



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

Safety Assessment Report

L-Leucine produced using LG-108 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

November 2019

ABSTRACT

FSCJ conducted a safety assessment of an additive produced using LG-108 strain, L-leucine, based on the documents submitted by the applicant.

LG-108 strain was generated from the host, *Escherichia coli* KY8227 strain, through introduction of the genes involved in L-leucine synthesis and the mutation, insertion of the promotor sequences, and deletion of the genes involved in L-leucine metabolism.

This additive meets the content specification of Japanese Standards of Food Additives. Amounts of known non-active ingredients were not increased to levels that could cause a safety issue, compared to those in the corresponding conventional L-leucine products. In addition, no new ingredients suggested to be harmful are thought to be included in this additive.

The 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”. As the result, it was considered that the safety of the additive has been confirmed from the documents.

Consequently, the assessment based on the “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms²” is not necessary for this additive.

¹ Decision of the Commission dated April 28, 2005

² Decision of the Commission dated March 25, 2004