

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

Risk Assessment Report

Ferrum

(Beverages)

Food Safety Commission of Japan (FSCJ) April 2017

Abstract

The Food Safety Commission of Japan (FSCJ) was asked by the Ministry of Health, Labour and Welfare to assess the risks related to the amendment of the standards for 'beverages. The question was estimated risks when ferrum in sterile and unsterile mineral water would not be prescribed in specifications that is defined according to the Food Sanitation Act.

FSCJ note that the adverse effects on stomach and intestines that provided the LOAEL of 70 mg/person/day (0.99 mg/kg bw) (as ferrum) in human intervention studies occur with low frequency, and that ferrum is a biologically essential mineral. Taking these facts into consideration, FSCJ specified 0.66 mg/kg bw as the upper limit of intake of ferrum for adults dividing this LOAEL by 1.5.

FSCJ estimated daily intake of ferrum from mineral water, tap water and meals in Japan. The estimation gave a value of 0.15 mg/kg bw/day as the average, and 0.27 mg/kg bw/day as for the case of high consumers. When comparing these values to the upper limit for ferrum intake, 0.66 mg/kg bw/day, FSCJ judged that the risk to human health from the intake of ferrum from mineral water, tap water and meals is low.

In order to assess risks on human health from deletion of prescriptions for the items related with ferrum from specification for sterile and unsterile mineral water, FSCJ estimated intake of ferrum from domestically distributed mineral water. Since the estimated average of daily intake and of high intake of ferrum from domestically distributed mineral water are respectively 0.0021 mg/person/day (0.000038 mg/kg bw/day) and 0.37 mg/person/day (0.0067 mg/kg bw/day), FSCJ considered that the intake of ferrum from domestically distributed mineral water is much lower than the intake from mineral water, tap water and meals. Hence, FSCJ concluded that the risk to human health from intake of ferrum from mineral water is low in Japan, even if prescriptions for the items related with ferrum from specification for sterile and unsterile mineral water is deleted.