - Domestic use of soybean and cotton
 - Export of soybean and cotton
- Agronomic practices in cotton and soybean production
- Worker safety
- Food and feed safety
- Animal and plant communities
- Soil microorganisms
- Physical environment
 - Surface and water groundwater
 - Air quality and climate change

The scope of this FEIS covered the direct and indirect impacts that would result from the cultivation and use of MON 87708 soybean and MON 88701 cotton.

APHIS considered the FDA regulatory assessments in making its evaluation of the potential impacts of determinations of nonregulated status of MON 87708 soybean and MON 88701 cotton. Monsanto submitted food and feed safety and nutritional assessments for MON 87708 soybean and MON 88701 cotton to the FDA. At this time, the FDA considers the consultations on MON 87708 soybean and MON 88701 cotton to be complete.¹⁰ The EPA, in its registration process, is considering any direct and indirect impacts from herbicide use on MON 87708 soybean and MON 88701 cotton.

PUBLIC COMMENTS RECEIVED ON THE FEIS

On December 12, 2014, APHIS published the FEIS for its determinations on petitions for nonregulated status of MON 87708 soybean and MON 88701 cotton. The 30-day “review period” required under NEPA¹¹ closed on January 12, 2015. APHIS received 29 total submissions from the public on the FEIS. None of the submissions supported the deregulation of MON 87708 soybean and MON 88701 cotton. These comments did not raise any new substantive issues with regard to the FEIS. As with previous public comments, these submissions expressed general concerns relating to pesticide use, GE plants, or MON 87708 soybean and MON 88701 cotton. Other commenters opposed to the deregulation were concerned about the projected increased use of dicamba on the MON 87708 soybean and MON 88701 cotton impacting the environment, including natural resources, sensitive plants, and humans. A number of growers and NGOs voiced concerns about the potential for injury to non-target plants resulting from the volatility and drift of dicamba that would be applied to MON 87708 soybean and MON 88701 cotton. Additionally, some opposing commenters thought that a large increase in the use of dicamba would result in the evolution of dicamba-resistant weeds or multiple herbicide-resistant weeds, leading to the abandonment of conservation tillage practices which

¹⁰ Completed FDA consultations (Biotechnology Notes to File (BNFs)) for MON 87708 soybean (BNF No. 125) and MON 88701 cotton (BNF No. 135) can be accessed at FDA’s website:

<http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon>.

¹¹ 40 CFR §1506.10(b)(2)

inevitably would increase soil erosion. However, such concerns and issues were previously assessed and addressed in the text and appendices of the FEIS.

E-Mail Form Letters Submitted to BiotechQuery

BiotechQuery (BTQ) is a public e-mail address posted on the BRS website intended to serve as a conduit between BRS subject matter experts and stakeholders seeking program-specific information. The BRS Communications staff responds to inquiries ranging from general biotechnology-related questions to complex regulatory matters. The most common inquiries received through BTQ are from individuals seeking information about their permit(s) or notification(s) (e.g., shipping labels).

On October 10, 2014, the public comment period for the DEIS closed after 61 days with approximately 4,700 comments submitted to the docket. The *Federal Register* notice provided the postal address, as well as a direct link to the docket on www.regulations.gov, where comments could be submitted. [Regulations.gov](http://www.regulations.gov) is a website developed in response to the 2002 E-Government Act and implemented in 2003. The site was designed to increase public participation and transparency in the Federal review process by providing public users ease of access to federal regulatory content and a user-friendly way to submit and review comments, while improving the efficiency and effectiveness of agency response. Public comments are to be sent to the docket at [regulations.gov](http://www.regulations.gov) or mailed to the docket in order to be considered by the originating Agency.

In early November 2014, Friends of the Earth began an e-mail form letter campaign directed to the BTQ inbox. The letter opposed deregulation of MON 87708 soybean and MON 88701 cotton, citing claims of adverse human health effects, toxicity to nontarget organisms and the environment associated with the increased use of dicamba, and impacts to other sensitive crops through herbicide drift. BTQ received more than 44,000 of these e-mails as of January 12, 2015. Friends of the Earth continued to encourage their constituents to send the letter, even though the public comment period had closed. Letters received through this campaign are consistent with comments received during the public comment period on the DEIS and during the review period on the FEIS. These letters did not raise new issues or provide additional information material to APHIS' environmental analysis. Therefore, for the public record, APHIS is acknowledging receipt of these letters via its BTQ e-mail address, rather than through the official comment process at [regulations.gov](http://www.regulations.gov).

