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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