

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

## Risk Assessment Report

### 2-deamino-2-hydroxymethionine Cu (Mintrex<sup>®</sup>CU) (Feed Additives)

Food Safety Commission of Japan (FSCJ)  
March 2019

#### ABSTRACT

FSCJ conducted a risk assessment of Mintrex<sup>®</sup>CU, 2-deamino-2-hydroxymethionine Cu (CAS No.292140-30-8), a feed additive, based on the documents prepared by an applicant for designation of a new feed additive.

An Acceptable Daily Intake (ADI) has not been set for a feed additive 2-deamino-2-hydroxymethionine Cu (Cu-(HMTBa)<sub>2</sub>) in Japan.

Cu-(HMTBa)<sub>2</sub>, an HMTBa chelated copper, is likely to be absorbed from the intestine of the animals as HMTBa and copper to provide increased in vivo mineral bioavailability.

FSCJ has previously assessed on HMTBa in animal dietary studies and concluded that in humans, excessive dietary intake of methionine derived from veterinary medicine or feed additive is unlikely. Moreover, FSCJ specified the tolerable upper intake level (UL) of copper in beverages to be 9mgCu/person/day.

In a dietary study in which the target animals were fed with Cu-(HMTBa)<sub>2</sub> supplemented feed, deposition of copper from Mintrex<sup>®</sup>CU was compared to that of inorganic copper. Mintrex<sup>®</sup>CU showed an increased trend in liver copper concentration, however, in the tissues including the muscles, the deposition level of copper from Mintrex<sup>®</sup>CU was not significantly different from inorganic copper. Therefore, FSCJ concluded that when used appropriately as feed additive, Mintrex<sup>®</sup>CU would not significantly alter the residue levels in tissues compared to that of copper containing feed additives designated in Japan.

In genotoxicity studies, copper compounds including Mintrex<sup>®</sup>CU induced chromosomal aberration, but did not induce gene mutation. Copper is not foreseen to have a genotoxic potential except under the condition of overload, and therefore copper is unlikely to be a genotoxic concern for human health through dietary source when used appropriately. Considering the findings including that of genotoxicity of HMTBa, FSCJ concludes that Cu-(HMTBa)<sub>2</sub> has no genotoxic concern relevant to human health through food consumption as long as appropriately used as a feed additive.

Although subacute toxicity, chronic toxicity, carcinogenicity or reproductive-developmental toxicity studies were not conducted, toxic effects were not observed in feeding trials in targeted animals.

FSCJ concluded that dietary intake of food containing Mintrex<sup>®</sup>CU supplemented feed would not pose much difference in toxicological effects on human health compared to copper containing feed additives that have been already designated in Japan.

Consequently, FSCJ concludes that risk to human health through dietary intake of food containing Cu-(HMTBa)<sub>2</sub> supplemented feed is negligible as long as used appropriately as feed additive.