

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

Safety Assessment Report

Soybean resistant to nematode and tolerant to 4-hydroxyphenylpyruvate dioxygenase inhibitor herbicide, GMB151 line

(Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)

June 2022

ABSTRACT

The FSCJ conducted a safety assessment of “Soybean resistant to nematode and tolerant to 4-hydroxyphenylpyruvate dioxygenase inhibitor herbicide, GMB151 line”, based on the documents submitted by the applicant.

GMB151 line was generated through the introduction of the following two genes into Thorne¹, commercial soybean (*Glycine max* (L.) Merr.), as a host: the *cry14Ab-1.b* gene derived from *Bacillus thuringiensis*; and the modified 4-hydroxyphenylpyruvate dioxygenase gene derived from *Pseudomonas fluorescens* A32 strain. The insertion of these genes results in expressions of the Cry14Ab-1 protein and 4-hydroxyphenylpyruvate dioxygenase. Therefore, this line will grow without negative consequences of nematode and 4-hydroxyphenylpyruvate dioxygenase inhibitor herbicide.

Referring to “Standards for the Safety Assessments of Genetically Modified Foods (Seed Plants)”², the FSCJ assessed the following:

- i. the safety of the inserted gene;
- ii. the toxicity and allergenicity of the protein expressed from inserted gene;
- iii. the base sequence analysis of the inserted gene, etc.;
- iv. the stability of the inserted gene in successive generations;
- v. the effect on the metabolic pathways in plants; and
- vi. the results of comparison of nutritional and toxic ingredients.

The FSCJ confirmed that any new finding to cause the adverse effects was not observed, compared with conventional soybeans.

Accordingly the FSCJ concluded that no concern relevant to human health is raised on the GMB151 line, a nematode resistant and 4-hydroxyphenylpyruvate dioxygenase inhibitor herbicide tolerant soybean.

¹ Thorne was developed by the Ohio Agricultural Research and Development Center and released in 1993. Thorne is a mid-Group III variety that has very good yield potential and good resistance to lodging. (Source: Purdue University Cooperative Extension Service)

² Decision of the FSCJ dated January 29, 2004