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 Gentically 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 (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 solicted 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 patato 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) the 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 patato 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

Notices

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