

Response from The Norwegian Scientific Committee for Food Safety, Panel of nutrition, dietetic products, novel food and allergy, on the Discussion Paper on setting of maximum and minimum amounts for vitamins and minerals in foodstuffs.

Q1: 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?

Answer to Q1:

The Norwegian Scientific Committee for Food Safety, Panel of nutrition, dietetic products, novel food and allergy, refers to work done by the Food Standards Agency, UK ¹, (<http://www.food.gov.uk/>) and elaborated by the Danish Institute of Food and Veterinary Research². We acknowledge their suggestions for (Temporary) Guidance Levels where upper levels have not been established by the Scientific Committee on Food (SCF).

Q2: For some vitamins and minerals the risk of adverse effects, even at high levels of intake, 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?

Answer to Q2:

The panel would like to start the response to this question by citing Paracelsus (1493-1541):

All substances are poisons: there is none which is not a poison. The right dose differentiates a poison and a remedy.

Although there is not sufficient scientific evidence to establish safe upper intake levels for several vitamins and minerals, this does not mean that these substances are harmless. 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. 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

¹ Safe upper levels for vitamins and minerals. Report of the expert group on vitamins and minerals. Food Standards Agency 2002. A summary is given in the annex of Discussion paper.

² Danish Expert Group. A summary is given in the annex of the Discussion paper.

vitamin E, - considered innocuous even in large doses until some years ago. A recent meta-analysis³ conveyed that doses that are common in many food supplements *increased* the risk of all-cause mortality. Thus we encourage the Norwegian Food Safety Authority to use the precautionary principle 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.

The Norwegian Scientific Committee for Food Safety, panel of nutrition, dietetic products, novel food and allergy is thus of the opinion that guidance levels should be set for all substances to be added in foods (fortification) or included in food supplements, including the four B vitamins hitherto considered harmless even in large doses: thiamine, riboflavin, pantothenic acid and biotin).

Q3: 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.

Answer to Q3

The added excel sheet provides an overview of intake of vitamins and minerals in various age groups in the Norwegian population.

The following consumption surveys are used in the intake estimates from Norway. Intakes from food supplements are not included. We have no recent data on supplement intake in the general population.

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).

³ 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.

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. The figures in the table have not been cross-checked, and can only be used as estimates for Norwegian intake of nutrients.

Q5: If such existing data refer only to the intake in some Member States, can they be used for setting legitimate and effective maximum levels of vitamins and minerals at European level? On the basis of what adjustments, if any?

Answer to Q5:

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. 95th 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 95th 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 B₆, calcium and iodine) and it was found useful and suitable for fitting in the Danish model. 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 95th 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 B₆, 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. We found ratios in the range of 1.9-2.8 for vitamin B₁₂, vitamin C, vitamin D, retinol and β-carotene.

Summing up, we suggest that available data from different European surveys can be merged and used as above until the day comes where a common dietary survey method has been agreed upon for use in all member states.

Q6: Should the intake from different population groups be taken into account in the setting of maximum levels of vitamins and minerals?

Answer to Q6:

YES! Children have to be considered in all modelling and the establishment of upper levels.

Q7: 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?

Answer to Q7:

Present-day Norwegian regulations on food supplements have, with a few exceptions, twice the RDAs 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. If this pragmatic approach is left, it will become much more complicated to figure out “allowances” for food fortification.

Which vitamins and minerals do we risk getting too little of?

Folate (pregnant women)

Vitamin D (all)

Iron (children and women of fertile age)

In addition, there are several minerals where we know too little about the dietary intake to know what the diet provides, e.g. chromium, manganese and magnesium.