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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2013-0043]

Monsanto Co.; Determination of Nonregulated Status of Herbicide Resistant Soybean and Cotton

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that soybean and cotton genetically engineered for herbicide resistance by the Monsanto Company are no longer considered regulated articles 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 in its two petitions for a determination of nonregulated status, our analysis of publically available scientific data, and comments received from the public on the petition for nonregulated status and its associated environmental impact statement and plant pest risk assessments. This notice also announces the availability of our written determination and record of decision.

DATES: EFFECTIVE DATE: January 20, 2015.

ADDRESSES: You may read the documents referenced in this notice and any 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/petitions_table_pending.shtml under APHIS Petition Numbers 10-188-01p (soybean) and 12-185-01p (cotton) and are posted with the comments we received on the Regulations.gov Web site at <http://www.regulations.gov#!docketDetail;D=APHIS-2013-0043>.

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:

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 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 two petitions (referred to below as “the petitions”) from the Monsanto Company seeking determinations of nonregulated status for soybean and cotton cultivars genetically engineered to be resistant to herbicides. The first petition, APHIS Petition Number

10-188-01p, seeks a determination of nonregulated status of soybean (Glycine max) designated as event MON 87708, which has been genetically engineered for tolerance to the herbicide dicamba. The second petition, APHIS Petition Number 12-185-01p, seeks a determination of nonregulated status of cotton (Gossypium spp.) designated as event MON 88701, which has been genetically engineered for tolerance to the herbicides dicamba and glufosinate. The petitions state that these articles are unlikely to pose a plant pest risk and, therefore, should not be regulated articles under APHIS' regulations in 7 CFR part 340.

Notices were published¹ in the Federal Register for each petition advising the public that APHIS had received the petition and was seeking public comments on the petition. The notices also announced that APHIS would prepare either an environmental assessment or an environmental impact statement (EIS) in accordance with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 et seq., NEPA) to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request.

Following review of public comments, we published another notice² in the Federal Register on May 16, 2013 (78 FR 28796-28797, Docket No. APHIS-2013-0043), advising the public of our intent to prepare an EIS for the potential determination of nonregulated status requested by the petitions. APHIS decided to prepare an EIS in order to perform a comprehensive environmental analysis of the potential environmental impacts that may occur as a result of granting determinations of nonregulated status for these two events.

¹ Docket No. APHIS-2012-0047 published on July 13, 2012, 77 FR 41356-41357; Docket No. APHIS-2012-0097 published on February 27, 2013, 78 FR 13308-13309. The Federal Register notices for the petitions and supporting and related materials, including public comments, are available at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0047> and <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0097>.

² To view the notice the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0043>.

National Environmental Policy Act and Record of Decision

To provide the public with documentation of APHIS' review and analysis of the potential environmental impacts associated with a determination of nonregulated status of MON 87708 soybean and MON 88701 cotton, an EIS has been 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).

A notice of availability regarding the draft EIS prepared by APHIS was published by the Environmental Protection Agency (EPA) in the Federal Register on August 11, 2014 (79 FR 46799, Docket No. ER-FRL-9016-4). Along with the draft EIS,³ APHIS also made available the plant pest risk assessments (PPRAs) for the petitions. APHIS reviewed and evaluated all of the public comments received on the draft EIS and prepared formal responses to them as part of the final EIS.

A notice of availability regarding the final EIS prepared by APHIS was published by EPA in the Federal Register on December 12, 2014 (79 FR 73890, Docket No. ER-FRL-9018-4). The NEPA implementing regulations in 40 CFR 1506.10 require a minimum 30-day review period between the time the notice of availability of a final EIS is published and the time an agency makes a decision on an action covered by the EIS. APHIS has reviewed and evaluated the comments received during the 30-day review period and has concluded that it has fully and appropriately analyzed the relevant environmental issues covered by the final EIS and those

³ To view the draft EIS, final EIS, supporting documents, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0043>.

comments. Based on our final EIS, the response to public comments, and other pertinent scientific data, APHIS has prepared a record of decision for the final EIS.

Determination of Nonregulated Status

Based on APHIS' analysis of field and laboratory data submitted by the Monsanto Company, references provided in the petitions, peer-reviewed publications, information analyzed in the EIS, the PPRAs, comments provided by the public, and APHIS' evaluation of and response to those comments, APHIS has determined that MON 87708 soybean and MON 88701 cotton are unlikely to pose a plant pest risk. Accordingly, the petitions requesting a determination of nonregulated status are approved and MON 87708 soybean and MON 88701 cotton are no longer subject to our regulations governing the introduction of certain genetically engineered organisms and to the plant pest provisions of the Plant Protection Act.

Copies of the two signed determination document and the signed record of decision, as well as copies of the final EIS and two PPRAs 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 13th day of January 2015.

Michael Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

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