



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

Safety Assessment Report

Phospholipase A2 produced using the PLA-54 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

May 2016

ABSTRACT

FSCJ conducted a safety assessment of "Phospholipase A2 produced using the PLA-54 strain" based on the documents submitted by the applicant.

The PLA-54 strain was generated through introduction of Phospholipase A2 gene originated from pig pancreas into a mutant strain derived from *Aspergillus niger* NRRL3122 strain, GAM-53 strain, as a host, to enhance the phospholipase A2 productivity.

The acetoamidase gene (*amdS gene*) derived from *Aspergillus nidulans* was also introduced as a selection marker, but was eliminated from the PLA-54 strain.

Phospholipase is an enzyme involved in the hydrolysis of phospholipids, thus is used for various aims such as phospholipid hydrolysis in oil and fat foods, quality improvement of breads and processing of noodles.

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 phospholipase A2 produced using the PLA-54 strain has no concern relevant to human health.

¹ Decision of the Commission Dated March 25, 2004.