

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

Risk Assessment Report
Formaldehyde (Beverages)
Food Safety Commission of Japan (FSCJ)
November 2008

Executive summary

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of formaldehyde as a chemical substance pertaining to beverages.

The test results used in the assessment are related to acute toxicity (rats and guinea pigs), subacute toxicity (rats and dogs), chronic toxicity and carcinogenicity (rats), reproductive and developmental toxicity (mice, rats and dogs), genotoxicity, etc.

Formaldehyde showed positive results in many genotoxicity tests and its carcinogenicity has been recognized in some oral administration tests on test animals and in human inhalation exposure studies, so it has been considered a genotoxic carcinogen. However, comprehensively considering the facts that no clear proof of carcinogenicity has been found in test animals with oral exposure, that low doses of formaldehyde rapidly oxidize into formic acid after ingestion, that the effect on the tissue at the first contact after ingestion largely depends on the concentration, etc., it is thought that a threshold value can be set in cases where the dosage is low, although the carcinogenicity of formaldehyde administered orally in high doses cannot be denied.

The basis for establishing a Tolerable Daily Intake (TDI) is the same as for having set that of the national water quality standards, that is, in the rat 2-year test by administration in drinking water, decrease in food intake and drinking water, weight loss, thickening of the gastric mucosa wall, increase in relative weight of the kidneys in females, and increase in the rate of occurrence of necrotizing papillitis were observed, and taking these effects as end-points, a no-observed-adverse-effect-level (NOAEL) value of 15mg/kg body weight/day was determined to be appropriate. Based on this NOAEL and applying an uncertainty factor of 1000 (10 for species difference, 10 for individual difference, 10 for uncertainty due to toxicity severity), the TDI was established as 15µg/kg body weight/day.