

**Position of the BLL of 18 August 2006
regarding the discussion paper of the European Commission:**

**"Discussion paper on the setting of maximum and minimum amounts
for vitamins and minerals in foodstuffs" (June 2006)**

I. General remark

Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, and the Council common position for adopting a regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods, call for setting of standards for maximum levels of vitamins and minerals that may be added to food supplements and to fortified foods.

Such maximum levels are to be established in order to fulfill the aims of ensuring the free movement of goods and of protecting consumers from adverse effects on health. The standards for maximum levels are to ensure that products are safe when used normally.

The BLL welcomes the European Commission's decision to request opinions regarding the basic approach that should be taken in deriving maximum levels. For this reason, the BLL is pleased to take the opportunity to communicate the position of the German food sector.

In general, the German food sector especially approves of the principles and strategies mentioned by the European Commission in numbers 21 and 22:

- Safety
- Proportionality
- Avoidance of undue constraints on business
- The Lisbon Strategy.

In addition, the German food sector welcomes the clear separation established between risk assessment (EFSA) and risk management (Commission).

The following remarks respond to the European Commission's questions, from the perspective of the German food sector.

II. Answers to the Commission's questions

Where there are not yet 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?

Some background:

The EFSA has not derived any UL for the following nutrients:

- Thiamine, riboflavin, biotin
- Vitamin K, vitamin B₁₂, chromium
- Pantothenic acid
- Iron, manganese, beta-carotene, vitamin C, sodium, potassium, chloride, phosphorus.

The U.S. Food and Nutrition Board (FNB) has also not derived any UL for the aforementioned nutrients, with the exception of iron, manganese and vitamin C.

The EFSA has thus not derived a UL in all cases. Significantly, the reasons why a UL is lacking vary from case to case, and thus the BLL maintains that a **differentiated approach** is necessary in answering the question:

- For some nutrients, no adverse effects were identified (thiamine, riboflavin, biotin)
- For other nutrients, not enough data is available to permit derivation of a UL. At the same time, no adverse effects have been observed in connection with certain amounts far in excess of the usual intake levels (vitamin K 10 mg, vitamin B₁₂ 1-5 mg, chromium 1 mg)
- For gram doses of pantothenic acid, adverse effects are thought to be possible, but not enough data was available for UL derivation
- For manganese, beta-carotene, vitamin C, sodium, potassium, chloride, phosphorus and iron, adverse effects have been identified, but the EFSA maintains that the available data with regard to dose-impacts relationships is not adequate for UL derivation.

The decisive aspect with regard to further steps is that neither Directive 2002/46/EC, nor the proposal for fortification, refers exclusively and expressly to the EFSA's ULs; instead, both refer to "upper safe levels of ... vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data".

In the BLL's view, this means that

- The EFSA's expert opinions are relevant even for cases in which no UL has been derived. The reasons are that its expert opinions often contain references to safe levels (see above) and provide indications regarding the nature/intensity of the adverse effects. They thus provide a qualitative basis for a suitable approach. For some nutrients, therefore, no UL need be derived – either because no adverse effects have been identified (**thiamine, riboflavin, biotin**) or because such effects occur only at doses far in excess of those obtained via food (including fortified foods and food supplements) (**vitamin K, vitamin B₁₂, chromium, pantothenic acid**).
- In cases in which adverse effects were identified, the UL of other scientific bodies¹ may be used:
 - **Iron** UL (FNB) = 45 mg
 - **Manganese** UL (FNB) = 11 mg
 - **Vitamin C** UL (FNB) = 2000 mg

In the case of **beta-carotene**, neither the FNB nor the SCF has established a UL; at the same time, these bodies' risk assessments point to relevant adverse effects that necessitate risk management measures: two intervention studies carried out in the 1990s (ATBC, CARET) showed that long-term heavy smokers (at least 20 cigarettes/day for more than 30 years) had a higher lung cancer risk than the placebo groups when given high doses of beta-carotene (20 or 30 mg).

Consequently, in 2001 the German food sector companies represented by the BLL offered to impose a voluntary self-restriction: not to add more than 2 mg of isolated beta-carotene per 100 ml of beverages. Food supplements for which the recommended dose levels deliver more than 4.8 mg of isolated beta-carotene are labelled with a warning to the effect that the product is not suited for heavy smokers or that the product should not be taken for prolonged periods of time (BLL, 2001).

