



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

Safety Assessment Report

Alpha-glucosyltransferase produced using *Bacillus subtilis* NTI04 (pHYT2TD) strain (Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
March 2022

ABSTRACT

The FSCJ conducted a safety assessment of a food additive, α -glucosyltransferase produced using *Bacillus subtilis* NTI04 (pHYT2TD) strain.

This additive is α -glucosyltransferase produced using *Bacillus subtilis* NTI04 (pHYT2TD) strain which was generated through the introduction of expression plasmid pHYT2TD including the α -glucosyltransferase gene derived from *Tepidibacillus decaturensis* into *Bacillus subtilis* ISW1214 strain as a host. This enzyme acts on hydrolyzed starch, catalyzes α -1,6-glucosyl transfer reaction, and is used in α -1,6-glucan production.

Referring to “Standards for Safety Assessments of Genetically Modified 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 -glucosyltransferase produced using *Bacillus subtilis* NTI04 (pHYT2TD) strain” has no concern relevant to human health.

¹ Decision of the FSCJ dated March 25, 2004