Comments of the German Federal Institute for Risk Assessment (BfR) on the Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

BfR adopts the following position on the discussion paper and, more particularly, on the questions raised by the European Commission:

Setting of maximum amounts for food supplements and other foods

1. 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 amounts?

The Scientific Committee on Food (SCF) or the European Food Safety Authority (EFSA) have not established tolerable upper intake levels for the following vitamins and minerals mentioned in Annex 1 to the Food Supplements Directive (Directive 2002/46/EC):

- Vitamins: biotin, pantothenic acid, vitamin B_1, vitamin B_2, vitamin B_{12}, vitamin C, vitamin K;
- Minerals: chloride, chromium, iron, potassium, manganese, sodium, phosphorus.

However for vitamin C, iron, sodium and manganese caution is called for in the sections on risk characterisation when it comes to their use in food supplements and/or for food fortification.

For beta-carotene (not mentioned in Annex 1) no UL could be established either. The same applies to vanadium, silicium, tin and nickel (not mentioned in Annex 1; not essential minerals for humans).

In the case of these vitamins and essential minerals the establishment of upper safe levels, used to set maximum amounts, should be done on a case by case basis. Furthermore, different recommendations may emerge concerning their use in food supplements and for fortification purposes.

BfR recommends the use of nutritional-physiological considerations when setting maximum amounts for biotin, pantothenic acid, vitamin B_1, vitamin B_2, vitamin B_{12} and chromium as well as the inclusion of additional criteria for vitamin C. For vitamin K it is recommended that the setting of maximum amounts be oriented towards risk groups, i.e. individuals undergoing treatment with anticoagulant medication. When setting maximum amounts in food supplements serum levels could be taken into account for potassium and for phosphorus the guidance level established by the British EVM. In the case of manganese and iron there are general objections to their addition to food supplements and use for food fortification. Hence, there is no need for information about which bases should be used to set maximum amounts. The same applies to sodium (exception: replacement of sodium losses). Chloride additions to food supplements and to fortified foods should only be accepted up to the level which results from the intentional addition of essential minerals like zinc, magnesium or calcium when they are used in the form of chloride compounds. For beta-carotene it is recommended that the maximum amount in food supplements (no use for food fortification) be based on the lower bound of the estimated value for adequate intake or on the habitual intake.

Justification:

BfR has derived maximum amounts of vitamins and essential minerals for use in food supplements and fortified foods (Domke *et al*., 2005; 2006). The procedures adopted to establish the option preferred by BfR for the above-mentioned vitamins and essential minerals can also be used in conjunction with the questions raised about the setting of maximum amounts. They are presented briefly below. For more details about the justification please refer to the two above-mentioned publications.

The non-essential minerals vanadium, silicon, tin and nickel were not included in the assessment by BfR. No further account is taken of them here. Furthermore, the risk benefit considerations in their case differ from those of nutrients whose intake is essential for the human body.

Biotin, pantothenic acid, vitamin B_1, vitamin B_2, vitamin B_{12}

Cf. question 2

Vitamin C

The BfR proposal for setting of maximum amounts in food supplements and fortified foods took into account the actual nutritional status of the population, the renal excretion threshold and the recommended dietary allowance as only inadequate findings are available about toxicological parameters and hazard potential and there are uncertainties about the setting of tolerable upper intake levels (EFSA, 2004a).

Vitamin K

The BfR proposal for setting of maximum amounts for vitamin K took into account possible risk groups, i.e. people undergoing treatment with anticoagulant medication. A dose of 150 µg vitamin K/day was identified as the threshold value for statistically significant interactions with medicinal products ofthis kind. No significant interaction was observed any longer at 100 µg/day (Schurgers *et al*., 2004). Given the low number of patients in this publication (N=12) BfR used an uncertainty factor of 1.2 to set the maximum amount (80 µg/per daily portion for food supplements and fortified foods)

Beta-carotene

As the intake of isolated beta-carotene led to an increase in the lung cancer rate amongst heavy smokers in intervention studies and because more than 18% of the adult population in Germany belong to this risk group, there is a risk of adverse health effects in a considerable part of the population in conjunction with the use of beta-carotene in food supplements and for food fortification. The effect of isolated beta-carotene in non-smokers has not been fully elucidated nor from what dose a negative effect can occur. BfR recommends that the maximum amount for beta-carotene in food supplements be equal to the lower estimated value for adequate or habitual intake. Foods for general consumption should not be fortified with beta-carotene.

Chromium

The BfR proposal for setting of maximum amounts in food supplements was based on nutritional-physiological aspects (half of the mean estimated range for adequate intake, calculated using the formula: (lower + upper estimated value)/2 * 0.5; with the DGE reference values from 1991; DGE, 1991). Because of uncertainties chromium should not be used for fortification purposes. Hence, there is no need for any further information about which basis should be used to set maximum amounts for chromium.

Phosphorus

The BfR proposal for setting of maximum amounts in food supplements was based on the guidance level for supplemental intake of 250 mg phosphorus/day from the British Expert Group on Vitamins and Minerals (EVM, 2003). Given the widespread presence of phosphorus in foods, the frequent use of phosphates as additives for technological purposes and the generally adequate intake, fortification of foods for general consumption with phosphorus is not considered wise. Hence, there is no need for any further information about which basis should be used to set maximum amounts for phosphorus fortification.

