

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

Safety Assessment Report

Alpha-amylase produced using NZYM-SO strain (Genetically modified food)

Food Safety Commission of Japan (FSCJ)

April 2015

ABSTRACT

FSCJ conducted a risk assessment of alpha-amylase produced using NZYM-SO strain based on the documents submitted by the applicant.

This additive is an amylase produced using *Bacillus subtilis* NYZM-SO strain, which is generated through the introduction of modified α -amylase gene originated from *Geobacillus stearothermophilus* C599 into the host *B. subtilis* A164 Δ 5 in order to enhance the quality of α -amylase.

This enzyme hydrolyzes glucose polymers linked with an α -1,4-glucosidic bond, and is used as an additive to produce maltose. This additive is applicable to reduce bread staling and to produce starch sugar such as high maltose syrup.

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 alpha-amylase produced using NZYM-SO strain.

¹ Decision of the Commission dated 25 March 2004