

Final Environmental Impact Statement Monsanto's Dicamba/Glufosinate Tolerant Cotton and Dicamba Tolerant Soybean

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is issuing a final environmental impact statement (EIS) on soybean and cotton plant varieties genetically engineered (GE) for resistance to several herbicides, including the one known as dicamba.

Following a 30-day public viewing period, APHIS will issue its Record of Decision (ROD) for the final EIS, its final plant pest risk assessment, and final regulatory decision for these GE plant varieties.

Q. Who is responsible for regulating GE crops?

A. The three main Federal agencies responsible for regulating the safe use of organisms derived from modern 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 that may 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. FDA sets limits on pesticide residues on food ensuring the safety of human food and animal feed, as well as 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 injure agricultural crops or other 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. An EIS 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.

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 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 needed to prepare an EIS?

A: In this case, APHIS prepared an EIS because, under NEPA, it determined that its regulatory decision regarding these two 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. In addition, similar issues were raised during the public comment period on a draft environmental assessment for APHIS' 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 by the developer 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 tolerant 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 final EIS?

A. In addition to broad environmental and human impacts, the final 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. Public comment periods have totaled 121 days. 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. 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.

In August 2014 APHIS issued its draft EIS with a 45-day public comment period. The draft EIS examined four regulatory alternatives: deny all petitions, deregulate cotton only, deregulate soybeans only, or deregulate both the cotton and soybeans.

In September, APHIS kept the comment period open for another 15 days in response to stakeholder requests to provide additional time for comments and to ensure that all interested parties had the opportunity to comment.

Following the close of the 60-day comment period, APHIS thoroughly reviewed and analyzed all comments received and has addressed them in the final EIS it is making available today.

Q: What is APHIS' preferred alternative?

A: Of the alternatives examined, APHIS is required by the National Environmental Policy Act (NEPA) to identify the alternative—known as the “preferred alternative”—that best meets the purpose and need for the EIS. Based on its plant pest risk assessment and under its authority through the Plant Protection Act, APHIS' preferred alternative in the draft EIS was full deregulation of these GE crops. APHIS selected this alternative based on its determination that the GE cotton and soybeans are unlikely to pose a plant pest risk to agricultural crops or other plants in the United States.

The final EIS affirms APHIS' preferred alternative to deregulate these new GE crops. This is also consistent with APHIS' plant pest risk assessment (PPRA) that found the GE cotton and soybeans are unlikely to pose a plant pest risk to agricultural crops or other plants in the United States.

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 final EIS will be available for public viewing for 30 days. Following the 30-day public viewing period, APHIS will issue its Record of Decision (ROD) for the final EIS, its final plant pest risk assessment, and final regulatory decision for these GE plant varieties.

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