



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

Safety Assessment Report

Protease produced using *Bacillus subtilis* BPN01 strain

(Genetically Modified Food/Feed)

Food Safety Commission of Japan (FSCJ)

May 2014

Abstract

FSCJ conducted a safety assessment of protease produced using *Bacillus subtilis* BPN01 strain, based on the documents submitted by the applicant.

This additive is a protease produced using *Bacillus subtilis* BPN01 strain generated through the introduction of gene for protease originated from *B. subtilis* BP1206 into the host BP1206 strain in order to enhance the productivity of protease.

FSCJ confirmed that only DNA derived from the host *B. subtilis* was introduced into BPN01 strain, the bacterial strain producing this additive.

This additive has been produced using a microorganism that falls under "the case where living cells which have genotypic composition equivalent to the relevant recombinant exist in nature", specified in Chapter 1 General Provisions, Section 3 "Scope and Objective" of "Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms (Decision of the Commission Dated 25 March 2004)". Accordingly, this additive is not categorized into the object of the above-mentioned Standards. FSCJ, thus, judged that safety assessment is not necessary for this additive.