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Newsroom

News Release

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USDA Announces Biotechnology Regulatory Actions

WASHINGTON, Dec. 21, 2011--The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is announcing four regulatory notices and supporting scientific evaluations related to the agency's oversight of genetically-engineered plants. Three notices will be published in the *Federal Register* on Dec. 27 and a fourth was published on Dec. 16.

APHIS has made a determination of nonregulated status of two separate items: corn genetically engineered to better withstand drought conditions, as well as a soybean which has been genetically engineered to have tolerance to the herbicide glyphosate and produce higher levels of oleic acid. In addition, APHIS has prepared plant pest risk assessments (PPRA) and draft environmental assessments (EA) to address requests from developers seeking determinations of nonregulated status of two separate items: a soybean that has been genetically engineered to produce an omega-3 fatty acid and corn that has been genetically engineered to be resistant to the herbicide 2,4-D.

MON 87460 Corn: Nonregulated Status

This is APHIS' first determination of nonregulated status of a product that has been genetically engineered to increase drought tolerance. Monsanto Co. petitioned APHIS for a determination of nonregulated status of its corn line designated as event MON 87460 in 2009. In a notice published in the *Federal Register* on May 11, 2011, APHIS announced the availability of the Monsanto petition, a PPRA, and a draft environmental assessment (EA) for public comment. APHIS solicited comments on the petition; whether the subject corn is unlikely to pose a plant pest risk; the draft EA; and the PPRA, for 60 days, ending July 11, 2011.

Based on the data submitted by Monsanto with its petition for deregulation, APHIS' risk assessment and evaluation of scientific information, and review of the public comments received, APHIS has determined that the product is unlikely to present a plant pest risk and is therefore determining nonregulated status. Further information on this product and APHIS' determination can be found at www.aphis.usda.gov/biotechnology/news.shtml.

MON 87705 Soybean: Nonregulated Status

Monsanto Co. also petitioned APHIS for a determination of nonregulated status of a soybean line designated as event MON 87705 in 2009. This soybean was genetically engineered to have a modified fatty acid profile and for tolerance to the herbicide glyphosate. In response, APHIS prepared a PPRA and an EA and made both documents, as well as Monsanto's petition, available for public comment on June 28, 2011. Through its evaluation of Monsanto's petition, the PPRA, and review of public comments received, APHIS has determined that the soybean is unlikely to pose a plant pest risk. The soybean is therefore no longer subject

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to APHIS regulation; the agency published its determination of nonregulated status of this event in the *Federal Register* on Dec. 16, 2011. Further information on this determination can be found at www.aphis.usda.gov/biotechnology/news.shtml.

MON 87769 Soybean: For Public Comment

APHIS is also announcing today that it has prepared a PPRA and a draft EA to address a request from Monsanto Co. seeking a determination of nonregulated status of its MON 87769 soybean. This soybean has been genetically engineered to produce stearidonic acid, an omega-3 fatty acid that helps to prevent a wide variety of adverse health conditions and not typically found in soybean oil.

APHIS' risk assessment indicates that MON 87769 is unlikely to pose a plant pest risk. APHIS is making available for public comment the Monsanto petition, the agency's PPRA, and the draft EA for the proposed determination of nonregulated status. These documents can be found at www.aphis.usda.gov/biotechnology/news.shtml; the public comment period will close on Feb. 27, 2012.

DAS-40278-9 Corn: For Public Comment

Finally, APHIS is also making available today a PPRA and a draft EA to address a request from Dow, Inc. seeking a determination of nonregulated status of its DAS-40278-9 corn. This corn has been genetically engineered to provide tolerance to 2,4-D and aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase (ACCase) inhibitors, also known as "fop" herbicides. DAS-40278-9 corn has been field tested in the major corn growing regions of the continental United States as well as Hawaii.

APHIS' risk assessment indicates that DAS-40278-9 corn is unlikely to pose a plant pest risk. APHIS is making available for public comment the Dow petition for nonregulated status, APHIS' PPRA and draft EA. These documents can be found at www.aphis.usda.gov/biotechnology/news.shtml; the public comment period will close on Feb. 27, 2012.

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