Potassium

BfR is of the opinion that the use of potassium in food supplements carries a risk of adverse health effects (for the definition of the risk categories used by BfR, please refer to Footnote 1). Potassium fortification of foods may constitute a risk for individuals with renal dysfunction. Potassium intakes from natural potassium-containing foods have not led to any negative effects in healthy consumers up to now. BfR has defined a safe upper level for intake from food supplements (1000 mg/day) and proposes a maximum amount for individual food supplements of 500 mg/day. The critical endpoint used was the increase in the serum potassium concentration following oral intake of potassium salts by healthy test persons. An intake of 1400 mg/day was identified as the No Observed Adverse Effect Level (NOAEL) (Perez *et al.*, 1984; Schwartz, 1955; Zwemer and Truszkowski, 1936). An uncertainty factor of 1.4 was used. BfR is of the opinion that no targeted fortification of foods should be undertaken as several conventional and easily available foods contain significant amounts of potassium. Hence the need for food fortification is questionable. The majority of the population has an adequate potassium intake. Therefore, there is no need for information about which foundation should be used for the setting of maximum amounts.

Manganese

In the section on risk characterisation in its expert opinion on manganese, SCF noted that the margin between the range of levels at which adverse effects in humans and experimental animals were described and the estimated amounts of dietary manganese intake, is very small. Given the findings on neurotoxicity and the possibly higher sensitivity of a few subpopulations, manganese intakes which go beyond what is normally ingested from beverages and solid food, could constitute a risk of adverse effects which are not offset by any recognised known benefits of additional manganese intake (SCF, 2000a). In the context of preventive consumer protection BfR believes that, at present, there is no alternative to the recommendation of a ban on the addition of manganese to food supplements and other (non-dietetic) foods. Hence, there is no need for any further information about which basis should be used to set maximum amounts for manganese.

Iron

BfR is of the opinion that the use of iron is linked to a high risk to health. A series of epidemiological studies provide indications that there could be an association between elevated iron intake / an increase in iron depots and specific risks of disease. Given these findings it cannot currently be ruled out that uncontrolled, longer-term iron supplementation can increase the risk, amongst other things, of cardiovascular disease or carcinomas of the gastrointestinal tract. BfR continues to be of the opinion that these experiences should be taken into account in accordance with the precautionary principle when setting maximum iron amounts. BfR insists on its opinion in the face of the lack of convincing evidence for causal relationships between iron intake or iron stores and chronic disorders including cancer, as was also pointed out inthe EFSA assessment.
Against the backdrop of the existing gaps in knowledge, the nutritional status of the German population and the potential risks, BfR believes it is wise – on grounds of precautionary health protection - to no longer permit the use iron in food supplements or for food fortification.
Furthermore, EFSA also points to the special risks of manifest haemochromatosis which faces homozygotic gene carriers who may account for up to 0.5% of the population. These individuals should not consume any iron-containing food supplements; but are often not aware of their genetic status (EFSA, 2004b). Hence, there is no need for further information about which basis should be used to set maximum amounts for iron.

Sodium

In consideration of the ubiquitous occurrence and widespread distribution of sodium in food, of population intakes of sodium above the recommendations and of recent findings about the potential risks that may be linked to a high sodium, specifically sodium chloride intake, BfR has proposed not to add sodium chloride to food supplements. Furthermore, it recommends that fortification should be restricted to those foods which serve to replenish significant losses (e.g. excessive sweat losses after intensive physical activity) and also contribute to significant fluid intake. In this opinion BfR believes it is backed by EFSA's risk characterisation of sodium, *"The habitual intake of sodium for populations across Europe is high and exceeds the amounts required for normal function. The current levels of sodium consumption as sodium chloride have been directly associated with a greater likelihood of increased blood pressure, which in turn has been directly related to the development of cardiovascular disease and renal disease. For these reasons, national and international bodies have set targets for a reduction in the sodium consumed in the diet......"* (EFSA, 2005).
Hence when setting maximum amounts for the fortification of the few foods specified above, the amounts needed to compensate for sodium losses should be used.

Chloride

Healthy individuals on a conventional western diet are at no risk of inadequate chloride intake. The data from the Federal Republic of Germany confirm that the population is (more than) adequately supplied with this nutrient. As there are no known advantages of additional chloride intake for healthy individuals and there are uncertainties about whether chronically high chloride intake has adverse effects on people, BfR recommends the restriction of chloride in food supplements and fortified foods to the levels which result from the intentional addition of essential minerals like zinc, magnesium or calcium when these are used in the form of chloride compounds. Hence, there is no need for any further information about which basis should be used to set maximum amounts for chloride.

2. According to the data available, for some vitamins and minerals the risk of adverse effects seems to be **extremely low** even at high intakes **or** not to exist at all. Are there any reasons for setting maximum amounts for these vitamins and minerals?

In the opinion of BfR this risk classification applies to biotin, pantothenic acid, vitamin B_1, vitamin B_2 and vitamin B_{12}.

BfR believes there are reasons for setting maximum amounts in food supplements and for food fortification for these nutrients, too.

Justification:

In its health assessment of vitamins and minerals BfR has classified biotin, pantothenic acid, vitamin B_1, vitamin B_2 and vitamin B_{12} in the risk category "low risk". This is the risk category for *"nutrients for which a UL cannot be defined because up to now no adverse effects have been identified despite intake 100 times above the RDA"* (Domke *et al*., 2005; 2006).

In the case of these vitamins no or only minor adverse effects were observed even at high intakes. Nevertheless, the data available for the individual nutrients were considered to be insufficient for the setting of a UL. Mostly no systematic dose-response studies were available for these high intakes or the existing studies were not of a sufficient standard, scale or did not suffice for the setting of a maximum amount for other reasons. Hence there is scientific uncertainty in the health assessment of these nutrients. This situation is reflected in the SCF risk characterisations of vitamin B_2 and biotin:

- *"No study has reported significant adverse effects in humans of excess riboflavin consumption from food supplements. This does not mean that there is no potential for adverse effects from high intakes"* (SCF, 2000b underlining by BfR),
- *"The risk of human toxicity from the usual dietary intake of biotin and from biotin supplements, such as described in Table 1, appears to be low according to available data. There are insufficient data to draw any conclusions concerning the safety of very high-level supplements"* (SCF, 2001; underlining by BfR)

This SCF risk characterisation can also be applied to the other vitamins mentioned above.

