

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. 95-007-1]

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 Ciba Seeds seeking a determination of nonregulated status for corn designated as "Event 176 Corn" 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 presents a plant pest risk.

DATES: Written comments must be received on or before April 24, 1995.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 95-007-1, 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. 95-007-01. 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, 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 of the agency 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, "Information 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 November 15, 1994, APHIS received a petition (APHIS Petition No. 94-319-01p) from Ciba Seeds (a division of Ciba-Geigy Corporation) of Research Triangle Park, NC, requesting a determination of nonregulated status under 7 CFR part 340 for insect-resistant corn designated as "Event 176 Corn." Event 176 Corn is genetically engineered with the synthetic gene that codes for an insecticidal protein naturally produced by *Bacillus thuringiensis* subsp. *kurstaki* (*Btk*). The Ciba Seeds petition states that the subject corn should not be regulated by APHIS because it does not present a plant pest risk.

As described in the petition, the subject corn was genetically engineered

to produce an insect control protein representing a truncated form of the CryIA(b) protein that occurs naturally in *Btk*, a common gram-positive soil bacterium. 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 very effective against certain lepidopteran (caterpillar) insects, including European corn borer (ECB) (*Ostrinia nubilalis* (Hubner)). ECB is a major corn pest that reduces yield by disrupting normal plant physiology and causing physical damage to the plant and ear that results in stalk lodging, dropped ears, and damaged grain. Results of field tests conducted by Ciba Seeds under permits granted by AHPIS and the Environmental Protection Agency (EPA) indicate that corn plants producing the CryIA(b) protein are quite effective in controlling ECB. The corn plants under evaluation preferentially express the insect control protein in leaf tissue and pollen (both feeding sources for ECB), while minimizing its production in other plant tissues, including kernels, where it is not needed for control of the target pest.

As described in the petition, the *cryIA(b)* gene expressed in the transgenic corn plants encodes a protein that is identical to the first 648 amino acids of the full-length, 1,155-amino-acid CryIA(b) protein that occurs in nature. This truncated protein contains the portion of the native protein that is responsible for its insecticidal activity. Two different tissue-specific promoters, both derived from corn, confer protein expression in green tissue and pollen, respectively. In addition to expressing the CryIA(b) protein, the plants also express the enzyme phosphinothricin acetyltransferase, currently used in the plant as a selectable marker. Expression of the selectable market gene is regulated by the 35S promoter, while expression of the CryIA(b) protein is controlled in part by the 35S terminator. The 35S promoter and the 35S terminator are derived from the plant pathogen cauliflower mosaic virus.

Ciba Seeds' Event 176 Corn is currently considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences

(vectors, promoters, and terminators) derived from plant pathogenic sources. Event 176 Corn was evaluated in field trials conducted under APHIS permits in 1992 and 1993, and under APHIS notifications in 1993 and 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 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 exempt by EPA regulation. Accordingly, Ciba Seeds has submitted to the EPA an application to register this transgenic plant pesticide, the *Btk* CryIA(b) insect control protein as produced in corn. On January 13, 1995, EPA announced receipt of this application (EPA File Symbol 66736-R) in the **Federal Register** (60 FR 3209; OPP-30377; FRL-4928-9).

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.

Ciba Seeds has also submitted to the EPA a pesticide petition (pp 4F4395) 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. On February 1, 1995, EPA announced receipt of this petition in the **Federal Register** (60 FR 6092-6093; PF-618; FRL-4930-3).

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 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 Ciba Seeds' Event 176 Corn 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 13th day of February 1995.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95-4182 Filed 2-17-95; 8:45 am]

BILLING CODE 3410-34-M

[Docket No. 95-010-1]

Receipt of Permit Applications for Release Into the Environment of Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that seven applications for permits to release genetically engineered organisms into the environment are being reviewed by the Animal and Plant Health Inspection Service. The applications have been submitted in accordance with 7 CFR part 340, which regulates the introduction of certain genetically engineered organisms and products.

ADDRESSES: Copies of the applications referenced in this notice, with any confidential business information deleted, are available for public inspection in room 1141, South Building, U.S. Department of Agriculture, 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 an application are requested to call ahead on (202) 690-2817 to facilitate entry into the reading room. You may obtain copies of the documents by writing to the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Foudin, Deputy Director, 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 contact will change when agency offices in Hyattsville, MD, move to Riverdale, MD, during February. Telephone: (301) 436-7612 (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," require a person to obtain a permit before introducing (importing, moving