

Final EIS for 2,4-D Corn and Soybeans and Draft EIS for Dicamba Resistant Cotton and Soybeans

U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is issuing a final environmental impact statement (EIS) that evaluates the potential environmental effects of deregulating one corn and two soybean varieties genetically engineered (GE) by Dow AgroSciences. APHIS is also issuing the final plant pest risk assessment (PPRA). These varieties have been engineered to be resistant to multiple herbicides, including 2,4 dichlorophenoxyacetic acid, or 2,4-D. The final EIS will be available for public review for at least 30 days before USDA will publish a record of decision on how it will proceed.

USDA is also issuing for public review and comment a draft EIS as part of its review to determine whether to deregulate genetically engineered (GE) cotton and soybean plants by Monsanto that are resistant to multiple herbicides, including dicamba.

Q. Who is responsible for regulating GE crops?

A. The three main Federal agencies responsible for regulating the safe use of organisms derived from biotechnology are APHIS, the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA). These agencies work together in what is commonly referred to as the Coordinated Framework for the Regulation of Biotechnology. The White House Office of Science and Technology Policy established this Federal framework as a formal policy in 1986.

- APHIS regulates the introduction (meaning the importation, interstate movement, and environmental release/field testing) of certain GE organisms to ensure that they don't pose a risk to plant health.

- EPA regulates pesticides, including plants with plant-incorporated protectants (pesticides intended to be produced and used in a living plant), to ensure public safety. EPA also sets limits on pesticide residues on food ensuring the safety of human food and animal feed.
- FDA has jurisdiction over proper labeling and safety of all plant-derived foods and feeds.

Q. Why does APHIS regulate the development of new GE plants?

A. Under the Plant Protection Act (PPA), APHIS regulates the importation, interstate movement, and field testing of new genetically engineered plants to protect plant health. APHIS approves a petition for non-regulated status only after it has determined that a GE plant does not pose a plant pest risk, i.e., it does not directly or indirectly injure, cause damage to, or cause disease in any plants or plant products. APHIS works in partnership with FDA and EPA to ensure that the development, testing, and use of the products of biotechnology occur in a manner that is safe for plant and animal health, human health, and the environment.

Q. How does preparing an EIS assist APHIS in its decision-making?

A. Before making its regulatory decision under the PPA, the National Environmental Policy Act (NEPA) requires APHIS to evaluate the potential impacts to the environment that may result from its decision. The NEPA review can take the form of an environmental assessment or a more rigorous EIS. NEPA review is helpful in informing APHIS regarding any potential environmental impacts before the Agency makes its regulatory determination under the PPA. Through an EIS, APHIS can consider regulatory alternatives and their potential environmental impacts, as well as other potential impacts to public health and endangered species. However, in regards to any potential environmental impacts evaluated in the EIS, NEPA does not provide APHIS any additional regulatory authority to address those impacts beyond what the PPA provides.

Final EIS for 2,4-D Corn and Soybeans

Q. What is 2,4-D?

A. 2,4-D is a selective aryloxyalkanoic acid known also as a 'phenoxy herbicide', which has

been used since the 1940s as a pre-plant or post-emergent herbicide to control broadleaf (dicot) weeds on a broad range of crop and non-crop sites, including cornfields. EPA has approved 2,4-D herbicide to control broadleaf weeds on a variety of food/feed sites, including field, fruit, and vegetable crops.

Q. Why is this important to farmers?

A. These GE varieties of soybeans and corn have been developed to provide farmers with new tools to manage weeds that have developed resistance to other herbicides.

Q. How long has 2,4-D been used in agriculture?

A. The herbicide has been used by farmers in the United States for more than 60 years.

Q. Is 2,4-D approved for any kind of agricultural use?

A. 2,4-D is the most widely used herbicide in the world and third most-used in the United States (after atrazine and glyphosate). EPA has approved the use of 2,4-D to control weeds on a variety of food and feed sites, including field, fruit, and vegetable crops. Currently, 2,4-D is approved for pre-plant and post-emergent application on corn and pre-plant application on soybean. It is also registered for use on turf, lawns, rights-of-way, aquatic sites, forestry applications, and is used as a plant growth regulator in citrus. Residents and professional applicators may use 2,4-D on home lawns.

Q. Is 2,4-D the same thing as “Agent Orange” defoliant?

A. No. “Agent Orange” was a mixture of herbicides 2,4,5-T and 2,4-D, kerosene and diesel fuel. Agent Orange contained high levels of dioxin, a contaminant found in 2,4,5-T that causes cancer and other health concerns in people. EPA cancelled all use of 2,4,5-T in 1985 because of these risks. By contrast, EPA has approved the use of 2,4-D and considers it safe when used according to the EPA-approved labeling.

