BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0014]

BASF Plant Science, LP; Availability of Petition for Determination of Nonregulated Status of Canola Genetically Engineered For Altered Oil Profile and Resistance to an Imidazolinone Herbicide

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 received a petition from BASF Plant Science, LP, seeking a determination of nonregulated status of canola designated as event LBFLFK, which has been genetically engineered (GE) to allow for the synthesis of long chain omega-3 polyunsaturated fatty acids, including eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), from oleic acid in canola seed. The GE canola has also been genetically engineered for resistance to an imidazolinone herbicide. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms. We are making the BASF Plant Science, LP petition available for review and comment to help us identify potential environmental and interrelated economic issues and impacts that the Animal and Plant Health Inspection Service may determine should be considered in our evaluation of the petition.

DATES: We will consider all comments that we receive on or before **[INSERT DATE 60 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-2018-0014.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2018-0014, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0014 or in our reading room, which 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.

The petition is also available on the APHIS website at: http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml under APHIS petition 17-321-01p.

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 petition, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.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," the Animal and Plant Health Inspection Service (APHIS) regulates, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms 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 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 has received a petition (APHIS Petition Number 17-321-01p) from BASF Plant Science, LP, of Florham Park, NJ (BASF), seeking a determination of nonregulated status of canola (*Brassica napus* L.) designated as event LBFLFK, which has been genetically engineered to allow for the synthesis of long chain omega-3 polyunsaturated fatty acids (LC-PUFAs), including eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), from oleic acid in canola seed. The GE canola has also been genetically engineered for resistance to an imidazolinone herbicide. The BASF petition states that information collected during field trials and laboratory analyses indicates that LBFLFK canola is not likely to be a plant pest and therefore should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the petition, LBFLFK canola was developed through *Agrobacterium rhizogenes*-mediated transformation of canola variety Kumily using a single transformation vector to introduce fatty acid synthesis genes (desaturases and elongases) and an herbicide

resistance gene. Characterization of the LBFLFK canola event demonstrated that there are no safety concerns according to the applicant. LBFLFK canola is currently regulated under 7 CFR part 340. Interstate movements and field tests of LBFLFK canola have been conducted under APHIS authorizations.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk of dissemination and persistence in the environment after completion of the tests. Data were gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data will be used by APHIS to determine if the new variety poses a plant pest risk.

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the *Federal Register* providing 60 days for public comment for petitions for a determination of nonregulated status. On March 6, 2012, we published in the *Federal Register* (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice[1] describing our process for soliciting public comment when considering petitions for determinations of nonregulated status for GE organisms. In that notice we indicated that APHIS would accept written comments regarding a petition once APHIS deemed it complete.

In accordance with § 340.6(d) of the regulations and our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. The petition is available for public

[1] To view the notice, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129.

review and comment, and copies are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above. We are interested in receiving comments regarding potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. We are particularly interested in receiving comments regarding biological, cultural, or ecological issues, and we encourage the submission of scientific data, studies, or research to support your comments.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. Any substantive issues identified by APHIS based on our review of the petition and our evaluation and analysis of comments will be considered in the development of our decision-making documents. As part of our decision-making process regarding a GE organism's regulatory status, APHIS prepares a plant pest risk assessment to assess its plant pest risk and the appropriate environmental documentation--either an environmental assessment (EA) or an environmental impact statement (EIS)--in accordance with the National Environmental Policy Act (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. For petitions for which APHIS prepares an EA, APHIS will follow our published process for soliciting public comment (see footnote 1) and publish a separate notice in the *Federal Register* announcing the availability of APHIS' EA and plant pest risk assessment.

Should APHIS determine that an EIS is necessary, APHIS will complete the NEPA EIS process in accordance with Council on Environmental Quality regulations (40 CFR part 1500-1508) and APHIS' NEPA implementing regulations (7 CFR part 372).

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, on March 26, 2018.

Kevin Shea,

Administrator,

Animal and Plant Health Inspection Service.

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