



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

Safety Assessment Report

Exomaltotetrahydrolase produced using JS1252 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

June 2020

ABSTRACT

FSCJ conducted a safety assessment of an additive, exomaltotetrahydrolase, produced using JS1252 strain, based on the documents submitted by the applicant.

The JS1252 strain was generated through the introduction of the modified exomaltotetrahydrolase gene derived from *Pseudomonas stutzeri* IAM 1504 into *Bacillus licheniformis* BRA7 as a host. This additive is a modified enzyme which hydrolyzes α -1,4-D-glucosidic bonds of starch from the unreduced terminal every four glucose molecules. This modified enzyme is heat resistant and thus used for maintaining the quality in bread manufacturing.

Safety of the inserted gene, toxicity and allergenicity of the proteins produced from the inserted gene and so on were evaluated based on the “Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms¹”. As the result, FSCJ considered that there was no change bringing out adverse effects on humans in the recombinant additive compared with the conventional counterpart.

Hence, FSCJ concluded that no concern relevant to human health is raised on exomaltotetrahydrolase produced using JS1252 strain.

¹ Decision of the Commission dated 25 March 2004.