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Translation

Subject: Discussion paper on the setting of maximum and minimum amounts of vitamins and minerals in foodstuffs
here: Comments by the Federal Government

Dear Madam/Sir,

We welcome the Commission's initiative on the setting of maximum and minimum amounts of vitamins and minerals in foodstuffs. Rules governing the setting of maximum levels for the addition of these substances to foodstuffs foster preventive consumer health protection.

In the process, we must weigh the optimal supply of the population with these nutrients against the protection of consumers from excessive intake. It must be ensured that the consumption of fortified food and of food supplements as part of a varied diet does not pose any risks. Therefore, the intake from all dietary sources, including the amounts that are naturally present in foodstuffs, must be taken as a basis. When setting the maximum levels, we should always also bear in mind that some consumers eat more than one food supplement and/or fortified food a day.

Specific nutrients that are set out on the positive lists of Directive 2002/46/EC of the European Parliament and the Council on the approximation of the laws of Member States relating to food supplements as well as the European Parliament and Council Regulation on the addition of vitamins and minerals and of certain other substances to foods (e.g. fluoride, iodide and iodate, iron and manganese) raise certain health concerns. Suitable measures should therefore be examined to prevent adverse effects being caused by adding these substances to foodstuffs. Such measures that could be considered are, for instance, the setting of reasonably low maximum levels, a restriction to specific categories of food or additional labelling indications for consumers.

The required scientific basis for setting the maximum amounts of vitamins and minerals in foodstuffs should be the health assessments conducted by the European Food Safety Authority (EFSA) or the Scientific Committee on Food (SCF). The latest scientific findings should therefore be taken into account.

A separate UL should, for example, be taken as the basis for vitamin or mineral compounds with a particularly large bio-availability (e.g. organic mineral compounds).

We wish to comment as follows on the individual questions:

- *On the first question*: 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?

  If an upper level (UL) has been set by EFSA or SCF, this level should be taken as the basis for deriving the maximum levels. Otherwise, a case-by-case analysis turns out to be necessary. If possible, typical intake levels should be taken as the basis for deriving maximum levels (e.g. the respective 97.5 percentile), taken from European data on consumption, if possible.

  What matters for the approach is whether adverse effects have been described or not for the respective vitamin or mineral. The setting of maximum levels for nutrients for which no adverse effects have so far been identified must not turn out to be more stringent than for nutrients where adverse effects were observed.

  Maximum demands should be made on the reliability of the European UL. In cases of doubt, EFSA should be requested to comment on the extent of scientific evidence or uncertainty of a specific UL or to communicate which data are lacking and on which scale.

- *On the second 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?

  The focus for setting the maximum levels should be on those vitamins and minerals for which health risks have been identified and that are set out on the positive lists of Directive 2002/46/EC of the European Parliament and the Council on the approximation of the laws of Member States relating to food supplements as well as of the European Parliament and Council Regulation on the addition of vitamins and minerals and of certain other substances to foods. A quantity restriction, also for substances where no adverse effects of high intakes have so far been observed, could provide greater legal certainty for economic operators and establish a uniform internal market in Europe for these products. However, these restrictions would have to be of an order that clearly indicates this.

- *On the third 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?

  The safe total intake of a specific vitamin or mineral should determine the setting of the maximum levels. Therefore, maximum levels should be set for food supplements as well as for fortified foods.

  Corresponding maximum levels must ensure that the sum of the expected total intake via a normal diet, via food supplements and via fortified food falls short of the UL. Which share should be envisaged to identify the maximum level of food supplements and which for fortified food in each case should be determined on a case-by-case basis by means of data on consumption. A flat-rate division between the two fields on the basis of parity would be unacceptable.

- *On the fourth 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.

  Please find attached an overview of the key studies conducted in Germany as encl. 1.

- *On the fifth 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?

  We must ensure that the European minimum and maximum amounts can neither result in deficiencies nor in an oversupply in a specific region in Europe. Regional differences should be highlighted to this end. Representative data on consumption from individual Member States should be taken as a basis, if possible.

  The latest data indicate a decrease in the differences between dietary patterns in northern and southern Europe (Naska et al.: Dietary patterns and their socio-demographic determinants in 10 European countries: data from the DAFNE databank, European Journal of Clinical Nutrition (2006) 60, 181 -190). Besides, we wish to refer to the 2001 EFCOSUM report of the TNO Nutrition and Food Research Institute at Zeist, the Netherlands:
  http://ec.europa.eu/health/ph_projects/1999/monitoring/monitoring_project_1999_full_en.htm.

- *On the sixth question:* Should the intake from different population groups be taken into account in the setting of maximum levels of vitamins and minerals?

  Adults should constitute the reference group first and foremost. The requirements of children (in accordance with their age group) should be adequately considered when setting the maximum levels. In those cases where SCF or EFSA had derived a separate UL for children, this UL should be borne in mind when setting the maximum levels.

  Differentiated maximum levels for foods aimed at specific age groups or target groups that go beyond that would entail a confusing offer of foodstuffs.

  Other population groups with specific needs should be adequately considered on a case-by-case basis. It should be examined in those cases whether labelling indications could provide the required information about the addition of the respective nutrient so as to enable a choice of foodstuffs adapted to individual needs.

- *On the seventh 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?

  The reference values for nutrient intake should be taken into account. They could also help to assess the risk of an upper level (UL) for a specific nutrient being exceeded. They could, in addition, indicate an under-supply and thus influence the setting of maximum levels.

