

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

## **Safety Assessment Report**

### **L-Cysteine hydrochloride**

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

October 2015

#### **ABSTRACT**

FSCJ conducted a safety assessment of L-cysteine hydrochloride, an additive produced using the CYS-No.1 strain, based on the documents submitted by the applicant.

The CYS-No.1 strain was generated through introduction of genes involved in L-cysteine synthesis and modification of the promotor sequences into a mutant strain derived from *Pantoea ananatis* No.359 as a host, to enhance the L-cysteine productivity. Distinct genes involved in L-cysteine synthesis were also deleted to generate the CYS-No.1 strain.

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

The documents were evaluated based on the “Stance on Safety Assessments of Additives Produced Using Generically Modified Microorganisms, whose End Product is 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. 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