The German food sector proposes that this approach also be used in the pending regulation. In addition, a model calculation based on intake data has shown that the amounts in question do not pose risks for any consumer groups – even smokers (BLL, 2006, Internet: www.bll.de/themen/anreicherung).

¹ For a comparative discussion of derived ULs and of identified adverse effects, see Annex 1 of Annex 3 of the following report: FAO/WHO (2006): A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment. Geneva, 2-6 May 2005 (http://www.who.int/ipcs/highlights/full_report.pdf).

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?

No, in general it may be questioned whether it is at all necessary to set maximum levels for nutrients for which no adverse effects have been observed, and for which sufficient data have been obtained; after all, the recitals of Directive 2002/46/EC and of the proposal on fortification are aimed at protecting consumers against adverse effects. Furthermore, recital 13 of the Directive, and recital 14 of the Council common position for adopting a regulation on fortification note that maximum and minimum levels are not planned for all nutrients per se (levels are to be set "as the case may be").

For the same reason, it does not seem absolutely necessary to derive daily maximum levels for – and, thus, to apply a relevant formula to – nutrients for which the SCF / the EFSA have observed no adverse effects even at very high doses far in excess of current consumption levels and of levels currently found in fortified foods and in food supplements.

The BLL thus maintains and that no maximum levels need be set for the following nutrients:

- Thiamine, riboflavin and biotin
- Chromium, vitamin K, pantothenic acid and vitamin B₁₂.

Where we set maximum levels, do we inevitably also have to set maximum levels 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?

Food supplements and fortified foods both play an important role in ensuring that diets include essential nutrients. Therefore, the nutrients listed in the annexes to the regulation on fortification and the food supplements directive should normally be available for both of these food categories. Furthermore, it is vital that both categories be treated in keeping with the principle of safety.

Fortified foods and food supplements differ in a number of ways:

Food supplements are consumed solely because of the specific nutrients they contain. Fortified foods, on the other hand, are chosen and consumed also for reasons of taste and enjoyment. Labelling for food supplements must include a recommended daily allowance and the obligatory warnings to the effect that the stated recommended daily dose should not be exceeded and that products should be stored out of the reach of young children

(Article 6 of Directive 2002/46/EC). It is also important to note that the markets in question differ at present: food supplements normally contain higher levels of nutrients per serving than do fortified foods. What is more, levels of nutrients typically obtained via fortified foods tend to differ from the corresponding levels obtained via food supplements. Such differences should be taken into account, where applicable, in derivation of maximum levels.

Another important point to be made before the Commission's question can be answered is that the risks of excessive nutrient intake differ from nutrient to nutrient: for some nutrients, no such risks have been identified to date. For others, mild and reversible risks apply (for example, flatulence in the case of vitamin C), and for still others the risks can be serious and lasting (for example, excessive vitamin A intake in pregnant women can be harmful to unborn children).

Consequently, in derivation of maximum levels – especially for those critical nutrients for which excessive intake poses risks of permanent damage – it could be appropriate to use different risk management strategies for a) food supplements and b) fortified foods.

Significantly, the market is not at all likely to be "flooded" with fortified foods and food supplements. Even after the Regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods enters into force, the share of food products that are fortified will not increase significantly. This is indicated, for example, by the fact that in Germany many types of options for fortification are not being made use of. The reasons for this include:

- technological challenges (stability, shelf life)
- changes in taste, smell, appearance, etc., and
- cost aspects.

Data from the UK – a highly liberalised market – show that intake of nutrients from all foods, including fortified foods, and compared to data from nutrition studies of 1986/1987 and 2000/2001, increased relevantly (> 20%) in only two cases: that of vitamin C and that of vitamin B₆ (UK Office for National Statistics, 2003). A model calculation carried out by Godfrey et al., for various Member States, revealed: "Significant consumption of fortified foods by high level consumers is limited to foods where vitamins are used to restore those lost in processing, such as milk and bread. Excluding those foods, a consumer could have a theoretical diet that comprised up to 10 % fortified foods. However, this is unlikely to be achieved in practice because it would require a consumer to consistently select foods that were fortified from a group of foods that included a wide range of brands and varieties. In reality, the majority of high level food consumers are unlikely to obtain more than 4 % of their diet from fortified food" (Godfrey et al, 2004).

