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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. 93-116-2]

Availability of Determination of Nonregulated Status of Calgene, Inc., Genetically Engineered Cotton Lines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of determination.

SUMMARY: The Animal and Plant Health Inspection Service (APHIS) is announcing the issuance of a determination that certain trademarked cotton lines, designated BXN™ cotton, do not present a plant pest risk and are therefore no longer regulated articles under its regulations. APHIS' determination has been made in response to a petition received from Calgene, Inc., of Davis, CA, on July 15, 1993, seeking a determination from APHIS that BXN™ cotton does not present a plant pest risk and is therefore no longer a regulated article. The effect of this determination is that cotton lines meeting the definition of BXN™ cotton and that have been field tested under permit, will no longer be subject to regulation. This notice also announces the availability of the determination that provides the basis for the ruling, as well as the availability of an environmental assessment of this action.

EFFECTIVE DATE: February 15, 1994.

ADDRESSES: The determination, the environmental assessment, the Calgene, Inc. submission, and written comments received in response to our September 8, 1993, notice published in the Federal Register 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 this room are requested to call ahead on (202) 690-2817.

FOR FURTHER INFORMATION CONTACT: Dr. Michael Schechtman, Senior Microbiologist, Biotechnology, Biologics, and Environmental Protection, APHIS, USDA, room 850 Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7601. For a copy of the determination or the environmental assessment, please write or call Ms. Kay Peterson at this same address and telephone number.

SUPPLEMENTARY INFORMATION: On September 8, 1993 (58 FR 47249-47250, Docket No. 93-116-1), the Animal and Plant Health Inspection Service (APHIS) published a notice announcing receipt of a petition from Calgene, Inc. (Calgene) of Davis, CA, that requested a determination on the regulatory status of BXN™ cotton. This notice also indicated the role of the Food and Drug Administration and the United States Environmental Protection Agency in the regulation of food products derived from BXN™ cotton and the potential use of the herbicide bromoxynil on BXN™ cotton, respectively. This notice further announced that the petition was available for public review and invited written comments on whether BXN™ cotton poses a plant pest risk, to be submitted on or before November 8, 1993.

Comments

APHIS received a total of 45 comments from State officials, universities, farmers associations and cooperative extension services, environmental and consumer organizations, and business and professional associations. Among these commenters, 34 were in favor of granting the petition, 9 were opposed, and 2 others addressed APHIS' decision on the petition itself only parenthetically. APHIS has provided a complete discussion of the comments and any issues raised by the commenters in the determination document, which is available upon request from the individual listed under FOR FURTHER INFORMATION CONTACT.

BXN™ cotton, as defined by its developer (Calgene, Inc., of Davis, CA), is any cotton cultivar or progeny of a cotton line containing the BXN gene (a gene, derived from the soil microbe *Klebsiella pneumoniae* subsp. *ozaenae* that encodes the enzyme nitrilase, which can degrade the herbicide bromoxynil) with its associated regulatory sequences, i.e., sequences that allow for expression of the gene's enzyme product. By definition, BXN™ cotton may also contain: the *kanr* marker gene (encoding the enzyme aminoglycoside 3'-phosphotransferase II, which confers resistance to the antibiotic kanamycin) with its associated regulatory sequences; a DNA fragment containing the origin of replication of the pRi plasmid from *Agrobacterium rhizogenes*; T-DNA left and right border sequences from an *Agrobacterium tumefaciens* Ti plasmid; a segment of DNA from transposon Tn5; a portion of a synthetic polylinker sequence from *lacZ'*; and a segment of DNA containing the origin of replication of plasmid pBR322. Expression of the BXN™ gene and the *kanr* gene is directed by copies of the promoter from the *35S* gene from cauliflower mosaic virus and terminated using sequences derived from the *tml* gene from the octopine-type Ti plasmid pTiA6 from *A. tumefaciens*.

BXN™ cotton contains components from organisms that are known plant pathogens, i.e., the bacterium *Agrobacterium tumefaciens* and cauliflower mosaic virus. BXN™ cotton has therefore been a regulated article under APHIS jurisdiction, and its field tests in 1989, 1990, 1991, 1992, and 1993 have been in accordance with APHIS regulations at 7 CFR part 340. APHIS' determination that BXN™ cotton that has been field tested under permit does not present a plant pest risk is based on an analysis of data provided to APHIS by Calgene and other relevant published scientific data obtained by APHIS concerning the components of BXN™ cotton and observable properties of the cotton lines themselves. From this review, we have determined that these BXN™ cotton lines: (1) Exhibit no plant pathogenic properties; (2) are no more likely to become a weed than their non-engineered parental varieties; (3) are unlikely to increase the weediness potential for any other cultivated plant or native wild species with which the organism can interbreed; (4) will not cause damage to processed agricultural commodities; and (5) are unlikely to harm other organisms, such as bees and earthworms, that are beneficial to agriculture. In addition, we have determined that there is a reasonable

certainty that progeny BXN™ cotton lines bred from these lines will not exhibit new plant pest properties, i.e., properties substantially different from any observed for the BXN™ cotton lines already field tested, or those observed for cotton in traditional breeding programs. However, APHIS believes that it is prudent to require information to corroborate that new BXN™ cotton lines, not derived from BXN™ lines already field tested under permit, do not exhibit unexpected qualities.

Calgene has provided information and data from field testing of some of the cotton lines fitting their definition of BXN™ cotton and intended to be representative of all those lines. Our determination, however, applies only to cotton lines that fit Calgene's definition of BXN™ cotton and that have been field tested under permit. The effect of this determination is that such cotton lines will no longer be considered regulated articles under the APHIS regulations at 7 CFR part 340. Permits under those regulations will no longer be required from APHIS for field testing, importation, or interstate movement of BXN™ cotton lines that have been field tested under permit or their progeny. Normal agronomic practices involving these BXN™ cotton lines, e.g., cultivation, propagation, movement, and cross-breeding with other non-regulated cotton lines, can now be conducted without an APHIS permit. (Importation of BXN™ cotton (and nursery stock or seeds capable of propagation) is still, however, subject to the restrictions found in the Foreign Quarantine Notices regulations at 7 CFR part 319.) Variety registration and/or seed certification for individual cotton lines carrying the BXN™ gene may involve future actions by the U.S. Plant Variety Protection Office and State Seed Certification officials.

The potential environmental impacts associated with this determination have been examined in accordance with regulations and guidelines implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*; 40 CFR parts 1500–1508; 7 CFR part 1b; 44 FR 50381–50384; and 44 FR 51272–51274). An Environmental Assessment (EA) was prepared and a Finding of No Significant Impact (FONSI) was reached by APHIS for the determination that BXN™ cotton that has been field tested under permit is no longer a regulated article under its regulations at 7 CFR part 340.

Done in Washington, DC, this 15th day of February 1994.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

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