



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0014]

BASF Plant Science, LP; 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 of our determination that canola designated as event LBFLFK, which has been genetically engineered to allow for the synthesis of long chain omega-3 polyunsaturated fatty acids, including eicosapentaenoic acid and docosahexaenoic acid, from oleic acid in canola seed, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by BASF Plant Science, LP, in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notices announcing the availability of the petition for nonregulated status and its 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 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-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.

Supporting documents are 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. Subray Hegde, Director, Biotechnology Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3901; email: subray.hegde@usda.gov. To obtain copies of the supporting documents for this petition, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@usda.gov.

SUPPLEMENTARY INFORMATION:

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. APHIS 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 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.

According to our process¹ for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice² published in the *Federal Register* on March 30, 2018 (83 FR 13722-13723, Docket No. APHIS-2018-0014), APHIS announced the availability of the BASF petition for public comment. APHIS solicited comments on the petition for 60 days ending on May 29, 2018, 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.

APHIS received eight comments on the petition. Three of the comments were from individuals, three were from the canola industry, one was from a public interest group, and one was from a State government. APHIS evaluated the issues raised during the comment period

¹ On March 6, 2012, we published in the *Federal Register* (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms (see <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>).

² To view the notice, the petition, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0014>.

and, where appropriate, provided a discussion of those issues in our draft environmental assessment (EA).

APHIS decided, based on its review of the petition and its evaluation and analysis of the comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues. According to our public review process for such petitions (see footnote 1), APHIS is following Approach 2, where we first solicit written comments from the public on a draft EA and a draft plant pest risk assessment (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 the draft PPRA and other information, APHIS revises the draft PPRA as necessary and prepares a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) finding document (either a finding of no significant impact (FONSI) or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS furnishes a response to the petitioner, either approving or denying the petition. APHIS also publishes a notice in the *Federal Register* announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

APHIS sought public comment on a draft EA and draft PPRA from April 4, 2019, to May 6, 2019.³ APHIS solicited comments on those documents and whether the subject canola is likely to pose a plant pest risk. APHIS received three comments on the petition and supporting documents, one of which opposed and two of which supported a decision of nonregulated status for LBFLFK canola. Those comments are addressed in our final EA.

³ 84 FR 13243-13244.

National Environmental Policy Act

After reviewing and evaluating the comments received during the comment period on the draft EA and draft PPRA and other information, APHIS has prepared a final EA. The EA has been prepared to provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of LBFLFK canola. The 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 our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a FONSI with regard to the preferred alternative identified in the EA (to make a determination of nonregulated status of LBFLFK canola).

Determination

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

Copies of the signed determination document, PPRA, final EA, FONSI, and response to comments, as well as the previously published petition and supporting documents, 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 1st day of August 2019 .

Kevin Shea,

Administrator,

Animal and Plant Health Inspection Service.

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