

# Notices

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Thursday, September 29, 2011

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. APHIS-2010-0040]

#### Florigene Pty., Ltd.; Determination of Nonregulated Status for Altered Color Roses

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

**ACTION:** Notice.

**SUMMARY:** We are advising the public of our determination that two hybrid rose lines developed by Florigene Pty., Ltd., designated as IFD-524Ø1-4 and IFD-529Ø1-9, which have been genetically engineered to produce novel flower color, are 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 Florigene Pty., Ltd., in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notice announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

**DATES:** *Effective Date:* September 29, 2011.

**ADDRESSES:** You may read the documents referenced in this notice and the comments we 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. Those documents are also available on the Internet at [http://www.aphis.usda.gov/biotechnology/not\\_reg.html](http://www.aphis.usda.gov/biotechnology/not_reg.html) and are posted with the previous notice and the comments we received on the Regulations.gov Web site at <http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0040>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Evan Chestnut, Policy Analyst, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-0942, e-mail: [evan.a.chestnut@aphis.usda.gov](mailto:evan.a.chestnut@aphis.usda.gov). To obtain copies of the documents referenced in this notice, contact Ms. Cindy Eck at (301) 734-0667, email: [cynthia.a.eck@aphis.usda.gov](mailto:cynthia.a.eck@aphis.usda.gov).

#### 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.

APHIS received a petition (APHIS Petition Number 08-315-01p) from Florigene Pty., Ltd. (Florigene) of Victoria, Australia, seeking a determination of nonregulated status for two hybrid rose lines designated as IFD-524Ø1-4 and IFD-529Ø1-9, which have been genetically engineered to produce novel flower color. The petition stated that these rose lines are unlikely to pose a plant pest risk and, therefore, should

not be regulated articles under APHIS’ regulations in 7 CFR part 340.

In a notice<sup>1</sup> published in the **Federal Register** on April 13, 2011 (76 FR 20623-20624, Docket No. APHIS-2010-0040), APHIS announced the availability of the Florigene petition, a plant pest risk assessment, and a draft environmental assessment (EA) for public comment. APHIS solicited comments on the petition, whether the subject roses are likely to pose a plant pest risk, the draft EA, and the plant pest risk assessment for 60 days ending on June 13, 2011.

APHIS received two comments during the comment period, with one commenter expressing support of the EA’s preferred alternative and one commenter expressing opposition. The commenter opposing a determination of nonregulated status cited scientific concerns related to the plant pest determination. APHIS has addressed the issues raised by this commenter in an attachment to the finding of no significant impact.

#### National Environmental Policy Act

To provide the public with documentation of APHIS’ review and analysis of any potential environmental impacts associated with the determination of nonregulated status for Florigene’s rose lines IFD-524Ø1-4 and IFD-529Ø1-9, an 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). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a finding of no significant impact with regard to the preferred alternative identified in the EA.

#### Determination

Based on APHIS’ analysis of field and laboratory data submitted by Florigene, references provided in the petition,

<sup>1</sup> To view the notice, petition, draft EA, the plant pest risk assessment, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0040>.

peer-reviewed publications, information analyzed in the EA, the plant pest risk assessment, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that Florigene's rose lines IFD-524Ø1-4 and IFD-529Ø1-9 are unlikely to pose a plant pest risk and therefore are no longer subject to our regulations governing the introduction of certain genetically engineered organisms.

Copies of the signed determination document, as well as copies of the petition, plant pest risk assessment, EA, finding of no significant impact, and response to comments are available as indicated in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** sections of this notice.

**Authority:** 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 23rd day of September 2011.

**Kevin Shea,**

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

[FR Doc. 2011-25090 Filed 9-28-11; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2007-0130]

#### Syngenta Biotechnology, Inc.; Determination of Nonregulated Status for Lepidopteran-Resistant Cotton

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

**ACTION:** Notice.

**SUMMARY:** We are advising the public of our determination that a cotton line developed by Syngenta Biotechnology, Inc., designated as event COT67B, which has been genetically engineered to express a protein to protect cotton plants from lepidopteran insect damage, 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 Biotechnology, Inc., in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notice announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also

announces the availability of our written determination and finding of no significant impact.

**DATES:** *Effective Date:* September 29, 2011.

**ADDRESSES:** You may read the documents referenced in this notice and the comments we 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. Those documents are also available *on the Internet at* [http://www.aphis.usda.gov/biotechnology/not\\_reg.html](http://www.aphis.usda.gov/biotechnology/not_reg.html) and are posted with the previous notice and the comments we received on the Regulations.gov Web site at <http://www.regulations.gov#!docketDetail;D=APHIS-2007-0130>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Evan Chestnut, Policy Analyst, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-0942, e-mail: [evan.a.chestnut@aphis.usda.gov](mailto:evan.a.chestnut@aphis.usda.gov). To obtain copies of the documents referenced in this notice, contact Ms. Cindy Eck at (301) 734-0667, e-mail: [cynthia.a.eck@aphis.usda.gov](mailto:cynthia.a.eck@aphis.usda.gov).

#### 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.

APHIS received a petition (APHIS Petition Number 07-108-01p) from

Syngenta Biotechnology, Inc. (Syngenta), seeking a determination of nonregulated status for cotton (*Gossypium* spp.) designated as event COT67B, which has been genetically engineered to express a Cry1Ab protein to protect cotton plants from lepidopteran insect damage. The petition stated that cotton event COT67B is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

In a notice<sup>1</sup> published in the **Federal Register** on May 11, 2011 (76 FR 27301-27303, Docket No. APHIS-2007-0130), APHIS announced the availability of the Syngenta petition, our plant pest risk assessment, and our draft environmental assessment (EA) for public comment. APHIS solicited comments on the petition, whether the subject cotton is likely to pose a plant pest risk, and on the draft EA for 60 days ending on July 11, 2011.

APHIS received 7 comments opposing a determination of nonregulated status during the comment period, with one comment having an additional 4,045 names attached. Commenters generally expressed opposition to genetically engineered organisms or crops but did not provide any specific disagreement with APHIS' analysis. One commenter expressed concern with gene flow. APHIS has addressed the issues raised during the comment period and has provided responses to these comments as an attachment to the finding of no significant impact.

#### National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status for Syngenta's cotton event COT67B, an 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). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a finding of no significant impact with

<sup>1</sup> To view the notice, petition, draft EA, the plant pest risk assessment, and the comments we received, go to <http://www.regulations.gov#!docketDetail;D=APHIS-2007-0130>.