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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0048]

J.R. Simplot Company; Availability of a Request and Plant Pest Risk Similarity Assessment for an Extension of a Determination of Nonregulated Status for Z6 Potatoes with Late Blight Protection, Low Acrylamide Potential, Lowered Reducing Sugars, and Reduced Black Spot

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 J.R. Simplot Company's (Simplot's) W8 potato to event Z6 (hereafter Z6 potato). Z6 potato has been genetically engineered for late blight protection, low acrylamide potential, lowered reducing sugars, and reduced black spot using the same construct and method of transformation as W8 potato. 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-2020-0048>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2020-0048, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The Simplot 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-2020-0048> 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.

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, "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 September 2, 2015,¹ APHIS announced its determination of nonregulated status of J.R. Simplot Company's (Simplot's) W8 potato (*Solanum tuberosum*), which was genetically engineered for late blight protection, low acrylamide potential, lowered reducing sugars, and reduced black spot. APHIS has received a request for an extension of that determination of nonregulated status of W8 potato to potato designated as event Z6 (APHIS Petition Number 19_099-02p), also from Simplot. Z6 potato also expresses late blight protection, low acrylamide potential, lowered reducing sugars, and reduced black spot. In its request, Simplot stated that this potato is similar to the antecedent organism W8 potato 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, Z6 potato was developed using the same constructs and method of transformation as W8 potato. Based on the information in the request, we have concluded that Z6 potato is similar to W8 potato. Z6 potato 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

¹<https://www.regulations.gov/document?D=APHIS-2014-0076-0160>.

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 has prepared a plant pest risk similarity assessment (PPRSA) to compare Z6 potato to the antecedent. As described in the PPRSA, the same genetic constructs used in W8 potato were previously used in Z6 potato, and APHIS has concluded that W8 potato is unlikely to pose a plant health risk. Therefore, based on the similarity between Z6 potato and W8 potato as described in the PPRSA, APHIS has concluded that Z6 potato is no more likely to pose a plant pest risk than W8 potato.

APHIS has analyzed information submitted by Simplot, 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 Z6 potato to the antecedent organism W8 potato, APHIS has determined that Z6 potato 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 W8 potato to Z6 potato, whereby Z6 potato 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 W8 potato to Z6 potato.

APHIS will accept written comments on the request for extension, PPRSA, and our preliminary determination for Z6 potato 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, APHIS will furnish a response to the petitioner regarding our final regulatory determination. APHIS will also publish a notice in the *Federal Register* announcing the regulatory status of Z6 potato.

National Environmental Policy Act

Previous requests for extension of nonregulated status were often accompanied by environmental documentation prepared pursuant to the National Environmental Policy Act of 1969 (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).

However, on May 24, 2018, APHIS issued a final rule (83 FR 24003-24011, Docket No. APHIS-2013-0049) that revised our NEPA Implementing Procedures in 7 CFR part 372. Among other revisions, it added extensions of nonregulated status under 7 CFR part 340 to organisms similar to those already deregulated to the categories of APHIS actions that meet the criteria for categorical exclusion.

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 22nd day of June 2020 .

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

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