FSA 06/07/07 **AGENDA ITEM 3.1, 13 JULY 2006**

VITAMINS AND MINERALS IN FOOD SUPPLEMENTS AND FORTIFIED FOODS - UPDATE ON STAKEHOLDER ENGAGEMENT ON THE EC DISCUSSION DOCUMENT

Executive Summary

1. The European Commission has published a discussion paper, for consultation, on the setting of minimum and maximum levels for vitamins and minerals in foodstuffs. Responses have been requested by 30 September and the Agency will be engaging with stakeholders to inform its position. The principles which will underpin discussions with stakeholders, and the Agency's engagement strategy are presented in this paper. The Agency position will contribute to the Government's response to the Commission.

2. The Board is asked to:

   - **agree** the engagement strategy with stakeholders.

   - **agree** the principles on which discussions will be taken forward with stakeholders.

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VITAMINS AND MINERALS IN FOOD SUPPLEMENTS AND FORTIFIED FOODS - UPDATE ON STAKEHOLDER ENGAGEMENT ON THE EC DISCUSSION PAPER

Issue

1. The Board was informed at its June meeting that the European Commission had published a discussion document on setting minimum and maximum levels of vitamins and minerals in foodstuffs. There are commitments to set these in both the food supplements directive and the proposed EC Regulation on the addition of vitamins and minerals to foods (fortification). The Board agreed that the FSA should base its response and strategy on some key principles and for these to be discussed at the Board meeting in July. This paper lists proposed principles and the basis for the Agency's engagement strategy with stakeholders to inform the Agency position which will contribute to the Government's response to the Commission.

2. Following consultation with the FSA Chair, officials have begun to take forward the process of stakeholder engagement in advance of the July meeting. This is not intended to pre-empt input from the Board but has been necessary given the short time frame we are working to, and the potential difficulty in engaging fully with stakeholders over the summer period. Further suggestions for engagement from the Board would be welcomed.

Strategic Aims

3. Protecting consumer interests by ensuring that regulation of food supplements is evidence-based and proportionate represents one of the aims of the Agency's strategic plan.

Background

4. The Board discussed the setting of maximum levels of vitamins and minerals in food supplements in September 2005 in the absence of any proposals from the European Commission.

5. The Commission has subsequently published a discussion document on 6 June and is seeking comments by 30 September. A copy of the document is attached at annex 1. The document is published on the Commission web site and stakeholders as well as member states are invited to submit comments. This is an information gathering exercise. The Commission has not scheduled a meeting with member states or with stakeholders to discuss the document in advance of its deadline, but has indicated that it may hold such meetings in the future. The Commission plans to publish proposals within 2 years which will form the basis of negotiations with member states. In the interim period discussions will continue

with the Commission and member states, and the Board will be updated on progress. When the Commission publishes its proposals the Board will be invited to comment on them and to review its position agreed in 2005.

6. In June the Board agreed that it would be useful for the Agency to articulate its overriding principles in advance of discussions with stakeholders. Officials have proposed the following principles:

   - Consumers should have the right to make an informed choice unless their safety is compromised

   - An evidence base is necessary to ensure consumer safety is safeguarded.

   - The evidence base needs to take into account the risk assessment by scientific experts (particularly drawing on the UK 2003 report from the Expert Group on Vitamins and Minerals), and the more recent advances in global risk management modelling post 2003.

   - There is a need for ongoing monitoring in the market place to continue to inform the evidence base.

7. The Commission document specifically asks a series of technical questions where input is requested. The document does not open up wider discussion on the Food Supplements Directive. The Agency is therefore seeking views from stakeholders who are able assisT in answering these questions. In advance of a stakeholder meeting, nutrition and toxicology experts in the FSA will draft initial views, which will be circulated to stakeholders and these will form the basis for discussions. Given the Commission timeframe, we have decided not to invite written comments (as stakeholders can submit these separately to the Commission) but to seek input via two meetings. Comments made at the meetings will be incorporated into the FSA position, which will contribute to the Government's response to the Commission.

8. An initial stakeholder meeting will be held on 25 July at Aviation House with video links to Scotland, Wales and Northern Ireland to allow wider participation in the meeting. The following stakeholders will be invited to attend the meeting – supplements industry trade associations, Food and Drink Federation, British Retail Consortium, British Soft Drink Association, British Dietetic Association, British Medical Association, Nutrition Society, Which?, National Consumer Council, Consumers for Health Choice, representation from the Scientific Advisory Committee on Nutrition (SACN) and the Committee on Toxicity (COT). Officials from other Government departments (e.g. Cabinet Office, DTI, Defra, DH), members of the FSA advisory committees in Scotland, Wales and Northern Ireland will also be invited. There will also be places available for other health NGOs, other consumer organisations, scientific experts and any Board member who expresses an interest in attending. In addition to inviting members to attend

the stakeholder meeting, we will also be consulting experts on SACN and COT separately at their July Committee meetings.

9. Following this meeting the FSA position will be drafted and circulated to stakeholders for further consideration. A second meeting will then be held on 4 September to allow additional input before the FSA position is finalised for discussion by the Board.

10. The FSA will be responding on behalf of the Government given our policy lead in this area. We will therefore need to consult other Government Departments on the draft UK response after the FSA position has been agreed with the Board at its meeting in September.

Impact

11. A Regulatory Impact Assessment is not required as formal proposals have yet to be published by the Commission.

Conclusion

12. The Agency will be engaging with stakeholders via two meetings to inform the FSA position in response to the questions raised by the Commission in its discussion document.

Board Action Required

13. The Board is asked to:

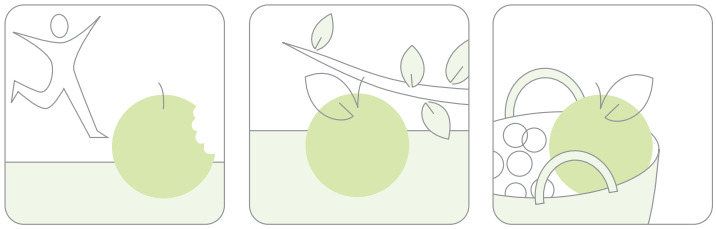
- **agree** the engagement strategy with stakeholders.

- **agree** the principles on which discussions will be taken forward with stakeholders.

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

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



EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

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

June 2006

Directorate E - Safety of the food chain

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INTRODUCTION

1. Directive 2002/46/EC on food supplements provides for the setting of maximum and minimum amounts of vitamins and minerals in these products via the Standing Committee procedure. Similar provisions are contained in the proposal for a Regulation on the addition of vitamins and minerals and of certain other substances to foods which is currently under discussion at the European Parliament in and Council and which is expected to be before adopted September/October of 2006.

2. This paper identifies the issues to be considered in the setting of maximum and minimum amounts of vitamins and minerals in foods.

3. The Health and Consumer Protection Directorate-General is keen to obtain the view of stakeholders on how these issues might be addressed and is issuing this discussion paper as a part of the consultation process.

4. Responses should reach the dedicated e-mail box SANCO-VITAMINS-AND-MINERALS@EC.EUROPA.EU by **30 September 2006**. Please note that any responses received could be made public.

Food Supplements

5. Food supplements are concentrated sources of vitamins, minerals and/or other substances (such as aminoacids, essential fatty acids, fibre and various plant and herbal extracts) sold as pills, tablets and other dose forms.

6. Directive 2002/46/EC on food supplements was adopted by the European Parliament and the Council in June 2002. Its aim is to facilitate the free circulation of those products, to ensure a high level of protection of public health and to provide a clear legal framework for manufacturers.

7. Directive 2002/46/EC on food supplements lays down provisions which:

   - regulate compositional aspects (e.g. positive lists of vitamins and minerals).

   - provide for appropriate specific rules on labelling, presentation and advertising of food supplements.

8. Although food supplements can contain a variety of ingredients, as a first step the Directive lays down specific provisions only for products containing vitamins and minerals. A report evaluating the advisability to cover products containing nutrients and/or ingredients other than vitamins and minerals have to be presented to the EP and to the Council in a report due by July 2007.

9. Moreover, the Directive foresees the setting of maximum and minimum levels for vitamins and minerals through the Standing Committee procedure and lays down the criteria for their setting.

Addition of vitamins and minerals to foods

10. A proposal for a Regulation on the addition of vitamins and minerals and of certain other substances to foods is currently under discussion at the European Parliament in and Council and is expected to be adopted by the end of 2006.

11. This proposal for a Regulation:

   - lists in Annex I the vitamins and minerals that may be added and in Annex II the sources of vitamins and minerals that may be used.

   - provides for certain restrictions regarding the foods to which vitamins and minerals may be added.

   - provides for specific rules on labelling, presentation and advertising of products to which vitamins and minerals have been added.

   - enables Member States to require the notification of the marketing of these products in order to facilitate their monitoring.

   - provides the basis for scrutinising and, where necessary, regulating the addition of certain substances, other than vitamins and minerals, to foods.

12. Moreover, it also sets the criteria for the establishment of maximum and minimum levels of vitamins and minerals in foods through the procedure of the Standing Committee on the Food Chain and Animal Health.

Maximum and minimum levels of vitamins and minerals

13. The importance of the diet for a healthy life has been amply demonstrated. Individual nutrients have received variable attention and vitamins and minerals are among them. The levels of intake of the latter have been cause of concerns both for being potentially on the low side but also because of the adverse effects that excessive intakes of certain vitamins and minerals may cause. It should, however, be noted that it is increasingly difficult to develop accurate assessments of the pattern of overall diets, since these vary across the regions of the EU, between population groups and over time.

14. Changing culinary and social habits have led to low intakes for some vitamins and minerals compared to those being recommended for certain groups of the population, although the vitamins and minerals and the groups of the population concerned may vary from Member State to Member State. In addition, some argue that optimal health may depend on higher levels of vitamins and minerals than those recommended today on the basis of avoiding deficiencies. As a result, products that contribute to the intake of vitamins and minerals beyond the levels that would be provided by the natural content of foods have increased considerably on the market. These may be food supplements but also foods to which vitamins and minerals have been added (fortified foods). With such proliferation of these products the setting of maximum levels for vitamins and minerals is becoming increasingly a pressing need for the responsible authorities to ensure that the potential sum of intakes from all sources on the market should not threaten to undermine the high level of human health which the Treaty sets as our policy objective.

15. In addition, it is important to underline that the application of divergent maximum permitted levels of vitamins and minerals in Members States is causing serious problems to the free circulation of the products concerned in the European market.

16. The maximum levels for vitamins and minerals have not been set in Directive 2002/46/EC on food supplements, but have to be established by the Commission through the Regulatory Committee as an implementing measure.

17. Article 5 of Directive 2002/46/EC reads:

    "*1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:*

    (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) intake of vitamins and minerals from other dietary sources.

2. When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population.

3. To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate.

4. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with the procedure referred to in Article 13(2).”

18. Similar provisions for the establishment of maximum levels for vitamins and minerals in foodstuffs are present in the proposal for a Regulation on the addition of vitamins and minerals and of certain other substances to foods. Article 6 of this proposal for a Regulation reads:

    “1. When a vitamin or a mineral is added to foods, the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed maximum amounts that shall be set in accordance with the procedure referred to in Article 14(2). For concentrated and dehydrated products, the maximum amounts set shall be those present in the foods when prepared for consumption according to the manufacturer's instructions.

