



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

## Safety Assessment Report

### L-isoleucine produced using the ILE-No.2 strain (Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)  
June 2025

## ABSTRACT

The FSCJ conducted a safety assessment of “L-isoleucine produced using the ILE-No.2 strain.”

This additive is an L-isoleucine produced using the ILE-No.2 strain developed by introducing the transgenes involved in the biosynthesis of L-isoleucine into the TP strain, which is a mutant strain derived from the *Escherichia coli* K-12 strain, as a host.

The assessment was 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 (Annex to Guidelines for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms.<sup>1)</sup>”. The result of the assessment confirmed that this additive meets the content standards of Japan’s Specifications and Standards for Food Additives, since bacteria and by-products are removed and this 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-isoleucine, and it is also considered that it does not contain additional non-active substances that could be considered toxic. Based on the above, this additive was considered safe.

Consequently, it was considered unnecessary to reconduct a safety assessment in reference to the “Guidelines for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms.”

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