BILLING C

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Parts 330 and 340

[Docket No: USDA-2026-0133]

Request for Information on Modified Organisms Subject to the Plant Protection Act

AGENCY: Office of the Secretary, U.S. Department of Agriculture.

ACTION: Request for information.

SUMMARY: The U.S. Department of Agriculture (USDA) proffers this Request for Information (RFI) to solicit the public's input on regulatory considerations related to the review of modified organisms subject to the Plant Protection Act. The information provided will help identify factors for potential risk-based deregulation and could inform future rulemaking; input might also offer non-regulatory solutions.

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: USDA invites public comments on this RFI and encourages stakeholders, including farmers, industry representatives, and state and local governments, to provide input. You may submit comments, identified by docket number USDA-2026-0133, in the Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the online instructions for submitting comments. All comments will be posted without change and will be publicly available on *www.regulations.gov*. No proprietary information, copyrighted information, or personally identifiable information should be submitted in response to this RFI.

FOR FURTHER INFORMATION CONTACT: **Michael Poe, Office of the General Counsel, USDA, 1400 Independence Avenue SW, Washington, DC 20250-1400, (202) 769-8247.**

SUPPLEMENTARY INFORMATION:

Background

Coordinated Framework

Along with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), the United States Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS) traditionally exercise oversight of certain organisms modified or developed using genetic engineering and the foods derived from them. In 1986, the Office of Science and Technology Policy (OSTP) published the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework). The Coordinated Framework explains the regulatory roles for EPA, FDA, and the USDA, i.e., APHIS and FSIS, and how existing Federal statutes protected public health and environmental safety while the Coordinated Framework's approach nonetheless ensured regulatory flexibility to foster innovation. The Coordinated Framework was subsequently updated in 1992 (*see* 57 FR 6753) and 2017 (*see* https://www.epa.gov/sites/default/files/2017-01/documents/2017_coordinated_framework_update.pdf) to consider advances that had occurred in the field of biotechnology. In 2023, USDA, EPA, and FDA published a document providing "plain language information" on the Coordinated Framework (*see* https://usbiotechnologyregulation.mrp.usda.gov/sites/default/files/coordinated-framework-plain-language.pdf).

USDA Biotechnology Regulations

Under the Plant Protection Act of 2000, as amended (7 U.S.C. 7701-7772, 7781-7786, referred to below as the PPA or the Act), the Secretary of Agriculture has authority to carry out operations or measures to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests. Section 411(a) of the Act (7 U.S.C. 7711(a)) provides that "no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit and in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States."

In addition, section 412(a) of the Act (7 U.S.C. 7712(a)) provides that "[t]he Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of . . . any biological control organism . . . if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States."

The regulations at 7 CFR part 340 have historically governed the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered (GE) organisms. APHIS first issued these regulations in 1987 under the authority of the Federal Plant Pest Act of 1957 and the Plant Quarantine Act of 1912; these two acts were later subsumed into the PPA in 2000 along with other provisions. Since 1987 and prior to 2020, APHIS amended the regulations six times, in 1988, 1990, 1993, 1994, 1997, and 2005. These various amendments instituted several exemptions, among other reforms. The amendments included exempting certain microorganisms and Arabidopsis from the requirement for permits, instituting a notification process and petition procedure, and specifying that plants engineered to

produce industrial compounds are not eligible for the notification process. On May 18, 2020, APHIS issued a final rule that marked the first comprehensive revision of the regulations since they were established in 1987, revising 7 CFR part 340 in its entirety (85 FR 29790-29838, Docket No. APHIS-2018-0034, referred to below as the SECURE rule). The rule updated APHIS's regulatory framework and focused regulatory efforts on the properties of the GE organism itself rather than on the method used to produce it. Different parts of the SECURE rule became effective on different dates; the final rule's latest effective date was October 1, 2021. On December 2, 2024, the United States District Court for the Northern District of California subsequently issued an order prospectively vacating these regulations; the Court held that APHIS had violated the Administrative Procedure Act in issuing the May 2020 final rule. *National Family Farm Coalition v. Vilsack*, 758 F.Supp.3d 1060 (N.D. Cal. 2024). The court order had the legal effect of restoring the pre-May 2020 regulations. On June 16, 2025, APHIS issued a final rule to make technical conforming amendments to the Code of Federal Regulations to reflect the court's vacatur.

