

Export Act that the importation of viable cannabis seeds must be carried out by persons registered with the DEA to do so. In addition, any USDA phytosanitary requirements that normally would apply to the importation of plant material will apply to the importation of industrial hemp seed.

- Section 7606 did not amend the Federal Food, Drug, and Cosmetic Act. For example, section 7606 did not alter the approval process for new drug applications, the requirements for the conduct of clinical or nonclinical research, the oversight of marketing claims, or any other authorities of the FDA as they are set forth in that Act.

- The Federal Government does not construe section 7606 to alter the requirements of the Controlled Substances Act (CSA) that apply to the manufacture, distribution, and dispensing of drug products containing controlled substances. Manufacturers, distributors, dispensers of drug products derived from cannabis plants, as well as those conducting research with such drug products, must continue to adhere to the CSA requirements.

- Institutions of higher education and other participants authorized to carry out agricultural pilot programs under section 7606 may be able to participate in USDA research or other programs to the extent otherwise eligible for participation in those programs.

## 2. Regulatory Requirements

This Statement of Principles does not establish any binding legal requirements. It is, therefore, exempt from notice and comment rulemaking requirements under the Administrative Procedure Act pursuant to 5 U.S.C. 553(b). Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis. 5 U.S.C. 603(a), 604(a). USDA has determined that this Statement of Principles does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*

Dated: July 25, 2016.

**Thomas J. Vilsack,**  
*Secretary of Agriculture.*

Dated: July 21, 2016.

**Louis J. Milione,**  
*Deputy Assistant Administrator, Drug Enforcement Administration.*

Dated: July 22, 2016.

**Leslie Kux,**  
*Associate Commissioner for Policy, Food and Drug Administration.*

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2016-0043]

#### Okanagan Specialty Fruits, Inc.; Availability of Preliminary Finding of No Significant Impact, Preliminary Plant Pest Risk Similarity Assessment, and Preliminary Determination for an Extension of a Determination of Nonregulated Status for Non-Browning Arctic® Apple Event NF872 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 reached a preliminary decision to extend our determination of nonregulated status of Okanagan Specialty Fruits' (OSF) GS784 and GD743 apples to OSF NF872 'Arctic® Fuji apple'. OSF's NF872 apple has been genetically engineered for enzymatic browning resistance using the same mode of action as GS784 and GD743 apples. We are making available for public comment our preliminary determination, preliminary plant pest risk similarity assessment, and preliminary finding of no significant impact for the proposed determination of nonregulated status.

**DATES:** We will consider all comments that we receive on or before September 12, 2016.

**ADDRESSES:** You may submit comments by either of the following methods:

- Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0043>.

- Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2016-0043, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The Okanagan Specialty Fruits extension request, our preliminary determination, preliminary plant pest risk similarity assessment, preliminary finding of no significant impact, and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0043> 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 (apple events GD743 and GS784), can be found at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0025>. Supporting documents may also be found on the APHIS Web site for NF872 'Arctic® Fuji apple' (the organism under evaluation) under APHIS Petition Number 16-004-01p, and the antecedent organisms (apple events GD743 and GS784) under APHIS Petition Number 10-161-01p.

**FOR FURTHER INFORMATION CONTACT:** Dr. John Turner, Director, Biotechnology 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](mailto:john.t.turner@aphis.usda.gov). To obtain copies of the supporting documents, contact Ms. Cindy Eck at (301) 851-3885, email: [cynthia.a.eck@aphis.usda.gov](mailto: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 notice<sup>1</sup> published in the **Federal Register** on November 8, 2013 (78 FR 67100, Docket No. APHIS–2012–0025), APHIS announced our determination of nonregulated status of apples (*Malus domestica*) designated as events GD743 and GS784, which have been genetically engineered to resist browning. APHIS has received a request for an extension of a determination of nonregulated status of GD743 and GS784 apples to Arctic® apple event NF872 (hereinafter NF872 apple) (APHIS Petition Number 16–004–01p) from Okanagan Specialty Fruits, Inc. (hereinafter referred to as OSF), of British Columbia, Canada. In the extension request, OSF named the two previously deregulated apple events as antecedents. Like the antecedents, NF872 apple is genetically engineered to be resistant to enzymatic browning. In its request, OSF stated that NF872 apple was produced by transforming an additional variety of apple using the same DNA and method that was used for the antecedent apples and, based on the similarity, is unlikely to pose a plant pest risk. Therefore, the request stated that NF872 apple should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the extension request, NF872 apple has been genetically engineered through the insertion of genetic elements from apples. APHIS has previously assessed the risks associated with the insertion of these same genetic elements into apples and concluded that the resulting organisms did not pose a plant pest risk. Based on the information in the request, we have concluded that NF872 apple is similar to the antecedent apples. NF872 apple is currently regulated under 7 CFR part 340.

