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 May 29, 2018.

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


• 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/#/docket Detail:D=APHIS-2016-0014 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.


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 Kumuly 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 comments 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 review and comment, and copies are available as indicated under ADDRESSES and FOR

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


Done in Washington, DC, on March 26, 2018.

Kevin Shea,
Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–06399 Filed 3–29–18; 8:45 am]

SUPPLEMENTARY INFORMATION:

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0016]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Infectious Salmon Anemia; Payment of Indemnity

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service’s intention to request a revision to and extension of approval of an information collection associated with the regulations for the payment of indemnity due to infectious salmon anemia.

DATES: We will consider all comments that we receive on or before May 29, 2018.

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


• Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2018–0016, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River, Room Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments received on this docket may be viewed at http://www.regulations.gov/#docketDetail;D=APHIS-2018-0016 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.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the payment of indemnity due to infectious salmon anemia, contact Mrs. Teresa Robinson, USDA–APHIS–VS, Maine ISA Program Aquaculture Liaison, 253 King Street, Edmonds Township, ME 04628; (207) 319–3703. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS’ Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Infectious Salmon Anemia; Payment of Indemnity.

OMB Control Number: 0579–0192.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 et seq.), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture is authorized, among other things, to prevent the interstate spread of serious diseases and pests of livestock within the United States when feasible. In connection with this mission, APHIS established regulations in 9 CFR part 53 to pay indemnity to salmon producers in Maine whose fish are destroyed because of infectious salmon anemia (ISA). However, payment is subject to the availability of funding.

ISA is a foreign animal disease of Atlantic salmon that is caused by an orthomyxovirus. The disease affects wild and farmed Atlantic salmon. ISA poses a substantial threat to the economic viability and sustainability of salmon aquaculture in the United States.

To take part in this indemnity program, producers must enroll in the cooperative ISA control program administered by APHIS and the State of Maine. Program participants must also inform the ISA Program Veterinarian in writing of the name of their accredited veterinarian, develop biosecurity protocols and a site-specific ISA action plan, submit fish inventory and mortality information, complete an appraisal and indemnity claim form, complete a proceeds from animals sold for slaughter form, and assist APHIS or State officials with onsite disease surveillance, testing, and biosecurity audits. Program participants, who may include certain aquaculture industry business owners, managers, site employees, accredited veterinarians, and designated laboratories, must also assist APHIS with certain disease surveillance activities.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

1. Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;