

## Risk Assessment Report: Genetically Modified Foods and Feeds

# MON 87411 line, a Maize Tolerant to Glyphosate and Resistant to Coleoptera

## Summary

Food Safety Commission of Japan

The Food Safety Commission of Japan (FSCJ) conducted a safety assessment of MON 87411 line, a maize tolerant to glyphosate and resistant to Coleoptera, based on the documents submitted by the applicant. The documents, evaluated based on the “Standards for the Safety Assessment of Genetically Modified Foods (Seed plants)” (Decision of the Commission dated 29 January 2004), included the safety of the inserted genes, toxicity and allergenicity of the protein produced from the inserted genes, post-insertion analyses of the nucleotide sequences, stability of the inserted genes in the successive generations, influence on metabolic pathways in the plants, comparative characterization of nutrients and toxic ingredients in plants. Consequently, no emergences of safety concerns were recognized based on the comparison between this line and the conventional counterpart. The dsRNA originated from *DvSnf7* fragment is unlikely to pose unintended adverse effect to human. In conclusion, no concern relevant to human health is raised on the maize MON 87411 line, tolerant to glyphosate and resistant to Coleoptera.

## Conclusion in Brief

The Food Safety Commission of Japan (FSCJ) conducted a safety assessment of MON 87411 line, a maize tolerant to glyphosate and resistant to Coleoptera, based on the documents submitted by the applicant.

MON 87411 line was generated through the introduction of an inverted repeat sequence of a fragment of *DvSnf7* gene (*Snf7* gene derived from western corn rootworm, *Diabrotica virgifera virgifera*). The sequence results in the formation of a double-stranded RNA (dsRNA). The insecticidal activity of the maize is explained as follows. The dsRNA derived from the maize is incorporated in Coleoptera’s cells at the time of the ingestion. The expression of *DvSnf7*, which is essential to maintain cellular function, is suppressed through the RNA interference.

In MON 87411 line, a modified *cry3Bb1* gene from *Bacillus thuringiensis* ssp. *kumamotoensis* and a modified *cp4 epsps* gene from *Agrobacterium* sp. CP4 strain are also introduced. The maize, the expressing of modified Cry3Bb1 and modified CP4 EPSPS can grow without being damaged by Coleoptera and glyphosate.

The documents, evaluated based on the “Standards for the Safety Assessment of Genetically Modified Foods (Seed plants)” (Decision of the Commission dated 29 January 2004), included the safety of the inserted genes, toxicity and allergenicity of the protein produced from the inserted genes, post-insertion analyses of the nucleotide sequences, stability of the inserted genes in the successive generations, influence on metabolic pathways in the plants, comparative charac-

---

Published online: 30 September 2016

This is an English translation of excerpts from the original full report (June 2016–FS/367/2016). Only original Japanese texts have legal effect.

The original full report is available in Japanese at <http://www.fsc.go.jp/fscjis/attachedFile/download?retrievalId=kya20150424345&fileId=201>

Acknowledgement: FSCJ wishes to thank the members of Expert Committee on Genetically Modified Foods and Feeds for the preparation of the original full report.

Suggested citation: Food Safety Commission of JAPAN. Maize tolerant to glyphosate herbicide and resistant to Coleoptera MON 87411 line: Summary. Food Safety. 2016; 4 (3): 91–92. doi:10.14252/foodsafetyfscj.2016016s

terization of nutrients and toxic ingredients in plants. Consequently, no emergences of safety concerns were recognized based on the comparison between this line and the conventional counterpart.

The dsRNA originated from *DvSnf7* fragment is unlikely to pose unintended adverse effect to human based on the following reasons. Food crops, such as rice, are known to contain various lengths of dsRNA and have been consumed safely. The amount of the dsRNA originated from *DvSnf7* fragment is negligible compared to the amount of RNA in plants. The RNAs ingested are decomposed by various enzymes including ribonuclease in vertebrates including humans. No sequences targeted by the dsRNA originated from *DvSnf7* fragment is found in the transcription database of human.

In conclusion, no concern relevant to human health is raised on the maize MON 87411 line, tolerant to glyphosate and resistant to Coleoptera.