

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

Safety Assessment Report

L-Histidine produced using HIS-No.2 strain (Genetically modified food)

Food Safety Commission of Japan (FSCJ)
May 2016

ABSTRACT

FSCJ conducted a risk assessment of L-histidine produced using HIS-No2 strain, based on the documents submitted by the applicant.

The HIS-No2 strain was generated through introduction/deletion of genes, originated from *E. coli* K-12 line, involved in L-histidine biosynthesis into a mutant strain derived from *Escherichia coli* K-12 as a host to enhance the L-histidine productivity.

This additive meets the content specification of Japanese Standards of Food Additives. Amounts of non-active ingredients were less compared to the corresponding conventional sodium 5-inosate products. In addition, no new harmful ingredients are suggested in the additive.

Documents were evaluated based on the “Stance on Safety Assessments of Additives Produced Using Genetically Modified Microorganisms, whose End Product is regarded as a Highly Purified Nonprotein Additive, such as Amino Acids ¹” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms ²”). Consequently, the safety of the additive has been confirmed.

In conclusion, the assessment based on the “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms” is not necessary for this additive.

¹ Decision of the Commission dated April 28, 2005

² Decision of the Commission dated March 25, 2004