

Notices

Federal Register

Vol. 63, No. 235

Tuesday, December 8, 1998

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

Animal and Plant Health Inspection Service

[Docket No. 98-114-1]

AgrEvo USA Co.; Receipt of Petition for Determination of Nonregulated Status for Canola Genetically Engineered for Male Sterility, Fertility Restoration, and Glufosinate Herbicide Tolerance

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 petition from AgrEvo USA Company seeking a determination of nonregulated status for certain canola transformation events, which have been genetically engineered for male sterility, fertility restoration, and tolerance to the herbicide glufosinate. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. In accordance with those regulations, we are soliciting public comments on whether these canola transformation events present a plant pest risk.

DATES: Written comments must be received on or before February 8, 1999.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 98-114-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 98-114-1. A copy of the petition and any comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday,

except holidays. Persons wishing access to that room to inspect the petition or comments are asked to call in advance of visiting at (202) 690-2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Susan Koehler, Biotechnology and Biological Analysis, PPQ, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-4886. To obtain a copy of the petition, contact Ms. Kay Peterson at (301) 734-4885; e-mail: Kay.Peterson@usda.gov.

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

On October 5, 1998, APHIS received a petition (APHIS Petition No. 98-278-01p) from AgrEvo USA Company (AgrEvo) of Wilmington, DE, requesting a determination of nonregulated status under 7 CFR part 340 for canola (*Brassica napus* L.) designated as In Vigor® Hybrid Canola Transformation Events (transformation events) MS8 and RF3, and their hybrid combination MS8/RF3. The subject transformation events have been genetically engineered for male sterility (MS8), fertility restoration (RF3), and tolerance to the herbicide glufosinate (both MS8 and RF3), to enable the production of pure hybrid canola varieties by the use of a pollination control system. AgrEvo's petition states that the subject canola transformation events should not be

regulated by APHIS because they do not present a plant pest risk.

As described in the petition, these canola transformation events have been genetically engineered to contain a *barnase* gene (MS8) for male sterility or the *barstar* gene (RF3) for fertility restoration. The *barnase* gene expresses a ribonuclease that blocks pollen development and results in a male sterile plant, while the *barstar* gene encodes a specific inhibitor of this ribonuclease and restores fertility. The *barnase* and *barstar* genes were derived from *Bacillus amyloliquefaciens*, and are linked in the subject transformation events to the *bar* gene derived from *Streptomyces hygroscopicus*. The *bar* gene encodes the enzyme phosphinothricin-N-acetyltransferase (PAT), which confers tolerance to the herbicide glufosinate. The herbicide tolerance trait allows for selection of plants carrying the linked genes for pollination control during breeding and for tolerance to the herbicide during commercial cultivation. Expression of the added genes is controlled in part by gene sequences derived from *Arabidopsis thaliana*, *Nicotiana tabacum*, and the plant pathogen *Agrobacterium tumefaciens*. The *A. tumefaciens* method was used to transfer the added genes into the parental canola variety, Drakkar.

Canola transformation events MS8, RF3, and their hybrid combination MS8/RF3 have been considered regulated articles under the regulations in 7 CFR part 340 because they contain gene sequences from a plant pathogen. These canola transformation events have been field tested in Canada since 1994, in Europe since 1995, and in the U. S. since 1997 under APHIS permits and notifications. In the process of reviewing the permit applications and notifications for field trials of these canola transformation events, APHIS determined that the vectors and other elements were disarmed and that the trials, which were conducted under conditions of reproductive and physical containment or isolation, would not present a risk of plant pest introduction or dissemination. Canola transformation events MS8, RF3, and their hybrid combination MS8/RF3 were approved in 1996 by Agriculture and Agri-Food Canada for unconfined environmental release and use as livestock feed in Canada, and in 1997, Health Canada

approved oil from the subject transformation events for sale as human food in Canada.

In the Federal Plant Pest Act, as amended (7 U.S.C. 150aa *et seq.*), *plant pest* is defined as "any living stage of: Any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured or other products of plants." APHIS views this definition very broadly. The definition covers direct or indirect injury, disease, or damage not just to agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees, rhizobia, etc.

The U. S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. In cases in which genetically modified plants allow for a new use of an herbicide or involve a different use pattern for the herbicide, EPA must approve the new or different use. When the use of the herbicide on the genetically modified plant would result in an increase in the residues of the herbicide in a food or feed crop for which the herbicide is currently registered, or in new residues in a crop for which the herbicide is not currently registered, establishment of a new tolerance or a revision of the existing tolerance would be required. Residue tolerances for pesticides are established by EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), and the Food and Drug Administration (FDA) enforces tolerances set by EPA under the FFDCA. Accordingly, AgrEvo has submitted to EPA both registration and tolerance exemption applications for glufosinate use on canola.

