

Notices

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. 04-085-4]

Return to Regulated Status of Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the United States District Court for the Northern District of California has vacated the Animal and Plant Health Inspection Service's (APHIS') June 2005 determination of nonregulated status with respect to the Monsanto Company and Forage Genetics International alfalfa lines designated as events J101 and J163, which have been genetically engineered for tolerance to the herbicide glyphosate. The effect of this action is that those alfalfa events, known as Roundup Ready alfalfa, are once again considered regulated articles under APHIS' regulations in 7 CFR part 340 and the requirements pertaining to regulated articles under those regulations will once again apply to the subject alfalfa and its progeny. This notice also advises Roundup Ready alfalfa sellers and growers that no Roundup Ready alfalfa seed may be planted after March 30, 2007; that only seed purchased by growers before March 12, 2007, may be planted by March 30, 2007; and that all sales of Roundup Ready alfalfa seed are prohibited pending the Court's issuance of permanent injunctive relief.

DATES: Effective Date: March 12, 2007.

FOR FURTHER INFORMATION CONTACT:

Thomas Sim, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-7324.

SUPPLEMENTARY INFORMATION:

Background

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.

On April 16, 2004, APHIS received a petition (APHIS petition number 04-110-01p) from Monsanto Company of St. Louis, MO, and Forage Genetics International of West Salem, WI (Monsanto/FGI), requesting a determination of nonregulated status under 7 CFR part 340 for alfalfa (*Medicago sativa* L.) designated as events J101 and J163, which have been genetically engineered for tolerance to the herbicide glyphosate. On November 24, 2004, APHIS published a notice in the **Federal Register** (69 FR 68300–68301, Docket No. 04-085-1) announcing that the Monsanto/FGI petition and an environmental assessment were available for public review and soliciting comments for 60 days ending January 24, 2005. In a second notice published February 3, 2005, APHIS extended the comment period until February 17, 2005 (see 70 FR 5601–5602, Docket No. 04-085-2). Subsequently, in a notice published in the **Federal Register** on June 27, 2005 (70 FR 36917–36919, Docket No. 04-085-3), APHIS advised the public of its determination, effective June 14, 2005, that the Monsanto/FGI alfalfa events J101 and J163 were no longer considered regulated articles under our regulations governing the introduction of certain genetically engineered organisms.

Recent Legal Decisions

On February 13, 2007, the United States District Court for the Northern District of California issued a ruling in

Federal Register

Vol. 72, No. 56

Friday, March 23, 2007

a lawsuit filed by the Center for Food Safety—along with several other nonprofit organizations and alfalfa growers—challenging APHIS' decision to deregulate alfalfa events J101 and J163 (referred to in the lawsuit as Roundup Ready alfalfa). The lawsuit alleged violations of the National Environmental Policy Act (NEPA), the Endangered Species Act, and the Plant Protection Act. The court ruled that the deregulation may have significant environmental impacts that require the preparation of an environmental impact statement (EIS), and that APHIS violated NEPA by not preparing an EIS.

Subsequently, on March 12, 2007, the court issued a preliminary injunction order in the case. As of March 12, 2007, all sales of Roundup Ready alfalfa seed are prohibited pending the Court's issuance of permanent injunctive relief. The court decided that growers who have already planted Roundup Ready alfalfa will not be required to remove the plants. Additionally, they will be permitted to harvest, use, and sell such Roundup Ready alfalfa. The court also prohibited all future planting of Roundup Ready alfalfa beginning March 30, 2007. Growers who intended to plant Roundup Ready alfalfa before that date and who had already purchased the seed prior to the March 12, 2007, preliminary injunction order may plant the seed. Growers who intended to plant alfalfa after March 30, 2007, or who did not purchase Roundup Ready alfalfa seed prior to March 12, 2007, must plant non-genetically engineered alfalfa.

In addition, the court vacated APHIS' June 2005 decision deregulating Roundup Ready alfalfa, and the plant line is once again a regulated article. In accordance with the court's order, APHIS is issuing the appropriate notices informing Roundup Ready alfalfa sellers and growers of the terms of the court's preliminary injunction order. The court has scheduled a hearing on a permanent injunction for April 27, 2007.

By the terms of the court's order, the Monsanto/FGI alfalfa lines that were the subject of APHIS' June 2005 determination of nonregulated status cited above are once again regulated articles under APHIS' regulations in 7 CFR part 340 and the requirements pertaining to regulated articles under those regulations will once again apply to the subject alfalfa and its progeny.

