

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

Safety Assessment Report

Maize resistant to coleopteran insect pests and tolerant to herbicide glufosinate (DP915635) (Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

The FSCJ conducted a safety assessment of “maize resistant to coleopteran insect pests and tolerant to herbicide glufosinate (DP915635).”

Maize line DP915635 is produced by recognizing dent PHR03 line of maize (*Zea mays* subsp. *mays*(L.) Ittis) as an existing variety and introducing the *ipd079Ea* transgene derived from *Ophioglossum pendulum*, the *pat* transgene derived from *Streptomyces viridochromogenes*, and the *pmi* transgene derived from *Escherichia coli* into this dent PHR03 line of maize. The expression of the IPD079Ea protein confers resistance to coleopteran 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 IPD079Ea protein is a selective insecticidal protein that exerts insecticidal activity by binding to receptors on the midgut epithelial cell membrane of insects, causing damage to the midgut tissue when ingested by Coleoptera such as western corn rootworm (*Diabrotica virgifera virgifera*).

The PAT protein acetylates L-glufosinate, an active component of the herbicide glufosinate, converting it to N-acetyl L-glufosinate, which lacks herbicidal activity. This modification allows the transgenic maize to grow without being affected by the herbicide glufosinate.

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. 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 coleopteran insect pests and tolerant to herbicide glufosinate (DP915635) is unlikely to pose concerns relevant to human health.

¹ Decision of FSCJ dated January 29, 2004