

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

## Safety Assessment Report

## Protease produced using JPBL012 strain

(Genetically Modified Food)

Food Safety Commission of Japan (FSCJ) June 2022

## ABSTRACT

The FSCJ conducted a safety assessment of a food additive, protease produced using JPBL012 strain.

This additive is protease produced using JPBL012 strain which was generated through the introduction of protease gene derived from the donor, *Bacillus licheniformis* Ca63 strain. This protease is subtilisin, a variety of serine endo-protease that hydrolyzes peptide bonds to produce peptides and amino acids. This enzyme is intended to be used to solubilize protein.

Based on "Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms"<sup>1</sup>, the FSCJ confirmed the safety of the inserted gene; and the toxicity and allergenicity of the protein produced from the inserted gene, and others. Consequently, any new safety concerns were not identified, compared with conventional additives.

Accordingly, the FSCJ concluded that "protease produced using JPBL012 strain" has no concern relevant to human health.

<sup>&</sup>lt;sup>1</sup> Decision of the FSCJ dated March 25, 2004