



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

Safety Assessment Report

Cyclodextrin glucanotransferase produced using *Bacillus subtilis* NTI05 (pHYT2Aopt) strain (Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
September 2022

ABSTRACT

The FSCJ conducted a safety assessment of a food additive, cyclodextrin glucanotransferase produced using *Bacillus subtilis* NTI05 (pHYT2Aopt) strain.

This additive is cyclodextrin glucanotransferase produced using *Bacillus subtilis* NTI05(pHYT2Aopt) strain which was generated through the introduction of expression plasmid including cyclodextrin glucanotransferase gene derived from *Paenibacillus campinasensis* into *Bacillus subtilis* ISW1214 strain as a host. This enzyme catalyzes α -1,4 glucan producing amylose, etc., and forms cyclic α -1,4-glucan. It is used to manufacture cyclodextrin.

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 “cyclodextrin glucanotransferase produced using *Bacillus subtilis* NTI05 (pHYT2Aopt) strain” has no concern relevant to human health.

¹ Decision of the FSCJ dated March 25, 2004