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

Risk Assessment Report

L-isoleucine produced by fermentation with *Corynebacterium glutamicum* KCCM80189 strain

(Feed Additive)

Food Safety Commission of Japan (FSCJ)
March 2022

ABSTRACT

The FSCJ conducted a risk assessment of a feed additive product with active substance of L-isoleucine (CAS No. 73-32-5), based on the required application materials for the assessment discussions (of MAFF, MHLW and FSCJ) to designate a new feed additive.

L-isoleucine is a biologically essential amino acid and broadly presents in feeds and foods. It is globally registered and used as a feed additive. It is also used as a food additive while its standard as a designated additive is not established.

This product contains ≥90% L-isoleucine produced by fermentation using *Corynebacterium glutamicum* KCCM80189 strain, which is a mutant of the wild *Corynebacterium glutamicum* ATCC13032 strain. It is a feed additive for all livestock species. The recommended additive amount is specified at 0.01% to 0.5% per assorted feed. The production strain, *Corynebacterium glutamicum* was identified for a taxonomic unit (TU) in EFSA's list of QPS (qualified presumption of safety) [1]. Its metabolites are believed to be safe. Most non-active substances of this product are free amino acids other than L-isoleucine. As a result of analyzing the harmful substances, the FSCJ found that substances to affect safety of the product were not identified nor their volume was significant. The product was made of the crude solution. It is thought that the human health effects of intake through foods could be negligible.

In a genotoxicity study, the FSCJ determined that L-isoleucine would have no genotoxicity as long as it is used as a feed additive.

In the following feeding tests of dietary administration in pigs and chicken, abnormal changes were not observed:

- Pigs: 10 times higher amount of the normal dosage in 21 days
- Chicken: 6 times higher amount of the maximum recommended additive in 10 days

Given the above, the FSCJ concluded that risk to human health of "L-isoleucine produced by fermentation with *Corynebacterium glutamicum* KCCM80189 strain" consumed through foods is negligible as long as it is appropriately used as a feed additive.

[1] The QPS process was developed to provide a harmonized genetic pre-evaluation procedure to support safety risk assessments of biological agents performed by EFSA's scientific Panels and Units.