

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

Risk Assessment Report

Calcium • Magnesium (water hardness) (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 related to the amendment of the standards for the sterile mineral water. The question was estimated risks when water hardness and the related dissolved substances in the mineral water would not be prescribed in specifications. Since water hardness is defined as the concentrations of calcium and magnesium in water expressed as an equivalent concentration of calcium carbonate, FSCJ conducted risk assessment on calcium and magnesium (water hardness) in this report.

1. Calcium

FSCJ considered ULS¹ of 2,000 mg/person/day is appropriate as was previously specified in the risk assessment of calcium carbonate (2016) applying a UF of 1.5 on an extradietary intake of calcium by a pregnant woman.

FSCJ estimated daily intake of calcium from mineral water, tap water and meal in Japan. The estimation gave a value of 529 mg/person/day as the average, and 1,563 mg/person/day as for the case of high consumers. Estimated intake of calcium from mineral water and tap water was 15.6 mg/person/day for average, and 558 mg/person/day for high consumers.

FSCJ compared the estimated daily intake of calcium from mineral water and tap water (15.6 mg/person/day for average, and 558 mg/person/day for high consumers) with the ULS of 2,000 mg/person/day, assuming that intake of extradietary calcium is exclusively from mineral water and tap water. As the result, FSCJ judged that the risk to human health is low.

2. Magnesium

FSCJ specified 350 mg/person/day as an appropriate upper limit of intake of extradietary magnesium for adults based on following facts; 1) LOAEL of 384 mg/person/day was established in human intervention studies due to diarrhea with low frequency. 2) The diarrhea caused by excess intake of magnesium is generally mild and transient. 3) SCF (2001) and EFSA (2006) have specified NOAEL for magnesium as 250 mg/person/day based on several

¹ ULS: The upper limit of supplementary intake other than usual meal.

reports on diarrhea by intake of magnesium supplement. 4) Tolerable upper level of supplementary intake of magnesium is specified as 350 mg/person/day for adults in the reports from the Ministry of Health, Labour and Welfare (Study Group for Development of Dietary Reference Intakes for Japanese (2015)) and Institute of Medicine (IOM) (1997). FSCJ estimated daily intake of magnesium from mineral water, tap water and meal in Japan. The estimation gave a value of 261 mg/kg bw/day as the average. While estimation of the daily intake including supplementary intake, such as from food with nutrient function claims, gave a high intake of 838 mg/person/day, though it may be an overestimation. Estimated daily intake of magnesium from mineral water and tap water was 13.3 mg/person/day for average and 131 mg/person/day for high consumers.

When comparing the estimated daily intake of magnesium from mineral water and tap water (13.3 mg/person/day for average, and 131 mg/person/day for high intake) to the tolerable upper level of supplementary intake of magnesium, 350 mg/person/day, FSCJ judged that the risk to human health from the intake of magnesium in mineral water and tap water is low. Assuming that one would have tap water and mineral water and food with nutrient function claims with high concentration of magnesium, the estimated daily intake of magnesium goes up to 431 mg/person/day exceeding 350 mg/person/day. Thus, attention must be paid to prevent excess intake of extradietary magnesium.

3. Water hardness

FSCJ assessed risks on human health from deletion of prescriptions for the items related with calcium and magnesium (water hardness) from specifications for sterile mineral water that is defined according to the Food Sanitation Act. As was described in the sections 1 and 2 above, FSCJ concluded that the intake of calcium and magnesium from mineral water is small and the risk to human health from withdrawing the standards on water hardness and the related dissolved substances in sterile mineral water is low.

However, care needs to be taken for preventing excess intake of magnesium from supplementary foods as was described in section 2.