



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

Safety Assessment Report

L-Proline produced using ECP strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

March 2016

ABSTRACT

FSCJ conducted a safety assessment of L-Proline produced using ECP strain, based on the documents submitted by the applicant.

The ECP strain was generated to enhance the L-proline productivity through mutataion of L-proline synthesis gene, insertion of the promoter sequences and delation of genes related to L-proline biosynthesis into a strain derived from *Escherichia coli* KY8227 as a host.

This additive meets the content specification of Japanese Standards of Food Additives. Amounts of non-active ingredients detected were less, compared to the corresponding conventional L-proline product. In addition, production of new harmful ingredients are not detected in this additive from the analysis.

Documents were evaluated based on the “Stance on Safety Assessments of Additives Produced Using Generically Modified Microorganisms, whose End Product is regarded as a Highly Purified Nonprotein Additive, such as Amino Acids¹” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms²”). Consequently, the safety of the additive has been confirmed from the document.

In conclusion, the assessment based on the “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms” is not necessary for this additive.

¹ Decision of the Commission dated April 28, 2005

² Decision of the Commission dated March 25, 2004