

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

Safety Assessment Report

Asparaginase produced using *Aspergillus niger* ASP-72 strain (Genetically modified food/feed)

Food Safety Commission of Japan (FSCJ)

September 2013

ABSTRACT

FSCJ conducted safety assessment of "Asparaginase produced from the *Aspergillus niger* ASP-72 strain" based on the documents submitted by the applicant.

The ASP-72 strain with enhanced asparaginase productivity is used for producing this additive, which was produced by the introduction of the asparaginase gene derived from the *A. niger* GAM-8 strain into the GAM-53 strain derived from *Aspergillus niger* NRRL3122. Asparaginase is an enzyme catalyzing the hydrolysis of asparagine to form aspartic acid and ammonia. Since asparagine is one of the causal substances of acrylamide in food, the addition of this enzyme is expected to suppress the formation of acrylamide in food during heating processes.

FSCJ confirmed that only DNA derived from *A. niger*, the host, was introduced into the ASP-72 strain, the bacterial 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 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 judged that safety assessment is not necessary for this additive.

Asparaginase is not designated as a food additive specified in Article 10 of Food Sanitation Law (Law No. 233 of 1947). So a risk assessment related to such designation has also been requested by the Ministry of Health, Labour and Welfare. Thus, the results of the risk assessment as a food additive are also required on the safety decision of this additive.