HERBICIDE USE

APHIS has no authority to authorize or regulate the use of dicamba, glufosinate, or any other herbicide, by growers. Under APHIS' current Part 340 regulations, APHIS only has the authority to regulate MON 87708 soybean and MON 88701 cotton or any GE organism as long as APHIS believes it may pose a plant pest risk. Any direct and indirect impacts associated with the potential increased use of dicamba, glufosinate, or other herbicides on MON 87708 soybean and MON 88701 cotton are outside the scope of this EIS because the authority to regulate and address the impacts of pesticide use resides with the EPA under FIFRA. The EPA's FIFRA registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. The EPA is conducting independent

assessments of the direct and indirect impacts associated with the use of dicamba on MON 87708 soybean and MON 88701 cotton and is making an independent action to determine whether to approve the registration of the new uses of dicamba.

APHIS' RECORD OF DECISION ON THE FEIS

APHIS is selecting Alternative 2, approving the petition requests for determinations of nonregulated status of MON 87708 soybean and MON 88701 cotton. This Record of Decision on the FEIS is based on APHIS' full and complete review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the PPRAs; the FEIS; the public comments on the DEIS; the agency's response to comments on the DEIS; and comments on the FEIS.

APHIS is selecting Alternative 2 of the FEIS because:

- Alternative 2 best meets the purpose and need for agency action, which is to make a decision on these petitions consistent with our statutory authority and 7 CFR part 340. APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as MON 87708 soybean and MON 88701 cotton. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS concludes, based on its PPRA, that the GE organism is unlikely to pose a plant pest risk, APHIS must then issue a determination of nonregulated status, since the agency does not have statutory authority to regulate GE organisms that are not plant pests.

According to the PPRAs published on August 6, 2014, APHIS concluded that the MON 87708 soybean and MON 88701 cotton events are unlikely to pose a plant pest risk. APHIS has therefore concluded that the selection of Alternative 2 in this Record of Decision is consistent with the plant pest provisions of the Plant Protection Act of 2000, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

- APHIS reviewed the conclusions it reached in the FEIS on the environmental consequences of Alternative 2 and, in light of those conclusions, as well as those of the final PPRAs, APHIS finds that Alternative 2 best serves the purpose and need for agency action as identified in the FEIS, as well as being in accord with APHIS' regulatory authority under 7 CFR 340. The potential environmental consequences of Alternative 2 are discussed in the next section.

ENVIRONMENTAL CONSEQUENCES ASSOCIATED WITH THE DETERMINATIONS OF NONREGULATED STATUS UNDER ALTERNATIVE 2

The following is a summary of the conclusions APHIS reached on the potential environmental consequences of Alternative 2. Under Alternative 2, MON 87708 soybean and MON 88701 cotton could be planted, but the new uses of the herbicide dicamba would not be allowed on these varieties. EPA regulates the use of herbicides under FIFRA and is making a separate decision on the use of dicamba on these plants.

Land Use and Acreage

- Land use for soybean and cotton production is driven by the price of soybean and cotton, as well as the suitability of the land for production of these crops. The decision to approve these petitions would not affect these factors. As a result, the availability of MON 87708 soybean and MON 88701 cotton would not have any direct or indirect effects on land use under Alternative 2 in comparison to the No Action Alternative. Additionally, the availability of MON 87708 soybean and MON 88701 cotton is not expected to change the acreage of GE soybean or cotton in the United States.

Socioeconomics

- MON 87708 soybean and MON 88701 cotton have been shown to be compositionally similar to currently available varieties of soybean and cotton and, therefore, are suitable for use in food, feed, and industrial applications. As a result, under Alternative 2, there are no expected direct or indirect effects associated with the cultivation of these events on the domestic use of soybean and cotton.
- Monsanto has submitted applications to various international regulatory authorities for food, feed, and/or cultivation approvals. Approvals for MON 87708 soybean and MON 88701 cotton have occurred in some countries and are pending in others. Although the primary U.S. soybean and cotton export destinations do not present major barriers in the trade of GE products, Monsanto will need to obtain approvals for MON 87708 soybean and MON 88701 cotton in destination countries before commercialization to avoid adversely affecting current trade flows.

Agronomic Practices in Soybean and Cotton Production

- MON 87708 soybean and MON 88701 cotton are similar to conventional soybean and cotton in their agronomic and compositional characteristics. As a result, under Alternative 2, growers would be able to continue using established soybean and cotton production practices, including crop rotation, tillage systems, EPA-approved pesticides, fertilizers, and planting and harvesting machinery currently being utilized. Growers would continue to manage weeds using a combination of chemical, mechanical, and cultural control methods. Therefore, no adverse impacts on current soybean and cotton production practices are expected following the introduction of MON 87708 soybean and MON 88701 cotton under Alternative 2 in comparison to the No Action Alternative.
- Under this alternative, growers would be able to plant MON 87708 soybean and MON 88701 cotton, but would not be able to make applications of dicamba other than currently approved by the EPA unless a new registration is granted. It is assumed that glufosinate will be able to be used on deregulated MON 88701 cotton varieties with the PAT protein. MON 87708 soybean and MON 88701 cotton are likely to be stacked with other deregulated traits currently found in production, such as glyphosate or insect resistance.

