Biotechnology Regulatory Services

July 2012

Questions and Answers: Monsanto's High-Yield Soybean (Event MON 87712)

APHIS received a petition from Monsanto, in July 2011, seeking a determination of nonregulated status for soybean MON 87712 developed to produce commercial soybean crops with increased yield. The yield increase in MON 87712 is achieved using the *BBX32* gene that causes the plant to express the protein that alters the plant's physiology; allowing it to make more efficient use of nutrients and sunlight.

Q: What would be the principal use of soybean MON 87712?

A. It will be used to produce soybeans with increased yield.

Q: What is BBX32?

A: BBX32 is a common protein in plants that regulates responses to light. BBX32 is introduced by genetic engineering in soybeans to allow for more efficient use of nutrients and sunlight.

Q: Is soybean MON 87712 intended for human consumption?

A: Yes. Monsanto submitted to FDA a food and feed safety and nutritional assessment for event MON 87712. It is currently under review at FDA.

Q: Has soybean MON 87712 been field tested in the U.S.?

A: Yes, it has been field tested since 2009 in the major soybean growing regions of the United States. All field tests have been conducted under permits, including strict movement controls, granted by USDA APHIS.

Q: Why is APHIS making this petition available to the public?

A: This first comment period provides the public an opportunity to review the petition for nonregulated status and provide input that will be considered by APHIS as it develops its ensuing environmental

assessment and plant pest risk assessment. 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 the Agency's notice in the Federal Register.

Q: What is the next step following the comment period?

A: After the comment period closes, APHIS will carefully consider all written comments received during the comment period and any other relevant information; any substantive issues identified by APHIS based on our review of the petition and our evaluation and analysis of comments will be considered in the development of the Agency's environmental assessment and plant pest risk assessment.

Q: Under APHIS' process, what does the Agency do after it prepares its draft assessments?

A: After the Agency prepares these documents, it makes them publicly available, providing a second 30-day opportunity for public input. The Agency then carefully reviews comments before any determination becomes final.

For more details on the petition process, go to:

http://www.aphis.usda.gov/biotechnology/pet_proc_imp_info.shtml

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