

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

Safety Assessment Report

Maize resistant to lepidopteran insects, MON95379 line (Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
December 2021

ABSTRACT

The FSCJ conducted a safety assessment of “Maize resistant to lepidopteran insects, MON95379 line”, based on the documents submitted by the applicant.

This line was generated through the introduction of the *cry1B.868* gene and the modified *cry1Da* gene from *Bacillus thuringiensis*. The insertions of these genes result in expressions of Cry1B.868 protein and modified Cry1Da protein intended to grow without being affected by lepidopteran insects.

Referring to “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)”¹, the FSCJ assessed the following:

- i. the safety of the donor 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 maize.

Accordingly, the FSCJ concluded that no concern relevant to human health is raised on the MON95379 line, a maize resistant to lepidopteran insects.

¹ Decision of the FSCJ dated January 29, 2004