As part of our decisionmaking process regarding a genetically engineered organism's regulatory status, APHIS evaluates the plant pest risk of the article. 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) for the antecedent organisms in which we concluded that the GD743 and GS784 apples are unlikely to present a plant pest risk.

NF872 apple expresses the same resistance to enzymatic browning as the antecedent apples. Therefore, based on our PPRA for the antecedents and the similarity between NF872 apple and the antecedents, APHIS has concluded that NF872 apple is unlikely to pose a plant pest risk. APHIS also prepared a plant pest risk similarity assessment (PPRSA) to compare NF872 to the antecedents. As described in the PPRSA, the NF872 apple was obtained using a polyphenol oxidase (PPO) suppression construct designed to reduce the expression of four apple genes coding for PPO proteins. The PPO suppression construct used in the NF872 apple event is the same construct used in the antecedent apple events GD743 and GS784, and APHIS has concluded that the PPO suppression construct used in GD743 and GS784 is unlikely to affect the plant pest risk of NF872. Furthermore, APHIS has previously reviewed the potential impacts on nontarget organisms beneficial to agriculture and concluded that it is unlikely that NF872 apple will have an adverse effect on nontarget organisms. Therefore, based on our PPRA for GD743 apple and GS784 apple and the similarity between GD743 apple, GS784 apple, and NF872 apple as described in the PPRSA, APHIS has concluded that the PPO suppression construct used to obtain the NF872 apple is unlikely to pose a plant pest risk and that NF872 apple is unlikely to pose a different plant pest risk than GD743 apple and GS784 apple.

The environmental assessment (EA) for the antecedent organisms was prepared using data submitted by OSF, 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 apples. 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 NF872 apple to the antecedent apples, APHIS has prepared a preliminary finding of no significant impact (FONSI) on NF872 apple using the EA prepared for GD743 and GS784 apples. APHIS considered

the following alternatives: (1) Take no action, *i.e.*, APHIS would not change the regulatory status of NF872 apple and it would continue to be a regulated article, or (2) make a determination of nonregulated status of NF872 apple. APHIS' preferred alternative is to make a determination of nonregulated status of NF872 apple.

APHIS has carefully examined the existing NEPA documentation completed for GD743 and GS784 apples and has concluded that OSF's request to extend a determination of nonregulated status to NF872 apple encompasses the same scope of environmental analysis as the antecedent apples.

Based on APHIS' analysis of information submitted by OSF, references provided in the extension request, peer-reviewed publications, information analyzed in the EA, and the similarity of NF872 apple to the antecedent organisms, APHIS has determined that NF872 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 of GD743 and GS784 apples to NF872 apple, whereby NF872 apple 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 apples to NF872 apple.

APHIS will accept written comments on the preliminary FONSI regarding a determination of nonregulated status of NF872 apple for a period of 30 days from the date this notice is published in the **Federal Register**. The preliminary FONSI, as well as the extension request, supporting documents, and our preliminary determination for NF872 apple, 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

<sup>1</sup> To view the notice, our determination, supporting documents, and the comments we have received, go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2012-0025>.

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](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 NF872 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 8th day of August 2016.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2016–19222 Filed 8–11–16; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0031]

#### Environmental Impact Statement; Fruit Fly Eradication Program

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of intent to prepare an environmental impact statement.

