



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2021-0027]

Okanagan Specialty Fruits Inc.; Availability of a Request, a Draft Plant Pest Risk Similarity Assessment, and Preliminary Determination for an Extension of Determination of Nonregulated Status for Non-Browning Apple

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 from Okanagan Specialty Fruits Inc. (OSF) to extend our determination of nonregulated status of GD743 apple and GS784 apple to PG451 apple which has been developed using genetic engineering to resist browning. We are making the OSF extension request, the preliminary determination, and the draft plant pest risk similarity assessment available for public comment.

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> and enter APHIS-2021-0027 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2021-0027, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The OSF extension request, the preliminary determination, and the draft plant pest risk similarity assessment, and any comments we receive on this docket may be viewed at www.regulations.gov 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.

Supporting documents for this petition are also available on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>.

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 (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 importation, interstate movement, or release into the environment of organisms modified or produced through genetic engineering that are plant pests or pose a plausible plant pest risk.

The extension for nonregulated status described in this notice is being evaluated under the version of the regulations effective at the time that it was received. The Animal and Plant Health Inspection Service (APHIS) issued a final rule, published in the *Federal Register* on May 18, 2020 (85 FR 29790-29838, Docket No. APHIS-2018-0034)¹, revising 7 CFR part 340; however, the final rule is being implemented in phases. This extension of a determination of

¹ To view the final rule, go to www.regulations.gov and enter APHIS-2018-0034 in the Search field.

nonregulated status is being evaluated in accordance with the regulations at 7 CFR 340.6 (2020) as it was received by APHIS on July 31, 2020.

On February 18, 2015², APHIS announced its determination of nonregulated status of Okanagan Specialty Fruits Inc.'s (OSF) GD743 and GS784 apple lines which were developed using genetic engineering to resist browning. OSF has submitted a request to extend a determination of nonregulated status of GD743 and GS784 apple lines to PG451 apple (APHIS Petition Number 20-213-01ext) which has been developed using genetic engineering to resist browning.

As described in the extension request, PG451 apple was developed through *Agrobacterium*-mediated transformation of apple leaf tissue using the binary plasmid vector pGEN-03 to suppress genes for polyphenol oxidase, which causes browning. GD743 and GS784 apple lines were developed using the same plasmid vector and the same *Agrobacterium*-mediated transformation method.

Based on the information in the request, we have concluded that PG451 apple is similar to GD743 and GS784 apple lines. PG451 apple is currently regulated under 7 CFR part 340.

As part of our decision-making process regarding the regulatory status of an organism developed using genetic engineering, APHIS prepared a draft plant pest risk similarity assessment (PPRSA) to compare PG451 apple to the antecedents. Based on the similarity of PG451 apple to the antecedents GD743 and GS784 apple lines as described in the PPRSA, APHIS concludes that PG451 apple is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived and should no longer be regulated under 7 CFR part 340.

APHIS has analyzed information submitted by OSF, references provided in the extension request, peer-reviewed publications, and supporting documentation prepared for the antecedent

² To view the notice, go to www.regulations.gov and enter APHIS-2012-0025 in the Search field.

organism. Based on APHIS' analysis of this information and the similarity of PG451 apple to the antecedents GD743 and GS784 apple lines, APHIS has determined that PG451 apple 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 for PG451 apple line, whereby PG451 apple would no longer be subject to our regulations governing organisms developed using genetic engineering.

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 PG451 apple.

APHIS will accept written comments on the request for extension, PPRSA, and our preliminary determination for PG451 apple 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 of PG451 apple.

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 24th day of June 2021 .

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

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