



DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0113]

Bayer U.S.-Crop Science: Availability of a Petition for a Determination of Nonregulated Status 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 received a petition from Bayer U.S.-Crop Science seeking a determination of nonregulated status for maize (corn) event MON 95379 that 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 petition available for review and comment to help us identify potential issues and impacts that we may determine should be considered in our evaluation of the petition.

DATES: We will consider all comments that we receive on or before **[INSERT DATE 60 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> and 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 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The petition and any comments we receive on this docket may be viewed at www.regulations.gov by entering APHIS-2020-0113 in the Search field, or in our reading room, which is located in Room 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 petition is also available on the APHIS website at:

<https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/petitions/petition-status/petitions-table>. Search for APHIS petition 20-205-01p.

FOR FURTHER INFORMATION CONTACT: Mr. Subray Hegde, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1238; (301) 851-3901; email: subray.hegde@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, "Movement of Organisms Modified or Produced Through Genetic Engineering," regulate, among other things, the importation, interstate movement, or release into the environment of organisms modified or produced through genetic engineering that are plant pests or pose a plausible plant pest risk.

The petition for nonregulated status described in this notice is being evaluated under the version of the regulations effective at the time that it was received. The Animal and Plant Health Inspection Service (APHIS) issued a final rule, published in the *Federal Register* on May 18, 2020 (85 FR 29790-29838, Docket No. APHIS-2018-0034)¹, revising 7 CFR part 340; however, the final rule was implemented in phases. The new Regulatory Status Review (RSR) process, which replaces the petition for determination of nonregulated status process, became effective on April 5, 2021, for corn, soybean, cotton, potato, tomato, and alfalfa. The RSR process was effective for all crops as of October 1, 2021. However, "[u]ntil RSR is available for a particular crop...APHIS will continue to receive petitions for determination of nonregulated status for the crop in accordance with the [legacy] regulations at 7 CFR 340.6." (85 FR 29815). This petition

¹ To view the final rule, go to www.regulations.gov and enter APHIS-2018-0034 in the Search field.

for a determination of nonregulated status is being evaluated in accordance with the regulations at 7 CFR 340.6 (2020) as it was originally received by APHIS on July 23, 2020.

Bayer U.S.-Crop Science (Bayer) has submitted a petition (APHIS Petition Number 20-205-01p) to APHIS seeking a determination of nonregulated status of maize (corn) designated as MON 95379, which has been developed using genetic engineering for resistance to feeding damage caused by target lepidopteran pests, including fall armyworm (*Spodoptera frugiperda*), sugarcane borer (*Diatraea saccharalis*), and corn earworm (*Helicoverpa zea*). We are making the Bayer petition available for public comment and requesting public input regarding potential issues and impacts that APHIS should be considering in our evaluation of the petition. The Bayer petition states that information collected during field trials and laboratory analyses 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.

As described in the Bayer petition, MON 95379 corn was developed to produce two insecticidal proteins, Cry1B.868 and Cry1Da_7, which protect against feeding damage caused by targeted lepidopteran insect pests. Cry1B.868 is a chimeric protein comprised of domains I and II from Cry1Be (*Bacillus thuringiensis*, Bt), domain III from Cry1Ca (Bt subsp. *aizawai*) and C-terminal protoxin domain from Cry1Ab (Bt subsp. *kurstaki*). Cry1Da_7 is a modified Cry1Da protein derived from Bt subsp. *aizawai*.

MON 95379 corn was developed to provide growers in South America an additional tool for controlling target lepidopteran corn pests, including fall armyworm resistant to current Bt technologies. MON 95379 corn will be combined through traditional breeding with other deregulated traits to provide protection against both above-ground and below-ground corn pests, as well as herbicide tolerance. These next-generation, combined-trait corn products will offer broader grower choice, improved production efficiency, increased pest control durability, and enhanced grower profit potential. MON 95379 corn will not be commercialized in the United States but is intended to only be cultivated in small-scale breeding, testing, and seed increase

nurseries to develop seed of products that will be sold in other countries, primarily in South America.

Field tests conducted under APHIS oversight allowed for evaluation of MON 95379 corn in a natural agricultural setting while imposing measures to minimize the likelihood of persistence in the environment after completion of the tests. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are used by APHIS to determine if the new variety poses a plant pest risk.

On March 6, 2012, we published in the *Federal Register* (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice² describing our process for soliciting public comment when considering petitions for determinations of nonregulated status for organisms developed using genetic engineering. In that notice, we indicated that APHIS would accept written comments regarding a petition once APHIS deemed it complete.

In accordance with our process for soliciting public input when considering petitions for determinations of nonregulated status for organisms developed using genetic engineering, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. The petition is 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 interested in receiving comments regarding potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the

² On March 6, 2012, APHIS published in the *Federal Register* (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for organisms developed using genetic engineering. To view the notice, go to www.regulations.gov and enter APHIS-2011-0129 in the Search field.

petition. We are particularly interested in receiving comments regarding biological, cultural, 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 all written comments received during the comment period and any other relevant information. Any substantive issues identified by APHIS based on our review of the petition and our evaluation and analysis of comments will be considered in the development of our decision-making documents. As part of our decision-making process regarding the regulatory status of an organism developed using genetic engineering, APHIS prepares a plant pest risk assessment to assess its plant pest risk and the appropriate environmental documentation--either an environmental assessment (EA) or an environmental impact statement (EIS)--in accordance with the National Environmental Policy Act (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. For petitions for which APHIS prepares an EA, APHIS will follow our published process for soliciting public comment (see footnote 2) and publish a separate notice in the *Federal Register* announcing the availability of APHIS' EA and plant pest risk assessment. Should APHIS determine that an EIS is necessary, APHIS will complete the NEPA EIS process in accordance with Council on Environmental Quality regulations (40 CFR part 1500-1508) and APHIS' NEPA implementing regulations (7 CFR part 372).

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 26th day of February 2024.

Michael Watson,

Administrator,

Animal and Plant Health Inspection Service.

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