This is provisional English translation of an excerpt from the original full report.

Safety Assessment Report

81419 soybean line resistant to lepidopteran insects and tolerant of the herbicide glufosinate

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a safety assessment of 81419 soybean line resistant to lepidopteran insects and tolerant of the herbicide glufosinate, based on the documents submitted by the applicant.

Soybean 81419 line was generated through the introduction of the modified cry1F gene derived from *Bacillus thuringiensis* subsp. *aizawai* PS811 and *B. thuringiensis* subsp. *berliner* 1715, and of the modified *cry1Ac* gene derived from *B. thuringiensis* subsp. *kurstaki* HD73, *B. thuringiensis* subsp. *aizawai* PS811and *B. thuringiensis* subsp. *berliner* 1715. These gene insertions result in the expression of the modified Cry1F protein and the modified Cry1Ac protein, thus the host soybean can survive being resistant to Lepidoptera.

The host soybean expressing phosphinothricin acetyltransferase (PAT) protein becomes tolerant of glufosinate herbicide, since the modified PAT gene derived from *Streptomyces viridochromogenes* (the modified *pat* gene) was also introduced as a selection marker.

The safety of the inserted gene, toxicity and allergenicity of the protein produced from the inserted gene, post-insertion analysis of the nucleotide sequence, stability of the inserted gene in the successive generations, influences on metabolic pathways in the plants, comparative characterization of nutrients and toxic ingredients in the plants and others were evaluated based on the "Approach to the Safety Assessment of Genetically Modified Foods (seed plants)"[1]. None of newly generated safety concerns were detected in comparison with the soybean line without genetical modification.

Consequently, FSCJ concluded that the stearidonic acid producing soybean MON87769 line has no concern relevant to human health.

[1] "Approach to the Safety Assessment of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)"