

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

Safety Assessment Report

Maize resistant to lepidopteran insect pests and tolerant to herbicide glyphosate (DAS1131) (Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

The FSCJ conducted a safety assessment of “Maize resistant to lepidopteran insect pests and tolerant to herbicide glyphosate (DAS1131).”

Maize line DAS1131 is developed by introducing the modified *cry1Da2* transgene derived from *Bacillus thuringiensis* and the *dgt-28 epsps* transgene derived from *Streptomyces sviveus* into the dent corn line B104 (*Zea mays* ssp. *mays*(L.) Iltis) as a host. The expression of the modified Cry1Da2 protein confers resistance to lepidopteran insect pests, and the expression of the DGT-28 EPSPS protein confers resistance to the herbicide glyphosate.

The modified Cry1Da2 protein forms a protease-resistant core protein with insecticidal activity when ingested by susceptible lepidopteran insect pests. The core proteins exhibit insecticidal effects by binding to specific receptors on midgut epithelial cell membranes of the insect pests, leading to disruption and damage of their midgut tissues. In contrast to the endogenous EPSPS protein in corn, the DGT-28 EPSPS protein is not competitively inhibited by the herbicide glyphosate. This allows the shikimate pathway to remain functional, enabling the recombinant maize to grow in the presence of the herbicide glyphosate.

Referring to the “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants) ¹”, evaluations were made regarding the safety of the donor of the inserted gene, toxicity and allergenicity of the protein expressed by the inserted gene, the base sequence analysis of the inserted gene, the stability of the inserted gene in successive generations, the effects on the metabolic pathway of plants, and the results of comparison of nutritional and toxic components of plants. In particular, as part of the evaluation of allergenicity, the results of the physicochemical sensitivity tests of the proteins expressed by the inserted gene showed that the proteins were rapidly digested by artificial gastric fluid treatment and subsequent artificial intestinal fluid treatment. Furthermore, heat-treatment showed reduction in the insecticidal or enzymatic activity of these proteins, making it unlikely that these proteins are allergenic. From these results, there were no additional factors that could impair safety in this line compared with non-recombinant maize.

Therefore, it has been concluded that maize resistant to lepidopteran insect pests and tolerant to herbicide glyphosate (DAS1131) is unlikely to pose concerns relevant to human health.



¹ Decision of FSCJ dated January 29, 2004