



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

Safety Assessment Report

Soybean MON87751 line resistant to Lepidoptera

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

August 2016

ABSTRACT

FSCJ conducted a safety assessment of a soybean, MON87751 line resistant to Lepidoptera, based on the documents submitted by the applicant.

This line was generated through the introduction of *cry1Ab* and *cry1Ac* genes derived from *Bacillus thuringiensis* ssp. *kurstaki*, *cry1A.105* gene generated from *cry1Fa1* gene derived from *Bacillus thuringiensis* ssp. *aizawai* EG6346, and modified *cry2Ab2* gene derived from *B. thuringiensis* ssp. *kurstaki*. Insertions of these genes result in expressions of Cry1A.105 proteins and modified Cry2Ab2 in the host line to be resistant to lepidoptera.

This line does not contain *splA* gene derived from *Rhizobium radiobacter* (*Agrobacterium tumefaciens*) C58 line, although it was temporarily introduced to the host line as a selection marker, because relevant gene was eliminated during the generating process.

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 “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)”¹. None of newly generated safety concerns were detected in comparison with soybean line without genetical modification.

In conclusion, no concern relevant to human health is raised on soybean MON87751 line resistant to Lepidoptera.

¹ “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants) (Decision of the Commission dated 29 January 2004)”