Organic and Specialty Production Systems

- When compared to other GE varieties of soybean and cotton being grown, MON 87708 soybean and MON 88701 cotton are not expected to present any new or different issues and impacts for organic and other specialty production systems. Isolation practices of organic growers that are already in place in their production systems would not need to change due to the introduction of MON 87708 soybean and MON 88701 cotton.
- The availability of MON 87708 soybean and MON 88701 cotton is not expected to change the acreage and areas where cotton would be grown in the United States. Similar to the No Action Alternative, organic soybean and cotton acreage is not likely to change as a result of whether new varieties of GE or non-GE cotton and soybean, including MON 88701 cotton and MON 87708 soybean, become available for commercial production.
- No major impacts to organic or specialty soybean or cotton production systems from MON 87708 soybean and MON 88701 cotton are anticipated under Alternative 2 in comparison to the No Action Alternative.

Worker Safety

- APHIS has not identified any direct or indirect effects on worker safety that would result from choosing the Alternative 2. Under Alternative 2, the availability of MON 87708 soybean and MON 88701 cotton would not change the agronomic practices used in the production of soybean and cotton. Potential hazards to workers associated with the various agronomic production practices used to grow soybean and cotton would be the same as those under the No Action Alternative. The decision to approve the two petitions does not authorize a change in herbicide use on these soybean or cotton varieties. The EPA regulates the use of herbicides under FIFRA and considers the effects on human health when approving the use of herbicides. The EPA, in its registration process, is considering any direct and indirect impacts from the new use of herbicides on MON 87708 soybean and MON 88701 cotton.

Food and Feed Safety

- Under the Alternative 2, MON 87708 soybean and MON 88701 cotton would be commercially available to growers who would be able to grow, harvest, and move their crop into commerce for food and feed. MON 87708 soybean and MON 88701 cotton have been shown to be compositionally similar to currently available varieties of soybean and cotton. These events are not expected to have different nutritional qualities than other available soybean or cotton varieties. Monsanto submitted safety and nutritional assessments to the FDA, providing information on the characterization, composition, allergenicity, and toxicity of the proteins inserted in MON 87708 soybean and MON 88701 cotton. The FDA evaluated the information in Monsanto's submissions to ensure that regulatory and safety issues regarding human food and animal feed derived from the new plant varieties have been resolved prior to commercial distribution. Monsanto concluded that foods and feeds derived from MON 87708 soybean and MON 88701

Record of Decision

cotton are as safe as conventional soybean and cotton varieties and are not materially different in composition or any other relevant parameters from other soybean and cotton varieties now grown, marketed, and consumed in the United States. The FDA did not identify any issues under the Federal Food, Drug, and Cosmetic Act that would require further evaluation at this time and the consultations were completed with the FDA on MON 87708 soybean (October 2011) and MON 88701 cotton (April 2013).¹² As a result, under Alternative 2, there are not likely to be any effects associated with consumption of food and feed containing MON 87708 soybean and MON 88701 cotton when compared to the No Action Alternative.

- MON 87708 soybean and MON 88701 cotton contain a demethylase gene from *Stenotrophomonas maltophilia* that expresses the dicamba mono-oxygenase (DMO) protein. *S. maltophilia* is an aerobic, Gram-negative, environmentally ubiquitous bacterium and is found in aquatic environments, household environments, soil, and plants. According to Monsanto, humans are exposed to *S. maltophilia* through consumption of ready-to-eat salads, vegetables, frozen fish, milk, and poultry. Published reports show that *S. maltophilia* is found in healthy individuals and does not cause harmful effects. Under Alternative 2, there are not likely to be any effects on humans or animals consuming food and feed containing the DMO protein, respectively, from MON 87708 soybean and MON 88701 cotton when compared to the No Action Alternative.
- MON 88701 cotton also contains the PAT protein that is isolated from *Streptomyces hygroscopicus* and is encoded by the *bar* gene. *S. hygroscopicus* is a saprophytic, soil-borne bacterium with no known safety issues. The PAT (*bar*) protein is identical to the wild type PAT protein produced in *S. hygroscopicus*. PAT (*bar*) is analogous to PAT proteins produced in numerous commercially available glufosinate-tolerant plant varieties. The PAT (*bar*) protein expressed in MON 88701 cotton has the same functional activity as the PAT proteins in all commercially available products that provide glufosinate tolerance in crops, including cotton, corn, soybean, rice, sugarbeet, and canola. FDA has previously reviewed submissions regarding the safety of food and feed derived from crops containing the *pat* gene (Biotechnology Notification Files (BNFs) 000055, 000073, 000081, 000085, and 000092). Because the PAT protein has already been evaluated by FDA and cotton and other crops containing the PAT protein are already in commerce, there are not likely to be any effects on humans and animals consuming food and feed, respectively, from MON 88701 cotton when compared to the No Action Alternative.

