



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

## Safety Assessment Report

### $\alpha$ -amylase produced using *Bacillus subtilis* MDT121 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

November 2014

#### ABSTRACT

FSCJ conducted a safety assessment of  $\alpha$ -amylase produced using a *Bacillus subtilis* MDT121 strain, based on the documents submitted by the applicant.

This additive was produced by the MDT121 strain, which was generated through the introduction of the modified  $\alpha$ -amylase gene derived from the *Geobacillus stearothermophilus* C599 strain into the *Bacillus subtilis* A164 $\Delta$ 5 in order to enhance the  $\alpha$ -amylase property of the strain.

This enzyme, hydrolyzing glucose 1,4- $\alpha$  bonds of glucose polymers to produce mainly maltose, is used as an anti-staling agent for breadmaking and also to produce starch sugars including high-maltose-syrup.

The documents, evaluated based on the “Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms<sup>1</sup>”, included the safety of the inserted gene, and toxicity and allergenicity of the protein produced from the inserted gene. Consequently, newly produced adverse effects on humans derived from this additive are unlikely based on the comparison between this line and the conventional counterpart.

In conclusion, no concern relevant to human health is raised on this  $\alpha$ -amylase produced using *Bacillus subtilis* MDT121 strain.

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<sup>1</sup> Decision of the Commission dated 25 March 2004.