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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0033]

Stine Seed Farm, Inc.; Extension of a Determination of Nonregulated Status of Corn Genetically Engineered for Herbicide Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service is extending to maize line HCEM485, which has been genetically engineered to be resistant to the herbicide glyphosate, our determination of nonregulated status of Roundup Ready® corn line GA21. Therefore, APHIS no longer considers maize line HCEM485 to be a regulated article under Agency regulations governing the introduction of certain genetically engineered organisms. Our decision is based on our evaluation of data submitted by Stine Seed Farm, Inc., in its request for an extension of a determination of nonregulated status, an analysis of other scientific data, and comments received from the public in response to a previous notice announcing our preliminary determination. This notice also announces the availability of our written determination, final environmental assessment, plant pest risk assessment, and our finding of no significant impact.

EFFECTIVE DATE: [Insert date of publication in the Federal Register].

ADDRESSES: Supporting documents, comments we received on our previous notice announcing our preliminary determination, and our responses to those comments may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0033> 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. Supporting documents are also available on the APHIS web site at [http://www.aphis.usda.gov/biotechnology/petitions\\_table\\_pending.shtml](http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml) under APHIS Petition Number 09-063-01p Extension of 97-099-01p.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Stankiewicz Gabel, Chief, Biotechnology Environmental Analysis Branch, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3927, email: [rebecca.l.stankiewicz-gabel@aphis.usda.gov](mailto:rebecca.l.stankiewicz-gabel@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](mailto: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 (GE) 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.

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 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 HCEM485<sup>1</sup> from Stine Seed Farm, Inc., (Stine Seed) of Research Triangle Park, NC. 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.

On February 27, 2013, APHIS published a notice<sup>2</sup> in the Federal Register (78 FR 13303-13304, Docket No. APHIS-2012-0033) announcing the availability of a draft environmental assessment (EA) and plant pest risk assessment (PPRA) for public comment for the Stine Seed extension request. The extension request and APHIS' preliminary decision were also published with that notice. APHIS received three comments on the subject EA and PPRA during the

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<sup>1</sup> 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.

<sup>2</sup> To view the notice, petition, draft EA, the PPRA, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0033>.

designated 30-day public comment period, which ended March 29, 2013. Issues raised during the comment period included effects of glyphosate, pollen drift, crop diversity, and human health concerns. 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 (FONSI).

#### 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 maize line HCEM485, 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 FONSI with regard to the preferred alternative identified in the EA.

#### Determination

Based on APHIS' analysis of field and laboratory data submitted by Stine Seed, references provided in the extension request, peer-reviewed publications, information analyzed in the EA, the similarity of maize line HCEM485 to the antecedent organism, Roundup Ready® corn line GA21, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that maize line HCEM485 is unlikely to pose a plant pest risk. We are therefore extending the determination of nonregulated status of Roundup Ready® corn line GA21 to maize line HCEM485, whereby maize line HCEM485 is 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 extension request, PPRA, EA, and FONSI 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 29<sup>th</sup> day of April 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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