    2. Any conditions restricting or prohibiting the addition of a specific vitamin or mineral to a food or a category of foods shall be adopted in accordance with the procedure referred to in Article 14(2).

    3. The maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 shall be set taking the following into account:

    (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally acceptable scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different groups of consumers;

    (b) intakes of vitamins and minerals from other dietary sources.

    4. When the maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 are set for vitamins and minerals whose reference intakes for the population are close to the upper safe levels, the following shall also be taken into account, as necessary:

    (a) the contribution of individual products to the overall diet of the population in general or of sub-groups of the population;

    (b) the nutrient profile of the product established as provided for by Regulation (EC) No .../... “(Regulation on nutrition and health claims).

19. Vitamins and minerals used in food supplements or added to foods should result in a minimum amount being present. Otherwise, the presence of too small

amount would not offer any benefit to consumers, namely to supplement the normal diet in the case of food supplements, and would be misleading.

20. These minimum levels should be set in accordance with the provisions of Article 5.3 of Directive 2002/46/EC cited above (see paragraph 17) and with the relevant provisions of the Draft Regulation on the addition of vitamins and minerals and of certain other substances to foods. Article 6.6 of the Common Position adopted by the Council reads:

"The addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to the Annex to Directive 90/496/EEC. The minimum amounts, including any lower amounts, by derogation from the significant amounts mentioned above, for specific foods or categories of foods shall be adopted in accordance with the procedure referred to in Article 14(2)".

SETTING OF MAXIMUM AMOUNTS

21. General food law principles aim to ensure that food is safe. Measures to achieve this goal should be proportionate in order to ensure a high level of protection of public health, where, at the same time, avoiding undue constraints for businesses.

22. Moreover, it should be noted that this exercise takes place in the political context of the renewed Lisbon Strategy where the EU focuses among other on better regulation (meaning also avoiding unnecessary overregulation) as a means to contribute to achieving economic growth and creating jobs and where measures should be taken following a broad dialogue with stakeholders.

23. A number of scientific bodies and stakeholders have considered the issue of setting maximum levels of vitamins and minerals in foods and have elaborated several models. Examples of certain of these models can be found in the annex of this document.

24. Taking into account these general considerations, in the context of the exercise of setting the maximum amounts for vitamins and minerals in foodstuffs, certain questions need to be carefully considered.

Establishment of maximum amounts for food supplements and other foods

25. In order to take into account the elements mentioned in Article 5.1.(a) of Directive 2002/46/EC, the Commission requested the Scientific Committee of Food (SCF) and later the European Food Safety Agency (EFSA) to provide scientific opinions on tolerable upper intakes levels of the 29 nutrients listed in Annex I of the Directive plus boron, vanadium, nickel, tin and silicon.

26. The SCF provided opinions on 22 nutrients[1] while EFSA issued the remaining opinions in summer 2005[2].

27. In those scientific opinions specific numerical tolerable upper intake levels are established for 16 nutrients. For the others the lack of sufficient scientific data, in particular, lack of systematic oral intake dose-response studies, did not allow to derive numerical upper levels. However, for some nutrients extremely low or non-existent toxicity even at high doses of administration is indicated from existing evidence that is available from observational studies. In other cases, even if adverse effects could be determined, the available data were insufficient to derive a tolerable upper intake level.

28. Although food supplements and foods to which vitamins and minerals are added are covered by different measures the considerations for setting maximum levels for vitamins and minerals in the different products are inevitably interrelated. In particular, the distribution of these nutrients in the two broad categories of food

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[1] *http://ec.europa.eu/comm/food/fs/sc/scf/outcome_en.html#opinions*

[2] *http://www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html*

products, food supplements and fortified foods, have to be considered together if we are to have a clear picture of the overall food offering.

Questions on which the Commission seeks comments:

- Where there is not yet a scientifically established numerical tolerable upper intake levels for several nutrients, what should be the upper safe levels for those nutrients that should be taken into account in setting their maximum levels?

- 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?

- Where we set maximum levels, do we inevitably also have to set maximum amounts for vitamins and minerals separately for food supplements and fortified foods in order to safeguard both a high level of public health protection and the legitimate expectations of the various food business operators? Are there alternatives?

Intake of vitamins and minerals from dietary sources

29. Vitamins and minerals may be ingested from a variety of foods that are eaten as part of the daily diet. They can be naturally present in foods or added to them both for technological or nutritional purposes. Innovation in the food sector tends to take increasingly into account the relationship between diet and health and may lead to an increase of the percentage of foodstuffs fortified with vitamins and minerals on the market. Moreover, it should also be taken into account that, especially in some Member States, food supplements are a non-negligible source of nutrients in the daily diet. The amounts contributed by these various sources have to be taken into account when setting maximum levels.

30. The estimates of intakes are essentially derived through dietary surveys data and relevant food composition data. The main types of dietary surveys are individual and household surveys. Individual dietary surveys include: duplicate meal surveys; weighed intakes; estimated intakes; diet histories; 24 hour recall and, food frequency questionnaires. Individual surveys might be conducted on specific population groups by age or other characteristics (pregnant women, low income groups, ethnic origin).

31. Household surveys record the food purchases of a household for a certain period of time with estimates of individual intake based on dividing the total purchases by the number of people in the household. As not all food is consumed in the home some household surveys include also a record of foods eaten outside the home.

32. The costs associated with conducting the surveys and the reliability and accuracy of the estimates of intake vary. In general, surveys are expensive, therefore, they are not conducted frequently and they are not available in all Member States. Moreover, when they do exist, they can be out of date and may not reflect current intakes of vitamins and minerals.

33. The data derived from dietary surveys of a population may be presented as mean intakes (possibly by age and sex). In some cases there may also be information on the extremes of intakes both the lower and higher levels and on intakes of specific population groups (e.g. infants, adolescents, elderly). In addition some surveys may differentiate intakes from food supplements whilst others may give only an estimate of intake from food sources either including or excluding food supplements.

Questions on which the Commission seeks comments:

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

Reference intakes of vitamins and minerals

34. Article 5.2 of Directive 2002/46/EC on food supplements stipulates that: *"When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population."*

35. The Population Reference Intakes (PRIs), also called Recommended Daily Allowances (RDAs), are based on the principle that most, if not all, individuals of a population or a specific population group should obtain an adequate nutrient intake to satisfy their requirements. Such recommended values are generally based on the principle of the average requirement plus two Standard Deviations (SD) for the nutrient in the population group.

36. In 1992 an SCF opinion on nutrient and energy intakes for the European Community[3] defined the PRIs for several nutrients.

37. These values were mainly determined on the basis of the concept of optimal nutrition which implied that these values were determined among other, to prevent deficiencies, to optimise body stores and to reduce the risk of diseases.

[3] *http://ec.europa.eu/comm/food/fs/sc/scf/out89.pdf*

38. More recently in 2003 the SCF issued an opinion on the Revision on Reference Labelling Values [4] which, of course are not the same as PRIs but are derived on the basis of national updated RDA/PRI tables.

39. It should also be noted that in 2005 the Commission requested EFSA to review the SCF recommendations on PRIs for micronutrients. However, EFSA has indicated that due to the complexity of the task, it is not expected to be completed in the next few years.

40. Population Reference Intakes are often used for purposes which are not the ones for which they were established. In the case of setting maximum levels for vitamins and minerals they Have been used:

    (1) To determine whether there is a nutritional need for a vitamins or a mineral in the population (e.g. due to estimated deficiencies) and accordingly allow the addition of the nutrient to foods or its presence in food supplements.

    (2) To set the maximum level of a vitamin or a mineral as a multiple of the reference intake, even if such a limitation could not be justified on a safety ground on a case-by-case evaluation.

41. In assessing such practices, the rulings that the European Court of Justice issued in the last few years concerning the use of PRI/RDI in some Member States must be also taken into consideration. In this context:

    - In Case C-192/01 the Court evaluated the Danish administrative practice which entailed that enriched foodstuffs lawfully produced or marketed in other Member States might be marketed in Denmark only if it is shown that such enrichment with nutrients met a need in the Danish population. The Court ruled that "*the absence of such a need cannot, by itself, justify a total prohibition, on the basis of Article 30 EC, of the marketing of foodstuffs lawfully manufactured and/or marketed in other Member States*", therefore "*the Danish administrative practice is disproportionate since, ..., it systematically prohibits the marketing of all foodstuffs to which vitamins and minerals have been added, without distinguishing according to the different vitamins and minerals added or according to the level of risk which their addition may possibly pose to public health*".

    - In Cases C-387/99 and C-150/00 the Court evaluated the German and Austrian practices classifying as medicinal products vitamin and mineral preparations which were lawfully produced or marketed as food supplements in the other Member States where they contained amounts of vitamins and minerals exceeding three times (one time for some vitamins and minerals in the case of Austria) the RDA/PRI. The Court ruled that *"the automatic nature of that practice does not make it possible to identify and assess a real risk to public health, which requires a detailed assessment on a case-by-case basis of the effects which the addition of the vitamins in question could entail"* and therefore that these practices are disproportionate.

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[4] *http://ec.europa.eu/comm/food/fs/sc/scf/out171_en.pdf*

42. The PRIs should, of course, be borne in mind when setting maximum levels for vitamins and minerals for which there is not a great difference between the PRI and the tolerable upper level in order to avoid that maximum levels set could lead to risk of intakes for a nutrient being lower than the PRI.

Question on which the Commission seeks comments:

- 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?

MINIMUM AMOUNTS

43. Council Directive 90/496/EEC on nutrition labelling requires that in order that vitamins or minerals may be declared in nutrition labelling they have to be present in a significant amount, which, as a rule, is the amount in 100 g or 100 ml of the food representing 15% of the recommended allowance specified in the Annex to Directive 90/496/EEC. The same amount has to be present if a nutrition claim is made that the food is a "source" of a vitamin or a mineral, according to the proposed Regulation on nutrition and health claims made on foods, expected to be adopted in September/October 2006.

44. The proposed Regulation on the addition of vitamins and minerals to foodstuffs foresees that, in order to guarantee consumers of the presence of vitamins and minerals in fortified foods in at least a meaningful amount, their addition shall result in the presence of at least a significant amount where this is defined according to the Annex to Directive 90/496/EEC on nutrition labelling. However, this provision allows discretion to set minimum amounts that are different from that significant amount for specific foods or categories of foods.

45. It should be noted that the lists of vitamins and minerals in the proposed Regulation on the addition of vitamins and minerals to foodstuffs include more nutrients than the ones listed in the Annex to Directive 90/496/EEC. In order to update this Annex and to approach several other technical issues on nutritional labelling of foodstuffs, the Commission has recently published a discussion paper[5].

46. While the use of significant amounts as minimum amounts may be considered generally acceptable for fortified foods, some argue that it would not be adequate for food supplements. Food supplements are by definition concentrated sources of nutrients. Therefore, some argue that these products should be providing minimum amounts of those nutrients, per recommended daily consumption dose, higher than the abovementioned significant amounts.

