DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0047]

Monsanto Co.: Availability of Petition for Determination of Nonregulated Status of Soybean Genetically Engineered for Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) has received a petition from the Monsanto Company (Monsanto) seeking a determination of nonregulated status of soybean designated as MON 87708, which has been genetically engineered for tolerance to the herbicide dicamba. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are making the Monsanto petition available for review and comment to help us identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

DATES: We will consider all comments that we receive on or before September 11, 2012.

ADDRESSES: You may submit comments by either of the following methods:
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2012–0047, 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-2012-0047 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:

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. 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 10–188–01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status of soybean (Glycine max) designated as event MON 87708, which has been genetically engineered for tolerance to the herbicide dicamba, stating that this soybean is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS’ regulations in 7 CFR part 340.

As described in the petition, soybean event MON 87708 has been genetically engineered to contain a gene from the bacteria Stenotrophomonas maltophilia that expresses a monoxygenase enzyme that rapidly demethylates dicamba rendering it inactive, thereby conferring tolerance to the herbicide dicamba. Soybean event MON 87708 is currently regulated under 7 CFR part 340. Interstate movements and field tests of soybean event MON 87708 have been conducted under permits issued or notifications acknowledged by APHIS. Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are 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 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 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 once APHIS deemed it complete.

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. We also request that, when possible, commenters provide relevant information regarding specific localities or regions as soybean growth, crop management, and crop utilization may vary considerably by geographic region.

After the comment period closes, APHIS will review all written comments.

To view the notice, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2011–0129.
DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS—2012–0035]

Monsanto Co.; Availability of Petition for Determination of Nonregulated Status of Canola Genetically Engineered for Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) has received a petition from the Monsanto Company (Monsanto) seeking a determination of nonregulated status of canola designated as MON 88302, which has been genetically engineered for tolerance to the herbicide glyphosate with more flexibility in the timing of herbicide application. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are making the Monsanto petition available for review and comment to help us identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

DATES: We will consider all comments that we receive on or before September 11, 2012.

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

• Federal eRulemaking Portal: Go to http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0035-0001.

• 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 and any comments 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.


FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 117, 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:

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. 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 11–188–01p) from the Monsanto Company 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 tolerance to the herbicide glyphosate with more flexibility in the timing of herbicide application, stating 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.

As described in the petition, canola event MON 88302 has been genetically engineered for tolerance to the herbicide glyphosate via the incorporation of a cp4 epsps coding sequence, producing the same 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein that is produced in commercial Roundup Ready® crop products. MON 88302 utilizes an improved promoter sequence to enhance CP4 EPSPS expression in male reproductive tissues (i.e., pollen). Enhanced CP4 EPSPS expression in the male reproductive tissues of MON 88302 allows the greater flexibility of glyphosate herbicide applications as MON 88302 plants can be sprayed with higher rates of glyphosate and at later stages of development with no detectable impact to male fertility. Canola event MON 88302 is currently regulated under 7 CFR part 340. Interstate movements and field tests of canola event MON 88302 have been conducted under notifications acknowledged by APHIS.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the...