¹² Completed FDA consultations (Biotechnology Notes to File (BNFs)) for MON 87708 soybean (BNF No. 125) and MON 88701 cotton (BNF No. 135) can be accessed at FDA's website: <http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon>.

Biological Resources

Animal Communities

- Animals found in the vicinity of agricultural fields of MON 87708 soybean or MON 88701 cotton would continue to feed on soybean and cotton in these fields. These soybean and cotton varieties have been shown to be compositionally similar to other commercially grown soybean and cotton varieties. As detailed under “Food and Feed,” the PAT protein is found in commercial varieties of corn, cotton, and soybeans. Organisms that feed on these crops are exposed to the protein in previously deregulated varieties with no documented negative effects. Monsanto completed consultations with FDA ensuring that regulatory and safety issues regarding human food and animal feed derived from the new plant varieties have been resolved prior to commercial distribution. No potential impacts to animal communities from consumption and exposure to MON 87708 soybean and MON 88701 cotton are anticipated under Alternative 2 in comparison to the No Action Alternative.
- Animals can also be impacted indirectly by agricultural practices, such as tillage and herbicide use. Adopting Alternative 2 will not result in any changes in agricultural practices in comparison to the No Action Alternative. Soybean and cotton growers will continue to use EPA-approved herbicides, and mechanical and cultural practices to manage weeds. Increases in tillage to control weeds can increase soil erosion and indirectly impact wildlife. The environmental risks of herbicide use on wildlife and wildlife habitat are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA.

Plant Communities

- Under Alternative 2, the direct and indirect effects of approving these two petitions on plant communities would be similar to the effects on plants under the No Action Alternative. MON 87708 soybean and MON 88701 cotton have been shown to be agronomically similar to conventional soybean and cotton varieties currently in cultivation. Thus, choosing Alternative 2 would not change the agronomic production practices used in the cultivation of soybean and cotton, and therefore, would not change the potential impacts to the plant communities in or around soybean and cotton fields.
- Weed management practices, such as herbicide use and mechanical cultivation (i.e., tillage), can select for weeds that are adapted to these management practices. Non-target plant communities in areas surrounding production fields would continue to be exposed to the effects associated with agricultural production. This can select for resistance to herbicides among these populations, just as in production fields, resulting in the establishment of novel resistant biotypes. Exposure to herbicide, e.g., through drift could also lead to plant population shifts in non-target populations, just as it could in weed populations associated with production fields.
- APHIS’ decision to grant nonregulated status to the two petitions, as described in Alternative 2, does not in any manner authorize or approve any herbicide use on these soybean or cotton varieties. APHIS has no regulatory authority over the use and

application of herbicides. EPA regulates the use of herbicides FIFRA and is making a separate decision on the new uses of dicamba on these plants. Therefore, there are no changes to the potential effects to plant communities under Alternative 2 when compared to the No Action Alternative.

Physical Environment

MON 87708 soybean and MON 88701 cotton are similar to conventional soybean and cotton in their agronomic and compositional characteristics. Growers would be able to continue using established soybean and cotton production practices on these GE varieties. As a result, under Alternative 2, MON 87708 soybean and MON 88701 cotton are not expected to have any different potential impacts on soils, climate or air quality, or water than those under the No Action Alternative. These natural resources are affected by agricultural practices, particularly those associated with weed management, such as tillage and herbicide use. The decision to approve these petitions will not directly or indirectly affect grower decisions to use tillage or herbicides to manage weeds. Under Alternative 2, MON 87708 soybean and MON 88701 cotton could be planted but no new herbicide uses would be allowed on these varieties. EPA regulates the use of herbicides under FIFRA and is making a separate decision on the use of dicamba on these plants.

Threatened and Endangered Species

Federal Section 7 (a)(2) of the Endangered Species Act requires that Federal agencies, in consultation with U.S. Fish & Wildlife Service (USFWS) and/or the National Marine Fisheries Service (NMFS), ensure that any action they authorize, fund, or carry out is “not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat.” It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action “may affect” listed species or designated critical habitat. To facilitate their ESA consultation requirements, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS’ regulatory authority and effects analysis for petitions for nonregulated status and developed a process for conducting an effects determination consistent with the Plant Protection Act of 2000 (Title IV of Public Law 106-224). APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

APHIS met with USFWS officials on June 15, 2011, to discuss whether APHIS has any obligations under the ESA regarding analyzing the effects of pesticide use associated with all GE crops on threatened and endangered species (TES). As a result of these joint discussions, USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on pesticide use associated with GE crops currently planted because the EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under FIFRA. APHIS has no statutory authority to authorize or regulate the use of dicamba, glufosinate, or any other herbicide, by cotton and soybean growers. Under APHIS’ current Part 340 regulations, APHIS only has the authority to regulate MON 87708 soybean and MON 88701 cotton or any GE organism as long as APHIS believes they may pose a plant pest risk (7 CFR § 340.1). APHIS has no regulatory jurisdiction over any

Record of Decision

other risks associated with GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms.

