



Comments by EHPM¹ on the Discussion Document on the setting of maximum and minimum amounts of vitamins and minerals in foodstuffs

29 September 2006

The European Federation of Associations of Health Product Manufacturers welcomes the Commission discussion paper and the consultation of stakeholders as the first steps towards the setting of maximum levels for food supplements and fortified foods.

Our Federation has always supported the setting of safe maximum amounts in food supplements based on a scientific assessment of vitamins and minerals and would therefore like to provide the following specific comments to the Commission's questions:

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

We believe that where no safety concern has been demonstrated, and no Upper Intake Level (UL) has been established by EFSA, no maximum level should be set.

However, we note that there are several potential reasons why EFSA has not established numerical tolerable upper intake levels (UL). In order to assess these reasons, a case by case analysis of the EFSA opinion needs to be carried out:

From such analysis, it becomes clear that for most of the nutrients where no UL has been established this is because at current intakes from foods, fortified foods and food supplements, no evidence of adverse effects has been found. These nutrients (vitamins B₁, B₂, B₁₂, biotin, pantothenic acid, vitamin K and trivalent chromium) do not represent a risk to human health at current levels of use in foods, fortified foods and food supplements. In the absence of any evidence to set a UL, there is no need to set an upper level as

¹ The European Federation of Association of Health Product Manufacturers (EHPM) represents the interests of health products manufacturers, in particular food supplements, in Europe. The EHPM is the only European organisation bringing together 25 associations from 22 European countries. It represents more than 2000 health products manufacturers across the EU, including large companies as well as SMEs.



there may not be any rationale for setting a maximum level for food fortification or for food supplements.

For a number of other nutrients such as vitamin C and manganese, ULs were not established because of limited data, but in these cases there was evidence of potential risk at excessive intakes. In such cases, evidence from international risk assessments and UL established by other organisations² may be taken into consideration, as well as a case-by-case qualitative risk assessment.

It should also be noted that the European food supplements industry has been working with the concept of upper safe levels for nearly 20 years as in 1997, established safe upper levels for 25 vitamins and minerals were determined as guidance for food supplement industry practice³ and have been used safely and effectively since.

Furthermore a review mechanism could be put in place so that any maximum level could be re-evaluated and changed in the light of new evidence.

2. 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?

For a number of nutrients there is no evidence of risk or observations of adverse effects at current levels of intake (See question 1). There are therefore no scientific basis nor any objective grounds for setting a maximum level for food fortification or for food supplements.

However, if the risk manager would judge that setting of maximum levels in food supplements and fortified foods to avoid unlimited additions would be an appropriate measure, such levels should be sufficiently high to reflect current safe practice and avoid reformulation of products. One example could be the maximum levels established by the UK EVM group, which are the current

² e.g. UK Food Standards Agency Expert Vitamins and Minerals Group (EVM): safe upper levels for vitamins and minerals (2003);

<http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf>;

e.g. Institute of Medicine, Institute of Medicine of the National Academies: Food and Nutrition Board (USA): Dietary Reference Intakes (1997-2001);

<http://www.iom.edu/?id=3788&redirect=0>

e.g. 'A model for establishing Upper Levels of intake for nutrients and related substances' Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment, Geneva 2nd to 6th May 2006, Internet version of 13th January 2006 and hard copy from 30th June 2006.

³ "Vitamins and Minerals, a scientific evaluation of the range of safe intakes", Dr. D Shrimpton, October 1997, Commissioned by EHPM.



standard in the UK.⁴ The FAO/WHO procedure⁵ to establish Highest Observed Intakes (HOI) with no evidence of adverse effect or the essentially similar approach of IADSA⁶ to establish Observed Safe Levels (OSL) could also be considered as useful tools in this exercise. The levels should in any case reflect current practice and industry guidelines.

Maximum levels for vitamins and minerals in fortified foods and food supplements need to take into consideration a number of variables:

- one is the current intake of these nutrients from all dietary sources;
- another is information on how this intake will evolve over time in the population.

The ERNA/EHPM risk management model that is included in the annex to the EC Discussion paper allows for an evidence-based assessment of these variables and offers a model that can be reapplied when new data become available. The information on evolution of intake, taken to apply the model comes from the comparison of surveys carried out in 1986/87 and 2000/01 (NDNS) in the UK, a liberal market place where fortified foods and food supplements coexist in the absence of maximum levels. It is worthy to note that increase of intake by more than 20% was only evident for Vitamin C and Vitamin B6 over the period between the surveys. For minerals an increase exceeding 5% was only observed for calcium. The current intake data were therefore based on the 97.5 percentile intakes from foods including fortified foods and then increased by 150% as a precautionary risk management factor for vitamins (based on the highest change, namely vitamin C data) and 110% for minerals (based on calcium data). Also noteworthy was the fact that mean intakes for several micronutrients actually declined over the period of the NDNS, e.g. for copper, zinc and magnesium.

