Partners in gezondheidsproducten

To:
European Commission
Health and Consumer Protection Directorate-General

Response to the European Commission Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

NPN, 28-9-2006

Referring to: Discussion paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs.

NPN (Natuur- en gezondheidsProducten Nederland) is the most leading Dutch trade associations representing more than 100 companies which have a business in food supplements. NPN cooperates closely with the European Federation of Trade associations, EHPM, which has developed a model to derive maximum levels for vitamins and mineral in food supplements. NPN supports this model.

NPN notes that food supplements and fortified foods to a lesser extent, have been consumed in the Netherlands for many decades without known safety concerns. We would like to point out the current Dutch legislation for food supplements where a satisfactory situation has been created while no maximum levels have been set, except for vitamins A and D. The responsible industry has applied maximum levels for vitamins and minerals based on one of the early published reports on risk assessment (Shrimpton, 1995).

In answer to the specific questions form the Commission:

<u>Establishment of maximum amounts for food supplements and other foods</u>

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?**

Where there is not yet a scientifically established numerical tolerable upper intake level for several nutrients, the upper safe levels for those nutrients could potentially be derived from the lowest LOAL if these are published and these values should be taken into account in setting maximum levels. However, 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.

We note that in spite of the fact that EFSA has not set UL's for certain nutrients the EFSA opinions contain references to safe levels and provide data on the nature of potential adverse effects. From this a qualitative approach can be made.

Then there are some different reasons why EFSA has not established numerical tolerable upper intake levels (UL). Analysing these reasons, 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 B_1, B_2, B_{12}, 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 and in the absence of any evidence to set a UL, there may also be no rationale for setting a maximum level for food fortification or for food supplements.

For 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 ULs established by other organisations may be taken into consideration, as well as a case-by-case qualitative risk assessment. Referral can be made to the USA FNB data and the UK EVM report.

There also could be set provisional values based on history of safe use. In addition to this 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 vitamins and minerals where the risk of adverse effects are extremely low or non-existent, i.e. there are no safety concerns, there is no reason to set maximum levels.

There have been approaches explored by FAO/WHO to establish Highest Observed Intakes (HOI) with no evidence of any adverse effects. If such levels would be used to set maximum levels they should be sufficiently high to reflect the current safe market practice and avoid unnecessary administrative burden and reformulation of products.

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 see no alternative for setting maximum amounts for vitamins and minerals separately for food supplements and fortified foods. For nutrients where there is a potential risk at excessive intake, due to a small margin between RLV and UL, the best option is to be cautious with food enrichment, because the intake of the nutrients by enriched foods is not always clear for the consumer. The choice to supplement the diet with a food supplement is a conscious choice. In such cases the consumer will be more acutely aware of the additional nutrients he or she ingests.

The other alternative, to set total maximum levels of intake and then split these arbitrary between food and supplements is not scientific and simplistic. It should be noted that for the majority of nutrients neither foods nor supplements will contain maximum levels. There are self limiting factors for the addition of certain nutrients to foods, like certain minerals for their taste and besides this there are economical reasons to limit the levels of fortification. The

upcoming legislation for Claims designates as a “source” a food which contains 15 % of the RDA and a “high” content would be 30% of the RDA.

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. 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 strange that few of the models take a differentiated approach.

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

- The French AFSSA model 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 how maximum amounts shall be set.

- The ILSI model does not consider food supplement use as being substantial and focuses solely on food fortification. It does not use detailed intake data but the mean of data available.

- The Danish model 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 German BfR model starts from a scientific risk assessment, which is later on only applied to three nutrients (Vit B6, K and Zn). 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,
  - 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.

Intake of vitamins and minerals from dietary sources

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.**

There is information available on intakes of vitamins and minerals in the Netherlands. A RIVM report called 'Our food, our health' has been presented and welcomed by EFSA. This report is a translation of the original Dutch report, published in 2004. NPN has made some comments on certain data regarding supplement nutrient levels in this report, to correct a false impression and an exaggerated worst case scenario. Unfortunately in the translated version there are still minor inaccuracies (misstatements), we would like the Commission and the EFSA take into account. They are mentioned in the annex .

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?**

If data refer only to the intake in some Member States, they can only be used for the setting of legitimate and effective maximum levels of vitamins and minerals at European level, if it could be assumed that the intake in other European countries are at a similar level, which we assume, is the case for most nutrients. For problematic nutrients (where intake, UL and RDA are close together) a specific case by case approach should be taken here.
It should be noted that for most nutrients the geographical variations in intake are minor in comparison to the ULs as established by EFSA.

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

The intake from different population groups should preferably not be taken into account in the setting of maximum levels of vitamins and minerals. We would prefer a simple system of one set of maximum levels without unnecessary administrative burden.

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.

We acknowledge nevertheless that it might be appropriate for consumer confidence to have maximum levels set for two groups, adults including young adults, and young children, to be applied in such cases where these products are specifically aimed at this latter group.

Reference intakes of vitamins and minerals

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?**

Not PRI, nor RDA should be taken into account when setting maximum levels for vitamins and minerals: setting of maxima should not be based on need. Maximum levels should be based on safety, by risk assessment and risk management as laid down in Directive 2002/46 and the coming Regulation for the Addition of Nutrients.

Minimum Amounts

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 claim is made, no minimum should be set. For food the minimum amount of a vitamin or a mineral required for making a claim in nutritional labelling could be lower, e.g. 15% of the recommended allowance in 100 g or 100 ml 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?**

   For food supplements the minimal amount of a vitamin or a mineral required for making a claim in nutritional labelling could be 15% of the recommended allowance. This percentage should be based on daily portion/ dose and not on the amount in 100g or 100 ml as prescribed in Directive 2002/46.

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