

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 12–185–01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status of cotton designated as event MON 88701, which has been genetically engineered for tolerance to the herbicides dicamba and glufosinate. The petition states that this cotton 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, cotton event MON 88701 has been genetically engineered to allow in-crop applications of dicamba herbicide for the control of broadleaf weeds from preemergence to 7 days preharvest and glufosinate herbicide for broad spectrum weed control from emergence through early bloom growth stage. Cotton event MON 88701 provides dicamba tolerance that allows for the in-crop application of dicamba beyond the current preplant uses in cotton and also provides glufosinate tolerance equivalent to current commercial glufosinate-tolerant cotton events. Cotton event MON 88701 is currently regulated under 7 CFR part 340. Interstate movements and field tests of cotton event MON 88701 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 notice¹ 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 cotton 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).

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 22nd day of February 2013.

Michael Gregoire,
Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

[FR Doc. 2013–04522 Filed 2–26–13; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0030]

ArborGen Inc.; Availability of Petition, Notice of Intent To Prepare an Environmental Impact Statement for Determination of Nonregulated Status of Freeze Tolerant Eucalyptus Lines, and Notice of Virtual Public Meetings

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 ArborGen Inc. seeking a determination of nonregulated status of Freeze Tolerant Eucalyptus lines designated 427 and 435, which have been genetically engineered (GE) to be more tolerant of cold conditions. The incorporation of the GE trait allows these eucalyptus hybrid trees to be grown in a broader geographic area than non-GE eucalyptus hybrid trees. The petition has been submitted in accordance with our regulations concerning the introduction of certain

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

GE organisms and products. We are making available for public comment the ArborGen Inc. petition and are soliciting comments on whether these GE eucalyptus lines are likely to pose a plant pest risk. We are also announcing to the public our intent to prepare an environmental impact statement (EIS) on the action with regard to the petition for nonregulated status, identifying potential issues and alternatives that may be studied in the EIS, and requesting public comments to further delineate the scope of the alternatives and environmental impacts and issues. We are also announcing that APHIS will be hosting two virtual meetings during the comment period. The purpose of the meetings will be to further delineate the scope of alternatives and environmental impacts and issues discussed in the EIS.

DATES: We will consider all comments that we receive on or before April 29, 2013. We will also consider comments made at virtual public meetings that will be held during the comment period.

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

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0030-0001>.

- **Postal Mail/Commercial Delivery:** Send your comment to Docket No. APHIS-2012-0030, 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-2012-0030> 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) 7997039 before coming.

The petition is also available on the APHIS Web site at http://www.aphis.usda.gov/brs/aphisdocs/11_01901p.pdf.

Other Information: Details regarding the virtual meetings, including times, dates, and how to participate, will be available at <http://www.aphisvirtualmeetings.com>.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1238; (301) 851-3954. To obtain copies of the petition, contact Ms. Cindy Eck at

(301) 851-851-3882, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (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.

Proposed Action

APHIS has received a petition (APHIS Petition Number 11-019-01p) from ArborGen Inc. of Summerville, SC, seeking a determination of nonregulated status of two Freeze Tolerant Eucalyptus (FTE) lines designated 427 and 435. The petition states that these eucalyptus trees are unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340. These regulations are authorized by the PPA to prevent the introduction or dissemination of plant pests, and the decision on whether or not to grant the petition will be based on this standard.

As described in the petition, FTE lines 427 and 435 have been genetically engineered to express the CBF2 gene to be more tolerant of cold conditions and a gene expression cassette that prevents pollen development. FTE lines 427 and 435 are currently regulated under 7 CFR part 340. Field tests of FTE lines 427 and 435 have been conducted under permits issued by APHIS at multiple sites representing both freeze stress and freeze stress-free environments in the southeastern United States, Alabama, Florida, Georgia, Louisiana, Mississippi, South Carolina, and Texas.

APHIS has conducted three separate environmental assessments (EA) on actions related to permitting confined field releases of FTE trees under conditions designed to prevent spread of the trees outside the field test area, and in each case announced the availability of the EA in the **Federal Register**. These notices¹ were published on April 20, 2007 (Docket No. APHIS-2007-0027, 72 FR 19876-19877), June 3, 2009 (Docket No. APHIS-2008-0059, 74 FR 26648-26649), and February 10, 2012 (Docket No. APHIS-2011-0130; 77 FR 7123-7124). In these assessments, APHIS concluded that the field trials would not pose a plant pest risk and that issuing permits for the field trials would not significantly affect the quality of the human environment.