**SUMMARY:** We are advising the public that the Animal and Plant Health Inspection Service plans to prepare an updated environmental impact statement to analyze the effects of a program to eradicate exotic fruit fly species from wherever they might occur in the United States, including Hawaii, Guam, American Samoa, Puerto Rico, and the U.S. Virgin Islands. This notice identifies potential issues and alternatives that will be studied in the environmental impact statement, and requests public comments to further delineate the scope of the alternatives and environmental impacts and issues.

**DATES:** We will consider all comments that we receive on or before September 26, 2016.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0031>.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No.

APHIS–2016–0031, 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-2016-0031> 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:** For questions related to the Fruit Fly Eradication Program, contact Mr. John C. Stewart, APHIS National Fruit Fly Eradication Program Manager, Center for Plant Health Science and Technology, PPQ, APHIS, 1730 Varsity Drive, Suite 400, Raleigh NC 27606, [John.C.Stewart@aphis.usda.gov](mailto:John.C.Stewart@aphis.usda.gov); (919) 855–7426. For questions related to the environmental impact statement, contact Dr. Jim Warren, Environmental Protection Specialist, Environmental and Risk Analysis Services, PPD, APHIS, 4700 River Road, Unit 149, Riverdale, MD 20737; [Jim.E.Warren@aphis.usda.gov](mailto:Jim.E.Warren@aphis.usda.gov); (202) 316–3216.

#### SUPPLEMENTARY INFORMATION:

##### Background

Non-native (exotic) fruit flies in the family Tephritidae have a wide host range, including more than 400 species of fruit and vegetables. Introduction of these pest species into the United States causes economic losses from destruction and spoiling of host commodities by larvae, costs associated with implementing control measures, environmental impacts due to increased pesticide usage if fruit flies become established, and loss of market share due to restrictions on shipment of host commodities. Three species pose the greatest risk to United States agriculture: the Mediterranean fruit fly (Medfly), *Ceratitis capitata*; the Oriental fruit fly (OFF), *Bactrocera dorsalis*; and the Mexican fruit fly (Mexfly), *Anastrepha ludens*.

Currently, Medfly is established in Hawaii where it was first detected in 1910. Although Medfly has been periodically introduced to the United States mainland since 1929, successful eradication programs have prevented it from becoming an established pest in the continental United States. OFF was introduced into Hawaii in the 1940s and has since become established there.

Although OFF is not established in the continental United States, new infestations have been detected on an almost annual basis since it was first detected in California in 1960. The Mexfly has been introduced repeatedly to Texas and eradicated since its first introduction in 1927. The risk of introduction along the Mexican and U.S. border continues to increase as the rate of infestations in Mexico increases annually.

The regulations in “Subpart—Fruit Flies” (7 CFR 301.32 through 301.32–10, referred to below as the regulations), restrict the movement of certain regulated articles from quarantined areas in order to prevent the spread of fruit flies to noninfested areas of the United States. Within the quarantined areas, Animal and Plant Health Inspection Service (APHIS) works with State and local officials to eradicate fruit flies, after which the quarantine can be removed.

Current efforts to eradicate infestations include chemical and nonchemical control measures. Chemical options may include applications of insecticides and/or the use of detection and control attractants that can be applied using various methods. Nonchemical control methods include sterile insect technique (SIT) and host removal from areas in and around the detection sites.

Under the provisions of the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C 4321 *et seq.*), Federal agencies must examine the potential environmental effects of the proposed Federal actions and alternatives. A final environmental impact statement (EIS) was prepared in 2001 to examine the environmental effects of the fruit fly cooperative control program. Since the publication of the 2001 EIS, there have been scientific and technological advances in the field. As a result, we are planning to prepare a new EIS to analyze and examine the environmental effects of control alternatives available to the agency, including a no action alternative. It will be used for planning and decisionmaking and to inform the public about the environmental effects of APHIS’ fruit fly eradication activities. It will also provide an overview of APHIS activities to which we can tier site-specific analyses and environmental assessments if new fruit fly infestations are discovered in the United States.

We are requesting public comment to help us identify or confirm potential alternatives and environmental issues that should be examined in the EIS, as well as comments that identify other