



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

Safety Assessment Report

L-serine produced using SKG strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

July 2019

ABSTRACT

FSCJ conducted a safety assessment of L-serine produced using SKG strain, based on the documents submitted by the applicant.

The SKG strain was generated through insertion of related genes, substitution into mutated genes and insertion of promoters sequences in the genes involved in L-serine biosynthesis, and through deletion in the genes involved in L-serine metabolization from the BDS strain. The BDS strain has previously been obtained from *Escherichia coli* KY8227 strain as a host by recombinant technology, and its safety has been confirmed in 2012.

This additive meets the content specification of Japanese Standards of Food Additives. Amounts of known non-active ingredients were not increased to levels that could cause a safety issue, compared to those in the corresponding conventional L-serine product. In addition, no new ingredients suggested to be harmful are thought to be included in this additive.

Documents were 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 Acids¹” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms²”). As the result, it was considered that the safety of the additive has been confirmed from the documents.

Consequently, it was concluded that 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