The inadequate data situation, which meant it was impossible for SCF or other bodies to set a UL, does not mean that higher intakes of the above vitamins couldnot constitute a risk to health. BfR is of the opinion that this situation and the SCF risk characterisations mentioned above are grounds for not allowing the level of these nutrients to be dictated arbitrarily by food business operators or market forces and for not permitting extremely high intakes. The ongoing uncertainty about the health risks of high intakes of the above-mentioned vitamins justifies, for reasons of preventive consumer protection, the setting of maximum amounts in food supplements and for food fortification.

Concerning the setting of maximum amounts for the above-mentioned nutrients in food supplements and food fortification, BfR based its proposals on nutritional-physiological aspects, i.e. requirements or recommended intake.

3. Where maximum levels are set, do maximum amounts have to be inevitably set 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?

There are various reasons which indicate a separate setting of maximum amounts for food supplements and fortified foods.

Justification:

Both food categories show differences in use, labelling, consumer information and market activities that should be taken into account when setting maximum amounts.

- Food supplements contain nutrients in precise doses (e.g. capsules or tablets). They must carry details about recommended daily intake and a warning about not exceeding the stipulated daily dose. There appearance differs considerably from conventional foods.
  By contrast, it is less easy to distinguish between fortified and unfortified foods. Like in foods for general consumption, the intake of fortified foods is not determined by the amount of vitamins and minerals they contain but is mainly influenced by factors like hunger, thirst, appetite or availability. This leads to uncertainties about the level of actual vitamin or mineral intake from individual products. By providing recommended portion indications on the label this problem could be solved. However, up to now information of this kind has not been mandatory, nor are there plans for warning statements to not exceed the stipulated daily amounts of consumption.

- At present, various food categories are already fortified like soft drinks, sweets, cereals, dairy products or ready-to-eat dishes. This plus a possible further widening of fortification practice increases the likelihood that individual vitamins or minerals will be ingested daily from several fortified foods (= multiple exposure, multiple consumption). The scale of multiple consumption may vary in the case of food supplements and fortified foods. Furthermore, possible multiple exposure in both product groups can be taken into account in different ways (see parameters).

Parameters for the setting of maximum amounts:

Whereas the recommended daily intake is used to set maximum amounts for food supplements, the parameter for setting maximum amounts for fortified foods has yet to be decided.

Various procedures aiming to respond to the questions raised above concerning actual portions or possible multiple exposure are possible e.g. setting of maximum amounts based on food portions as suggested by BfR (Domke *et al*., 2005), energy content, i.e. per 100 kcal (Flynn *et al*., 2003) or on a weight or volume base, i.e. per 100 g or 100 ml.

Different ways of setting the total intake of a vitamin or a mineral for the product category food supplements and for the product category fortified foods:

> The level of total intake of a vitamin or mineral via food supplements (FS) and fortified foods (FF) can be chosen freely for each product category as long as it is ensured that the intake of a nutrient from conventional diet together with the intake from food supplements and fortified foods does not exceed the UL (cf. here also the procedure for setting maximum amounts for individual products proposed by BfR, Domke *et al*., 2005; pages 18-21). This situation can be summed up using the following formula

UL $\geq$ intake from conventional diet[1] **+** intake from FS **+** intake from FF

> For the individual nutrients the breakdown between the two food categories should be chosen in such a way that the derived maximum levels for individual food supplements or fortified foods still reach significant sizes. In the opinion of BfR, in cases of conflict the decision should favour addition to food supplements. Nevertheless for vitamins and minerals with large margins between the tolerable upper intake level and the 95 or 97.5 percentile of intake, the remaining amount available should be broken down into equal parts between food supplements and fortified foods. By contrast in the case of vitamins and minerals with low margins, e.g. zinc, it is recommended that the remaining amount be allocated solely to the category food supplements and that no conventional foods should be fortified.

Intake of vitamins and minerals from various food sources

4. The European Commission asks for the provision of available information about the actual intake of vitamins and minerals or about suitable sources that can provide data of this kind within the European framework.

The following representative food consumption surveys were conducted in Germany and used by BfR to determine the intake of vitamins and minerals from a conventional diet:

a) National Food Consumption Study/ VERA Study b) Nutrition Survey 1998 c) Nutrition Report 2000 d) EPIC Study	Intake data for adults
e) DONALD Study	Intake data for children and adolescents

a) National Food Consumption Study/ VERA Study

The National Food Consumption Study (NVS), and the related integrated Nutrition Survey and Risk Factors Analysis (VERA), was conducted between 1985 and 1988 within the

[1] For intake from conventional food the highest percentile available for the corresponding studies is used, as a rule the 95 or 97.5 percentile

boundaries of the Federal Republic of Germany at that time. The study population encompassed all age groups from 4 up to > 65 years of age. Individuals with acute or chronic disorders were excluded from the surveys.

Over a period of seven days all people (n = 24,865) in a random household survey (n = 11,141) recorded the types and amounts of foods consumed in a food diary. The quantitative recording of the foods consumed was done with the help of conventional measures, calibrated household scales, templates or standardised models. The later conversions were undertaken using corresponding amount keys. The frequency of consumption and amounts of vitamin and mineral supplements were also recorded. Nutrient intake was calculated using the food composition data from the German Food Code and Nutrient Data Base (BLS) plus nutrient intake from supplements. The contribution of food supplements to total nutrient intake was not (yet) calculated in the NVS.

Participants in the VERA Study were a random sub-sample of NVS participants; the eating habits were recorded using the same method as in the NVS.

