

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

Safety Assessment Report

Alpha-amylase produced using BML780 MDT06-221 strain (Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
June 2021

ABSTRACT

The FSCJ conducted a safety assessment of a food additive, α -amylase produced using BML780 MDT06-221 strain, based on the documents submitted by the applicant.

This additive is α -amylase produced using BML780 MDT06-221 strain which was generated through the introduction of the modified α -amylase gene derived from *Geobacillus stearothermophilus* C599 strain into *Bacillus licheniformis* BRA7 strain as a host. This enzyme hydrolyzes α -1,4-glycosidic bonds of starch, converting starch into low-molecular-weight products. Due to its thermostability, it can be used at high temperature while maintaining the quality of bread production.

Referring to “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms”¹, the FSCJ confirmed the following:

- i. the safety of the inserted gene; and
- ii. the toxicity and allergenicity of the protein produced from the inserted gene, and others.

Consequently, any new safety concerns were not identified, compared with conventional additives.

The FSCJ concluded that “ α -amylase produced using BML780 MDT06-221 strain” has no concern relevant to human health.

¹ Decision of the FSCJ dated March 25, 2004