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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 94-139-1]

Receipt of Petition for Determination of Nonregulated Status for Genetically Engineered Cotton

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 the Monsanto Company seeking a determination of nonregulated status for cotton lines genetically engineered for insect resistance. 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 these genetically engineered cotton lines present a plant pest risk.

DATES: Written comments must be received on or before April 10, 1995.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 94-139-1, Animal and Plant Health Inspection Service, Policy and Program Development, Regulatory Analysis and Development, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 94-139-1. 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. Keith Reding, Biotechnologist, Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Biotechnology Permits, 4700 River Road Unit 147, Riverdale, MD 20737-1237. The telephone number for the agency contract will change when agency offices in Hyattsville, MD, move to Riverdale, MD, during February. Telephone: (301) 436-7612 (Hyattsville); (301) 734-7612 (Riverdale). To obtain a copy of the petition, contact Ms. Kay Peterson at (301) 436-7601 (Hyattsville) or (301) 734-7601 (Riverdale).

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 regulation 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 4, 1994, APHIS received a petition (APHIS Petition No. 94-308-01p) from the Monsanto Company of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for a cotton line designated as 531, genetically engineered to produce an insecticidal protein for resistance to lepidopteran insect pests. On January 10, 1995, Monsanto amended the petition to add two additional lines designated as 757 and 1076. The three cotton lines, 531, 757, and 1076, are trademarked by Monsanto as Bollagard™ Cotton Lines. The Monsanto petition states that the subject cotton lines 531, 757, and 1076,

should not be regulated by APHIS because they do not present a plant pest risk.

As described in the petition, the subject cotton lines were developed to produce an insect control protein derived from the common soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* (*Btk*). This genetically engineered insect control protein is nearly identical (differing in only 6 of 1,178 nonessential amino acids) to one of the proteins encoded by the *cryIA(c)* gene. This protein is naturally produced by *Btk* and found in commercial microbial *Btk* formulations registered as pesticides with the Environmental Protection Agency (EPA). According to Monsanto, the protein is highly selective in controlling such lepidopteran cotton pests as cotton bollworm, tobacco budworm, and pink bollworm, and is expressed at a consistent level in the cotton plant throughout the growing season. The expression of this insect control protein is regulated by a promoter and terminating sequence. The promoters were either the 35S sequence derived from the cauliflower mosaic virus or a promoter from an alternate source. Terminating sequences used were either the 7S 3' non-translated region of the soybean alpha subunit of the beta-conglycinin gene or the E9 3' sequence from the pea ribulose-1,5-bisphosphate carboxylase, small subunit (*rbcS*).

The subject cotton lines also contain the *nptII* gene from the prokaryotic transposon Tn5 which encodes the enzyme neomycin phosphotransferase II. The expression of this gene in the subject cotton lines is regulated by the 35S promoter, as described above, and the nontranslated 3' region of the nopaline synthase gene derived from the plant pathogen *Agrobacterium tumefaciens*. The expression of this enzyme in the subject cotton 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 cotton plants using *A. tumefaciens*-mediated transformation utilizing a binary, single-border plant expression vector.

Monsanto's cotton lines 531, 757, and 1076 are currently considered regulated articles under the regulations in 7 CFR part 340 because they contain gene sequences (vectors, promoters, and