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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2019-0050]

Monsanto Company; Availability of a Draft Plant Pest Risk Assessment and Draft Environmental Assessment for Determination of Nonregulated Status of Cotton Genetically Engineered for Insect 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 has prepared a draft plant pest risk assessment and draft environmental assessment regarding a request from Monsanto Company seeking a determination of nonregulated status for cotton designated as MON 88702, which has been genetically engineered for resistance to certain insects, primarily *Lygus* spp. We are making these documents available for public review and comment.

DATES: We will consider all comments that we receive on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0050>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2019-0050, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The draft environmental assessment, draft plant pest risk assessment, and any comments we receive on this docket may be viewed at

<http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0050> or in our reading room, which is located in room 1620 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 for this petition are also available on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Eck, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3892, email: cynthia.a.eck@usda.gov.

SUPPLEMENTARY INFORMATION:

Under the authority of the plant pest provisions of the Plant Protection Act (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."

Pursuant to the terms set forth in a final rule published in the *Federal Register* on May 17, 2020 (85 FR 29790-29838, Docket No. APHIS-2018-0034),¹ 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 19-091-01p) from Monsanto Company (Monsanto) seeking a determination of nonregulated status of a cotton event designated as MON 88702, which has been genetically engineered for resistance to certain insects, primarily *Lygus* spp. The Monsanto petition stated that this cotton 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 process² for soliciting public comment when considering petitions for determination of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. On Sep 26, 2019, APHIS announced in the *Federal Register*³ (84 FR 50818-50819, Docket No. APHIS-2019-0050) the availability of the Monsanto petition for public comment. APHIS solicited comments on the petition for 60 days ending November 25, 2019, 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.

¹ To view the final rule, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0034>.

² 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>.

³ To view the notice, its supporting documents, or the comments that we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0050>.

Thirty-five comments were received during the comment period. Fifteen comments from the agricultural, academic, and private sector were in support of Monsanto's petition. Fourteen comments from individuals were opposed to approval of Monsanto's petition. Six comments provided input on analyses to be considered in the environmental assessment (EA), or comments on insect-resistant crops in general. Issues raised during the comment period include evaluation of potential ecological and economic impacts, and potential impacts on non-target organisms. APHIS has evaluated the issues raised during the comment period and, where appropriate, has provided a discussion of these issues in our EA.

After public comments are received on a completed petition, APHIS evaluates those comments and then provides a second opportunity for public involvement in our decisionmaking process. According to our public review process (see footnote 2), the second opportunity for public involvement follows one of two approaches, as described below.

If APHIS decides, 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 no substantive new issues, APHIS will follow Approach 1 for public involvement. Under Approach 1, APHIS announces in the *Federal Register* the availability of APHIS' preliminary regulatory determination along with its draft EA, preliminary finding of no significant impact (FONSI), and its draft plant pest risk assessment (PPRA) for a 30-day public review period. APHIS will evaluate any information received related to the petition and its supporting documents during the 30-day public review period.

For this petition, we are following approach 2. Under this approach, if APHIS decides, 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, APHIS first solicits written comments from the public on a draft EA and draft 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 draft PPRA and other information, APHIS will revise the draft PPRA as necessary. It will then prepare a final EA, and based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a FONSI or a notice of intent to prepare an environmental impact statement).

As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS prepares a PPRA to assess the plant pest risk of the article. APHIS also prepares the appropriate environmental documentation—either an EA or an environmental impact statement—in accordance with NEPA. This will provide the Agency and the public with a review and analysis of any potential environmental impacts that may result if the petition request is approved.

APHIS concludes in its draft PPRA that MON 88702 cotton, which as stated above has been genetically engineered for resistance to certain insects, primarily *Lygus* spp., is unlikely to pose a plant pest risk. In section 403 of the Plant Protection Act, “plant pest” is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS has also prepared a draft EA in which we present two alternatives based on our analysis of data Monsanto submitted, a review of other scientific data, field tests conducted under APHIS' oversight, and comments received on the petition (see footnote 3). APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the

regulatory status of MON 88702 cotton, or (2) make a determination of nonregulated status for insect-protected MON 88702 cotton.

The draft 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 APHIS' analysis of field and laboratory data submitted by Monsanto, references provided in the petition, peer-reviewed publications, information analyzed in the draft EA, the draft PPRA, comments provided by the public on the petition, and discussion of issues in the draft EA, APHIS has determined that cotton designated as event MON 88702 is unlikely to pose a plant pest risk.

We are making available for a 30-day review period our draft PPRA and draft EA. The draft EA and draft PPRA are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above. Copies of these documents may also be obtained from the person listed under FOR FURTHER INFORMATION CONTACT.

After the 30-day review period closes, APHIS will review and evaluate any information received during the 30-day review period. APHIS will revise the draft PPRA as necessary and prepare a final EA and, based on the final EA, a NEPA decision document (either a FONSI or a notice of intent to prepare an environmental impact statement).

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 9th day of October 2020.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.