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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2006-0140]

#### Bayer CropScience; Availability of an Environmental Assessment and a Preliminary Decision for an Extension of a Determination of Nonregulated Status for Rice Genetically Engineered for Glufosinate 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 prepared an environmental assessment for a preliminary decision to extend a determination of nonregulated status. The original determination and the requested extension involve rice lines genetically engineered to be tolerant to the herbicide glufosinate. We have received a petition from Bayer CropScience requesting the extension for a rice line, designated as LLRICE601, based on its similarity to previously deregulated rice lines, LLRICE62 and LLRICE06.

**DATES:** We will consider all comments we receive on or before October 10, 2006.

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

*Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and, in the lower "Search Regulations and Federal Actions" box, select "Animal and Plant Health Inspection Service" from the agency drop-down menu, then click on "Submit." In the Docket ID column, select APHIS-2006-0140 to submit or view public comments and to view supporting and related materials available electronically. Information on using [Regulations.gov](http://www.Regulations.gov), including instructions for accessing documents,

submitting comments, and viewing the docket after the close of the comment period, is available through the site's "User Tips" link.

*Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. APHIS-2006-0140, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2006-0140.

*Reading Room:* You may read any comments that we receive on this docket in our reading room. The reading room 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.

*Other Information:* Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Neil Hoffman, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-6331. To obtain copies of the extension request or the environmental assessment, contact Mr. Steve Bennett at (301) 734-5672; e-mail: [steven.m.bennett@aphis.usda.gov](mailto:steven.m.bennett@aphis.usda.gov). The extension request and the environmental assessment are also available on the Internet at [http://www.aphis.usda.gov/brs/aphisdocs/06\\_23401p.pdf](http://www.aphis.usda.gov/brs/aphisdocs/06_23401p.pdf) and [http://www.aphis.usda.gov/brs/aphisdocs/06\\_23401p\\_ea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/06_23401p_ea.pdf).

#### SUPPLEMENTARY INFORMATION:

##### Background

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 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. The section describes the form that a petition for a determination of nonregulated status must take, the information that must be included in the petition, and the actions that will be taken by APHIS once a petition has been submitted. Under the regulations in § 340.6(e), 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 (*i.e.*, the organism with nonregulated status) and the regulated article in question.

On August 18, 2006, APHIS received a request for an extension of a determination of nonregulated status (APHIS No. 06-234-01p) from Bayer CropScience (Bayer) of Research Triangle Park, NC, for rice (*Oryza sativa* L.) designated as Liberty Link® Transformation Event LLRICE601, which has been genetically engineered for tolerance to the herbicide glufosinate. The request Bayer CropScience submitted seeks an extension of the determination of nonregulated status issued<sup>1</sup> in response to APHIS petition number 98-329-01p for glufosinate-tolerant rice transformation events LLRICE06 and LLRICE62, the antecedent organisms. Because rice line LLRICE601 is similar to antecedent rice lines LLRICE06 and LLRICE62, Bayer CropScience requests a determination that rice line LLRICE601 does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

On July 31, 2006, Bayer CropScience notified APHIS that trace levels of LLRICE601 were detected in long grain commercial rice. Subsequently, Bayer CropScience supplied APHIS and the Food and Drug Administration (FDA) with information about the molecular characterization and agronomic performance of LLRICE601. APHIS completed a preliminary risk

<sup>1</sup> See 64 FR 22595, published April 27, 1999, Docket No. 98-126-2.

assessment and determined that LLRICE601 did not pose any environmental concerns.

### Analysis

Like the antecedent organisms LLRICE62 and LLRICE06, rice line LLRICE601 has been genetically engineered to contain the *bar* gene isolated from the bacterium *Streptomyces hygrosopicus*, under the control of a 35S promoter sequence derived from cauliflower mosaic virus (35S CaMV). The *bar* gene encodes a phosphinothricin acetyltransferase (PAT) enzyme that confers tolerance to the herbicide glufosinate. LLRICE601 and LLRICE62 produce a single PAT protein of the same apparent molecular weight, as demonstrated by Western blotting. LLRICE06 does not produce sufficient protein for the size to be determined by this method. The level of expression of the PAT protein produced in LLRICE601 plants falls between that of the two antecedent organisms LLRICE62 and LLRICE06.

