BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0067]

J.R. Simplot Co.; Availability of Petition for Determination of Nonregulated Status of Potato Genetically Engineered for 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 (APHIS) has received a petition from the J.R. Simplot Company (Simplot) seeking a determination of nonregulated status of potatoes 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 (acrylamide is a human neurotoxicant and potential carcinogen that may form in potatoes and other starchy foods under certain cooking conditions) and reduced black spot bruise. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are making the Simplot petition available for review and comment to help us identify potential environmental and interrelated economic 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/#!documentDetail;D=APHIS-2012-0067-0001.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2012-0067, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0067 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.

The petition is also available on the APHIS Web site at http://www.aphis.usda.gov/brs/aphisdocs/13_02201p.pdf.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Stankiewicz Gabel, Chief, Biotechnology Environmental Analysis Branch , Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3927, email: rebecca.l.stankiewicz-gabel@aphis.usda.gov. To obtain copies of the petition, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

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 genetically engineered (GE) 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. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 13-022-01p) from the J.R. Simplot Company (Simplot) of Boise, ID, seeking a 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 conditions. The petition states that these potatoes are 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 petition, Innate™ potatoes have 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. Simplot's Innate™ technologies allow researchers to isolate genetic elements from any plant genome, rearrange

them, or link them together in desired permutations, and introduce them back into the genome, without incorporating anything other than plant DNA. Innate™ potatoes are currently regulated under 7 CFR part 340. Interstate movements and field tests of Innate™ potatoes have been conducted under notifications acknowledged by APHIS.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk 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.

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the Federal Register providing 60 days for public comment for petitions for a determination of nonregulated status. On March 6, 2012, we published in the Federal Register (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice[1] describing our process for soliciting public comment when considering petitions for determinations of nonregulated status for GE organisms. In that notice we indicated that APHIS would accept written comments regarding a petition once APHIS deemed it complete.

In accordance with § 340.6(d) of the regulations and our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, 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 copies are available as indicated under ADDRESSES and FOR FURTHER

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

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 information regarding the extent of true potato seed use for planting in the United States as compared to the use of asexually propagated fragments of potato tubers. We are also 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. We also request that, when possible, commenters provide relevant information regarding specific localities or regions as potato growth, crop management, and crop utilization may vary considerably by geographic region.

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 decisionmaking documents.

As part of our decisionmaking process regarding a GE 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 1) 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 29th day of April 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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