Notices

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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

FOR FURTHER INFORMATION CONTACT:

of visiting at (202) 690-2817.

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 insectresistant 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 5enolpyruvylshikimate-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