Record of Decision

Dow AgroSciences Petitions (09-233-01p, 09-349-01p, and 11-234-01p) for Determination of Nonregulated Status for 2,4-D-Resistant Corn and Soybean 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 three petitions submitted by Dow AgroSciences LLC, of Indianapolis, Indiana (Dow), seeking determinations of nonregulated status for corn and soybean cultivars genetically engineered to be resistant to herbicides. The first petition, APHIS Petition Number 09-233-01p, seeks a determination of nonregulated status for corn (*Zea mays*) designated as event DAS-40278-9. This event has been genetically engineered for increased resistance to certain broadleaf herbicides in the phenoxy auxin group (particularly the herbicide 2,4-D) and resistance to grass herbicides in the aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase (ACCase) inhibitor group (i.e.,"fop" herbicides, such as quizalofop-p-ethyl). The second petition, APHIS Petition Number 09-349-01p, seeks a determination of nonregulated status for soybean (*Glycine max*) designated as DAS-68416-4. This soybean event has been genetically engineered for resistance to certain broadleaf herbicides in the phenoxy auxin growth regulator group (particularly the herbicide 2,4-D) and the nonselective herbicide glufosinate. The third petition, APHIS Petition Number 11-234-01p, seeks a determination of nonregulated status for soybean designated as event DAS-44406-6, which has been genetically engineered for resistance to certain broadleaf herbicides in the auxin growth regulator group (particularly the herbicide 2,4-D) and the nonselective herbicides glyphosate and glufosinate.

The petitions state that these articles are unlikely to pose a plant pest risk and, therefore, should not be regulated articles 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 DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean (also known as Enlist™ corn and soybean) and the potential interrelated socioeconomic impacts associated with determinations of nonregulated status of these genetically engineered (GE) corn and soybean events. APHIS examined four alternatives in the FEIS:

- Alternative 1: No Action;
- Alternative 2: Determination of Nonregulated Status of DAS-40278-9 Corn, DAS-68416-4 Soybean, and DAS-44406-6 Soybean;
- Alternative 3: Determination of Nonregulated Status of DAS-40278-9 Corn, Only; and
- Alternative 4: Determination of Nonregulated Status of DAS-68416-4 Soybean and DAS-44406-6 Soybean, Only.

In this Record of Decision (ROD), 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. APHIS' regulatory Determinations of nonregulated status of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean will become effective upon publication in the Federal Register. The three Determinations are entitled:

- Determination of Nonregulated Status for Dow AgroSciences'DAS-40278-9 Corn;
- Determination of Nonregulated Status for Dow AgroSciences' DAS-68416-4 Soybean; and
- Determination of Nonregulated Status for Dow AgroSciences' DAS-444Ø6-6 Soybean.

BACKGROUND

Coordinated Framework

APHIS is one of the Federal agencies with regulatory responsibilities under 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 policy statement which "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 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[1]. The EPA regulates these plant-incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*) and certain biological control organisms under the Toxic Substances Control Act (TSCA) (15 U.S.C. 53, *et seq.*). Before planting a crop containing a PIP, a company must seek an experimental use permit from EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 Registration with EPA. Before 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, 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 (FPPA) and the Plant Quarantine Act (PQA)[3] to address potential

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[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 FPPA and PQA 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.

risks that certain 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 which 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 Dow seeking determinations of nonregulated status of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean. Petition 09-233-01p for DAS-40278-9 corn was received on August 19, 2009; Petition 09-349-01p for DAS-68416-4 soybean was received on December 8, 2009; and Petition 11-234-01p for DAS-44406-6 soybean was received on August 18, 2011.

In response to the receipt of the three Dow petitions, APHIS prepared plant pest risk assessments (PPRAs) to assess the plant pest risk for each plant variety pursuant to the Plant Protection Act. APHIS also examined the environmental impacts of its potential regulatory decisions for nonregulated status of Enlist™ corn and soybean pursuant to the National Environmental Policy Act (NEPA).

