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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. 94-121-2]

Availability of Determination of Nonregulated Status for Genetically Engineered Potato Lines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that certain potato lines genetically engineered for resistance to the Colorado potato beetle by the Monsanto Company are no longer considered regulated articles under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by the Monsanto Company 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 Monsanto Company 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: March 2, 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. Susan Koehler, Biotechnologist, Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Biotechnology Permits, 4700 River Road Unit 147, Riverdale, MD 20737-1228; (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 September 14, 1994, the Animal and Plant Health Inspection Service (APHIS) received a petition from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination that seven Russet Burbank potato lines designed at BT6, BT10, BT12, BT16, BT17, BT18, and BT23, that have been genetically engineered for resistance to the Colorado potato beetle (CPB) (hereinafter CPB-resistant potato lines) do not present a plant pest risk and, therefore, are not regulated articles under APHIS' regulations in 7 CFR part 340.

On December 2, 1994, APHIS published a notice in the Federal Register (59 FR 61866-61867, Docket No. 94-121-1) announcing receipt of the Monsanto petition and announcing that the petition 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 potato lines and food products derived from them. In the notice, APHIS solicited written comments from the public as to whether the subject potato lines posed a plant pest risk. The comments were to have been received by APHIS on or before January 31, 1995.

APHIS received a total of 61 comments on the Monsanto petition. Comments were received from the following categories of respondents, with the categories containing the larger number of respondents listed first: potato farmers; universities; registered dietitians; regional and national potato growers' association, councils, and boards; cooperative extension service offices; State departments of agriculture; high school educators; individuals; potato marketing services; a potato research company; an agricultural experiment station; the department of agriculture of a foreign government; a

food company; an international technology transfer agency; a potato processor; and a member of the U.S. House of Representatives. Fifty-eight of the commenters urged approval of the petition or provided information in support of nonregulated status for the subject potato lines. Three of the 61 commenters did not directly or indirectly support approval of the petition: one of the three did not address the APHIS approval process; another endorsed the concept of the development of a CPB-resistant potato but expressed certain concerns; and one commenter asked that APHIS deny the petition. APHIS has provided a summary and discussion of the comments in the determination document, which is available upon request from the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Analysis

The Monsanto CPB-resistant potato lines have been genetically engineered to express a gene from the common soil bacterium *Bacillus thuringiensis* subsp. *tenebrionis* (*Btt*) that encodes a highly selective insecticidal delta-endotoxin crystalline protein, CryIIIa. This insect control protein is identical in amino acid sequence to one of the proteins naturally produced by *Btt* and found in commercial microbial *Btt* formulations. According to Monsanto, the protein is highly selective in controlling CPB and is expressed at an effective level in the potato foliage throughout the growing season. The expression of the insect control protein in the subject potato lines is regulated by an enhanced 35S promoter derived from the plant pathogen cauliflower mosaic virus and by the nontranslated region of the small subunit of ribulose-1,5-bisphosphate carboxylase referred to as E9 3' derived from pea plants. The CPB-resistant potato lines also express a selectable marker gene derived from the prokaryotic transposon Tn5 encoding the enzyme neomycin phosphotransferase II (*nptII*). The expression of the *nptII* gene in the subject potato lines is regulated by the 35S promoter and the nontranslated 3' region of the nopaline synthase gene derived from the plant pathogen *Agrobacterium tumefaciens*. The expression of *nptII* in the subject potato lines allows for selective growth of transgenic plant cells on the antibiotic

kanamycin during plant tissue culture. These genes were stably transferred into the genome of potato plants through an *A. tumefaciens*-mediated transformation.

The subject potato lines have been considered "regulated articles" under APHIS' regulations in 7 CFR part 340 because their noncoding regulatory sequences were derived from the plant pathogens *A. tumefaciens* and cauliflower mosaic virus. However, evaluation of field data reports from field tests of the subject potato lines conducted since 1991 in the major potato-growing areas of the country indicate that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the subject potato lines' release into the environment.

Determination

Based on its analysis of the data submitted by Monsanto, a review of other scientific data, the comments received from the public, and a review of field tests of the subject potato lines, APHIS has determined that the subject potato lines: (1) Exhibit no plant pathogenic properties; (2) are no more likely to become weeds than CPB-resistant potato lines that could potentially be developed by traditional breeding techniques; (3) are unlikely to increase the weediness potential of any other cultivated plant or native wild species with which the organisms can interbreed; (4) will not cause damage to processed agricultural commodities; (5) are unlikely to harm other organisms, such as bees or earthworms, that are beneficial to agriculture; and (6) should pose no greater threat to the ability to control CPB in potatoes and other crops than that posed by the widely-practiced method of applying insecticides to control CPB on potatoes. APHIS has also concluded that there is a reasonable certainty that new varieties developed from the subject potato lines will not exhibit new plant pest properties, i.e., properties substantially different from any observed in the field-tested potato lines, or those observed in standard potatoes in traditional breeding programs.

The effect of this determination is that the seven Russet Burbank potato lines designated as BT6, BT10, BT12, BT16, BT17, BT18, and BT23 and all other lines developed from them are no longer considered regulated articles under APHIS' regulations in 7 CFR part 340. Therefore, the permit and notification requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of

the subject potato lines or their progeny. However, the importation of the subject potato lines and any potato nursery stock or seeds capable of propagation is still subject to the restrictions from APHIS' foreign quarantine notices in 7 CFR part 319.

National Environmental Policy Act

An environmental assessment (EA) has been prepared to examine the potential environmental impacts associated with this determination. The EA was prepared in accordance with: (1) The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500-1508), (3) USDA Regulations Implementing NEPA (7 CFR part 1b), and (4) APHIS NEPA Procedures. Based on that EA, APHIS has reached a finding of no significant impact (FONSI) with regard to its determination that the subject potato lines and other lines developed from those lines are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and the FONSI are available upon request from the individual listed under FOR FURTHER INFORMATION CONTACT.

Done in Washington, DC, this 6th day of March 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95-5993 Filed 3-9-95; 8:45 am]

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