

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 glufosinate (DP910521)

(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 the herbicide glufosinate (DP910521).”

Maize line DP910521 was developed by introducing the *cry1B. 34* transgene derived from *Bacillus thuringiensis*, the *pat* transgene derived from *Streptomyces viridochromogenes*, and the *pmi* transgene derived from *Escherichia coli* into the dent maize line PH184C (*Zea mays* ssp. *mays* (L.) Iltis) as a host. The expression of the Cry1B. 34 protein confers resistance to lepidopteran insect pests, the expression of the PAT protein confers tolerance to the herbicide glufosinate, and the expression of the PMI protein confers selection markers for transformants.

The Cry1B.34 protein is a chimeric protein that forms a protease-resistant core protein with insecticidal activity when ingested by specific lepidopteran insect pests, including *Spodoptera frugiperdia* (fall armyworm). The core protein exhibits its 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.

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 Cry1B.34 proteins 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 activity of these proteins, making it unlikely that the protein expressed by the inserted gene 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 glufosinate (DP910521)” is unlikely to pose concerns relevant to human health.

¹ Decision of FSCJ dated January 29, 2004