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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2013-0013]

Monsanto Company and Forage Genetics International; Determination of Nonregulatory Status of Genetically Engineered Alfalfa

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that an alfalfa event developed by the Monsanto Company and Forage Genetics International, designated as event KK179, which has been genetically engineered to express reduced levels of guaiacyl lignin, 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 the Monsanto Company and Forage Genetics International in its petition for a determination of nonregulatory status, our analysis of available scientific data, and comments received from the public in response to our previous notices 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 [Insert date of publication in the Federal Register].

ADDRESSES: You may read the documents referenced in this notice and the comments we received at <http://www.regulations.gov#!docketDetail;D=APHIS-2013-0013> 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 12-321-01p.

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](mailto:john.t.turner@aphis.usda.gov). To obtain copies of the supporting documents for this petition, contact Ms. Cindy Eck at (301) 851-3892, 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 (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. APHIS received a petition (APHIS Petition Number 12-321-01p) from the Monsanto Company and Forage Genetics International (Monsanto and FGI), seeking a determination of nonregulated status of alfalfa designated as event KK179, which has been genetically engineered to express reduced levels of guaiacyl lignin, a major subunit component of total lignin that slows the digestion of cellulose in livestock, as compared to conventional alfalfa at the same stage of growth. The petition states that this alfalfa is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process<sup>1</sup> for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice<sup>2</sup> published in the Federal Register on April 22, 2013, (78 FR 23738-23740, Docket No. APHIS-2013-0013), APHIS announced the availability of the Monsanto and FGI petition for public comment. APHIS solicited comments on the petition for 60 days ending on June 21, 2013, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

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<sup>1</sup> On March 6, 2012, APHIS published in the Federal Register (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms. To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

<sup>2</sup> To view the notice, the petition, the comments we received, and other supporting documents, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0013>.

APHIS received 55 comments on the petition. APHIS decided, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues. According to our public review process for such petitions (see footnote 1), APHIS first solicits written comments from the public on a draft environmental assessment (EA) and a plant pest risk assessment (PPRA) for a 30-day comment period through the publication of a Federal Register notice. Then, after reviewing and evaluating the comments on the draft EA and the PPRA and other information, APHIS revises the PPRA as necessary and prepares a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a finding of no significant impact (FONSI) or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS furnishes a response to the petitioner, either approving or denying the petition. APHIS also publishes a notice in the Federal Register announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

In a notice (see footnote 2) published in the Federal Register on May 30, 2014, (79 FR 31082-31083, Docket No. APHIS-2013-0013), APHIS announced the availability of a draft EA and a PPRA for public comment. APHIS solicited comments on the draft EA, the PPRA, and whether the subject alfalfa is likely to pose a plant pest risk for 30 days ending on June 30, 2014. During the comment period, APHIS received a total of 177 comments, of which, 13 were opposed to a determination of nonregulated status and 164 were supportive of a determination of nonregulated status. Issues raised include potential effects on human health, effects from gene flow and effects on pollinators. APHIS has addressed the issues raised during the comment period and has provided responses to the comments as an attachment to the FONSI.

## National Environmental Policy Act

After reviewing and evaluating the comments received during the comment period on the draft EA and the PPRA and other information, APHIS has prepared a final EA. The EA has been prepared to provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of Monsanto and FGI's KK179 alfalfa. The EA was prepared in accordance with: (1) 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 (to make a determination of nonregulated status of KK179 alfalfa).

## Determination

Based on APHIS' analysis of field and laboratory data submitted by Monsanto and FGI, 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 Monsanto and FGI's KK179 alfalfa is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain GE organisms.

Copies of the signed determination document, PPRA, final EA, FONSI, and response to comments, as well as the previously published petition and supporting documents, 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 3<sup>rd</sup> day of November 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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