

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

Safety Assessment Report

Alpha-amylase produced using JPAN004 strain (Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
April 2022

ABSTRACT

The FSCJ conducted a safety assessment of a food additive, α -amylase produced using JPAN004 strain, based on the documents submitted by the applicant.

This additive is α -amylase produced using JPAN004 strain which was generated through the introduction of *amyJA126PE096* gene into *Aspergillus niger* BO-1 strain as a host. The *amyJA126PE096* gene is starch binding domain sequence of *glucoamylase* gene derived from *A. niger* BO-1 strain, which was added to α -amylase gene derived from *Rhizomucor pusillus* IFO2457 strain. This enzyme hydrolyzes α -1,4 bonds of amylose, amylopectin and others. It is used for producing starch sugar.

Referring to “Standards for Safety Assessment 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 “the α -amylase produced using JPAN004 strain” has no concern relevant to human health.

¹ Decision of the FSCJ dated March 25, 2004