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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0035]

Monsanto Co.; Availability of Plant Pest Risk Assessment, Environmental Assessment, Preliminary Finding of No Significant Impact, and Preliminary Determination of Nonregulated Status of Canola Genetically Engineered for Herbicide Resistance

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 determination regarding a request from the Monsanto Company seeking a determination of nonregulated status of canola designated as MON 88302, which has been genetically engineered for resistance to the herbicide glyphosate with more flexibility in the timing of herbicide application. We are also making available for public review our plant pest risk assessment, environmental assessment, and preliminary finding of no significant impact for the preliminary determination of nonregulated status.

DATES: We will consider any information that we receive on or before [Insert date 30 days after date of publication in the Federal Register].

ADDRESSES: You may submit any information by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0035>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2012-0035, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents for this petition and any other information we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0035> 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 for this petition are also available on the APHIS Web site at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml under APHIS Petition Number 11-188-01p.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Stankiewicz Gabel, Chief, Biotechnology Environmental Analysis Branch, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3927, email: rebecca.l.stankiewicz-gabel@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:

Background

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.”

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 11-188-01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status of canola (Brassica napus) designated as event MON 88302, which has been genetically engineered for resistance to the herbicide glyphosate with more flexibility in the timing of herbicide application. The petition stated that this canola is unlikely to pose a plant pest risk 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 July 13, 2012, (77 FR 41357-41358, Docket No. APHIS-2012-0035), APHIS announced the availability of the Monsanto petition for public comment. APHIS solicited

¹ 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>.

² To view the notice, the petition, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0035>.

comments on the petition for 60 days ending on September 11, 2012, 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 67 comments on the petition. Several of these comments included electronic attachments consisting of a document of identical or nearly identical letters, for a total of 4,670 comments on the petition. Issues raised during the comment period include effects of herbicide use, such as the development of herbicide-resistant weeds and effects on non-target organisms, gene flow, and effects on organic crop production. APHIS has evaluated the issues raised during the comment period and, where appropriate, has provided a discussion of these issues in our 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 decisionmaking process. According to our public review process (see footnote 1), 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 EA, preliminary finding of no significant impact (FONSI), and its 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. For this petition, we are using Approach 1.

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 will follow Approach 2. Under Approach 2, APHIS first solicits written comments from the public on a draft EA and 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 PPRA and other information, APHIS will revise the PPRA as necessary and 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).

As part of our decisionmaking 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, to 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 has prepared a PPRA and has concluded that canola event MON 88302 is 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 prepared an EA in which we present two alternatives based on our analysis of data submitted by Monsanto, a review of other scientific data, field tests conducted under APHIS

oversight, and comments received on the petition. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of canola event MON 88302 and it would continue to be a regulated article, or (2) make a determination of nonregulated status of canola event MON 88302.

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 and other pertinent scientific data, APHIS has reached a preliminary FONSI with regard to the preferred alternative identified in the EA.

Based on APHIS' analysis of field and laboratory data submitted by Monsanto, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public on the petition, and discussion of issues in the EA, APHIS has determined that canola event MON 88302 is unlikely to pose a plant pest risk. We have therefore reached a preliminary decision to make a determination of nonregulated status of canola event MON 88302, whereby canola event MON 88302 would no longer be subject to our regulations governing the introduction of certain GE organisms.

We are making available for a 30-day review period APHIS' preliminary regulatory determination of canola event MON 88302, along with our PPRA, EA, and preliminary FONSI for the preliminary determination of nonregulated status. The EA, preliminary FONSI, PPRA, and our preliminary determination for canola event MON 88302, as well as the Monsanto petition and the comments received on the petition, 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. If, after evaluating the information received, APHIS determines that we have not received substantive new information that would warrant APHIS altering our preliminary regulatory determination or FONSI, substantially changing the proposed action identified in the EA, or substantially changing the analysis of impacts in the EA, APHIS will notify the public through an announcement on our Web site of our final regulatory determination. If, however, APHIS determines that we have received substantive new information that would warrant APHIS altering our preliminary regulatory determination or FONSI, substantially changing the proposed action identified in the EA, or substantially changing the analysis of impacts in the EA, then APHIS will notify the public of our intent to conduct additional analysis and to prepare an amended EA, a new FONSI, and/or a revised PPRA, which would be made available for public review through the publication of a notice of availability in the Federal Register. APHIS will also notify the petitioner.

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 19th day of July 2013.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