Representative nutrition data on daily consumption, in Germany, of a single nutrient from more than one food supplement also show that multiple exposition from the food-supplements product group is normally overestimated: only a small percentage of the

population consumes multiple supplements, on a daily basis, that contain the same nutrient (Beitz et al., 2004). Such multiple exposition, which was highest for vitamins C and E, was still quite low: 0.5 % of the population take two or more daily supplements that contain vitamin C and/or vitamin E; for magnesium, the corresponding percentage is 0.4 %. No use of more than 3 supplements was reported.

It is also important to note that neither food supplements nor fortified foods always contain the highest possible nutrient levels that they could contain; they contain the levels that represent the most efficient combination in terms of cost, demand and technology criteria.

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.

No EU-wide, representative data on all of the nutrients listed in the annexes of the Directive and of the proposed ordinance on fortification are available that meet both of the following criteria:

- are differentiated by sources (foods, fortified foods, food supplements), and
- include information about intake distribution throughout the population (for example, 90th/95th/97.5th percentile).

It is proposed that such issues be included in the **Seventh Framework Programme for Research and Technological Development** (2007 – 2013).

The following surveys, inter alia, are available for Germany:

Representative surveys:

Dietary survey in the framework of the German National Health Interview and Examination Survey (GNHIES, Bundesgesundheitsurvey) of the Robert Koch Institute (1991 and 1998; for 1998, including intake of food supplements, and information on multiple intake of nutrients via consumption of food supplements)

In addition: the first national nutrition survey (NVS, 1985 – 1988; for western Germany)

Regional surveys:

- Bavarian nutrition survey (representative for Bavaria)
- Nutrition survey for Saxony (representative for Saxony)
- DONALD (Dortmund Nutritional and Anthropometric Longitudinally Designed Study; not representative; carried out in Dortmund, with a focus on children, including information on food supplements)

Multicentric (European) studies:

- MONICA (Heidelberg, including intake from food supplements)
- EPIC (Berlin/Potsdam)

Model calculations on the basis of market surveys

- AFG-V: intake of beta-carotene from non-alcoholic beverages

While first national nutrition survey (NVS) provides information about intake of vitamins and minerals from traditional foods, it is considerably outdated. The nutrition survey of the Robert Koch Institut, which is more recent, also contains representative information about intake of food supplements (Mensink, 2002) and about multiple intake of nutrients from food supplements (Beitz et al., 2004). In addition, a range of representative data is available for certain regions of Germany (Bavarian nutrition survey, nutrition survey for Saxony).

Representative data on food fortification in Germany are lacking. On the other hand, data are available on intake of food supplements and food supplements by children and young people living in Dortmund; these data were obtained in the framework of the DONALD study (Sichert-Hellert). Representative data on intake of vitamins and minerals by children and adolescents, in Germany, are expected to be provided by mid-2007 in the "Eskimo module" of the Robert Koch Institut's survey of children and adolescents (KIGGS).

In addition, the following multicentric studies provide information about intake of vitamins and minerals in specific regions of Germany, as well as – and this is a major advantage of these studies – about intake in other regions of Europe: EPIC (European Prospective Investigation into Cancer) and MONICA (Monitoring of Trends and Determinants in Cardiovascular Disease), a somewhat older study.

Furthermore, data are available on intake, in Germany, of beta-carotene from non-alcoholic beverages – the product group of greatest importance with regard to intake of beta-carotene in fortified foods (AGV-V).

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?

Yes, representative data from individual Member States should be used and compiled for this purpose. ILSI compiled the highest-level intake data available (90th, 95th or 97.5th percentile) from the various Member States, for the group "adult men" (who tend to have higher intake levels than do women and children) and used this data to obtain an average highest intake (Flynn et al, 2005). This approach is welcomed. Member States that express concerns to the effect that consumption patterns within their own territories differ significantly from the compiled data should substantiate their concerns with

reliable data. Significantly, a recently published study of differences and similarities in dietary patterns in Europe, conducted on the basis of the DAFNE database, indicates that eating patterns point towards a progressive narrowing of dietary differences between North and South European (Naska, et al., 2006).

The need for nutrition data obtained as a result of compliance with regulatory requirements indicates that joint pan-European surveys of nutrition data would be of great usefulness. Within the framework of the Seventh Framework Programme, efforts should be made to have such studies carried out.

