

Done in Washington, DC, this 2nd day of December 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2008-0094]

#### Pioneer Hi-Bred International, Inc.; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Corn Genetically Engineered for Tolerance to Glyphosate and Acetolactate Synthase-Inhibiting Herbicides

**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., seeking a determination of nonregulated status for corn designated as transformation event 98140, which has been genetically engineered for tolerance to glyphosate and acetolactate synthase-inhibiting herbicides. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. In accordance with those regulations, we are soliciting comments on whether this genetically engineered corn is likely to pose a plant pest risk. We are also making available for public comment an environmental assessment for the proposed determination of nonregulated status.

**DATES:** We will consider all comments we receive on or before February 6, 2009.

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

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0094> to submit or view comments and to view supporting and related materials available electronically.

- **Postal Mail/Commercial Delivery:** Please send two copies of your comment to Docket No. APHIS-2008-0094, 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-2008-0094.

**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. Natalia Weinsetel, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-0809, *e-mail:* [natalia.a.weinsetel@aphis.usda.gov](mailto:natalia.a.weinsetel@aphis.usda.gov). To obtain copies of the petition or the draft environmental assessment, contact Ms. Cindy Eck at (301) 734-0667, *e-mail:* [cynthia.a.eck@aphis.usda.gov](mailto:cynthia.a.eck@aphis.usda.gov). The petition and the draft environmental assessment are also available on the Internet at [http://www.aphis.usda.gov/brs/aphisdocs/07\\_15201p.pdf](http://www.aphis.usda.gov/brs/aphisdocs/07_15201p.pdf) and [http://www.aphis.usda.gov/brs/aphisdocs/07\\_15201p\\_ea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/07_15201p_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(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.

On June 1, 2007, APHIS received a petition seeking a determination of

nonregulated status (APHIS Petition Number 07-152-01p) from Pioneer Hi-Bred International, Inc., of Johnston, IA (Pioneer), for corn (*Zea mays* L.) designated as transformation event 98140, which has been genetically engineered for tolerance to glyphosate and acetolactate synthase (ALS)-inhibiting herbicides, stating that corn line 98140 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, the 98140 corn line has been genetically engineered to express modified glyphosate acetyltransferase (GAT4621) and modified maize acetolactate synthase (ZM-HRA) proteins. The GAT4621 protein, encoded by the *gat4621* gene, confers tolerance to glyphosate-containing herbicides by acetylating glyphosate and thus rendering it non-phytotoxic. The ZM-HRA protein, encoded by the *zm-hra* gene, confers tolerance to the ALS-inhibiting class of herbicides (e.g., sulfonylureas and imidazolinones). Expression of the *zm-hra* gene is controlled by the maize ALS (acetolactate synthase) promoter. ALS is the enzyme required for the production of essential branched-chain amino acids such as valine, leucine, and isoleucine. The *gat4621* gene is based on the sequences of three *gat* genes from *Bacillus licheniformis*, a common soil bacterium. Expression of the *gat4621* gene is driven by the corn ubiquitin promoter (*ubiZM1*). The *zm-hra* gene was made by isolating the herbicide sensitive maize *ALS* gene and introducing two specific changes known to confer herbicide tolerance to tobacco ALS.

The genetic insert also contains the terminator sequence from *Solanum tuberosum* (potato) and two sequences from two prevalent plant pests, cauliflower mosaic virus (enhancer) and *Agrobacterium tumefaciens* (border region). All of these sequences are well-characterized and are non-coding regulatory regions only. Therefore, these sequences will not cause the 98140 corn line to promote plant disease.

A single copy of these genes and other DNA regulatory sequences were introduced into the corn genome with the transformation vector PHP24279 using disarmed (non-plant pest causing) *A. tumefaciens* transformation of immature embryos. Plant cells containing the introduced DNA were selected by culturing in the presence of glyphosate. After the initial transformation, the antibiotic carbenicillin was included in the culture medium to kill any remaining

*Agrobacterium*. Therefore, no part of the plant pest *A. tumefaciens* remained in Pioneer HT corn due to the transformation method.

Pioneer's 98140 corn line has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from plant pathogens. The 98140 corn line has been field tested in the United States since 2005 as authorized by APHIS notifications and permits. In the process of reviewing the permits for field trials of the subject corn, APHIS determined that the vectors and other elements used to introduce the new genes were disarmed and that the trials, which were conducted under conditions of reproductive and physical confinement or isolation, would not present a risk of plant pest introduction or dissemination. Field tests conducted under APHIS regulatory 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 field test data, in turn, are used by APHIS to determine if the regulated corn event poses a plant pest risk. Pioneer has petitioned APHIS to make a determination that the 98140 corn line and the progeny derived from its crosses with other nonregulated corn will no longer be considered regulated articles under 7 CFR part 340.

APHIS has prepared an environmental assessment (EA) in which it presents two alternatives for the determination of nonregulated status based on its analyses of data submitted by Pioneer, 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 the 98140 corn line and it would continue to be a regulated article, or (2) grant nonregulated status to corn line 98140 in whole.

In section 403 of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), "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 views this PPA definition to cover direct or indirect injury, disease, or damage not just to agricultural crops, but also to other

plants, for example, native species, as well as to plant parts and plant products whether natural, manufactured, or processed.

The 98140 corn line and any pesticides contained in or added to it are also subject to regulation by other Federal agencies. The U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt from EPA regulation. In order to be registered as a pesticide under FIFRA, it must be demonstrated that when used with common practices, a pesticide will not cause unreasonable adverse effects in the environment. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA, and the U.S. Food and Drug Administration (FDA) enforces the tolerances set by EPA. Pioneer submitted the appropriate regulatory package to EPA in 2007 to amend the corn tolerance for glyphosate to include the degradation-by-product of glyphosate, N-acetylglyphosate; the assessment is currently under review. Conditions for the safe use of glyphosate (EPA, 1993) and a number of ALS-inhibiting herbicides (<http://www.epa.gov/pesticides/reregistration/status.htm>) have been established by the EPA through their registration of those pesticides for use on corn and the setting of tolerances.

The FDA's policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the **Federal Register** on May 29, 1992 (57 FR 22984–23005). Under this policy, FDA uses what is termed a consultation process to ensure that human and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of a bioengineered food. In compliance with the FDA policy, Pioneer submitted a food and feed safety and nutritional assessment summary to FDA for their 98140 corn line in 2007; the assessment is currently under FDA review.

#### National Environmental Policy Act

A draft EA has been prepared to inform the public of, and provide the

APHIS decisionmaker with, a review and analysis of potential environmental impacts associated with the proposed determination of nonregulated status for the 98140 corn line. 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 draft EA prepared to examine potential environmental impacts of the proposed determination for the deregulation of the subject corn line. The petition and the draft EA are available for public review, and copies of these documents are available as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above.

After the comment period closes, APHIS will evaluate all written comments received during the comment period and any other relevant information. All public comments received regarding the petition and draft EA will be available for public review. After reviewing and evaluating the comments on the petition and the draft EA and other data, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of Pioneer's 98104 corn line and the availability of APHIS' written regulatory and environmental decision.

**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 2nd day of December 2008.

**Kevin Shea,**

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

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