



DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2019-0050]

Monsanto Company; Determination of Nonregulated Status for Insect Resistant Cotton

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the cotton event designated as MON 88702, which has been genetically engineered for resistance to certain insects, primarily *Lygus* spp., is no longer considered regulated under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on evaluation of information Monsanto Company submitted in its petition for a determination of nonregulated status, our analyses, and public comments received in response to previous notices announcing the availability of the petition for nonregulated status and our 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: This change in regulatory status will be recognized **[INSERT THE 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-2019-0050>, or in our reading 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 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 (PPA) (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products modified or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests.

Pursuant to the terms set forth in a final rule published in the *Federal Register* on May 18, 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) on May 28, 2019, seeking a determination of nonregulated status for a cotton event designated as MON 88702, which has been genetically engineered for resistance to

¹ Although this final rule (termed the SECURE rule) published revisions to 7 CFR part 340 with phased effective dates beginning August 17, 2020 (https://www.aphis.usda.gov/brs/fedregister/BRS_2020518.pdf), the SECURE rule stated that the petition evaluation process found in the previous regulations would continue to be used for a period of time following that August 17, 2020 effective date. This product was evaluated in accordance with that process.

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 regulated 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 organisms developed using genetic engineering, APHIS accepts written comments regarding a petition once APHIS deems it complete. On September 26, 2019, APHIS published a notice³ in the *Federal Register* (84 FR 50818-50819, Docket No. APHIS-2019-0050) announcing the availability of the Monsanto petition for public comment. Thirty-five comments were received. 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. APHIS evaluated the issues raised during the initial comment period and, where appropriate, incorporated a discussion of them within a draft EA.

A second opportunity for public involvement was provided on October 16, 2020, with a notice⁴ published in the *Federal Register* (85 FR 65789-65790, Docket No. APHIS-2019-0050) announcing the availability of the draft EA and draft plant pest risk assessment (PPRA) for public review and comment. That comment period closed November 16, 2020. APHIS received 14 comments. Most were supportive of Monsanto's petition request; three were opposed. None of the comments identified new information or data regarding the draft EA or draft PPRA.

National Environmental Policy Act

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 organisms developed using genetic engineering. To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

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

⁴ See footnote 3.

After reviewing and evaluating the comments received during the comment period on the draft EA, draft PPRA, and other information, APHIS has prepared a final EA, which provides the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of MON 88702 cotton. The EA was prepared in accordance with: (1) the National Environmental Policy Act (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 finding of no significant impact (FONSI) with regard to the preferred alternative identified in the EA (to make a determination of nonregulated status of MON 88702 cotton).

Determination

Based on APHIS' analysis of field and laboratory data submitted by Monsanto, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, the public comments, and information provided in APHIS' response to those public comments, APHIS has determined that MON 88702 cotton is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain organisms developed using genetic engineering.

Copies of the signed determination document, PPRA, final EA, and FONSI, as well as the previously published petition and supporting documents, are available as indicated under ADDRESSES and from the person listed under the FOR FURTHER INFORMATION CONTACT section in 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 12th day of January 2021.

Michael Watson,

Acting Administrator,

Animal and Plant Health Inspection Service.

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