



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

Safety Assessment Report

Pullulanase produced using BML780PULm104 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)
July 2019

ABSTRACT

FSCJ conducted a safety assessment of pullulanase, produced using BML780PULm104 strain based on the documents submitted by the applicant.

This additive is an enzyme produced using BML780PULm104 strain, which was generated through the introduction of a modified pullulanase gene derived from *Bacillus deramificans* T89.117D strain into *Bacillus licheniformis* BRA7 as a host. This enzyme hydrolyzes α -1,6-D-glucosidic bond in amylopectin, and is used for enhancing saccharification efficiency in beer and starch sugar production.

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.

Consequently, FSCJ concluded that pullulanase produced using BML780PULm104 strain has no concern relevant to human health.

¹ Decision of the Commission dated 25 March 2004.