

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

Safety Assessment Report

Phospholipase produced using JPAN002 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

March 2019

ABSTRACT

FSCJ conducted a safety assessment of a phospholipase produced using JPAN002 strain, based on the documents submitted by the applicant.

This additive is phospholipase A1 produced by JPAN002 strain which was generated through the introduction of phospholipase A1 gene derived from *Talaromyces leycettanus* CBS 398.68 strain into *Aspergillus niger* BO-1 strain as the host. Phospholipase A1 is an enzyme that hydrolyses ester bond at position1 of a phospholipid to produce a lyso-phospholipid and a fatty acid.

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 phospholipase produced using JPAN002 strain has no concern relevant to human health.

¹ Decision of the Commission dated 25 March 2004.