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

Safety Assessment Report

DHA-producing canola tolerant to herbicide glufosinate (NS-B50027-4)

(Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
May 2025

ABSTRACT

The FSCJ conducted a safety assessment of "DHA-producing canola tolerant to herbicide glufosinate (NS-B50027-4)."

This line is developed through introducing five desaturase transgenes and two elongase transgenes derived from microalgae or yeast, into AV Jade, a canola variety of rapeseed (*Brassica napus* L.), as the existing variety. The expressions of these fatty acid synthesis enzymes in the seed enable the production of fatty acids such as docosahexaenoic acid (DHA) from oleic acid, an endogenous fatty acid. Furthermore, the introduction of the *pat* transgene derived from *Streptomyces viridochromogenes* leads to the expression of the PAT protein, which confers tolerance to the herbicide glufosinate.

In this line's fatty acid synthesis pathway, five desaturases introduce double bonds (desaturation), and two elongases extend the carbon chain (elongation) of fatty acids. These enzymes convert oleic acid, an endogenous fatty acid present in the seed, into long-chain polyunsaturated fatty acids, ultimately producing DHA as the final product.

The PAT protein acetylizes the free amino group in L-glufosinate and converts it into N-acetyl-L-glufosinate, thereby detoxicating it and conferring glufosinate tolerance to the plant.

Referring to the "Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants) [1]" (hereinafter referred to as "the guidelines") , 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.

As a result, it was not possible to conclude that this line did not pose any additional safety concerns compared to non-recombinant rapeseed. This was due to insufficient information regarding alkaline and enzymatic treatment using artificial gastric fluid. On the other hand, the oil extracted and refined from the seeds of this line was evaluated using a tiered approach based on weight-of-evidence (WOE), considering information including the manufacturing process, the total protein content in the oil (below the detection limit of 0.07%), and also considering the forms in which it is used as food in

accordance with Items 2 and 4 of Section 4, Chapter 1 of the guidelines. From these results, there were no additional factors that could impair safety in oil extracted and refined from this line compared with that from non-recombinant rapeseed.

Therefore, it has been concluded that oil extracted and refined from the seed of “DHA-producing canola tolerant to herbicide glufosinate (NS-B50027-4)” is unlikely to pose concerns relevant to human health.

---

[1] Decision of FSCJ dated January 29, 2004