



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

## Safety Assessment Report

### Alpha-amylase produced using NYZM-AV strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

March 2016

#### ABSTRACT

FSCJ conducted a safety assessment of  $\alpha$ -amylase produced using NYZM-AV strain, based on the documents submitted by the applicant.

The NYZM-AV strain was generated through introduction of *mayLE2488* gene and *prsA* gene into the *Bacillus licheniformis* Ca63 strain in order to enhance the  $\alpha$ -amylase property. The *mayLE2488* is a modified  $\alpha$ -amylase gene originated from the host strain, and the *prsA* gene is a gene related to protein secretion. Alpha-amylase, hydrolyzing glucose 1,4-alpha bonds of glucose polymers to produce mainly dextrin and oligosaccharide, is used as a processing aid for starch sugars.

The safety of the inserted gene, toxicity and allergenicity of the protein produced from the inserted gene, and others were evaluated based on the “Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms<sup>1</sup>”. None of the newly generated safety concerns were detected in comparison with conventional additives without genetical modification.

Consequently, FSCJ concluded that the  $\alpha$ -amylase produced using NYZM-AV strain has no concern relevant to human health.

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<sup>1</sup> Decision of the Commission Dated 25 March 2004.