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

The use of data from different population groups is problematic especially with regard to defining relevant groups (children, senior citizens, pregnant women, nursing women?) and to delimiting these groups (by age?). In addition, data availability plays a significant role (are representative data available in the various countries concerned?) as well as, ultimately, the issue of what sort of marketing is concerned.

Since adults may be assumed to have higher intake levels than children or senior citizens, it is proposed that this group of persons be chosen as the reference group for setting of maximum levels for intake of vitamins and minerals.

Furthermore, it must be remembered that foods intended for nursing babies and small children are already subject to regulations for foods intended for particular nutritional uses. Finally, labels of food supplements include warnings to the effect that the supplements are to be kept out of the reach of children.

Reference levels for nutrient intake

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 levels for nutrient intake may be taken into account in two ways in derivation of maximum levels of vitamins and minerals.

Firstly, they may be used as a contribution to **assessment of safety**: Where the quotient $[(UL - \text{intake}) / \text{reference level}]$ for relevant nutrient intake is high, the risk of exceeding the UL is low. If the quotient is small, the risk is higher, however. This procedure can be

used to divide nutrients into different categories. By way of example, the reader is referred to the ERNA risk management model.

Secondly, a special aspect of assessment of the risks connected with nutrients is that a risk of "too little" also exists, in addition to the risk of "too much"; i.e. there is a risk of **insufficient intake**. Reference levels can help minimise this risk. While the general population's average intake levels are certainly adequate for many nutrients, average intake levels are not suitable for identifying population groups that would benefit especially from supplementation. For example, a majority of the German population does not attain the reference intake levels for some nutrients (for example, about 90% of all women do not attain these levels for vitamin D and folic acid, over half of the population do not attain them for vitamin E and about one-fourth of the population do not attain them for calcium; cf. Mensink, 2002). Furthermore, specific population segments, in special life situations, can profit from specific types of fortification or supplementation (DGE, 2004).

In the opinion of the BLL, therefore, the reference levels may only be used in terms of safety. A standard orientation for setting maximum levels is not acceptable. Attention is called to relevant rulings of the European Court of Justice (Case C-387/99, Case C-192/01). Furthermore, the discussions within the framework of CCNFSDU has to be born in mind. At the November 2004 meeting, the committee expressed the position that orientation to reference levels must not lead to basing of most maximum levels on the reference levels (Alinorm 05/28/26).

Minimum amounts

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 minimum amount and the significant amount should be identical. Setting of various different minimum amounts for certain nutrients and certain food categories should not be laid down.

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?

Minimum amounts of vitamins and minerals in food supplements should be oriented to the manufacturer's recommended doses. In 2005, in the framework of the "Guidelines for Vitamin and Mineral Supplements" (CAC/GL 55-2005) the Codex Alimentarius adopted 15 % of the RDA as the minimum amount per recommended daily dose. German manufacturers of food supplements propose that this value also be used for relevant European regulation.

III. Specific remarks concerning the models mentioned in the Annexes:

1) The BfR's proposals relative to the derivation of maximum levels of vitamins and minerals added to foods based on risk assessment

In January 2005, the Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung - BfR) presented proposals for derivation of maximum levels of vitamins and minerals. These proposals are to be understood as a basis for discussion and as an aid in making decisions relative to determination of maximum levels of relevant substances in food supplements and fortified foods. The relevant dossiers identify options for action and describe the advantages and disadvantages of each option.

In the introductory section, a risk management model for calculation of maximum levels is presented: The quantity of a relevant nutrient ingested via food is subtracted from the Tolerable Upper Intake Level (UL). The difference is divided by 2 or 4 ("MEF"), a factor is intended as a way of accounting for simultaneous use of fortified foods and / or food supplements that contain the same nutrient ("multiexposition").

In principle, the German food industry welcomes this model – with the exception of its use of a general and arbitrary multiexposition factor - since it is in keeping with the principle of safety as set forth in the relevant legal provisions.

The main section of the paper then provides a risk assessment for each nutrient in question. Still, the BfR's proposed model is seldom used in derivation of maximum levels of the various vitamins and minerals. Only in a few cases (for example, for vitamin D, vitamin B₆, folic acid, vitamin C, potassium, zinc, magnesium) is the model used to calculate maximum levels for food supplements. And in only three of these cases (vitamin B₆, potassium and zinc) is the level calculated using the formula also the BfR's preferred option for the maximum level. What is more, the UL for potassium is a value derived by the BfR for supplements. In no instance is the model used to calculate maximum levels for fortified foods.

