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

Safety Assessment Report

Alpha-amylase produced using ROM strain

(Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
April 2023

ABSTRACT

The FSCJ conducted a safety assessment of "α-amylase produced using the ROM strain."

This additive is an α-amylase produced using the ROM strain, which was developed by introducing a modified α-amylase transgene derived from the *Geobacillus stearothermophilus* into the *Bacillus subtilis* DS18174 strain as a host. This additive is an enzyme that hydrolyzes the α-1,4 glycosidic linkages of starch to reduce molecular size, and is used for quality maintenance in bread production.

Referring to the "Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms,[1]" evaluations were conducted on the safety of the inserted gene and the toxicity and allergenicity of the protein expressed by the inserted gene, which indicated no additional factors that could impair safety compared to conventional additives.

Therefore, it has been concluded that "α-amylase produced using the ROM strain" is unlikely to pose safety concerns relevant to human health.

[1] Decision of the FSCJ dated March 25, 2004