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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 95-059-1]

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 Dekalb Genetics Corporation seeking a determination of nonregulated status for a corn line designated as B16 that has been genetically engineered for tolerance to the herbicide glufosinate. 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 October 2, 1995.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 95-059-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 95-059-1. 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, 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 May 25, 1995, APHIS received a petition (APHIS Petition No. 95-145-01p) from the Dekalb Genetics Corporation (Dekalb) of Mystic, CT, requesting a determination of nonregulated status under 7 CFR part 340 for a glufosinate tolerant corn line designated as B16. The Dekalb 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 B16 has been genetically engineered with the *bar* gene isolated from *Streptomyces hygrosopicus* that encodes a phosphinothricin acetyltransferase (PAT) enzyme, which, when introduced into a plant cell, inactivates glufosinate, also known as phosphinothricin, the active ingredient in the herbicide Liberty®. The *bar* gene was introduced into the subject corn line by microprojectile bombardment and its expression is under the control of the 35S promoter derived from the plant pathogen cauliflower mosaic virus

and the *Agrobacterium tumefaciens* transcript 7 (Tr 7) 3' regulatory region. Dekalb's corn line B16 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 has been evaluated in field trials conducted since 1991 under APHIS permits or notifications. 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 U.S. Environmental Protection Agency (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 herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. Plants that have been genetically modified for tolerance or resistance to herbicides are not regulated under the FIFRA because the plants themselves are not considered pesticides.

In cases in which the genetically modified plants allow for a new use of an herbicide or involve a different use pattern for the herbicide, the EPA must approve the new or different use. In

conducting such an approval, the EPA considers the possibility of adverse effects to human health and the environment from the use of this herbicide. When the use of the herbicide on the genetically modified plant would result in an increase in the residues of the herbicide in a food or feed crop for which the herbicide is currently registered, or in new residues in a crop for which the herbicide is not currently registered, establishment of a new tolerance or a revision of the existing tolerance would be required. Residue tolerances for pesticides are established by the EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 201 *et seq.*), and the Food and Drug Administration (FDA) enforces tolerances set by the EPA under the FFDCA.

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's 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 Dekalb's corn line B16 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 24th day of July 1995.

Lonnie J. King,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95-18777 Filed 7-31-95; 8:45 am]

BILLING CODE 3410-34-P

Grain Inspection, Packers and Stockyards Administration

Opportunity for Designation in the Alton (IL), Columbus (OH), and Farwell (TX) Areas

AGENCY: Grain Inspection, Packers and Stockyards Administration (GIPSA).

ACTION: Notice.

SUMMARY: The United States Grain Standards Act, as amended (Act), provides that official agency designations will end not later than triennially and may be renewed. The designation of Alton Grain Inspection Department (Alton), will end March 31, 1996; the designation of Columbus Grain Inspection, Inc. (Columbus), will end February 28, 1996; and the designation of Farwell Grain Inspection, Inc. (Farwell), will end January 31, 1996, according to the Act, and GIPSA is asking persons interested in providing official services in the Alton, Columbus, and Farwell areas to submit an application for designation.

DATES: Applications must be postmarked or sent by telecopier (FAX) on or before August 30, 1995.

ADDRESSES: Applications must be submitted to Janet M. Hart, Chief, Review Branch, Compliance Division, GIPSA, USDA, Room 1647 South Building, P.O. Box 96454, Washington, DC 20090-6454. Telecopier (FAX) users may send applications to the automatic telecopier machine at 202-690-2755, attention: Janet M. Hart. If an application is submitted by telecopier, GIPSA reserves the right to request an original application. All applications will be made available for public inspection at this address located at 1400 Independence Avenue, S.W., during regular business hours.

FOR FURTHER INFORMATION CONTACT: Janet M. Hart, telephone 202-720-8525.

SUPPLEMENTARY INFORMATION:

This action has been reviewed and determined not to be a rule or regulation as defined in Executive Order 12866 and Departmental Regulation 1512-1; therefore, the Executive Order and Departmental Regulation do not apply to this action.

Section 7(f)(1) of the Act authorizes GIPSA' Administrator to designate a qualified applicant to provide official

services in a specified area after determining that the applicant is better able than any other applicant to provide such official services.

GIPSA designated Alton, main office located in Florissant, Missouri, to provide official inspection services under the Act on April 1, 1993; Columbus, main office located in Circleville, Ohio, to provide official inspection services under the Act on March 1, 1993; and Farwell, main office located in Farwell, Texas, to provide official inspection services under the Act on February 1, 1993.

Section 7(g)(1) of the Act provides that designations of official agencies shall end not later than triennially and may be renewed according to the criteria and procedures prescribed in Section 7(f) of the Act. The designation of Alton ends on March 31, 1996. The designation of Columbus ends on February 28, 1996, and the designation of Farwell ends on January 31, 1996.

The geographic area presently assigned to Alton, in the State of Illinois, pursuant to Section 7(f)(2) of the Act, which may be assigned to the applicant selected for designation is as follows:

Calhoun, Jersey, and Madison (West of State Route 4 and North of Interstate 70 and 270) Counties.

The geographic area presently assigned to Columbus, in the States of Ohio and Michigan, pursuant to Section 7(f)(2) of the Act, which may be assigned to the applicant selected for designation is as follows:

In Ohio:

Bounded on the North by the northern Lucas County line east to Lake Erie; the Lake Erie shoreline east to the Ohio-Pennsylvania State line;

Bounded on the East by the Ohio-Pennsylvania State line south to the Ohio River;

Bounded on the South by the Ohio River south-southwest to the western Scioto County line; and

Bounded on the West by the western Scioto County line north to State Route 73; State Route 73 northwest to U.S. Route 22; U.S. Route 22 west to U.S. Route 68; U.S. Route 68 north to Clark County; the northern Clark County line west to State Route 560; State Route 560 north to State Route 296; State Route 296 west to Interstate 75; Interstate 75 north to State Route 47; State Route 47 northeast to U.S. Route 68 (including all of Sidney, Ohio); U.S. Route 68 north to U.S. Route 30; U.S. Route 30 east to State Route 19; State Route 19 north to Seneca County; the southern Seneca County line west to State Route 53; State Route 53 north to Sandusky County; the southern Sandusky County line west to State Route 590; State Route 590 north