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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. 95-023-2]

#### Availability of Determination of Nonregulated Status for Genetically Engineered Cotton

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** We are advising the public of our determination that the Monsanto Company's cotton lines designated as 1445 and 1698 that have been genetically engineered for tolerance to the herbicide glyphosate 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:** July 11, 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. Sivramiah Shantharam, 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 February 14, 1995, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 95-045-01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination that cotton lines designated as 1445 and 1698 that have been genetically engineered for tolerance to the herbicide glyphosate do not present a plant pest risk and, therefore, are not regulated articles under APHIS' regulations in 7 CFR part 340.

On March 30, 1995, APHIS published a notice in the **Federal Register** (60 FR 16428-16430, Docket No. 95-023-1) announcing that the Monsanto 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 cotton lines and food products derived from them. In the notice, APHIS solicited written comments from the public as to whether the subject cotton lines posed a plant pest risk. The comments were to have been received by APHIS on or before May 30, 1995.

APHIS received a total of 10 comments on the Monsanto petition, from universities, cooperative extension service offices, agricultural experiment stations, a council representing cotton interests, and a State department of agriculture. All the commenters supported the Monsanto petition for nonregulated status for the subject cotton lines.

##### Analysis

Cotton lines 1445 and 1698 contain the gene for CP4 EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) isolated from *Agrobacterium* sp. strain CP4, which encodes an enzyme conferring tolerance to glyphosate, the active ingredient in Roundup® herbicide. The subject cotton lines also contain the *nptII* gene, which

encodes the selectable marker neomycin phosphotransferase II. Cotton lines 1445 and 1698 were produced through the use of *Agrobacterium tumefaciens* transformation.

The subject cotton lines were considered regulated articles because they contain certain gene sequences (vectors, vector agents, promoters, and terminators) derived from plant pathogens. However, evaluation of field data reports from field tests of the subject cotton lines conducted under APHIS permits or notifications since 1992 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the subject cotton plants' release into the environment.

##### Determination

Based on its analysis of the data submitted by Monsanto and a review of other scientific data, comments received from the public, and field tests of the subject cotton lines, APHIS has determined that cotton lines 1445 and 1698: (1) Exhibit no plant pathogenic properties; (2) are no more likely to become weeds than cotton developed by traditional breeding techniques; (3) are unlikely to increase the weediness potential for any other cultivated or wild species with which they can interbreed; (4) will not harm other organisms, such as bees, that are beneficial to agriculture; and (5) should not cause damage to processed agricultural commodities. APHIS has also concluded that there is no reason to believe that new progeny cotton varieties derived from cotton lines 1445 and 1698 will exhibit new plant pest properties, i.e., properties substantially different from any observed for the cotton lines 1445 and 1698 already field tested, or those observed for cotton in traditional breeding programs.

The effect of this determination is that cotton lines designated as 1445 and 1698 are no longer considered regulated articles under APHIS' regulations in 7 CFR part 340. Therefore, the notification requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of cotton lines 1445 and 1698 or their progeny. However, the importation of the subject cotton lines or seeds capable of propagation is still subject to the