

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.

Please state that your comment refers to Docket No. 05-062-1.

• 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. 05-062-1.

**Reading Room:** You may read 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:** Mr. Michael Blanchette, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-5141. To obtain copies of the petition or the environmental assessment (EA), contact Ms. Ingrid Berlanger at (301) 734-4885; e-mail: [ingrid.e.berlanger@aphis.usda.gov](mailto:ingrid.e.berlanger@aphis.usda.gov). The EA is also available on the Internet at [http://www.aphis.usda.gov/brs/aphisdocs/05\\_15201r\\_ea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/05_15201r_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." A permit must be obtained or a notification acknowledged before a regulated article may be introduced. The regulations set forth the permit application requirements and the notification procedures for the importation, interstate movement, or release into the environment of a regulated article.

On June 1, 2005, the Animal and Plant Health Inspection Service (APHIS) received a permit application (APHIS permit number 05-152-01r) from the

University of Kentucky, Department of Plant Pathology, for a confined field release of two mutant strains of *Neotyphodium* sp isolate LP1, which is an endophytic fungus of *Lolium perenne* (perennial ryegrass). These two mutants were generated by inserting a gene construct containing a hygromycin phosphotransferase gene (*hph*) into specific genes in the ergovaline synthesis pathway. The literature is obscure regarding the specific donor of the *hph* gene to the plasmid that was used to create this construct. The identical *hph* gene has been identified in three bacterial species, *Klebsiella* sp., *Streptomyces hygroscopicus* and *Escherichia coli*. Expression of the *hph* gene is regulated by the *Neurospora crassa* cross-pathway control gene (*cpc-1*) promoter and a transcription termination sequence from the *trpC* gene of *Aspergillus nidulans*.

Strain Lp1-4175 results from an insertion of the *hph* construct in the dimethylallyltryptophan synthase (*dmaW*) gene. This strain does not produce ergot alkaloids or clavine mycotoxins that are believed to cause toxicoses to grazing livestock and wildlife. Strain Lp1-981 was generated by an insertion of the *hph* construct in lysergyl peptide synthetase subunit 1 (*lpsA*). This line lacks the ability to produce ergovaline and other amides of lysergic acid, but retains the ability to produce clavines and lysergic acid.

Perennial ryegrass plants that have been inoculated with either mutant strain will be planted in the trial for the purpose of increasing seed. The endophyte is only transmitted vertically through seed. Therefore this trial will result in an increase in inoculated seed for future experiments.

The genetically engineered *Neotyphodium* are considered regulated articles under the regulations in 7 CFR part 340 because they may be plant pests. To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts and plant pest risk associated with the proposed field trial of these strains of genetically engineered *Neotyphodium*, 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). Copies of the EA are available as indicated in the **FOR FURTHER**

**INFORMATION CONTACT** section of this notice.

Done in Washington, DC, this 8th day of August 2005.

**Kevin Shea,**

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

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## DEPARTMENT OF AGRICULTURE

### Animal And Plant Health Inspection Service

[Docket No. 05-053-1]

#### University of Wisconsin-Madison; Availability of Environmental Assessment for Field Tests of Genetically Engineered *Erwinia carotovora*

**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 a bacterium, *Erwinia carotovora*, the causal agent of tuber soft rot disease in potato. The bacteria have been genetically engineered to disrupt the disease causing pathway. This field trial will allow researchers to better understand the function of each mutated gene under field conditions. 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. 05-053-1, 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. 05-053-1.

- **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. 05-053-1.

**Reading Room:** You may read the environmental assessment and any comments that we receive in our reading room. The reading room is located in room 1141 of the USDA