

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

Risk Assessment Report

Methionine¹ (Second edition) (Exempted Substances²)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

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 initially assessed methionine in October, 2012. On the premise of assessing a feed additive of 2-deamino-2-hydroxymethionine [Zn-(HMTBa)₂]³ requested by the Ministry of Agriculture, Forestry and Fisheries (MAFF), the FSCJ reassessed methionine as it is an active substance of Zn-(HMTBa)₂. New study results of fate in animals and genotoxicity were submitted in line with the assessment for Zn-(HMTBa)₂.

The FSCJ reaffirmed the previously assessed view on methionine since the new scientific findings did not affect the existing assessment results. Accordingly, the description of methionine stated in 2012 should be reiterated as follows.

- Methionine is an amino acid composed of proteins. Humans usually take proteins containing methionine as macronutrients through food.
- Methionine and 2-deamino-2-hydroxymethionine (HMTBa) (a hydroxy analog of methionine, which is metabolized to methionine *in vivo*) 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 those substances (derived from veterinary medicinal products and feed additives) through food.

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.

³ Food safety assessment of effects on health is a prerequisite of the regulatory process for the criteria and specification of feed additives established by the risk management organizations (MAFF, MHLW and Consumer Affairs Agency).

- 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.