



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

Safety Assessment Report

L-Methionine produced using K12KCCM11252P and K12 KCCM11340P strains

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a safety assessment of a feed additive produced using K12KCCM11252P and K12 KCCM11340P strains, L-methionine, based on the documents submitted by the applicant.

K12KCCM11252P strain was generated from the host, *Escherichia coli* K-12 strain, through introduction and deletion of the genes involved in L-methionine precursor synthesis. K12 KCCM11340P strain was also generated through introduction of the genes encoding an enzyme converting to L-methionine using the same host strain. L-Methionine is produced by the reaction of mercaptane with the L-methionine precursor produced by K12KCCM11252P strain, using the converting enzyme produced by K12 KCCM11340P strain.

This additive meets the content specification draft of L-methionine established according to that of DL-methionine designated in the Japanese standards of feed additives. Amounts of known non-active ingredients were not increased to levels that could cause a safety issue, compared to the corresponding conventional DL-methionine products. In addition, no new suggested to be harmful ingredients are thought to be included in this additive.

The risk assessment of genetically modified feed additives is supposed to be conducted in accordance with “Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms (Decision of the Commission Dated 25 March 2004)” in “Stance on Safety Assessments of Genetically Modified Feed and Feed Additives (Food Safety Commission Decision of May 6, 2004)”.

Therefore, FSCJ decided to conduct the risk assessment of this feed additive pursuant to that of genetically modified additives; assessed it based on “Stance on Safety Assessments of Additives Produced Using Genetically Modified Microorganisms, whose End Product is a Highly Purified Nonprotein Additive, such as Amino Acids. (Decision of the Food Safety Commission Dated 28 April, 2005)”. As the result, the food safety risk from the relevant feed additive through livestock products was judged to be negative,



thus FSCJ concluded that the assessment based on the “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms¹” is not necessary for this feed additive.

Note that FSCJ has already submit the other assessment report regarding L-methionine that risk to human health from the assessed item through consumption is negligible as long as it is used appropriately as feed additive to the Minister of Agriculture, Forestry and Fisheries, on January 29, 2019. The relevant assessment report must be also referred when the Ministry of Agriculture, Forestry and Fisheries handles this feed additive.

¹ Decision of the Commission dated March 25, 2004