

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

Risk Assessment Report

Asparaginase produced using *Aspergillus niger* ASP-72 strain (Food additives)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

FSCJ conducted a risk assessment of Asparaginase (as L-asparagine amidohydrolase, EC number 3.5.1.1, CAS number: 905-68-3), an additive used as an enzyme, produced using *Aspergillus niger* ASP-72 strain (hereinafter referred to as “the item”), based on the results from various studies.

The data used in the assessment were on: the pathogenicity and toxigenicity of *A. niger* ASP-72 strain, the genotoxicity, repeated dose toxicity and allergenicity of the item.

FSCJ concluded that *A. niger* ASP-72 strain, properly maintained and used to produce the item, had no pathogenicity and toxigenicity relevant to consumption of this substance as a food additive.

FSCJ also concluded that the item comes under Article 6 of Chapter 2 of the Guideline for Assessment of the Effect of Food on Human Health Regarding Food Additives (Decision of the Commission dated 27 May 2010), “when it is scientifically proven that the enzyme is degraded in the digestive tract to become a common component of food”. Therefore, FSCJ conducted safety assessment of the item using the data on its genotoxicity, repeated dose toxicity and allergenicity based on the guideline.

FSCJ subsequently examined findings on the toxicity of active components before preparation of the item, and concluded that the item has no genotoxicity, repeated dose toxicity and developmental toxicity.

As the item is easily digestive and has no homology with existing allergens, FSCJ considered it non-allergenic if properly used as a food additive.

There is a sufficient safety margin between NOAEL of 1,038 mg TOS/kg bw per day obtained at the highest dose level in 13-week repeated dose oral toxicity studies in rats and the EDI (Estimated Daily Intake) of the item (0.549 mg TOS/kg bw per day). In addition, the item is produced using *A. niger* which is a microorganism with experiences being used as a human food component. Based on these results, the assessed item is considered to be of no concern for food safety as long as used appropriately as a food additive. Therefore, it is not necessary to specify ADI.