



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0098]

Pioneer Hi-Bred International, Inc.: Availability of a Petition for the Determination of Nonregulated Status for Insect Resistant and Herbicide-Tolerant 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 (APHIS) has received a petition from Pioneer Hi-Bred International, Inc. seeking a determination of nonregulated status for DP23211 maize (corn). The corn is engineered for insect resistance against corn rootworm and contains the gene that codes for the phosphinothricin acetyltransferase protein responsible for tolerance to glufosinate-ammonium herbicides. DP23211 corn also contains the gene that encodes for the phosphomannose isomerase protein, which is used as a selectable marker. We are making the petition available for review and comment to help us identify potential issues and impacts that APHIS 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/#!docketDetail;D=APHIS-2020-0098>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2020-0098, 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 <http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0098> 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 petition is also available on the APHIS website at: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status> under APHIS petition 20-203-01p.

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. Secondary contact: Dr. Subray Hegde, Director, Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (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, "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 developed using genetic engineering are considered "regulated articles."

Pursuant to the terms set forth in a final rule published in the *Federal Register* on May 18, 2020 (85 FR 29790-29838, Docket No. APHIS-2018-0034),¹ 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.

APHIS has received a petition (APHIS Petition Number 20-203-01p) from Pioneer Hi-Bred International, Inc. (Pioneer) seeking a determination of nonregulated status of maize (corn) designated as DP23211, which has been genetically engineered for insect resistance against corn rootworm that consists of a double-stranded RNA combined with a novel protein. DP23211 corn also contains the gene that codes for the phosphinothricin acetyltransferase (PAT) protein responsible for the tolerance to glufosinate-ammonium herbicides and the gene that encodes for phosphomannose isomerase (PMI) protein, which is used as a selectable marker. We are making the Pioneer 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 Pioneer petition states that information collected during field trials and laboratory analyses indicates that DP23211 corn is not likely to be a plant pest and therefore should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the petition, DP23211 corn was genetically engineered to produce DvSSJ1 double-stranded ribonucleic acid (dsRNA) and the IPD072Aa protein for control of corn

¹ To view the final rule, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0034>.

rootworm pests, the PAT protein for tolerance to glufosinate-ammonium herbicides, and the PMI protein used as a selectable marker. Agronomic performance assessments for DP23211 corn were conducted in replicated field studies at a total of 12 locations in the United States and Canada. The Pioneer petition states that agronomic performance of DP23211 corn is comparable to the non-genetically modified conventional counterpart and reference varieties and that these data support the conclusion that DP23211 corn lacks weediness potential and plant pest risk.

Field tests conducted under APHIS oversight allowed for evaluation of DP23211 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 for 60 days once APHIS deemed it complete.

In accordance with our process for soliciting public input when considering petitions for determinations of nonregulated status, 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

² To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

under ADDRESSES and FOR FURTHER INFORMATION CONTACT above. 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 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 an organism's regulatory status, 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 28th day of October 2020.

Michael Watson,

Acting Administrator,

Animal and Plant Health Inspection Service.

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