



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

## Safety Assessment Report

### L-Histidine hydrochloride produced using HIS-No.2 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

March 2016

#### ABSTRACT

FSCJ conducted a safety assessment of L-histidine hydrochloride produced using HIS-No.2 strain, based on the documents submitted by the applicant.

HIS-No.2 strain was generated through introduction of genes originated from *Escherichia coli* K-12 for L-histidine synthesis into a mutant host strain derived from *E. coli* K-12, to enhance the L-histidine productivity. Distinct genes related in L-histidine synthesis were deleted to generate the HIS-No.2 strain.

This additive meets the content specification of Japanese Standards of Food Additives. Amounts of non-active ingredients detected were less compared to the corresponding conventional L-histidine hydrochloride. In addition, production of no new harmful ingredients are not expected in the additive from the analysis.

Documents on HIS-No.2 was evaluated based on the “Stance on Safety Assessments of Additives Produced Using Generically Modified Microorganisms, whose End Product is regarded as a Highly Purified Nonprotein Additive, such as Amino Acids<sup>1</sup>” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms<sup>2</sup>”). Consequently, the safety of the additive has been confirmed from the document.

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.

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<sup>1</sup> Decision of the Commission dated April 28, 2005

<sup>2</sup> Decision of the Commission dated March 25, 2004