



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

Safety Assessment Report

Maize tolerant to glyphosate herbicide and resistant to coleopteran

MZIR098 line

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

FSCJ conducted a safety assessment of maize tolerant to glyphosate herbicide and resistant to coleopteran MZIR098 line (hereinafter referred to as “MZIR098 line”), based on the documents submitted by the applicant.

This line was generated through the introduction of modified *cry3A* gene (*mcr3A* gene) derived from *Bacillus thuringiensis* subsp. *tenebrionis* and modified *cry3.1 Ab* gene (*ecry 3.1 Ab* gene), a chimeric gene produced based on the nucleotide sequences of , *cry1Ab* gene derived from *B. thuringiensis* subsp. *kurstaki* and the *mcry3A* gene.

Insertions of these genes result in expressions of the mCry3A, and eCry3.1Ab proteins, and thus MZIR098 line becomes resistant to coleoptera. The modified phosphinothricin acetyltransferase gene (*pat-08*) derived from *Streptomyces viridochromogenes* strain Tü494 was also inserted into this line. This gene insertion results in expression of the PAT protein, to make this line tolerant to glufosinate herbicide.

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.

Consequently, FSCJ concluded that the maize tolerant to glyphosate herbicide and resistant to coleopteran MZIR098 line has no concern relevant to human health.