

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

## Safety Assessment Report

### **6- $\alpha$ -glucanotransferase produced using NZYM-RO strain** (Genetically modified food)

Food Safety Commission of Japan (FSCJ)

September 2015

#### ABSTRACT

FSCJ conducted a risk assessment of 6- $\alpha$ -glucanotransferase produced using a NZYM-RO strain based on the documents submitted by the applicant.

This additive is 6- $\alpha$ -glucanotransferase produced using *Bacillus subtilis* NYZM-RO strain, which is generated through the introduction of a modified 6- $\alpha$ -glucanotransferase gene originated from *Rhodothermus obamensis* JCM 9785 line into the host *B. subtilis* 168 in order to produce 6- $\alpha$ -glucanotransferase. This additive is an enzyme, that cuts  $\alpha$ -1,4-D-glucosidic bond and to form  $\alpha$ -1,6-D-glucosidic bond in starch, and used as a processing aid for starch.

The safety of the inserted gene, toxicity of the protein produced from the inserted gene and issues associated with allergenicity were assessed based on “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms<sup>1</sup>”. 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 6- $\alpha$ -glucanotransferase produced using NZYM-RO strain.

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