

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

## **Risk Assessment Report Nickel (beverages)**

Food Safety Commission of Japan (FSCJ)  
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### **Abstract**

The Food Safety Commission of Japan (FSCJ) was asked by the Ministry of Health, Labour and Welfare to assess the risks of chemical substances related to the revision of the standards and criteria for ‘beverages.’ Since nickel is one of the substances, the risk assessment on nickel was conducted.

The data used in the assessment include acute toxicity (rats and rabbits), subacute toxicity (rats), chronic toxicity and carcinogenicity (rats and dogs), genotoxicity, and data from clinical studies among others.

As for effects of nickel on humans, allergic contact dermatitis is the most well-known effect. Regarding carcinogenicity, no data on carcinogenic risk from oral exposure to nickel is available.

*In vitro* studies using mammalian cell culture showed DNA damages, gene mutation and chromosomal aberration. FSCJ examined the results of *in vivo* micronucleus tests and judged *in vivo* chromosomal aberration was negative. Since no *in vivo* study on gene mutation by nickel is available, its mutagenicity is presently obscure.

From the above results, it was not possible to determine the carcinogenicity of nickel through oral exposure at the present. Hence, FSCJ concluded that it was appropriate to establish a tolerable daily intake (TDI) of nickel for non-carcinogenic toxicity.

Fasting women with nickel dermatitis were given a single dose of 12 µg Ni/kg bw in water. This dose aggravated eczema and maculopapule on their hands. FSCJ thus established the TDI of nickel to be 4 µg/kg bw/day, applying an uncertainty factor of 3 (for using a lowest-observed-adverse-effect level (LOAEL) close to a no-observed-adverse-effect level (NOAEL)), to the LOAEL of 12 µg Ni/kg bw obtained above.