
Risk assessment report: Genetically Modified Foods and Feeds

Stearidonic Acid Producing Soybean MON87769 Line

Summary

Food Safety Commission of Japan

The Food Safety Commission of Japan (FSCJ) conducted a safety assessment of MON87769 line, a soybean producing stearidonic acid, based on the documents submitted by the applicant. The documents evaluated included the safety of the inserted genes, toxicity and allergenicity of the protein produced from the inserted genes, post-insertion analysis of the nucleotide sequences, stability of the inserted genes in the successive generations, influence on metabolic pathways in plants, comparative characterization of nutrients and toxic ingredients in plants. Newly produced adverse effects on humans derived from this line are unlikely based on the comparison between this line and the conventional counterpart. In conclusion, no concern relevant to human health is raised on the stearidonic acid producing soybean MON87769 line.

Conclusion in Brief

The Food Safety Commission of Japan (FSCJ) conducted a safety assessment of MON87769 line, a soybean producing stearidonic acid, based on the documents submitted by the applicant.

Soybean MON87769 line was generated through the introduction of *Pj.D6D* gene derived from *Primula juliae* and the modified *Nc.Fad3* gene derived from *Neurospora crassa*. These gene insertions result in the expression of delta-6 desaturase-protein and the modified delta-15 desaturase-protein. These enzymes desaturate fatty acids in the host line, and thus stearidonic acid is newly synthesized in the seeds.

While modified *cp4 epsps* gene derived from *Agrobacterium* sp. CP4 strain was also introduced as a selection marker in the initial procedure to generate this line, the line which lacks the modified *cp4 epsps* gene was selected by means of genetic segregation by hybridization.

The documents, evaluated based on the “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)” (Decision of the Commission dated 29 January 2004), included the safety of the inserted genes, toxicity and allergenicity of the protein produced from the inserted genes, post-insertion analysis of the nucleotide sequences, stability of the inserted genes in the successive generations, influence on metabolic pathways in plants, comparative characterization of nutrients and toxic ingredients in plants. Consequently, newly produced adverse effects on humans derived from this line are unlikely based on the comparison between this line and the conventional counterpart.

In conclusion, no concern relevant to human health is raised on the stearidonic acid producing soybean MON87769 line.

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This is an English translation of excerpts from the original full report (June 2014–FS/480/2014). Only original Japanese texts have legal effect.

The original full report is available in Japanese at <http://www.fsc.go.jp/fsciis/evaluationDocument/show/kya20110712002>

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