  In the case of specific nutrients that raise specific health concerns (e.g. vitamin A, zinc, copper, fluoride, iodine, iron and manganese), we need to set maximum levels in such a way that the total intake is safe and closely approximates the recommended intake.

  With regard to foodstuffs that are eaten or drunk in an uncontrolled manner according to hunger or appetite, especially staple foods and beverages, reference is made to the particularly high risk of exceeding the maximum level.

- *On the eighth 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?

  We are generally in favour of using the significant amount as the minimum amount. We should discuss exceptions for beverages and in the event of a particularly large bioavailability of the vitamin or mineral compound in question.

- *On the ninth 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?

  The significant amount of 15 % of the recommended dietary allowance (RDA) should, in principle, be used as a minimum amount for food supplements.

Yours sincerely,
signed: Dr. O. Mellenthin

Encl.

With regard to the fourth question:
Reference to data sources in Germany
on the actual intake of vitamins and minerals

- First national food consumption survey *(Erste Nationale Verzehrstudie)* / VERA-study (1985 – 1988, West Germany)

- Food survey *(Ernährungssurvey)* by the Robert Koch Institute (RKI) as part of the Federal Health Survey *(Bundes-Gesundheitssurvey)* (BGS) 1991 and 1998

- Nutrition Report *(Ernährungsbericht)* 2000, the income and consumption random testing (EVS) by the Federal Statistical Office (EVS)

- EPIC Study (EPIC = European Prospective Investigation into Cancer and Nutrition) in nine European countries

- MONICA Study (Monitoring of Trends and Determinants in Cardiovascular Disease, Heidelberg)

- DONALD Study (Dortmund Nutritional and Anthropometric Longitudinally Designed Study), Research Institute for Child Nutrition (Forschungsinstituts für Kinderernährung) (FKE), since 1985

- Nutrition Report 2004 by the German Nutrition Society DGE

- Bavarian study on consumption (representative for Bavaria)

- Saxonian study on consumption (representative for Saxony)

- AFG-V: intake of β-carotene from soft drinks

We also expect data from the following studies in the coming year:

- NVS II (Survey phase of the second National food consumption survey commissioned by BMELV); data expected from 2007 onwards

- Child and Adolescent Health Survey (Kinder- und Jugendgesundheitssurvey (KiGGS)) by the RKI, data collection since 2003, the „Eskimo-Modul" records children and adolescents, data expected from 2007 onwards

Setting of maximum levels for vitamins and minerals in food supplements and fortified food

- Consensus paper drawn up by the Working Party "Maximum Levels" at the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV)
September 2006

The Working Party makes the following recommendations from a scientific perspective:

- Maximum levels should, in principle, be set for all vitamins and minerals.

- If an upper level (UL) has been set by the Scientific Committee on Food (SCF) or the European Food Safety Authority (EFSA), this should serve as a basis for deriving the maximum levels. Maximum demands should be made on the reliability of the European UL values. The EFSA should be requested to provide explanations in cases of doubt. It will also be important to examine the respective UL once new data become available.

- Adjusted UL might have to be taken as the basis for vitamin or mineral compounds with a particularly large bio-availability (e.g. chromium organic compounds).

- In those cases where no UL could be derived by SCF or EFSA and no adverse effects of large doses have been described, typical intake levels could be taken as the basis for deriving maximum levels (97.5 percentile), possibly from European data on consumption. The setting of maximum levels for nutrients where no adverse effects of large doses have so far been identified is required because an unchecked intake cannot be deemed safe due to a lack of data. However, it must not turn out to be more restrictive than in the case of nutrients where adverse effects were observed. Deriving the maximum level only from the recommended daily allowance, therefore, seems inappropriate in the case of nutrients such as the vitamins B_1, B_2, B_{12}, biotin and pantothenic acid.

- Particular health aspects that could cause additional restrictions must be heeded in the case of specific nutrients set out on the positive lists of food supplements or fortified foods (e.g. fluoride, iodide and iodate, iron and manganese). Particular measures should be examined to prevent adverse effects being caused by adding these substances to foodstuffs. Such measures that could be considered are, in particular, the setting of reasonably low maximum levels, a restriction to specific groups of food or additional labelling indications for consumers, as appropriate.

- The safe total intake of a specific vitamin or mineral should be decisive for setting the maximum levels. In the process, maximum levels should be set for food supplements as well as for fortified food. The normal intake from solid and liquid foodstuffs must be taken into account here. Which share should be envisaged to identify the maximum level of food supplements and which for fortified food in each case should be determined in individual cases by means of data on consumption. A flat-rate division between the two fields on the basis of parity would be unacceptable.

- When setting the maximum levels, we should always also take into account that some consumers eat more than one food supplement and/or fortified food a day. This is especially important in the case of such nutrients that could cause adverse effects as the result of excessive intake. Additional safety factors could be envisaged in such cases that would have to be determined in individual cases based on available data.

- In those cases where SCF or EFSA had derived a separate UL value for children, this UL should be considered when setting maximum levels. Population groups with specific requirements should be adequately considered in individual cases, e.g. women of childbearing age for folic acid. Additional labelling indications for consumers should be contemplated in such cases. Differentiated maximum levels for foods aimed at specific age and target groups that go beyond that do not make any sense in scientific terms.

- We do not support approaches that select the energy content of food or the portion size as the reference quantity for maximum levels.

- We are generally in favour of using the significant amount as the minimum level. Analogously to the Codex Alimentarius agreements, the significant amount for beverages should be set at a lower level.

Bonn, 29 September 2006