The BfR's recommendations thus represent the restrictive option among the available options for action; in the main, the recommendations are not based on the model but on considerations from nutritional physiology, and in many cases they are oriented to existing recommendations.

With regard to fortification, in many cases the recommendations specify that certain nutrients – such as beta-carotene or calcium – should not be added at all (except in a few isolated applications). The recommendations thus cover nutrients that to date have been approved for fortification. With regard to food supplements, "zero" levels are recommended for iron, fluoride, copper and manganese; in other cases, the recommendations call for levels below existing customary levels (for example, 2.25 mg for zinc, 15 mg for vitamin E).

From the perspective of the BLL, the reasons advanced by the BfR for rejecting the model are not always clear:

- **BfR: The ULs of the European Food Safety Authority (EFSA) are lacking.**
The BLL maintains that a lack of EFSA ULs cannot automatically justify proposals for restrictive levels – such as 4.8 mg for thiamine, 4.5 mg for riboflavin or 180 µg for biotin. The reason for this is that Directive 2002/46/EC does not expressly refer to the EFSA's ULs; instead, it refers to "upper safe levels of vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data". In cases, for example, in which the EFSA concludes that no disadvantageous effects have been identified even for high doses (as, for example, with thiamine, riboflavin and biotin), the industry maintains that no maximum levels need be defined and, therefore, that the proposed BfR model need not be rejected (cf. also the recitals in Directive 2002/46/EC and in the common position on fortification). On the other hand, the EFSA assessments also include references to the strength and reversibility of identified disadvantageous effects of other nutrients, and thus they contain bases for risk management. In the cases of vitamin C, iron and manganese, the Food and Nutrition Board (FNB) has derived ULs that can be included in a model.
- **BfR: The model cannot be applied because inadequate intake data are available.**
A general factor of "2" is used to compensate for a lack of data on multiple intake of food supplements. The findings of GNHIES published in 2004 indicate that levels of daily multiple intake of food supplements are generally low in Germany, however – the highest such levels are seen with regard to vitamins C and E and magnesium: 0.5 and 0.4 % of the population, respectively. The data cannot be used to justify non-differentiated application of a multi-exposition factor of 2 for food supplements, for all vitamins and minerals. What is more, the assumption that significant groups of consumers, on a daily basis and for prolonged periods, i.e. on a chronic basis, take 2 food supplements and 2 fortified foods, in addition to their "normal diets", that all contain the same nutrient (such as vitamin E), is rather unrealistic. As a result, the BfR's proposed multi-exposition factor of 4 exceeds the requirements arising from precautionary principle.

- **BfR: The therapeutic dose is exceeded when the model is applied.**
With regard to the relevant legal basis, the BLL maintains that safety must be the decisive criterion for defining maximum levels – and not the exceeding of an (assumed) therapeutic dose. Within certain ranges, some products can be both food supplements and medications – and such possibilities depend on the usage intended by the manufacturer, so also the European Court of Justice (Decision of June, 9 2005, no 63)

- **The BfR has reservations concerning the UL of the SCF and the EFSA (iodine, vitamin E).**
If the occasion for reassessment of a given nutrient should arise, then relevant consensus should be sought at the European level.

- **BfR: The levels resulting from the model are not linked to any benefits.**
Justifications for low levels, in cases in which no serious risks of disadvantageous effects exist at higher levels, do not stand up to legal review. Safety is the deciding criterion in derivation of maximum levels.

On the other hand, reference levels of nutrient intake certainly can play a useful role: Where the quotient $(UL - \text{intake}) / \text{reference level}$ for relevant nutrient intake is high, the risk of exceeding the UL is low. If the quotient is small, the risk is higher, however. By way of example, the reader is referred to the ERNA risk-management model.

These considerations also make it easier to identify risks of inadequate intake. One of the special aspects of assessment of the risks of nutrients is that the risk of "too much" can co-exist with the risk of "too little". It is true that deficiency disorders, i.e. clinically relevant disorders with characteristic deficiency symptoms, do not occur frequently in Germany (DGE, 2004). At the same time, GNHIES found that large segments of the population do not attain the reference levels for intake of certain nutrients (this is the case, for example, for about 90% of all women with regard to vitamin D and folic acid, for half of the population with regard to vitamin E and for about one-fourth with regard to calcium; Mensink, 2002). Furthermore, specific population segments, in special life situations, can profit from specific types of fortification or supplementation (DGE, 2004).

