

European Commission  
Health and Consumer Protection Directorate  
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DG SANCO  
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Your ref:  
Our ref: 2006/28141  
Date: 29.09.2006  
Org.nr: 985 399 077

Statens tilsyn for planter, fisk, dyr og næringsmidler



## Comments from the Norwegian Food Safety Authority on the “Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs” June 2006

Comments to the questions from the Commission follow beneath:

### SETTING OF MAXIMUM AMOUNTS

#### Establishment of maximum amounts for food supplements and other foods

- *Where there is not yet a scientifically established numerical tolerable upper intake level for several nutrients, what should be the upper safe levels for those nutrients that should be taken into account in setting their maximum levels?*

The Norwegian Food Safety Authority supports the work done by the Food Standards Agency, UK<sup>1</sup> and elaborated by the Danish Institute of Food and Veterinary Research<sup>2, 3</sup>, and acknowledge their suggestions for Guidance Levels and Temporary Guidance Levels where upper levels have not been established by the Scientific Committee on Food (SCF).

- *For some vitamins and minerals the risk of adverse effects, even at high levels of intakes, appears to be extremely low or non-existent according to available data. Is there any reason to set maximum levels for these vitamins and minerals?*

<sup>1</sup> Safe upper levels for vitamins and minerals. Report of the expert group on vitamins and minerals. Food Standards Agency 2002 (<http://www.food.gov.uk/>)

<sup>2</sup> Danish Expert Group. A summary is given in the annex of the “Discussion paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs, June 2006”

<sup>3</sup> Rasmussen et al., Eur J Nutr 2005 Oct 12. A safe strategy for addition of vitamins and minerals to foods <http://www.vkm.no/dav/692c4c7bcb.pdf>

The Norwegian Food Safety Authority is of the opinion that it is necessary to set maximum limits for all the vitamins and minerals in question. Lack of sufficient scientific data to establish safe upper intake levels for several vitamins and minerals (or indication of low toxicity on the basis of present knowledge) does not necessarily mean that high doses are without adverse effects.

Even with large doses, there should be long-time human experience with use of such doses, in addition to an appropriate biochemical basis, before a permissible view is taken. Such data are scarce, or totally lacking for some nutrients. History has taught us that nutrients considered harmless at one time point may turn out to increase the risk of disease when summing up the existing evidence. The most recent example is with vitamin E, - considered innocuous even in large doses until some years ago. A recent meta-analysis<sup>4</sup> conveyed that doses that are common in many food supplements *increased* the risk of all-cause mortality.

Caution should therefore be applied wherever data are uncertain or missing. Caution should especially be applied to all minerals and trace elements, where there is substantial evidence that they interact with each other, whether it is connected to absorption, transport, metabolism or excretion.

In conclusion, where there is lack of sufficient scientific data to establish an UL, temporary guidance levels should be set for all substances to be added in foods and food supplements.

- *Where we set maximum levels, do we inevitably also have to set maximum amounts for vitamins and minerals separately for food supplements and fortified foods in order to safeguard both a high level of public health protection and the legitimate expectations of the various food business operators? Are there alternatives?*

The Norwegian Food Safety Authority is of the opinion that it is necessary to set maximum amounts for use of vitamins and minerals both in food supplements and fortified foods, in order to be able to calculate the total intake of vitamins and minerals. However, the maximum levels might differ between the two, due to the fact that food supplements are concentrated sources of nutrients intended to supplement an inadequate diet. Maximum levels for food fortification should prevent a too high intake when all sources including food supplements are considered.

### **Intake of vitamins and minerals from dietary sources**

- *The Commission would appreciate receiving available information on intakes of vitamins and minerals or indications of the best sources providing such data at EU level.*

An overview of daily dietary intake of vitamins and minerals in various age groups in the Norwegian population is provided in the enclosed excel sheet.

The following consumption surveys are used in the intake estimates from Norway. Intakes from food supplements are not included in these surveys. Data for intake from food supplements can be derived from The Norwegian Mother and Child Cohort Study<sup>5</sup>.

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<sup>4</sup> Miller ER, III, Pastor-Barriuso R, Dalal D et al. Meta-analysis: high-dosage vitamin E supplementation may increase all-cause mortality. *Ann Intern Med* 2005; 142: 37-46.

<sup>5</sup> [The Norwegian Mother and Child Cohort Study](http://www.fhi.no) (www.fhi.no)

Adults; NORKOST 1997 is based on a quantitative frequency questionnaire that was answered by 1291 males and 1381 females aged 16-79 years in 1997 (Johansson, L. and Solvoll, K. Norkost 1997. Landsomfattende kostholdsundersøkelse blant menn og kvinner i alderen 16-79 år. Statens råd for ernæring og fysisk aktivitet, 1999).

9- and 13-year-old children/adolescents; UNGKOST 2000 is based on a 4-day food consumption registration, where portions should be assigned according to an illustrative book with different food portion sizes (Øverby, N. C. & Andersen, L. F. Ungkost 2000. Landsomfattende kostholdsundersøkelse blant elever i 4.- og 8. klasse i Norge. Sosial- og helsedirektoratet, avdeling for ernæring, 2002).

4-year-old children; UNGKOST 2000 is based on a 4-day food consumption registration, where portions should be assigned according to an illustrative book with different food portion sizes (Pollestad, M. L., Øverby, N. C. and Andersen, L. F. Kosthold blant 4-åringer. Landsomfattende kostholdsundersøkelse. Ungkost 2000. Sosial- og helsedirektoratet, 2002).

2-year-old children; Småbarnskost is based on a semi quantitative food frequency questionnaire answered by 868 males and 852 females (Lande, B., Andersen, L.F. Kosthold blant 2-åringer. Landsomfattende kostholdsundersøkelse – Småbarnskost. Sosial- og helsedirektoratet, 2005. Rapport nr. IS-1299).

