



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

## Safety Assessment Report

### Cotton GHB811

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)  
June 2018

#### ABSTRACT

FSCJ conducted a safety assessment of cotton GHB811 line which is tolerant of glyphosate herbicide and of 4-hydroxyphenylpyruvate dioxygenase inhibitor herbicide, based on the documents submitted by the applicant.

Cotton GHB811 line is generated through the introduction of a modified 5-enolpyruvylshikimate 3-phosphate synthase gene derived from maize (*Zea mays*) and a modified 4-hydroxyphenylpyruvate dioxygenase gene derived from *Pseudomonas fluorescens* into cotton (*Gossypium hirsutum* L.). These gene insertions result in the expression of 2mEPSPS protein and HPPD W336 protein in the host line, and thus the host line becomes tolerant of glyphosate herbicide and of 4-hydroxyphenylpyruvate dioxygenase inhibitor herbicide.

The documents, evaluated based on the “Standards for Safety Assessments of Genetically Modified Foods (seed plants)”<sup>1</sup>, included the safety of the inserted genes, toxicity and allergenicity of the proteins 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. Consequently, newly produced adverse effects on humans derived from this line are unlikely based on the comparison between this line and the conventional counterpart.

Consequently, FSCJ concluded that “cotton GHB811 line which is tolerant of glyphosate herbicide and of 4-hydroxyphenylpyruvate dioxygenase inhibitor herbicide” has no concern relevant to human health.

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<sup>1</sup> Decision of the Commission dated January 29, 2004.