Biotechnology Regulatory Services

July 2012

Questions and Answers: Okanagan Specialty Fruits' Non-Browning Apple (Events GD743 and GS784)

APHIS received a petition from Okanagan Specialty Fruits Inc. (OSF), in April 2011, seeking a determination of nonregulated status for ArcticTM Apple developed to be resistant to apple browning. The apples contain an inserted gene sequence that allows the fruit to resist browning; when the apples are subjected to mechanical damage, such as slicing or bruising, the apple flesh remains its original color.

Q: What is the intended purpose of the ArcticTM Apple?

A: ArcticTM Apple will offer growers, packers, processors, wholesalers, retailers, the foodservice industry and consumers nonbrowning apple variants.

Q: How are ArcticTM Apples different from traditional apples?

A: The ArcticTM apples contain an inserted gene that allows the fruit to resist browning. The appearance and quality of these apples, however, are comparable to the appearance and quality of traditional apples.

Q: Is FDA aware of this petition?

A: OSF submitted to FDA a food and feed safety and nutritional assessment for events GD743 and GS784 in 2010. It is currently under review at FDA.

Q: Has ArcticTM Apple been field tested in the U.S.?

A: Yes, ArcticTM Apple has been field tested in Washington and New York States. All field tests that have occurred in the United States were under permits, including strict movement controls, granted by 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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