



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

Safety Assessment Report

Beta-Galactosidase produced using JPBL003 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

September 2019

ABSTRACT

FSCJ conducted a safety assessment of β -galactosidase produced using JPBL003 strain, based on the documents submitted by the applicant.

This additive is β -galactosidase produced by JPBL003 strain which was generated through the introduction of β -galactosidase gene derived from *Bifidobacterium bifidum* NCIMB 41171 and *prsA* gene involved in protein secretion into *Bacillus licheniformis* Ca63 strain as the host. This enzyme, hydrolyzing β -galactoside bonds in disaccharides, is used to decrease lactose content in dairy products.

Safety of the inserted gene, toxicity and allergenicity of the protein produced from the inserted gene, post-insertion analysis of nucleotide sequence and so on were evaluated based on the “Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms¹”. As the result, it was considered that there was no new factor bringing out adverse effects on humans in this additive, compared with the conventional counterpart.

Hence, FSCJ concluded that no concern relevant to human health is raised on β -galactosidase produced using JPBL003 strain.

¹ Decision of the Commission dated 25 March 2004.