It is under discussion that the 7-day food diary (or another time interval) leads to the systematic underestimation of energy and nutrient intake because the test persons change their eating habits as a consequence of keeping a diary or indicate incomplete or inaccurately estimated amounts (Adolf *et al*., 1995; Heseker *et al*., 1994).

b) Nutrition Survey 1998

In conjunction with the Federal Health Survey (BGS) the Robert Koch Institute, Berlin, conducted a Nutrition Survey in 1998. Between October 1997 and March 1998 a nutrition interview was conducted on the basis of the dietary history method in a randomly selected BGS sub-sample of 4,030 people aged between 18-79 (Bellach *et al*., 1998; Mensink *et al*., 1999). The data were, therefore, collected retrospectively and covered the daily course of meals as well as detailed information about eating habits during and between meals.

The foods were recorded using the nutrition interview programme *Dishes-Quest*, which is directly linked to the German Food Code and Nutrient Data Base (BLS) II.3. Sample cutlery was developed to estimate the amounts consumed. The portions recorded were converted into grams using a portion database.

c) Nutrition Report 2000

Random income and consumption sampling (EVS) is carried out on a statutory basis every five years in Germany by the Federal Statistics Office. Here a maximum 0.3% of all German private households are included in a random sample.

To record the food purchasing data a distinction is made between a so-called rough description and a detailed description. In the case of the rough description the participating households only record income and expenditure for a period of 3 months broken down into the categories "foods", "soft drinks", "coffee, tea, alcoholic beverages, tobacco products" and "meals outside the home". By contrast in the detailed description the type, amount and price for foods purchased for home consumption are recorded. The detailed description is broken down into a random sub-sample of 20% over a year, which rotates for a randomly selected month.

This procedure records the total supply of a household. However, no direct conclusions can be drawn about the consumption of individual members in the household even if attempts are made using statistical methods to draw conclusions about individual eating habits.

As the EVS does not record the food losses that occur between purchase and consumption, they can at best be estimated and this means that consumption data of this kind generally lead to an over-estimation of actual consumption. Another disadvantage of EVS is that the time between recording and access to the data is very long. For instance, the nutrient intake data published in the Nutrition Report 2000 are based on the EVS from 1993. In the meantime the Nutrition Report 2004 has been published which drew on the EVS data from 1998.

The strengths of EVS are the large random sampling and the detailed recording programme (DGE, 2000; DGE, 2004).

d) EPIC Study

The EPIC Study (EPIC = European Prospective Investigation into Cancer and Nutrition) is a large-scale prospective study aiming to extend knowledge about the role of nutrition and lifestyle in triggering and preventing cancer and other chronic diseases. The study is being conducted in parallel in nine European countries (Denmark, France, Germany, Greece, Italy, the Netherlands, Spain, Sweden and the United Kingdom). Statistical data on nutrition, lifestyle, environmental factors, body size and -weight as well as blood samples are collected from around 400,000 healthy adults in these countries.

The nutrition survey was conducted with the help of Food Frequency Questionnaires (FFQ) which cover 148 individual foods and also specific questions about the fat content of dairy products or the type of fat used to prepare meals.

Questionnaires from 25,212 participants from Heidelberg and 26,270 participants from Potsdam age? were evaluated. The portion sizes were determined using comparisons of portion sizes or if available using standard portion sizes depicted on photos. The frequency of expected consumption was recorded in 9 categories ranging from "once a month or less" to "five times a day". In one sub-group of the study population a 24-hour recall was also conducted to calibrate the FFQ data (Brandstetter *et al*., 1999).

e) DONALD Study

Some of the consumption studies presented here did also record the eating habits of children and adolescents. However, the DONALD Study (Dortmund Nutritional and Anthropometric Longitudinally Designed Study) is a study which is specifically tailored to the eating habits of these groups.

DONALD is an open cohort study in which 700 healthy children and adolescents are currently actively participating. From infancy up to an age of 18 years data on eating habits are recorded at regular intervals using three-day weighing food diaries. The participants (parents on behalf of young children) weigh all foods and beverages consumed on three consecutive days using digital weighing scales (accuracy: 1 g) made available by the Research Institute of Child Nutrition (FKE). They record the date, time and place of consumption. Foods consumed (on-the-go) and snacks can be estimated using conventional household measures (teaspoon, soup spoon, cup, piece, etc.) stating the type, brand name and recipe if it is not possible to use the weighing scales. In the case of any ready-to-eat products the packaging or labels are collected and attached to the diary. The diaries are collected from the study participants' homes and examined using a questionnaire for plausibility.

All recorded foods are linked up with the Institute's own food database LEBTAB in order to calculate nutrient intake. The nutrient data in LEBTAB are based on the German food composition (Souci, Fachmann, Kraut; BLS) supplemented by data from other national food tables (especially from the United Kingdom, the USA and the Netherlands). Missing nutrient information on new products is determined on the basis of the list of ingredients using simulated recipes. Changes in the composition of commercial foods (e.g. through fortification) are continuously monitored.

The following table gives an overview of the intake of micronutrients by adults in Germany (medians or mean values as well as lowest and highest percentile of intake). Not all studies have determined the entire range of nutrient intake. Some nutrients are not recorded in any of the listed food consumption surveys. For instance in Germany there are no representative data about the intake of vitamin K or the intake of selenium, manganese, chromium or molybdenum.

What is noticeable overall is that the intake data vary depending on the recording method (highly deviating data are indicated in bold). However, between the end of the 1980s (NVS/ VERA) and 2000 (Nutrition Report), no fundamental changes could be observed in nutrient intake of the adult population.

It should be borne in mind that up to now the consumption of fortified foods was not taken into account in any of the studies; their number has increased heavily particularly in recent years.

In November 2005 the recording phase of the second National Food Consumption Study commissioned by the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) began. There are plans to extend this NVS II into a monitoring tool which can be used in future to regularly record representative data about eating habits in Germany.