7 CFR Part 330

The regulations in part 330 govern the movement of plant pests, biological control organisms, and associated articles, such as soil. 7 CFR Part 330 aims to prevent the dissemination of plant pests into the United States, or interstate, by regulating the importation and movement in interstate commerce of plant pests, biological control organisms, soil, and associated articles. In 2020, when APHIS revised the regulations in part 340, it also revised § 330.200 to indicate that genetically engineered plant pests and biological control organisms were exempt from regulation under 7 CFR Part 330 and were regulated under 7 CFR Part 340. However, the court's vacatur in December 2024, also vacated these revisions.

7 CFR Part 340

Under the current regulations, APHIS oversees the importation, interstate movement, and environmental release of certain GE organisms. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent is a plant pest or if the Administrator has reason to believe the GE organism is a plant pest. Persons that wish to move or release a regulated article must obtain authorization through a permit or notification. Upon issuance of a permit, APHIS specifies conditions that prevent the organism's dissemination and establishment in the environment. A notification, on the other hand, is a streamlined alternative to a permit for GE organisms that fall within certain criteria and are subject to pre-defined performance standards. In addition to issuing permits and acknowledging notifications, APHIS responds to petitions that request nonregulated status under these regulations. Notably, the burden rests with the developer of a GE organism to petition the agency and show that its GE organism does not pose a plant pest risk. Such a petition for nonregulated status, if successful, allows for movement and environmental release of a GE organism without the regulatory requirements of notifications or permits.

Executive Order 13874

Executive Order 13874, "Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products" (June 11, 2019), directs the Federal Government to adopt regulatory approaches for the products of agricultural biotechnology that are proportionate to the risks such products pose, and that avoid arbitrary or unjustifiable distinctions across like products developed through different technologies. Among other things, Executive Order 13874 states that regulatory decisions should be science- and evidence-based, taking economic factors into account as appropriate and consistent with applicable law; that regulatory reviews should be

conducted in a timely and efficient manner; and that biotechnology regulations should be transparent, predictable, and consistent.

APHIS's decades of experience in evaluating GE plants and microorganisms for plant pest risk have not revealed a materially different or distinct set of risks associated with GE plants and microorganisms when compared to conventional plants and microorganisms. Further, APHIS's regulations do not take clear notice of substantial advances in biotechnology since the late 1980s. APHIS, therefore, wishes to explore alternative frameworks for regulation of GE organisms under the plant pest provisions of the PPA, to ensure that regulation and oversight are proportionate to risk, that biotechnology developers in the United States have a predictable regulatory pathway to commercialization and, importantly, to ensure APHIS operates within its statutory authority.

Based on this background information, we solicit public comments regarding the following questions:

1. Are there material differences in plant pest risk between conventional and genetically engineered organisms (plants, microorganisms, or insects)? What is the basis, e.g., science-based studies, if such a difference exists? If not, should APHIS continue to distinguish between conventional and genetically engineered organisms in its Plant Protection Act regulations?
2. Describe your experiences of regulation under the SECURE rule. Were there areas that could have been improved? Were there obstacles to performing field trials? What about obstacles advancing from field trials to commercialization? What were the costs incurred complying with and/or navigating the regulatory requirements of the SECURE rule? What areas of the SECURE rule worked well?

3. Describe your experiences of regulation under the current 7 CFR Part 340. Are there areas that could be improved? Are there obstacles to performing field trials? What about obstacles advancing from field trials to commercialization? What are the costs incurred complying with and/or navigating the regulatory requirements of 7 CFR Part 340?
4. Could APHIS effectively address plant pest risks of modified organisms by regulating them under 7 CFR Part 330 instead of 7 CFR Part 340? What should APHIS consider when determining whether 7 CFR Part 330 could replace regulation of modified organisms under 7 CFR Part 340? For example, what might be the trade implications of a new regulatory framework for modified organisms under the Plant Protection Act?
5. What would the benefits and challenges of regulating modified organisms under 7 CFR Part 330? What changes, if any, would need to be made to 7 CFR Part 330 for effective regulation?
6. Describe key elements of a regulatory framework, including oversight of field trials, that would enable a scientifically sound assessment of a modified organism's plant pest risk.
7. Did the SECURE rule – and does the current 7 CFR Part 340 – impose disproportionate burdens on smaller entities developing regulated plants or microorganisms?
8. Are there any other specific issues or topics APHIS should consider in developing a regulatory framework for assessing the plant pest risk of modified organisms, or possible pathways to commercialization for modified organisms?

We welcome all comments on the above questions.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Andrew Perry, Office of the General Counsel
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