

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

Safety Assessment Report

Soybean FG72 line tolerant of glyphosate and isoxaflutole herbicide (Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ) February 2016

ABSTRACT

FSCJ conducted a safety assessment of a soybean FG72 line tolerant of glyphosate and isoxaflutole herbicides, based on the documents submitted by the applicant.

Soybean FG72 line was generated through introduction of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene derived from *Zeaa mays* and also of 4-hydroxyphenylpyruvate dioxygenase gene derived from *Pseudomonas fluorescens*. These gene insertions result in the expression of 2mEPSPS and HPPD W336 proteins, and thus Soybean FG72 line becomes tolerant of glyphosate and isoxaflutole herbicides.

The modified phosphinothricin acetyltransferase (PAT) gene derived from *Streptomyces viridochromogenes* (the modified *pat* gene) was also introduced as a selection marker.

The documents, evaluated based on the "Standards for Safety Assessments of Genetically Modified Foods (seed plants)"¹, included the safety evaluations of the inserted genes, toxicity and allergenicity of the protein produced from the inserted genes, post-insertion analysis of nucleotide sequence, stability of the inserted genes in the generation after crossing, effects on metabolic pathways in the plants, comparative characterization of nutrients and toxic ingredients in the plants. None of the newly generated safety concerns were detected as compared to a soybean line without genetical modification.

Consequently, FSCJ concluded that soybean FG72 line tolerant of glyphosate and isoxaflutole herbicides has no concern relevant to human health.

¹ Decision of the Commission dated 29 January 2004.