Federal Register notices sought public comments on two petitions, 09-233-01p (DAS-40278-9 corn) and 09-349-01p (DAS-68416-4 soybean), as well as a draft PPRA and a draft Environmental Assessment (EA) for each of these two petitions. An EA was not prepared for the third petition, 11-234-01p (DAS-44406-6 soybean), so that notice only sought comments for the petition. After APHIS initiated its NEPA process by preparing the two EAs, APHIS came to the decision that it was appropriate to use one NEPA document to evaluate the three similar Enlist events. Accordingly, APHIS decided to prepare an environmental impact statement (EIS) to analyze and examine the potential environmental impacts of all three of the Enlist petitions.

On January 10, 2014, APHIS published a *Federal Register* notice of availability for the draft PPRAs and the draft environmental impact statement (DEIS) for the petitions for determination of nonregulated status for Enlist corn and soybean for public review and comment (79 FR 1861).

(C) A parasitic plant.
(D) A bacterium.
(E) A fungus.
(F) A virus or viroid.
(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 CFR 340.0)

The PPRAs and DEIS were available for public comment for a 60-day comment period which closed on March 11, 2014. APHIS received 10,147 submissions to the docket (APHIS-2013-0042). Of these comments, 8,940 opposed and 1,082 supported the approval of nonregulated status of the three Enlist varieties. The remaining 125 comments were submissions of attachments, requests for extensions, or were submissions to an incorrect docket. 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 conducted a virtual public meeting on January 29, 2014, at which a total of 24 participants provided comments (9 opposed to and 15 in favor of deregulation).

APHIS reviewed and evaluated all of the public comments received on the DEIS for the three Enlist petitions and prepared formal responses to them as part of the FEIS. On August 8, 2014, a Notice in the *Federal Register* 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[5].

PURPOSE AND NEED FOR AGENCY ACTION

In the FEIS, APHIS identified a purpose and need to respond to the Enlist petitions for determinations of nonregulated status for the three GE events 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 GE organisms, including GE plants such as Enlist corn and soybean, and must make a 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 its regulatory requirements in 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 PPRAs that DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean are unlikely to pose a plant pest risk. APHIS found no evidence of Enlist corn and soybean 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 DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean.

[5] The FEIS can be viewed at http://www.aphis.usda.gov/brs/aphisdocs/24d_feis.pdf or under docket number APHIS-2013-0042 at regulations.gov.

(2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in Enlist corn and soybean and derived hybrids compared to their nontransgenic control counterparts or other comparators in field trials conducted in growing regions representative of where DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean are expected to be grown. Observed agronomic traits also did not reveal any significant differences that would indirectly indicate that DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean are more susceptible to pests or diseases. Therefore, no plant pest effects are expected based on these or other agricultural products.

(3) Based on an evaluation of the gene products (AAD-1 protein in DAS-40278-9 corn; AAD-12 and PAT proteins in DAS-68416-4 soybean; AAD-12, PAT, and 2mEPSPS in DAS-44406-6 soybean) and agronomic and compositional data, exposure to and/or consumption of Enlist corn and soybean are unlikely to adversely impact nontarget organisms beneficial to agriculture.

(4) DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean 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, the weediness potential of the crops and current agronomic management practices that would be available to control DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean as a weed.

(5) DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean 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 Enlist corn and soybean to other sexually compatible relatives with which they can interbreed is not likely to occur.

(6) Major changes in agricultural or cultivation practices associated with the adoption of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean are not expected with the exception of those associated with the use or the timing of applications of certain phenoxy-auxin herbicides and ACCase inhibitor "fop" herbicides (pending EPA approval). These changes are not likely to increase plant diseases or pests or compromise their management.