APHIS, as described below, evaluated the potential effects that the two determinations of nonregulated status of MON 87708 soybean and MON 88701 cotton may have, if any, on federally-listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation.

MON 87708 soybean and MON 88701 cotton, APHIS concluded that availability of MON 87708 soybean and MON 88701 cotton would not extend the range of soybean and cotton production or lead to cultivation on land not previously used for agricultural production. Accordingly, APHIS' analysis focused on TES species in the areas where soybean and cotton are currently grown, reviewing the USFWS list of TES species (listed and proposed) for each state where soybean and cotton are commercially produced.

For its analysis of potential effects on TES plants and critical habitat, APHIS focused on the agronomic differences between the regulated articles (MON 87708 soybean and MON 88701 cotton) and soybean and cotton varieties currently grown; the potential for increased weediness; and the potential for gene movement to native plants, listed species, and species proposed for listing. For its analysis of potential effects on TES animal species, APHIS focused on the implications of exposure of the novel proteins expressed in the plants as a result of the transformations, and the ability of the plants to serve as a host for a TES. APHIS' analysis is summarized as follows:

- APHIS considered as part of the analysis for TES and critical habitat if the new phenotype imparted to MON 87708 soybean and MON 88701 cotton may allow the plants to naturalize in the environment and potentially have an effect on TES. No differences were detected between MON 87708 soybean and MON 88701 cotton and conventional varieties in growth, reproduction, or interactions with pests and diseases, other than the intended effect of herbicide resistance. Based on agronomic field data and a survey of scientific literature on weediness potential, the inserted genes do not alter weediness potential of MON 87708 soybean and MON 88701 cotton, and thus these varieties will have no effect on federally-listed TES or critical habitat as troublesome or invasive weeds.
- After reviewing the list of threatened and endangered plant species or plants proposed for listing in the states where soybean are grown, APHIS concluded that MON 87708 soybean would not be sexually compatible with any federally-listed TES or species proposed for listing, as none of these listed plants are in the same genus nor are known to cross pollinate with species of the genus *Glycine*.

The potential for gene introgression from cultivated *G. hirsutum* (upland cotton), such as MON 99701 cotton, to native or naturalized *G. barbadense* (Pima cotton) within the United States is expected to be rare. None of the relatives of cotton are federally-listed (or proposed) as endangered or threatened species. In Florida wild populations of upland cotton, *G. hirsutum*, have been listed as endangered by the state. However, wild *G. hirsutum* is not present in the northwestern panhandle where commercial cotton

cultivation occurs, and cultivation of cotton is prohibited by the EPA in those areas of southern Florida where it is found. Thus, outcrossing from MON 88701 cotton to wild *G. hirsutum* in Florida is highly unlikely. Accordingly, a determination of nonregulated status of MON 88701 cotton is not expected to impact Florida state-listed endangered cotton populations.

- Compositional analysis of MON 87708 soybean and MON 88701 cotton demonstrated that these GE soybean and cotton are compositionally equivalent to conventional soybean and cotton with respect to key nutrients and components. Additionally, Monsanto submitted food and feed safety and nutritional assessments for MON 87708 soybean and MON 88701 cotton to the FDA and completed their consultations with the FDA. Consequently, MON 87708 soybean and MON 88701 cotton are not expected to have adverse nutritional effects on any animal that feeds upon them including any federally-listed TES and species proposed for listing.
- Safety evaluations conducted by Monsanto included evaluations of the protein structure and function of MON 87708 soybean and MON 88701 cotton, including homology searches of the amino acid sequences with comparison to all known allergens, gliadins, glutenins, toxins, and any other biologically active proteins that may be harmful to humans or animals. Additionally, an *in vitro* digestibility assay of the proteins and an acute oral toxicity feeding study in mice were completed. MON 87708 soybean and MON 88701 cotton proteins were determined to have no amino acid sequences similar to known allergens, lacked toxic potential to mammals, and degraded rapidly and completely in gastric fluid. APHIS concluded that no substantial differences exist compared to conventional soybean or cotton and consumption of MON 87708 soybean and MON 88701 cotton by any federally-listed TES or species proposed for listing will not result in a toxic or allergic reaction.
- APHIS evaluated whether MON 87708 soybean and MON 88701 cotton could serve as host plants for federally-listed TES or species proposed for listing (i.e., a listed insect or other organism that may use the soybean or cotton plant to complete its lifecycle). A review of the species list indicated there are no federally-listed TES or species proposed for listing that use soybean or cotton as a host plant.