Table: Comparison of the micronutrient intake data for adults recorded in various food consumption surveys in Germany

Nutrient	National Food Consumption Study[2] (19 - = 65 years.)		VERA Study[3] (19 - = 65 years)		Nutrition Survey 1998[4] (18 – 7 years)		Nutrition Report 2000[5] (19 - = 65 J.)		EPIC Study[6] (35 resp. 40 - 64 years)	
	n = 18,875		n = 1,988		n = 4,030		n = 38,924		n = 4,021	
	Median		Median		Median		Mean values		Median	
	P 2.5 / P97.5		P 2.5 / P97.5		P10 / P90				P10 / P90	
	Men	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**
Retinol equivalent [mg]	0.9 – 1.0	0.8 – 0.9	0.9 – 1.1	0.8 – 1.0	1.7 – 1.9	1.4 – 1.7	1.4 - 1.7	1.1 - 1.5	-	-
	0.3 – 0.8	0.3	0.3 - 0.4	0.3 - 0.4	0.9 - 1.0	0.8 - 1.0			-	-
	3.9 – 4.4	3.7 - 4.0	3.8 - 5.5	3.4 - 4.8	2.9 - 3.3	2.5 - 3.0				
Retinol [mg]	0.6 - 0.7	0.5 - 0.6	0.6 - 0.7	0.5 - 0.6	0.7 - 0.9	0.5 - 0.6	0.9 - 1.2	0.7 - 0.9	0.5 - 0.7	0.4 - 0.5
	0.2	0.2	0.2 - 0.3	0.1 - 0.2	0.3 - 0.4	0.2 - 0.3			0.3	0.2
	3.5 - 4.0	2.8 - 3.7	3.5 - 4.7	2.7 - 3.9	1.7 - 2.0	1.3 - 1.6			1.6 - 2.5	1.1 - 1.3
Beta-carotene [mg]	1.4 - 1.6	1.3 - 1.6	1.2 - 1.7	1.3 - 1.9	**3.4 - 3.9**	**3.7 - 4.3**	2.2 - 2.7	2.1 - 3.5	2.0	1.9 - 2.2
	0.4	0.3 - 0.4	0.3 - 0.5	0.2 - 0.5	1.6 - 2.2	1.6 - 2.2			0.5 - 0.7	0.6
	6.0 - 6.3	6.2 - 6.8	6.0 - 10.6	6.4 - 9.9	7.3 - 8.1	6.9 - 9.5			5.9 - 6.6	7.6 - 8.0

[2] Adolf et al., 1995
[3] Heseker et al., 1994
[4] Mensink et al., 2002
[5] DGE, 2000
[6] Schulze et al., 2001

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	n = 18,875		n = 1,988		n = 4,030		n = 38,924		n = 4,021	
	Median		Median		Median		Mean values		Median	
	P 2.5 / P97.5		P 2.5 / P97.5		P10 / P90				P10 / P90	
	Men	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**
Vitamin D [µg]	3.8 - 4.4	3.0 - 3.4	3.8 - 4.3	2.8 - 3.4	2.6 - 3.0	1.8 - 2.6	4.2 - 6.9	3.7 - 5.5	2 - 2.5	1.5 - 1.7
	1.1 - 1.2	0.8 - 1.0	1.0 - 1.3	0.9 - 1.2	1.2 - 1.4	0.8 - 1.2			0 - 0.8	0.0
	12.0 - 17.8	**10.8 - 15.0**	**10.7 - 18.6**	**9.5 - 10.8**	5.8 - 7.7	3.9 - 6.5			5.9 - 6	4.8 - 5.1
Vitamin E [mg]	13.6 - 14.4	11.5 - 12.0	13.6 - 15.7	12.0 - 12.8	10.3 - 15.3	9.3 - 11.8	12.6 - 14.9	10.7 - 13.2	12.2 - 12.9	9.5 - 10.3
	6.0 - 6.6	5.1 - 5.4	5.9 - 6.9	5.0 - 5.8	6.7 - 8.6	6.1 - 7.2			5.1 - 5.7	4.5 - 4.9
	30.9 - 33.0	25.5 - 27.2	28.1 - **43.8**	24.3 - **43.4**	21.4 - 24.6	19.0 - 27.4			25.2 - 26.1	19.5 - 22.4
Vitamin K	-	-	-	-	-	-	-	-	-	-
	-	-	-	-	-	-			-	-
Vitamin B_1 [mg]	1.3 - 1.5	1.1	1.3 - 1.5	1.0 - 1.1	1.3 - 1.9	1.0 - 1.2	1.4 - 1.6	1.1 -1.3	1.3	0.9 - 1.0
	0.6 - 0.7	0.5 - 0.6	0.7 - 0.8	0.5 - 0.6	1.0 - 1.2	0.7 - 0.8			0.6 - 0.7	0.5
	2.3 - 2.9	2.0 - 2.1	2.0 - 3.0	1.8 - 2.8	2.1 - 3.1	1.6 - 2.1			2.3 - 2.4	1.6 - 1.7
Vitamin B_2 [mg]	1.5 - 1.6	1.3	1.5 - 1.7	1.3 - 1.4	1.7 - 2.3	1.4 - 1.6	1.7 - 1.9	1.4 - 1.7	1.6	1.2 - 1.3
	0.7 - 0.8	0.6 - 0.7	0.8 - 1.0	0.5 - 0.7	1.1 - 1.4	0.9 - 1.1			0.9 - 1.0	0.7 - 0.8
	2.8 - 3.5	2.5 - 2.8	2.3 - 3.6	2.4 - 3.2	2.7 - 4.0	2.4 - 2.8			2.5 - 2.6	2.1

