



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

Safety Assessment Report

Phospholipase C produced using PRF strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

September 2017

ABSTRACT

FSCJ conducted a safety assessment of an additive, phospholipase C, produced using PRF strain based on the documents submitted by the applicant.

The PRF strain was generated through introduction of a fusion gene into *Pichia pastoris* SMD1168 as a host in order to enhance phospholipase C productivity. The introduced gene is formed from phospholipase C gene isolated from soil DNA libraries and α -mating factor secretion signal gene originated from *Saccharomyces cerevisiae*. This additive, an enzyme hydrolyzing phosphodiester bond of phospholipids, is used in 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 Microorganisms¹”. None of the newly generated safety concerns were detected in comparison with conventional additives without genetical modification.

Consequently, FSCJ concluded that the phospholipid C produced using PRF strain has no concern relevant to human health.

¹ Decision of the Commission Dated 25 March 2004.