



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

Safety Assessment Report

Chymosin produced using DSM32805 strain (Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)
August 2021

ABSTRACT

FSCJ conducted a safety assessment of a chymosin produced using DSM32805 strain, based on the documents submitted by the applicant.

This additive is a chymosin produced by *A. niger* DSM32805 strain which was generated through the introduction of modified prochymosin gene originated from dromedary (*Camelus dromedaries*) into *Aspergillus niger* NRRL3112 strain as the host. This additive is a protease that cleaves specific site of casein, the major protein component of milk, forming hydrophobic casein micelles thus aggregating the milk. For this activity, this enzyme is used mainly in cheese making.

Safety of the inserted gene, toxicity and allergenicity of the protein produced from the inserted gene, post-insertion analysis of nucleotide sequence 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 the chymosin produced using DSM32805 strain has no concern relevant to human health.

¹ Decision of the Commission dated 25 March 2004.