

Notices

Federal Register

Vol. 60, No. 109

Wednesday, June 7, 1995

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. 95-041-1]

Receipt of Petition for Determination of Nonregulated Status for Genetically Engineered Corn

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 the Monsanto Company seeking a determination of nonregulated status for a corn line designated as MON 80100 that has been genetically engineered for insect resistance. 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 this corn line presents a plant pest risk.

DATES: Written comments must be received on or before August 7, 1995.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 95-041-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1237. Please state that your comments refer to Docket No. 95-041-1. 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.

FOR FURTHER INFORMATION CONTACT:

Dr. Ved Malik, Biotechnologist, Biotechnology Permits, BBEP, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1237; (301) 734-7612. To obtain a copy of the petition, contact Ms. Kay Peterson at (301) 734-7601.

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 April 3, 1995, APHIS received a petition (APHIS Petition No. 95-093-01p) from the Monsanto Company (Monsanto) of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for an insect-resistant corn line designated as MON 80100. The Monsanto petition states that the subject corn line should not be regulated by APHIS because it does not present a plant pest risk.

As described in the petition, corn line MON 80100 has been genetically engineered with the *cryIA(b)* gene that encodes for a CryIA(b) insect control protein derived from the common soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* (*Btk*). This protein is a member of a class of insecticidal proteins, also known as delta-endotoxins, that are produced as parasporal crystals by *B. thuringiensis* in nature, and are known to be quite selective in their toxicity to specific organisms, while nontoxic to all other organisms. *Btk* proteins are effective against certain lepidopteran insects, including European corn borer

(ECB). ECB is a major corn pest that reduces yield by disrupting normal plant physiology and causing damage to the leaves, stalks, and ears. Results of field tests conducted by Monsanto under permits and notifications granted by APHIS and under an experimental use permit obtained from the Environmental Protection Agency (EPA) indicate that corn plants producing the CryIA(b) protein were protected throughout the growing season from leaf and stalk feeding damage caused by ECB. In addition to expressing the CryIA(b) protein, the plants also express the selectable marker enzyme 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS). The *cryIA(b)* gene and the CP4 EPSPS marker gene were introduced into the subject corn line by a particle acceleration method and their expression is under the control of the enhanced 35S promoter derived from the plant pathogen cauliflower mosaic virus.

Monsanto's MON 80100 corn line is currently considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences derived from plant pathogenic sources. The subject corn line was evaluated in field trials conducted under APHIS permits or notifications from 1992 through 1994. In the process of reviewing the applications for field trials of the subject corn, 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.

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.

This genetically engineered corn line is also currently subject to regulation by other agencies. The 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 insecticides, be registered prior to distribution or sale, unless exempted by EPA regulation. Accordingly, Monsanto has submitted to the EPA an application to register the transgenic plant pesticide *Btk* CryIA(b) insect control protein as produced in corn.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301 *et seq.*), pesticides added to raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Foods containing unsafe pesticides are deemed to be adulterated. Residue tolerances for pesticides are established by the EPA under the FFDCA; the Food and Drug Administration (FDA) enforces the tolerances set by the EPA. Monsanto has also submitted to the EPA a pesticide petition (PP 5F4473) proposing to amend 40 CFR part 180 to establish a tolerance exemption for residues of the plant pesticide active ingredient *B. thuringiensis* delta-endotoxin as produced in corn by a *cryIA(b)* gene and its controlling sequences.

Consistent with the "Coordinated Framework for Regulation of Biotechnology" (51 FR 23302-23350, June 26, 1986), APHIS and the EPA are coordinating their review of this genetically engineered corn line to avoid duplication and ensure that all relevant issues are addressed.

The 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 the FDA 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.

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 Monsanto's MON 80100 corn line 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 2.17, 2.51, and 371.2(c).

Done in Washington, DC, this 1st day of June 1995.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95-13919 Filed 6-6-95; 8:45 am]

BILLING CODE 3410-34-M

Commodity Credit Corporation

Secretary of Agriculture's Special Cotton Quota Announcement Number 1

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice.

SUMMARY: Special import quota for upland cotton equal to 46,757,469 kilograms (103,082,657 pounds) is established in accordance with section 103B(a)(5)(F) of the Agricultural Act of 1949, as amended (1949 Act). This quota is established under Proclamation 6301 of June 7, 1991, and is referenced as the Secretary of Agriculture's Special Cotton Quota Announcement Number 1, chapter 99, subchapter III, subheading 9903.52.01 of the Harmonized Tariff Schedule (HTS).

DATES: The quota was established on April 12, 1995, and applies to upland cotton purchased not later than July 10, 1995 (90 days from the date the quota was established) and entered into the United States not later than October 8, 1995 (180 days from the date the quota was established).

FOR FURTHER INFORMATION CONTACT: Janise Zygmont, Consolidated Farm Service Agency, United States Department of Agriculture, room 3756-S, PO Box 2415, Washington, DC 20013-2415 or call (202) 720-8841.

SUPPLEMENTARY INFORMATION: The 1949 Act requires that a special import quota

be determined and announced immediately if, for any consecutive 10-week period, the Friday through Thursday average price quotation for the lowest-priced U.S. growth, as quoted for Middling 1 3/32 inch cotton, C.I.F. northern Europe, (U.S. Northern Europe price), adjusted for the value of any cotton user marketing certificates issued, exceeds the Northern Europe price by more than 1.25 cents per pound. This condition was met during the consecutive 10-week period that ended April 6, 1995. The quota amount is equal to 1 week's consumption of upland cotton by domestic mills at the seasonally-adjusted average rate of the most recent 3 months for which data are available—December 1994 through February 1995. The special import quota identifies quantity of imports that is not subject to the over-quota tariff rate of a tariff-rate quota. The quota is not divided by staple length or by country of origin. The quota does not affect existing tariff rates or phytosanitary regulations. The quota does not apply to Extra Long Staple cotton.

Authority: 7 U.S.C. 1444-2(a) and U.S. Note 6(a), Subchapter III, Chapter 99 of the HTS.

Signed at Washington, DC, on May 25, 1995.

Dan Glickman,

Secretary.

[FR Doc. 95-13914 Filed 6-6-95; 8:45 am]

BILLING CODE 3410-05-M

Secretary of Agriculture's Special Cotton Quota Announcement Number 2

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice.

SUMMARY: A special import quota for upland cotton equal to 46,757,469 kilograms (103,082,657 pounds) is established in accordance with section 103B(a)(5)(F) of the Agricultural Act of 1949, as amended (1949 Act). This quota is established under Proclamation 6301 of June 7, 1991, and is referenced as the Secretary of Agriculture's Special Cotton Quota Announcement Number 2, chapter 99, subchapter III, subheading 9903.52.02 of the Harmonized Tariff Schedule (HTS).

DATES: The quota was established on April 19, 1995, and applies to upland cotton purchased not later than July 17, 1995 (90 days from the date the quota was established) and entered into the United States not later than October 15, 1995 (180 days from the date the quota was established).