



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

Safety Assessment Report

Peptidase produced using pXPO strain

(Genetically Modified Food/Feed)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

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

This additive is a peptidase produced using pXPO strain, which is generated through the introduction of an insert DNA and an expression plasmid into the host *Streptomyces violaceoruber* 1326 strain, for the enhanced productivity of peptidase. The insert DNA was consisted of the promoter and terminator genes originated from *Streptomyces cinnamoneus* NBRC 12852 and of the structural gene for peptidase originated from *Streptomyces violaceoruber* NBRC 15146. The expression plasmid also included a thiostreptone resistant (tsr) gene originated from *Streptomyces azureus*.

Gene exchanges are considered to occur naturally among *S. violaceoruber*, *S. cinnamoneus* and *S. azureus*. These suggest the existence of living cells with a genotypic composition equivalent to that of pXPO strain are likely to exist in nature.

This additive has been produced using a microorganism corresponding to "the case where a living cell showing the 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, and FSCJ, thus, judged that safety assessment is not necessary for this additive.