



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

Safety Assessment Report

Carboxypeptidase produced using PEG strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

March 2016

ABSTRACT

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

This additive is a carboxypeptidase produced using PEG strain, which is generated through introduction of a carboxypeptidase gene originated from *Aspergillus niger* N400 into the host ISO-502 strain derived from *A. niger* NRRL3122 strain in order to enhance the productivity of carboxypeptidase.

Carboxypeptidase is in the Current List of Food Additives, and is used in wide variety of foods.

FSCJ confirmed that DNA derived only from a host *A. niger* strain, was introduced into the PEG strain producing this additive.

This additive has been produced using a microorganism that falls under "the case where the DNA ultimately introduced to the host through recombinant DNA techniques is only DNA from a microorganism belonging to the same taxonomic species as a microorganism in question" specified in Chapter 1 General Provisions, Section 3 "Scope and Objective" of Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms¹. Accordingly, this additive is not categorized into the object of the above-mentioned Standards. FSCJ thus judged that the safety assessment is not necessary for this additive.

¹ Section 3 of Chapter 1 of Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms (Decision of the Commission Dated 25 March 2004), laying down the case where living cells with genotypic composition equivalent to the relevant recombinant exist in nature.