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

Risk Assessment Report

Asparaginase

(Food Additives)

Food Safety Commission of Japan (FSCJ)
December 2015

ABSTRACT

FSCJ conducted a risk assessment of asparaginase (EC Number : 3.5.1.1, CAS No. 9015-68-3), an additive produced using *Aspergillus oryzae* NZYM-SP strain and used as an enzyme, based on results from various studies.
The data used in the assessment include the pathogenicity and toxigenicity of *Aspergillus oryzae* NZYM-SP strain, the genotoxicity, repeated dose toxicity and allergenicity of asparaginase produced using *Aspergillus oryzae* NZYM-SP strain.

FSCJ concluded that *Aspergillus oryzae* NZYM-SP 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 assessed item corresponds to a case which is specified in Article 6 of Chapter 2 of the Guideline for Assessment of the Effect of Food on Human Health Regarding Food Additives[1]. Therefore, FSCJ conducted a 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 the item, and concluded that the item has no genotoxicity and repeated dose toxicity.
FSCJ also concluded that allergenicity of the item is extremely low.

Based on these results, there is a sufficient safety margin between no-observed-adverse-effect level (NOAEL) of 10.0 mL/kg bw per day (equivalent to 880 mg TOS/kg bw per day) obtained at the highest dose level in 13-week repeated oral dose toxicity studies in rats and an estimated daily intake (EDI) of the item (114 μgTOS/kg bw per day). In addition, the item is produced using *A. oryzae* which is a microorganism with experiences being used as a human food component.
Since the assessed item is considered to be of no concern for food safety as long as used appropriately as a food additive, it is not necessary to specify an acceptable daily intake (ADI).

[1] Decision of the Commission of 27 May 2010 on the Guideline for Assessment of the Effect of Food on Human Health Regarding Food Additives. In Article 6 of Chapter 2 of the Guideline lays down the case when it is scientifically proven that the enzyme is decomposed in the digestive tract to become a common component of food.