Questions on which the Commission seeks comments:

- 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?

- 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?

[5] *http://ec.europa.eu/comm/food/food/labellingnutrition/nutritionlabel/discussion_paper_rev_tech_issues.pdf*

ANNEX

EXAMPLES OF EXISTING MODELS FOR THE SETTING OF MAXIMUM AMOUNTS OF VITAMINS AND MINERALS IN FOODS

Model developed by the French Agency of Food Safety (AFSSA)

Subject: Addition of vitamins and minerals in food

It should be underlined that for France, any addition of vitamins or minerals should be justified by the need of answering the double requirement of public health and food safety: the evaluation must integrate both **nutritional dimension** and the concern of the **optimal food safety** of the consumer.

Part I: Methodology followed to determine the optimal contents

The procedure was designed by the French Agency of food safety (AFSSA). It is held in several stages.

1. Safety factors and nutritional interest

Firstly, the heavily consumed nutrients (for which the **97.5th percentile** of intakes of populations or of targeted groups reaches or exceeds the safety limits) are excluded. This choice of the 97.5th percentile is based on a WHO report (*Methodology for exposure assessment off contaminant and toxins in food* - 2000).

Moreover, preference is given to the nutrients that are of nutritional interest for a population or a group of individuals. In the absence of validated markers allowing to demonstrating the existence of a deficiency, the expert shall use the concept of **prevalence of inadequacy of intakes** compared to the requirements. This prevalence is estimated by the percentage of individuals whose contributions are lower than the "Besoin Nutritionnel Moyen" (BNM or Estimated Average Requirement: EAR).

The estimate of the prevalence of inadequacy makes it possible to identify the groups at the risk of inadequacy of requirements. From the data of consumption available for the various categories of age and sex, it is possible to determine the various prevalence of inadequacy for each selected nutrient, as well as the confidence intervals (because the data are not exhaustive and were carried out on samples representative of the population).

The risk of inadequecy of requirements is based on the estimate of the confidence interval (95%) of the prevalence of inadequacy of intakes compared to the requirements. To determine the groups at the risk of inadequacy of intakes, the experts considered as scientifically relevant the confidence intervals excluding the median value of 50% in lower limit (because it means that half of the population has intakes higher than EAR) and including the threshold of 70% (which testifies to a strong prevalence of inadequacy).

2. Classification of the nutrients

From these data, it is then possible to distinguish the nutrients:

1. Those for which risks of inadequacy of contribution were identified in certain categories of the population with a limited risk of exceeding the safety limit: **vitamin C, magnesium** ;
2. Those for which risks of deficiencies or inadequacy of intakes were identified in certain categories of the population but for which the risk of exceeding the safety limits is possible for certain populations (heavy consuming…): **vitamins C, D, B9, calcium, iron, iodine**;
3. Those for which the risk of inadequacy of intakes is relatively weak and for which there are no safety limits: **vitamins B1, B2, B5, B8, B12** and for which, the risk of exceeding the safety limit is weak**: vitamin B3** ;

4. Those for which the risk of inadequacy of intakes is relatively weak but for which a risk of exceeding the safety limits is possible: **vitamins E, K, B6, fluorine, sodium;**

Vitamin A constitutes a particular case insofar as the 97.5th percentile of consumption in France exceeds the safety limit of vitamin A.

If a risk of exceeding the upper limits is possible, simulation studies are necessary. From these studies, various levels of addition can then be considered. The chemical form of the nutrient can also play an important part in the amount selected (cf. example of the vitamin B3).

Part II: Adaptations according to the problems

1. Normal foods

First of all, it should be reminded that in France the enrichment of normal foods is subjected to a preliminary authorization. The French authorities have to take some decisions on a case-by-case basis on the operators' requests. The authorizations reflect the condition of uses requested by the applicant. Even if the AFSSA carried out a global reflection on the topic of enrichment, the authorities made no simulations for each nutrient.

In addition to methodology presented above, the manufacturers should observe the conditions presented in the AFSSA report entitled "Specification for the selection of a nutrient-vector food pair". This report envisages in particular that the food vector of enrichment is consumed by the groups of population presenting the highlighted deficiency and that this food is, as far as possible, in conformity with the general nutritional recommendations: it is indeed preferable to enrich a food which an increase of consumption is recommended. A priority is given to the food, which naturally contains the added nutrient in order not to create distortion in food perceptions of the consumers and to avoid the problems of nutritional interactions. For this reason, France always privileged the steps aiming at restoring the contents of nutrients, which could have been lost during the process of a product.

Lastly, the safety of enrichment and its utility must be checked by simulations when that proves to be necessary (cf. part I). A monitory of consumption of the enriched product is also required.

2. Food supplements

From the preceding data, a distinction was established between the nutrients for which a risk of exceeding the safety limit exists and those for which this risk is weak.

In the first case, the maximum content was limited to the recommended daily intakes or even to a lower content still because:

- of a risk of exceeding the safety limits and of the risk of fluorose for children due to an over-consumption of fluorine;
- problems of public health: patients under anti-vitamin K and vitamin K or sanitary messages aiming to the reduction of salt and sodium consumption.

In the second case, the maximum content was limited to three times the recommended daily intakes by also taking into account nutrient requirements and intakes, as the directive n° 2002/46 envisages it.
These contents were fixed temporarily before the harmonization.

Model developed by the Danish Institute of Food and Veterinary Research

Subject: A safe strategy for addition of vitamins and minerals to foods (the Danish budget model)

The Danish Institute of Food and Veterinary Research has for its safety assessment of fortification of foods developed a model based on a scientific paper by Flynn et al. 2003. The Danish model has developed and extended the model previously proposed by Flynn by considering the common use of micronutrient supplements and by introducing age-differentiated ULs and thereby focusing in particular on the safety of children and adolescents.

The Danish model makes use of the Tolerable Upper Intake Level (UL) established by SCF/EFSA and other international expert groups compared with the 95-percentile intakes of micronutrients from the regular diet. Estimated dietary intakes of energy, vitamins and minerals for selected groups of the population are based on Danish nation-wide dietary surveys. The model includes the contribution from supplement intake (SI), a combined multi-vitamin-mineral tablet to the total intake of micronutrients as approximately half of the adult population and about two thirds of the children in Denmark take supplements regularly.

The model employs three main elements, the ULs, the 95th percentile intake of micronutrients from the regular diet (CI_{95}), and supplements (SI), and the resulting maximal allowance (MA) for fortification. By using these factors it is possible to estimate the level of each micronutrient that can be added to foods without any appreciable risk of adverse effects for any age group in the population, including individuals with high food intakes. The model is based on the following factors and mathematical formulas:

UL: the Tolerable Upper Intake Level established by SCF or other expert committees. Where no UL has been established, guidance levels (GLs) suggested by the UK Expert Group on Vitamins and Minerals (EVM) are used instead. In general the database on adverse effects of nutrients in children and adolescents is limited. Therefore, it has been chosen to correct for differences in basal metabolic rate by extrapolating from adults to children on a body surface area basis ($bw^{0,75}$).

CI_{95}: the current 95th percentile dietary intakes of micronutrients from the regular diet. Data is derived from the Danish dietary intake surveys mainly from 2000-2002. Budget calculations are conducted for five age groups of children and for younger men - the adult group with the highest energy intake compared to their weight.

SI: supplement intake; daily micronutrient intake from a normal vitamin/mineral supplement (100 % of ADT). For children less than ten years old: ADT for that age group.

MA: maximal allowance for intake of micronutrients from fortified foods: $MA = UL - (CI_{95} + SI)$
EI_{95}: the 95th percentile energy intake.

PFF_n: the fraction of foods in the market that is available for fortification.

ALA: Acceptable level of addition with each nutrient per energy portion of the food.

$$ALA = \frac{MA}{EI_{95} \times PFF_n}$$

However not all foods can or will be fortified. In agreement with Flynn we estimate that about half of the Danish diet consists of foods, which are potentially fortifiable. Among these not all foods will be fortified. Assuming that potentially 25% of the energy intake comes from fortified foods the acceptable levels of addition (ALAs) can be distributed in energy portions: $ALA_{25} = MA/(EI_{95} \times 0.25)$. For light products an energy density similar to the non-light analog is applied. In this way addition to light products will be accepted at the same level as their high-energy analogs.

Derivation of Maximum Levels of Vitamins and Minerals Added to Foods Based on Risk Assessment

BfR
Risiken erkennen – Gesundheit schützen

Grossklaus R, Hembeck A, Niemann B, Przyrembel H, Richter K, Schmidt E, Weissenborn A, Wörner B, Ziegenhagen R

FEDERAL INSTITUTE FOR RISK ASSESSMENT

Background:

Although an adequate and varied diet can, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life, consumers often desire to improve the perceived quality of their diet because of their particular lifestyles or other reasons. Food supplements and fortified foods, enriched with vitamins and minerals, have become increasingly available and popular on the European market.

Relevant national regulations for the addition of micronutrients to foods vary widely within the European Community. The first steps towards harmonisation of existing regulations were the adoption of Directive 2002/46/EC on food supplements and the publication of a draft proposal for the regulation of the voluntary addition of vitamins and minerals to foods. Both regulations contain rules on the range of vitamins and minerals that may be added to supplements and normal foods. However, as some micronutrients may cause adverse effects if consumed in excessive amounts, values for maximum levels of vitamins and minerals added to those products are foreseen in the EU regulation.

Objective: To develop a model to determine the level of each micronutrient that can be added safely to dietary supplements and/or normal foods per daily portion of consumption.

