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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2016-0002]

Syngenta Seeds Inc.; Availability of a Preliminary Finding of No Significant Impact and Preliminary Decision for an Extension of a Determination of Nonregulated Status of Corn Genetically Engineered for Insect and Glufosinate-Ammonium Resistance

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 reached a preliminary decision to extend our determination of nonregulated status of Pioneer corn event DP-ØØ4114-3 (hereinafter Pioneer 4114 corn) to Syngenta's corn event MZIR098 in response to a request from Syngenta Seeds Inc. MZIR098 corn has been genetically engineered for resistance to insects and to the herbicide glufosinate-ammonium using the same mechanism of action as Pioneer 4114. We are making available for public comment our preliminary regulatory determination, preliminary finding of no significant impact, and plant pest risk similarity assessment for the proposed 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-2016-0002.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2016-0002, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The Syngenta Seeds Inc. extension request, our preliminary finding of no significant impact, our preliminary determination, and any comments we receive on this docket may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0002 or in our reading room, which is located in room 1141 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 and any comments we received regarding our determination of nonregulated status of the antecedent organism, Pioneer 4114 corn, can be found at http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0026. Supporting documents may also be found on the APHIS Web site for MZIR098 corn (the organism under evaluation) under APHIS Petition Number 15-218-01p, and the antecedent organism Pioneer 4114 corn under APHIS Petition Number 11-244-01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Biotechnology Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147 Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the supporting documents, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.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, "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 genetically engineered organisms (GE) 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. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

On June 20, 2013,[1] APHIS announced its determination of nonregulated status of Pioneer 4114 corn, which was genetically engineered for resistant to certain lepidopteran and coleopteran pests and resistance to the herbicide glufosinate-ammonium. APHIS has received a request for an extension of a determination of nonregulated status of Pioneer 4114 corn to corn designated as event MZIR098 (APHIS Petition Number 15-218-01p) from Syngenta Seeds Inc. (Syngenta) of Research Triangle Park, NC. MZIR098 corn expresses resistance to both coleopteran pests and the herbicide glufosinate-ammonium. In its request, Syngenta stated that this corn is similar

[1] https://www.aphis.usda.gov/brs/aphisdocs/11_24401p_det.pdf.

to the antecedent organism Pioneer 4114 corn 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, MZIR098 corn was developed through agrobacterium-mediated transformation to stably incorporate genes designated as ecry3.1Ab and mcry3A, which encode the insecticidal proteins eCry3.1Ab and mCry3A, and pat-08, which encodes the enzyme phosphinothricin acetyltransferase (PAT) to provide herbicide resistance. The native Cry3A, derived from the soil bacterium Bacillus thuringiensis subsp. Tenebrionis, is active against certain coleopteran pests. MZIR098 contains a modified version, mCry3A, which has enhanced activity against western corn rootworm (Diabrotica virgifera virgifera) and other related coleopteran pests of corn. The other insecticidal protein in MZIR098 is the engineered eCry3.1Ab protein which is a chimera of mCry3A and Cry1Ab. Like mCry3A, eCry3.1Ab is active against D. virgifera virgifera and certain other coleopteran pests of corn. The native Cry1Ab from B. thuringiensis subsp. kurstaki is active against certain lepidopteran pests, however, the portion of Cry1Ab included in eCry3.1Ab does not retain activity against lepidopterans. The transgene pat-08 was derived from the soil bacterium Streptomyces viridochromogenes. The PAT enzyme deactivates glufosinate herbicides thus conferring glufosinate resistance to the plants. PAT was also used as a selectable marker in the development of MZIR098 corn. The antecedent organism, Pioneer 4114 corn, was similarly genetically engineered to produce proteins which have the same mechanisms of action as do the proteins produced in MZIR098 corn. Based on the information in the request, we have concluded that MZIR098 corn is similar to Pioneer 4114 corn. MZIR098 corn is currently regulated under 7 CFR part 340.

As part of our decisionmaking 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.

APHIS completed a plant pest risk assessment (PPRA) on the antecedent organism in which we concluded that Pioneer 4114 corn is unlikely to present plant pest risks. APHIS also prepared a plant pest risk similarity assessment (PPRSA) to compare MZIR098 to the antecedent. As described in the PPRSA, the proteins expressed in MZIR098 corn are similar to those expressed in Pioneer 4114 corn, and APHIS has concluded that the proteins expressed in Pioneer 4114 corn are unlikely to pose a plant health risk. Furthermore, the Environmental Protection Agency reviewed the safety of the proteins expressed in MZIR098 corn and concluded that there would "no unreasonable adverse effects on the environment" from exposures to these proteins. Therefore, based on our PPRA for Pioneer 4114 corn and the similarity between Pioneer 4114 corn and MZIR098 corn as described in the PPRSA, APHIS has concluded that the proteins expressed in MZIR098 corn are unlikely to pose a plant pest risk.

In addition, APHIS has carefully examined the existing National Environmental Policy Act (NEPA) documentation completed for Pioneer 4114 corn and has concluded that Syngenta's request to extend a determination of nonregulated status to MZIR098 corn encompasses the same scope of environmental analysis as Pioneer 4114 corn. Therefore, based on the similarity of MZIR098 corn to Pioneer 4114 corn, APHIS has prepared a preliminary finding of no significant impact (FONSI) on MZIR098 corn. The FONSI 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).

APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of MZIR098 corn and it would continue to be a regulated article, or (2) make a determination of nonregulated status of MZIR098 corn. APHIS' preferred alternative is to make a determination of nonregulated status of MZIR098 corn.

APHIS has analyzed information submitted by Syngenta, references provided in the extension request, peer-reviewed publications, and information in the NEPA documentation prepared for the antecedent organism. APHIS has also analyzed information in the PPRA for the antecedent organism and other information. Based on APHIS' analysis of this information and the similarity of MZIR098 corn to the antecedent organism Pioneer's 4114 corn, APHIS has determined that MZIR098 corn 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 Pioneer 4114 corn to MZIR098 corn, whereby MZIR098 corn would no longer be subject to our regulations governing the introduction of certain genetically engineered organisms.

Paragraph (e) of § 340.6 provides that APHIS will publish a notice in the Federal Register announcing all preliminary decisions to extend determinations of nonregulated status for 30 days before the decisions become final and effective. In accordance with § 340.6(e) of the regulations, we are publishing this notice to inform the public of our preliminary decision to extend the determination of nonregulated status of Pioneer 4114 corn to MZIR098 corn.

APHIS will accept written comments on the preliminary FONSI regarding a determination of nonregulated status of MZIR098 corn for a period of 30 days from the date this notice is published in the Federal Register. The preliminary FONSI, as well as the extension request, supporting documents, and our preliminary determination with appended PPRSA for MZIR098 corn, 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 or FONSI, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our Web site at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml. 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 MZIR098 corn.

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 10th day of February 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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