

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.

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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.

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

to the herbicide glufosinate (MS1, RF1, and RF2). Aventis requested an extension of a determination of nonregulated status issued in response to APHIS petition number 98-278-01p for male sterile canola transformation event MS8 and fertility restoration canola transformation event RF3, the antecedent organisms (see 64 FR 15337-15338, Docket No. 98-114-2, published March 31, 1999), which are also tolerant to the herbicide glufosinate. Based on the similarity of canola events MS1 and RF1 and RF2 to the antecedent organisms, Aventis requested a determination that MS1 and RF1 and RF2 do not present a plant pest risk and, therefore, are not regulated articles under APHIS' regulations in 7 CFR part 340.

On February 25, 2002, APHIS published a notice in the **Federal Register** (67 FR 8509-8510, Docket No. 01-100-1), announcing that an environmental assessment (EA) for the Aventis extension request had been prepared and was available for public comment. APHIS received one comment on the subject EA during the designated 30-day public comment period, which ended March 27, 2002. The comment, which was from a consumer organization, cited alleged deficiencies in the EA prepared for the antecedent organism and the EA for events MS1 and RF1 and RF2. APHIS has provided a response to this comment as an attachment to the finding of no significant impact (FONSI). The EA and FONSI are available from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Analysis

Like the antecedent organisms, canola events MS1 and RF1 and RF2 have been genetically engineered to contain a *barnase* gene (MS1) for male sterility or a *barstar* gene (RF1 and RF2) for fertility restoration. The *barnase* gene expresses a ribonuclease that blocks pollen development and results in a male-sterile plant, and the *barstar* gene encodes a specific inhibitor of this ribonuclease and restores fertility. The *barnase* and *barstar* genes were derived from *Bacillus amyloliquefaciens*, and are linked in the subject canola events to the *bar* gene derived from *Streptomyces hygroscopicus*. The *bar* gene encodes the enzyme phosphinothricin-N-acetyltransferase (PAT), which confers tolerance to the herbicide glufosinate. The subject canola events and the antecedent organisms were developed through use of the *Agrobacterium tumefaciens* method, and expression of the added genes in MS1 and RF1 and RF2 and the

antecedent organisms is controlled in part by gene sequences derived from the plant pathogen *A. tumefaciens*. In summary, the Aventis extension request states that canola events MS1 and RF1 and RF2 and the antecedent organisms contain the same genetic elements with the exception of the antibiotic resistance marker gene *nptII* in MS1 and RF1 and RF2, which was used as a transformant selection tool during the developmental process. The parental variety Drakkar was used to develop both the antecedent organisms and MS1 and RF1 and RF2.

Canola events MS1 and RF1 and RF2 and the antecedent organisms were genetically engineered using the same transformation method and contain the same enzymes for male sterility, fertility restoration, and glufosinate herbicide tolerance. Accordingly, we have determined that canola events MS1 and RF1 and RF2 are similar to the antecedent organisms in APHIS petition number 98-278-01p, and that canola events MS1 and RF1 and RF2 should no longer be regulated under the regulations in 7 CFR part 340.

The subject canola events have been considered regulated articles under APHIS' regulations in 7 CFR part 340 because they contain gene sequences derived from a plant pathogen. However, canola events MS1 and RF1 and RF2 have been field tested in numerous countries, including the United States and Canada, and after having received the appropriate Canadian approvals, have been marketed commercially in Canada since 1996 with no reports of adverse effects on human health or the environment.

Determination

Based on an analysis of the data submitted by Aventis and a review of other scientific data, APHIS has determined that canola events MS1 and RF1 and RF2: (1) Exhibit no plant pathogenic properties; (2) are no more likely to become a weed than canola varieties developed by traditional breeding techniques and are unlikely to increase the weediness potential for any other cultivated or wild species with which they can interbreed; (3) will not cause damage to raw or processed agricultural commodities; (4) will not harm threatened or endangered species or other organisms, such as bees, that are beneficial to agriculture; and (5) are unlikely to have any significant adverse impact on agricultural practices. Therefore, APHIS has concluded that canola events MS1 and RF1 and RF2 and any progeny derived from crosses with other canola varieties will be as safe to grow as canola that is not subject to regulation under 7 CFR part 340.

Because APHIS has determined that the subject canola events do not present a plant pest risk based on their similarity to the antecedent organisms, Aventis' canola events MS1 and RF1 and RF2 will no longer be considered regulated articles under APHIS' regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of the subject canola events or their progeny. However, importation of canola events MS1 and RF1 and RF2 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 any potential environmental impacts associated with the proposed extension of a determination of nonregulated status for the subject canola events. 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 the determination that Aventis canola events MS1 and RF1 and RF2 and events developed from them 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.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 01-101-2]

Aventis CropScience; Extension of Determination of Nonregulated Status for Canola Genetically Engineered for Glufosinate Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.