3. 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?

We believe that there is generally no need for setting different maximum levels for fortified food and food supplements. The setting of maximum levels should be considered on a case-by-case basis, and the development of

⁴ The UK EVM report dates from 2003. EHPM would like to point to the fact that the scientific evidence for preformed retinol, beta-carotene and manganese would need to be reviewed.

⁵ A model for establishing upper safe levels of intake for nutrients and related substances: Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment, Geneva, May 2006

⁶ The Risk Assessment and Safety of Bio-active Substances in Food Supplements, IADSA 2006, Brussels, of June 2006, by the International Alliance of Dietary/Food Supplement Associations (IADSA)



maximum levels based on arbitrary proportions that are split between fortified foods and food supplements is unscientific and is not consistent with internationally accepted risk analysis procedures. However, for a limited number of specific nutrients, the need to set different maximum levels may have to be considered on the basis of a common approach based on a case by case scientific assessment of vitamins and minerals.

The ULs set by the SCF and EFSA represents total amounts of vitamins and minerals from conventional foods, fortified foods and food supplements that can be ingested safely over a lifetime. Models to establish maximum levels for addition to foods and food supplements should base themselves upon the highest intakes in the population from all dietary sources (as represented by the 97.5th percentile) on a nutrient-by-nutrient basis.

The development of a 'maximum total intake' from which arbitrary proportions are split between fortified foods and food supplements is unscientific and simplistic. For one thing, the vast majority of foods and food supplements will not contain vitamins and minerals at the maximum allowed levels. For many nutrients, particularly minerals, used in food fortification, the levels used are self-limiting for technical and taste reasons. Furthermore, the amounts of nutrients to be added for making a 'source' and 'high' content claim under the upcoming Claims legislation, namely 15% RDA and 30% RDA per 100 g/100 ml, respectively, represents another bench mark for addition of vitamins and minerals to foods.

An approach, more scientific than just an arbitrary split, would be to 'categorise' the nutrients on a case-by-case basis. Taking appropriate measures for each of the groups seems a logical and practical method for risk management. The ERNA/EHPM illustrates how a model could be used to test the sensitivity and specificity for different scenarios and input variables.

The ERNA/EHPM categorisation is:

- Group A** No evidence of risk within ranges currently consumed; does not represent a risk to human health
No maximum levels necessary
- Group B** Low risk of exceeding the UL (from all sources)
A single maximum level can be set for both foods and food supplements by applying the EHPM_ERNA model for calculation
- Group C** Potential risk of exceeding the UL.
Need for a case-by-case assessment to determine whether separate maximum levels should be set for supplements and foods

Interestingly, also the ILSI, Danish and German model come to a similar risk categorisation as the ERNA/EHPM model, so a broad consensus appears to exist in this respect. But as to the approach for setting maximum levels, it is disappointing that few of the models take a differentiated approach.

Three of the models (AFSSA, ILSI, DK) only concern fortification:

- The French AFSSA model⁷ takes on nutritional need as the primary objective for setting maximum levels for food fortification. This approach does not seem in line with the criteria of the fortification Directive itself, which specify that maximum amounts shall be set taking into account upper safe levels of vitamins and minerals established by scientific risk assessment based on generally acceptable scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different groups of consumers and intakes of vitamins and minerals from other dietary sources. It specifies only in second order that due account shall also be taken of reference intakes of vitamins and minerals for the population.
- The ILSI model⁸ does not consider food supplement use as being substantial and focuses solely on food fortification. It does not use detailed intake data but mean of data available.
- The Danish model⁹ is a refinement of the ILSI model. It is based on the most sensitive population, Danish intake data and the assumption of current intake of one multivitamin food supplement a day in the Danish population. The basis of intake of 1 time RDA is not reflective of maximum levels established by a scientific risk assessment.
- The German BfR model¹⁰ starts from a scientific risk assessment, which is later on only applied to three nutrients (Vitamin B6, K and Zn).