(7) Horizontal gene transfer of the new genetic material inserted into Enlist corn and soybean 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 an FEIS to examine the potential impacts on the human environment from determinations of nonregulated status of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean[6]. APHIS evaluated potential impacts in the FEIS associated with the decision to approve the three petitions requesting a determination of nonregulated status for each of the three Enlist events. A summary of the analyses contained in the FEIS is set forth below, in the

[6] The FEIS can be viewed at http://www.aphis.usda.gov/brs/aphisdocs/24d_feis.pdf or under docket number APHIS-2013-0042 at regulations.gov.

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 three petitions seeking a determination of nonregulated status of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean. All movements and environmental releases for Enlist corn and soybean varieties would be subject to the regulations in 7 CFR part 340. Notifications or permits with conditions specified by APHIS would be required to move viable plant material and to plant it outdoors.

Alternative 2: Deregulation of DAS-40278-9 Corn, DAS-68416-4 Soybean, and DAS-44406-6 Soybean

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

Alternative 3: Deregulation of DAS-40278-9 Corn, Only

Under Alternative 3, only DAS-40278-9 corn and progeny derived from its cultivation would be granted nonregulated status and no longer be subject to the regulations at 7 CFR part 340. DAS-68416-4 and DAS-44406-6 soybean would continue to be regulated as described under Alternative 1. APHIS would no longer require BRS permits or notifications for introductions of Enlist corn and progeny derived from these events. APHIS made the determination that Enlist corn and soybean 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 DAS-68416-4 Soybean and DAS-44406-6 Soybean, Only

Under Alternative 4, only DAS-68416-4 and DAS-44406-6 soybean and progeny derived from their cultivation would be granted nonregulated status and no longer be subject to the regulations at 7 CFR part 340. DAS-40278-9 corn would continue to be regulated as described under Alternative 1. APHIS would no longer require BRS permits or notifications for introductions of Enlist soybean and progeny derived from these events. APHIS made the determination that Enlist corn and soybean 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 Enlist crops on the human environment. APHIS sought input from member of the public on issues and alternatives the Agency should consider in preparation of the EIS related to determinations of nonregulated status of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean. 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. The following resource areas were assessed and evaluated by APHIS in the FEIS:

- Food and Feed Safety
- Worker Safety
- Animal and Plant Communities
- Socioeconomic Impacts
    - Domestic Use of Corn and Soybeans
    - Export of Corn and Soybean
- Agronomic Inputs and Cost of Production
- Land Use
- Physical Environment
    - Surface and Ground Water Quality
    - Air Quality and Climate Change

The scope of this EIS covered the direct and indirect impacts that would result from the cultivation and use of Enlist corn and soybean. The EPA, in its registration process, is considering any direct and indirect impacts from herbicide use on Enlist crops[7]. Additionally, APHIS considered the FDA regulatory assessment in making its evaluation of the potential impacts of a determination of nonregulated status of Enlist corn and soybean. DAS-40278-9 corn would be the first commercially available food crop expressing the AAD-1 protein, while DAS-68416-4 soybean and DAS-44406-6 soybean would be the first expressing the AAD-12 protein. DAS has submitted food and feed safety and nutritional assessments for DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean to the FDA. At this time, the FDA considers the consultations on the Enlist crops to be complete[8].

PUBLIC COMMENTS RECEIVED ON THE FEIS

On August 8, 2014, APHIS published the FEIS for its determinations on petitions for nonregulated status of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean. During the 30-day "review period" required under NEPA, 40 CFR §1506.10(b)(2), APHIS received comments from the public on the FEIS. This 30-day review period closed on September

[7] The EPA docket for evaluation of 2,4-D choline salt herbicide on Enlist corn and soybeans (EPA-HQ-OPP-2014-0195) can be accessed at regulations.gov at this web address: http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0195.

[8] Completed FDA consultations (Biotechnology Notes to File (BNFs)) for DAS-40278-9 corn (BNF No. 120), DAS-68416-4 soybean (BNF No. 124), and DAS-44406-6 soybean (BNF No. 133) can be accessed at FDA's website: http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon.