Methods: The following steps were applied in establishing maximum levels of vitamins and minerals for use in dietary supplements and fortified foods:

Step 1: Hazard (Nutrient) Identification	- Nutrient description, substance characterisation - Metabolism, function - Recommended Dietary Allowance (RDA)
Step 2: Intake Assessment	- Food intake data, Biomarkers - Groups susceptible to sub-optimal intake/ deficiency or excessive intake/ toxicity
Step 3: Hazard Characterisation, Dose-Response Assessment	- NOAEL/ LOAEL, uncertainty factors (UF) - Upper Intake Level (UL) by SCF/ EFSA or FNB
Step 4: Risk Characterisation	- Conclusions from steps 1 to 3 - Information gaps/ lack of data - Derivation of maximum levels of micronutrients for addition to supplements and normal foods

Special Considerations for Essential Nutrients

- When evaluating the adverse effects of micronutrients it has to be taken into account that, in contrast to non-essential substances, there is a level of intake below which the risk of deficiency or sub-optimal function rises.
- There is a long history of safe consumption of nutrients at the levels found in balanced human diets.
- For some nutrients there may be experience of chronic consumption at levels significantly above those obtained from endogenous nutrients in foods without reported adverse effects.
- Many nutrients are subject to homeostatic regulation of body content through adaptation of absorptive, excretory or metabolic processes.
- Added nutrients may differ from endogenous nutrients in foods in a number of ways, e.g. chemical form, timing of intake and amount consumed in a bolus dose, effect of the food matrix, bioavailability, and interaction of the nutrient with other constituents of the diet.
- Nutrients can be classified according to the risk of adverse effects through excessive intake (table 1) and to the degree of risk of inadequate intake (table 2):

Categories	Criteria
high	Nutrients for which the margin between the RDA (or actual intake) and UL is very narrow (≤ 5) **(e.g. Vitamin A, D, Copper, Iron, Zinc)**
moderate	Nutrients for which the UL is 5 to 100 times above the RDA (or actual intake) **(e.g.Vitamin E, K, C, B_6, Magnesium, Molybdenum)**
low	Nutrients for which a UL cannot be set as no adverse effects have been observed till now, even at intake 100 times the RDA **(e.g. Vitamin B_1, B_2, B_{12}, Chromium)**

Table 1: Risk of excessive intake

Categories	Criteria
1	Risk of a clinically manifest deficiency or a depletion of body stores in specific age groups, with specific physiological conditions/ with specific eating habits/ in specific regions **(e.g. Folate, Iodine, Vitamin D)**
2	Uncertainty about the risk of a clinically manifest deficiency or a depletion of body stores because of the lack of or the questionable validity of biomarkers, inadequate food tables, or a lack of epidemiological studies **(e.g. Vitamin K, Biotin, Fluoride, Zinc, Selenium)**
3	No indication of inadequate nutrient intake, or nutrient intake in the range of recommended intake **(e.g. Vitamin B_1, Vitamin B_2, Copper)**
4	Indication of nutrient intake above recommended intake **(e.g. Vitamin B_6, B_{12}, Sodium, Chloride, Phosphorus)**

Table 2: Risk of inadequate intake

Risk Model applied to determine maximum levels of micronutrients for addition to supplements and foods per daily portion of consumption:

The model is based on the following factors:

- UL = Upper Intake Level
- DINF = current estimated level of intake of a micronutrient from non-fortified foods at P 95 or P 97.5
- MEF = Multi-Exposure Factor = estimated number of food supplements and fortified foods with the respective nutrient

The amount of each nutrient which may be added to the diet as a whole with no appreciable risk of adverse health effects can be determined as the difference between the UL and the current estimated intake of the respective micronutrient from non-fortified foods at P95 or P97.5.

$$R = UL - DINF$$

Example: Folic Acid R = (1000* - 0) µg/d
R = 1000 µg/d
*UL only applies to folic acid

The resulting figure (R) constitutes the amount available for addition to supplements (R_S) and fortified foods (R_F). The percentage of "R" to be allocated to supplements and fortified foods is selectable and may vary between 0 and 100%.

$$R = R_S + R_F$$

Example: Folic Acid R (1000 µg/d) = $R_S + R_F$
R = (500 + 500) µg/d
or R = (400 + 600) µg/d

Considering that people might take more than one supplement or consume several portions of fortified foods per day, a Multi-Exposure Factor (MEF) has been introduced, and maximum levels for single portion of supplements (ML_S) or foods (ML_F) were calculated as follows:

$$ML_S = \frac{R_S}{MEF}$$

Example: Folic Acid $ML_S = \frac{400\ \mu g/d}{1} = 400\ \mu g/d$

$$ML_F = \frac{R_F}{MEF}$$

Example: Folic Acid $ML_F = \frac{600\ \mu g/d}{3} = 200\ \mu g/d$

Nutrients for which this model was not applicable	Reasons
• Vitamin A	Intake via normal foods at P97,5 is above the UL
• β Carotene	UL has not been set because of insufficient scientific basis; no dose- response-relationship available
• Vitamin K; Vitamin C; Chloride; Sodium; Phosphorus	UL has not been set because of lack of data
• Vitamin B_1; Vitamin B_2; Biotin; Pantothenic Acid; Vitamin B_{12}	UL has not been set because of lack of data (no systematic toxicological studies reported), no adverse effects have been observed
• Nicotinamide	Intake data do not distinguish between nicotinic acid and nicotinamide
• Iron	UL has not been set because available data on associations between iron status and disease are inconsistent
• Fluoride; Selenium; Molybdenum	Intake data are not available
• Manganese	Intake data are not available; UL has not been set because of lack of data and considerable degree of uncertainty
• Chromium	Intake data are not available; UL has not been set because of lack of information on the dose-response relationship

- **For the first time maximum levels of micronutrients for addition to food supplements and fortified foods per daily portion of consumption have been derived based on risk assessment.**
- **While the model approach is based solely on safety considerations, BfR strongly emphasises that when establishing maximum levels of micronutrients, nutritional aspects have to be taken into consideration as well.**
- **The model is not always applicable, e.g. in cases when no UL was set, but also when insufficient data on dietary intake/ nutritional status were available .**
- **Whenever the model was not applicable, maximum levels were determined on the basis of physiological and nutritional considerations.**

Domke A, Großklaus R, Niemann B, Przyrembel H, Richter K, Schmidt E, Weißenborn A, Wörner B, Ziegenhagen R: Verwendung von Vitaminen in Lebensmitteln. Teil I, Bundesinstitut für Risikobewertung, BfR-Wissenschaft 04/2004, Berlin, 2004.
Domke A, Großklaus R, Niemann B, Przyrembel H, Richter K, Schmidt E, Weißenborn A, Wörner B, Ziegenhagen R: Verwendung von Mineralstoffen in Lebensmitteln. Teil II, Bundesinstitut für Risikobewertung, BfR-Wissenschaft 04/2004, Berlin, 2004

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ILSI Europe 'Vitamins and minerals: a model for safe addition to foods'

Reference: Flynn, A., Moreiras, O., Stehle, P., Fletcher, R.J., Müller, D.J.G., Rolland, V. 2003. Vitamins and Minerals: A model for safe addition to foods. *European Journal of Nutrition*, 42 (2): 118-130

Available on: *http://europe.ilsi.org/file/ilsieuroope-vitandmineralsarticle.pdf*

This ILSI Europe paper describes the use of a theoretical model to assess the safety of the (voluntary) addition of vitamins and minerals to foods. It is based on actual food energy and nutrient intakes from national dietary surveys, and takes into account the special needs of people who consume large amounts of food (at the 95th centile of energy intakes). The yardstick of safety used is the tolerable upper intake level (UL) for each nutrient, i.e. the maximum average daily amount of each nutrient which can be consumed safely over a long period of time.

The results suggest that at least 15% EU RDA per serving can be added safely to foods in Europe for most micronutrients. This is consistent with a similar assessment carried out by AFSSA (the French food standards agency) in the context of the French diet. The results presented are based on data currently available in Europe, but alternative values can be used for other populations, assumptions or dietary reference values.

The maximum amount of a micronutrient which can be added safely to the diet overall is estimated as the difference between the UL and the P95 for the mean daily intake of the nutrient from food in adults obtained from large scale surveys of food consumption in European countries. This is then expressed per 100 kcal of food energy assuming:

- P95 for mean daily food energy intake is 3600 kcal (i.e. an indication of energy intake of high consumers - this exceeds the energy intake of 95% of consumers), derived from large scale surveys of food consumption in European countries, or P95 for mean daily number of typical servings of food consumed is 36. (Expressing values per typical serving (e.g. 100 kcal) allows assessment of safe addition to low calorie and energy reduced products, as well as to foods generally).

- a maximum of 50% of average daily food energy consumed is potentially fortifiable, derived from evaluation of food consumption data. (In European countries where voluntary fortification has been a long-term practice, an average of 3-9 percent of daily food energy comes from foods fortified with one or more nutrients).

Three categories of micronutrients were identified in which micronutrients can be added safely to foods at levels per serving (or per 100 kcal) of:

1. greater than 1 EC Recommended Daily Allowance (RDA): vitamin B 12, vitamin C, vitamin E, riboflavin, pantothenic acid, niacin and thiamin (even if all potentially fortifiable foods were fortified with that nutrient);

2. between 50 and 100% of the EC RDA: vitamin B6, vitamin D, folic acid, biotin, copper, iodine, and selenium (provided a maximum of 25% of all potentially fortifiable food energy was fortified with that nutrient);

3. between 10 and 40 % of the EC RDA iron, zinc, calcium, phosphorus, and magnesium (provided a maximum of 25% of all potentially fortifiable food energy was fortified with that nutrient).

A fourth category consisting of retinol (vitamin A), for which high end intake levels are close to the UL for some population subgroups in Europe, which requires further consideration.

The current model is applied to adults; however its application to the diets of children is also discussed.

VITAMIN and MINERAL SUPPLEMENTS: A RISK MANAGEMENT MODEL (ERNA-EHPM[1], Nov 04, ISBN: 9080920614, http://www.erna.org/data/pdf/INF206.pdf)

This paper, developed by ERNA and EHPM, describes a risk management methodology for establishing upper level food vitamins and minerals in food supplements.

Part 1: Quantitative and qualitative safety characterisation of the vitamins and minerals

a. When tolerable upper intake levels (UL)[2] are set by the Scientific Committee for Food (SCF) or European Food Safety Authority (EFSA), a **quantitative safety characterisation** is able to indicate the relative potential of higher intake groups to exceed the UL by the calculation of the Population Safety Index (PSI). Using the UL set by the SCF and EFSA, the following quantitative risk characterisation can be established (based on calculated PSI value above or below 1.5):

$$PSI = \frac{UL - (MHI + IW)}{RLV}$$

PSI: Population Safety Index
UL: Tolerable upper intake level as set by SCF or EFSA
IW: Intake from water (only relevant for minerals)
MHI: Mean Highest Intake: Highest intake from dietary sources (97.5th percentile) based on adult male intake data from available studies (Ire, It, Nl, UK)
RLV: Reference Values for Nutritional Labelling as set by SCF (Opinion of 5 March 2003, SCF/CS/NUT/GEN/18 Final)

Low risk of exceeding the UL			
Nicotinamide	52.8	Vitamin D	8.1
Vitamin E	23.2	Molybdenum	7.4
Vitamin C	22.0	Selenium	3.6
Vitamin B6	21.9	Phosphorus	2.1
Potential risk of exceeding the UL			
Iron	1.5	Zinc	0.4
Iodine	1.1	Vitamin A (preformed retinol)	-1.2
Copper	0.8		
Calcium	0.6		

b. In those cases where an UL is not established, a **qualitative risk characterisation** is required on the basis of available risk assessment. Extensive reviews by the SCF and EFSA give indications of the nature of the adverse effects associated with each nutrient and potential risks in relation to existing patterns of intake. Qualitative assessment of the SCF opinions (and other authoritative reports) show no adverse effects in healthy individuals associated with high intakes of biotin, chromium, pantothenic acid, vitamin B2, vitamin B1, vitamin B12 and Vitamin K.