⁷ Agence Française de Sécurité Sanitaire des Aliments (French Agency for Food Sanitary Safety - AFSSA - Fr). Cahier des charges pour le choix d'un couple Nutriment-Aliment Vecteur (Specification for the selection of a Nutrient-Vector Food Pair 2003); <http://www.afssa.fr/ftp/afssa/actu/CDCversionfinale.pdf>

⁸ ILSI. Vitamins and Minerals: a model for safe addition to foods (2003); Eur. J. Nutr. 42;118-130(2003); <http://europe.ilsa.org/file/ilsieurope-vitandmineralsarticle.pdf>

⁹ Danmarks Fødevareforskning (Danish Institute for Food and Veterinary Research - DFVF - Dk). A Safe Strategy for Addition of Vitamins and Minerals to Foods (2005); Eur J Nutr DOI: 10.1007/s00394-005-0580-9 (2005)

¹⁰ Bundesinstituts für Risikobewertung (Federal Institute for Risk Assessment - BfR - D). Verwendung von Vitaminen in Lebensmitteln (Use of Vitamins in Foods 2005); http://www.bfr.bund.de/cm/238/verwendung_von_vitaminen_in_lebensmitteln.pdf
http://www.bfr.bund.de/cm/238/use_of_vitamins_in_foods.pdf
Verwendung von Mineralstoffen in Lebensmitteln (Use of Minerals in Foods 2005); http://www.bfr.bund.de/cm/238/verwendung_von_mineralstoffen_in_lebensmitteln_bfr_wissenschaft_4_2004.pdf



For the others a conservative nutritional need approach is used, assuming the daily consumption of two food supplements and two fortified foods, containing nutrients at maximum level.

For fortified foods, the model does not take into consideration that:

- not all foods are fortifiable (only 30-50%),
- that not all fortifiable foods are fortified (estimated maximum: only 50%),
- that not all fortified foods are consumed daily, that not all fortified foods are fortified up to the maximum level because of cost implications or technological limitations (taste, stability, ...),
- that criteria for “source of” and “high in” nutrition claims will in most cases determine levels added,
- that not all nutrients are used for food fortification,
- and that the contribution of fortified foods to the mean highest intake in the population is low.

For Food Supplements, neither does it take into consideration that:

- not all consumers take food supplements (15-20% only),
- that not all food supplements are used daily or over long periods,
- that not all food supplements contain the maximum levels of nutrients,
- that consumption of food supplements is conscious, and in dose form so that it is relatively easy to keep track of levels consumed,
- that labelling is a valid risk management option for informing consumers on responsible use of food supplements,
- that contribution of food supplements to the mean highest intake is low and multiple use of similar food supplements is rare.
- That consumers are generally unlikely to consumer both high dose supplements and highly fortified foods over a lifetime, and that this situation can be appropriately managed by labelling and education.

4. 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.

Some intake data available, with the UK as the most comprehensive and detailed.

Other sources of intake data include:

- The Irish Universities Nutrition Alliance (IUNA),
- The North-South Ireland Food Consumption Survey 2001,
- Gezondheidsraad, Enkele belangrijke ontwikkelingen in de voedselconsumptie (2002),
- Turrini A, Saba A, Perrone D, Cialfa E & D'Amiels A (2001) Food consumption patterns in Italy (to be extended).
- Several Surveys conducted by Spanish Regional Authorities such as Catalan Nutritional Surveys, Cataluña, Generalitat de Catalunya, Departament de Sanitat i Seguretat Social, 1986, 1992-93 y 2002-03.

Unfortunately these databases are incompatible, even at the level of micronutrients.

Currently there are a number of projects in progress to improve this situation:

- a) A project to create a complete European data base is under active discussion and development by EFSA (Phillippe Verger, Research Unit INRA; Met@risk: EFSA Colloquium No 3, Brussels, April 2005).
- b) The development of such a data base of consumption at nutrient level is in progress through the TNO coordinated EFCOSUM Project.
- c) A EU 6th framework funded project, EFCOVAL (European Food Consumption Validation) aims to develop and validate a method for assessing food consumption and nutrient intake across Europe.
- d) The 6th-framework EUROFIR (European Food Information Resource) project develops a European food composition databank.
- e) A revision of the ERNA/EHPM model, including application with new intake data is currently underway.

5. 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?

Yes, data referring to intake in one member state may be useful.

An analysis of existing intake data from several Member States does not show marked differences. If the highest intakes (as represented by the 97.5th percentile) are grouped and the means highest intake is used as a basis for applying the models, this would be representative.



Furthermore, the most representative state for applying a model would be the Member State with the highest intake from all sources. The best candidate for this would be UK because that data would reflect intakes of nutrients in a liberal market place, where both fortified foods and food supplements coexist. Therefore this database was primarily used for the application of the ERNA/EHPM model.

