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

Safety Assessment Report

L-leucine produced using LEU-No.4 strain

(Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
April 2024

ABSTRACT

The FSCJ conducted a safety assessment of "L-leucine produced using the LEU-No.4 strain."

This additive is an L-leucine produced using the LEU-No. 4 strain, which was generated through the insertion of transgenes related to the biosynthesis of L-leucine into the 55ilvTT4 strain, a mutant strain derived from the *Escherichia coli* K-12 strain as a host.

The assessment, conducted referring to the "Stance on Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms, whose End Product is a Highly Purified Nonprotein Additive, such as Amino Acids,[1]" indicated that this additive meets the content standards of Japan's Specifications and Standards for Food Additives, since bacteria and fermentation by-products are removed and the additive is highly purified by crystallization during its manufacturing process. Additionally, it is deemed that the amount of the existing non-active ingredients has not increased to a level that would pose safety concerns compared to conventional L-leucine, and that no additional non-active substances that could be considered harmful are present. Based on the above, this additive was considered as safe.

Consequently, it was considered unnecessary to conduct a safety assessment in reference to the "Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms.[2]"

[1] Decision of the FSCJ dated April 28, 2005
[2] Decision of the FSCJ dated March 25, 2004