8, 2014. APHIS received 969 total submissions. The majority of the 969 submissions did not support the deregulation of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean, with few submissions in support of deregulation. Three submissions from non-government organizations contained a total of 240,670 signatures opposing the deregulation of Enlist crops. These submissions did not raise any new substantive issues with regard to the FEIS. These submissions expressed general concerns relating to pesticide use, GE plants, or DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean. Commenters opposed to the deregulation were concerned about the projected increased use of 2,4-D on the Enlist crops impacting the environment, including impacts to natural resources and to sensitive plants and humans from herbicide drift. Additionally, some opposing commenters thought that a large increase in the use of 2,4-D would result in the evolution of 2,4-D-resistant weeds or multiple herbicide-resistant weeds, leading to the abandonment of conservation tillage practices which inevitably would increase soil erosion. However, such concerns and issues were previously assessed and addressed in the text and appendices of the FEIS.

HERBICIDE USE

APHIS has no statutory authority to authorize or regulate the use of 2,4-D, glufosinate, quizalofop, glyphosate, or any other herbicide, by growers. Under APHIS' current part 340 regulations, APHIS only has the authority to regulate DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean or any GE organism as long as APHIS believes it may pose a plant pest risk. Any direct and indirect impacts associated with the expected increased use of 2,4-D or other herbicides on Enlist corn and soybean are outside the scope of this EIS because the authority to regulate the impacts of herbicide use resides with the EPA under FIFRA. 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 has conducted independent assessments of direct and indirect effects associated with the use of 2,4-D on Enlist corn and soybean and is making an independent action to determine whether to approve registration of the 2,4-D and glyphosate premix, Enlist Duo[9]. The EPA has also conducted assessments for the new use of quizalofop on DAS-40278-9 corn as part of the requested label amendment for Assure® II Herbicide (EPA Reg. No. 352-541).

APHIS' RECORD OF DECISION ON THE FEIS

APHIS is selecting Alternative 2, approving the three petition requests for determinations of nonregulated status of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean. 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.

[9] The EPA docket for evaluation of 2,4-D choline salt herbicide on Enlist corn and soybeans (EPA-HQ-OPP-2014-0195) can be accessed at regulations.gov at this web address: http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0195.

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 the regulatory requirements in 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 DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean. 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 non-regulated 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 8, 2014, APHIS concluded that the Enlist corn and soybean 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 PPRA, 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 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 environmental consequences of Alternative 2. Under Alternative 2, Enlist corn and soybean could be planted, but no new herbicide uses, such as 2,4-D or quizalofop, would be allowed on these varieties. EPA regulates the use of herbicides under FIFRA and is making a separate decision on the use of 2,4-D and quizalofop on these plants.

Food and Feed Safety

- Under the Alternative 2, Enlist corn and soybean would be commercially available to growers who would be able to grow, harvest, and move their crop into commerce for food and feed. Enlist corn and soybean have been shown to be compositionally similar to currently available varieties of corn and soybean. These events are not expected to have different nutritional qualities than other available corn or soybean varieties. Dow submitted safety and nutritional assessments to the FDA, providing information on the characterization, composition, allergenicity, and toxicity of the proteins inserted in DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean. The FDA evaluated the information in Dow'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. Dow concluded that foods and feeds derived

from Enlist corn and soybean are as safe as conventional corn and soybean varieties and are not materially different in composition or any other relevant parameters from other corn and soybean 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 these events. Under Alternative 2, there are not likely to be any effects associated with consumption of food and feed containing Enlist corn and soybean when compared to the No Action Alternative.

- The AAD-1 protein in DAS-40278-9 corn is derived from the common gram-negative soil bacterium *Sphingobium herbicidovorans* (Herman *et al.*, 2010)[10]. *Sphingobium* is a member of the sphingomonads, a widely distributed bacteria group isolated from soil and water as well as plant root systems (DAS, 2009; DAS, 2010b). The sphingomonads have been used widely in biotechnology applications, including bioremediation of environmental contaminations as well as production of sphingans, bio-based polymers which are used in the food industry (Pollock and Armentrout, 1999; Lal et al., 2006; DAS, 2010a). Considering this safe history of use, under the Alternative 2, there are not likely to be any effects associated with consumption of food and feed containing the AAD-1 protein in DAS-40278-9 corn when compared to the No Action Alternative.

