

## DEPARTMENT OF AGRICULTURE

## Animal and Plant Health Inspection Service

[Docket No. 97-114-1]

**Monsanto Co.; Receipt of Petition for Determination of Nonregulated Status for Genetically Engineered Tomato**

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 Monsanto Company seeking a determination of nonregulated status for a tomato line designated as 5345, which has been genetically engineered for resistance to certain lepidopteran insect pests. 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 this tomato line presents a plant pest risk.

**DATES:** Written comments must be received on or before January 27, 1998.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 97-114-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 97-114-1. 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 to facilitate entry into the reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. Sivramiah Shantharam, Biotechnology Evaluation, BSS, PPQ, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-4882. To obtain a copy of the petition, contact Ms. Kay Peterson at (301) 734-4885; e-mail: mkpeterson@aphis.usda.gov.

**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 regulations 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 October 14, 1997, APHIS received a petition (APHIS Petition No. 97-287-01p) from Monsanto Company (Monsanto) of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for a genetically engineered, insect-resistant tomato line designated as 5345. The petition states that the subject tomato line should not be regulated by APHIS because it does not present a plant pest risk.

As described in the petition, tomato line 5345 has been genetically engineered to express a CryIA(c) insect control protein derived from the common soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* HD-73 (Btk). The petitioner states that expression of the Btk delta-endotoxin protein protects the subject tomato line from damage caused by certain lepidopteran insect pests. Tomato line 5345 also expresses the NPTII protein which serves as a selectable marker in the plant transformation process. While the subject tomato line contains the *aad* gene, tests indicate that the AAD protein, which serves as a selectable marker in the laboratory prior to plant transformation, is not expressed in the plant. The added genes were introduced into the UC82B parental tomato plants by the *Agrobacterium tumefaciens* transformation system, and their expression is controlled in part by gene sequences derived from the plant pathogens cauliflower mosaic virus and *A. tumefaciens*.

The subject tomato line is currently considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences derived from plant pathogenic sources. Tomato line 5345 has been evaluated in field trials conducted since 1994 under APHIS notifications. In the process of reviewing the notifications for field trials of this tomato line, APHIS

determined that the vectors and other elements were disarmed and that the trials, which were conducted under conditions of reproductive and physical containment or isolation, would not present a risk of plant pest introduction or dissemination.

In the Federal Plant Pest Act, as amended (7 U.S.C. 150aa *et seq.*), "plant pest" is defined as "any living stage of: Any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured or other products of plants." APHIS views this definition very broadly. The definition covers direct or indirect injury, disease, or damage not just to agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees, rhizobia, etc.

The U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including insecticides, be registered prior to distribution or sale, unless exempt by EPA regulation. In cases in which the genetically modified plant allows for a new or different use pattern for a pesticide, EPA must approve the new or different use. Residue tolerances for pesticides are established by the EPA under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), and the Food and Drug Administration (FDA) enforces tolerances set by the EPA under the FFDCA. The EPA has granted exemptions from the requirement of a tolerance for residues of the CryIA(c) and NPTII proteins and the genetic material necessary for their production in all plants.

The FDA published a statement of policy on foods derived from new plant varieties in the **Federal Register** on May 29, 1992 (57 FR 22984-23005). The FDA statement of policy includes a discussion of the FDA's authority for ensuring food safety under the FFDCA, and provides guidance to industry on the scientific considerations associated with the development of foods derived from new plant varieties, including those plants developed through the techniques of genetic engineering.

In accordance with § 340.6(d) of the regulations, we are publishing this notice to inform the public that APHIS will accept written comments regarding the Petition for Determination of Nonregulated Status from any interested person for a period of 60 days from the date of this notice. The petition and any comments received are available for public review, and copies of the petition may be ordered (see the **ADDRESSES** section of this notice).

After the comment period closes, APHIS will review the data submitted by the petitioner, all written comments received during the comment period, and any other relevant information. Based on the available information, APHIS will furnish a response to the petitioner, either approving the petition in whole or in part, or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of Monsanto's insect-resistant tomato line 5345 and the availability of APHIS' written decision.

**Authority:** 7 U.S.C. 150aa-150jj, 151-167, and 1622n; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(c).

Done in Washington, DC, this 20th day of November 1997.

**Craig A. Reed,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 97-31222 Filed 11-26-97; 8:45 am]

BILLING CODE 3410-34-P

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Procurement List Additions

**AGENCY:** Committee for Purchase From People Who Are Blind or Severely Disabled

**ACTION:** Additions to the Procurement List.

**SUMMARY:** This action adds to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

**EFFECTIVE DATE:** December 29, 1997.

**ADDRESSES:** Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Gateway 3, Suite 310, 1215 Jefferson Davis Highway, Arlington, Virginia 22202-4302.

**FOR FURTHER INFORMATION CONTACT:** Beverly Milkman (703) 603-7740.

**SUPPLEMENTARY INFORMATION:** On October 10, 1997, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (62 FR 52969) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the services and impact of the additions on the current or most recent contractors, the Committee has determined that the services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 51-2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action will not have a severe economic impact on current contractors for the services.

3. The action will result in authorizing small entities to furnish the services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the services proposed for addition to the Procurement List.

Accordingly, the following services are hereby added to the Procurement List:

Janitorial/Custodial, Keene USARC, 682 Main Street, Keene, New Hampshire.  
Janitorial/Custodial, Grenier Field USARC, Manchester, New Hampshire.  
Janitorial/Custodial, Craft Bros. USARC, 11 St. Anselm's Drive, Manchester, New Hampshire.  
Janitorial/Custodial, Paul A. Doble USARC, 125 Cottage Street, Portsmouth, New Hampshire.  
Janitorial/Custodial, Raymond Bisson USARC, 70 Rochester Hill Road, Rochester, New Hampshire.  
Janitorial/Custodial, Rainbow Bridge U.S. Plaza, Niagara Falls, New York.  
Switchboard Operation, Veterans Affairs Medical Center, 423 East 23rd Street, New York, New York.

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

**Beverly L. Milkman,**  
*Executive Director.*

[FR Doc. 97-31379 Filed 11-26-97; 8:45 am]

BILLING CODE 6353-01-P

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Procurement List; Proposed Additions

**AGENCY:** Committee for Purchase From People Who Are Blind or Severely Disabled.

**ACTION:** Proposed Additions to Procurement List.

**SUMMARY:** The Committee has received proposals to add to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

**COMMENTS MUST BE RECEIVED ON OR BEFORE:** December 29, 1997.

**ADDRESSES:** Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Gateway 3, Suite 310, 1215 Jefferson Davis Highway, Arlington, Virginia 22202-4302.

**FOR FURTHER INFORMATION CONTACT:** Beverly Milkman (703) 603-7740.

**SUPPLEMENTARY INFORMATION:** This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action will result in authorizing small entities to furnish the commodities and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the commodities and services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which