
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 09–015–01p) from BASF Plant Science LP of Research Triangle Park, NC, seeking a determination of nonregulated status of soybean (Glycine max) designated as event BPS–CV127–9, which has been genetically engineered for tolerance to herbicides in the imidazolinone family, 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 BPS–CV127–9 has been genetically engineered for tolerance to herbicides in the imidazolinone family through the introduction of the imidazolinone-tolerant acetohydroxyacid synthase large subunit (ahs) gene cvrt–2 with its native promoter from the plant Arabidopsis thaliana. Soybean event BPS–CV127–9 is currently regulated under 7 CFR part 340. Interstate movements and field tests of soybean event BPS–CV127–9 have been conducted under notifications acknowledged by APHIS.

For this petition, most field tests were conducted by BASF in Brazil, which allowed for evaluation in a natural agricultural setting. 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 part 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. 2012–17139 Filed 7–12–12; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0031]

Pioneer Hi-Bred International, Inc.; 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 Pioneer Hi-Bred
International, Inc., (Pioneer) seeking a determination of nonregulated status of canola designated as DP–073496–4, which has been genetically engineered for tolerance to the herbicide glyphosate. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are making the Pioneer 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–2012–0031, 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/ and setting Docket D=APHIS–2012–0031 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 11–063–01p) from Pioneer Hi-Bred International, Inc., of Johnston, IA, requesting a determination of nonregulated status of canola (Brassica napus) designated as event DP–073496–4, which has been genetically engineered for tolerance to the herbicide glyphosate, 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 DP–073496–4 has been genetically engineered to express the glyphosate acetyltransferase (GAT4621) protein, which gives the plant tolerance to the herbicide glyphosate. The gat4621 gene is a variant of three gat genes from the common soil bacterium Bacillus licheniformis. The GAT4621 protein is encoded by the gat4621 gene, which confers tolerance to glyphosate-containing herbicides by acetylation glyphosate and thereby rendering it nonphytotoxic. Canola event DP–073496–4 is currently regulated under 7 CFR part 340. Interstate movements and field tests of canola event DP–073496–4 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 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 canola 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...

\(^1\)To view the notice, go to http://www.regulations.gov/ and search Docket D=APHIS–2011–0129.
Resistance Genetically Engineered for Insect Assessment for Determination of
[Docket No. APHIS–2012–0024]

DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service

[A Docket No. APHIS–2012–0024]

Syngenta Biotechnology, Inc.; Availability of Petition, Plant Pest Risk Assessment, and Environmental Assessment for Determination of Nonregulated Status of Corn Genetically Engineered for Insect 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 received a petition from Syngenta Biotechnology, Inc., seeking a determination of nonregulated status of corn designated as SYN–05307–1, which has been genetically engineered for resistance to corn rootworm, an insect pest of corn. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are soliciting comments on whether this genetically engineered corn is likely to pose a plant pest risk. We are making available for public comment the Syngenta Biotechnology, Inc., petition, our plant pest risk assessment, and our draft environmental assessment for the proposed determination of nonregulated status.

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–2012–0024, 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-2012-0024 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, draft environmental assessment, or plant pest risk assessment, 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 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 10–336–01p) from Syngenta Biotechnology, Inc., (Syngenta) of Research Triangle Park, NC, seeking a determination of nonregulated status of corn (Zea mays L.) designated as event SYN–05307–1, which has been genetically engineered for resistance to corn rootworm, an insect pest of corn. The petition states that this corn 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, corn event SYN–05307–1 has been genetically engineered to contain the transgene ecy3.1Ab encoding a novel rootworm-control protein, eCry3.1Ab, and the transgene pmi (also known as manA), encoding the enzyme phosphomannose isomerase (PMI). The eCry3.1Ab protein is an engineered chimera of the modified Cry3A (mCry3A) and Cry1Ab proteins, members of a class of insecticidal proteins derived from Bacillus thuringiensis. Corn event SYN–05307–1 is currently regulated under 7 CFR part 340. Interstate movements and field tests of corn event SYN–05307–1 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 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.

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...