Notices

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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. 95-042-1]

Receipt of Petition for Determination of Nonregulated Status for Genetically Engineered Tomato Line

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 a tomato line designated as 8338 that has been genetically engineered for delayed ripening. 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 August 14, 1995. ADDRESSES: Please send an original and three copies of your comments to Docket No. 95–042–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1237. Please state that your comments refer to Docket No. 95–042–1. 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. Susan Koehler, Biotechnologist, Biotechnology Permits, BBEP, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1237; (301) 734–7612. To obtain a copy of the petition, contact Ms. Kay Peterson at (301) 734–7601.

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 February 22, 1995, APHIS received a petition (APHIS Petition No. 95–053–01p) from the Monsanto Company (Monsanto) of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for a tomato line designated as 8338 that has been genetically engineered for delayed ripening. The Monsanto petition states that the subject tomato line shall not be regulated by APHIS because it does not present a plant pest risk.

As described in the petition, tomato line 8338 has been genetically engineered to express the enzyme 1aminocyclopropane-1-carboxylic acid deaminase (ACCd), which catalizes deamination of ACC, an essential precursor for ethylene biosynthesis. Levels of ethylene control the rate of fruit ripening, and removal of ACC in the subject tomato line reduces ethylene production and delays ripening. The *accd* gene, which confers the delayedripening trait, was isolated from the soil bacterium *Pseudomonas chloroaphis*,

strain 6G5. Tomato line 8338 also contains the neomycin phosphotransferase (nptII) selectable marker gene which encodes the enzyme NPTII. The presence of the NPTII protein in the plant genome confers tolerance to the antibiotic kanamycin and allows selection of the transformed cells in the presence of kanamycin. Expression of the *accd* gene and the *nptII* gene is driven by constitutive 35S promoters derived from the plant pathogenic caulimoviruses figwort mosaic virus and cauliflower mosaic virus, respectively. The subject tomato line was transformed through the use of disarmed vectors from a common soilborne bacterium, the plant pathogen Agrobacterium tumefaciens.

Tomato line 8338 is currently considered a regulated article under the regulations in 7 CFR part 340 because it contains the 35S promoters and 3' regulatory gene sequences derived from the plant pathogens mentioned above, and because A. tumefaciens was used as the plant transformation vector. Tomato line 8338 was evaluated in field trials conducted under APHIS permits or notifications since 1992. In the process of reviewing the applications for those field trials, APHIS determined that the vectors and other elements were disarmed and that the trials, which were conducted under conditions of reproductive confinement, 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.

Food or animal feed uses of the subject tomato line may be subject to