

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

[Docket No. 04-076-1]

Monsanto Co.; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Cotton Genetically Engineered for Tolerance to the Herbicide Glyphosate**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 Monsanto Company seeking a determination of nonregulated status for cotton designated as MON 88913, which has been genetically engineered for tolerance to the herbicide glyphosate. 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 public comments on whether this cotton presents 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 December 3, 2004.

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

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04-076-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 04-076-1.

- E-mail: Address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files.

- Agency Web Site: Go to <http://www.aphis.usda.gov/ppd/rad/cominst.html> for a form you can use to submit an e-mail comment through the APHIS Web site.

- Federal eRulemaking Portal: Go to <http://www.regulations.gov> and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read the petition, the environmental assessment, and 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: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Blanchette, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-5141. To obtain copies of the petition or the environmental assessment, contact Ms. Terry Hampton at (301) 734-5715; e-mail: TerryA.Hampton@aphis.usda.gov. The petition and environmental assessment are also available on the Internet at http://www.aphis.usda.gov/brs/aphisdocs/04_08601p.pdf and http://www.aphis.usda.gov/brs/aphisdocs/04_08601p_ea.pdf.

SUPPLEMENTARY INFORMATION: 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 March 26, 2004, APHIS received a petition from Monsanto Company of St. Louis, MO, (Monsanto), requesting a determination of nonregulated status under 7 CFR part 340 for cotton (*Gossypium hirsutum* L.) designated as MON 88913, which has been genetically engineered for tolerance to the herbicide

glyphosate. The Monsanto petition states that the subject cotton should not be regulated by APHIS because it does not present a plant pest risk.

As described in the petition, MON 88913 has been genetically engineered to express a 5-enolpyruvylshikimate-3-phosphate synthase protein from *Agrobacterium* sp. strain CP4 (CP4 EPSPS), which confers tolerance to the herbicide glyphosate. Expression of the added genes is controlled in part by gene sequences derived from the plant pathogens figwort mosaic virus and cauliflower mosaic virus. The *Agrobacterium tumefaciens* transformation method was used to transfer the added genes into the recipient upland cotton variety Coker 312.

MON 88913 cotton has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from plant pathogens. In the process of reviewing the notifications for field trials of the subject cotton, APHIS determined that the vectors and other elements 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.

In § 403 of the Plant Protection Act (7 U.S.C. 7701-7772), 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 definition very broadly. The definition covers direct or indirect injury, disease, or damage not just to agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees, rhizobia, etc.

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 by EPA regulation. In cases in which genetically modified plants allow for a new use of a pesticide or involve a different use pattern for the pesticide, EPA must approve the new or different use. Accordingly, Monsanto has submitted glyphosate residue data and proposed labeling to EPA for the

expanded use of Roundup UltraMAX(®) herbicide on MON 88913.

When the use of the pesticide on the genetically modified plant would result in an increase in the residues in a food or feed crop for which the pesticide is currently registered, or in new residues in a crop for which the pesticide is not currently registered, establishment of a new tolerance or a revision of the existing tolerance would be required. Residue tolerances for pesticides are established by EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), and the Food and Drug Administration (FDA) enforces tolerances set by EPA under the FFDCA. EPA has previously established an exemption from the requirement for a tolerance for the CP4 EPSPS protein in or on all raw agricultural commodities.

FDA published a statement of policy on foods derived from new plant varieties in the **Federal Register** on May 29, 1992 (57 FR 22984–23005). The FDA statement of policy includes a discussion of FDA's authority for ensuring food safety under the FFDCA, and provides guidance to industry on the scientific considerations associated with the development of foods derived from new plant varieties, including those plants developed through the techniques of genetic engineering. Monsanto has begun consultation with FDA on the food and feed safety and nutritional assessment of the subject cotton.

To provide the public with documentation of APHIS' review and analysis of the environmental impacts and plant pest risk associated with a proposed determination of nonregulated status for Monsanto's 88913 cotton, 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).

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 persons for a period of 60 days from the date of this notice. We are also soliciting written comments from interested persons on the EA prepared to examine any environmental impacts of the

proposed determination for the subject cotton. The petition and the EA and any comments received are available for public review, and copies of the petition and the EA are available as indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

After the comment period closes, APHIS will review the data submitted by the petitioner, all written comments received during the comment period, and any other relevant information. After reviewing and evaluating the comments on the petition and the EA and other data and information, APHIS will furnish a response to the petitioner, either approving the petition in whole or in part, or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of Monsanto's glyphosate-tolerant MON 88913 cotton and the availability of APHIS' written decision.

Authority: 7 U.S.C. 1622n and 7701–7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 28th day of September 2004.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E4–2471 Filed 10–1–04; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–040–2]

Old World Climbing Fern; Availability of an Environmental Assessment and Finding of No Significant Impact

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that an environmental assessment and finding of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to issuing a permit for the environmental release of the nonindigenous moth *Cataglyphis camptozonale* (Hampson) (Lepidoptera: Crambidae), a potential biological control agent of Old World climbing fern (*Lygodium microphyllum*). The environmental assessment documents our review and analysis of environmental impacts associated with, and alternatives to, issuing a permit for the environmental release of the moth in Florida. Based on its finding of no significant impact, the Animal and Plant Health Inspection

Service has determined that an environmental impact statement need not be prepared.

ADDRESSES: Copies of the environmental assessment and finding of no significant impact are available for public inspection 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.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Flanders, Branch Chief, Biological and Technical Service, Pest Permit Evaluations, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 734–5930.

SUPPLEMENTARY INFORMATION:

Background

Old World climbing fern, *Lygodium microphyllum* (Cav.) R. Br. (Lygodiaceae), is a climbing fern that has a large native range that extends through much of the Old World tropics. It has become established in central and southern peninsular Florida where it grows in a number of wetland and mesic (having a moderate supply of moisture) habitats including hammocks, cypress swamps, flatwoods, bayheads, and disturbed sites.

The climbing fern is a highly invasive, exotic weed that climbs over plants, including tall trees, to form massive walls of vegetation. It also forms thick mats on the ground that smother native plants. New infestations can arise great distances from existing populations because the weed produces millions of spores that are spread by wind and other physical carriers. A single spore is capable of starting a new infestation.

In Florida, the potential distribution of this weed includes all habitats from Lake Okeechobee south. It also has the potential to invade the Gulf Coast of Mexico and southern Texas.

On July 1, 2004, we published in the **Federal Register** (69 FR 39894–39895, Docket No. 04–040–1) a notice in which we announced the availability, for public review and comment, of an environmental assessment documenting our review and analysis of environmental impacts associated with issuing a permit for the release of the nonindigenous moth *Cataglyphis camptozonale* (Hampson) (Lepidoptera: Crambidae) as a biological control agent of Old World climbing fern in the State of Florida. Larvae of the moth feed on the leaves of *L. microphyllum* for