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. 95–097–1]

Agritope, Inc.; Receipt of Petition for Determination of Nonregulated Status for Cherry Tomato Line Genetically Engineered for Modified Fruit Ripening

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 Agritope, Inc., seeking a determination of nonregulated status for a cherry tomato line designated as 35–1–N that has been genetically engineered for modified fruit ripening. 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 cherry tomato line presents a plant pest risk.

DATES: Written comments must be received on or before March 25, 1996.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 95–097–1, 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. 95–097–1. 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. Ved Malik, 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) 734–7612.

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 November 20, 1995, APHIS received a petition (APHIS Petition No. 95–324–01p) from Agritope, Inc., (Agritope) of Beaverton, OR, requesting a determination of nonregulated status under 7 CFR part 340 for a cherry tomato line designated as 35–1–N (line 35–1–N) that has been genetically engineered to contain a gene that alters fruit ripening. The Agritope petition states that cherry tomato line 35–1–N should not be regulated by APHIS because it does not present a plant pest risk.

As described in the petition, line 35–1–N has been genetically engineered to contain the *sam-k* gene derived from *Escherichia coli* bacteriophage T3 that encodes an enzyme, *S*-adenosylmethionine hydrolase (SAMase), which alters the ethylene biosynthetic pathway and delays ripening of the tomato on the vine. The fruit of line 35–1–N ripen normally when exposed to exogenous ethylene. The subject tomato line also contains the *nptII* gene from the prokaryotic transposon Tn5, which encodes the enzyme neomycin phosphotransferase II and is used as a selectable marker for transformation. Expression of the added genes is controlled by the untranslated 3' region of the nopaline synthase gene from *Agrobacterium tumefaciens.* The modified E8 gene promoter from tomatoes is used to drive the *sam-k* gene in a developmentally regulated manner. The *A. tumefaciens* vector system was used to transfer the construct pAG–5420 containing the DNA elements described above into the Large Red Cherry parental line.

Line 35–1–N has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from the plant pathogen *A. tumefaciens.* The subject cherry tomato line has been evaluated in field trials conducted since 1992 under APHIS permits or notifications. In the process of reviewing the applications for field trials of line 35–1–N, 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.

The Food and Drug Administration (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 FDA's authority for ensuring food safety under the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 201 *et seq.*), 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 Agritope's cherry tomato line 35–1–N 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 2.22, 2.80, and 371.2(c).

Done in Washington, DC, this 17th day of January 1996.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–871 Filed 1–22–96; 8:45 am]

BILLING CODE 3410–34–P

[Docket No. 95–059–2]

Dekalb Genetics Corporation; Availability of Determination of Nonregulated Status for Corn Line Genetically Engineered for Glufosinate Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that a corn line developed by the Dekalb Genetics Corporation designated as B16 that has been genetically engineered for tolerance to the herbicide glufosinate is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by the Dekalb Genetics Corporation in its petition for a determination of nonregulated status, an analysis of other scientific data, and our review of comments received from the public in response to a previous notice announcing our receipt of the Dekalb Genetics Corporation's petition. This notice also announces the availability of our written determination document and its associated environmental assessment and finding of no significant impact.

EFFECTIVE DATE: December 19, 1995.

ADDRESSES: The determination, an environmental assessment and finding of no significant impact, the petition, and all written comments received regarding the petition 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 to inspect those documents are asked to call in advance of visiting at (202) 690–2817.

FOR FURTHER INFORMATION CONTACT: Dr. Keith Reding, Biotechnologist, Biotechnology Permits, BBEP, APHIS, 4700 River Road, Unit 147, Riverdale, MD 20737–1237; (301) 734–7612. To obtain a copy of the determination or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734–7612.

SUPPLEMENTARY INFORMATION:

Background

On May 25, 1995, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 95–145–01p) from the Dekalb Genetics Corporation (Dekalb) of Mystic, CT, seeking a determination that a corn line designated as B16 that has been genetically engineered for tolerance to the herbicide glufosinate does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

On August 1, 1995, APHIS published a notice in the Federal Register (60 FR 39146–39147, Docket No. 95–059–1) announcing that the Dekalb petition had been received and was available for public review. The notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject corn line and food products derived from it. In the notice, APHIS solicited written comments from the public as to whether the subject corn line posed a plant pest risk. The comments were to have been received by APHIS on or before October 2, 1995.

APHIS received a total of six comments on the subject petition from universities, State departments of agriculture, and an agency of the U.S. government. None of the commenters expressed opposition to the subject petition.

Analysis

Corn line B16 has been genetically engineered with a modified version of the *bar* gene from *Streptomyces hygroscopicus* that encodes a phosphinothricin acetyltransferase (PAT) enzyme. When introduced into the plant cell, the PAT enzyme can inactivate glufosinate herbicides. 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 Tr7 terminator from *Agrobacterium tumefaciens*.

Corn line B16 has been considered a regulated article under APHIS' regulations in 7 CFR part 340 because it contains regulatory gene sequences derived from the plant pathogens mentioned above. However, evaluation of field data reports from field tests of the subject corn line conducted under APHIS permits or notifications since 1991 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the subject corn plants' release into the environment.

Determination

Based on its analysis of the data submitted by Dekalb and a review of other scientific data, comments received, and field tests of the subject corn line, APHIS has determined that corn line B16: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than corn developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not harm other organisms, including agriculturally beneficial organisms and threatened and endangered species; and (5) should not cause damage to raw or processed agricultural commodities. Therefore, APHIS has concluded that corn line B16 and any progeny derived from hybrid crosses with other nontransformed corn varieties will be just as safe to grow as traditionally bred corn lines that are not regulated under 7 CFR part 340.

The effect of this determination is that a corn line designated as B16 is no