



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

## Safety Assessment Report

### L-Threonine produced using THR-No.2 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

January 2016

#### ABSTRACT

FSCJ conducted a safety assessment of L-threonine, a feed additive produced using the THR-No.2 strain, based on the applicant documents submitted.

The THR-No.2 strain was generated through introduction of genes involved in L-threonine synthesis and carbohydrate assimilation, and of modification of promoter sequences into a mutant strain derived from *Escherichia coli* K-12, to enhance the L-threonine productivity. Specific genes involved in L-threonine synthesis were also deleted to generate the THR-No.2 strain.

This additive meets the compositional specification of Japanese Compositional Standards for Feed Additives. Amounts of non-active ingredients were less compared to the corresponding conventional L-threonine products. In addition, no new harmful ingredients are suggested in the additive.

The document was evaluated, based on the “Stance on Safety Assessments of Genetically Modified Feed and Feed Additives<sup>1</sup>”, following the “Stance on Safety Assessments of Additives Produced Using Genetically Modified Microorganisms, whose End Product is a Highly Purified Nonprotein Additive, such as Amino Acids<sup>2</sup>” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms<sup>3</sup>”). Consequently, FSCJ concluded no warrant food-safety risks from the livestock use of the assessed item.

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<sup>1</sup> Decision of the Commission dated May 6, 2004

<sup>2</sup> Decision of the Commission dated April 28, 2005

<sup>3</sup> Decision of the Commission dated March 25, 2004