



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

Safety Assessment Report

L-proline produced using PRO-No.1 strain

(Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)

August 2024

ABSTRACT

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

This additive is an L-proline produced using the PRO-No.1 strain, which was developed by inserting transgenes involved in the biosynthesis of L-proline into the 240-18 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 Acids¹”, indicated that this additive met the content standards of Japan’s Specifications and Standards for Food Additives (JSFA) because the bacteria and fermentation by-products were removed, and the additive was highly purified by crystallization during the manufacturing process. Additionally, it was considered that the levels of the existing non-active ingredients were not increased to amounts that would pose safety concerns compared to conventional L-proline, and that the additive did not contain any additional non-active ingredients that could be considered harmful. Based on the above, the additive was considered 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 Microorganisms²”.

¹ Decision of the FSCJ dated April 28, 2005

² Decision of the FSCJ dated March 25, 2004