



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

## Safety Assessment Report

### Pullulanase produced using JPBL002 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)  
May 2018

#### ABSTRACT

FSCJ conducted a safety assessment of pullulanase, produced using JPBL002 strain based on the documents submitted by the applicant.

This additive is an enzyme produced using JPBL002 strain which was generated through the introduction of a fusion gene produced from a partial region of pullulanase gene derived from *Bacillus acidopullulyticus* NCIMB 11639 strain and a partial region of pullulanase mutant gene derived from *Bacillus deramificans* LMGP 13056 into *Bacillus licheniformis* Ca63 as a host. This enzyme is an endo-type enzyme which hydrolyze  $\alpha$ -1,6-D-glucosidic bond in amylopectin and pullulan, and is used for enhancing saccharification efficiency in starch sugar production.

The documents, evaluated based on the “Standards for Safety Assessments 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.

Consequently, FSCJ concluded that pullulanase produced using JPBL002 strain has no concern relevant to human health.

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