Biotechnology Regulatory Services

July 2012

Monsanto's Modified Oil Soybean (Event MON 87769)

APHIS received a petition from Monsanto, in July 2009, seeking a determination of nonregulated status for MON 87769 developed to increase the levels of the omega-3 fatty acid, stearidonic acid.

In a notice published in the Federal Register on December 27, 2011, APHIS announced the availability of the Monsanto petition, a draft plant pest risk assessment (PPRA), and a draft environmental assessment (EA) for public comment. APHIS solicited comments on all these documents for 60 days ending on February 27, 2012. APHIS received 226 comments during the comment period.

APHIS has determined that MON 87769 is unlikely to pose a plant pest risk to agricultural crops and other plants and plant products. APHIS' determination is based on 1) the Agency's analysis of available scientific data, 2) its evaluation of data submitted by the Monsanto Company in its petition for a determination of nonregulated status, and 3) comments received from the public in response to our previous notice announcing the availability of the petition for nonregulated status and its associated EA and PPRA.

Under the Plant Protection Act and APHIS' regulations, the Agency is specifically required to evaluate if the modified oil soybean variety is a plant pest to agricultural crops or other plants or plant products. The Act defines a plant pest as organisms, such as bacteria, fungi, or insects that can cause harm to agricultural crops or other plants or plant products.

Q: What is stearodonic acid?

A: Stearidonic acid is an omega-3 fatty acid that helps to prevent a wide variety of adverse health conditions and is not typically found in soybean oil.

Q: Is this product intended for human consumption?

A: Yes. Monsanto submitted to FDA a food and feed safety and nutritional assessment for event MON 87769. It is currently under review at FDA.

Q: Has Soybean MON 87769 been field tested in the U.S.?

A: Yes, it has been field tested in the major soybean growing regions of the continental United States. All field tests were conducted under field permits, including strict movement controls, granted by USDA APHIS.

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