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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2019-0084]

Agrivida, Inc.; Availability of a Draft Plant Pest Risk Assessment, Draft Environmental Assessment, Preliminary Determination, and Preliminary Finding of No Significant Impact for Determination of Nonregulated Status of Maize Developed Using Genetic Engineering for the Production of Phytase Enzyme

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 preliminary determination of status, draft plant pest risk assessment, draft environmental assessment, and preliminary finding of no significant impact regarding a request from Agrivida, Inc., seeking a determination of nonregulated status for PY203 maize that has been developed using genetic engineering for the production of phytase enzyme. We are making these documents 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. Enter APHIS-2019-0084 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-2019-0084, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The preliminary determination of status, draft environmental assessment, draft plant pest risk assessment, preliminary determination, preliminary finding of no significant impact, and any comments we receive on this docket may be viewed at www.regulations.gov, 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.

Supporting documents for this petition are also available on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Eck, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3892, email: cynthia.a.eck@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 is being implemented in phases. The new Regulatory Status Review (RSR)

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

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 is 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 for a determination of nonregulated status is being evaluated in accordance with the regulations at 7 CFR 340.6 (2020) as it was received by APHIS on June 25, 2019.

Agrivida, Inc. (Agrivida) has submitted a petition (APHIS Petition Number 19-176-01p) to APHIS seeking a determination of nonregulated status under 7 CFR part 340, for PY203 maize that has been developed using genetic engineering for the production of phytase enzyme. The petition states that such maize 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 process² 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 April 16, 2020, APHIS announced in the *Federal Register*³ (85 FR 21170-21171, Docket No. APHIS-2019-0084) the availability of the Agrivida petition for public comment. APHIS solicited comments on the petition for 60 days ending June 15, 2020.

APHIS received 13 comments during the comment period. They were from the agricultural, academic, and private sectors. Eleven comments were in support of Agrivida’s

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.

³ To view the notice, its supporting documents, and the comments that we received, go to www.regulations.gov and enter APHIS-2019-0084 in the Search field.

petition, while two expressed objections to crops developed or modified through genetic engineering in general.

After public comments are received on a completed petition, APHIS evaluates those comments and then provides a second opportunity for public involvement in our decision-making process. According to our public review process (see footnote 2), the second opportunity for public involvement follows one of two approaches, as described below.

If APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves an organism that raises no substantive new issues, APHIS will follow Approach 1 for public involvement. Under Approach 1, APHIS prepares and announces in the *Federal Register* the availability of APHIS' preliminary regulatory determination along with its draft EA, preliminary finding of no significant impact (FONSI), and its draft plant pest risk assessment (PPRA) for a 30-day public review period. APHIS will evaluate any information received related to the petition and its supporting documents during the 30-day public review period. If APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination or FONSI, or substantially change the analysis of impacts in the EA, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our website. No further *Federal Register* notice will be published announcing the final regulatory determination.

Under Approach 2, if APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves an organism that raises substantive new issues, APHIS first solicits written comments from the public on a draft EA and draft PPRA for a 30-day comment period through the publication of a *Federal Register* notice. Then, after reviewing and evaluating the comments on the draft EA and draft PPRA and other information, APHIS will revise the draft PPRA as necessary. It will then prepare a final EA, and based on the final EA, a

National Environmental Policy Act (NEPA) decision document (either a FONSI or a notice of intent to prepare an environmental impact statement).

For this petition, we will be following Approach 1.

As part of our decision-making process regarding an organism's regulatory status, APHIS prepared a PPRA to assess the plant pest risk of the organism, and an EA to evaluate potential impacts on the human environment. This will provide the Agency and the public with a review and analysis of any potential environmental impacts that may result if the petition request is approved.

APHIS' draft PPRA compared the pest risk posed by the Maize Event PY203 with that of the unmodified variety from which it was derived. The draft PPRA concluded that PY203 maize is unlikely to pose an increased plant pest risk compared to the unmodified corn.⁴

The draft EA evaluated potential impacts that may result from the commercial production of PY203 maize, 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; animal health and welfare; and socioeconomic impacts. No significant impacts were identified with the production and marketing of PY203 maize.

The draft EA was prepared in accordance with (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

We are making available for a 30-day review period our preliminary determination, draft EA, preliminary FONSI, and draft PPRA. The preliminary determination, draft EA, preliminary FONSI, and draft PPRA are available as indicated under ADDRESSES and FOR FURTHER

⁴ Maize is the botanical term used globally for the cereal plant *Zea mays*. In the United States maize is commonly referred to as corn. Both terms are used interchangeably in this document.

INFORMATION CONTACT above. Copies of these documents may also be obtained from the person listed under FOR FURTHER INFORMATION CONTACT.

After the 30-day review period closes, APHIS will review and evaluate any information received during the 30-day review period.

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 15th day of June 2021.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

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