Q. What are the 2,4-D resistant products that are included in the EIS?

A. Dow AgroSciences (Dow) has filed three petitions asking APHIS to deregulate its GE corn and soybean plants that are resistant to the herbicide 2,4-D:

- Dow Herbicide-Resistant Corn (DAS-40278-9),
- Dow Herbicide-Resistant Soybean (DAS-68416-4), and
- Dow Herbicide-Resistant Soybean (DAS-44406-6).

Q. Why did APHIS decide it needs to prepare an EIS?

A. APHIS decided to prepare an EIS to further assist the agency in evaluating any potential environmental impacts before making a final determination regarding their regulatory status since the agency determined that its regulatory decisions may significantly affect the quality of the human environment. (NEPA does not provide APHIS with any additional regulatory authority beyond what the Plant Protection Act provides).

Q. What were some the main issues the EIS focused on?

A: The key issues that the EIS focused on were the increased use of 2,4-D (and the other herbicides to which these crops are resistant) in these production systems compared to that currently used in corn and soy, and the effect of this use on the development of herbicide resistant weeds.

Q. What is APHIS’ preferred alternative?

A. APHIS’ preferred alternative is to deregulate all three varieties. APHIS prefers this alternative based on its determination that the corn and soybean varieties do not pose a plant pest risk.

Q. Did APHIS consider public input into the EIS?

A. Yes. APHIS held two virtual public meetings on June 26 and 27 of 2013 during the scoping process for the development of the draft EIS. On January 29, 2014, APHIS held a 3-hour virtual public meeting on the draft EIS itself. Those transcripts of the meetings and associated documents are here:

http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_biotechnology%2Fsa_stakeholder_meetings%2Fct_24d_eis

On May 16, 2013, APHIS published in the Federal Register a Notice of Intent (NOI) to prepare an EIS with a 60-day public comment period. The comment period for the NOI closed July 17, 2013, and received 49 comments. APHIS received 10,140 comments on the draft EIS. APHIS previously made available for public review and comment petitions by Dow to deregulate the products along with draft environmental assessments and plant pest risk assessments for two of the three products.

Q. How were public comments taken into consideration through the virtual meetings?

A. APHIS reviewed and considered all public comments made during the virtual meeting and through www.Regulations.gov before finalizing the

EIS and preliminary plant pest risk assessment, and making its final regulatory decision on the Dow petitions.

Q. How is the final EIS different than the draft EIS?

A. The final EIS updates APHIS' herbicide weed resistance assessment and control strategies incorporating EPA's proposed label language and registration decision addressing its role in managing the issue. It also updates some of the original statistical data used in the draft assessment, e.g., crop pricing information, tillage information, more fully incorporates an assessment of environmental justice, and provides an updated assessment of the EPA's threatened and endangered species for the Enlist product. The overall assessment of impacts does not materially change as a result of these improved analyses.

Q. How is EPA involved with this environmental review process?

A. EPA has authority over the review and approval of pesticidal substances and plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act as amended and the Federal Food, Drug, and Cosmetic Act. EPA is currently reviewing information submitted by Dow to assess the potential for environmental and human risks associated with the use of 2,4-D on corn and soy. In addition, in June of 2005, EPA completed 2,4-D's Reregistration Eligibility Decision that reassessed labeled uses, including current uses on corn, to ensure they meet today's more stringent standards.

Q. Have APHIS and EPA coordinated to address concerns around the potential emergence of 2,4-D resistant weeds?

A. Yes. EPA and APHIS have coordinated to take steps to analyze potential environmental impacts associated with adoption of 2,4-D resistant corn and soybeans should the emergence of 2,4-D resistant weeds emerge where none were known to exist previously. APHIS thoroughly analyzed the possible increased use of herbicides and the related potential development of resistant weeds and EPA has proposed placing registration terms and conditions on the use of the new 2,4-D herbicide formulation that would ensure that EPA could react quickly should resistance emerge.

Q. What is EPA proposing on the label relative to the potential emergence of 2,4-D resistant weeds?

A. EPA is taking the issue of weed resistance extremely seriously. To help prevent resistance from becoming an issue, EPA has proposed on the label for

Enlist management practices that are designed to help users avoid initial occurrences of weed resistance. These appear directly on the product labeling under the Resistance Management heading of the label and must be adhered to by users.

In addition, EPA is requiring that Dow react immediately and thoroughly investigate any reports by growers of Enlist failing to kill weeds in fields planted with these new GE crops. Should a report be made, Dow or its representative must conduct a site visit and evaluate the issue using decision criteria identified by leading weed science experts in order to determine if likely herbicide resistance is present. Should Dow identify resistance, it must take immediate action to eradicate likely resistant weeds in the infested area. This may be accomplished by re-treating with an herbicide or using mechanical control methods. Dow must also notify EPA that likely herbicide resistance has been identified and report this on a monthly basis. EPA would also require Dow to develop a laboratory diagnostic test to quickly identify herbicide resistance.