- **BfR: In the case of vitamin C, the model cannot be applied because the FNB failed to take account of groups of patients with rare primary hyperoxaluria, of patients with chronic intestinal disorders such as M. Crohn and of patients with extensive intestinal resections.**

The BLL maintains that these groups do not have to be taken into account in derivation of maximum levels. On the one hand, clinical studies to date have not found any actual risks for these groups. On the other hand – and this is of relevance for risk management – such persons are normally in a doctor's care and are familiar with the necessary lifestyle guidelines. Furthermore, the group of persons with primary hyperoxaluria is very small in Germany (ca. 8-29 cases for every 10 million persons). Neither the FNB nor the SCF has concluded that the aforementioned risk groups have to be taken into account.

These remarks relative to vitamin C provide an example of how the BfR's proposed options for risk management cannot be justified solely on the basis of precautionary health protection.

For the aforementioned reasons, the German food industry has reservations with regard to the BfR's report. At the same time, the risk-management model developed in the introduction to the BfR's report – with the exception of the multi-exposition factor of 4 – is greatly to be welcomed, in principle. It takes account of the relevant legal requirements.

The criticism is aimed primarily at the facts that, in the main part of the report, this model is not used, for the great majority of nutrients, and that considerations from nutrition physiology are applied instead. And yet, in the BLL's view, such an approach is by no means necessary, and the grounds given for using the restrictive approach and for the extensive rejection of the model are not always convincing.

2) Models developed with the participation of industry:

ILSI-Europe: "Vitamins and Minerals: A Model for safe addition to Foods"

ERNA model: "Vitamins and Mineral Supplements:
A risk management model"

Both the ILSI model and the ERNA model propose that nutrients be categorised on the basis of their risks (cf. the green markings in the ILSI model):

Appendix 1 Maximum levels of addition of vitamins and minerals to foods (assuming 50 % of all foods can be fortified)

Micronutrient	EC RDA	Units mg or µg			% Foods fortified (of total available)				
		Upper Level	95 th percentile Intakes	Max available for Adding to Foods ¹ MA (UL-CI)	100%	50%	25%	10%	5%
					Max amount per 100 kcal portion ⁴ Units mg or µg				
FA ₅₀									
Vitamin B12 µg	1	3,000 ²	20	2,980	166	331	662	1656	3311
Riboflavin mg	1.6	200 ²	3.2	197	11	22	44	109	219
Vitamin E mg	10	1,000 ²	21	979	54	109	218	544	1088
Pantothenic acid mg	6	500 ²	10	490	27	54	109	272	544
Niacin mg (nicotinamide)	18	900 ²	41	859	48	95	191	477	954
Thiamin mg	1.4	50 ²	2.8	47.2	3	5	10	26	52
Vitamin C mg	60	2,000 ²	186	1814	101	202	405	1008	2016
Biotin µg	150	2,500 ²	68	2432	135	270	540	1351	2702
Vitamin B6 mg	2	25 ²	3.4	21.6	1	2	5	12	24
Vitamin D µg	5	50 ²	9.9	40	2	4	9	22	45
Copper mg	1.15 ³	10 ²	3	7	0	1	2	4	8
Iodine µg	130	1,100 ²	357	743	41	83	165	413	826
Selenium µg	55 ²	300 ²	90	210	12	23	47	117	233
Folic acid µg	200	1,000 ²	450	550	31	61	122	306	611
Phosphorus mg	800	4,000 ²	2598	1402	78	156	312	779	1558
Iron mg	14	45 ²	24	21	1	2	5	12	23
Zinc mg	15	40 ²	18	22	1	2	5	12	24
Magnesium mg	300	250 ^{1*}	–	240	15	28	54	138	276
Calcium mg	800	2,500 ²	1918	136	8	15	30	76	151
Vitamin A µg	800	3,000 ²	3195	0	0	0	0	0	0

¹ EC SCF Tolerable Upper Intake Level
² US FNB Tolerable Upper Intake Levels
³ EU PRI
⁴ Maximum which can be added per 100 kcal food without exceeding UL at the 95th percentile intake
⁵ Apparent errors in subtraction are due to rounding of presented figure, i. e., after not before calculation
⁶ EU UL for magnesium excludes magnesium present in normal foods and beverages. It is intended for added magnesium and that present in water only; current intakes of magnesium from water are assumed to be generally very low compared to the UL

Quelle: Flynn et al (2003): Eur J Nutr 42:118-130.

