



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

Safety Assessment Report

Soybean 44406 line tolerant to aryloxyalkanoate, glyphosate and glufosinate herbicides

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)
September 2014

ABSTRACT

FSCJ conducted a safety assessment of a soybean 44406 line tolerant to aryloxyalkanoate, glyphosate and glufosinate herbicides, based on the documents submitted by the applicant.

Soybean 44406 line is generated through the introduction of a modified aryloxyalkanoate dioxygenase-12 gene derived from *Delftia acidovorans* MC1 and a modified 5-enol pyruvylshikimate-3-phosphate synthase gene derived from *maize*. These gene insertions result in the expression of the modified aryloxyalkanoate dioxygenase-12 protein and 2mEPSPS protein in the host line, and thus the host line becomes tolerant to aryloxyalkanoate herbicide, glyphosate herbicide and glufosinate herbicide.

A modified phosphinothricin acetyltransferase gene derived from *Streptomyces viridochromogenes* was also introduced as a selection marker.

Data in the documents, evaluated based on the “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)”¹, include 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, no apparent adverse effects are expected on humans due to the genetic modification of soybean 44406 in comparison with the conventional counterpart.

Hence, FSCJ concluded that no concern relevant to human health is raised on the soybean 44406 line

¹ Decision of the Commission dated 29 January 2004.