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

# Safety Assessment Report

# Lipase produced using JPAo001 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)
July 2017

## ABSTRACT

FSCJ conducted a safety assessment of lipase produced using JPAo001 strain, based on the documents submitted by the applicant.

The JPAo001 strain was generated through introduction of the lipase fusion gene into *Aspergillus oryzae* IFO4177 strain as a host in order to enhance lipase productivity. The lipase gene was constructed from a mutation-introduced lipase gene originated from *Thermomyces lanuginosus* CBS 586.94 strain and a lipase gene originated from *Fusarium oxysporum* DSM2672 strainThis additive, an enzyme catalyzing the hydrolysis of ester bonds in triglycerides and separating fatty acids, is used in bread production and oil/fat refining process.

The safety of the inserted gene, toxicity and allergenicity of the protein produced from the inserted gene, and others were evaluated based on the "Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms [1]". None of the newly generated safety concerns were detected in comparison with conventional additives without genetical modification.

Consequently, FSCJ concluded that the lipase produced using JPAo001 strain has no concern relevant to human health.

[1] Decision of the Commission Dated 25 March 2004.