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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0025]

Okanagan Specialty Fruits, Inc.; Determination of Nonregulated Status of Apples Genetically Engineered to Resist Browning

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that apple events developed by Okanagan Specialty Fruits, Inc., designated as events GD743 and GS784, which have been genetically engineered to resist browning, are no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Okanagan Specialty Fruits, Inc., in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notices announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

DATES: Effective [Insert date of publication in the Federal Register].

ADDRESSES: You may read the documents referenced in this notice and the comments we received at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0025> 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 are also available on the APHIS Web site at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml under APHIS Petition Number 10-161-01p.

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 for this petition, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

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. APHIS received a petition (APHIS Petition Number 10-161-

01p) from Okanagan Specialty Fruits, Inc., (Okanagan) of British Columbia, Canada, seeking a determination of nonregulated status of apples (Malus x domestica) designated as events GD743 and GS784, which have been genetically engineered to resist browning. The petition states that these apples are unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process¹ for soliciting public comment when considering petitions for determinations of nonregulated status of genetically engineered (GE) organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice² published in the Federal Register on July 13, 2012 (77 FR 41362-41363, Docket No. APHIS-2012-0025), APHIS announced the availability of the Okanagan petition for public comment. APHIS solicited comments on the petition for 60 days ending on September 11, 2012, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

APHIS received 1,939 comments on the petition. Several of these comments included electronic attachments consisting of consolidated documents of many identical or nearly identical letters, for a total of 72,745 comments. Issues raised during the comment period included concerns regarding marketing and economic impacts; cross-pollination; and health, nutrition, and food safety. APHIS decided, based on its review of the petition and its evaluation and analysis of the comments received during the 60-day public comment period on the petition,

¹ On March 6, 2012, APHIS published in the Federal Register (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms. To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

² To view the notice, the petition, the comments we received, and other supporting documents, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0025>.

that the petition involves a GE organism that involves a new crop trait or raises substantive new issues. According to our public review process for such petitions (see footnote 1), APHIS first solicits written comments from the public on a draft environmental assessment (EA) and a plant pest risk assessment (PPRA) for a 30-day comment period through the publication of a Federal Register notice. Then, after reviewing and evaluating the comments on the draft EA and the PPRA and other information, APHIS revises the PPRA as necessary and prepares a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a finding of no significant impact (FONSI) or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS furnishes a response to the petitioner, either approving or denying the petition. APHIS also publishes a notice in the Federal Register announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

APHIS sought public comment on a draft EA and a PPRA from November 8, 2013, to January 30, 2014.³ APHIS solicited comments on the draft EA, the PPRA, and whether the subject apples are likely to pose a plant pest risk. APHIS received 105,971 comments during the comment period, of which 100,976 were form letters. The majority of the comments expressed general opposition to APHIS making a determination of nonregulated status of GE organisms. Issues raised during the comment period included concerns regarding potential effects on human

³ In a notice (see footnote 2) published in the Federal Register on November 8, 2013, (78 FR 67100-67101, Docket No. APHIS-2012-0025), APHIS announced the availability of a draft EA and a PPRA for public comment for 30 days, ending December 9, 2013. In a notice published in Federal Register on December 31, 2013, (78 FR 79568-79569, Docket No. APHIS-2012-0025), APHIS reopened the comment period on the draft EA and the PPRA for an additional 30 days, ending January 30, 2014. We also indicated in that notice that we would consider all comments received between December 10, 2013 (the day after the close of the original comment period) and the date of the notice.

and animal health and nontarget organisms and economic impacts on apple growers. APHIS has addressed the issues raised during the comment period and has provided responses to comments as an attachment to the FONSI.

National Environmental Policy Act

After reviewing and evaluating the comments received during the comment period on the draft EA and the PPRA and other information, APHIS has prepared a final EA. The EA has been prepared to provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of Okanagan's apple events GD743 and GS784. The EA 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). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a FONSI with regard to the preferred alternative identified in the EA (to make a determination of nonregulated status of apple events GD743 and GS784).

Determination

Based on APHIS' analysis of field and laboratory data submitted by Okanagan, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that Okanagan's apple events GD743 and GS784 are unlikely to pose a plant pest risk and therefore are no longer subject to our regulations governing the introduction of certain GE organisms.

Copies of the signed determination document, PPRA, final EA, FONSI, and response to comments, as well as the previously published petition and supporting documents, are available as indicated in the ADDRESSES and FOR FURTHER INFORMATION CONTACT sections of this notice.

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 12th day of February 2015.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

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