

# 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. 01-025-2]

#### Monsanto Co.; Availability of Determination 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 of our determination that the Monsanto Company cotton designated as Event 15985, which has been genetically engineered for insect resistance, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Monsanto Company in its petition for a determination of nonregulated status, our analysis of other scientific data, and comments received from the public in response to a previous notice. This notice also announces the availability of our written determination and our finding of no significant impact.

**EFFECTIVE DATE:** November 5, 2002.

**ADDRESSES:** You may read a copy of the determination, an environmental assessment and finding of no significant impact, the petition for a determination of nonregulated status submitted by Monsanto Company, and all comments received on the petition and the environmental assessment in our reading room. The reading room is located in room 1141, 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 that someone is

available to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.gov/ppd/rad/webrepor.html>.

**FOR FURTHER INFORMATION CONTACT:** Dr. David Heron, Biotechnology Regulatory Services, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-5141. To obtain a copy of the determination or environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734-4885; e-mail: [Kay.Peterson@aphis.usda.gov](mailto:Kay.Peterson@aphis.usda.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

On December 7, 2000, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 00-342-01p) from Monsanto Company (Monsanto) of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for cotton (*Gossypium hirsutum L.*) designated as Bollgard II Cotton Event 15985 (event 15985), which has been genetically engineered for resistance to certain lepidopteran insect pests. The Monsanto petition states that the subject cotton should not be regulated by APHIS because it does not present a plant pest risk.

On March 18, 2002, APHIS published a notice in the **Federal Register** (67 FR 11973-11974, Docket No. 01-025-1) announcing that the Monsanto petition and an environmental assessment (EA) were available for public review. That notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject cotton and food products developed from it. APHIS received seven comments on the petition and the EA during the 60-day comment period, which ended May 17, 2002. The comments were received from university entomologists and extension specialists, an agricultural services company, and a consumer advocacy group. Six comments were in support of the subject petition, and one comment was critical of the EA prepared for the proposed determination of nonregulated status. The commenters supporting nonregulated status for the subject

cotton emphasized its effectiveness in insect control and the related reductions in insecticide applications, the importance of the two *Bacillus thuringiensis* (Bt) toxins in high dose insect resistance management strategies, its usefulness in integrated pest management, the absence of the risk of development of a new plant pest, and the similarities in the environmental effects of event 15985 cotton to traditionally-bred varieties. One commenter stated that the EA prepared for the petition was inadequate and the preparation of an environmental impact statement was necessary because allowing large-scale commercialization of this cotton constituted a major Federal action that would significantly impact the environment. The alleged inadequacies in the EA included failures to address the cumulative effects of gene stacking, the concerns of organic farmers, and the environmental impacts of the approval of a so-called illegal grant of the genetic resource of insect susceptibility to Bt from the public trust into the possession of commercial entities. We have provided a response to these comments as an attachment to our finding of no significant impact (FONSI), which is available from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Cotton event 15985 has been genetically engineered to express a Cry2Ab insecticidal protein derived from the common soil bacterium *B. thuringiensis* subsp. *kurstaki* (Btk). The petitioner states that the Cry2Ab protein is effective in providing protection from the feeding of lepidopteran insect pests such as tobacco budworm, pink bollworm, and cotton bollworm. The subject cotton event also expresses the  $\beta$ -D-glucuronidase (GUS) protein used as a selectable marker. Expression of the added genes is controlled in part by gene sequences from the plant pathogens cauliflower mosaic virus and *Agrobacterium tumefaciens*. Particle acceleration technology was used to transfer the added genes into the recipient Delta and Pine Land Company variety 50B (DP50B). Cotton cultivar DP50B expresses a Btk Cry1Ac insecticidal protein and a NPTII selectable marker protein, and was developed from cotton event 531, which was deregulated by APHIS in 1995 (APHIS No. 94-308-01p).

Cotton event 15985 has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from plant pathogens. This cotton has been field tested since 1998 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 containment or isolation, would not present a risk of plant pest introduction or dissemination.

#### Determination

Based on its analysis of the data submitted by Monsanto, a review of other scientific data, field tests of the subject cotton, and comments submitted by the public, APHIS has determined that cotton event 15985: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than cotton developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not cause damage to raw or processed agricultural commodities; and (5) will not harm threatened or endangered species or organisms, such as bees, that are beneficial to agriculture. Therefore, APHIS has concluded that the subject cotton and any progeny derived from hybrid crosses with other nontransformed cotton varieties will be as safe to grow as cotton in traditional breeding programs that is not subject to regulation under 7 CFR part 340.

The effect of this determination is that Monsanto's cotton event 15985 is no longer considered a regulated article under APHIS' regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the subject cotton or its progeny. However, importation of cotton event 15985 and 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 EA was prepared to examine the potential environmental impacts associated with a determination of nonregulated status for Monsanto's cotton event 15985. 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 FONSI with regard to its determination that cotton event 15985 and lines developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and FONSI are available from the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Done in Washington, DC, this 19th day of November 2002.

**Peter Fernandez,**

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

[FR Doc. 02–29752 Filed 11–21–02; 8:45 am]

**BILLING CODE 3410–34–P**

#### DEPARTMENT OF AGRICULTURE

##### Animal and Plant Health Inspection Service

[Docket No. 01–100–2]

##### **Aventis CropScience; Extension of Determination of Nonregulated Status for Canola Genetically Engineered for Male Sterility, Fertility Restoration, and Glufosinate Herbicide Tolerance**

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

**ACTION:** Notice.

**SUMMARY:** We are advising the public of our decision to extend to additional canola events our determination that certain canola events developed by Aventis CropScience, which have been genetically engineered for male sterility, fertility restoration, and tolerance to the herbicide glufosinate, are no longer considered regulated articles under our regulations governing the introduction of certain genetically engineered organisms. Our decision is based on our evaluation of data submitted by Aventis CropScience in its request for an extension of a determination of nonregulated status, an analysis of other scientific data, and a comment received from the public in response to a previous notice. This notice also announces the availability of our finding of no significant impact.

**EFFECTIVE DATE:** December 23, 2002.

**ADDRESSES:** You may read the extension request, the environmental assessment and finding of no significant impact, and the comment received 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.

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

**FOR FURTHER INFORMATION CONTACT:** Dr. James White, Biotechnology Regulatory Services, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–5490. To obtain a copy of the extension request or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734–4885; e-mail: [Kay.Peterson@aphis.usda.gov](mailto:Kay.Peterson@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. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

#### Background

On July 25, 2001, APHIS received a request for an extension of a determination of nonregulated status (APHIS No. 01–206–01p) from Aventis CropScience (Aventis) of Research Triangle Park, NC, for canola (*Brassica napus* L.) transformation events designated as MS1 and RF1 and RF2, which have been genetically engineered for male sterility (MS1), fertility restoration (RF1 and RF2), and tolerance