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

Risk Assessment Report
Fluorine (beverages)

Food Safety Commission of Japan (FSCJ)
December 2012

Exective summary

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment on fluorine, a chemical substance related to the revision of the standards and criteria for beverages.

The data used in the assessment include those from: acute toxicity tests in mice and rats, subacute toxicity tests in mice, rats, rabbits, dogs and pigs, chronic toxicity and carcinogenicity tests in mice, rats and rabbits, neurovirulence tests in mice and rats, immunotoxicity tests in mice, rats and rabbits), reproductive and developmental toxicity tests in mice and rats, genotoxicity tests, and epidemiological studies among others.

Although fluorine has been considered to be an essential element, clear evidences to suggest the fact have not been presented. Moreover, its daily minimum requirement has not been determined. The carcinogenicity of fluoride in drinking water has been studied epidemiologically, but failed to provide clear evidence of carcinogenicity either to humans or tolaboratory animals. Fluorine has been found to be weakly genotoxic by *in vitro* studies used cultured mammalian cells in the one hand, it has been suggested by comprehensively judging the results from *in vivo* DNA damage tests, on the other hand, that fluoride is non-genotoxic.Consequently, the FSCJ considered at the present moment that fluorine is not genotoxic as to severely affect living roganisms.

Hence, the FSCJ concluded that it is appropriate to establish a tolerable daily intake (TDI) of fluorine in terms of non-carcinogenic toxicity.

Based on the epidemiological studies of 5,800 children from 12 to 14 years old in the United States, a concentration of 1.0 ppm at which effect was not ovserved, was taken as a base. Given that the body weight of a child is 20 kg and the water amount that a child drinks per day is 1 L, NOAEL was calculated to be 0.05 mg/kg body weight per day. Since this value was that obtained from the studies of highly susceptible populations, the FSCJ considered that this value could be taken as TDI without applying uncertainty factors.

As a conclusion, FSCJ determined the TDI of fluorine to be 0.05 mg/kg body weight per day.