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

Safety Assessment Report

Cyclodextrin glucanotransferase produced by genetically modified strain *Bacillus subtilis* DTS1451 (pHYT2G)

(Genetically modified food)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

FSCJ conducted a safety risk assessment of "Cyclodextrin glucanotransferase produced by a genetically modified strain *Bacillus subtilis* DTS1451 (pHYT2G)" using summary reports made by applicants.

This enzyme, which hydrolyzes starch and catalyzes the cyclization by forming α-(1,4)-glycosidic bonds, is used as an additive to produce cyclodextrin containing sugars. To manufacture this additive, a modified cyclodextrin glucanotransferase gene originated from *Bacillus clarkii* 7364 was transfected into host strain *Bacillus subtilis* DTS 1451 using expression vector (pHYT2G). This enzyme is used to improve the production and quality of cyclodextrin glucanotransferase.

The safety of the inserted gene, toxicity of the protein produced from the inserted gene, and issues associated with allergenicity were assessed based on the Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms (March 25, 2004). As a result, the enzyme is without new safety concerns compared to conventional additives.

Thus, FSCJ concluded that "Cyclodextrin glucanotransferase produced by genetically modified strain *Bacillus subtilis* DTS1451 (pHYT2G)" has no concern relevant to human health.