This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service

[Docket No. APHIS–2017–0096]

Nuseed Americas Inc.; Determination of Nonregulated Status of Canola Genetically Engineered for Altered Oil Profile

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that canola designated as event B0050–027, which has been genetically engineered to accumulate the long chain omega-3 fatty acid known as docosahexaenoic acid (DHA) in 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 Nuseed Americas Inc. 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 August 27, 2018.

ADDRESSES: You may read the documents referenced in this notice and the comments we received at http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0096] 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 supporting documents for this petition, contact Ms. Cindy Eck at (301) 851–3892, email: cynthia.a.eck@aphis.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 17–236–01p) from Nuseed Americas Inc. (Nuseed) of Breckenridge, MN, seeking a determination of nonregulated status of canola (Brassica spp.) designated as event B0050–027, which has been genetically engineered to accumulate the long chain omega-3 fatty acid known as docosahexaenoic acid (DHA) in seed. The Nuseed petition states that information collected during field trials and laboratory analyses indicates that B0050–027 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 process 1 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 notice 2 published in the Federal Register on December 11, 2017 (82 FR 58167–58168, Docket No. APHIS–2017–0096), APHIS announced the availability of the Nuseed petition for public comment. APHIS solicited comments on the petition for 60 days ending on February 9, 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 four comments on the petition. Issues raised during the comment period included concerns regarding product stewardship during production and marketing. These concerns were addressed by Nuseed with supplemental product stewardship data provided to APHIS in support of the petition.

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 environmental assessment (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


2 To view the notice, the petition, and the comments we received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0096.
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 canola designated as event B0050–027. 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 canola designated as event B0050–027).

Determination

Based on APHIS’ analysis of field and laboratory data submitted by Nuseed, 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 canola designated as event B0050–027 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.


Done in Washington, DC, this 22nd day of August 2018.

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

For further information contact:

Supplementary Information:
The Foreign Agricultural Service, under a delegation of authority from the Under Secretary for Trade and Foreign Agricultural Affairs, administers the Dairy Tariff-Rate Import Quota Licensing Regulation codified at 7 CFR 6.20–6.36 that provides for the issuance of licenses to import certain dairy articles under tariff-rate quotas (TRQs) as set forth in the Harmonized Tariff Schedule (HTS) of the United States. These dairy articles may only be entered into the United States at the low-tier tariff by or for the account of a person or firm to whom such licenses have been issued and only in accordance with the terms and conditions of the regulation.

Licenses are issued on a calendar year basis, and each license authorizes the license holder to import a specified quantity and type of dairy article from a specified country of origin. The Import Policies and Export Reporting Division, Foreign Agricultural Service, U.S. Department of Agriculture, issues these licenses and, in conjunction with U.S. Customs and Border Protection, U.S. Department of Homeland Security, monitors their use.

The regulation at 7 CFR 6.34(a) states: “Whenever a historical license (Appendix 1) is not issued to an applicant pursuant to the provisions of 6.23, is permanently surrendered or is revoked by the Licensing Authority, the amount of such license will be transferred to Appendix 2.” Section 6.34(b) provides that the cumulative annual transfers will be published by notice in the Federal Register. Accordingly, this document sets forth the revised Appendices 1 and 2 for the 2018 tariff-rate quota year below.

Issued at Washington, DC, the 6th day of July 2018.

Ronald Lord,
Licensing Authority.