Part 2: Setting of maximum levels based on the risk characterisation described in part 1

Three risk categories for setting maximum levels for food supplements (MSL) can be differentiated:

A: No evidence of risk within ranges currently consumed; Does not represent a risk to human health
Vitamin B1, Vitamin B2, Biotin, Vitamin B12, Pantothenic acid, Vitamin K, Chromium
→ **No setting of MSL required**

B: Low risk of exceeding the UL
Vitamin B6, Vitamin C, Vitamin D, Vitamin E, Nicotinamide, Molybdenum, Phosphorus, Selenium
UL for supplementation set by SCF: Magnesium, Folic acid
→ **MSL to take into account changing dietary patterns**

Based on UK surveys (1986/7 - 2000/1): intake from foods and fortified foods (in a liberal market place)

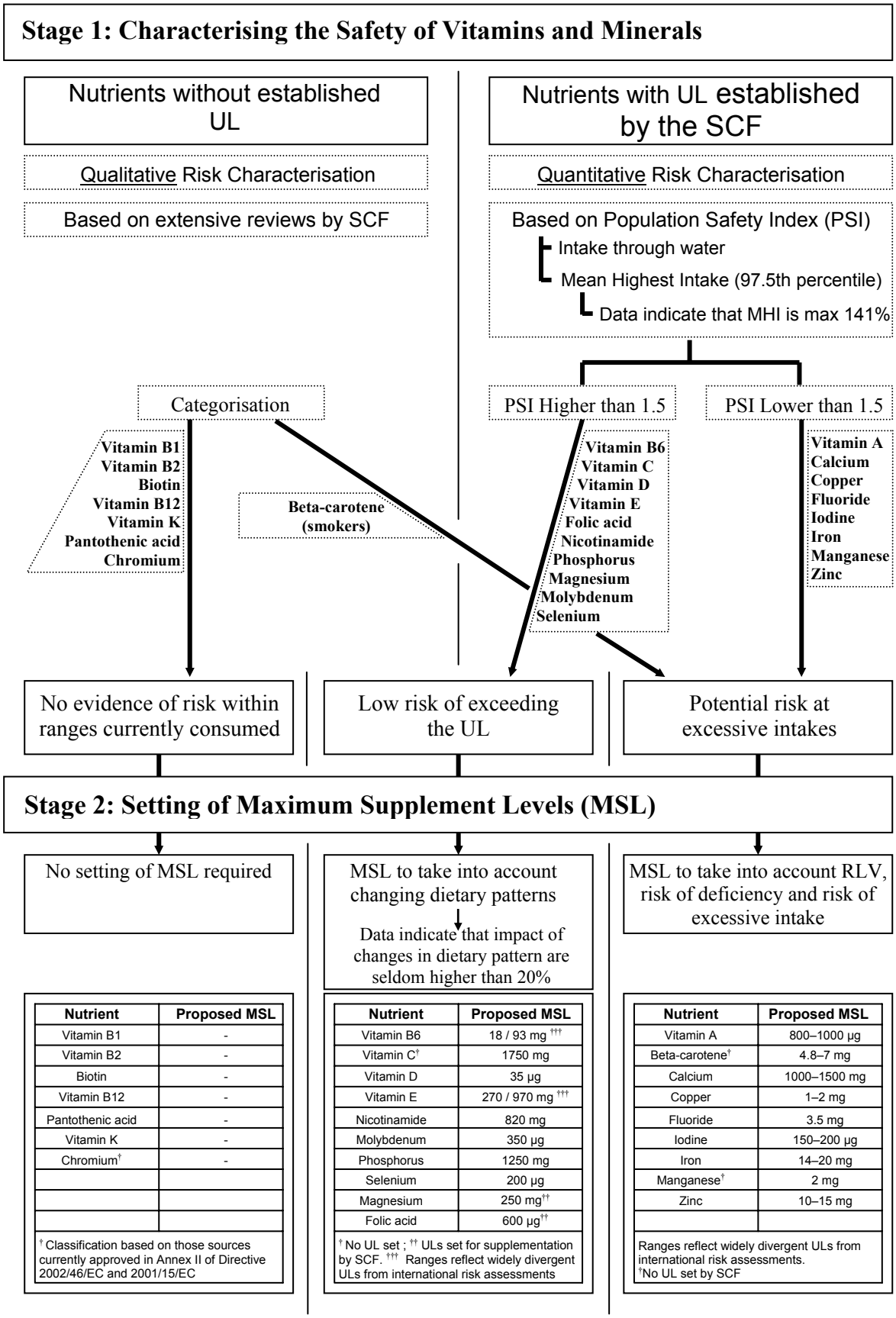
For vitamins
Show increase of intake more than 20 % only for Vitamin B6 and C.
A precautionary risk management factor of 50% to take into account potential changes in dietary pattern.
MSL = UL – (MHI x 150%)

For minerals
For technical and taste reasons, mineral fortification is self-limiting.
Therefore a factor of 10% could be set.
MSL = UL –[(MHI x 110%) + IW]

C: Potential risk of exceeding the UL
Vitamin A, Beta-carotene (smokers), Calcium, Copper, Fluoride, Iodine, Iron, Manganese, Zinc
→ **MSL to take into account RLV, risk of deficiency and risk of excessive intake**

[1] ERNA: European Responsible Nutrition Alliance; EHPM: European Federation of Associations of Health Product Manufacturers.
[2] UL: Intake levels that can be consumed daily over a lifetime without being likely to pose a risk to health according to available evidence.

GENERAL SUMMARY



Nutrient	Proposed MSL
Vitamin B1	-
Vitamin B2	-
Biotin	-
Vitamin B12	-
Pantothenic acid	-
Vitamin K	-
Chromium†	-

† Classification based on those sources currently approved in Annex II of Directive 2002/46/EC and 2001/15/EC

Nutrient	Proposed MSL
Vitamin B6	18 / 93 mg †††
Vitamin C†	1750 mg
Vitamin D	35 µg
Vitamin E	270 / 970 mg †††
Nicotinamide	820 mg
Molybdenum	350 µg
Phosphorus	1250 mg
Selenium	200 µg
Magnesium	250 mg††
Folic acid	600 µg††

† No UL set ; †† ULs set for supplementation by SCF. ††† Ranges reflect widely divergent ULs from international risk assessments

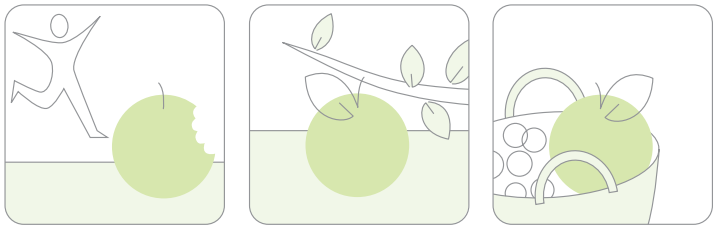
Nutrient	Proposed MSL
Vitamin A	800–1000 µg
Beta-carotene†	4.8–7 mg
Calcium	1000–1500 mg
Copper	1–2 mg
Fluoride	3.5 mg
Iodine	150–200 µg
Iron	14–20 mg
Manganese†	2 mg
Zinc	10–15 mg

Ranges reflect widely divergent ULs from international risk assessments.
†No UL set by SCF

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

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



EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

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

June 2006

Directorate E - Safety of the food chain

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INTRODUCTION

1. Directive 2002/46/EC on food supplements provides for the setting of maximum and minimum amounts of vitamins and minerals in these products via the Standing Committee procedure. Similar provisions are contained in the proposal for a Regulation on the addition of vitamins and minerals and of certain other substances to foods which is currently under discussion at the European Parliament in and Council and which is expected to be before adopted September/October of 2006.

2. This paper identifies the issues to be considered in the setting of maximum and minimum amounts of vitamins and minerals in foods.

3. The Health and Consumer Protection Directorate-General is keen to obtain the view of stakeholders on how these issues might be addressed and is issuing this discussion paper as a part of the consultation process.

4. Responses should reach the dedicated e-mail box SANCO-VITAMINS-AND-MINERALS@EC.EUROPA.EU by **30 September 2006**. Please note that any responses received could be made public.

Food Supplements

5. Food supplements are concentrated sources of vitamins, minerals and/or other substances (such as aminoacids, essential fatty acids, fibre and various plant and herbal extracts) sold as pills, tablets and other dose forms.

6. Directive 2002/46/EC on food supplements was adopted by the European Parliament and the Council in June 2002. Its aim is to facilitate the free circulation of those products, to ensure a high level of protection of public health and to provide a clear legal framework for manufacturers.

7. Directive 2002/46/EC on food supplements lays down provisions which:

   - regulate compositional aspects (e.g. positive lists of vitamins and minerals).

   - provide for appropriate specific rules on labelling, presentation and advertising of food supplements.

8. Although food supplements can contain a variety of ingredients, as a first step the Directive lays down specific provisions only for products containing vitamins and minerals. A report evaluating the advisability to cover products containing nutrients and/or ingredients other than vitamins and minerals have to be presented to the EP and to the Council in a report due by July 2007.

9. Moreover, the Directive foresees the setting of maximum and minimum levels for vitamins and minerals through the Standing Committee procedure and lays down the criteria for their setting.

Addition of vitamins and minerals to foods

10. A proposal for a Regulation on the addition of vitamins and minerals and of certain other substances to foods is currently under discussion at the European Parliament in and Council and is expected to be adopted by the end of 2006.

11. This proposal for a Regulation:

   - lists in Annex I the vitamins and minerals that may be added and in Annex II the sources of vitamins and minerals that may be used.

   - provides for certain restrictions regarding the foods to which vitamins and minerals may be added.

   - provides for specific rules on labelling, presentation and advertising of products to which vitamins and minerals have been added.

   - enables Member States to require the notification of the marketing of these products in order to facilitate their monitoring.

   - provides the basis for scrutinising and, where necessary, regulating the addition of certain substances, other than vitamins and minerals, to foods.

12. Moreover, it also sets the criteria for the establishment of maximum and minimum levels of vitamins and minerals in foods through the procedure of the Standing Committee on the Food Chain and Animal Health.

Maximum and minimum levels of vitamins and minerals

13. The importance of the diet for a healthy life has been amply demonstrated. Individual nutrients have received variable attention and vitamins and minerals are among them. The levels of intake of the latter have been cause of concerns both for being potentially on the low side but also because of the adverse effects that excessive intakes of certain vitamins and minerals may cause. It should, however, be noted that it is increasingly difficult to develop accurate assessments of the pattern of overall diets, since these vary across the regions of the EU, between population groups and over time.

14. Changing culinary and social habits have led to low intakes for some vitamins and minerals compared to those being recommended for certain groups of the population, although the vitamins and minerals and the groups of the population concerned may vary from Member State to Member State. In addition, some argue that optimal health may depend on higher levels of vitamins and minerals than those recommended today on the basis of avoiding deficiencies. As a result, products that contribute to the intake of vitamins and minerals beyond the levels that would be provided by the natural content of foods have increased considerably on the market. These may be food supplements but also foods to which vitamins and minerals have been added (fortified foods). With such proliferation of these products the setting of maximum levels for vitamins and minerals is becoming increasingly a pressing need for the responsible authorities to ensure that the potential sum of intakes from all sources on the market should not threaten to undermine the high level of human health which the Treaty sets as our policy objective.

15. In addition, it is important to underline that the application of divergent maximum permitted levels of vitamins and minerals in Members States is causing serious problems to the free circulation of the products concerned in the European market.

16. The maximum levels for vitamins and minerals have not been set in Directive 2002/46/EC on food supplements, but have to be established by the Commission through the Regulatory Committee as an implementing measure.