1-year-old children; Spedkost is based on a semi quantitative food frequency questionnaire answered by 1022 males and 910 females. However, only those children who were not breastfed were included in the exposure assessment (674 males and 557 females) (Lande, B., Andersen, L.F. Spedkost 12 måneder. Landsomfattende kostholdsundersøkelse blant spedbarn i Norge. Sosial- og helsedirektoratet, 2005. Rapport nr. IS-1248).

The data in the enclosed excel sheet are limited to two significant figures and should only be used as estimates for Norwegian intake of nutrients.

- *If such existing data refer only to the intake in some Member States, can they be used for the setting of legitimate and effective maximum levels of vitamins and minerals at European level? On the basis of what adjustments, if any?*

The The Norwegian Food Safety Authority suggest that available data from different European surveys can be merged and used as explained beneath until a common dietary survey method has been agreed upon for use in all member states.

Professor Niels Lyhne at the Danish Institute of Food and Veterinary Research has suggested a *simple* and *pragmatic* way to merge intake data from different countries and create common estimates of what constitute high intakes.

There are 4 steps in the process of getting estimates of high intakes of micronutrients (approx. 95<sup>th</sup> percentile). These steps are repeated for all vitamins and minerals and for each age and sex group.

1. Calculate the mean of the mean intakes from each of the dietary surveys (an estimate of mean European intake)
2. Calculate the ratio between the 95<sup>th</sup> percentile and mean intake in each survey.
3. Calculate the mean of the ratios.
4. Calculate the common estimate for high intake as the product between (1) and (3).

This procedure has been tested in minor scale on Nordic data for a few selected nutrients (retinol, thiamine, vitamin B<sub>6</sub>, calcium and iodine) and it was found useful and suitable for fitting in the

Danish model<sup>6</sup>. Experience from these Nordic data show that for each nutrient the ratio has nearly the same value from one survey to another. Most nutrients are widely distributed in many foods and thus the ratios are similar to the ratio between the 95<sup>th</sup> percentile and the mean energy intake. Based on Danish data (adult males) the ratio for energy intake is 1.5 and 1.5-1.7 for vitamin E, thiamine, riboflavin, niacin, vitamin B<sub>6</sub>, folate, calcium, phosphorus, magnesium, iron, zinc, iodine, selenium, sodium and potassium. When the intake distribution is highly skewed because of only a few significant food sources the ratios are higher. Ratios were in the range of 1.9-2.8 for vitamin B<sub>12</sub>, vitamin C, vitamin D, retinol and β-carotene.

- *Should the intake from different population groups be taken into account in the setting of maximum levels of vitamins and minerals?*

The Norwegian Food Safety Authority is of the opinion that intake from different population groups should be taken into account in the setting of maximum levels of vitamins and minerals for fortification of foods; since foods are eaten by all age groups. Calculations of maximum levels should be based on the most vulnerable group, which most often are children. If vulnerable groups are excluded from the calculations they could be exposed to fortified products with a content of vitamins and minerals that may represent (an unnoticed) risk for the group. Also for food supplements, one should consider setting different maximum levels for different population groups (i.e. children and adults).

## Reference intakes of vitamins and minerals

- *Taking into account all the above-mentioned considerations, how far should PRIs/RDAs be taken into account when setting maximum levels for vitamins and minerals?*

It is important that the overall intake of vitamins and minerals does not exceed the upper safe limit for vitamins and minerals, and consequently that the approach for establishing maximum limits for use in food supplements and fortification of ordinary foods ensures this. In Norway, a version of the Danish model adapted to Norwegian conditions<sup>7</sup> is used for assessing safe addition of vitamins and minerals to foods. The assessment also takes into account intake from food supplements. Present-day Norwegian regulations on food supplements have, with a few exceptions, twice the RDA as a maximum level (and ¼ as the minimum level). This is a pragmatic way of approaching the issue, resulting in most multi-vitamin-mineral supplements containing one time the RDA for most of the substances.

## MINIMUM AMOUNTS

- *Should the minimum amount of a vitamin or a mineral in a food to which these nutrients are added be the same as the significant amount required to be present for a claim and/or declaration of the nutrient in nutrition labelling? Should different minimum amounts be set for certain nutrients in specific foods or categories of foods? If yes, on what basis?*

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<sup>6</sup> Danish Expert Group. A summary is given in the annex of the “Discussion paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs, June 2006”

<sup>7</sup> [Norwegian Scientific Committee for Food Safety 27 February 2006. Opinion of the Scientific Panel for Nutrition, Dietetic Products, Novel Food and Allergies on model for assessing applications concerning food fortification \(www.vkm.no\)](http://www.vkm.no)

The Norwegian Food Safety Authority is of the opinion that addition of vitamins and minerals to foods/food supplements in general should assure a significant contribution of nutrients in each individual product (this does not comprise restoration). The minimum amount of a nutrient in a food should reflect the amount that is regarded as a significant contribution of the nutrient. Presence of significant amounts of nutrients should be labelled as designated in Council Directive 90/496/EEC on nutrition labelling and the proposed Regulation on nutrition and health claims made on foods.

The risk of intakes below PRI/RDAs for some nutrients in the population must be taken into account when setting minimum amounts.

- *Should minimum amounts for vitamins and minerals in food supplements also be linked to the significant amounts that should be present for labelling purposes or should they be set in a different way?*

Food supplements are concentrated sources of nutrients, according to the definition. Minimum amounts for vitamins and minerals in food supplements should therefore not necessarily be linked to the significant amounts that should be present for labelling purposes.

Yours Sincerely

Merethe Steen  
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Enclosed:

1. Overview of intake of vitamins and minerals in various age groups in the Norwegian population