- The AAD-12 protein in DAS-68416-4 and DAS-44406-6 soybean is derived from the common gram-negative soil bacterium *Delftia acidovorans. D. acidovorans* is non glucose-fermenting, gram-negative, non-spore-forming rod type bacterium present in soil, fresh water, activated sludge, and clinical specimens. It has a history of safe use in the food processing industry, including having been used in transforming ferulic acid into vanillin and related flavor metabolites (DAS, 2010a). Because the AAD-12 protein has a safe history of use in food processing, under the Alternative 2, there are not likely to be any effects on humans or animals consuming food and feed, respectively, from Enlist soybean when compared to the No Action Alternative.

- The *pat* gene is derived from *Streptomyces viridochromogenes,* a gram-positive soil bacterium. The *pat* gene conveys resistance to glufosinate (Wohlleben *et al.*, 1988). The PAT protein in DAS-68416-4 and DAS-44406-6 soybean is the same as that used as a selectable marker during development and to confer herbicide resistance in other previously deregulated GE crops (Brenner *et al.*, 2001; USDA-FAS, 2004; USDA-ERS, 2005; Duke and Powles, 2008). Additionally, 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 expressed in DAS-68416-4 and DAS-44406-6 soybean has already been evaluated by FDA and soybean (and other crops) containing the *pat* gene are already in commerce, there are not likely to be any effects on humans and animals consuming food and feed, respectively, from Enlist soybean when compared to the No Action Alternative.

[10] Citations for references may be found in the FEIS.

- The *mepsps* gene in DAS-44406-6 is derived from *Zea mays*, corn. It contains two mutations which convey resistance to glyphosate (Lebrun and Leroux, 1996; Lebrun *et al.*, 2003). It is similar to the *epsps* gene expressed in GA21 corn, GHB614 cotton, and HCEM485 corn which have been deregulated by APHIS. GA21 corn (BNF 51), GHB614 cotton (BNF 109), and HCEM485 corn (BNF 106) have completed consultations with FDA. Because of the similarity of the EPSPS protein expressed in DAS-44406-6 and the corn and cotton varieties noted above, under the Alternative 2, there are not likely to be any effects on humans and animals consuming food and feed, respectively, from Enlist soybean when compared 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 DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean would not change the agronomic management practices used in the cultivation of corn and soybean. Potential hazards to workers associated with the various agronomic management practices used to grow corn and soybean would be the same as those under the No Action Alternative. The decision to approve the three petitions does not authorize a change in herbicide use on these corn or soybean 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 Enlist crops.

Biological Resources

Animal Communities

- Animals found in the vicinity of agricultural fields of DAS-40278-9 corn, DAS-68416-4 soybean, or DAS-44406-6 soybean would continue to feed on corn and soybean in these fields. These corn and soybean varieties have been shown to be compositionally similar to other commercially available corn and soybean varieties. As detailed under "Food and Feed," the PAT and mEPSPS proteins are found in commercial varieties of corn, cotton, and soybeans. Organisms that feed on these crops are exposed to these proteins in previously deregulated varieties with no documented negative effects. Dow 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 Enlist corn and soybean are anticipated under the 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. Growers will continue to use EPA-approved herbicides and cultural practices to manage weeds. Increases in tillage to control weeds can increase soil erosion and indirectly impact wildlife. Agricultural production of corn and soybean would continue to use currently EPA-registered pesticides for weed management. The environmental risks of pesticide 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 three petitions on plant communities would be similar to the effects on plants under the No Action Alternative. Enlist corn and soybean have been shown to be agronomically similar to conventional corn and soybean varieties currently in cultivation. Thus, choosing Alternative 2 would not change the agronomic practices used in the cultivation of corn and soybean and, therefore, would not change the potential impacts to the plant communities in or around corn and soybean fields. Agronomic 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 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 approve the three petitions as described in Alternative 2, does not in any manner authorize or approve any herbicide use on these corn or soybean varieties. APHIS has no regulatory authority over the use and application of herbicides or pesticides. EPA regulates the use of herbicides under FIFRA and is making a separate decision on the new uses of herbicides 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.

