

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

**Risk Assessment Report**  
**Bromic acid (Beverages)**  
Food Safety Commission of Japan (FSCJ)  
November 2008

**Executive summary**

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

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

Bromic acid showed positive results in both *in vitro* tests (gene mutation tests, chromosomal aberration tests, etc.) and *in vivo* tests (micronucleus tests, genotoxicity tests for DNA damage, etc.)

The Tolerable Daily Intake (TDI) of bromic acid for non-carcinogenic toxicity was set at 11 µg/kg body weight/day using no-observed-adverse-effect-level (NOAEL) of 1.1 mg/kg body weight/day based on kidney urothelial hyperplasia due to administration of drinking water to rats for 100 weeks, applying an uncertainty factor value of 100 (10 each for the specific and individual differences).

There is clear evidence of carcinogenicity in tests using rats. IARC classifies potassium bromate into Group 2B (possibly carcinogenic to humans), and the American EPA classifies bromic acid into Group B2 (probable human carcinogen).

From the above, bromic acid is judged to be a carcinogen whose carcinogenesis involves genotoxicity. Based on data from testicular mesothelioma in tests where potassium bromate was administered in drinking water, quantitative evaluation of carcinogenic risk based on mathematical models using model extrapolation methods was conducted and the carcinogenic unit risk (the carcinogenic risk related to the oral exposure with a dose of 1mg/day for every 1 kg of body weight over the lifetime of the subject) of the substance was calculated to be  $2.8 \times 10^{-2} / (\text{mg/kg body weight/day})$ .

As above, FSCJ established the TDI of bromic acid for non-carcinogenic toxicity as 11 µg/kg body weight/day and estimated the carcinogenic unit risk as  $2.8 \times 10^{-2} / (\text{mg/kg body weight/day})$ .