Source: Flynn et al, 2003. [The graph elements in color have been added]

The ILSI model also shows that a broad range of vitamins and minerals can be safely added to foods – and that this holds even under the assumption of an unrealistically large share of fortified foods (25% in the present case). The ILSI model provides no solution, however, for nutrients for which neither the SCF nor the FNB has derived a UL. Furthermore, it provides no answers on the issue of maximum levels for food supplements. And the maximum level is oriented to kcal content.

The ERNA model begins by categorising nutrients via a two-stage procedure:

For nutrients for which the SCF (or FNB) has not set a UL, a quotient is formed from the UL, minus intake from food. This quotient is termed the "Population Safety Index – PSI".

The smaller the PSI, the higher the risk that the UL could be exceeded. Nutrients with a PSI < 1.5 are placed in category "C". Nutrients with PRI > 1.5 are placed in category "B".

Nutrients with no UL are assessed on the basis of the reports of the SCF/the EFSA. Nutrients for which no adverse effects are expected, throughout a broad range that extends even above customary dietary levels, are placed in category "A". Due to the lung-cancer risks it presents, at high dosages, for heavy, long-term smokers, beta carotene is placed in Group C:

Table 4

A. No evidence of risk within ranges currently consumed; does not represent a risk to human health	B. Low risk of exceeding the UL	C. Potential risk at excessive intakes
Vitamin B ₁	Vitamin B ₆	Vitamin A
Vitamin B ₂	Vitamin C	Beta-carotene (smokers)
Biotin	Vitamin D	Calcium
Vitamin B ₁₂	Vitamin E	Copper
Pantothenic acid	Folic Acid	Fluoride**
Vitamin K	Nicotinamide	Iodine
*Chromium	Phosphorus	Iron
	Magnesium	Manganese
	Molybdenum	Zinc
	Selenium	

No maximum level required;	MSL = UL – intake x factor (intake data from the UK are used; not only are these representative, they also include intake of food supplements and fortified foods; furthermore, they represent a liberalised	Maximum level ~ 1 RDA
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* The classification is based on those sources currently approved in Annex II of Directive 2002/46/EC and 2001/15/EC.

** Intake data for fluoride were not available in the UK NDNS study, so is provisionally placed in Group C. US FNB reported potential risk of fluorosis in children. The final categorisation would depend on relevant intake data.

Source: ERNA (<http://www.erna.org/data/pdf/RiskManagementFinal.pdf>)

[the graph elements in colour have been added]

The ERNA model thus permits use of safety-oriented risk management measures even for nutrients with no UL. What is more, the intake data include nutrient quantities consumed in the UK as a result of fortification. Furthermore, the calculations provide for theoretical expansion of the market for fortified foods, amounting to 50% for vitamins and to 10% for minerals.

Conclusion:

The BLL supports models that are oriented to the principles of safety and proportionality and that provide a wide range of fortification options for both food supplements and fortified foods.

About BLL:

The Bund für Lebensmittelrecht und Lebensmittelkunde e. V. (BLL) is the leading association of the German food sector. In this role, it represents the food sector throughout the entire production chain, "from farm to fork". Its membership includes some 90 associations, representing the areas of agriculture, food trades, food industry and food sellers; 100 individual members and 300 companies – ranging from mid-sized firms to international corporations.

The BLL's tasks include facilitating the development of German, European and international food laws and actively supporting the relevant scientific fields. It carries out its work on a solid scientific foundation. In addition, the BLL functions as a partner for dialogue with political, administrative and scientific sectors, with consumer organisations and with the media, relative to the areas of food, food production, quality and safety, food laws and consumer protection.

In the BLL, lawyers and scientists work together interdisciplinarily. The BLL reinforces its expertise through cooperation with scientists – in particular, the BLL's Scientific Advisory Board, which advises the BLL in both legal and scientific issues.

Further information:

www.bll.de

<http://www.bll.de/themen/nahrungsergaenzungsmittel/>

<http://www.bll.de/themen/anreicherung/>