17. Article 5 of Directive 2002/46/EC reads:

    "*1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:*

    (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) intake of vitamins and minerals from other dietary sources.

2. When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population.

3. To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate.

4. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with the procedure referred to in Article 13(2).”

18. Similar provisions for the establishment of maximum levels for vitamins and minerals in foodstuffs are present in the proposal for a Regulation on the addition of vitamins and minerals and of certain other substances to foods. Article 6 of this proposal for a Regulation reads:

    “1. When a vitamin or a mineral is added to foods, the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed maximum amounts that shall be set in accordance with the procedure referred to in Article 14(2). For concentrated and dehydrated products, the maximum amounts set shall be those present in the foods when prepared for consumption according to the manufacturer's instructions.

    2. Any conditions restricting or prohibiting the addition of a specific vitamin or mineral to a food or a category of foods shall be adopted in accordance with the procedure referred to in Article 14(2).

    3. The maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 shall be set taking the following into account:

    (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally acceptable scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different groups of consumers;

    (b) intakes of vitamins and minerals from other dietary sources.

    4. When the maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 are set for vitamins and minerals whose reference intakes for the population are close to the upper safe levels, the following shall also be taken into account, as necessary:

    (a) the contribution of individual products to the overall diet of the population in general or of sub-groups of the population;

    (b) the nutrient profile of the product established as provided for by Regulation (EC) No .../... “(Regulation on nutrition and health claims).

19. Vitamins and minerals used in food supplements or added to foods should result in a minimum amount being present. Otherwise, the presence of too small

amount would not offer any benefit to consumers, namely to supplement the normal diet in the case of food supplements, and would be misleading.

20. These minimum levels should be set in accordance with the provisions of Article 5.3 of Directive 2002/46/EC cited above (see paragraph 17) and with the relevant provisions of the Draft Regulation on the addition of vitamins and minerals and of certain other substances to foods. Article 6.6 of the Common Position adopted by the Council reads:

"The addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to the Annex to Directive 90/496/EEC. The minimum amounts, including any lower amounts, by derogation from the significant amounts mentioned above, for specific foods or categories of foods shall be adopted in accordance with the procedure referred to in Article 14(2)".

SETTING OF MAXIMUM AMOUNTS

21. General food law principles aim to ensure that food is safe. Measures to achieve this goal should be proportionate in order to ensure a high level of protection of public health, where, at the same time, avoiding undue constraints for businesses.

22. Moreover, it should be noted that this exercise takes place in the political context of the renewed Lisbon Strategy where the EU focuses among other on better regulation (meaning also avoiding unnecessary overregulation) as a means to contribute to achieving economic growth and creating jobs and where measures should be taken following a broad dialogue with stakeholders.

23. A number of scientific bodies and stakeholders have considered the issue of setting maximum levels of vitamins and minerals in foods and have elaborated several models. Examples of certain of these models can be found in the annex of this document.

24. Taking into account these general considerations, in the context of the exercise of setting the maximum amounts for vitamins and minerals in foodstuffs, certain questions need to be carefully considered.

Establishment of maximum amounts for food supplements and other foods

25. In order to take into account the elements mentioned in Article 5.1.(a) of Directive 2002/46/EC, the Commission requested the Scientific Committee of Food (SCF) and later the European Food Safety Agency (EFSA) to provide scientific opinions on tolerable upper intakes levels of the 29 nutrients listed in Annex I of the Directive plus boron, vanadium, nickel, tin and silicon.

26. The SCF provided opinions on 22 nutrients[1] while EFSA issued the remaining opinions in summer 2005[2].

27. In those scientific opinions specific numerical tolerable upper intake levels are established for 16 nutrients. For the others the lack of sufficient scientific data, in particular, lack of systematic oral intake dose-response studies, did not allow to derive numerical upper levels. However, for some nutrients extremely low or non-existent toxicity even at high doses of administration is indicated from existing evidence that is available from observational studies. In other cases, even if adverse effects could be determined, the available data were insufficient to derive a tolerable upper intake level.

28. Although food supplements and foods to which vitamins and minerals are added are covered by different measures the considerations for setting maximum levels for vitamins and minerals in the different products are inevitably interrelated. In particular, the distribution of these nutrients in the two broad categories of food

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[1] *http://ec.europa.eu/comm/food/fs/sc/scf/outcome_en.html#opinions*

[2] *http://www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html*

products, food supplements and fortified foods, have to be considered together if we are to have a clear picture of the overall food offering.

Questions on which the Commission seeks comments:

- Where there is not yet a scientifically established numerical tolerable upper intake levels for several nutrients, what should be the upper safe levels for those nutrients that should be taken into account in setting their maximum levels?

- 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?

- Where we set maximum levels, do we inevitably also have to set maximum amounts for vitamins and minerals separately for food supplements and fortified foods in order to safeguard both a high level of public health protection and the legitimate expectations of the various food business operators? Are there alternatives?

Intake of vitamins and minerals from dietary sources

29. Vitamins and minerals may be ingested from a variety of foods that are eaten as part of the daily diet. They can be naturally present in foods or added to them both for technological or nutritional purposes. Innovation in the food sector tends to take increasingly into account the relationship between diet and health and may lead to an increase of the percentage of foodstuffs fortified with vitamins and minerals on the market. Moreover, it should also be taken into account that, especially in some Member States, food supplements are a non-negligible source of nutrients in the daily diet. The amounts contributed by these various sources have to be taken into account when setting maximum levels.

30. The estimates of intakes are essentially derived through dietary surveys data and relevant food composition data. The main types of dietary surveys are individual and household surveys. Individual dietary surveys include: duplicate meal surveys; weighed intakes; estimated intakes; diet histories; 24 hour recall and, food frequency questionnaires. Individual surveys might be conducted on specific population groups by age or other characteristics (pregnant women, low income groups, ethnic origin).

31. Household surveys record the food purchases of a household for a certain period of time with estimates of individual intake based on dividing the total purchases by the number of people in the household. As not all food is consumed in the home some household surveys include also a record of foods eaten outside the home.

32. The costs associated with conducting the surveys and the reliability and accuracy of the estimates of intake vary. In general, surveys are expensive, therefore, they are not conducted frequently and they are not available in all Member States. Moreover, when they do exist, they can be out of date and may not reflect current intakes of vitamins and minerals.

33. The data derived from dietary surveys of a population may be presented as mean intakes (possibly by age and sex). In some cases there may also be information on the extremes of intakes both the lower and higher levels and on intakes of specific population groups (e.g. infants, adolescents, elderly). In addition some surveys may differentiate intakes from food supplements whilst others may give only an estimate of intake from food sources either including or excluding food supplements.

Questions on which the Commission seeks comments:

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

Reference intakes of vitamins and minerals

34. Article 5.2 of Directive 2002/46/EC on food supplements stipulates that: *"When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population."*

35. The Population Reference Intakes (PRIs), also called Recommended Daily Allowances (RDAs), are based on the principle that most, if not all, individuals of a population or a specific population group should obtain an adequate nutrient intake to satisfy their requirements. Such recommended values are generally based on the principle of the average requirement plus two Standard Deviations (SD) for the nutrient in the population group.

36. In 1992 an SCF opinion on nutrient and energy intakes for the European Community[3] defined the PRIs for several nutrients.

37. These values were mainly determined on the basis of the concept of optimal nutrition which implied that these values were determined among other, to prevent deficiencies, to optimise body stores and to reduce the risk of diseases.

[3] *http://ec.europa.eu/comm/food/fs/sc/scf/out89.pdf*

38. More recently in 2003 the SCF issued an opinion on the Revision on Reference Labelling Values [4] which, of course are not the same as PRIs but are derived on the basis of national updated RDA/PRI tables.

39. It should also be noted that in 2005 the Commission requested EFSA to review the SCF recommendations on PRIs for micronutrients. However, EFSA has indicated that due to the complexity of the task, it is not expected to be completed in the next few years.

40. Population Reference Intakes are often used for purposes which are not the ones for which they were established. In the case of setting maximum levels for vitamins and minerals they Have been used:

    (1) To determine whether there is a nutritional need for a vitamins or a mineral in the population (e.g. due to estimated deficiencies) and accordingly allow the addition of the nutrient to foods or its presence in food supplements.

    (2) To set the maximum level of a vitamin or a mineral as a multiple of the reference intake, even if such a limitation could not be justified on a safety ground on a case-by-case evaluation.

41. In assessing such practices, the rulings that the European Court of Justice issued in the last few years concerning the use of PRI/RDI in some Member States must be also taken into consideration. In this context:

    - In Case C-192/01 the Court evaluated the Danish administrative practice which entailed that enriched foodstuffs lawfully produced or marketed in other Member States might be marketed in Denmark only if it is shown that such enrichment with nutrients met a need in the Danish population. The Court ruled that "*the absence of such a need cannot, by itself, justify a total prohibition, on the basis of Article 30 EC, of the marketing of foodstuffs lawfully manufactured and/or marketed in other Member States*", therefore "*the Danish administrative practice is disproportionate since, ..., it systematically prohibits the marketing of all foodstuffs to which vitamins and minerals have been added, without distinguishing according to the different vitamins and minerals added or according to the level of risk which their addition may possibly pose to public health*".

    - In Cases C-387/99 and C-150/00 the Court evaluated the German and Austrian practices classifying as medicinal products vitamin and mineral preparations which were lawfully produced or marketed as food supplements in the other Member States where they contained amounts of vitamins and minerals exceeding three times (one time for some vitamins and minerals in the case of Austria) the RDA/PRI. The Court ruled that *"the automatic nature of that practice does not make it possible to identify and assess a real risk to public health, which requires a detailed assessment on a case-by-case basis of the effects which the addition of the vitamins in question could entail"* and therefore that these practices are disproportionate.

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[4] *http://ec.europa.eu/comm/food/fs/sc/scf/out171_en.pdf*

42. The PRIs should, of course, be borne in mind when setting maximum levels for vitamins and minerals for which there is not a great difference between the PRI and the tolerable upper level in order to avoid that maximum levels set could lead to risk of intakes for a nutrient being lower than the PRI.

Question on which the Commission seeks comments:

- 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?

MINIMUM AMOUNTS

43. Council Directive 90/496/EEC on nutrition labelling requires that in order that vitamins or minerals may be declared in nutrition labelling they have to be present in a significant amount, which, as a rule, is the amount in 100 g or 100 ml of the food representing 15% of the recommended allowance specified in the Annex to Directive 90/496/EEC. The same amount has to be present if a nutrition claim is made that the food is a "source" of a vitamin or a mineral, according to the proposed Regulation on nutrition and health claims made on foods, expected to be adopted in September/October 2006.

44. The proposed Regulation on the addition of vitamins and minerals to foodstuffs foresees that, in order to guarantee consumers of the presence of vitamins and minerals in fortified foods in at least a meaningful amount, their addition shall result in the presence of at least a significant amount where this is defined according to the Annex to Directive 90/496/EEC on nutrition labelling. However, this provision allows discretion to set minimum amounts that are different from that significant amount for specific foods or categories of foods.

