

Notices

Federal Register

Vol. 63, No. 68

Thursday, April 9, 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. 97-114-2]

Monsanto Co.; Availability of Determination of Nonregulated Status for Tomato Genetically Engineered for Insect Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the Monsanto Company's tomato line designated as 5345, which has been genetically engineered for resistance to certain lepidopteran insect pests, is 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 Monsanto Company in its petition for a determination of nonregulated status, an analysis of other scientific data, and our review of comments received from the public in response to a previous notice announcing our receipt of the Monsanto Company's petition. This notice also announces the availability of our written determination document and its associated environmental assessment and finding of no significant impact.

EFFECTIVE DATE: March 26, 1998.

ADDRESSES: The determination, an environmental assessment and finding of no significant impact, the petition, and all written comments received regarding the petition 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 to inspect those documents are asked to call in advance of visiting at (202) 690-

2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Sivramiah Shantharam, Biotechnology and Biological Analysis, PPQ, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-4882. To obtain a copy of the determination or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734-4885; e-mail: mkpeterson@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

On October 14, 1997, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 97-287-01p) from Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination that a tomato line designated as 5345, which has been genetically engineered for resistance to certain lepidopteran insect pests, does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

On November 28, 1997, APHIS published a notice in the **Federal Register** (62 FR 63312-63313, Docket No. 97-114-1) announcing that the Monsanto petition had been received and was available for public review. The notice also discussed the role of APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration in regulating the subject tomato line and food products derived from it. In that notice, APHIS solicited written comments from the public as to whether this tomato line posed a plant pest risk. The comments were to have been received by APHIS on or before January 27, 1998. During the designated 60-day comment period, APHIS received two negative comments on the subject petition, both of which were from consumer policy organizations. The commenters argue that APHIS should deny the subject petition because the petitioner's insect pest resistance management strategies are inadequate based on recently published information in scientific journals. However, APHIS regulatory authority is based on an assessment of plant pest risk. EPA is the lead agency dealing with pest resistance management strategies for transgenic insect resistant plants, and EPA has established a pest resistance management working group

to deal with pest resistance management issues. APHIS is working with EPA to examine the issues surrounding the development of pest resistance, and scientific consultations in public forums are being pursued in conjunction with the registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). While APHIS has carefully considered the comments submitted, our determination has not been affected by the points made by the commenters because they extend to authority exercised by EPA under FIFRA.

Analysis

Tomato line 5345 has been genetically engineered to express a CryIA(c) insect control protein derived from the common soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* HD-73 (Btk). The subject tomato line also expresses the *nptII* gene, which codes for the enzyme neomycin phosphotransferase (NPTII) and has been used as a selectable marker in the development of the transgenic tomato plants. While tomato line 5345 contains the *aad* gene, tests indicate that the AAD protein is not expressed in the subject tomato plants. Expression of the added genes is controlled in part by noncoding DNA sequences derived from the plant pathogens *Agrobacterium tumefaciens* and cauliflower mosaic virus. The *Agrobacterium* transformation method was used to transfer the added genes into the UC82B parental tomato plants.

The subject tomato line has been considered a regulated article under APHIS' regulations in 7 CFR part 340 because it contains gene sequences derived from plant pathogens. However, evaluation of field data reports from field tests of this tomato line conducted under APHIS notifications since 1995 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the environmental release of tomato line 5345.

Determination

Based on its analysis of the data submitted by Monsanto and a review of other scientific data and field tests of the subject tomato line, as well as comments submitted by the public regarding the subject petition, APHIS has determined that tomato line 5345:

(1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than tomato lines developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not cause damage to raw or processed agricultural commodities; and (5) will not harm threatened or endangered species or other organisms, such as bees, that are beneficial to agriculture. Therefore, APHIS has concluded that the subject tomato line and any progeny derived from hybrid crosses with other nontransformed tomato varieties will be as safe to grow as tomato in traditional breeding programs that are not subject to regulation under 7 CFR part 340.

The effect of this determination is that Monsanto's tomato line 5345 is no longer considered a regulated article under APHIS' regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of the subject tomato line or its progeny. However, importation of tomato line 5345 or seeds capable of propagation is still subject to the restrictions found in APHIS' foreign quarantine notices in 7 CFR part 319.

National Environmental Policy Act

An environmental assessment (EA) has been prepared to examine the potential environmental impacts associated with this determination. The EA was prepared in accordance with: (1) The National Environmental Policy Act of 1969, as amended (NEPA) (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 that EA, APHIS has reached a finding of no significant impact (FONSI) with regard to its determination that Monsanto's tomato line 5345 and lines developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and the FONSI are available upon request from the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Done in Washington, DC, this 3rd day of April 1998.

Craig A. Reed,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–9376 Filed 4–8–98; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request; Food Stamp Program Form FCS–278–B, Food Stamp Redemption Certificate and Form FCS–278–4, Wholesaler Redemption Certificate

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on proposed information collection. The Food Stamp Act of 1977 requires that FNS will provide all authorized retail food stores and wholesale food concerns with redemption certificates. The redemption certificates are to be used by retailers and wholesale firms to present food coupons to insured financial institutions for credit or for cash. Requirements in the Food Stamp Regulations are the basis for the information collected on Form FCS–278B, Food Stamp Redemption Certificate and Form FCS–287–4, Wholesaler Redemption Certificate.

DATES: Written comments must be submitted on or before June 8, 1998.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to: Suzanne M. Fecteau, Chief, Redemption Management Branch, Food Stamp Program, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, Virginia 22302–1594. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become matter of public record.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection form and instructions should be directed to Suzanne M. Fecteau, (703) 305–2418.

SUPPLEMENTARY INFORMATION:

Title: Food Stamp Redemption Certificate.

OMB Number: 0584–0085.

Expiration Date: 09/30/98.

Type of Request: Extension of a currently approved collection for which approval expires on September 30, 1998.

Abstract: The Food and Nutrition Service (FNS), of the U.S. Department of Agriculture, formerly known as the Food and Consumer Service (FCS), is the Federal Agency responsible for the Food Stamp Program. Section 10 of the Food Stamp Act of 1977, as amended, (the Act) (7 U.S.C. 2019), requires that FNS provide for the redemption through financial institutions, of food coupons accepted by approved retail food stores and wholesale food concerns from program participants. Sections 278.3 and 278.4 of the Food Stamp Program regulations govern the participation of authorized wholesale food concerns and retail stores in the food coupon redemption process. Form FCS–278B, Food Stamp Redemption Certificate and Form FCS–278–4, Wholesaler Redemption Certificate (RCs) are required to be used by all authorized wholesalers or retailers, and are processed by financial institutions when they are represented for credit or for cash. Without the RCs, no vehicle would exist for financial institutions, Federal Reserve Banks, and the FNS to track deposits of food coupons.

The burden associated with this form is derived from the number of RCs processed annually, based on information available in our STARS (Store Tracking Redemption System) database. As of December 1997, the number of program respondents was 184,300 retailers and wholesalers and 5,850 banks participating in the Food Stamp Program. The number of completed RC responses by authorized retailers was 20,750,000 annually, with total annual burden hours calculated to be 415,000 hours. We estimate that it takes an average of 1.2 minutes (or .020 hours) for a retailer to complete the information on the RC and for the financial institution to handle and process the document. In fiscal year 1999, we estimate that the number of program respondents will be 176,928 respondents with 5,850 banks continuing to participate in the Food Stamp Program—a reduction of 7,372 (or 4 percent) respondents. We also