Nutrient	National Food Consumption Study[2] (19 - = 65 years.)		VERA Study[3] (19 - = 65 years)		Nutrition Survey 1998[4] (18 – 7 years)		Nutrition Report 2000[5] (19 - = 65 J.)		EPIC Study[6] (35 resp. 40 - 64 years)	
	n = 18,875		n = 1,988		n = 4,030		n = 38,924		n = 4,021	
	Median		Median		Median		Mean values		Median	
	P 2.5 / P97.5		P 2.5 / P97.5		P10 / P90				P10 / P90	
	Men	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**
Vitamin C [mg]	72 -78	76 - 86	68 - 85	75 - 99	136 - 153	124 - 161	120 - 127	103 - 124	93 - 103	98 - 102
	20 - 22	**20 - 25**	**20 - 23**	**16 - 31**	66 - 76	66 - 83			31 - 34	32 - 55
	228 - 339	226 - 308	206 - 350	231 - 351	266 - 308	251 - 309			256 - 259	257 - 259
Niacin equivalent [mg]	-	-	**-**	-	32.7 - 43.1	25.1 - 29.8	35.0 - 41.5	26.1 - 35.0	33.8 - 34.0	23.2 - 24.5
	-	-	**-**	-	21.6 - 30.1	17.1 - 22.0			20.4 - 21.0	14.6
					49.7 - 67.7	37.4 - 43.9			55.4 - 56.0	36.8 - 39.3
Vitamin B_6 [mg]	1.7 - 1.8	1.3 - 1.4	1.7 - 1.9	1.3 - 1.5	1.9 - 2.5	1.6 - 1.8	1.8 - 2.1	1.4 - 1.8	1.7 - 1.8	1.3
	0.9 - 1.0	0.6 - 0.8	0.9 - 1.1	0.6 - 0.8	1.3 - 1.6	1.1 - 1.2			1.0 - 1.1	0.7
	3.0 - 3.4	2.5 - 2.7	2.7 - 4.6	2.6 - 3.9	2.9 - 4.1	2.3 - 2.9			2.8 - 2.9	2.2
Folate equivalent [µg]	256 - 269	219 - 231	190 - 218	158 - 174	260 - 312	217 - 260	236 - 280	206 - 254	226 - 229	183 - 197
	123 - 209	98 - 106	-	-	170 - 201	151 - 172			125 - 134	99 - 110
	558 - 683	488 - 544			418 - 496	355 - 439			350 - 376	312 - 352

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Nutrient	National Food Consumption Study[2] (19 - = 65 years.)		VERA Study[3] (19 - = 65 years)		Nutrition Survey 1998[4] (18 – 7 years)		Nutrition Report 2000[5] (19 - = 65 J.)		EPIC Study[6] (35 resp. 40 - 64 years)	
	n = 18,875		n = 1,988		n = 4,030		n = 38,924		n = 4,021	
	Median		Median		Median		Mean values		Median	
	P 2.5 P97.5		P 2.5 P97.5		P10 P90				P10 P90	
	Men	Women	Men	Women	Men	Women	Men	Women	Men	Women
Pantothenic acid [mg]	-[7]	-[1]	-[1]	-[1]	5.4 - 7.4	4.4 - 5.2	5.1 - 6.0	4.2 - 5.2	-	-
	-[1]	-[1]	-[1]	-[1]	3.6 - 4.6 8.6 - 12.4	3.0 - 3.5 7.1 - 8.8			-	-
Biotin [µg]	-[1]	-[1]	-[1]	-[1]	42.9 - 61.9	37.3 - 43.6	47.0 – 51.8	38.3 - 45.8	-	-
	-[1]	-[1]	-[1]	-[1]	27.6 -35.9 69.7 - 101.3	24.3 - 28.7 55.2 - 74.8			-	-
Vitamin B_{12} [µg]	5.8 - 6.5	4.2 - 4.7	5.5 - 6.6	4.0 - 4.7	6.1 - 8.0	4.2 - 5.1	6.5 - 7.7	4.7 - 6.1	5 - 6	4
	2.4 - 2.7 16.9 - 21.4	1.5 - 1.9 13.4 - 18.2	2.6 - 2.8 14.9 - 22.6	1.5 - 1.8 11.7 - 19.0	3.6 - 4.4 11.1 - 14.1	1.9 - 3.0 8.2 - 9.7			2 - 3 13	1 9
Sodium [g]	3.4 - 3.7	2.7 - 2.8	3.4 - 3.7	2.6 - 2.9	2.9 - 3.8	2.3 - 2.6	3.3 - 3.6	2.7 - 3.1	-	-
	1.6 - 1.8 6.5 - 6.8	1.2 - 1.4 4.7 - 5.4	1.7 - 2.2 5.7 - 6.6	1.1 - 1.5 4.4 - 5.0	1.9 - 2.6 4.1 - 6.0	1.5 - 1.9 3.2 - 3.7			-	-

[7] These data are not included in the NVS on the grounds that the details of amounts in the BLS are incomplete or unreliable.

