

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

Safety Assessment Report

Alkaline protease produced using JPBL001 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a safety assessment of an additive, alkaline protease, produced using JPBL001 strain based on the documents submitted by the applicant.

This additive is alkaline protease produced using JPBL001 strain which was generated through the introduction of the alkaline protease gene derived from *Nocardiopsis prasina* NRRL 18262 strain into *Bacillus licheniformis* Si3 as a host. This enzyme is an endo-type protease which hydrolyzes peptide-bonds of proteins thus producing peptides and amino acids, and is used for enhancing the efficacy to produce meat extracts and fish extracts.

The documents, evaluated based on the “Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms¹”, 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 alkaline protease produced using JPBL001 strain has no concern relevant to human health.

¹ Decision of the Commission dated 25 March 2004.