Socioeconomics

- Enlist corn and soybean have been shown to be compositionally similar to currently available varieties of corn and soybean 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 corn and soybean.

- As with the No Action Alternative, under Alternative 2, growers of specialty value added corn and soy crops, including organic corn and soybean, would see production and demand for these value added crops unchanged by nonregulated status of the Enlist crops.

- Dow has submitted applications to various international regulatory authorities for food, feed, and/or cultivation approvals. Approvals for one or more of the Enlist crops have occurred in some countries and are pending in others. Although the primary U.S. corn and soybean export destinations do not present major barriers in the trade of GE products, Dow will need to obtain approvals for DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean in destination countries before commercialization to avoid

adversely affecting current trade flows. In some export markets where Enlist corn or soybean are not approved from import or for non-genetically modified, identity-preserved corn or corn flour shipments, testing for the presence of Enlist corn or soybean may be required. If a new type of test would be needed for Enlist corn and soybean, current testing costs may increase by 10 to 15 percent.

Land Use and Physical Environment

- Land use for corn and soybean production is driven by the price of corn and soybean, as well as the suitability of the land for production of these crops. As a result, the availability of Enlist corn and soybean would not have any direct or indirect effects on land use under Alternative 2 in comparison to the No Action Alternative.

- Under Alternative 2, growers of specialty value added corn and soybean crops would see production and demand for these value added crops unchanged by nonregulated status for the three varieties.

- Under Alternative 2, Enlist corn and soybean 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, Enlist corn and soybean 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 2,4-D on these plants.

Threatened and Endangered Species

APHIS, as described below, evaluated the potential effects that the three determinations of nonregulated status of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean may have, if any, on federally-listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation.

For its analysis of potential effects on TES plants and critical habitat, APHIS focused on the agronomic differences between the regulated articles (Enlist corn and soybean) and corn and soybean 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 species, APHIS focused on the implications of exposure of the novel proteins expressed in the plants as a result of the transformation, and the ability of the plants to serve as a host for a TES.

APHIS concluded that the determinations of nonregulated status of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean and the corresponding environmental releases of these corn and soybean varieties are not expected to affect listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation.

- Based on a lack of weediness in Enlist corn and soybean, APHIS concluded that availability of Enlist corn and soybean would not extend the range of corn and soybean production or lead to cultivation on land not previously used for agricultural production.

- APHIS considered as part of the analysis for TES and critical habitat if the new phenotype imparted to Enlist corn and soybean may allow the plant to naturalize in the environment and potentially have an effect on TES. No differences were detected between Enlist corn and soybean and conventional varieties in growth, reproduction, or interactions with pests and diseases, other than the intended effect of herbicide tolerance. Based on agronomic field data and a survey of scientific literature on weediness potential, the inserted genes do not alter weediness potential of Enlist corn and soybean, and thus these varieties are unlikely to affect 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 corn and soybean are grown, APHIS concluded that Enlist corn and soybean would not be sexually compatible with any listed species 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 *Zea* or *Glycine*.

- Compositional analysis of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean demonstrated that Enlist corn and soybean are compositionally equivalent to conventional corn and soybean with respect to key nutrients and components. Additionally, Dow submitted food and feed safety and nutritional assessments for Enlist corn and soybean to the FDA and completed their consultations with the FDA. Consequently, Enlist corn and soybean are not expected to have adverse nutritional effects on any animal that feeds upon them.

