

# 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. 04-114-1]

#### Monsanto Company; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Corn Genetically Engineered for Insect 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 corn designated as transformation event MON 88017, which has been genetically engineered for resistance to a corn rootworm complex and 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 corn 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 October 11, 2005.

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

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04-114-1, 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. 04-114-1.

• **EDOCKET:** Go to <http://www.epa.gov/feddocket> to submit or view public comments. Once you have entered EDOCKET, click on the "View Open APHIS Dockets" link to locate Docket No. 04-114-1.

**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 on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Robyn Rose, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-0489. To obtain copies of the petition or the environmental assessment (EA), contact Ms. Ingrid Berlinger at (301) 734-4885; e-mail: [ingrid.e.berlinger@aphis.usda.gov](mailto:ingrid.e.berlinger@aphis.usda.gov). The petition and the EA are also available on the Internet at [http://www.aphis.usda.gov/brs/aphisdocs/04\\_12501p.pdf](http://www.aphis.usda.gov/brs/aphisdocs/04_12501p.pdf) and [http://www.aphis.usda.gov/brs/aphisdocs/04\\_12501p.ea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/04_12501p.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 May 4, 2004, APHIS received a petition (APHIS Petition Number 04-125-01p) from Monsanto Company (Monsanto) of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for corn (*Zea mays* L.) designated as transformation event MON 88017 which has been genetically engineered for resistance to corn rootworm and for tolerance to the herbicide glyphosate. The Monsanto petition states that the subject corn should not be regulated by APHIS because it does not present a plant pest risk.

As described in the petition, event MON 88017 corn has been genetically engineered to express a Cry3Bb1 insecticidal protein derived from *Bacillus thuringiensis* (Bt) subspecies *kumamotoensis* strain EG4691. This gene has been modified to encode six specific amino acid substitutions when compared to strain EG4691. Cry3Bb1 expression is regulated by the enhanced 35S promoter (e35S) from cauliflower mosaic virus, the rice actin intron (*ract1* intron) 5' leader sequence from wheat chlorophyll a/b-binding protein (wt CAB), and the 3' nontranslated region of the 17.3 kDa heat shock protein from wheat. Event MON 88017 has also 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 *cp4 epsps* is regulated by the rice actin 1 (*ract1*) 5' untranslated region containing the promoter and first intron and nopaline synthase 3' polyadenylation signal (NOS 3') from *Agrobacterium tumefaciens*. A construct containing both genes was delivered to the recipient corn variety, A xHi-II, through *Agrobacterium*-mediated gene transfer. The petitioner states that the Cry3Bb1 protein expressed in MON 88017 is 99.8 percent identical to the Cry3Bb1 protein expressed in nonregulated corn line MON 863. The CP4 EPSPS protein is identical to corn line NK603.

Event MON 88017 has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from plant pathogens. This corn event has been field tested since 1999 in the United States under APHIS notifications. In the process of reviewing the notifications for field trials of the subject corn, 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 § 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 submitted a request for Section 3 Registration of Cry3Bb1 as a plant-incorporated protectant in corn. On December 22, 2004, EPA announced the receipt of the application on its Web site (<http://www.epa.gov/pesticides/biopesticides/regtools/frnotices2004.htm>).

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. On March 31, 2004, EPA granted a tolerance exemption for Cry3Bb1 (69 FR 16809–16814, March 31, 2004). The exemption concluded that there was a reasonable certainty of no harm from consumption of the protein, as it is digestible in gastric fluid and not considered an allergen.

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 has completed consultation with FDA on the subject corn event (BNF No. 97, <http://www.cfsan.fda.gov/lrd/biocon.html>).

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 Monsanto's event MON 88017 corn, an environmental assessment 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 environmental assessment prepared to examine any environmental impacts of the proposed determination for the subject corn event. The petition and the environmental assessment, and any comments received are available for public review, and copies of the petitions and the environmental assessment 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 environmental assessment 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 Monsanto's insect-resistant corn event MON 88017 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 8th day of August 2005.

**Kevin Shea,**

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

[FR Doc. E5–4384 Filed 8–11–E5; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. 05–062–1]

#### University of Kentucky; Availability of Environmental Assessment for Field Tests of Genetically Engineered *Neotyphodium*

**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 prepared an environmental assessment for a field trial of genetically engineered strains of an endophytic fungus of perennial ryegrass, *Neotyphodium* sp. isolate Lp1. The fungi have been genetically engineered to disrupt the ergovaline synthesis pathway. This environmental assessment is available for public review and comment.

**DATES:** We will consider all comments we receive on or before September 12, 2005.

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

- **Postal Mail/Commercial Delivery:** Please send four copies of your comment (an original and three copies) to Docket No. 05–062–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238.