Based on the analysis, summarized above, APHIS concluded that the determinations of nonregulated status of MON 87708 soybean and MON 88701 cotton and the corresponding environmental releases of these soybean and cotton varieties will have no effect on federally-listed TES or species proposed for listing, and would not affect designated habitat or habitat proposed for designation.

ENVIRONMENTALLY PREFERRED ALTERNATIVE

The environmentally preferred alternative is not only the alternative that causes the least harm to the biological and physical environment, but also the alternative which best protects, preserves, and enhances historic, cultural, and natural resources. APHIS analyzed the impacts of four alternatives on the human environment in detail in the FEIS. Because there is no difference in the

Record of Decision

potential impacts among the alternatives when compared to the No Action Alternative, APHIS has not identified an Environmentally Preferred Alternative.

Under Alternatives 2, no direct or indirect effects associated with growing MON 87708 soybean and MON 88701 cotton were identified as being different when compared to the direct and indirect effects associated with growing soybean and cotton under the No Action Alternative, because these GE varieties are not agronomically or compositionally different from non-GE soybean and cotton plants or other GE soybean or cotton plants that are no longer regulated by the Agency. APHIS determined that the deregulation and commercial availability of MON 87708 soybean and MON 88701 cotton varieties would not result in an increase in soybean and cotton acreage in areas already in soybean and cotton production or result in changes in where soybean and cotton are currently grown. In addition, these two GE plant varieties would not affect natural (e.g., soil, water, air, and climate) or biological (e.g., animal, insect, plant) resources any differently than those soybean and cotton varieties currently grown under the No Action Alternative. Food and feed derived from MON 87708 soybean and MON 88701 cotton are not expected to result in effects in humans and animals.

The continued emergence of glyphosate-resistant weeds under the No Action Alternative will itself call for modifications of agronomic production practices to address these weeds. Growers will likely continue to use glyphosate because it is still effective on hundreds of weed species, but will become less reliant on glyphosate for the control of weeds it is no longer effective in controlling. Farmers are expected to use additional non-glyphosate herbicides and non-chemical methods, such as crop rotation and tillage practices, to control these glyphosate-resistant weeds. Herbicide-resistant weeds would continue to be selected for by the weed management practices growers choose to adopt.

As with the No Action Alternative, under Alternative 2, growers may continue to rely on glyphosate, other EPA-approved herbicides, and other non-chemical methods to manage weeds in soybean and cotton. They could not apply herbicides differently on MON 87708 soybean and MON 88701 cotton than currently allowed on other soybean and cotton varieties. That is because the new uses of dicamba are not registered for use on these soybean or cotton events until EPA approves the label. Therefore, herbicide-resistant weeds would be selected for by weed management practices in the same ways that they are in the No Action Alternative.

The potential impacts on each resource from herbicide use are outside the scope of this EIS because the EPA is thoroughly analyzing the potential impacts of the proposed new uses of dicamba as part of their pesticide registration process. The expected increased use of dicamba on MON 87708 soybean and MON 88701 cotton has the potential to impact the selection of herbicide resistance in weeds due to the use of dicamba as an herbicide, and not due to any properties of MON 87708 soybean and MON 88701 cotton plants themselves. Measures EPA may include on the dicamba label addressing this potential development of resistant weeds are discussed in the following section discussing mitigations of impacts. Weed scientists and agronomists will continue to encourage growers to use best management practices like under the No Action Alternative.

As a result, the direct and indirect impacts on each resource area for Alternative 2 are the same as for the No Action Alternative. Under Alternative 2, neither of these two events (MON 87708

soybean and MON 88701 cotton), either individually or together, would have different effects on the human environment than the No Action Alternative. Therefore, approving the petition for deregulation of MON 88701 cotton under Alternative 3 or MON 87708 soybean under Alternative 4 is also not expected to have different direct and indirect effects on resource areas in comparison to the No Action Alternative. Because there is no difference in the potential impacts among the alternatives, there is no environmentally preferable alternative.