45. It should be noted that the lists of vitamins and minerals in the proposed Regulation on the addition of vitamins and minerals to foodstuffs include more nutrients than the ones listed in the Annex to Directive 90/496/EEC. In order to update this Annex and to approach several other technical issues on nutritional labelling of foodstuffs, the Commission has recently published a discussion paper[5].

46. While the use of significant amounts as minimum amounts may be considered generally acceptable for fortified foods, some argue that it would not be adequate for food supplements. Food supplements are by definition concentrated sources of nutrients. Therefore, some argue that these products should be providing minimum amounts of those nutrients, per recommended daily consumption dose, higher than the abovementioned significant amounts.

Questions on which the Commission seeks comments:

- 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?

- 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?

[5] *http://ec.europa.eu/comm/food/food/labellingnutrition/nutritionlabel/discussion_paper_rev_tech_issues.pdf*

ANNEX

EXAMPLES OF EXISTING MODELS FOR THE SETTING OF MAXIMUM AMOUNTS OF VITAMINS AND MINERALS IN FOODS

Model developed by the French Agency of Food Safety (AFSSA)

Subject: Addition of vitamins and minerals in food

It should be underlined that for France, any addition of vitamins or minerals should be justified by the need of answering the double requirement of public health and food safety: the evaluation must integrate both **nutritional dimension** and the concern of the **optimal food safety** of the consumer.

Part I: Methodology followed to determine the optimal contents

The procedure was designed by the French Agency of food safety (AFSSA). It is held in several stages.

1. Safety factors and nutritional interest

Firstly, the heavily consumed nutrients (for which the **97.5th percentile** of intakes of populations or of targeted groups reaches or exceeds the safety limits) are excluded. This choice of the 97.5th percentile is based on a WHO report (*Methodology for exposure assessment off contaminant and toxins in food* - 2000).

Moreover, preference is given to the nutrients that are of nutritional interest for a population or a group of individuals. In the absence of validated markers allowing to demonstrating the existence of a deficiency, the expert shall use the concept of **prevalence of inadequacy of intakes** compared to the requirements. This prevalence is estimated by the percentage of individuals whose contributions are lower than the "Besoin Nutritionnel Moyen" (BNM or Estimated Average Requirement: EAR).

The estimate of the prevalence of inadequacy makes it possible to identify the groups at the risk of inadequacy of requirements. From the data of consumption available for the various categories of age and sex, it is possible to determine the various prevalence of inadequacy for each selected nutrient, as well as the confidence intervals (because the data are not exhaustive and were carried out on samples representative of the population).

The risk of inadequecy of requirements is based on the estimate of the confidence interval (95%) of the prevalence of inadequacy of intakes compared to the requirements. To determine the groups at the risk of inadequacy of intakes, the experts considered as scientifically relevant the confidence intervals excluding the median value of 50% in lower limit (because it means that half of the population has intakes higher than EAR) and including the threshold of 70% (which testifies to a strong prevalence of inadequacy).

2. Classification of the nutrients

From these data, it is then possible to distinguish the nutrients:

1. Those for which risks of inadequacy of contribution were identified in certain categories of the population with a limited risk of exceeding the safety limit: **vitamin C, magnesium** ;
2. Those for which risks of deficiencies or inadequacy of intakes were identified in certain categories of the population but for which the risk of exceeding the safety limits is possible for certain populations (heavy consuming…): **vitamins C, D, B9, calcium, iron, iodine**;
3. Those for which the risk of inadequacy of intakes is relatively weak and for which there are no safety limits: **vitamins B1, B2, B5, B8, B12** and for which, the risk of exceeding the safety limit is weak**: vitamin B3** ;

4. Those for which the risk of inadequacy of intakes is relatively weak but for which a risk of exceeding the safety limits is possible: **vitamins E, K, B6, fluorine, sodium;**

Vitamin A constitutes a particular case insofar as the 97.5th percentile of consumption in France exceeds the safety limit of vitamin A.

If a risk of exceeding the upper limits is possible, simulation studies are necessary. From these studies, various levels of addition can then be considered. The chemical form of the nutrient can also play an important part in the amount selected (cf. example of the vitamin B3).

Part II: Adaptations according to the problems

1. Normal foods

First of all, it should be reminded that in France the enrichment of normal foods is subjected to a preliminary authorization. The French authorities have to take some decisions on a case-by-case basis on the operators' requests. The authorizations reflect the condition of uses requested by the applicant. Even if the AFSSA carried out a global reflection on the topic of enrichment, the authorities made no simulations for each nutrient.

In addition to methodology presented above, the manufacturers should observe the conditions presented in the AFSSA report entitled "Specification for the selection of a nutrient-vector food pair". This report envisages in particular that the food vector of enrichment is consumed by the groups of population presenting the highlighted deficiency and that this food is, as far as possible, in conformity with the general nutritional recommendations: it is indeed preferable to enrich a food which an increase of consumption is recommended. A priority is given to the food, which naturally contains the added nutrient in order not to create distortion in food perceptions of the consumers and to avoid the problems of nutritional interactions. For this reason, France always privileged the steps aiming at restoring the contents of nutrients, which could have been lost during the process of a product.

Lastly, the safety of enrichment and its utility must be checked by simulations when that proves to be necessary (cf. part I). A monitory of consumption of the enriched product is also required.

2. Food supplements

From the preceding data, a distinction was established between the nutrients for which a risk of exceeding the safety limit exists and those for which this risk is weak.

In the first case, the maximum content was limited to the recommended daily intakes or even to a lower content still because:

- of a risk of exceeding the safety limits and of the risk of fluorose for children due to an over-consumption of fluorine;
- problems of public health: patients under anti-vitamin K and vitamin K or sanitary messages aiming to the reduction of salt and sodium consumption.

In the second case, the maximum content was limited to three times the recommended daily intakes by also taking into account nutrient requirements and intakes, as the directive n° 2002/46 envisages it.
These contents were fixed temporarily before the harmonization.

Model developed by the Danish Institute of Food and Veterinary Research

Subject: A safe strategy for addition of vitamins and minerals to foods (the Danish budget model)

The Danish Institute of Food and Veterinary Research has for its safety assessment of fortification of foods developed a model based on a scientific paper by Flynn et al. 2003. The Danish model has developed and extended the model previously proposed by Flynn by considering the common use of micronutrient supplements and by introducing age-differentiated ULs and thereby focusing in particular on the safety of children and adolescents.

The Danish model makes use of the Tolerable Upper Intake Level (UL) established by SCF/EFSA and other international expert groups compared with the 95-percentile intakes of micronutrients from the regular diet. Estimated dietary intakes of energy, vitamins and minerals for selected groups of the population are based on Danish nation-wide dietary surveys. The model includes the contribution from supplement intake (SI), a combined multi-vitamin-mineral tablet to the total intake of micronutrients as approximately half of the adult population and about two thirds of the children in Denmark take supplements regularly.

The model employs three main elements, the ULs, the 95th percentile intake of micronutrients from the regular diet (CI_{95}), and supplements (SI), and the resulting maximal allowance (MA) for fortification. By using these factors it is possible to estimate the level of each micronutrient that can be added to foods without any appreciable risk of adverse effects for any age group in the population, including individuals with high food intakes. The model is based on the following factors and mathematical formulas:

UL: the Tolerable Upper Intake Level established by SCF or other expert committees. Where no UL has been established, guidance levels (GLs) suggested by the UK Expert Group on Vitamins and Minerals (EVM) are used instead. In general the database on adverse effects of nutrients in children and adolescents is limited. Therefore, it has been chosen to correct for differences in basal metabolic rate by extrapolating from adults to children on a body surface area basis ($bw^{0,75}$).

CI_{95}: the current 95th percentile dietary intakes of micronutrients from the regular diet. Data is derived from the Danish dietary intake surveys mainly from 2000-2002. Budget calculations are conducted for five age groups of children and for younger men - the adult group with the highest energy intake compared to their weight.

SI: supplement intake; daily micronutrient intake from a normal vitamin/mineral supplement (100 % of ADT). For children less than ten years old: ADT for that age group.

MA: maximal allowance for intake of micronutrients from fortified foods: $MA = UL - (CI_{95} + SI)$
EI_{95}: the 95th percentile energy intake.

PFF_n: the fraction of foods in the market that is available for fortification.

ALA: Acceptable level of addition with each nutrient per energy portion of the food.

$$ALA = \frac{MA}{EI_{95} \times PFF_n}$$

However not all foods can or will be fortified. In agreement with Flynn we estimate that about half of the Danish diet consists of foods, which are potentially fortifiable. Among these not all foods will be fortified. Assuming that potentially 25% of the energy intake comes from fortified foods the acceptable levels of addition (ALAs) can be distributed in energy portions: $ALA_{25} = MA/(EI_{95} \times 0.25)$. For light products an energy density similar to the non-light analog is applied. In this way addition to light products will be accepted at the same level as their high-energy analogs.

Derivation of Maximum Levels of Vitamins and Minerals Added to Foods Based on Risk Assessment

BfR
Risiken erkennen – Gesundheit schützen

Grossklaus R, Hembeck A, Niemann B, Przyrembel H, Richter K, Schmidt E, Weissenborn A, Wörner B, Ziegenhagen R

FEDERAL INSTITUTE FOR RISK ASSESSMENT

Background:

Although an adequate and varied diet can, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life, consumers often desire to improve the perceived quality of their diet because of their particular lifestyles or other reasons. Food supplements and fortified foods, enriched with vitamins and minerals, have become increasingly available and popular on the European market.

Relevant national regulations for the addition of micronutrients to foods vary widely within the European Community. The first steps towards harmonisation of existing regulations were the adoption of Directive 2002/46/EC on food supplements and the publication of a draft proposal for the regulation of the voluntary addition of vitamins and minerals to foods. Both regulations contain rules on the range of vitamins and minerals that may be added to supplements and normal foods. However, as some micronutrients may cause adverse effects if consumed in excessive amounts, values for maximum levels of vitamins and minerals added to those products are foreseen in the EU regulation.

Objective: To develop a model to determine the level of each micronutrient that can be added safely to dietary supplements and/or normal foods per daily portion of consumption.

