

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

Safety Assessment Report

Asparaginase produced using *Aspergillus oryzae* NZYM-SP strain (Genetically modified food)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

FSCJ conducted a risk assessment of asparaginase produced using *Aspergillus oryzae* NZYM-SP strain based on the documents submitted by the applicant.

This additive is an asparaginase produced using *Bacillus subtilis* NYZM-SP strain, which is generated through the introduction of asparaginase gene originated from *A. oryzae* IFO4177 into the host *Aspergillus oryzae* BECh2 in order to enhance the production of asparaginase. Asparaginase mediates the hydrolysis of asparagine to form aspartic acid and ammonia. Since asparagine is one of the causal substances of acrylamide formation in food, the addition of this enzyme is expected to reduce the formation of acrylamide in food during heating processes.

Acetamidase gene derived from *Aspergillus nidulans* and orotidine-5'-phosphate decarboxylase gene derived from *Saccharomyces cerevisiae* FL100 strain were introduced as selection markers in this strain

The safety of the inserted gene, toxicity of the protein produced from the inserted gene and issues associated with allergenicity were assessed based on the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms¹. The enzyme is thus without newly generated safety concerns in comparison with the conventional counterpart.

In conclusion, no concern relevant to human health is raised on the asparaginase produced using *Bacillus subtilis* NYZM-SP strain.

This additive is not designated as a food additive specified in Article 11 of Food Sanitation Law (Law No. 233 of 1947). So a risk assessment related to such designation has also been requested by the

¹ Decision of the Commission dated 25 March 2004



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.