Nutrient	National Food Consumption Study[2] (19 - = 65 years.)		VERA Study[3] (19 - = 65 years)		Nutrition Survey 1998[4] (18 – 7 years)		Nutrition Report 2000[5] (19 - = 65 J.)		EPIC Study[6] (35 resp. 40 - 64 years)	
	n = 18,875		n = 1,988		n = 4,030		n = 38,924		n = 4,021	
	Median P 2.5 P97.5		Median P 2.5 P97.5		Median P10 P90		Mean values		Median P10 P90	
	Men	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**
Chloride [g]	5.2 - 5.6	3.9 - 4.2	5.2 - 5.7	3.9 - 4.3	-	-	-	-	-	-
	2.6 - 2.8 9.9 - 10.0	1.9 - 2.0 6.9 - 7.9	2.4 - 3.4 8.3 - 11.0	1.8 - 2.2 6.8 - 7.5	-	-			-	-
Potassium [g]	3.2 - 3.3	2.7 - 2.8	3.1 - 3.4	2.8 - 2.9	3.4 - 4.3	2.9 - 3.3	3.3 - 4.0	2.7 - 3.6	3.2	2.7 - 2.8
	1.7 - 1.8 5.0 - 5.9	1.4 - 1.6 4.5 - 4.6	1.7 - 2.0 5.3 - 5.8	1.3 - 1.6 4.5 - 4.8	2.4 - 2.8 4.7 - 6.7	2.1 - 2.3 4.0 - 4.6			1.9 - 2.1 4.8	1.7 4.0 - 4.1
Calcium [mg]	677 - 808	621 - 690	674 - 937	661 - 719	949 - 1.395	972.5 - 1.129	855 - 953	781 -891	689	633 -777
	291 - 318 1.476 - 2.035	233 -297 1.245 - 1.414	291 - 348 1.271 - 2.043	253 - 333 1.295 - 1.743	591 - 790 1.567 - 2.549	586 - 724 1.667 - 1.790			334 - 369 1.330	287 - 385 1.225 - 1.396
Phosphorus [g]	1.4 - 1.6	1.2	1.4 - 1.6	1.2	-	-	1.4 - 1.5	1.1 - 1.4	1.3 - 1.4	1.0 - 1.1
	0.7 - 0.8 2.3 - 2.8	0.6 1.9 - 2.0	0.8 - 0.9 2.2 - 2.9	0.6 1.9 - 2.0	-	-			0.8 2.0 - 2.1	0.6 - 0.7 1.6 - 1.7

Nutrient	National Food Consumption Study[2] (19 - = 65 years.)		VERA Study[3] (19 - = 65 years)		Nutrition Survey 1998[4] (18 – 7 years)		Nutrition Report 2000[5] (19 - = 65 J.)		EPIC Study[6] (35 resp. 40 - 64 years)	
	n = 18,875		n = 1,988		n = 4,030		n = 38,924		n = 4,021	
	Median P 2.5 P97.5		Median P 2.5 P97.5		Median P10 P90		Mean values		Median P10 P90	
	Men	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**
Magnesium [mg]	341 - 367	282 - 288	350 - 404	289 - 311	403 - 554	362 - 419			349 - 368	279 - 300
	190 - 202	146 - 168	193 - 232	142 - 167	296 - 371	265 - 302	392 - 454	322 - 405	228 - 241	173 - 190
	580 - 704	475 - 525	522 - 680	468 - 529	583 - 813	539 - 605			532 -558	404 - 450
Iron [mg]	15.1 - 15.8	12.2 - 13.0	15.3 - 16.2	12.6 - 13.7	14.2 - 19.0	11.3 - 13.8			13.4 - 14.1	11.0 - 11.6
	8.0 - 8.7	6.3 - 7.6	7.5 - 9.1	5.6 - 7.9	10.2 - 11.8	8.8 - 10.0	14.4 - 16.8	12.4 - 15.3	8.4 - 8.7	6.9 - 7.2
	25.2 - 27.5	21.8 - 22.9	23.7 - 31.4	20.6 - 22.8	20.6 - 27.4	16.0 - 20.1			21.6 - 22.1	17.2 - 18.0
Iodine [µg]	105 - 118	99 - 114	123 - 134	100 - 129	-	-			-	-
	39 - 44	33 - 40	38 - 45	31 - 42	-	-	94.3 - 112.7	75.8 - 101.1	-	-
	331 - 369	284 - 345	362 - 448	282 - 398						
Fluoride [µg]	-	-	-	-	-	-			-	-
	-	-	-	-	-	-	635.9 - 726.5	557.0 - 643.5	-	-
Zinc [mg]	11.1 - 12.5	9.4 - 9.7	11.0 - 12.9	9.5 - 10.0	-	-			11.2 - 12.0	8.5 - 9.7
	5.9 - 6.8	4.8 - 5.4	6.2 - 7.2	4.8 - 5.3	-	-	10.9 - 12.6	9.1 - 11.0	7.0 - 7.4	5.5 - 6.1
	18.5 - 21.8	16.0 - 16.2	16.2 - 23.6	14.8 - 16.5					18.3 - 18.8	13.3 - 15.0

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Nutrient	National Food Consumption Study[2] (19 - = 65 years.)		VERA Study[3] (19 - = 65 years)		Nutrition Survey 1998[4] (18 – 7 years)		Nutrition Report 2000[5] (19 - = 65 J.)		EPIC Study[6] (35 resp. 40 - 64 years)	
	n = 18,875		n = 1,988		n = 4,030		n = 38,924		n = 4,021	
	Median		Median		Median		Mean values		Median	
	P 2.5 / P97.5		P 2.5 / P97.5		P10 / P90				P10 / P90	
	Men	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**	**Men**	**Women**
Selenium [µg]	-	-	-	-	-	-			-	-
	-	-	-	-	-	-			-	-
Copper [mg]	2.0 - 2.3	1.7 - 1.8	2.1 - 2.4	1.8 - 1.9	-	-	2.5 - 3.1	2.1 - 2.8	-	-
	1.1 - 1.2 3.4 - 4.3	0.9 3.1 - 3.5	1.1 - 1.5 3.0 - 5.0	0.8 - 1.0 3.0 - 3.6	-	-			-	-
Manganese [mg]	-	-	-	-	-	-	4.7 - 5.5	4.2 - 5.1	-	-
	-	-	-	-	-	-			-	-
Chromium [µg]	-	-	-	-	-	-			-	-
	-	-	-	-	-	-			-	-
Molybdenum [µg]	-	-	-	-	-	-			-	-
	-	-	-	-	-	-			-	-

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?

In the past nutrition surveys have been conducted in most European countries. However, the quality of the available data varies considerably which means that it is not possible to directly compare the consumption and nutrient intake data available on the national levels or to draw overall conclusions about the situation in Europe. This applies both to the group of adults (SCOOP Task 7.1.1 Working Group, 1997; Elmadfa and Weichselbaum, 2005), as well as to surveys which have specifically examined the nutritional situation of children and adolescents (Lambert *et al*., 2004).

