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

Risk Assessment Report

Zinc

(Exempted Substances)

Food Safety Commission of Japan (FSCJ)
February 2018

SUMMARY

FSCJ conducted a risk assessment of zinc that has been designated as Exempted Substances[1] by use of various documents including data from previous risk assessment of zinc as a food additive and the requested documents for designating it as a feed additive.

FSCJ considered ADME of zinc as follows; zinc is mainly absorbed from the small intestine, the absorption rate will decrease and endogenous zinc clearance increases as the homeostatic regulation when intake of zinc increases.

In dietary administration studies of zinc compounds (zinc sulfate, Zn bis (2-hydroxy-4-methylthio butyrate (Zn-(HMTBa)2), etc.) on body accumulation in livestock, concentration of zinc in the organs and bone tended to increase along with increasing the concentration of zinc added to feed. Plasma concentration of zinc after administration in lactating cows differed depending on the source of administered zinc in the pharmacokinetics study, while no such difference in the tissue levels of zinc was observed in the body accumulation study.

FSCJ judged that zinc has no genotoxicity relevant to human health based on the previously reported evaluation by FSCJ and data of the genotoxicity study on Zn-(HMTBa)2.

Concerning subacute toxicity, NOAEL of zinc was 48~102 mg/kg bw/day (as zinc). In a chronic toxicity and carcinogenicity study, NOAEL as well as sign of carcinogenicity were not obtained.

On the basis of the reproductive developmental toxicity study, FSCJ considered that zinc compounds have no effect on offspring in a condition that no adverse effect of zinc compounds was observed in dams.

The daily intake of zinc in Japan is estimated to be 0.090~0.14 mg/kg bw/day as the mean intake, 0.26 mg/kg bw/day as the high intake, and 0.55 mg/kg bw/day as excessive intake. When compared these estimated values to the UL for zinc intake 0.63 mg/kg bw/day, FSCJ considered that risk of zinc ingested through drinking water and foods to human health is low.

[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.

Zinc has a long history of use as a veterinary medicinal product and a feed additive, and amount of zinc ingested through the products derived from livestock that were exposed to zinc is included in the intake through foods in the abovementioned estimated daily intake. In addition, the absorption rate of zinc is considered to decrease and endogenous zinc clearance increases when zinc is administered in animals. For the moment, adverse effects of zinc on human health attributed to the administration of zinc into livestock as a veterinary medicinal product or feed additive have not been reported.

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