- Safety evaluations conducted by Dow included evaluations of the protein structure and function of Enlist corn and soybean, including homology searches of the amino acid sequences with comparison to all known allergens and toxins, and in vitro digestibility assay of the proteins, and acute oral toxicity feeding study in mice, and a feeding study in broiler chickens. Enlist corn and soybean 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 corn or soybean and consumption of Enlist corn or soybean by any listed species or species proposed for listing will not result in a toxic or allergic reaction.

- APHIS evaluated whether Enlist corn and soybean could serve as host plants for TES or listed species (i.e., a listed insect or other organism that may use the corn or soybean plant to complete its lifecycle). A review of the species list indicated there are no TES or species proposed for listing that use corn or soybean as a host plant.

ENVIRONMENTAL ALTERNATIVE

The environmental 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 potential impacts among the alternatives when compared to the No Action Alternative, APHIS has not identified an Environmentally Preferred Alternative as per 40 CFR 1505.2(b).

Under Alternatives 2, no direct or indirect effects associated with growing DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean were identified as being different when compared to the direct and indirect effects associated with growing corn and soybeans in the No Action Alternative, because these GE varieties are not agronomically different from non-GE corn and soybean plants or other GE corn or soybean plants that are no longer regulated by the Agency. APHIS determined that the deregulation and commercial availability of Enlist corn and soybean varieties would not result in an increase in corn and soybean acreage in areas already in corn and soybean production or result in changes in where corn and soybean are currently grown. In addition, these three 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 corn and soybean varieties currently grown under the No Action Alternative.

The continued emergence of glyphosate-resistant weeds under the No Action Alternative will itself call for modifications of agronomic management 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 agronomic management practices growers choose to adopt.

Under Alternative 2, as with the No Action Alternative, growers may continue to rely on glyphosate, other EPA-approved herbicides, and other non-chemical methods to manage weeds in corn and soybean. They could not apply herbicides differently on Enlist corn or soybean than currently allowed on other corn and soybean varieties. That is because Enlist Duo is not registered for use on these corn or soybean events until EPA approves the label. Therefore, herbicide-resistant weeds would be selected for by agronomic management practices in the same ways that they are in the No Action Alternative.

The potential impacts on each resource that derives from herbicide use are outside the scope of this EIS because the EPA is the federal agency responsible for the analysis of these impacts. The EPA has thoroughly analyzed the potential impacts of proposed new uses of Enlist Duo as part of their pesticide registration process. The expected increased use of 2,4-D on DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean has the potential to impact the selection of herbicide resistance in weeds due to the use of 2,4-D as an herbicide, and not due to any properties of Enlist corn and soybean plants themselves. Measures EPA is proposing to include on the Enlist Duo label addressing this potential development of resistant weeds are discussed in

the following section discussing mitigations of impacts. Weed scientists 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, none of these three events (DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean), either individually or together, would have different effects on the human environment than the No Action Alternative. Therefore, approving the petition for deregulation of Enlist corn under Alternative 3 or Enlist 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 registration of Enlist Duo, a premix of 2,4-D choline salt and glyphosate, for use on Enlist crops is reasonably foreseeable. APHIS concluded that the potential increased use of 2,4-D associated with cultivation of Enlist corn and soybean is expected to increase the pressure for selection of 2,4-D-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 dicamba-resistant soybean (called Xtend soybean) varieties on the market is reasonably foreseeable. The EPA is conducting independent assessments of direct and indirect effects associated with the use of dicamba on Xtend soybean to determine whether to approve this new dicamba registration. It is reasonable foreseeable that EPA will approve the registration of the new use of dicamba on Xtend soybean, although the details of the registration are not known at this time. The potential increased use of dicamba associated with growing of Xtend soybean is expected to increase selection pressure of dicamba-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 in the production of herbicide-resistant crops.

