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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2019-0037]

Westhoff Vertriebsgesellschaft mbH; Availability of Preliminary Plant Pest Risk Assessment, Draft Environmental Assessment, and Preliminary Finding of No Significant Impact for Determination of Nonregulated Status of Petunias Genetically Engineered for Flower Color

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 preliminary plant pest risk assessment, draft environmental assessment, and preliminary finding of no significant impact regarding a request from Westhoff Vertriebsgesellschaft mbH seeking a determination of nonregulated status of petunias containing the A1 gene from maize (A1-DFR Petunias), which have been genetically engineered to add a new color (orange) and brilliance to the flowers. 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-2019-0037>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2019-0037, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The preliminary plant pest risk assessment, draft environmental assessment, and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0037> 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.

The petition is also available on the APHIS website at: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status> under APHIS petition 19-099-01p.

FOR FURTHER INFORMATION CONTACT: Ms. Cynthia Eck, Team Lead, Communications Group, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737-1236; (301) 851-3892; 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 19-099-01p) from Westhoff Vertriebsgesellschaft mbH (Westhoff) seeking a determination of nonregulated status for petunias containing the A1 gene from maize (A1-DFR Petunias), which have been genetically engineered to add a new color (orange) and brilliance to the flowers. The Westhoff petition stated that the plants with the new flower color and brilliance are unlikely to pose a plant pest risk and, therefore, should not be considered a regulated article under APHIS' regulations in 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 July 25, 2019, we published in the *Federal Register* (84 FR 35849-35850, Docket No. APHIS-2019-0037) a notice³ regarding the availability of the Westhoff petition for public comment. APHIS solicited comments on the

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 document, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0037>.

petition for 60 days ending September 23, 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.

Nine comments were received. Seven were supportive of the petition, while two were opposed but did not discuss the petition itself. APHIS evaluated the issues raised during the initial comment period and, where appropriate, provided a discussion of these issues in our draft environmental assessment (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 decision-making 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 preliminary 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.

Under Approach 2, 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 preliminary 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 preliminary PPRA and other information, APHIS will revise the preliminary 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).

For this petition, we will be following Approach 1.

As part of our decision-making 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 preliminary PPRA that A1-DFR Petunias, which as stated above have been genetically engineered for the new color orange and brilliance are 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 Westhoff 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 A1-DFR Petunias, or (2) make a determination of nonregulated status for A1-DFR Petunias.

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 Westhoff, references provided in the petition, peer-reviewed publications, information analyzed in the draft EA, the preliminary PPRA, comments provided by the public on the petition, and discussion of issues in the draft EA, APHIS has determined that petunias designated as event A1-DFR are unlikely to pose a plant pest risk.

We are making available for a 30-day review period our preliminary determination, draft EA, preliminary FONSI, and our PPRA. The preliminary determination, draft EA, preliminary FONSI, and 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.

(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 16th day of September 2020.

Mark Davidson,

Acting Administrator,

Animal and Plant Health Inspection Service.

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