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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0034]

Bayer CropScience LP; Availability of a Finding of No Significant Impact and a Preliminary Decision for an Extension of a Determination of Nonregulated Status of Cotton 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 prepared a finding of no significant impact and a preliminary decision regarding a request from Bayer CropScience LP to extend to cotton event T303-3, which has been genetically engineered to be tolerant to the herbicide glufosinate and resistant to several lepidopteran pests, our determination of nonregulated status of TwinLink™ cotton (event T304-40). We are making available for public comment our finding of no significant impact for the proposed determination of nonregulated status.

DATES: We will consider all comments that we receive on or before [Insert date 30 days after date of publication in the Federal Register].

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

- Federal eRulemaking Portal: Go to http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0034-0001.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2012-0034, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The Bayer CropScience LP extension request, our finding of no significant impact (FONSI), our preliminary determination, and any comments we receive on this docket may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0034 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. Supporting documents regarding our determination of nonregulated status of TwinLink™ cotton, the antecedent organism, including Bayer's petition, our environmental assessment, FONSI, plant pest risk assessment, and determination, and any comments we received regarding our determination of nonregulated status of TwinLink™ cotton, can be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0102 or in our reading room.

The extension request, finding of no significant impact, and preliminary determination for this docket, as well as Bayer's petition and our combined environmental assessment, FONSI, plant pest risk assessment, and determination for TwinLink™ cotton, the antecedent organism, are also available on the APHIS Web site at

http://www.aphis.usda.gov/brs/aphisdocs/12_03301p.pdf,

http://www.aphis.usda.gov/brs/aphisdocs/12_03301p_fonsi.pdf,

http://www.aphis.usda.gov/brs/aphisdocs/12_03301p_pdet.pdf,

http://www.aphis.usda.gov/brs/aphisdocs/08_34001p.pdf, and http://www.aphis.usda.gov/brs/aphisdocs/08_34001p_com.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 supporting documents, 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. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

In a notice[1] published in the Federal Register on October 12, 2011 (76 FR 63278-63279, Docket No. APHIS-2010-0102), APHIS announced our determination of nonregulated status of TwinLink™ cotton (events T304-40 and GHB119). APHIS has received a request for an extension of a determination of nonregulated status (APHIS Number 12-033-01p) of TwinLink™ cotton event T304-40 from Bayer CropScience LP (BCS) of Research Triangle Park, NC, seeking a determination of nonregulated status of cotton (Gossypium spp.) designated as event T303-3, which has been genetically engineered to be tolerant to the herbicide glufosinate and resistant to several lepidopteran pests. In its request, BCS stated that this cotton is similar to TwinLink™ cotton (event T304-40) and, based on the similarity to the antecedent organism, 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 extension request, cotton event T303-3 has been genetically engineered by Agrobacterium-mediated transformation utilizing vector pTDL004 containing a cry1Ab gene construct, encoding insect resistance, and the bar gene as a selectable marker conferring tolerance to glufosinate ammonium herbicides. The antecedent organism, cotton event T304-40, was also generated through Agrobacterium-mediated transformation utilizing a slightly different vector (pTDL008). Both cotton events produce the same insecticidal crystal protein (ICP) Cry1Ab (expression product of the cry1Ab gene) and PAT protein (expression product of the bar gene). Cotton event T303-3 is currently regulated under 7 CFR part 340. Interstate movements and field tests of cotton event T303-3 have been conducted under notifications acknowledged by APHIS.

[1] To view the notice, determination, supporting documents, and the comments we received go to http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0102.

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.

APHIS completed an environmental assessment (EA) and finding of no significant impact (FONSI) for TwinLink™ cotton (see footnote 1). The EA and FONSI were prepared, in accordance with the National Environmental Policy Act (NEPA), to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the proposed determination of nonregulated status of TwinLink™ cotton. APHIS has carefully examined the NEPA documentation completed for TwinLink™ cotton and has concluded that the BCS extension request for a determination of nonregulated status of cotton event T303-3 encompasses the same scope of environmental analysis as TwinLink™ cotton. Therefore, the existing NEPA documentation completed for TwinLink™ cotton is being used to evaluate and determine if there are any potentially significant impacts to the human environment from APHIS' response to the BCS extension request for a determination of nonregulated status of cotton event T303-3.

Based on APHIS' analyses of data submitted by Bayer, a review of other scientific data, and field tests conducted under APHIS oversight, the TwinLink™ cotton EA presented two 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 of TwinLink™ cotton. Based on the similarity of cotton event T303-4 to the antecedent organism TwinLink™ cotton event T304-40, APHIS has concluded that the

alternatives considered for TwinLink™ cotton are relevant to APHIS' regulatory actions associated with cotton event T303-3 and are therefore being used in their entirety.

The EA was prepared in accordance with (1) the 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). Based on our previous NEPA review completed for TwinLink™ cotton and our conclusion that the BCS extension request for a determination of nonregulated status of cotton event T303-3 encompasses the same scope of environmental analysis as TwinLink™ cotton, APHIS has reached a FONSI with regard to a determination of nonregulated status of cotton event T303-3.

Based on APHIS' analysis of field and laboratory data submitted by BCS, references provided in the extension request, peer-reviewed publications, information analyzed in the TwinLink™ cotton EA, and the similarity of cotton event T303-3 to the antecedent organism, cotton event T304-40, APHIS has determined that cotton event T303-3 is unlikely to pose a plant pest risk. We have therefore reached a preliminary decision to approve the request to extend the determination of nonregulated status of cotton event T304-40 to cotton event T303-3, whereby cotton event T303-3 would no longer be subject to our regulations governing the introduction of certain genetically engineered organisms.

Paragraph (e) of § 340.6 provides that APHIS will publish a notice in the Federal Register announcing all preliminary decisions to extend determinations of nonregulated status for 30 days before the decisions become final and effective. In accordance with § 340.6(e) of the regulations, we are publishing this notice to inform the public of our preliminary decision to extend the determination of nonregulated status of cotton event T304-40 to cotton event T303-3.

APHIS will accept written comments on the FONSI regarding a determination of nonregulated status of event T303-3 for a period of 30 days from the date of this notice. The extension request, FONSI, and preliminary determination for event T303-3, as well as the supporting documents, are available for public review 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 FONSI will be available for public review. After reviewing and evaluating the comments on the FONSI, if APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination or FONSI, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our Web site at

http://www.aphis.usda.gov/biotechnology/pet_proc_imp.shtml. APHIS will also furnish a response to the petitioner regarding our final regulatory determination. No further Federal Register notice will be published announcing the final regulatory determination regarding cotton event T303-3.

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 9th day of July 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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