



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0097]

Pioneer Hi-Bred International, Inc.; Availability of a Request and Plant Pest Risk

Similarity Assessment for an Extension of Determination of Nonregulated Status for Maize for Use in the Seed Production Technology for Africa Process

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 request to extend our determination of nonregulated status of Pioneer Hi-Bred International, Inc.'s (Pioneer's) DP-32138-1 SPT maintainer maize to maize MS44 maintainer line DP56113 for use in the Seed Production Technology for Africa (SPTA) process (hereafter DP56113 SPTA maintainer maize). DP56113 SPTA maintainer maize has been genetically engineered for maintenance and recovery of male-sterile maize breeding lines using the same construct and method of transformation as DP-32138-1 SPT maintainer maize. We are making available for public comment the request and our plant pest risk similarity assessment and preliminary determination of nonregulated status.

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 <http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0097>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2020-0097, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The Pioneer extension request, our plant pest risk similarity assessment and preliminary determination of nonregulated status, and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0097> 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.

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 (PPA) (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 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.

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, or that APHIS extend a determination of

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

nonregulated status to other organisms. Such an extension request must include information to establish the similarity of the antecedent organism and the regulated article in question.

On June 28, 2011², APHIS announced its determination of nonregulated status of Pioneer Hi-Bred International, Inc.'s (Pioneer's) DP-32138-1 SPT maintainer maize, which was genetically engineered for maintenance and recovery of male-sterile maize breeding lines. APHIS has received a request for an extension of that determination of nonregulated status of DP-32138-1 SPT maintainer maize to maintainer maize designated as MS44 maintainer line maize event DP-Ø56113-9 and referred to as DP56113 SPTA maintainer maize (APHIS Petition Number 20-043-01.ext), also from Pioneer. DP56113 SPTA maintainer maize has also been genetically engineered for maintenance and recovery of male-sterile maize breeding lines. In its request, Pioneer stated that this maintainer maize is similar to the antecedent organism DP-32138-1 SPT maintainer maize and, based on the similarity to the antecedent organism, is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the extension request, DP56113 SPTA maintainer maize was developed using the same constructs and method of transformation as DP-32138-1 SPT maintainer maize. Based on the information in the request, we have concluded that DP56113 SPTA maintainer maize is similar to DP-32138-1 SPT maintainer maize. DP56113 SPTA maintainer maize is currently regulated under 7 CFR part 340.

As part of our decision-making process regarding a GE organism's regulatory status, APHIS evaluates the plant pest risk of the article. In section 403 of the PPA, "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

² <https://www.regulations.gov/document?D=APHIS-2010-0041-0057>.

APHIS has prepared a plant pest risk similarity assessment (PPRSA) to compare DP56113 SPTA maintainer maize to the antecedent. As described in the PPRSA, the same genetic constructs used in DP56113 SPTA maintainer maize were previously used in DP-32138-1 SPT maintainer maize, and APHIS has concluded that DP56113 SPTA maintainer maize is unlikely to pose a plant health risk. Therefore, based on the similarity between DP56113 SPTA maintainer maize and DP-32138-1 SPT maintainer maize as described in the PPRSA, APHIS has concluded that DP56113 SPTA maintainer maize is no more likely to pose a plant pest risk than DP-32138-1 SPT maintainer maize.

APHIS has analyzed information submitted by Pioneer, references provided in the extension request, peer-reviewed publications, and supporting documentation prepared for the antecedent organism. Based on APHIS' analysis of this information and the similarity of DP56113 SPTA maintainer maize to the antecedent organism DP-32138-1 SPT maintainer maize, APHIS has determined that DP56113 SPTA maintainer maize is unlikely to pose a plant pest risk. We have therefore reached a preliminary decision to approve the request to extend the determination of nonregulated status of DP-32138-1 SPT maintainer maize to DP56113 SPTA maintainer maize, whereby DP56113 SPTA maintainer maize would no longer be subject to our regulations governing the introduction of certain genetically engineered organisms.

We are therefore publishing this notice to make available our evaluation and inform the public of our preliminary decision to extend the determination of nonregulated status of DP-32138-1 SPT maintainer maize to DP56113 SPTA maintainer maize.

APHIS will accept written comments on the request for extension, PPRSA, and our preliminary determination for DP56113 SPTA maintainer maize for 30 days. These documents are available for public review as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above. Copies of these documents may also be obtained by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments will be available for public review. After reviewing and evaluating the comments, if APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>. APHIS will also furnish a response to the petitioner regarding our final regulatory determination. No further *Federal Register* notice will be published announcing the final regulatory determination regarding DP56113 SPTA maintainer maize.

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 6th day of November 2020.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020-25037 Filed: 11/10/2020 8:45 am; Publication Date: 11/12/2020]