



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0034]

Notice of Intent to Prepare an Environmental Impact Statement; Movement and Outdoor Use of Certain Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent to prepare a programmatic environmental impact statement.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) plans to prepare a programmatic environmental impact statement (EIS) in connection with potential changes to the regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms. This notice identifies potential issues to be evaluated in the EIS and requests public comments to define the scope of the alternatives and environmental impacts and issues for APHIS to consider.

DATES: We will consider all comments that we receive on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0034>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2018-0034, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Any comments we receive may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0034> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Joanne Serrels, Biotechnologist, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1238; (301) 851-3867.

SUPPLEMENTARY INFORMATION:

Background

The Plant Protection Act (PPA) authorizes the Animal and Plant Health Inspection Service (APHIS) to protect plant health in the United States. Under that authority, APHIS currently regulates the introduction (movement into the United States or interstate, or release into the environment) of genetically engineered (GE) organisms that may present a plant pest risk through its regulations in 7 CFR part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests.” These regulations are intended to protect against plant pest risks to plant health by providing for the safe importation, interstate movement, or release into the environment of certain GE organisms.

APHIS’ regulation of certain GE organisms to protect plant health is aligned with the Federal Coordinated Framework for the Regulation of Biotechnology (henceforth referred to as the Coordinated Framework), the comprehensive Federal regulatory policy for ensuring the

safety of biotechnology research and products in the United States. The Coordinated Framework describes how Federal agencies will use their regulatory authorities under existing Federal statutes to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework sets forth a science- and risk-based approach for the oversight of activities that introduce biotechnology products into the environment and describes the roles and responsibilities for the three major Federal agencies involved in regulating biotechnology products: APHIS, the Environmental Protection Agency, and the Food and Drug Administration. This document addresses only proposed changes to the APHIS regulations and is not intended to circumscribe, restrict, or otherwise preclude future actions taken by other Federal agencies under their respective authorities.

During the past 30 years, there have been major advances in the science of biotechnology, and new issues have been brought to APHIS' attention by a range of stakeholders. Over this period, APHIS has also gained considerable experience in assessing the plant health risks of GE organisms. Accordingly, APHIS is considering amending the regulations pertaining to movement and outdoor use of certain GE organisms to address the advances in biotechnology and APHIS' understanding of the issues raised by stakeholders. The proposed revisions would allow APHIS to more effectively protect plant health under the PPA by focusing APHIS' regulations in 7 CFR part 340 on risks that may be posed by certain GE organisms rather than on the methods used to produce the products and would also make the regulatory processes more transparent while removing unnecessary regulatory burdens.

Under the provisions of the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), Federal agencies must examine the potential environmental

impacts of proposed Federal actions and alternatives. We are planning to prepare a programmatic environmental impact statement (EIS) in connection with the proposed revisions to APHIS' biotechnology regulations that are being considered. Aspects of the human environment that may be affected by the proposed regulatory changes and that we have preliminarily identified for evaluation in the EIS will include potential impacts on:

- U.S. agriculture and forestry production (e.g., conventional, biotechnology-based, and organic);
- Current and future uses of certain GE organisms in agriculture and forestry;
- Agronomic practices employed in GE crop production that may have environmental consequences or effects (e.g., tillage, crop rotation, weed and pest control, and agronomic inputs);
- Aspects of the physical environment, including soil quality, water resources, and air quality, with consideration given to the effects of dynamic climate conditions;
- Aspects of the biological environment, such as animal and plant communities, the development of weed, pathogen, and insect resistance to pesticides, the potential gene flow from certain GE organisms to sexually compatible species, the weediness of GE crop plants, and biodiversity;
- Consumer health and agricultural worker safety; and
- Animal feed safety, availability, quality, and animal health.

We will also examine socioeconomic considerations, such as the potential impacts of crop plants that are GE organisms on the domestic economic environment, international trade, and coexistence among all forms of U.S. agriculture—conventional, biotechnology-based, and organic—and on market demand for food, feed, fiber, and fuel.

The EIS will be prepared in accordance with: (1) NEPA, (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) U.S. Department of Agriculture regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

This notice identifies the potential issues that will be evaluated in the EIS, and requests public comment to help APHIS further define the issues and alternatives that should be considered and to help APHIS identify additional impacts, both positive and negative, to the human environment that should be examined in the EIS. Public input will also be helpful in developing our proposed regulations. All comments received during the comment period will be carefully considered. A notice will be published in the *Federal Register* to announce the availability of the draft EIS when it is issued and to invite the public to provide comments.

Done in Washington, DC, this 26th day of June 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.
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