

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

## Safety Assessment Report

### Glyphosate herbicide tolerant and lepidopteran and coleopteran resistant maize line containing event DP-004114-3 (Genetically modified food)

Food Safety Commission of Japan (FSCJ)

December 2014

#### ABSTRACT

FSCJ conducted a risk assessment of glyphosate herbicide tolerant and lepidopteran and coleopteran resistant maize line, DP-004114-3, based on the documents submitted by the applicant.

This line was generated through the introduction of *cry1F* gene derived from *Bacillus thuringiensis* var. aizawai, *cry34Ab1* and *cry35Ab1* gene derived from *Bacillus thuringiensis* PS194B1. Insertions of these genes result in expressions of the modified Cry1F, Cry34Ab1 and Cry35Ab1 proteins in the host line to be tolerant to lepidoptera and coleoptera. The modified *pat* gene derived from *Streptomyces viridochromogenes* was also inserted into this line. This gene insertion results in expression of the PAT protein in the host line, to be tolerant to a glyphosate herbicide.

The documents, evaluated based on the “Standards for the Safety Assessment of Genetically Modified Foods (seed plants)”<sup>1</sup>, included the safety of the inserted genes, toxicity and allergenicity of the protein produced from the inserted genes, post-insertion analysis of nucleotide sequence, stability of the inserted genes in the generation after crossing, effects on metabolic pathways in the plants, comparative characterization of nutrients and toxic ingredients in the plants. Consequently, newly produced adverse effects on humans derived from this maize line are unlikely based on the comparison between this line and the conventional counterpart.

In conclusion, no concern relevant to human health is raised on the glyphosate herbicide tolerant and lepidopteran and coleopteran-resistant maize line, DP-004114-3.

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<sup>1</sup> Decision of the Commission dated 29 January 2004.