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.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments received will be available for public review. Any substantive issues identified by APHIS based on our review of the petition and our evaluation and analysis of the 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 EA or an environmental impact statement (EIS)—in accordance with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*) (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. Upon completion of these documents, APHIS will furnish

¹ The notices and environmental assessments are available at <http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0027>, <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0059>, and <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0130>.

a response to the petitioner and will notify the public of our regulatory determination.

Under the provisions of NEPA, Federal agencies must examine the potential environmental impacts of proposed Federal actions before actions are taken. In accordance with NEPA, regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), U.S. Department of Agriculture (USDA) regulations implementing NEPA (7 CFR part 1b) and APHIS' NEPA Implementing Procedures (7 CFR part 372), APHIS has considered how to properly examine these potential environmental impacts. In each of the previous three APHIS actions concerning FTE trees, we determined that an EA was the appropriate means to consider and document environmental impacts. Also, in response to a legal challenge to the adequacy of these EAs and the NEPA process, the United States District Court for the Southern District of Florida granted summary judgment affirming the APHIS actions (Case No. 10–14175–CIV–MOORE/LYNCH).

An EA might also be used in this case, where the relevant Federal action would be determination of nonregulated status of two FTE lines. However, APHIS is choosing the option of preparing an EIS to analyze the potential environmental impacts of responding to this petition request.

APHIS is exercising its option to prepare an EIS rather than an EA to address unresolved proposed or adopted local, regional, State, interstate, or Federal land use plans or policies that may result in adverse environmental impacts. In preparing an EIS, APHIS would be responsive to other agencies that have an interest in the possible future establishment of FTE trees in forest areas. Federal and State agencies have expressed interest in this issue from several perspectives. The USDA Forest Service has agreed to serve as a cooperating agency in the preparation of this EIS and will provide expertise in hydrology, to assess the effects of eucalyptus on water resources, and economic modeling, to predict where in the United States FTE trees may be adopted. The United States Department of Energy considers eucalyptus as a candidate bioenergy feedstock. The United States Fish and Wildlife Service has expressed interest in studies of the impacts of eucalyptus tree plantations on wildlife diversity and ecosystem sustainability. Various States, including Georgia and Florida, have conducted studies or hearings on the possible use

of tree plantations as sources of bioenergy feedstocks. APHIS believes that choosing to prepare an EIS rather than an EA would allow us to fully consider potential environmental impacts of the Federal action under consideration and would also provide, in an efficient way, data that could address a wide variety of government interests and could shed light on issues relevant to possible future actions under the jurisdiction of interested agencies. By preparing an EIS at this time, APHIS may provide agencies with an opportunity to adopt all or part of the EIS for future actions in accordance with the adoption provisions of the Council on Environmental Quality's NEPA implementing regulations (40 CFR 1506.3).

Alternatives

This notice identifies reasonable alternatives and potential issues that may be studied in the EIS. We are requesting public comments to further delineate the scope of alternatives and environmental impacts and issues. We will be hosting two virtual meetings during the comment period to discuss the scope of the EIS (see **ADDRESSES** above). 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.

The EIS will consider a range of reasonable alternatives. APHIS is considering including a “no action” and “approve the petition request” alternatives. Under the “no action” alternative, in accordance with 7 CFR part 340, FTE would continue to be regulated and the environmental release and interstate movement of FTE lines 427 and 435 would require permits issued or notifications acknowledged by APHIS. APHIS might choose this alternative if there was insufficient evidence to demonstrate that the regulated eucalyptus events were not plant pests or the lack of plant pest risk from the unconfined cultivation of FTE lines 427 and 435. Under the “approve the petition request” alternative, FTE lines 427 and 435 would no longer be regulated articles under the regulations at 7 CFR part 340.

Environmental Issues for Consideration

We have also identified the following potential environmental issues for consideration in the EIS:

- Alteration in susceptibility to disease or insects—Potential of FTE lines 427 and 435 to harbor plant pests or diseases and the impacts of these pests or diseases on natural resources,

forestry, or agriculture within the range of FTE lines 427 and 435.

- Alteration in weediness characteristics—Potential of FTE lines 427 and 435 to be invasive in certain environments and the impacts to natural resources and sociocultural resources if it is invasive.

