MINISTRY OF FAMILY
AND CONSUMER AFFAIRS
Danish Veterinary
and Food Administration

DIVISION FOR NUTRITION

European Commission
Health and Consumer Protection Directorate General
DG SANCO
B-1049 Brussels

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Comments from The Danish Veterinary and Food Administration to the:

Discussion Paper, June 2006, on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

Establishment of maximum amounts for food supplements and other foods (25-28)

Question: 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?

Comments:

- Denmark recommends using provisional guidance levels (GL) as suggested by Rasmussen et al. (2006) [1] where no UL are established yet. Enclosed is also a list of the safe upper intake levels set by different expert committees [2].

Question: 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?

Comments:

- For safety reasons, maximum levels should be set for all vitamins and minerals. This is a consequence of acknowledging that the available data are insufficient for the establishment of a UL.

Question: 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?

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Comments:

- This is a key question. As it cannot be excluded that some consumers both take food supplements and prefer fortified foods maximum amounts must be set for both categories. For safety reasons it should be avoided to use up to the UL twice. One simple way to address this issue is to use the Danish model for setting safe amounts of added nutrients to foods Rasmussen et al. (2006) [1] and set the maximum level in supplements equal to the reference labelling value (RLV). Food supplements containing 100% of RLV are included in the Danish model.

Intake of vitamins and minerals from dietary sources (29-33)

Question: 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.

Comments:

- Intakes of vitamins and minerals are available from dietary surveys in all the Nordic countries and several other Member States. The Danish dietary survey is only available in Danish and can be found via the following link: http://www.dfvf.dk/Default.aspx?ID=8366, under *Danskernes kostvaner 2000-2002*. The survey is also enclosed, please see [3].

Question: 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?

Comments:

- Below we suggest a *simple* and *pragmatic* way to merge intake data from different countries and create common estimates of what constitute high intakes. This procedure has been tested in minor scale on Nordic data and it was found useful and suitable for fitting in the Danish model. 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).

- Experience from Nordic data shows 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 B_6, 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 B_{12}, vitamin C, vitamin D, retinol and β-carotene.

- If the Commission is interested, Denmark can expand this calculation to also cover intake data from other Member States.

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

Comments:

- It is very important to take the most vulnerable group into consideration when setting the maximum levels of vitamins and minerals. According to the Danish model the most vulnerable group, i.e. children, is taken into account. Please see Table 4 in Rasmussen et al. (2006) [1].

Reference intakes of vitamins and minerals (34-42)

Question: 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?

Comments:

- PRIs/RDAs as well as ULs should be taken into account when the authorities decide mandatory fortification for nutritional purposes. If no indication of deficiency is present PRIs/RDAs are not important.

Minimum amounts (43-46)

Question: 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?

Comments:

- In order for the declaration not to be misleading it is important that the total amount of a given declared nutrient, i.e. the natural content and the added content, is minimum 15% of RLV per 100 g, which is considered a significant amount according to directive 90/496/EEC. However, Denmark finds, that for beverages which normally

are consumed in larger amounts, the minimum amount should be 7,5% of RLV per 100 mL. This is also in accordance with the Codex Guidelines for use of nutrition and health claims.

Question: 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?

Comments:

- Regarding minimum amounts of vitamins and minerals in food supplements, Denmark agrees with the Codex Guidelines for vitamin and mineral food supplements on the use of a minimum level of 15% of the recommended daily intake.

Yours faithfully

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Enclosed:

1. Rasmussen, S.E., Andersen, N.L., Dragsted, L.O., Larsen, J.C. (2006) A safe strategy for addition of vitamins and minerals to foods, European journal of nutrition, 45, p. 123-135.
2. Safe upper intake levels for vitamins and minerals, Fødevarestyrelsen, 2006.
3. Danskernes kostvaner (The Danish dietary survey), 2000-2002.