

# 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. 04-085-1]

#### **Monsanto Co. and Forage Genetics International; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate**

**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 and Forage Genetics International seeking a determination of nonregulated status for alfalfa designated as events J101 and J163, which have been genetically engineered for tolerance to the herbicide glyphosate. 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 alfalfa presents a plant pest risk. We are also making available for public comment an environmental assessment for the proposed determination of nonregulated status.

**DATES:** We will consider all comments we receive on or before January 24, 2005.

**ADDRESSES:** You may submit comments by any of the following methods:

- **Postal Mail/Commercial Delivery:** Please send four copies of your comment (an original and three copies) to Docket No. 04-085-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Please state that your comment refers to Docket No. 04-085-1.

- **E-mail:** Address your comment to [regulations@aphis.usda.gov](mailto:regulations@aphis.usda.gov). Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 04-085-1" on the subject line.

- **Agency Web Site:** Go to <http://www.aphis.usda.gov/ppd/rad/cominst.html> for a form you can use to submit an e-mail comment through the APHIS Web site.

**Reading Room:** You may read the petition, the environmental assessment, and any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

**Other Information:** You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Virgil Meier, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-3363. To obtain copies of the petition or the environmental assessment (EA), contact Ms. Terry Hampton at (301) 734-5715; e-mail: [Terry.A.Hampton@aphis.usda.gov](mailto:Terry.A.Hampton@aphis.usda.gov). The petition and the EA are also available on the Internet at [http://www.aphis.usda.gov/brs/aphisdocs/04\\_11001p.pdf](http://www.aphis.usda.gov/brs/aphisdocs/04_11001p.pdf) and [http://www.aphis.usda.gov/brs/aphisdocs/04\\_11001p\\_ea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/04_11001p_ea.pdf).

**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 a determination of nonregulated status must take and the information that must be included in the petition.

On April 16, 2004, APHIS received a petition from Monsanto Company of St. Louis, MO, and Forage Genetics International of West Salem, WI (Monsanto/FGI), requesting a determination of nonregulated status under 7 CFR part 340 for alfalfa (*Medicago sativa* L.) designated as events J101 and J163, which have been genetically engineered for tolerance to the herbicide glyphosate. The Monsanto/FGI petition states that the subject alfalfa should not be regulated by APHIS because it does not present a plant pest risk.

As described in the petition, alfalfa events J101 and J163 have been genetically engineered to express a 5-enolpyruvylshikimate-3-phosphate synthase protein from *Agrobacterium* sp. strain CP4 (CP4 EPSPS), which confers tolerance to the herbicide glyphosate. Expression of the added genes is controlled in part by the 35S promoter derived from the plant pathogen figwort mosaic virus. The *Agrobacterium tumefaciens* transformation method was used to transfer the added genes into the proprietary alfalfa line R2336.

Alfalfa events J101 and J163 have been considered regulated article under the regulations in 7 CFR part 340 because they contain gene sequences from plant pathogens. In the process of reviewing the notifications for field trials of the subject alfalfa, APHIS determined that the vectors and other elements were disarmed and that the trials, which were conducted under conditions of reproductive and physical confinement or isolation, would not present a risk of plant pest introduction or dissemination.

In section 403 of the Plant Protection Act (7 U.S.C. 7701-7772), plant pest is

defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing. 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 herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. In cases in which genetically modified plants allow for a new use of a pesticide or involve a different use pattern for the pesticide, EPA must approve the new or different use. Accordingly, Monsanto/FGI are seeking registration for the use of glyphosate on glyphosate-tolerant alfalfa from the EPA.

When the use of the pesticide on the genetically modified plant would result in an increase in the residues in a food or feed crop for which the pesticide is currently registered, or in new residues in a crop for which the pesticide is not currently registered, establishment of a new tolerance or a revision of the existing tolerance would be required. Residue tolerances for pesticides are established by 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 EPA under the FFDCA. EPA is currently evaluating the residue tolerance for glyphosate-tolerant alfalfa.

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 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. Monsanto/FGI has begun consultation with FDA on the subject alfalfa event.

To provide the public with documentation of APHIS' review and

analysis of the environmental impacts and plant pest risk associated with a proposed determination of nonregulated status for the Monsanto/FGI events J101 and J163 alfalfa, an environmental assessment (EA) has been prepared. 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).

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 a determination of nonregulated status from interested persons for a period of 60 days from the date of this notice. We are also soliciting written comments from interested persons on the EA prepared to examine any environmental impacts of the proposed determination for the subject alfalfa event. The petition and the EA and any comments received are available for public review, and copies of the petition and the EA are available as indicated in the **FOR FURTHER INFORMATION CONTACT** 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. After reviewing and evaluating the comments on the petition and the EA and other data and 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 the Monsanto/FGI glyphosate-tolerant alfalfa events J101 and J163 and the availability of APHIS' written decision.

**Authority:** 7 U.S.C. 1622n and 7701–7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 18th day of November 2004.

**Kevin Shea,**

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

[FR Doc. E4–3315 Filed 11–23–04; 8:45 am]

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. 04–076–2]

#### Monsanto Co.; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Cotton Genetically Engineered for Tolerance to the Herbicide Glyphosate

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

**ACTION:** Notice.

**SUMMARY:** We are advising the public of the availability of an addendum to a petition from Monsanto Company seeking a determination of nonregulated status for cotton designated as MON 88913, which has been genetically engineered for tolerance to the herbicide glyphosate. 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 cotton presents a plant pest risk. We are also making available for public comment an environmental assessment for the proposed determination of nonregulated status. The content of the addendum does not impact the environmental assessment. However, the information contained within the addendum may add clarity to the review of the petition by the public.

**DATES:** We will consider all comments we receive on or before December 3, 2004.

**ADDRESSES:** You may submit comments by any of the following methods:

- **Postal Mail/Commercial Delivery:** Please send four copies of your comment (an original and three copies) to Docket No. 04–076–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–076–1.

- **E-mail:** Address your comment to [regulations@aphis.usda.gov](mailto:regulations@aphis.usda.gov). Your comment must be contained in the body of your message; do not send attached files.

- **Agency Web Site:** Go to <http://www.aphis.usda.gov/ppd/rad/cominst.html> for a form you can use to submit an e-mail comment through the APHIS Web site.

**Reading Room:** You may read the amended petition, the environmental assessment, and any comments that we receive on this docket in our reading