



## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0113]

#### **Bayer U.S.-Crop Science: Availability of a Draft Plant Pest Risk Assessment and Draft Environmental Assessment for Lepidopteran-Protected Maize**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** We are advising the public that the Animal and Plant Health Inspection Service has prepared a draft plant pest risk assessment and draft environmental assessment regarding a petition from Bayer U.S.-Crop Science seeking a determination of nonregulated status for maize (corn) event MON 95379 which has been developed using genetic engineering to produce two insecticidal proteins to protect against feeding damage caused by target lepidopteran pests. We are making the draft plant pest risk assessment, and draft environmental assessment available for public review and comment.

**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 [www.regulations.gov](http://www.regulations.gov). Enter APHIS-2020-0113 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2020-0113, Regulatory Analysis and Development, PPD, APHIS, Station 2C-10.16, Unit 25, 4700 River Road Unit 25, Riverdale, MD 20737-1238.

The draft plant pest risk assessment, draft environmental assessment, and any comments we receive on this docket may be viewed at [www.regulations.gov](http://www.regulations.gov), or in our reading room, which

is located in 1620 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.

The draft plant pest risk assessment and draft environmental assessment are also available on the APHIS website at: <https://www.aphis.usda.gov/biotechnology/legacy-petition-process/petitions>. Search for APHIS petition 20-205-01p.

**FOR FURTHER INFORMATION CONTACT:** Mr. Alan Pearson, Biotechnology Regulatory Services, APHIS, USDA, 4700 River Road Unit 78, Riverdale, MD 20737-1236; (301) 851-3944; email: [alan.pearson@usda.gov](mailto:alan.pearson@usda.gov).

**SUPPLEMENTARY INFORMATION:** Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the 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," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 20-205-01p) from Bayer U.S.-Crop Science (Bayer) seeking a determination of nonregulated status for MON 95379 corn which has been developed using genetic engineering to produce two insecticidal proteins to

protect against feeding damage caused by target lepidopteran pests. The petition states that the information provided indicates that MON 95379 corn is unlikely to pose a plant pest risk and therefore should not be regulated under APHIS' regulations in 7 CFR part 340.

According to our process for soliciting public comment when considering petitions for determination of nonregulated status of organisms developed using genetic engineering, APHIS accepts written comments regarding a petition once APHIS deems the petition complete. On March 4, 2024, APHIS announced in the *Federal Register* (89 FR 15542, Docket No. APHIS-2020-0113) the availability of the Bayer's petition for public comment. APHIS solicited comments on the petition for 60 days ending May 3, 2024.

APHIS received 5 comments during the comment period. They were from the agricultural, academic, and private sectors. Four comments were general opposition to deregulating MON 95379 and did not provide any substantive information that contributed to the development of this draft Environmental Assessment (EA). One commenter supported the petition and submitted a recommendation letter.

As part of our decision-making process regarding the organism's regulatory status, APHIS has prepared a draft plant pest risk assessment (PPRA) to assess the plant pest risk of the organism and a draft EA to evaluate potential impacts on the human environment that may result if the petition request is approved.

APHIS' draft PPRA compared the plant pest risk posed by the MON 95379 corn with that of the unmodified variety from which it was derived. The draft PPRA concluded that MON 95379 corn is unlikely to pose an increased plant pest risk compared to the unmodified corn.

The draft EA evaluated potential impacts that may result from the commercial production of MON 95379 corn, to include potential impacts on conventional and organic corn production; the acreage and area required for U.S. corn production; agronomic practices and inputs; the physical environment; biological resources; human health and worker safety; and animal health and welfare.

The draft EA also explains that Bayer has registered MON 95379 with the Environmental Protection Agency (EPA). The registration is restricted to breeding and seed increases only; commercial plantings will not be permitted. Regardless of APHIS' decision on this petition, EPA registration limits MON 95739 to small-scale breeding, testing, and seed increase nurseries, in the United States, to no more than 100 total acres across NE, HI, and IA.

APHIS applied USDA's regulation at 7 CFR part 1b, and APHIS' National Environmental Policy Act (NEPA) implementing regulations (7 CFR part 372), when preparing this draft EA.

In accordance with § 340.6(d), we are publishing this notice to inform the public that APHIS will accept written comments regarding the draft PPRA and draft EA from interested or affected persons for a period of 30 days from the date of this notice. The draft PPRA and draft EA are available for public review and comment, and copies are available as indicated under ADDRESSES and from the individual listed under the FOR FURTHER INFORMATION CONTACT section of this notice. We are particularly interested in receiving comments regarding biological or ecological issues, and we encourage the submission of scientific data, studies, or research to support your comments.

After the comment period closes, APHIS will review and evaluate any information received during the comment period and any other relevant information. After reviewing and evaluating the comments and other information, APHIS will prepare a final PPRA and EA. Based on the final EA, APHIS will prepare a NEPA decision document (either a Finding of No Significant Impact (FONSI) or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will also publish a notice in the *Federal Register* announcing the regulatory status of the modified plant and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

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

Done in Washington, DC, this 29th day of May 2025.

**Michael Watson,**

*Administrator, Animal and Plant Health Inspection Service.*

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