

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

Safety Assessment Report

L-arginine produced using ARG-No.4 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

August 2017

ABSTRACT

FSCJ conducted a safety assessment of L-arginine produced using ARG-No.4 strain, based on the documents submitted by the applicant.

The ARG-No.4 strain was generated through introduction/reintroduction of genes involved in L-arginine synthesis, insertion of the promoter sequences and deletion of genes involved in L-arginine metabolism into the ARG-No.3 strain to enhance the L-arginine productivity. ARG-No.3 strain used was a product derived from a mutant strain derived from *Escherichia Coli* K-12 and its safety assessment was completed in 2013.

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-proline product. In addition, production of new harmful ingredients are not detected in this additive from the analysis.

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 Acids¹” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms²”). 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.

¹ Decision of the Commission dated April 28, 2005

² Decision of the Commission dated March 25, 2004