Done in Washington, DC, this 19th day of March 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7-5344 Filed 3-22-07; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2006-0157]

Syngenta Seeds, Inc.; Availability of 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 of our determination that a corn line developed by Syngenta, designated as transformation event MIR604, which has been genetically engineered for resistance to corn rootworm, 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 Syngenta Seeds, Inc., in their 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 announcing the availability of the petition for nonregulated status and an environmental assessment. This notice also announces the availability of our written determination and our finding of no significant impact.

DATES: Effective Date: March 16, 2007.

ADDRESSES: You may read the petition, the environmental assessment, the determination, the finding of no significant impact, the comments we received on our previous notice, and our responses to those comments 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. To view those documents on the Internet, go to <http://www.regulations.gov>, click on the "Advanced Search" tab, and select "Docket Search." In the Docket ID field, enter APHIS-2006-0157, then click

"Submit." Clicking on the Docket ID link in the search results page will produce a list of all documents in the docket.

FOR FURTHER INFORMATION CONTACT: Dr. Catherine Preston, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-5874. To obtain copies of the petition or the environmental assessment (EA) and finding of no significant impact (FONSI), contact Ms. Cynthia Eck at (301) 734-0667, e-mail: cynthia.a.eck@aphis.usda.gov. The petition, EA, and FONSI are also available on the Internet at: http://www.aphis.usda.gov/brs/aphisdocs/04_36201p.pdf and http://www.aphis.usda.gov/brs/aphisdocs/04_36201p_ea.pdf.

SUPPLEMENTARY INFORMATION:

Background

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 December 24, 2004, APHIS received a petition (APHIS No. 04-362-01p) from Syngenta Seeds, Inc. (Syngenta) of Research Triangle Park, NC, requesting a determination of nonregulated status under 7 CFR part 340 for corn (*Zea mays* L.) designated as transformation event MIR604, which has been genetically engineered for resistance to corn rootworm (CRW). In response to APHIS' subsequent requests for additional information and clarification, Syngenta submitted a revised final petition on August 2, 2006. The Syngenta petition states that the subject corn should not be regulated by APHIS because it does not present a plant pest risk.

Analysis

As described in the petition, corn transformation event MIR604 has been genetically engineered to express two transgenes: (1) The modified *cry3A* (*mcry3A*) gene derived from a well-characterized gene sequence from *Bacillus thuringiensis*, encoding the mCRY3A insect control protein and (2) the *pmi* (*manA*) gene from *Escherichia coli*, which encodes the enzyme phosphomannose isomerase (PMI) for use as a selectable marker. Expression of the *mcry3A* gene by corn plants renders the corn line resistant to CRW. Regulatory elements for the *mcry3A* and *pmi* genes were derived from maize and *Agrobacterium tumefaciens*. These regulatory sequences are not transcribed and do not encode proteins. The DNA was introduced into corn cells using *Agrobacterium*-mediated transformation methodology with the T-DNA transformation vector designated pZM26. In addition to transgenes necessary for insertion into the plant genome, the T-DNA vector also contained two additional genetic elements: (1) A gene conferring bacterial resistance to the antibiotics erythromycin, streptomycin, and spectinomycin and (2) the bacterial origin of replication. Plant cells containing the introduced DNA were then selected by culturing in the presence of mannose. After the initial incubation with *Agrobacterium*, the broad-spectrum antibiotic cefotaxime was included in the culture medium to kill any remaining *Agrobacterium*.

In a notice published in the **Federal Register** on January 10, 2007 (72 FR 1212-1214, Docket No. APHIS-2006-0157), APHIS announced the availability of the Syngenta petition and an environmental assessment (EA). APHIS solicited comments on whether the subject corn would present a plant pest risk for 60 days ending on March 12, 2007, and on the EA for 30 days ending on February 9, 2007. In order to provide interested persons additional time to prepare and submit comments on the draft EA, APHIS extended the comment period for the EA until March 9, 2007, i.e., the date 15 days after the publication of our notice of extension. APHIS received 14 comments on the EA and 27 comments on the petition by the close of their respective comment periods. There were 20 comments submitted in support of the petition to grant nonregulated status to MIR604 corn and 7 that were opposed. With regard to the EA prepared by APHIS to examine the potential environmental impacts of granting nonregulated status to MIR604 corn, there were seven