



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

Safety Assessment Report

Acidic phosphatase produced using OYC-GM1 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

FSCJ conducted a safety assessment of acidic phosphatase produced using OYC-GM1 strain, based on the documents submitted by the applicant.

The OYC-GM1 strain was generated through the introduction of an expression vector pET-21(+)-HIGM1 that contains an acidic phosphatase gene originated from *Haemophilus influenzae* into *Escherichia coli* BL21(DE3) strain as a host so as to obtain productivity of acidic phosphatase. This additive is an enzyme that has a high reaction specificity with specific substrates besides the activity to hydrolyze phosphoric monoesters, and used for production of the materials for supplements.

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 Microorganisms¹”. None of the newly generated safety concerns were detected in comparison with conventional additives without genetical modification.

Consequently, FSCJ concluded that acidic phosphatase produced using OYC-GM1 strain has no concern relevant to human health.

¹ Decision of the Commission Dated 25 March 2004.