

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

Risk Assessment Report

DL-methionine, L-methionine

2nd version

(Exempted Substances)

Food Safety Commission of Japan (FSCJ)
December 2017

SUMMARY

FSCJ conducted a risk assessment of methionine that has been designated as Exempted Substances¹ based on various assessment reports.

Data on the pharmacokinetics and genotoxicity study were newly provided for this assessment.

Methionine is an amino acid component of proteins, and human ingest methionine containing protein as macronutrients from daily foods.

Methionine and 2-deamino-2-hydroxymethionine, which is a hydroxylated methionine and metabolized to methionine *in vivo* when administered, are used for consecutive metabolism of intracellular proteins. Thus, methionine is metabolized *in vivo* and not accumulated even if it is ingested excessively.

Therefore, FSCJ considered that methionine derived from veterinary medicinal products and feed additives is unlikely ingested in humans to an excess amount through food consumption.

Moreover, methionine has been used in the variety of fields including veterinary medicinal products and feed additives, and has not caused any major food safety concerns from its use.

Consequently, FSCJ considered that risks of methionine to human health through residues in foods are negligible as long as normally used as veterinary medicinal products and feed additives.

¹ On May 29, 2006 the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods to prohibit the distribution of foods that contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. Exempted Substances are designated as substances having no potential to cause damage to human health by the Minister of Health, Labour and Welfare, based on the provision of Paragraph 3, Article 11 of the Food Sanitation Act, and these substances are not subjected to the positive list system.