



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2015-0088]

J.R. Simplot Company; Availability of Preliminary Finding of No Significant Impact, Similarity Assessment, and Preliminary Decision for an Extension of a Determination of Nonregulated Status to V11 Snowden Potatoes with Low Acrylamide Potential and Reduced Black Spot Bruise

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 Innate™ potato to Snowden potato variety event SPS-00V11-6 (hereinafter V11 potato) in response to a request from the J.R. Simplot Company. V11 potato has been genetically engineered to exhibit low acrylamide potential in cooked potatoes and reduced black spot bruise. We are making available for public comment our preliminary finding of no significant impact, our similarity assessment, and our preliminary extended 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-2015-0088>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2015-0088, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The J.R. Simplot Company extension request, our preliminary finding of no significant impact, our similarity assessment, our preliminary determination, and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0088> 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 organisms (Innate™ Potato events E12, F10, and J3), can be found at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0067>. Supporting documents may also be found on the APHIS Web site for V11 potato (the organism under evaluation) under APHIS Petition Number 15-140-01p, and the antecedent organisms (Innate™ Potato events E12, F10, and J3) under APHIS Petition Number 13-022-01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental 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. Cynthia Eck at (301) 851-3885, 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 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.

In a notice¹ published in the **Federal Register** on November 10, 2014 (79 FR 66688-66689, Docket No. APHIS-2012-0067), APHIS announced our determination of nonregulated status of potatoes (*Solanum tuberosum*) designated as Innate™ potatoes (events E12, E24, F10, F37, J3, J55, J78, G11, H37, and H50), which have been genetically engineered for low acrylamide potential and reduced black spot bruise. Acrylamide is a human neurotoxicant and potential carcinogen that may form in potatoes and other starchy foods under certain cooking

¹ To view the notice, our determination, supporting documents, and the comments we have received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0067>.

conditions. APHIS has received a request for an extension of a determination of nonregulated status of Innate™ potatoes (APHIS Petition Number 13-022-01p) to Snowden potato variety event SPS-00V11-6 (hereinafter V11 potato) (APHIS Petition Number 15-140-01p) from the J.R. Simplot Company (Simplot) of Boise, ID. In the extension request, Simplot named three of the ten previously deregulated events as antecedents. Like the antecedents, V11 potato has been genetically engineered for low acrylamide potential and reduced black spot bruise. In its request, Simplot stated that V11 potato was produced by transforming an additional variety of potato, Snowden, using the same DNA and method that was used for the antecedent potatoes and, based on the similarity, is unlikely to pose a plant pest risk. Therefore, the request stated that V11 potato should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the extension request, V11 potato has been genetically engineered through the insertion of genetic elements from potato or wild potato (a group of related plant species that are sexually compatible with potato) using Simplot's Innate™ technologies. APHIS has previously assessed the risks associated with the insertion of these same genetic elements into potato and concluded that the resulting organisms did not pose a plant pest risk. Based on the information in the request, we have concluded that V11 potato is similar to the antecedent potatoes. V11 potato is currently regulated under 7 CFR part 340.

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) and an environmental assessment (EA) for the antecedent organisms. Based on those assessments, we concluded that

the antecedent organisms are unlikely to present a plant pest risk. V11 potato expresses the same low acrylamide potential and reduced black spot bruise prevalence as the antecedent potatoes. Therefore, based on our PPRA for the antecedents and the similarity between V11 potato and the antecedents, APHIS has concluded that V11 potato is unlikely to pose a plant pest risk.

The EA for the antecedent organisms was prepared using data submitted by Simplot, a review of other scientific data, and field tests conducted under APHIS oversight. The EA was prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the proposed determination of nonregulated status of the antecedent potatoes. The EA was prepared in accordance with (1) 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).

Based on the similarity of V11 potato to the antecedent potatoes, APHIS has prepared a preliminary finding of no significant impact (FONSI) on V11 potato using the EA prepared for Innate™ potato. APHIS considered the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of V11 potato and it would continue to be a regulated article, or (2) make a determination of nonregulated status of V11 potato. APHIS' preferred alternative is to make a determination of nonregulated status of V11 potato.

APHIS has carefully examined the existing NEPA documentation completed for Innate™ potato and has concluded that Simplot's request to extend a determination of nonregulated status to V11 potato encompasses the same scope of environmental analysis as the antecedent potatoes.

Based on APHIS' analysis of information submitted by Simplot, references provided in the extension request, peer-reviewed publications, information analyzed in the EA, and the similarity of V11 potato to the antecedent organisms, APHIS has determined that V11 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 Innate™ potato to V11 potato, whereby V11 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 the antecedent potatoes to V11 potato.

APHIS will accept written comments on the FONSI regarding a determination of nonregulated status of V11 potato for a period of 30 days from the date this notice is published in the **Federal Register**. The FONSI, as well as the extension request, supporting documents, and our preliminary determination for V11 potato, 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 V11 potato.

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 2nd day of December 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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