



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

Safety Assessment Report

Soybean tolerant to aryloxyalkanoate herbicide and glufosinate herbicide

68416 line

(Genetically modified food/feed)

Food Safety Commission of Japan (FSCJ)
September 2014

ABSTRACT

FSCJ conducted a safety assessment of soybean tolerant to aryloxyalkanoate and glufosinate herbicides 68416 line, based on the documents submitted by the applicant.

Soybean 68416 line was generated through the introduction of the modified aryloxyalkanoate dioxygenase-12 gene derived from *Delftia acidovorans* MC1. This gene insertion results in the expression of the modified aryloxyalkanoate dioxygenase-12 protein in the host line, and thus makes the host tolerant to aryloxyalkanoate herbicide.

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

The assessment was conducted to evaluate the safety of the inserted gene, toxicity and allergenicity of the protein produced from the inserted gene, post-insertion analysis of nucleotide sequence and others, stability of the inserted gene in the generation after crossing, effects on metabolic pathways in the plants, comparative characterization of nutrients and toxic ingredients in the plants and others based on the “Approach to the Safety Assessment of Genetically Modified Foods (seed plants)”¹. None of newly generated safety concerns were detected as compared to soybean line without genetical modification.

Hence, FSCJ concluded that soybean tolerant to aryloxyalkanoate and glufosinate herbicides, 68416 line posed no concern on human health.

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