- Potential impacts of growing FTE lines 427 and 435 on soil hydrology and water resources and how potential changes in soil hydrology or water use may affect natural resources and sociocultural resources.

- Potential impacts of FTE lines 427 and 435 on fire incidence and ecology and how this may affect natural resources and sociocultural resources.

- Potential impacts of allelopathy of FTE lines 427 and 435 on forestry practices or land use.

- Potential direct or indirect effects of FTE lines 427 and 435 on human health.

- Potential direct or indirect effects of FTE lines 427 and 435 on wildlife and their habitats.

In considering reasonable alternatives, the EIS will also study whether these potential environmental issues pose any potential plant pest risks that FTE may exhibit. In addition to plant pest risks that may be posed by characteristics of an individual GE eucalyptus, like allelopathy (suppression of growth of nearby plants due to toxin release), the EIS will also examine potential plant pest risks associated with environmental issues arising from the potential scale of nonregulated GE eucalyptus plantings. Plantings under the earlier permits were of small scale and limited duration. A decision to approve the petition would allow for larger sized plantings, closer together, over a longer period of time.

Additionally, it is the first time APHIS has received a petition for deregulation for a GE tree like eucalyptus, where the species tends to be the dominant species in many forest areas, and the engineered change will increase the range of the species. These changes in scope from the small trials require analysis of the potential environmental and plant pest risk effects of large-scale FTE planting of local hydrology, fire ecology, and other potential issues discussed above.

While the EIS will consider a comprehensive range of potential environmental impacts that FTE eucalyptus may cause, impacts that are not plant pest risks will not affect APHIS' decision as to whether or not to make a determination of nonregulated status of FTE. As explained above, under the PPA, APHIS must make a determination of nonregulated status based on the GE organism's potential to pose a plant pest risk and nothing more.

Comments that identify other issues or alternatives that should be considered for examination in the EIS would be especially helpful. All comments received during the comment period will be carefully considered in developing the final scope of the EIS. Upon completion of the draft EIS and the plant pest risk assessment for FTE lines 427 and 435, a notice announcing their availability and an opportunity to comment on them will be published in the **Federal Register**.

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 22nd day of February 2013.

Michael Gregoire,

Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0026]

Pioneer Hi-Bred International, Inc.; Availability of Petition, Plant Pest Risk Assessment, and Environmental Assessment for Determination of Nonregulated Status of Maize Genetically Engineered for Herbicide Tolerance and 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 Pioneer Hi-Bred International, Inc., (Pioneer) seeking a determination of nonregulated status of maize designated as maize event DP–ØØ4114–3, which has been genetically engineered to be resistant to certain lepidopteran and coleopteran pests and tolerant to the herbicide glufosinate. 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 maize is likely to pose a plant pest risk. We are making available for public comment the Pioneer 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 April 29, 2013.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0026-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2012–0026, 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-2012-0026> 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.

The petition, draft environmental assessment, and plant pest risk assessment are also available on the APHIS Web site at http://www.aphis.usda.gov/brs/aphisdocs/11_24401p.pdf, http://www.aphis.usda.gov/brs/aphisdocs/11_24401p_dea.pdf, and http://www.aphis.usda.gov/brs/aphisdocs/11_24401p_dpra.pdf.

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 11–244–01p) from Pioneer Hi-Bred International, Inc., (Pioneer) of Johnston, IA, seeking a determination of nonregulated status of maize (*Zea mays*) designated as maize event DP–ØØ4114–3 (event 4114). Event 4114 has been genetically engineered to be resistant to certain lepidopteran pests, including European corn borer (*Ostrinia nubilalis*), and certain coleopteran pests, including western corn rootworm (*Diabrotica virgifera virgifera*), and tolerant to the herbicide glufosinate. The petition states 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, event 4114 has been genetically engineered to produce the Cry proteins Cry1F, Cry34Ab1, and Cry35Ab1, as well as the herbicide tolerance protein phosphinothricin acetyltransferase (PAT). The Cry1F protein confers resistance to certain lepidopteran pests, including European corn borer; the Cry34Ab1 and Cry35Ab1 proteins confers resistance to certain coleopteran pests, including the western corn rootworm; and the PAT protein confers tolerance to the herbicidal active ingredient glufosinate-ammonium at current labeled rates. Event 4114 is currently regulated under 7 CFR part 340. Interstate movements and field tests of event 4114 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.

In section 403 of the Plant Protection Act, “plant pest” is defined as any