

# 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. 97-067-2]

#### Bejo Zaden BV; Availability of Determination of Nonregulated Status for Genetically Engineered Radicchio Rosso

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

**ACTION:** Notice.

**SUMMARY:** We are advising the public of our determination that Bejo Zaden BV's Radicchio rosso lines designated as RM3-3, RM3-4, and RM3-6, which have been genetically engineered for male sterility and tolerance to the herbicide glufosinate as a marker, 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 Bejo Zaden BV in its petition for a determination of nonregulated status and an analysis of other scientific data. This notice also announces the availability of our written determination document and its associated environmental assessment and finding of no significant impact.

**EFFECTIVE DATE:** November 7, 1997.

**ADDRESSES:** The determination, an environmental assessment and finding of no significant impact, the petition, and any 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 to facilitate entry into the reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. Subhash Gupta, Biotechnology Evaluation, BSS, PPQ, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-8761. To obtain a copy of the determination or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734-4885; e-mail: mkipeterson@aphis.usda.gov.

#### SUPPLEMENTARY INFORMATION:

##### Background

On May 28, 1997, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 97-148-01p) from Bejo Zaden BV (Bejo) of Warmerhuizen, The Netherlands, seeking a determination that Radicchio rosso (red-hearted chicory) lines designated as RM3-3, RM3-4, and RM3-6, which have been genetically engineered for male sterility and tolerance to the herbicide glufosinate as a marker, do not present a plant pest risk and, therefore, are not regulated articles under APHIS' regulations in 7 CFR part 340.

On August 27, 1997, APHIS published a notice in the **Federal Register** (62 FR 45387-45388, Docket No. 97-067-1) announcing that the Bejo 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 Radicchio rosso lines RM3-3, RM3-4, and RM3-6 and food products derived from them. In the notice, APHIS solicited written comments from the public as to whether these Radicchio rosso lines posed a plant pest risk. The comments were to have been received by APHIS on or before October 27, 1997. APHIS received no comments on the subject petition during the designated 60-day comment period.

##### Analysis

Radicchio rosso (*Chichorium intybus* L.) lines RM3-3, RM3-4, and RM3-6 have been genetically engineered with a *barnase* gene from *Bacillus amyloliquefaciens* encoding a ribonuclease which inhibits pollen formation and results in male sterility of the transformed plants. The subject Radicchio rosso lines also contain the *nptII* selectable marker gene and the *bar* gene isolated from the bacterium *Streptomyces hygroscopicus*. The *bar*

gene encodes a phosphinothricin acetyltransferase (PAT) enzyme, which, when introduced into a plant cell, inactivates glufosinate. Linkage of the *barnase* gene, which induces male sterility, with the *bar* gene, a glufosinate tolerance gene used as a marker, enables identification of the male sterile line for the production of pure hybrid seed. The subject Radicchio rosso lines were transformed by the *Agrobacterium tumefaciens* method, and expression of the introduced genes is controlled in part by gene sequences derived from the plant pathogen *A. tumefaciens*.

Radicchio rosso lines RM3-3, RM3-4, and RM3-6 have been considered regulated articles under APHIS' regulations in 7 CFR part 340 because they contain regulatory gene sequences derived from a plant pathogen. However, evaluation of field data reports from field tests of the subject Radicchio rosso lines conducted in Europe since 1993 and under an APHIS permit since 1995, indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the environmental release of these Radicchio rosso lines.

##### Determination

Based on its analysis of the data submitted by Bejo and a review of other scientific data and field tests of the subject Radicchio rosso lines, APHIS has determined that Radicchio rosso lines RM3-3, RM3-4, and RM3-6: (1) Exhibit no plant pathogenic properties; (2) are no more likely to become a weed than Radicchio rosso lines 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 cause damage to raw or processed agricultural commodities; and (5) will not harm threatened or endangered species or other organisms, such as bees, that are beneficial to agriculture. Therefore, APHIS has concluded that Radicchio rosso lines RM3-3, RM3-4, and RM3-6 and any progeny derived from hybrid crosses with other nontransformed Radicchio rosso varieties will not exhibit new plant pest properties, i.e., properties substantially different from any observed for the subject Radicchio rosso lines already field tested, or those observed for Radicchio rosso in traditional breeding programs.

The effect of this determination is that Bejo's Radicchio rosso lines designated as RM3-3, RM3-4, and RM3-6 are no longer considered regulated articles under APHIS' regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of Bejo's Radicchio rosso lines RM3-3, RM3-4, and RM3-6 or their progeny. However, the importation of the subject Radicchio rosso lines or seeds capable of propagation are still subject to the restrictions found in APHIS' foreign quarantine notices in 7 CFR part 319.

### National Environmental Policy Act

An environmental assessment (EA) has been prepared to examine the potential environmental impacts associated with this determination. The EA was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on that EA, APHIS has reached a finding of no significant impact (FONSI) with regard to its determination that Radicchio rosso lines RM3-3, RM3-4, and RM3-6 and lines developed from them are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and the FONSI are available upon request from the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Done in Washington, DC, this 14th day of November 1997.

**Craig A. Reed,**

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

[FR Doc. 97-30507 Filed 11-19-97; 8:45 am]

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. 97-094-1]

### Monsanto Co.; Receipt of Petition for Determination of Nonregulated Status for Potato Lines Genetically Engineered for Insect and Virus Resistance

**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 certain potato lines genetically engineered for resistance to the Colorado potato beetle and potato leaf roll virus. 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 potato lines present a plant pest risk.

**DATES:** Written comments must be received on or before January 20, 1998.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 97-094-1, 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. 97-094-1. 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. James White, Biotechnology Evaluation, BSS, PPQ, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-5940. To obtain a copy of the petition, contact Ms. Kay Peterson at (301) 734-4885; e-mail: mkipeterson@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 July 23, 1997, APHIS received a petition (APHIS Petition No. 97-204-01p) from Monsanto Company (Monsanto) of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for seven NewLeaf® Plus Russet Burbank potato lines (RBMT21-129, RBMT21-152, RBMT21-350, RBMT22-82, RBMT22-186, RBMT22-238, RBMT22-262), which have genetically engineered for resistance to the Colorado potato beetle (CPB) and potato leaf roll virus (PLRV). The Monsanto petition states that the subject potato lines should not be regulated by APHIS because they do not present a plant pest risk.

As described in the petition, all seven of the subject Russet Burbank potato lines have been genetically engineered to contain the *cryIIIA* gene from *Bacillus thuringiensis* subsp. *tenebrionis* (Btt), which encodes an insecticidal protein that is effective against CPB, and the PLRV replicase gene (*PLRVrep*), which imparts resistance to PLRV. In addition to the *cryIIIA* gene and the *PLRVrep* gene, these potato lines contain either the *nptII* selectable marker gene (RBMT21-129, RBMT21-152, and RBMT21-350) or the *CP4 EPSPS* selectable marker gene (RBMT22-82, RBMT22-186, RBMT22-238, and RBMT22-262). The subject potato lines were developed through the use of the *Agrobacterium tumefaciens* transformation system, and expression of the introduced genes is controlled in part by gene sequences derived from the plant pests *A. tumefaciens* and Figwort mosaic virus.

The subject potato lines have been considered regulated articles under the regulations in 7 CFR part 340 because they contain gene sequences derived from plant pests. These potato lines have been evaluated in field trials conducted since 1994 under APHIS permits. In the process of reviewing the applications for field trials of the subject potato lines, 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