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Comments to the Commission's "Discussion Paper on the setting of maximum and minimum amounts for vitamins and mineral in foodstuffs" (June 2006)

The above mentioned discussion paper on setting of maximum and minimum amounts for vitamins and minerals in foodstuffs i.e. food supplements and fortified food focuses on general principles how to find an optimal way to estimate appropriate levels of these compounds.

According to our opinion it is very important that maximum amounts of vitamins and minerals are regulated in foodstuffs in order to limit potential adverse effects, which might appear especially after high and chronic intakes of certain micronutrients.
It may be noted that these issues have been addressed in a Nordic report on health risks related to foods and food supplements (Meltzer&Alexander, 2001).

In the following we will comment the questions in the discussion paper regarding setting of maximum amounts from the Commission.

Comments to questions from the Commission
1. Question from the Commission: Where there is not yet a scientifically established numerical tolerable upper intake levels (UL) for several nutrients, what should be the upper safe levels for those nutrients that should be taken into account in setting their maximum levels?
An obvious proposal would be to use guidance levels established by internationally recognised expert groups, e.g. the British EVM (2003) and U.S. Institute of Medicine, if available. However, it should be pointed out that these guidance levels have been derived from an insufficient database and important data for risk assessment are often lacking, consequently they do not have the same status regarding safety as the ULs.

2. Question from the Commission: 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?
The nutritional need for such high levels has, however, never been scientifically well documented. As the databases for micronutrients often include uncertainties regarding interactions, allergy or intolerance, and effects on vulnerable groups like people with specific genetic disorders, pregnant women and small children, it would in this context be unwise not to set maximum levels also for these micronutrients.

3. Question from the Commission: 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?
Intake patterns from these different sources will differ considerably among consumers in the European countries and also in relation to social circumstances, age, and gender etc. Food supplements are intended to provide a specified daily amount of micronutrients, while foods are consumed in various amounts. Therefore it is important to set maximum levels separately for food supplements and fortified foods.

4. Question from the Commission: 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.
Swedish data on intakes of micronutrients are available for both adults (Becker and Pearson 2002) and children (Enghardt Barbieri et al. 2006).

5. Question from the Commission: 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?
Calculations from national dietary surveys in the Nordic countries indicate that a relatively simple and pragmatic approach can be used to estimate high intakes of micronutrients. This is based on the ratio between high intakes (e.g. 95^{th} percentile) and mean intakes. This approach could be tested for other countries with intake data and applied in suitable models.

6. Question from the Commission: Should the intake from the different population groups be taken into account in the setting of maximum levels of vitamins and minerals?
This is an important issue, but difficult to deal with. We believe that the intake from the different population groups should be taken into account in the setting of maximum levels of vitamins and minerals. Ideally the most vulnerable group, e.g. small children, pregnant women, should be considered as worst case in the setting of maximum levels of vitamins and minerals. However, nutritional aspects must also be considered.

7. Question from the Commission: *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?*
There is no obvious known relation between RDAs and toxicity. The idea to limit daily intake of certain micronutrients to 3xRDA is in general not based on risk for potential toxic effects, but on the practical use of some kind of default value, which could be accepted from a nutritional point of view.
It should be noted that the marginal between the RDA and the daily dose, which potentially may cause adverse effects is quite narrow in some cases. A classification according to their safety margin, i.e. the size of the interval between the recommended intake (PRI/RDA) and the upper safe level of intake has been suggested by Meltzer et al (2003, see below) and can be used as a basis.

8. Question from the Commission: *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?*

The addition of a micronutrient to a food should be such that the total content of the micronutrient in the food is at least the significant amount (e.g. 15% of the reference labelling value) required to be present for a claim and/or declaration. This principle may not be appropriate for restoration, i.e. in cases where nutrients are added to replace losses during processing.

9. 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 same principle as for foods can, in principle, be applied to supplements, although one can discuss whether the percentage of the daily dose should be based on the significant amount or a higher level, e.g. level corresponding to "rich" or "high" as used in claims (e.g. 30% of the reference labelling value).

Existing models for the setting of maximum amounts of vitamins and minerals in foods

A common European model for the setting of maximum amounts of vitamins and minerals in foods would be useful. The model should be representative and flexible. Furthermore, it must take into account the variation of estimated intakes of micronutrients both from foods (including the contribution from currently fortified foods) and food supplements in different countries, in different social groupings, in different age groups, different genders, different physiological conditions, etc.

A major problem, apart from the choice of model, is the lack of solid data on UL for children, which usually are based on extrapolation from values established with respect to long-term intakes in adults. Also, there is a lack of basic data on toxicity (there are few humans studies) as well as a general lack of data on bioavailability studies regarding micronutrients in different chemical forms. It must be emphasized that there are many interactions described for minerals as well as trace elements, which affect the margins of safety.

These circumstances will limit the usefulness of any model. It is important to highlight the limitations when applying any chosen model.

<u>Additional general viewpoints</u>

Regarding the general summary of this discussion paper, which ends up in a proposal of setting Maximum Supplement levels (MSL) it may be noted that related issues have been addressed in a Nordic report on health risks related to foods and food supplements (Meltzer and Alexander 2001). An article based on the report has also been published in Public Health Nutrition (Meltzer et al. 2003).

These documents describe how the risk analysis can be applied to food fortification, with emphasis on voluntary fortification and intake levels that might exceed usual dietary levels. The authors proposed that micronutrients could be classified according to their safety margin, i.e. the size of the interval between the recommended intake (PRI/RDA) and the upper safe level of intake. It was suggested that nutrients with a small safety margin, i.e. for which the upper safe level is less than five times the recommended intake, be placed in a category A and should be handled with care (retinol, vitamin D, niacin, folate and all minerals). Category B comprises nutrients with an intermediate safety margin, 5-100 times the recommendation (vitamins E, B6, B12 and C). Finally nutrients that according to present knowledge are harmless even at 100 times the recommendation (vitamin K, thiamin, riboflavin, pantothenic acid and biotin) are categorised as C. According to this paper the risk analysis model is a useful tool when assessing the risk of both too low and excess intakes of single micronutrients, but it can also be applied to analyse the consequences of fortification practices on eating behaviour and disease patterns.

References

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