COT 678 and the availability of APHIS’ written environmental decision and regulatory determination.


Done in Washington, DC this 4th day of May 2011.

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–2011–0023]

Monsanto Co.; Availability of Petition, Plant Pest Risk Assessment, and Environmental Assessment for Determination of Nonregulated Status for Corn Genetically Engineered for Drought 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 the Monsanto Company seeking a determination of nonregulated status for corn designated as MON 87460, which has been genetically engineered for drought tolerance. We are making available for public comment the Monsanto petition, our draft environmental assessment, or plant pest risk assessment, contact Ms. Cindy Eck at (301) 734–0667, e-mail: cynthia.a.eck@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.

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 (h) 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 09–055–01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status for corn (Zea mays L.) designated as event MON 87460, which has been genetically engineered for drought tolerance, stating that this corn 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, an introduced gene called cold shock protein B, derived from the bacterium Bacillus subtilis, appears to help maintain plant cellular functions and is expected to reduce yield loss under water-limited conditions compared to conventional corn. Corn event MON 87460 is currently regulated under 7 CFR part 340. Interstate movements and field tests of corn event MON 87460 have been conducted under permits issued or 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 data are used by APHIS to determine if the new variety poses a plant pest risk. Monsanto has petitioned APHIS to make a determination that corn event MON 87460 should not be regulated under 7 CFR part 340.

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 corn event MON 87460 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 Monsanto, a review of 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 corn event MON 87460 and it would continue to be a regulated article, or (2) approve the petition based on a determination of the nonregulated status of corn event MON 87460 in whole.

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 corn event MON 87460. 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 for the deregulation of the subject corn line. 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 corn event MON 87460 and the availability of APHIS’ written environmental decision and regulatory determination.