

Done in Washington, DC, this 20th day of February 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013-04496 Filed 2-26-13; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0024]

Syngenta Biotechnology, Inc.; Determination of Nonregulated Status of 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 the Syngenta Biotechnology, Inc., designated as event SYN-05307-1, which has been genetically engineered for resistance to corn rootworm, an insect pest of corn, 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:* February 27, 2013.

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) 799-7039 before coming. Those documents are also available on the Internet at 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-2012-0024>.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the documents referenced in this notice, contact Ms. Cindy Eck at (301) 851-3892, email: 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 10-336-01p) from Syngenta Biotechnology, Inc., (Syngenta) of Research Triangle Park, NC, seeking a determination of nonregulated status of corn (*Zea mays* L.) designated as event SYN-05307-1, which has been genetically engineered for resistance to corn rootworm, an insect pest of corn. The petition states that this corn 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 notice¹ published in the **Federal Register** on July 13, 2012 (77 FR 41366-41367, Docket No. APHIS-2012-0024), APHIS announced the availability of the Syngenta petition, a plant pest risk

assessment (PPRA), and a draft environmental assessment (EA) for public comment. APHIS solicited comments on the petition, whether the subject corn is likely to pose a plant pest risk, the draft EA, and the PPRA for 60 days ending on September 11, 2012.

APHIS received 86 comments during the comment period, with 14 commenters expressing support of the EA's preferred alternative to make a determination of nonregulated status and the remaining 72 commenters expressing opposition. One of the comments opposing a determination of nonregulated status included submitted electronic attachments that consisted of many signed letters containing identical material (4,601 letters). Issues raised during the comment period included adequacy of the EA, effects on nontarget organisms, and potential effects on human and animal health. 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 of Syngenta's corn event SYN-05307-1, 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 Syngenta, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that Syngenta's corn event SYN-05307-1 is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain genetically engineered organisms.

¹ To view the notice, petition, draft EA, the PPRA, and the comments we received, go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2012-0024>.

Copies of the signed determination document, as well as copies of the petition, PPRA, 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 22nd day of February 2013.

Michael Gregoire,

Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

[FR Doc. 2013–04517 Filed 2–26–13; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0033]

Stine Seed Farm, Inc.; Availability of Plant Pest Risk Assessment, Environmental Assessment, and Preliminary Decision for an Extension of a Determination of Nonregulated Status of Corn Genetically Engineered for Herbicide Tolerance

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 prepared a preliminary decision regarding a request from Stine Seed Farm, Inc., to extend to maize line HCEM485, which has been genetically engineered to be tolerant to the herbicide glyphosate, our determination of nonregulated status of Roundup Ready® corn line GA21. We are seeking comment on whether this genetically engineered corn is likely to pose a plant pest risk. We are making available for public comment our plant pest risk assessment and draft environmental assessment for the proposed determination of nonregulated status.

DATES: We will consider all comments that we receive on or before March 29, 2013.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0033-0001>.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No.

APHIS–2012–0033, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-033> or in our reading room, which 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) 799–7039 before coming.

The extension request, draft environmental assessment, and plant pest risk assessment are also available on the APHIS web site at http://www.aphis.usda.gov/brs/aphisdocs/09_06301p.pdf, http://www.aphis.usda.gov/brs/aphisdocs/09_06301p_dea.pdf, and http://www.aphis.usda.gov/brs/aphisdocs/09_06301p_dpra.pdf.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147 Riverdale, MD 20737–1236; (301) 851–3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the supporting documents, contact Ms. Cindy Eck at (301) 851–3885, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 *et seq.*), 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 (GE) 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.

In a notice published in the **Federal Register** on December 5, 1997 (62 FR 64350–64351, Docket No. 97–052–2), APHIS announced our determination of nonregulated status of Roundup Ready® corn line GA21. APHIS has received a request for an extension of a determination of nonregulated status (APHIS Number 09–063–01p) of Roundup Ready® corn line GA21 to maize line HCEM485¹ from Stine Seed Farm, Inc., (Stine Seed) of Research Triangle Park, NC. Stine Seed seeks a determination of nonregulated status of corn designated as maize line HCEM485, which has been genetically engineered to be glyphosate tolerant. In its request, Stine Seed stated that this corn is similar to Roundup Ready® corn line GA21 and, based on the similarity to the antecedent organism, is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS’ regulations in 7 CFR part 340.

As described in the extension request, maize line HCEM485 has been genetically engineered by a 6.0 kb corn genomic fragment, originally isolated from a bacterial chromosome library derived from the corn inbred line B73, containing a modified form of the endogenous *Zea mays* EPSPS encoding gene. The antecedent organism, Roundup Ready® corn line GA21, was made with a 1.3kb restriction fragment of the corn EPSPS gene. Both corn lines were produced with the same mutations responsible for conferring glyphosate herbicide tolerance. Maize line HCEM485 is currently regulated under 7 CFR part 340. Interstate movements and field tests of maize line HCEM485 have been conducted under notifications acknowledged by APHIS.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are used by APHIS to determine whether the new variety poses a plant pest risk.

¹ The terms “corn” and “maize” both refer to *Zea mays*. In this notice, we refer to “maize line HCEM485” as this is the name used by Stine Seed in its extension request to identify its GE corn. Otherwise, we use the more common term “corn” when referring to *Zea mays*.