FDA published a statement of policy on foods derived from new plant varieties in the **Federal Register** on May 29, 1992 (57 FR 22984-23005). The FDA statement of policy includes a discussion of FDA's authority for ensuring food safety under the FFDCA, and provides guidance to industry on the scientific considerations associated with the development of foods derived

from new plant varieties, including those plants developed through the techniques of genetic engineering. AgrEvo has completed consultation with FDA on the subject canola transformation events.

In accordance with § 340.6(d) of the regulations, we are publishing this notice to inform the public that APHIS will accept written comments regarding the Petition for Determination of Nonregulated Status from any interested person for a period of 60 days from the date of this notice. The petition and any comments received are available for public review, and copies of the petition may be ordered (see the **ADDRESSES** section of this notice).

After the comment period closes, APHIS will review the data submitted by the petitioner, all written comments received during the comment period, and any other relevant information. Based on the available information, APHIS will furnish a response to the petitioner, either approving the petition in whole or in part, or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of AgrEvo's canola transformation events MS8, RF3, and their hybrid combination MS8/RF3, and the availability of APHIS' written decision.

Authority: 7 U.S.C. 150aa-150jj, 151-167, and 1622n; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(c).

Done in Washington, DC, this 2nd day of December 1998.

Joan M. Arnoldi,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98-32519 Filed 12-7-98; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Forest Service

Frank Church—River of No Return Wilderness (FC-RONR) Programmatic Management Plan, Boise, Bitterroot, Nez Perce, Payette, and Salmon-Challis National Forests; Boise, Custer, Idaho, Lemhi and Valley Counties, ID

AGENCY: Forest Service, USDA.

ACTION: Supplement of a Notice of Intent to extend the public comment period.

SUMMARY: This **Federal Register** notice revises the Notice of Availability published in the January 23, 1998 **Federal Register** (40 CFR 1506.9) Vol. 63, No. 15, page 3563. On January 15, 1998, the Forest Service issued a Draft Environmental Impact Statement for the

management of the Frank Church-River of No Return Wilderness. This revised notice of availability extends the time for public review and comment.

Comments will be due February 1, 1999.

FOR FURTHER INFORMATION CONTACT:

Kenneth T. Wotring, FC-RONR Wilderness Coordinator, RR 2 Box 600, H2y 93 S, Salmon ID 83467, telephone 208-756-5131.

Dated: December 1, 1998.

George Matejko,

Forest Supervisor, Salmon-Challis National Forest.

[FR Doc. 98-32499 Filed 12-7-98; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Action Affecting Export Privileges; KIYOYUKI YASUTOMI; Order Denying Permission To Apply for or Use Export Licenses

In the Matter of Kiyoyuki Yasutomi, M.E.I. Japan, 6F Sanyo Bldg., 1 Naitocho, Shinjuku-ku, Tokyo 160, Japan.

On January 5, 1998, Kiyoyuki Yasutomi (Yasutomi) was convicted in the United States District Court for the District of Columbia on one count of violating the Export Administration Act of 1979, as amended (currently codified at 50 USCA app. §§ 2401-2420 (1991 & Supp. 1998)) (the Act).¹ Yasutomi was convicted of knowingly reexporting and causing to be reexported, from Japan to Pakistan, computer equipment designated on the Commodity Control List, without obtaining the required authorization from the Department of Commerce.

Section 11(h) of the Act provides that, at the discretion of the Secretary of Commerce,² no person convicted of violating the Act, or certain other provisions of the United States Code, shall be eligible to apply for or use any license, including any License Exception, issued pursuant to, or provided by, the act or the Export

¹ The Act expired on August 20, 1994. Executive Order 12924 (3 CFR, 1994 Comp. 917 (1995)), extended by Presidential Notices of August 15, 1995 (3 CFR, 1995 Comp. 501 (1996)), August 14, 1996 (3 CFR, 1996 Comp. 298 (1997)), August 13, 1997 (3 CFR, 1997 Comp. 306 (1998)), and August 13, 1998 (63 FR 44121, August 17, 1998), continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act (50 USCA §§ 1701-1706 (1991 & Supp. 1998)).

² Pursuant to appropriate delegations of authority that are reflected in the Regulations, the Director, Office of Exporter Services, in consultation with the Director, Office of Export Enforcement, exercises the authority granted to the Secretary by Section 11(h) of the Act.