

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

Safety Assessment Report L-threonine produced using *Escherichia coli* K-12 (DM 235 strain)

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ) February 2018

ABSTRACT

FSCJ conducted a safety assessment of L-threonine produced using *Escherichia coli* K-12 (strain DM 235), based on the documents submitted by the applicant.

E.coli K-12 (DM 235 strain) was generated to enhance the productivity of L-threonine through introduction of genes involved in L-threonine biosynthesis and genes involved in utilization of carbon sources, as well as deletion of genes involved in L-threonine decomposition into *E.coli* K-12 as a host.

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

Documents were evaluated applying 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"). Consequently, the FSCJ concluded that the livestock products derived from livestock animals that have consumed this feed additive would not cause concern relevant to food safety.

_

¹ Decision of the Commission dated April 28, 2005

² Decision of the Commission dated March 25, 2004