

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

## **Safety Assessment Report**

### **Exomaltotetraohydrolase produced using MDT06-228 strain**

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

May 2017

#### **ABSTRACT**

FSCJ conducted a safety assessment of exomaltotetraohydrolase produced using MDT06-228 strain, based on the documents submitted by the applicant.

The MDT06-228 strain was generated through introduction of *sas3* gene into *Bacillus licheniformis* BRA7 strain as a host in order to enhance thermal stability of exomaltotetraohydrolase. The *sas3* gene is a modified exomaltotetraohydrolase gene originated from *Pseudomonas stutzeri* IAM 1504 strain.

This exomaltotetraohydrolase, an enzyme catalyzing hydrolysis of  $\alpha$ -1,4-D-glucosidic bond linkages in starch at every four glucose molecules from the non reducing ends, is used to maintain the quality of bread and for sugar production including maltotetraose. The additive is heat resistant and usable at high temperature.

The safety of the inserted gene, toxicity and allergenicity of the protein produced from the inserted gene, and others were evaluated based on the “Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms<sup>1</sup>”. None of the newly generated safety concerns were detected in comparison with conventional additives without genetical modification.

Consequently, FSCJ concluded that exomaltotetraohydrolase produced using MDT06-228 strain has no concern relevant to human health.

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