If EPA finds that resistance is becoming a significant issue, it can also revise the label for Enlist, including new actions or refinements to address the problem.

Q. Is the agency taking any actions in the final EIS?

A. The final EIS is not a final decision on the regulatory status of 2,4-D resistant corn and soybeans. It is an analysis of the impacts of the various alternatives with regard to their potential environmental and related economic impacts. APHIS' decisions regarding regulatory status are made pursuant to its plant pest authority under the Plant Protection Act.

Q. What are APHIS' next steps?

A. The final EIS will be available for public review for at least 30 days before USDA will publish a record of decision on how it will proceed.

Q. Will USDA take comments during this 30 day review period?

A. No. The purpose of this review period, as opposed to the 45-day public comment period on the draft EIS, is to allow a sufficient waiting period that provides the agency's decision makers time to consider the purpose and need, weigh the alternatives, balance their objectives, and make an informed decision. The review period also provides the Council on Environmental Quality (CEQ) an opportunity to review the EIS for conformity with NEPA and CEQ regulations.

Draft EIS for Dicamba Resistant Cotton and Soybeans

Q. What is dicamba?

A. Dicamba is a selective benzoic acid herbicide and is part of the aromatic acids family of herbicides. The herbicide has been approved by EPA since 1967 for use on a wide range of agricultural, industrial, and residential sites. Dicamba provides effective control for more than 95 types of weeds and suppression of over 100 perennial broadleaf and woody plant species.

Q. What are the dicamba resistant products that are included in the EIS?

A. Monsanto has filed two petitions asking APHIS to deregulate its specific GE cotton and soybean plants that are resistant to the herbicide dicamba:

- Monsanto Double Herbicide-Resistant Cotton (MON 88701),
- Monsanto Herbicide-Resistant Soybean (MON 87708)

Q. Why did APHIS decide it needs prepare an EIS?

A. In this case APHIS prepared an EIS because, under NEPA, it determined that its regulatory decision regarding these 2 products could significantly affect the quality of the human environment. APHIS reached this conclusion through the comments received during the public comment period on the petition and similar issues raised during its preparation of environmental analyses of its regulatory decision regarding the 2,4-D products, a similar chemistry and mode-of-action, synthetic auxin, with many of the same environmental issues. These products are the first GE plants resistant to dicamba for which APHIS has been petitioned to deregulate; they have the potential to be planted widely in the United States; and the potential environmental impacts of the Agency's decision, including the potential development of dicamba resistant weeds, warranted further analysis prior to APHIS' ruling on the deregulation petition. (NEPA does not provide APHIS with any additional regulatory authority beyond what the Plant Protection Act provides).

Q. What issues are analyzed in the draft EIS?

A. The draft EIS analyzes the potential development of new herbicide-resistant weeds. While APHIS found that the wider use of these new GE plants would help growers manage weeds, the wider use would also likely result in an increased chance of the development of weeds resistant to dicamba. However, APHIS' analysis showed that growers can implement diversified weed management practices to mitigate this impact.

Q. Has APHIS taken any public input on these products?

A. Yes. On May 16, 2013 APHIS published in the Federal Register a notice of intent (NOI) to prepare an EIS for a 60-day public comment period. APHIS previously made these Monsanto petitions to deregulate the products available for public review and comment. The comment period for the NOI closed July 17, 2013, and received 65 comments. APHIS took these comments into consideration when preparing the draft EIS.

Q. Why are developers of GE-products creating new herbicide-resistant varieties?

A. These new herbicide-resistant varieties have been developed to give growers – especially those dealing with weeds that have become resistant to glyphosate – additional weed management tools.

Q. Is this APHIS' final regulatory decision regarding these new GE plants?

A. No. The draft EIS will be available for public review and comment for 45 days from the date of publication by the EPA in the Federal Register. APHIS encourages public input on its draft EIS and will host a virtual public meeting to receive comments on it. APHIS will then carefully consider all public comments submitted during the comment period before finalizing the draft EIS and then making its final decision regarding the regulatory status of these GE plants.

Q. How will APHIS reach its final regulatory decision?

A. APHIS will issue a final EIS along with a Record of Decision for the final EIS. It will also finalize its plant pest risk assessment. Should the final plant pest risk assessment conclude, as did the preliminary one, that these new GE plants do not pose a plant pest risk to agricultural crops or other plants in the United States, APHIS would deregulate them.

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