There are major differences between the studies with respect to the period covered and its length, the population or population groups examined, the breakdown into age groups, the selection of portion sizes and the recording method itself. The food composition databases used also vary considerably in terms of quality.

At present there are two European projects which provide comparable consumption data: EPIC (nutrition and cancer) and DAFNE (food consumption in the household).

In order to facilitate comparisons of countries on the level of nutrient intake, work has begun within the EPIC Study on building up a joint food database, the European Nutrient Database (ENDB). Aside from this the EuroFIR Project aims to set up a joint food database. The project was launched in January 2005 and is to run initially up to December 2009.

The report of the EFCOSUM Group "European food Consumption Survey Method" (EFCOSUM-Group, 2001) gives an overview of the food consumption surveys conducted up to now in Europe and makes proposals for the ex post harmonisation of intake data from 15 countries.

As food supplements and fortified foods must be composed in such a way that they are safe for the entire European population, it is proposed that a maximum amount which is justifiable from the nutritional-physiological and toxicological angle be set on the basis of the respectively lowest and highest recorded nutrient intake in the lower and upper intake percentiles from all food consumption surveys available in Europe.

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

The vitamin and mineral intake of children and adolescents from conventional diets should be taken into account in order to estimate whether these groups may suffer deficiencies in respect of specific nutrients or in which cases the additional intake of food supplements and the consumption of fortified foods would lead to high, possibly adverse intake levels. The same applies to other sensitive groups in the population like pregnant women, breastfeeding women and old people.

All the same we do not believe that a special presentation of age specific or target group specific food supplements with varying doses is a suitable consumer protection measure. A highly differentiated spectrum of age-specific products with different doses would render the market intransparent and probably only confuse consumers.

In the opinion of BfR maximum nutrient amounts must be set in such a way that the taking of supplements or the consumption of fortified foods even by sensitive groups in the population does not lead to undesirably high intakes of the nutrients concerned.

Reference values for vitamins and minerals

7. Taking into account all the above-mentioned considerations in the discussion document, how far should recommended intakes based on the concept of PRIs (Population Reference Intakes) or RDAs (Recommended Daily Allowances) be taken into account when setting maximum levels for vitamins and minerals?

When setting maximum amounts of vitamins and minerals the recommended intakes based on the concept of the Population Reference Intakes (PRIs) and Recommended Daily Allowances (RDAs) should be taken into account. This would allow risks of deficiency in the population or specific population groups to be taken into account. A careful risk assessment is necessary in individual cases particularly for nutrients for which the margin between recommended intake and the amounts above which health risks cannot be excluded or are liable to occur (e.g. vitamin A).

Minimum amounts

8. Should the minimum amount of a vitamin or a mineral in the 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?

Up to now information in accordance with Article 3 or Article 4 para 3 in conjunction with the annex to Directive 90/496/EEC may only be provided when these vitamins/minerals are present in significant amounts, i.e. when their content "as a rule" is 15% of the daily dose listed in the Annex per 100 g or ml Only for packs containing one single portion may this value appear on the pack. This minimum amount is too high for individual food groups. For instance a 1 litre bottle of a beverage would have to contain 150% of the recommended daily intake; this corresponds to 30% in a 200 ml glass. On the other hand, the reference sizes (100 g, 100 ml, portion) lead to scarcely justifiable distortions from the nutritional-physiological angle. Full-fat milk (3.5% fat) for instance contains on average 0.18 mg vitamin B_2 per 100 ml; this corresponds to 11% of the recommended daily intake of riboflavin. Vitamin B_2 or riboflavin cannot be declared although milk, because of the normally high daily intake, is an important source of riboflavin in diet. By contrast riboflavin may be declared in a sandwich spread which has been fortified with 0.24 mg vitamin B_2 per 100 g although the normal portion of 20 g only contains 0.05 mg vitamin B_2 i.e. 3% of the recommended daily intake.

BfR, therefore, supports the recommendation of the Food Chemistry Society to reformulate Article 6 para 2, "Information is given for 100 g or 100 ml. When portions are indicated the information refers instead to one portion" (GDCh, 2003).

Justification:

Different options for information are important because there are a number of products for which a clear reference to a portion is not possible (e.g. dried ready-to-eat dishes for 2-3 portions or ready-made ingredients used as preparation aids for variable meal preparations). In other cases, however, the reference to portions could be helpful.

In the case of products which can only be eaten after preparation like for instance powders or tablets for the preparation of beverages or powdered products for the preparation of potato dumplings, the labelling should refer to 100ml/100g of the ready-to-eat product or to the concrete portion if indicated.

Justification:

The consumer would have to convert the data relating to the non-ready-to-eat products in order to determine what amount of nutrients he is actually consuming. The percentage indication of micronutrients would be completely distorted and could be well over 100% of daily requirements for instance in the case of vitaminised basic substances for beverages (see also GDCh, 2003).

The nutrient labelling of foods should enable the consumer to compare the nutrient content of different foods and where appropriate to consciously choose products. The Codex guidelines for nutrient labelling (CAC/GL 2-1985; Rev1-1993) also envisage there being no declaration of nutrients in the case of vitamins and minerals whose content in 100 g, 100 ml or portion is less than 5% of the reference intake. In the case of specific foods or categories of foods BfR can also – on this basis – support the labelling of lower contents than 15% of the reference intake.

9. Should minimum amounts of vitamins and minerals and 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 "significant" minimum amounts of vitamins and minerals (15% of the reference intake) should be referred to the daily portion. The same provision is contained in the Codex guidelines for food supplements (ALINORM 05/28/26, Appendix II, level 8). The consumer rightly expects that a food supplement makes a significant contribution to his diet.

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