

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. 04-010-1]

#### Mycogen c/o Dow; Availability of Petitions and Environmental Assessment for Determinations of Nonregulated Status for Cotton 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 two petitions from Mycogen Seeds c/o Dow AgroSciences LLC seeking determinations of nonregulated status for cotton lines designated as Cry1F cotton event 281-24-236 and Cry1Ac cotton event 3006-210-23, which have been genetically engineered for insect resistance. The petitions have 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 cotton lines present a plant pest risk. We are also making available for public comment an environmental assessment for the proposed determinations of nonregulated status.

**DATES:** We will consider all comments we receive on or before May 10, 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. 04-010-1, 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. 04-010-1.

- 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. 04-010-1" 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.

- Federal eRulemaking Portal: Go to <http://www.regulations.gov> and follow the instructions for locating this docket and submitting comments.

**Reading Room:** You may read the petitions, 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/webrep.html>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Susan Koehler, Biotechnology Regulatory Services, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-4886. To obtain copies of the petitions or the environmental assessment, contact Ms. Kay Peterson at (301) 734-4885; e-mail: [Kay.Peterson@aphis.usda.gov](mailto:Kay.Peterson@aphis.usda.gov). The petitions are also available on the Internet at [http://www.aphis.usda.gov/brs/aphisdocs/03\\_03601p.pdf](http://www.aphis.usda.gov/brs/aphisdocs/03_03601p.pdf) and [http://www.aphis.usda.gov/brs/aphisdocs/03\\_03602p.pdf](http://www.aphis.usda.gov/brs/aphisdocs/03_03602p.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 February 5, 2003, APHIS received two petitions from Mycogen Seeds c/o Dow AgroSciences LLC (Mycogen/Dow) of Indianapolis, IN, requesting determinations of nonregulated status under 7 CFR part 340 for cotton (*Gossypium hirsutum* L.) designated as Cry1F cotton event 281-24-236 (cotton event Cry1F) (APHIS Petition No. 03-036-01p) and Cry1Ac cotton event 3006-210-23 (cotton event Cry1Ac) (APHIS Petition No. 03-036-02p), which have been genetically engineered for resistance to certain lepidopteran insect pests. The Mycogen/Dow petitions state that the subject cotton events should not be regulated by APHIS because they do not present a plant pest risk.

As described in the petitions, cotton events Cry1F and Cry1Ac have been genetically engineered to express synthetic insecticidal proteins derived from the common soil bacterium *Bacillus thuringiensis* (*Bt*). The petitioner states that the Cry1F and Cry1Ac proteins are effective in providing protection from the feeding of lepidopteran insect pests such as tobacco budworm, beet armyworm, soybean looper, and cotton bollworm. The subject cotton events also express the *pat* gene derived from *Streptomyces viridochromogenes*, a non-pathogenic bacterium. The *pat* gene encodes the enzyme phosphinothricin acetyltransferase (PAT), which confers tolerance to glufosinate herbicides and is present in cotton events Cry1F and Cry1Ac as a selectable marker. The subject cotton events were developed through use of the *Agrobacterium*-mediated transformation method.

Cotton events Cry1F and Cry1Ac were developed primarily so that they could be crossed to produce a cotton line which contains both the insecticidal proteins and thereby to maintain a range of effective control options for lepidopteran insect pests and to reduce the potential for the development of resistance to *Bt* insecticides.

Cotton events Cry1F and Cry1Ac have been considered regulated articles under the regulations in 7 CFR part 340 because they contain gene sequences from the plant pathogen *Agrobacterium tumefaciens*. These cotton events have 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 cotton, 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, Mycogen/Dow has submitted a request to EPA for registration of the stacked Cry1F and Cry1Ac protein construct as a plant-incorporated protectant in cotton.

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. Mycogen/Dow has submitted a request to EPA for a tolerance exemption for both the Cry1F and Cry1Ac proteins as expressed in the subject cotton events.

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. Mycogen/Dow has begun consultation with FDA on the subject cotton events.

To provide the public with documentation of APHIS's review and analysis of the environmental impacts and plant pest risk associated with proposed determinations of nonregulated status for Mycogen/Dow's cotton events Cry1F and Cry1Ac, 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's 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 petitions for determinations 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 determinations for the subject cotton events. The petitions 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 petitions and the environmental assessment and other data and information, APHIS will furnish a response to the petitioner, either approving the petitions in whole or in part, or denying the petitions. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of the Mycogen/Dow insect-resistant cotton events Cry1F and Cry1Ac and the availability of APHIS's 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 4th day of March, 2004.

**Kevin Shea,**

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

[FR Doc. 04–5252 Filed 3–8–04; 8:45 am]

**BILLING CODE 3410–34–P**

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## DEPARTMENT OF AGRICULTURE

### Food and Nutrition Service

#### **Agency Information Collection Activities: Proposed Collection; Comment Request; Food Stamp Program Regulations, Part 275—Quality Control**

**AGENCY:** Food and Nutrition Service, USDA.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on a proposed information collection. This notice is an extension of the currently approved information collection burden for the Quality Control (QC) system which includes the sampling plan and the arbitration and good cause processes. The reporting and recordkeeping burdens associated with the Food Stamp Program QC System are approved through August 31, 2004, under OMB No. 0584–0303. Part 275 of the Food Stamp Program regulations on QC requires these burdens.

**DATES:** Written comments must be submitted on or before May 10, 2004.

**ADDRESSES:** Send comments and requests for copies of this information collection to: Daniel Wilusz, Chief, Quality Control Branch, Program Accountability Division, Food and