

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. 94-139-1]

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

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 cotton lines 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 these genetically engineered cotton lines present a plant pest risk.

DATES: Written comments must be received on or before April 10, 1995.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 94-139-1, Animal and Plant Health Inspection Service, Policy and Program Development, Regulatory Analysis and Development, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 94-139-1. 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. Keith Reding, Biotechnologist, Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Biotechnology Permits, 4700 River Road Unit 147, Riverdale, MD 20737-1237. The telephone number for the agency contract will change when agency offices in Hyattsville, MD, move to Riverdale, MD, during February. Telephone: (301) 436-7612 (Hyattsville); (301) 734-7612 (Riverdale). To obtain a copy of the petition, contact Ms. Kay Peterson at (301) 436-7601 (Hyattsville) or (301) 734-7601 (Riverdale).

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 regulation 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 November 4, 1994, APHIS received a petition (APHIS Petition No. 94-308-01p) from the Monsanto Company of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for a cotton line designated as 531, genetically engineered to produce an insecticidal protein for resistance to lepidopteran insect pests. On January 10, 1995, Monsanto amended the petition to add two additional lines designated as 757 and 1076. The three cotton lines, 531, 757, and 1076, are trademarked by Monsanto as Bollgard™ Cotton Lines. The Monsanto petition states that the subject cotton lines 531, 757, and 1076,

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

As described in the petition, the subject cotton lines were developed to produce an insect control protein derived from the common soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* (*Btk*). This genetically engineered insect control protein is nearly identical (differing in only 6 of 1,178 nonessential amino acids) to one of the proteins encoded by the *cryIA(c)* gene. This protein is naturally produced by *Btk* and found in commercial microbial *Btk* formulations registered as pesticides with the Environmental Protection Agency (EPA). According to Monsanto, the protein is highly selective in controlling such lepidopteran cotton pests as cotton bollworm, tobacco budworm, and pink bollworm, and is expressed at a consistent level in the cotton plant throughout the growing season. The expression of this insect control protein is regulated by a promoter and terminating sequence. The promoters were either the 35S sequence derived from the cauliflower mosaic virus or a promoter from an alternate source. Terminating sequences used were either the 7S 3' non-translated region of the soybean alpha subunit of the beta-conglycinin gene or the E9 3' sequence from the pea ribulose-1,5-bisphosphate carboxylase, small subunit (*rbcS*).

The subject cotton lines also contain the *nptII* gene from the prokaryotic transposon Tn5 which encodes the enzyme neomycin phosphotransferase II. The expression of this gene in the subject cotton lines is regulated by the 35S promoter, as described above, and the nontranslated 3' region of the nopaline synthase gene derived from the plant pathogen *Agrobacterium tumefaciens*. The expression of this enzyme in the subject cotton lines allows for selective growth of transgenic plant cells on the antibiotic kanamycin during plant tissue culture. These genes were stably transferred into the genome of cotton plants using *A. tumefaciens*-mediated transformation utilizing a binary, single-border plant expression vector.

Monsanto's cotton lines 531, 757, and 1076 are currently considered regulated articles under the regulations in 7 CFR part 340 because they contain gene sequences (vectors, promoters, and

terminators) derived from plant pathogenic sources. In cotton growing locations throughout the United States, cotton line 531 was evaluated under 5 APHIS permits issued between 1991 and 1993, and cotton lines 757 and 1076 were tested under 6 APHIS permits or notifications in 1993 and 1994. After reviewing Monsanto's permit applications for field trials of cotton lines 531, 757, and 1076, 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.

These genetically engineered cotton lines are 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 exempt by EPA regulation. Accordingly, Monsanto has submitted to EPA an application for a conditional registration for a transgenic plant pesticide containing the new active ingredient Btk delta endotoxin protein as produced by the cryIA(c) gene and its controlling sequences. On September 29, 1994, EPA announced receipt of this application (EPA File Symbol 524-UTT) in the **Federal Register** (59 FR 49663, OPP-30373; FRL-4913-5).

Under the Federal Food, Drug, and Cosmetic Act (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 EPA under the Federal Food, Drug, and Cosmetic Act; the Food and Drug Administration (FDA) enforces the tolerances set by the EPA. Monsanto has also submitted to the EPA a pesticide petition (PP 4F4331) proposing to amend 40 CFR part 180 to establish a tolerance exemption for residues of the plant pesticide active ingredient Btk delta endotoxin protein as produced by the cryIA(c) gene and its controlling sequences. On September 14, 1994, EPA announced receipt of this petition in the **Federal Register** (59 FR 47136-47137, PF-605; FRL-4904-7). Consistent with the "Coordinated Framework for Regulation of Biotechnology" (51 FR 23302-23350, June 26, 1986), APHIS and the EPA are coordinating their reviews of these genetically engineered cotton lines to avoid duplication and assure 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 Federal Food, Drug, and Cosmetic Act, 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 genetically engineered cotton lines 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 3rd day of February 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95-3290 Filed 2-8-95; 8:45 am]

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[Docket 94-119-3]

Boll Weevil Control Program; Change of Public Hearing Site

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 changed the location and time of one of two public hearings scheduled to be held regarding an environmental assessment and preliminary finding of no significant impact for a proposed program to eradicate the boll weevil in the Lower Rio Grande Valley, Texas. The hearings were announced in a notice published in the **Federal Register** on January 30, 1995. We have changed the site and time of the second hearing in response to requests from the public.

DATES: Two public hearings will be held on February 16, 1995, in Weslaco, TX; one from 1 p.m. to 5:30 p.m., the other from 7:30 p.m. to 10:30 p.m. Pre-hearing registration for oral participation at a hearing may be made by mail (postmarked on or before February 8, 1995), or at the hearing site on the date of the hearings, beginning one hour prior to each hearing.

ADDRESSES: The first public hearing (1 p.m. to 5:30 p.m.) will be held in the Hoblitzelle Auditorium, Texas Agriculture Experiment Station, 2415 East Highway 83, Weslaco, TX. The second public hearing (7:30 p.m. to 10:30 p.m.) will be held at the Best Western Palm Air Motor Inn, 415 South International Boulevard (Highway 1015), Weslaco, TX. Registration for oral participation at either hearing may be mailed to Vicki Wickheiser, Environmental Analysis and Documentation, BBEP, APHIS, USDA, Room 543, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

FOR FURTHER INFORMATION CONTACT: Vicki Wickheiser at the address listed above or by telephone at (301) 436-8963.

SUPPLEMENTARY INFORMATION: On January 30, 1995, the Animal and Plant Health Inspection Service published in the **Federal Register** (60 FR 5617-5618, Docket No. 94-119-2) a notice that, in part, announced that two public