

Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Principles on Industrial Hemp

AGENCY: Office of the Secretary, USDA; Drug Enforcement Administration, DOJ; Food and Drug Administration, HHS.

ACTION: Notice

SUMMARY: The U.S. Department of Agriculture, in consultation with the U.S. Drug Enforcement Administration and the U.S. Food and Drug Administration, has developed a *Statement of Principles on Industrial Hemp* to inform the public how Federal law applies to activities associated with industrial hemp that is grown and cultivated in accordance with Section 7606 of the Agricultural Act of 2014. The purpose of this notice is to set forth the statement in its entirety.

DATES: This Statement of Principles is applicable August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Michael Poe, Telephone Number: (202) 720-3257.

SUPPLEMENTARY INFORMATION:

1. Statement of Principles

With publication of this notice, the U.S. Department of Agriculture (USDA) issues, with the concurrence of the U.S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA), the following Statement of Principles regarding the applicability of Federal laws to activities associated with growing and cultivating industrial hemp:

Section 7606 of the Agricultural Act of 2014 legalized the growing and cultivating of industrial hemp for research purposes in States where such growth and cultivation is legal under State law, notwithstanding existing Federal statutes that would otherwise criminalize such conduct. The statutorily sanctioned conduct, however, was limited to growth and cultivation by an institution of higher education or State department of agriculture for purposes of agricultural or other academic research or under the auspices of a State agricultural pilot program for the growth, cultivation, or marketing of industrial hemp.

Section 7606 authorized State departments of agriculture to promulgate regulations to carry out these pilot programs but did not provide a specific delegation to the U.S. Department of Agriculture (USDA) or any other agency to implement the program. As well, the statute left open many questions regarding the continuing application of Federal drug control statutes to the growth, cultivation, manufacture, and distribution of industrial hemp products, as well as the extent to which growth by private parties and sale of industrial hemp products are permissible. Section 7606 did not remove industrial hemp from the controlled substances list. Therefore, Federal law continues to restrict hemp-related activities, to the extent that those activities have not been legalized under section 7606.

USDA, having consulted with and received concurrence from the U.S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA), therefore, is issuing this statement of principles to inform the public regarding how Federal law applies to activities involving industrial hemp so that individuals, institutions, and States that wish to participate in industrial hemp agricultural pilot programs can do so in accordance with Federal law.

- The growth and cultivation of industrial hemp may only take place in accordance with an agricultural pilot program to study the growth, cultivation, or marketing of industrial hemp established by a State department of agriculture or State agency responsible for agriculture in a State

where the production of industrial hemp is otherwise legal under State law.

- The State agricultural pilot program must provide for State registration and certification of sites used for growing or cultivating industrial hemp. Although registration and certification is not further defined, it is recommended that such registration should include the name of the authorized manufacturer, the period of licensure or other time period during which such person is authorized by the State to manufacture industrial hemp, and the location, including Global Positioning System coordinates, where such person is authorized to manufacture industrial hemp.

- Only State departments of agriculture, and persons licensed, registered, or otherwise authorized by them to conduct research under an agricultural pilot program in accordance with section 7606, and institutions of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)), or persons employed by or under a production contract or lease with them to conduct such research, may grow or cultivate industrial hemp as part of the agricultural pilot program.

- The term “industrial hemp” includes the plant *Cannabis sativa* L. and any part or derivative of such plant, including seeds of such plant, whether growing or not, that is used exclusively for industrial purposes (fiber and seed) with a tetrahydrocannabinols concentration of not more than 0.3 percent on a dry weight basis. The term “tetrahydrocannabinols” includes all isomers, acids, salts, and salts of isomers of tetrahydrocannabinols.

- For purposes of marketing research by institutions of higher education or State departments of agriculture (including distribution of marketing materials), but not for the purpose of general commercial activity, industrial hemp products may be sold in a State with an agricultural pilot program or among States with agricultural pilot programs but may not be sold in States where such sale is prohibited. Industrial hemp plants and seeds may not be transported across State lines.

- Section 7606 specifically authorized certain entities to “grow or cultivate” industrial hemp but did not eliminate the requirement under the Controlled Substances Import and

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. To obtain copies of the supporting documents, contact Ms. Cindy 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.