MITIGATIONS OF IMPACTS ASSOCIATED WITH ALTERNATIVE 2

In an analysis of cumulative impacts, the independent action by EPA to approve the new uses of dicamba on MON 87708 soybean and MON 88701 cotton is reasonably foreseeable. APHIS concluded that the potential increased use of dicamba associated with cultivation of MON 87708 soybean and MON 88701 cotton is expected to increase the pressure for selection of dicamba-resistant weeds, as management regimes that incorporate only a single herbicide are more likely to result in selection of weeds resistant to that herbicide. APHIS also acknowledges that the availability of 2,4-D-resistant corn and soybean (called Enlist soybean and corn) varieties on the market is reasonably foreseeable. The EPA approved the registration for the new use of 2,4-D on Enlist soybean and cotton in Illinois, Indiana, Ohio, South Dakota, and Wisconsin on October 15, 2014.¹³ The EPA is currently considering expanding the registration in ten additional states: Arkansas, Kansas, Louisiana, Minnesota, Missouri, Mississippi, Nebraska, Oklahoma, Tennessee, and North Dakota. The potential increased use of 2,4-D associated with growing of Enlist soybean and cotton is expected to increase selection pressure of 2,4-D-resistant weeds if the herbicide is used without rotating to other herbicides. Dicamba and 2,4-D are both synthetic auxins with very similar herbicide chemistries, however they are not likely to be used simultaneously. Cultivation of herbicide-resistant crops is not the cause of herbicide-resistant weeds, but results from the failure of growers to apply best management practices when growing herbicide-resistant crops.

Growers may mitigate the rate at which weeds develop resistance by the weed management practices they choose. The impact of increased dicamba or 2,4-D use on the selection of dicamba- or 2,4-D-resistant weeds may be mitigated by use of best management practices. Some examples of the practices that can be followed to reduce or delay the selection of herbicide-resistant weeds include, rotating crops, rotating types of herbicides, using cover crops, scouting for weeds, and using mechanical tillage to prevent weeds from flowering. Resistance to dicamba or 2,4-D represents no more of a threat to agricultural production than resistance to other critical herbicides, and the likelihood that it will be used in a manner consistent with best management practices is good. Farmers are aware of the problems of resistant weed biotypes and are increasingly proactive in the identification and removal of new weeds. Societies such as the Weed Science Society of America, university extension agents, and industry, have made a concerted effort to increase grower awareness of best management practices for herbicide-resistant weeds.

When considering the cumulative impacts for Alternative 2, dicamba use is expected to increase if EPA approves the amended use of dicamba on the MON 87708 soybean and MON 88701

¹³ See EPA's docket EPA-HQ-OPP-2014-0195, Evaluation of 2,4-D Choline Salt Herbicide on Enlist Corn and Soybeans, on regulations.gov for its decision and related documents.

Record of Decision

cotton. However, increases in other herbicide sites of action under Alternative 2 are expected to be less than under the No Action Alternative because dicamba is expected to be preferentially adopted if approved for use on these crops by EPA. The availability of dicamba combined with MON 87708 soybean and MON 88701 cotton may delay the adoption of non-chemical management strategies. Fewer growers would be expected to adopt aggressive tillage when herbicides remain effective for weed control. Selection of weeds resistant to glyphosate and non-glyphosate herbicides will still occur. The selection pressure for herbicide-resistant weeds will depend on the weed management practices employed by growers under each alternative and cannot be predicted. More diversified weed management practices will result in less selective pressure for resistance to any given herbicide or management technique.

APHIS does not have the authority to regulate grower management practices. Further, APHIS has no authority to regulate herbicide use or to impose any mitigation measures with regard to the use of any herbicides, including dicamba. Under FIFRA, the EPA registers herbicides and prescribes the conditions for use of the herbicide. The EPA must ensure that the herbicide, when used according to label directions, will not cause unreasonable adverse effects to human health or the environment. Mitigation measures to oversee the proper usage of herbicides are determined by the EPA and specified on the EPA-approved herbicide labels. Applying herbicides in a way that is inconsistent with the label is illegal.

The EPA is thoroughly analyzing the potential impacts of the proposed new uses of dicamba as part of their pesticide registration process. Although the terms of that registration are not known at this time, EPA has indicated that, in the future, the Agency intends to apply the approach to weed resistance management used for the registration of Enlist Duo for all existing and new herbicides used on herbicide-tolerant crops.¹⁴ Therefore, it is anticipated that herbicide resistance management requirements will be included as part of the EPA registration of the new uses of dicamba on MON 87708 soybean and MON 88701 cotton.

EPA has recognized the increasing economic issues resulting from herbicide-resistant weeds and has included measures to address weed resistance as part of the recent registration for Dow AgroSciences' Enlist Duo.¹⁵ Among other label requirements, EPA is requiring Dow to develop an Herbicide Resistance Management plan that will promote herbicide resistance management efforts. The plan mandates that Dow must investigate any reports of lack of herbicide efficacy. The label will also contain information on resistance management consistent with the Weed Science Society of America's Best Management Practices for comprehensive resistance management approaches, including: rotating herbicide chemistries, limiting herbicide applications per season; scouting fields both before and after herbicide treatment; incorporating non-chemical weed control strategies, and preventing weeds from setting seed.

