

# 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. 94-092-2]

#### Availability of 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 of our determination that a DNA Plant Technology Corporation delayed-ripening tomato line, designated as line 1345-4, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. The determination is based on our analysis of a petition submitted by DNA Plant Technology Corporation for a determination of nonregulated status, and our review of scientific data and comments received from the public in response to a previous notice announcing receipt of the DNA Plant Technology Corporation's 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:** January 17, 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. Ved Malik, Biotechnologist, Biotechnology Permits, BBEP, APHIS, USDA, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7612. The telephone number for the agency 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 determination or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 436-7601 (Hyattsville); (301) 734-7601 (Riverdale).

#### SUPPLEMENTARY INFORMATION:

##### Background

On August 16, 1994, the Animal and Plant Health Inspection Service (APHIS) received a petition from DNA Plant Technology Corporation (DNAP) of Oakland, CA, seeking a determination that its delayed-ripening tomato line 1345-4 (tomato line 1345-4) and any progeny derived from hybrid crosses between that line and other non-transformed tomato varieties do not present a plant pest risk and, therefore, are not regulated articles under APHIS' regulations in 7 CFR part 340.

On September 26, 1994, APHIS published a notice in the Federal Register (59 FR 49055-49056, Docket No. 94-092-1) announcing receipt of the DNAP petition and stating that the petition was available for public review. The notice also discussed the role of APHIS and the Food and Drug Administration in regulating tomato line 1345-4 and food products derived from it. In the notice, APHIS solicited written comments from the public as to whether tomato line 1345-4 posed a plant pest risk. The comments were to have been received by APHIS on or before November 25, 1994.

APHIS received seven comments on the DNAP petition submitted by universities, State officials, and a tomato grower. One comment concerned the information provided in the notice of receipt of the petition; the remainder of the comments were in favor of the petition. APHIS has provided a summary of the comments in the determination document, which is available upon request from the individual listed under FOR FURTHER INFORMATION CONTACT.

#### Analysis

Tomato line 1345-4, as described by its developer, DNAP, contains a gene that delays ripening. Using Transwitch™ gene suppression technology, DNAP introduced a truncated version of the tomato aminocyclopropane carboxylate (ACC) synthase gene into the tomato genome in the "sense" or normal orientation, resulting in tomato plants that exhibit significantly reduced levels of ACC synthase. ACC synthase is the rate-limiting enzyme that converts s-adenosylmethionine to 1-aminocyclopropane-1-carboxylic acid, the immediate precursor to ethylene. Tomato line 1345-4 contains a gene which is derived from the tomato ACC synthase gene, but which does not encode a functional ACC synthase enzyme. Though the fruit of these plants exhibits delayed-ripening, they ripen as usual when exogenous ethylene is applied. Tomato line 1345-4 has also been transformed with the nptII gene from E. coli that encodes the enzyme neomycin phosphotransferase II and serves as a selectable marker enabling identification of the transformed plant cells. This gene is fused to a nos promoter sequence and octopine synthase termination sequence from *A. tumefaciens*, a known plant pest.

Tomato line 1345-4 has been considered a regulated article under APHIS' regulations in 7 CFR part 340 because the line has been engineered using noncoding regulatory sequences derived from the plant pathogens *A. tumefaciens* and cauliflower mosaic virus. However, field tests of tomato line 1345-4 have been conducted at tomato growing regions in the United States since 1992 under permits issued by APHIS, and the field reports from those tests indicate that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of this testing.

#### Determination

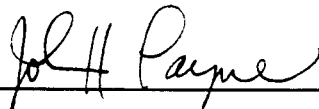
Based on its analysis of data submitted by DNAP, a review of other scientific data and comments received from the public, APHIS has determined that tomato line 1345-4: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than the nonengineered parental variety; (3) is unlikely to increase the weediness potential of any other cultivated plant or

USDA/APHIS Petition 94-228-01 for Determination of Nonregulated Status  
for Delayed-Ripening Tomato Line 1345-4

Environmental Assessment and  
Finding of No Significant Impact

January 1995

The Animal and Plant Health Inspection Service (APHIS) of the U. S. Department of Agriculture has conducted an environmental assessment prior to issuing a determination of nonregulated status for a genetically engineered delayed-ripening tomato designated line 1345-4. APHIS received a petition, from the DNA Plant Technology Corporation, regarding the status of the line 1345-4 as a regulated article under APHIS regulations at 7 CFR Part 340. APHIS has conducted an extensive review of the petition and supporting documentation, as well as other relevant scientific information. Based upon the analysis documented in this environmental assessment, APHIS has reached a finding of no significant impact on the environment from its determination that delayed-ripening tomato line 1345-4 shall no longer be a regulated article.



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Acting Director  
Biotechnology, Biologics, and Environmental Protection  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture

Date:

JAN 17 1995