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

Risk Assessment Report

Sodium selenite

(Food Additives)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of sodium selenite (CAS No. 26970-82-1, as sodium selenite pentahydrate), an additive used as a nutritional enrichment, based on results from various studies.

The data used in the assessment include genotoxicity and human data on selenium compounds including sodium selenite as the test substance.

Sodium selenite is used as additive in powdered formula and also as substitute for breast milk. Data on the estimated daily intake in infants from 0 month to 2 years old were presented from the applicants for its designation.
On the additive use of sodium selenite, FSCJ considered it appropriate to evaluate as the intake of selenium in the assessment. Consequently FSCJ forcussed on specification of an upper level of intake for selenium with no adverse health effects on infants of zero month to 2 years old (hereinafter referred to as the upper level of intake for infants of zero month to 2 years old).

Data on pharmacokinetics suggest that inorganic selenium absorbed *in vivo* distributes in forms of organic selenium in the body. Therefore, FSCJ considered it appropriate to assess the toxicity of sodium selenite as an additive comprehensibly based on the data on various selenium compounds.

FSCJ concluded that sodium selenite has no clear genotoxicity relevant to human health as long as ingested in appropriate amounts as an additive. The threshold can be specified, although its genotoxicity could not be clearly judged.

The assessment based on selenium in beverage (2012) and on recent data on animal studies on selenium are unable to provide the assessment basis of its toxicity relevant to infant health.

Selenium in breast milk is very likely to exist as organic selenium forms. However, inorganic sodium selenite is added in powdered formula and substitutes for breast milk. Pharmacokinetic studies suggest rather lower bioavailability of sodium selenite sometimes than that of organic selenium, and also the shorter half-life in the body is without the substantial accumulation. Because of these facts, FSCJ

recognized the availability of the upper limit for infant intakes of 0 month to 2 years based on the ocnse r vative estimation on selenium concentration in breast milk. In addition, FSCJ estimated the “maximum value of conventional intake without apparent harmful effects to human health” to be 36 μg/day for selenium according to the reports by Brätter (1991). The estimated value mentioned above is also supported from the domestic data on the selenium concentration in breast milk.

Because the “maximum value of conventional intake known to be unharmful to human health” estimated from above-mentioned report by Brätter (1991) was based on the findings with infants, FSCJ considered it appropriate to specify “the upper level of intake for infants of 0 month to 2 years old” dividing the value of 36 μg/day with an uncertainty factor of 1. Consequently, FSCJ specified “the upper level of intake for infants of 0 month to 2 years old” of 36 μg/day (equivalent to 5.9 μg/kg bw/day as selenium).

Selenium is considered to be an indispensable nutrient in Japan, and recommended daily intake for infants of 0 to 11 months old. The average requirement for infants of 1 to 2 years old are specified to be 15 μg/day and 10 μg/day, respectively. For infants of 0 month to 2 years old, it is thus necessary to consider both sides to prevent from the lack of selenium and to specify “the upper level of intake”.
The applicant expected to add selenium at 7.0 μg/100 kcal maximally in the standard for additive use.Taking into account the assumption presented by the applicants for designation, FSCJ specified the estimated daily intake of selenium to be 37.4 μg/person/day for 0 to 5 months of age, 54.3 μg/person/day for 6 to 11 months of age and 64.0 μg/person/day for 1 to 2 years of age.
These estimated values suggest the possibility that the estimated daily intake level presented by the applicants for designation exceeds “the upper level of intake for infants of 0 month to 2 years old”. Therefore, risk management authorities should revise risk control measures including the standards for use at the occasion, when they newly designate sodium selenite as a food additive.