

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

Safety Assessment Report

Maize glyphosate-induced male sterility and tolerant to herbicides: dicamba, glufosinate, aryloxyalkanoate and glyphosate, MON87429 line (Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
June 2021

ABSTRACT

The FSCJ conducted a safety assessment of “Maize glyphosate-induced male sterility and tolerant to herbicides: dicamba, glufosinate, aryloxyalkanoate and glyphosate, MON87429 line”, based on the documents submitted by the applicant.

This line was generated through the introduction of the following four genes:

- a modified *dmo* gene derived from *Stenotrophomonas maltophilia* DI-6 strain. This gene insertion results in expression of a dicamba mono-oxygenase (modified MON87429 DMO protein) ;
- a *pat* gene derived from *Streptomyces viridochromogenes*. This gene insertion results in expression of a phosphinothricin-N-acetyltransferase (PAT protein);
- a *ft_t* gene derived from *Sphingobium herbicidovorans*. This gene insertion results in expression of alpha aketoglutarate (α KG) dependent non-hem iron dioxygenase (FT_T protein); and
- a modified *cp4 epsps* gene derived from *Rhizobium radiobacter* CP4 strain. This gene insertion results in expression of a 5-enolphyruzylyshikimate-3-phosphate synthase (modified CP4 EPSPS protein).

Subsequently, spraying the herbicides of dicamba, glufosinate, aryloxyalkanoate and glyphosate does not affect the growth of maize. In addition, spray application of glyphosate at early stage of ear formation induces male sterility, which enables to produce hybrid seeds effectively.

Referring to “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)”¹, the FSCJ assessed the following:

- i. the safety of the donor of the inserted gene;
- ii. the toxicity and allergenicity of the protein expressed from inserted gene;
- iii. the base sequence analysis of the inserted gene, etc.;
- iv. the stability of the inserted gene in successive generations;
- v. the effect on the metabolic pathways in plants; and
- vi. the results of comparison of nutritional and toxic ingredients.

The FSCJ confirmed that any new finding to cause the adverse effects was not observed, compared with conventional maize.

Accordingly, the FSCJ concluded that no concern relevant to human health is raised on the MON87429

¹ Decision of the FSCJ dated January 29, 2004



line, a maize glyphosate-induced male sterility and tolerant to herbicides: dicamba, glyphosinate, aryloxyalkanoate and glyphosate.