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

Safety Assessment Report

Alpha-amylase produced using JSF-07-170-3 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)
June 2018

ABSTRACT

FSCJ conducted a safety assessment of an additive, α-amylase, produced using JSF-07-170-3 strain based on the documents submitted by the applicant.

This additive is α-amylase produced using JSF-07-170-3 strain which was generated through the introduction of modified α-amylase gene derived from *Geobacillus stearothermophilus* strain into *Bacillus licheniformis* BRA7 as a host. This modified enzyme, which hydrolizes α-1,4-glucosidic bonds of starch, is heat resistant and thus used for enhancing liquefaction efficacy in beer and sirop production.

The documents, evaluated based on the "Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms [1]", 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 additive and the conventional counterpart.

Consequently, FSCJ concluded that "α-amylase produced using JSF-07-170-3 strain" has no concern relevant to human health.

[1] Decision of the Commission dated 25 March 2004.