

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

Safety Assessment Report

L-carnosine produced using the AH-No.1 strain (Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
June 2025

ABSTRACT

The FSCJ conducted a safety assessment of “L-carnosine produced using the AH-No.1 strain.”

This food is an L-carnosine produced using the AH-No.1 strain developed by introducing the transgenes involved in the biosynthesis of L-carnosine into the JM109 strain, which is a mutant strain derived from the *Escherichia coli* K-12 strain, as a host.

During the manufacturing process, the production bacteria and by-products are removed, and the food is highly purified by crystallization. Additionally, it is deemed that the amount of the existing non-active ingredients has not significantly increased to a level that would pose safety concerns compared to conventional L-carnosine, and it is also considered that it does not contain additional non-active substances that could be considered toxic.

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.¹)”. The result of the assessment indicated that it was considered unnecessary to reconduct a safety assessment in reference to the “Standards for the Safety Assessments of Genetically Modified Foods (Microorganisms)²” and that its safety is confirmed to be equivalent to the conventional food as long as the usage pattern is the same as the current practice.

This assessment confirms that the risk of “L-carnosine produced using the AH-No.1 strain” does not increase compared to conventional food. Thus, it is necessary for risk management organizations to provide thorough guidance to business entities to ensure compliance with the specified product standards and to collect information on the cases of adverse health effects among consumers.

¹ Decision of the FSCJ dated March 25, 2004

² Decision of the FSCJ dated June 26, 2008