¹⁴ "EPA Announces Final Decision to Register Enlist Duo, Herbicide Containing 2,4-D and Glyphosate/Risk assessment ensures protection of human health, including infants, children," <http://yosemite.epa.gov/opa/admpress.nsf/bd4379a92ceceac8525735900400c27/72fde554930f3f6985257d7200591180!OpenDocument>

¹⁵ EPA's registration decision, including the approved label, risk assessments, and analyses, on the registration of Enlist Duo can be accessed at the EPA docket EPA-HQ-OPP-2014-0195 at [regulations.gov](http://www.regulations.gov).

EPA has determined that the registration must contain a term that requires DAS to submit annual summary reports to EPA that include a summary of the number of instances of likely and confirmed weed resistance by weed species, crop, county and state. EPA believes that it is important to address likely weed resistance and not wait until confirmation of resistance has been found. Because the issue of weed resistance is an extremely important issue to keep under control and can be very fast moving, EPA has determined that the registration must contain terms that ensure that EPA retains control to easily and quickly modify or cancel the registration if necessary. The registration will expire in six years, allowing EPA to revisit the issue of resistance.

There is increasing awareness of herbicide stewardship needs among growers. Industry, academia and weed science professionals are providing more tools to help growers adopt the farming practices that will both delay the selection of herbicide resistance and help control the spread of herbicide-resistant weeds from field to field. The likelihood of success will depend on the extent to which growers rely exclusively on dicamba versus employing a range of other management techniques. Because of losses recently experienced with glyphosate-resistant weeds, growers may be more motivated to employ best management practices.

REQUEST TO ADD THE MON 87708 SOYBEAN AND MON 88701 COTTON EVENTS TO THE APHIS FEDERAL NOXIOUS WEED LISTING

As mentioned above, on August 11, 2014, APHIS published the DEIS for the petitions for determination of nonregulated status for MON 87708 soybean and MON 88701 cotton for public review and comment (79 FR 46799) for a 60-day comment period which closed on October 10, 2014. APHIS received approximately 4,700 public comments on its DEIS. One commenter on the DEIS included a specific request for APHIS to consider their comments simultaneously as a noxious weed petition to APHIS and for APHIS to apply its noxious weed authority to the proposed deregulation of MON 87708 soybean and MON 88701 cotton.

APHIS, in its Response to Comments in Appendix 11 of the FEIS, addressed the noxious weed petition that was included with the commenter's comments on the DEIS. APHIS explained to the commenter that APHIS regulates plant pests and noxious weeds under separate and distinct regulatory frameworks. A petition for a determination of nonregulated status under 7 CFR 340 of a GE organism is evaluated pursuant to those regulations; APHIS makes such a determination on the basis of whether the GE organism is likely to pose a plant pest risk. On the other hand, a petition to list a plant as a noxious weed is evaluated under APHIS' 7 CFR part 360 regulations, and pursuant to those regulations, APHIS makes a determination on the basis of whether the plant should be listed on APHIS' noxious weed list. APHIS noted in its response to that comment that the commenter acknowledged the separate regulatory framework of 7 CFR part 340 and 7 CFR part 360 by submitting several pages of comments to the DEIS specifically as a noxious weed petition. APHIS has contacted the commenter and requested that they formally submit a separate noxious weed petition to the APHIS administrator.

Upon receipt of the separate petition, APHIS will accept and evaluate that noxious weed petition requesting that APHIS list MON 87708 soybean and MON 88701 cotton, and their progeny as Federal noxious weeds pursuant to 7 CFR 360.500, "Petitions to Add a Taxon to the Noxious Weed List." APHIS will evaluate the commenter's noxious weed petition based on an analysis of

Record of Decision

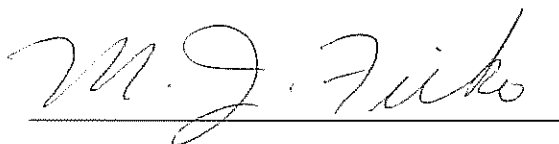
available scientific data, a weed risk assessment, and other available information; and when such evaluation is complete will inform the petitioner and the public of their decision on the noxious weed petition.

COMPLIANCE WITH APPLICABLE LAWS, EXECUTIVE ORDERS, AND REGULATIONS

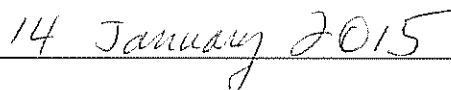
This Record of Decision has been prepared in accordance with: (1) the National Environmental Policy Act (NEPA), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The Record of Decision considered Executive Order (EO) 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations;" EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks;" EO 13112, "Invasive Species;" EO 13186, "Responsibilities of Federal Agencies to Protect Migratory Birds;" and EO 12114, "Environmental Effects Abroad of Major Federal Actions." No disproportionate adverse effects are expected on minorities, low-income populations, or children.

The Record of Decision was determined to be compliant with other Federal Statutes including, the Clean Water Act; the Clean Air Act; the National Historic Preservation Act of 1966 as amended; and the Endangered Species Act.



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



Date

Record of Decision

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