For the 6 micronutrients with a UL established, which are categorized into the *potential risk* group (see above answer to question 3) it should be practicable to check exposure using current ULs as determined by the EU against exposure using national data. Should a risk be exposed, then that particular nutrient would have to be regulated downwards to accommodate the risk until the doubt was either confirmed or refuted when re-examined with the data of the completed EFCOSUM project.

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

It may be considered appropriate to have maximum levels set for two groups: adults including young adults, and children.

However, we note that the risk assessment process already recognises that there may be sensitive groups, e.g. children, certain adult individuals, the elderly, women during pregnancy or lactation. There can be a range of sensitivities to adverse effects that are influenced by such things as body weight and lean body mass.

The derivation of ULs for the essential nutrients is based on the principle that the most sensitive members of the general population must be protected from the adverse effects of high nutrient intakes. So, ULs established on the basis of scientific risk assessment already take into consideration the most vulnerable groups of the population. Besides, the size of population subgroups used in survey data is generally small and therefore may not give a very accurate/representative picture of the intake/highest intake levels of population sub-groups. The extent to which ULs for a subpopulation are considered separately from the general population is an area of scientific judgement, and the nutrients are usually assessed on a case-by-case basis.

We acknowledge nevertheless that it might be appropriate for consumer confidence to have maximum levels set for two groups, adults including young adults, and children.

In this case, UL for children will need to be used in the models. The US FNB and the SCF have made extrapolations from adult ULs for children, on the basis of known differences in body weight, body size, physiology and metabolism of the nutrient concerned. However, data across the EU are too



sparse to be definitive at the present time, and it may be more prudent to defer a decision until more conclusive data become available. We would recommend that the Commission encourages member states to develop such data.

An application of the ERNA/EHPM model specifically for children is underway.

7. 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?

They should only be taken into account in setting minimum levels to avoid deficiency conditions, the situation for which they were developed.

The setting of maximum levels should be based on scientific risk assessment, as is specified in the criteria of the legislation (see point 3). The use of arbitrary multiples or fractions of RDAs/PRIs to set ULs are no longer acceptable from the scientific risk assessment point of view or as an objective approach to risk management. RDAs can be considered as a marker for the lowest end of the range of safe intake for each nutrient but cannot be used in risk assessment to establish upper safe levels.

However, RDAs can be used as an indicator to help establish the extent of the range of safe intake and could form an approach to help clarify the relative safety of each nutrient for the population. If the UL and RDA are closer together, the safe range of intake is relatively small. Where the UL and RDA are further apart, the safe range of intake is relatively large. The RDA as an 'indicator' can therefore be taken into account in establishing the breadth of the range of safe intake and for risk characterisation.

This approach was adopted in the ERNA/EHPM model to develop a 'Population Safety Index' for the quantitative risk characterisation of nutrients into 3 categories (see point 3). In the case of Group C nutrients, the UL is close to the RDA and therefore risk of exceeding the UL (be it a European level, or if not set, an internationally accepted level) is a real possibility, especially in the higher intake groups (97.5th percentile). However, in such case risk of intake below the RDA or even deficiency is also real, especially in the lower intake groups (2.5th percentile). In such case the RDA needs to be carefully considered in establishing max levels.

8. 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?



If no claims are made, no minima should be set.

The amount added is of no regulatory significance provided no claim is made and provided the product is not packed to imply benefit from the vitamin/mineral/trace element added.

For claims for nutrients in conventional and fortified foods, there is a need for consistency across several legislative instruments, namely the Nutrition Labelling Directive (under review), the addition of vitamins and minerals and certain other substances in food, and the legislation on nutrition and health claims made on foods. It seems appropriate to maintain consistency for the 15% RDA per 100 g/100 ml or per specified portion size as the basis for a 'significant amount' and the minimum to make a claim on a food.

9. Should different minimum amounts be set for certain nutrients in specific foods or categories of foods? If yes, on what basis? 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?

The Nutrition Labelling Directive 90/496/EC states in article 1.2 that it does not apply to food supplements. The minimum amounts should relate to the use of the (RLVs) RDAs set by SCF/EFSA for both foods and food supplements. The definition of a food supplement refers to concentrated sources of nutrients, and hence the 'minimum' criteria are not directly relevant.

Where dietary supplements contain low levels of vitamins and minerals this may be due to technological reasons (e.g. organoleptic properties). However these amounts can still be a useful addition to the diet. In this case, these amounts should be allowed to be added and labelled in the nutrition panel.

In any case, where a claim is made, the requirements of the Nutrition and Health Claims legislation with regard to the minimum content should apply.