



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

Safety Assessment Report

Protease produced using JPFV001 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

July 2018

ABSTRACT

FSCJ conducted a safety assessment of “Protease produced using JPFV001 strain” based on the documents submitted by the applicant.

This additive is a protease produced using JPFV001 strain, which is generated through the introduction of a gene for protease originated from *Fusarium oxysporum* DSM2672 strain into *Fusarium venenatum* A3/5 strain as the host. This enzyme is an endo-type protease which hydrolyzes peptide-bonds of proteins thus producing peptides and amino acids, and is used in the production process of dairy products for reducing allergenicity of proteins derived from milk by appropriately decomposing them.

The phosphinothricin acetyltransferase gene derived from *Streptomyces hygroscopicus* and acetoamidase derived from *Aspergillus nidulans* was also introduced as a selection marker.

The documents, evaluated based on the “Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms¹”, included the safety of the inserted gene, and toxicity and allergenicity of the protein produced from the inserted gene. Consequently, newly produced adverse effects on humans derived from this additive are unlikely based on the comparison between this line and the conventional counterpart.

Consequently, FSCJ concluded that the protease produced using JPFV001 strain has no concern relevant to human health.

¹ Decision of the Commission dated 25 March 2004.