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

Safety Assessment Report

Lipase produced using JPAN006 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ) August 2021

ABSTRACT

FSCJ conducted a safety assessment of a lipase produced using JPAN006 strain, based on the documents submitted by the applicant.

This additive is a lipase produced by JPAN006 strain which was generated through the introduction of lipase gene originated from *Candida antarctica* DSM3855 into *Aspergillus niger* BO-1 strain as the host. This additive is an enzyme that hydrolyses ester bond of triacylglycerol that is main component of fats and oils, and is used in oil processing.

Safety of the inserted gene, toxicity and allergenicity of the protein produced from the inserted gene and so on were evaluated, based on the "Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms¹". As the result, it was considered that there was no new factor bringing out adverse effects on humans in this additive, compared with the conventional counterpart. Consequently, FSCJ concluded that the lipase produced using JPAN006 strain has no concern relevant to human health.

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¹ Decision of the Commission dated 25 March 2004.