The DNA construct was introduced into the LLRICE06 and LLRICE62 by direct gene transfer, but was introduced into LLRICE601 by *Agrobacterium*-mediated transformation. Both direct gene transfer and *Agrobacterium*-mediated transformation are standard practices for introduction of genetic material into plant genomes; APHIS does not, therefore, consider this difference significant.

The 35S CaMV promoter is slightly longer for LLRICE601 than it is for LLRICE06 or LLRICE62. APHIS does not consider this difference significant. The promoter in LLRICE601 has been used in other events that have APHIS and FDA approval, and no unusual effects have been observed in those events. The 35S CaMV promoter is among the most common gene sequences used in genetically engineered plants and has a long history of safe use.

LLRICE601 uses the *nos* (nopaline synthase) terminator, while LLRICE06 and LLRICE62 use the 35S CaMV terminator. The function of the 3' terminator is to provide a polyadenylation site, a necessary part of the mRNA transcript of the gene. In LLRICE601, the *nos* terminator is truncated. However, the PAT protein is still made, so the truncation does not affect the function of the transgene. The *nos* terminator is widely used in genetic engineering, and has been approved in a number of deregulated products, *e.g.*, LLCotton25 and MON810 corn. APHIS does not consider LLRICE601's use of a different terminator than the antecedent organisms to be a significant difference

because both sequences provide the same function.

LLRICE06 was originally genetically engineered into the medium grain variety M202, and LLRICE62 was originally genetically engineered into the medium grain variety Bengal and has since been bred into other rice varieties, including long grain varieties. LLRICE601 was originally genetically engineered in the long grain variety Cocodrie. APHIS does not consider this difference significant.

Rice line LLRICE601 has been considered a regulated article under APHIS regulations in 7 CFR part 340, and it was field tested under APHIS authorization between 1998 and 2001. Numerous field trials of LLRICE601 were conducted under notification during this time period.

The sequence of the PAT protein produced in LLRICE601 is identical to the sequence produced in the approved cotton line LLCotton25. These sequences vary from the PAT proteins in LLRICE06 and LLRICE62 by a single amino acid at position 2, where the former have an aspartic acid residue and the latter have a serine. APHIS does not consider this difference to be significant because lines corresponding to both versions of the protein have undergone applicable reviews by APHIS and FDA.

### Conclusion

Accordingly, we have concluded that rice line LLRICE601 is similar to the antecedent organisms in APHIS petition number 98-329-01p, and we have reached a preliminary decision that rice line LLRICE601 should no longer be regulated under the regulations in 7 CFR part 340.

We will consider all comments we receive regarding this preliminary decision during the comment period for this notice (see **DATES** above), after which APHIS will issue its final decision. Until the final decision is made, LLRICE601 will remain a regulated article.

Should the preliminary decision be made final, LLRICE601 would no longer be considered a regulated article under the regulations in 7 CFR part 340, and the requirements pertaining to regulated articles under those regulations would no longer apply to the field testing, importation, or interstate movement of LLRICE601 or its progeny.

### National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the proposed extension of a determination of nonregulated status for LLRICE601, an

environmental assessment (EA) has been prepared. The 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).

The EA may be viewed on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for instructions for accessing Regulations.gov and information on the location and hours of the reading room). The EA is also available as described under **FOR FURTHER INFORMATION CONTACT**. We will consider all comments we receive regarding the EA during the comment period for this notice (see **DATES** above).

In accordance with § 372.9(e) of APHIS' NEPA Implementing Procedures, the APHIS decisionmaker will consider the alternatives discussed in environmental documents in reaching a determination on the merits of the proposed action (*i.e.*, the decision regarding the regulatory status of rice line LLRICE601).

**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 1st day of September 2006.

**W. Ron DeHaven,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. E6-14921 Filed 9-7-06; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

[Docket No. FSIS-2006-0027]

#### National Advisory Committee on Microbiological Criteria for Foods

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Notice of public meeting.

**SUMMARY:** This notice announces that the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) will hold public meetings of the full Committee and subcommittees on September 18-22, 2006. The Committee will discuss: (1) Determination of Cooking Parameters for Safe Seafood for Consumers, and (2) Assessment of the Food Safety