APHIS has received a petition (APHIS Petition Number 11–342–01p) from GENETIVE SA of Chappes, France, seeking a determination of nonregulated status of maize (Zea mays L.) designated as event VCO-Ω1981–5, which has been genetically engineered for tolerance to the herbicide glyphosate, stating that this maize 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, maize event VCO-Ω1981–5 has been genetically engineered to contain the stably integrated epsps ggr23ace5 gene expressing the EPSPS ACE5 protein, an improved EPSPS enzyme which confers tolerance to the herbicide glyphosate. The EPSPS ACE5 protein was derived from the bacteria Arthrobacter globiformis. Maize event VCO-Ω1981–5 is currently regulated under 7 CFR part 340. Interstate movements and field tests of maize event VCO-Ω1981–5 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. Field tests were also conducted in Europe and Canada. 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 1 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 for a determination of nonregulated status from interested or affected persons for 60 days from the date of this notice. The petition is available for public review, and copies are available as indicated below.

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

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 11–202–01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status of soybean (Glycine max) designated as event MON 87712, which has been genetically engineered for increased yield, 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 87712 has been genetically engineered to increase yield through the insertion of the BBX32 gene from the plant Arabidopsis thaliana. This gene produces a protein that interacts with transcription factors to regulate the plant’s day/night processes, and increases availability of assimilates (products of plant metabolism from processes such as carbon and nitrogen fixation). Soybean event MON 87712 is currently regulated under 7 CFR part 340. Interstate movements and field tests of soybean event MON 87712 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 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 copies are available as indicated under ADDRESSES and FOR 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. 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 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 decisionmaking documents.

As part of our decisionmaking 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 parts 1500–1508) and APHIS’ NEPA implementing regulations (7 CFR part 372).


Done in Washington, DC, this 9th day of July 2012.

Kevin Shea,
Acting Administrator, Animal and Plant Health Inspection Service.
[FR Doc. 2012–17164 Filed 7–12–12; 8:45 am]
BILLING CODE 3410–34–P