

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

Risk Assessment Report

Methionine¹ (Exempted Substances²)

Food Safety Commission of Japan (FSCJ)
October 2012

ABSTRACT

The FSCJ conducted a risk assessment of methionine in response to the request from the Ministry of Health, Labour and Welfare. Methionine has been designated as an exempted substance by the Minister of Health, Labour and Welfare. This substance does not have adverse effects on human health in accordance with the provision of Article 11 paragraph (3) of the Food Sanitation Act (Act No. 233 of 1947). Methionine is used for a veterinary medicinal product or a feed additive.

The FSCJ concluded the following assessed view after reviewing various documents.

- Methionine is an amino acid composed of proteins. Humans usually take proteins containing methionine as macronutrients through food.
- Methionine administered to animals are used for the consecutive metabolic processes of Intra-Cellular proteins. As they are metabolized *in vivo* in animals without accumulating there, it is assumed that humans would not consume too much of this substance (derived from veterinary medicinal products and feed additives) through food.
- The use of methionine-based veterinary medicinal products, additives and others have not caused particular safety issues.
- Given the above, the FSCJ thought that there would be no concern about adverse effects on human health through the residues in food as long as methionine is normally applied as a veterinary medicinal product or a feed additive.

¹ Methionine is an essential amino acid that occurs in two types of enantiomers as D-methionine and L-methionine. DL-methionine is a racemic mixture of D and L enantiomers of methionine. L-methionine is the L enantiomer of methionine.

² On May 29, 2006, the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods- the system 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 defined by the MHLW as substances having no potential to cause damage to human health, based on the provision of Article 11, paragraph (3) of the Food Sanitation Act. These substances are not subject to the positive list system.