

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

Safety Assessment Report

CHY-MAX M

(Genetically Modified Foods)

Food Safety Commission of Japan (FSCJ)

January 2019

ABSTRACT

FSCJ conducted a safety assessment of an additive, CHY-MAX M, based on the documents submitted by the applicant.

This additive is chymosin produced using *A. luchuensis* CBS 125278 strain which was generated through the introduction of prochymosin gene derived from *Camelus dromedaries* into *Aspergillus luchuensis* CBS 108914 strain as the host. Chymosin is a protease that cleavages the specific site of casein, a major protein contained in milk, producing hydrophobic casein micelles thus coagulates milk. For this reason, this enzyme is used mainly in cheesemaking.

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 no concern relevant to human health is raised on “CHY-MAX M”.

¹ Decision of the Commission dated 25 March 2004.