

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

Risk Assessment Report

Zinc oxide (Exempted Substances¹)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

The FSCJ conducted a risk assessment of a fungicide, zinc oxide (CAS No. 1314-13-2) based on submitted documents to apply to a designated exempted substance defined by the Minister of Health, Labour and Welfare (MHLW). The exempted substance does not have adverse effects on human health in accordance with the provision of Article 13 paragraph (3) of the Food Sanitation Act (Act No. 233 of 1947). The FSCJ also used the findings of its assessments on zinc because zinc oxide is deemed to be dissolved in the stomach and absorbed *in vivo* as zinc through the intestine.

From the past FSCJ's assessments, the kinetics of zinc *in vivo* suggest that it is primarily absorbed in the small intestine. When intake increases, homeostatic mechanisms regulate the body by reducing zinc absorption efficiency and increasing endogenous excretion.

The no-observed-adverse-effect level (NOAEL) in the subacute toxicity study is identified in the range of 48-102 mg/kg bw per day for zinc. As for chronic toxicity and carcinogenicity, findings have not been obtained to determine the NOAEL and carcinogenicity.

In reproductive and developmental toxicity, it was thought that zinc compounds would not affect offspring under the condition that no adverse effect on their dams was observed.

The FSCJ thought that, from the results of its past assessments and additional genotoxicity studies of zinc oxide, zinc compounds would not have genotoxicity to cause particular problems for living organisms.

Noting that zinc is a biologically essential nutrient, the FSCJ determined that the ceiling of zinc intake should be 0.63 mg/kg bw per day, the lowest-observed-adverse-effect level (LOAEL) of 0.94 mg/kg bw per day from human findings divided by 1.5. The estimated daily intake (EDI) of zinc from the diet and other sources of the Japanese population was 0.10-0.15 mg/kg bw per day on average and 0.55 mg/kg bw per day when overestimated further. The maximum estimated intake is 0.0223 mg/kg bw per day

through the crops applied with zinc oxide as a pesticide. Consequently, intake from consuming crops applied with zinc oxide as a pesticide is unlikely to exceed the ceiling of zinc intake.

Given the above, the FSCJ determined with reasonable certainty that no adverse effects would occur in human health from dietary exposure to the residues of zinc oxide as long as the substance is normally used as a pesticide.

¹ 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 13, paragraph (3) of the Food Sanitation Act. These substances are not subject to the positive list system.