Growers may mitigate the rate at which weeds develop resistance by the agronomic practices they choose. The impact of increased 2,4-D or dicamba use on the selection of 2,4-D- or dicamba- 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 2,4-D or dicamba 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 cumulative impacts for Alternative 2, 2,4-D use is expected to increase if EPA approves the amended use of 2,4-D on the Enlist crops. However, increases in other herbicide sites of action under Alternative 2 are expected to be less than under the No Action Alternative because the Enlist Duo herbicide are expected to be preferentially adopted if approved for use on these crops by EPA. The availability of inexpensive and effective herbicides in Enlist Duo combined with Enlist corn and soybean 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 agronomic management practices employed 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 2,4-D. Under FIFRA, the EPA registers pesticides and prescribes the conditions for use of the pesticide. The EPA must ensure that the pesticide, 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 pesticide labels. Applying pesticides in a way that is inconsistent with the label is illegal.

Recognizing the increasing economic issues resulting from herbicide-resistant weeds, the EPA is including measures to address weed resistance as part of the registration terms for Enlist Duo[11]. Best management practices for helping prevent the development of resistant weeds will appear on the Enlist Duo label, 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.

Additionally, the EPA is requiring that Dow develop a stewardship program with its customers that will aggressively promote resistance management efforts, with an overall goal to assist and support responsible use of the product. The program mandates that Dow must immediately investigate any claims of non-performance and take immediate action to eradicate weeds identified as likely resistant weeds. Additionally, the stewardship program also includes educating and training retailers, farmers, and applicators on the appropriate use of Enlist technology, reporting verified cases of resistance to Enlist Duo to interested parties, developing diagnostic testing for evaluating resistant weed species, and monitoring whether Enlist Duo is being used on Enlist seed.

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

[11] EPA's registration decision, including daft label, risk assessments, and analyses, on the registration of Enlist Duo can be accessed at regulations.gov at this web address: http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0195.

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.

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 Enlist Duo 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 THREE ENLIST EVENTS TO THE APHIS FEDERAL NOXIOUS WEED LISTING

As mentioned above, on January 10, 2014, APHIS published the DEIS for the petitions for determination of nonregulated status for Enlist corn and soybean for public review and comment (79 FR 1861) and the DEIS was available for public comment for a 60-day comment period which closed on March 11, 2014. APHIS received over 10,000 public comments on its DEIS. A commenter that provided comments on the DEIS included a specific request for APHIS to consider the commenter's comments simultaneously as a noxious weed petition to APHIS and for APHIS to apply its noxious weed authority to the proposed deregulation of the three Enlist events. APHIS has accepted that noxious weed petition pursuant to 7 CFR 360.500, "Petitions to Add a Taxon to the Noxious Weed List," requesting that APHIS list DAS-40278-9 corn, DAS-68416-4 soybean, DAS-44406-6 soybean, and their progeny as Federal noxious weeds, and will evaluate that petition separately pursuant to those regulations.

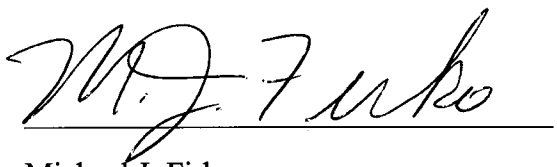
APHIS, in its Response to Comments section of the FEIS, addressed that noxious weed petition that was included with the commenter's comments on the DEIS. APHIS explained to the commenter that APHIS regulates plant pests and noxious weeds under two separate and distinct regulatory frameworks. A petition for a determination of nonregulated status of a GE organism is evaluated pursuant to APHIS' 7 CFR part 340 regulations, and pursuant to that regulation, 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 some organism 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 organism 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 informed the commenter that it accepted the commenter's noxious weed petition and that it would be evaluated separately. APHIS has also sent the commenter a letter acknowledging its request. APHIS will evaluate the commenter's noxious weed petition based on an analysis of 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 the directives of Executive Order (EO) 12898 (US-NARA, 2008), "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."

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.



9/16/2014

Michael J. Firko
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
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Date