

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 Feed)

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.

In accordance with “Stance on Safety Assessments of Genetically Modified Feed and Feed Additives”<sup>1</sup>, the following possibilities were considered:

- i. new harmful substances derived from recombinants are generated in said genetically modified feed and transferred to meat, milk, eggs and other livestock products;
- ii. components in said genetically modified feed which are derived from genetic modification are transformed into harmful substances and accumulate in livestock products; and
- iii. components in said genetically modified feed which are the result of genetic modification interact with the metabolism system of livestock animals and produce new harmful substances.

As a result of assessing this line, none of these possibilities could be putative. Accordingly, the FSCJ determined that it is unnecessary to assess this line based on “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)”<sup>2</sup>.

The FSCJ concluded that there is no concern about human consumption of products derived from livestock fed this line.

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<sup>1</sup> Decision of the FSCJ dated May 6, 2004

<sup>2</sup> Decision of the FSCJ dated January 29, 2004