

**DEPARTMENT OF AGRICULTURE****Animal and Plant Health Inspection Service**

[Docket No. APHIS-2010-0102]

**Bayer CropScience LP; Availability of Petition, Plant Pest Risk Assessment, and Environmental Assessment for Determination of Nonregulated Status for Cotton Genetically Engineered for Insect Resistance and 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 has received a petition from Bayer CropScience LP seeking a determination of nonregulated status for cotton designated as TwinLink™ cotton (events T304-40 and GHB119), which has been genetically engineered to be tolerant to the herbicide glufosinate and resistant to several lepidopteran pests. 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 cotton is likely to pose a plant pest risk. We are making available for public comment the Bayer 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 August 29, 2011.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2010-0102-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2010-0102, 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-2010-0102> 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) 690-2817 before coming.

*Availability of Documents:* The petition, draft environmental assessment, and plant pest risk assessment are available on the Regulations.gov Web site (see link above) and on the APHIS Web site at [http://www.aphis.usda.gov/brs/aphisdocs/08\\_34001p.pdf](http://www.aphis.usda.gov/brs/aphisdocs/08_34001p.pdf), [http://www.aphis.usda.gov/brs/aphisdocs/08\\_34001p\\_dea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/08_34001p_dea.pdf), and [http://www.aphis.usda.gov/brs/aphisdocs/08\\_34001p\\_dpra.pdf](http://www.aphis.usda.gov/brs/aphisdocs/08_34001p_dpra.pdf).

**FOR FURTHER INFORMATION CONTACT:** Mr. Evan Chestnut, Policy Analyst, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737-1236; (301) 734-0942, e-mail: [evan.a.chestnut@aphis.usda.gov](mailto:evan.a.chestnut@aphis.usda.gov). To obtain copies of the petition, draft environmental assessment, or plant pest risk assessment, contact Ms. Cindy Eck at (301) 734-0667, e-mail: [cynthia.a.eck@aphis.usda.gov](mailto: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 08-340-01p) from Bayer CropScience LP (Bayer), seeking a determination of nonregulated status for TwinLink™ cotton (events T304-40 and GHB119), which has been genetically engineered to be tolerant to the herbicide glufosinate and resistant to several lepidopteran pests, stating

that TwinLink™ 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, TwinLink™ cotton is a combined-trait cotton developed using conventional breeding techniques to link two deoxyribonucleic acid (DNA) transformation events, each developed using DNA recombinant techniques. By crossing Bayer's Cry1Ab Cotton (event T304-40) with Bayer's Cry2Ae Cotton (event GHB119), Bayer has developed a cotton resistant to lepidopteran pests. The TwinLink™ cotton also expresses a glufosinate ammonium herbicide tolerance trait based on LibertyLink® technology. TwinLink™ cotton is currently regulated under 7 CFR part 340. Interstate movement, importation, and field testing of TwinLink™ cotton 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 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 a plant pest risk assessment to determine if TwinLink™ cotton is unlikely to pose a plant pest risk.

APHIS has also prepared a draft environmental assessment (EA) in which it presents two alternatives based on its analyses of data submitted by Bayer, a review of other scientific data, and field tests conducted under APHIS oversight. APHIS is considering the following alternatives: (1) Take no action, *i.e.*, APHIS would not change the regulatory status of TwinLink™ cotton and it would continue to be a regulated article, or (2) make a determination of nonregulated status for TwinLink™ cotton.

The draft EA has been prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the proposed determination of

nonregulated status for TwinLink™ cotton. The draft EA was prepared in accordance with (1) the National Environmental Policy Act of 1969 (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).

In accordance with § 340.6(d) of the regulations, 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. We are also soliciting written comments from interested or affected persons on the plant pest risk assessment and the draft EA prepared to examine any potential environmental impacts of the proposed determination of the nonregulated status of the subject cotton lines. The petition, draft EA, and plant pest risk assessment are available for public review, and copies of the petition, draft EA, and plant pest risk assessment 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 regarding the petition, draft EA, and plant pest risk assessment will be available for public review. After reviewing and evaluating the comments on the petition, the draft EA, plant pest risk assessment, and other data, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will also publish a notice in the **Federal Register** announcing the regulatory status of TwinLink™ cotton and the availability of APHIS' written environmental decision and regulatory determination.

**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 June 2011.

**John R. Clifford,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2011–16126 Filed 6–27–11; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS–2011–0038]

#### **Monsanto Co.; Availability of Petition, Plant Pest Risk Assessment, and Environmental Assessment for Determination of Nonregulated Status for Soybean 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 the Monsanto Company seeking a determination of nonregulated status for soybean designated as MON 87701, which has been genetically engineered for insect resistance. 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 soybean is likely to pose a plant pest risk. We are making available for public comment the Monsanto 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 August 29, 2011.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#/documentDetail;D=APHIS-2011-0038-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2011–0038, 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/#/documentDetail;D=APHIS-2011-0038> 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) 690–2817 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/09\\_08201p.pdf](http://www.aphis.usda.gov/brs/aphisdocs/09_08201p.pdf),

[http://www.aphis.usda.gov/brs/aphisdocs/09\\_08201p\\_dea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/09_08201p_dea.pdf), and

[http://www.aphis.usda.gov/brs/aphisdocs/09\\_08201p\\_dpra.pdf](http://www.aphis.usda.gov/brs/aphisdocs/09_08201p_dpra.pdf).

**FOR FURTHER INFORMATION CONTACT:** Mr. Evan Chestnut, Policy Analyst, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–0942; *e-mail:*

[evan.a.chestnut@aphis.usda.gov](mailto:evan.a.chestnut@aphis.usda.gov). To obtain copies of the petition, draft environmental assessment, or plant pest risk assessment, contact Ms. Cindy Eck at (301) 734–0667; *e-mail:* [cynthia.a.eck@aphis.usda.gov](mailto: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 09–082–01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status for soybean (*Glycine max*) designated as event MON 87701, which has been genetically engineered for insect resistance, 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, event MON 87701 has been genetically engineered to express a Cry1Ac insecticidal protein derived from the