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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2017-0015]

Bayer CropScience LP: Determination of Nonregulated Status of Canola Genetically

Engineered for Male Sterility and Glufosinate-Ammonium Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination to extend the nonregulated status of InVigor® MS8 canola (hereinafter MS8 canola) to Bayer CropSciences LP's (Bayer) canola event MS11 which has been genetically engineered for male sterility and resistance to the herbicide glufosinate-ammonium using the same mechanism of action as Bayer's MS8 canola. Our determination is based on our evaluation of data submitted by Bayer in its petition 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 assessment and plant pest risk similarity 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].

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Eck, Document Control Officer/Team Leader, Policy Coordination Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147 Riverdale, MD 20737-1236; (301) 851-3954, 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 (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. 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 request for an extension of the determination of nonregulated status of MS8 canola to canola designated as canola event MS11 (APHIS Petition Number 16-235-01p) from Bayer CropScience LP (Bayer) of Research Triangle Park, NC. MS11 canola expresses male sterility and resistance to the herbicide glufosinate-ammonium. In its request, Bayer stated that this canola is similar to the antecedent organism MS8 canola 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.

In a notice¹ published in the Federal Register on April 12, 2017 (82 FR 17625-17626, Docket No. APHIS-2017-0015), APHIS announced the availability of the Bayer's petition, draft environmental assessment, preliminary finding of no significant impact, draft plant pest risk similarity assessment, and preliminary determination for nonregulated status for public comment. We solicited comments on the notice for 30 days ending May 12, 2017. We extended the deadline for comments until May 30, 2017, in a document published in the Federal Register on May 10, 2017 (82 FR 21790-21791, Docket No. APHIS-2017-0015). We received 5 comments by that date. The comments are discussed in the finding of no significant impact (FONSI) that accompanies this notice.

Determination of Nonregulated Status

Based on APHIS' analysis of field and laboratory data submitted by Bayer, references provided in the petitions, peer-reviewed publications, information analyzed in the environmental assessment, the plant pest risk similarity assessment (PPRSA), comments provided by the public, and APHIS' evaluation of and response to those comments, APHIS has determined that MS11 canola is unlikely to pose a plant pest risk. Accordingly, the petition requesting a determination of nonregulated status is approved and MS11 canola is 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.

¹To view the notice, the petition, the comments we received, and other supporting documents, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0015>.

Copies of the signed determination document and the signed record of decision, as well as copies of the final environmental assessment, FONSI, and the PPRSA 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 25th day of July 2017.

Christine Zakarka,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017-15949 Filed: 7/27/2017 8:45 am; Publication Date: 7/28/2017]