

Risk assessment of essential trace elements – considerations from the Swedish National Food Administration

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The Swedish National Food Administration carries out risk and/or benefit assessments of essential trace elements for the following two product categories: (i) enrichment substances (eg, iron for the enrichment of flour) and (ii) nutritional supplements that include minerals, often in multicomponent preparations (eg, with vitamins).

Enrichment substances are defined as food additives — they are intended to be added to food to improve its nutritive value. A list of the mineral salts accepted as enrichment substances by the National Food Administration (1) is presented in table 1. Iron in its reduced form is permitted as an enrichment substance at levels up to 90 mg · kg⁻¹ in wheat and rye flour, as well as in pasta products. General permission has been granted for such use, and a special permit is not necessary. The same principle applies to the addition of sodium and potassium iodide to common salt and table salt with a reduced sodium content, for which general permission has been granted for such use up to a maximum level of 7.0 mg of iodine per 100 g of salt. The general enrichment of flour with iron is currently the subject of debate in Sweden because of its catalytic effect on the endogenous production of free radicals (2). It is necessary to obtain permission from the National Food Administration to enrich foodstuffs with other trace elements. The possibility that an overdose of essential trace elements may result from the use of enrichment substances is very small, as there is a limit to the amount of enriched foods that can be consumed.

Since nutritional supplements might, however, be consumed in excessive amounts, it is particularly important to evaluate the toxicologic risk and to determine the safety margin between essential and toxic doses. For many essential trace elements, such evaluations have not yet been made. There is an obvious risk of overdose if the same element is consumed in the form of several different nutritional supplements, as well as in the normal diet. Nutritional supplements are regulated by paragraph 5 of the Swedish Food Act (3), which states that food offered for

sale *cannot be* of such a composition or quality in other respects that it can be assumed to be *harmful to consume*, a carrier of infection, or otherwise unfit for human consumption.

An example of a recent risk evaluation of a nutritional supplement, germanium, follows. The Nordic Group on Food Toxicology and Risk Evaluation under the Nordic Council of Ministers has evaluated the risk of some health food products, including nutritional supplements (4).

Germanium, which has been marketed as a nutritional supplement in several countries, is a ubiquitous element with no proved nutritional requirement. The organogermanium compounds sold as health

Table 1. Enrichment substances (mineral salts) (1).

Nutrient	Enrichment substance ^a
Phosphorus	Calcium orthophosphates Potassium orthophosphates
Iodine	Potassium iodide Sodium iodide
Iron	Ferric ammonium citrate (brown and green) Sodium ferric pyrophosphate Ferric orthophosphate Ferric pyrophosphate Ferrous fumarate Ferrous gluconate Ferrous sulfate Reduced iron Electrolytic iron Carbonyl iron
Calcium	Calcium citrate Calcium carbonate Calcium orthophosphate
Potassium	Potassium citrate Potassium chloride Potassium orthophosphates
Copper	Copper sulfate
Magnesium	Magnesium hydroxide Magnesium chloride Magnesium sulfate
Manganese	Manganese sulfate
Sodium	Sodium citrate
Zinc	Zinc chloride Zinc oxide Zinc sulfate

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^a The enrichment substances included in this table may only be used after permission has been granted by the Swedish National Food Administration in accordance with paragraphs 2-5 of Ordinance SLV FS 1983:2.

food products are generally of low toxicity when tested in experimental animals. However, several case reports from Japan have described fatal kidney damage after the consumption of a germanium preparation over a period of several months. Such damage is characterized by the insidious onset of renal failure without proteinuria or hematuria and by the degeneration of renal tubular cells with minor glomerular abnormality in histology. It has been suggested that contamination with inorganic germanium, in the form of germanium dioxide, may be the cause of the observed toxic effects of germanium products. The conclusion reached by the group was that, until more scientific information on the biological effects of germanium is available and reliable control of the purity of the product is assured, organogermanium compounds should be regarded as potentially harmful to humans.

Some questions of particular concern in evaluating trace elements for use as nutritional supplements are:

1. Is there really a nutritional need for the element?
2. What is the safety margin between the essential and toxic doses? What is the risk of overdose when intakes from all possible sources are added together?

3. Are there special risk groups (eg, persons with metabolic disorders such as hemochromatosis, Wilson's disease, etc)?

4. What is the bioavailability, both when the element is naturally present in foods and when it is taken in the form of mineral preparations?

5. Are there interactions with "normal" constituents of foods?

For progress to be made in this area, collaboration between nutritionists and toxicologists is essential.

References

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4. Nordic Council of Ministers. Risk evaluation of health food products — report of a Nordic project group. Århus: Aka-print A/S, 1991. (Nord 1991:40.)