

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

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

Executive summary

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of trichloroethylene as a chemical substance pertaining to the revision of the standards and criteria for beverages.

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

With regard to the genotoxicity of trichloroethylene, chromosomal aneugenic effect is suspected, although the test results were inconsistent due to the effect of the mutagenetic stabilizer. Therefore the possibility of genotoxicity could not be ignored although uncertainty remains.

The Tolerable Daily Intake (TDI) for non-carcinogenic toxicity of trichloroethylene was obtained by applying the BMD (bench mark dose) method to the test data which showed the occurrence of heart abnormalities in embryos of dam rats that had been administered trichloroethylene in drinking water during the period from pre-mating to gestation. An uncertainty factor of 100 (10 each for species and individual differences) was applied to BMDL₁₀ of 0.146 mg/kg body weight/day, and thus FSCJ established the TDI of 1.46 µg/kg body weight/day.

Regarding carcinogenicity, several cancers were observed in occupational cohorts of humans, but in almost all cases it was thought that there were possibilities of confounding by exposure to smoking and other materials. The increase in kidney cancer in industrial laborers with high-concentration, long-term industrial exposure has also been observed. From these factors, the possibility that trichloroethylene itself causes cancer cannot be denied. Also, with test animals, it has been observed that oral exposure or inhalation exposure causes an increase in the occurrence of tumors in rats and mice. Trichloroethylene is classified into Group 2A by the IARC, as a substance that is probably carcinogenic to humans.

From the above, although it is uncertain whether the genotoxicity is involved in the carcinogenesis of trichloroethylene, tumors were observed in several organs with oral administration to several species, showing an effect like genotoxic carcinogen; thus a cancer risk evaluation based on mathematical models was considered appropriate. Based on dose-response data for liver cancer observed in a mouse carcinogenicity study, quantitative evaluation of carcinogenic risk based on multi-stage mathematical models was conducted and the carcinogenic unit risk (the carcinogenic risk related to oral exposure with a dose of 1mg/day per 1 kg body weight over the lifetime of the subject) of the substance was calculated to be $8.3 \times 10^{-3}/(\text{mg/kg body weight/day})$.

As above, FSCJ established the TDI of trichloroethylene for non-carcinogenic toxicity as 1.46µg/kg body weight/day and the carcinogenic unit risk index as $8.3 \times 10^{-3}/(\text{mg/kg body weight/day})$.