Methods: The following steps were applied in establishing maximum levels of vitamins and minerals for use in dietary supplements and fortified foods:

Step 1: Hazard (Nutrient) Identification	- Nutrient description, substance characterisation - Metabolism, function - Recommended Dietary Allowance (RDA)
Step 2: Intake Assessment	- Food intake data, Biomarkers - Groups susceptible to sub-optimal intake/ deficiency or excessive intake/ toxicity
Step 3: Hazard Characterisation, Dose-Response Assessment	- NOAEL/ LOAEL, uncertainty factors (UF) - Upper Intake Level (UL) by SCF/ EFSA or FNB
Step 4: Risk Characterisation	- Conclusions from steps 1 to 3 - Information gaps/ lack of data - Derivation of maximum levels of micronutrients for addition to supplements and normal foods

Special Considerations for Essential Nutrients

- When evaluating the adverse effects of micronutrients it has to be taken into account that, in contrast to non-essential substances, there is a level of intake below which the risk of deficiency or sub-optimal function rises.
- There is a long history of safe consumption of nutrients at the levels found in balanced human diets.
- For some nutrients there may be experience of chronic consumption at levels significantly above those obtained from endogenous nutrients in foods without reported adverse effects.
- Many nutrients are subject to homeostatic regulation of body content through adaptation of absorptive, excretory or metabolic processes.
- Added nutrients may differ from endogenous nutrients in foods in a number of ways, e.g. chemical form, timing of intake and amount consumed in a bolus dose, effect of the food matrix, bioavailability, and interaction of the nutrient with other constituents of the diet.
- Nutrients can be classified according to the risk of adverse effects through excessive intake (table 1) and to the degree of risk of inadequate intake (table 2):

Categories	Criteria
high	Nutrients for which the margin between the RDA (or actual intake) and UL is very narrow (≤ 5) **(e.g. Vitamin A, D, Copper, Iron, Zinc)**
moderate	Nutrients for which the UL is 5 to 100 times above the RDA (or actual intake) **(e.g.Vitamin E, K, C, B_6, Magnesium, Molybdenum)**
low	Nutrients for which a UL cannot be set as no adverse effects have been observed till now, even at intake 100 times the RDA **(e.g. Vitamin B_1, B_2, B_{12}, Chromium)**

Table 1: Risk of excessive intake

Categories	Criteria
1	Risk of a clinically manifest deficiency or a depletion of body stores in specific age groups, with specific physiological conditions/ with specific eating habits/ in specific regions **(e.g. Folate, Iodine, Vitamin D)**
2	Uncertainty about the risk of a clinically manifest deficiency or a depletion of body stores because of the lack of or the questionable validity of biomarkers, inadequate food tables, or a lack of epidemiological studies **(e.g. Vitamin K, Biotin, Fluoride, Zinc, Selenium)**
3	No indication of inadequate nutrient intake, or nutrient intake in the range of recommended intake **(e.g. Vitamin B_1, Vitamin B_2, Copper)**
4	Indication of nutrient intake above recommended intake **(e.g. Vitamin B_6, B_{12}, Sodium, Chloride, Phosphorus)**

Table 2: Risk of inadequate intake

Risk Model applied to determine maximum levels of micronutrients for addition to supplements and foods per daily portion of consumption:

The model is based on the following factors:

- UL = Upper Intake Level
- DINF = current estimated level of intake of a micronutrient from non-fortified foods at P 95 or P 97.5
- MEF = Multi-Exposure Factor = estimated number of food supplements and fortified foods with the respective nutrient

The amount of each nutrient which may be added to the diet as a whole with no appreciable risk of adverse health effects can be determined as the difference between the UL and the current estimated intake of the respective micronutrient from non-fortified foods at P95 or P97.5.

$$R = UL - DINF$$

Example: Folic Acid R = (1000* - 0) µg/d
R = 1000 µg/d
*UL only applies to folic acid

The resulting figure (R) constitutes the amount available for addition to supplements (R_S) and fortified foods (R_F). The percentage of "R" to be allocated to supplements and fortified foods is selectable and may vary between 0 and 100%.

$$R = R_S + R_F$$

Example: Folic Acid R (1000 µg/d) = $R_S + R_F$
R = (500 + 500) µg/d
or R = (400 + 600) µg/d

Considering that people might take more than one supplement or consume several portions of fortified foods per day, a Multi-Exposure Factor (MEF) has been introduced, and maximum levels for single portion of supplements (ML_S) or foods (ML_F) were calculated as follows:

$$ML_S = \frac{R_S}{MEF}$$

Example: Folic Acid $ML_S = \frac{400\ \mu g/d}{1} = 400\ \mu g/d$

$$ML_F = \frac{R_F}{MEF}$$

Example: Folic Acid $ML_F = \frac{600\ \mu g/d}{3} = 200\ \mu g/d$

Nutrients for which this model was not applicable	Reasons
• Vitamin A	Intake via normal foods at P97,5 is above the UL
• β Carotene	UL has not been set because of insufficient scientific basis; no dose- response-relationship available
• Vitamin K; Vitamin C; Chloride; Sodium; Phosphorus	UL has not been set because of lack of data
• Vitamin B_1; Vitamin B_2; Biotin; Pantothenic Acid; Vitamin B_{12}	UL has not been set because of lack of data (no systematic toxicological studies reported), no adverse effects have been observed
• Nicotinamide	Intake data do not distinguish between nicotinic acid and nicotinamide
• Iron	UL has not been set because available data on associations between iron status and disease are inconsistent
• Fluoride; Selenium; Molybdenum	Intake data are not available
• Manganese	Intake data are not available; UL has not been set because of lack of data and considerable degree of uncertainty
• Chromium	Intake data are not available; UL has not been set because of lack of information on the dose-response relationship

- **For the first time maximum levels of micronutrients for addition to food supplements and fortified foods per daily portion of consumption have been derived based on risk assessment.**
- **While the model approach is based solely on safety considerations, BfR strongly emphasises that when establishing maximum levels of micronutrients, nutritional aspects have to be taken into consideration as well.**
- **The model is not always applicable, e.g. in cases when no UL was set, but also when insufficient data on dietary intake/ nutritional status were available .**
- **Whenever the model was not applicable, maximum levels were determined on the basis of physiological and nutritional considerations.**

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ILSI Europe 'Vitamins and minerals: a model for safe addition to foods'

Reference: Flynn, A., Moreiras, O., Stehle, P., Fletcher, R.J., Müller, D.J.G., Rolland, V. 2003. Vitamins and Minerals: A model for safe addition to foods. *European Journal of Nutrition*, 42 (2): 118-130

Available on: *http://europe.ilsi.org/file/ilsieuroope-vitandmineralsarticle.pdf*

This ILSI Europe paper describes the use of a theoretical model to assess the safety of the (voluntary) addition of vitamins and minerals to foods. It is based on actual food energy and nutrient intakes from national dietary surveys, and takes into account the special needs of people who consume large amounts of food (at the 95th centile of energy intakes). The yardstick of safety used is the tolerable upper intake level (UL) for each nutrient, i.e. the maximum average daily amount of each nutrient which can be consumed safely over a long period of time.

The results suggest that at least 15% EU RDA per serving can be added safely to foods in Europe for most micronutrients. This is consistent with a similar assessment carried out by AFSSA (the French food standards agency) in the context of the French diet. The results presented are based on data currently available in Europe, but alternative values can be used for other populations, assumptions or dietary reference values.

The maximum amount of a micronutrient which can be added safely to the diet overall is estimated as the difference between the UL and the P95 for the mean daily intake of the nutrient from food in adults obtained from large scale surveys of food consumption in European countries. This is then expressed per 100 kcal of food energy assuming:

- P95 for mean daily food energy intake is 3600 kcal (i.e. an indication of energy intake of high consumers - this exceeds the energy intake of 95% of consumers), derived from large scale surveys of food consumption in European countries, or P95 for mean daily number of typical servings of food consumed is 36. (Expressing values per typical serving (e.g. 100 kcal) allows assessment of safe addition to low calorie and energy reduced products, as well as to foods generally).

- a maximum of 50% of average daily food energy consumed is potentially fortifiable, derived from evaluation of food consumption data. (In European countries where voluntary fortification has been a long-term practice, an average of 3-9 percent of daily food energy comes from foods fortified with one or more nutrients).

Three categories of micronutrients were identified in which micronutrients can be added safely to foods at levels per serving (or per 100 kcal) of:

1. greater than 1 EC Recommended Daily Allowance (RDA): vitamin B 12, vitamin C, vitamin E, riboflavin, pantothenic acid, niacin and thiamin (even if all potentially fortifiable foods were fortified with that nutrient);

2. between 50 and 100% of the EC RDA: vitamin B6, vitamin D, folic acid, biotin, copper, iodine, and selenium (provided a maximum of 25% of all potentially fortifiable food energy was fortified with that nutrient);

3. between 10 and 40 % of the EC RDA iron, zinc, calcium, phosphorus, and magnesium (provided a maximum of 25% of all potentially fortifiable food energy was fortified with that nutrient).

A fourth category consisting of retinol (vitamin A), for which high end intake levels are close to the UL for some population subgroups in Europe, which requires further consideration.

The current model is applied to adults; however its application to the diets of children is also discussed.

VITAMIN and MINERAL SUPPLEMENTS: A RISK MANAGEMENT MODEL (ERNA-EHPM[1], Nov 04, ISBN: 9080920614, http://www.erna.org/data/pdf/INF206.pdf)

This paper, developed by ERNA and EHPM, describes a risk management methodology for establishing upper level food vitamins and minerals in food supplements.

Part 1: Quantitative and qualitative safety characterisation of the vitamins and minerals

a. When tolerable upper intake levels (UL)[2] are set by the Scientific Committee for Food (SCF) or European Food Safety Authority (EFSA), a **quantitative safety characterisation** is able to indicate the relative potential of higher intake groups to exceed the UL by the calculation of the Population Safety Index (PSI). Using the UL set by the SCF and EFSA, the following quantitative risk characterisation can be established (based on calculated PSI value above or below 1.5):

$$PSI = \frac{UL - (MHI + IW)}{RLV}$$

PSI: Population Safety Index
UL: Tolerable upper intake level as set by SCF or EFSA
IW: Intake from water (only relevant for minerals)
MHI: Mean Highest Intake: Highest intake from dietary sources (97.5th percentile) based on adult male intake data from available studies (Ire, It, Nl, UK)
RLV: Reference Values for Nutritional Labelling as set by SCF (Opinion of 5 March 2003, SCF/CS/NUT/GEN/18 Final)

Low risk of exceeding the UL			
Nicotinamide	52.8	Vitamin D	8.1
Vitamin E	23.2	Molybdenum	7.4
Vitamin C	22.0	Selenium	3.6
Vitamin B6	21.9	Phosphorus	2.1
Potential risk of exceeding the UL			
Iron	1.5	Zinc	0.4
Iodine	1.1	Vitamin A (preformed retinol)	-1.2
Copper	0.8		
Calcium	0.6		

b. In those cases where an UL is not established, a **qualitative risk characterisation** is required on the basis of available risk assessment. Extensive reviews by the SCF and EFSA give indications of the nature of the adverse effects associated with each nutrient and potential risks in relation to existing patterns of intake. Qualitative assessment of the SCF opinions (and other authoritative reports) show no adverse effects in healthy individuals associated with high intakes of biotin, chromium, pantothenic acid, vitamin B2, vitamin B1, vitamin B12 and Vitamin K.

Part 2: Setting of maximum levels based on the risk characterisation described in part 1

Three risk categories for setting maximum levels for food supplements (MSL) can be differentiated:

A: No evidence of risk within ranges currently consumed; Does not represent a risk to human health
Vitamin B1, Vitamin B2, Biotin, Vitamin B12, Pantothenic acid, Vitamin K, Chromium
→ **No setting of MSL required**

B: Low risk of exceeding the UL
Vitamin B6, Vitamin C, Vitamin D, Vitamin E, Nicotinamide, Molybdenum, Phosphorus, Selenium
UL for supplementation set by SCF: Magnesium, Folic acid
→ **MSL to take into account changing dietary patterns**

Based on UK surveys (1986/7 - 2000/1): intake from foods and fortified foods (in a liberal market place)

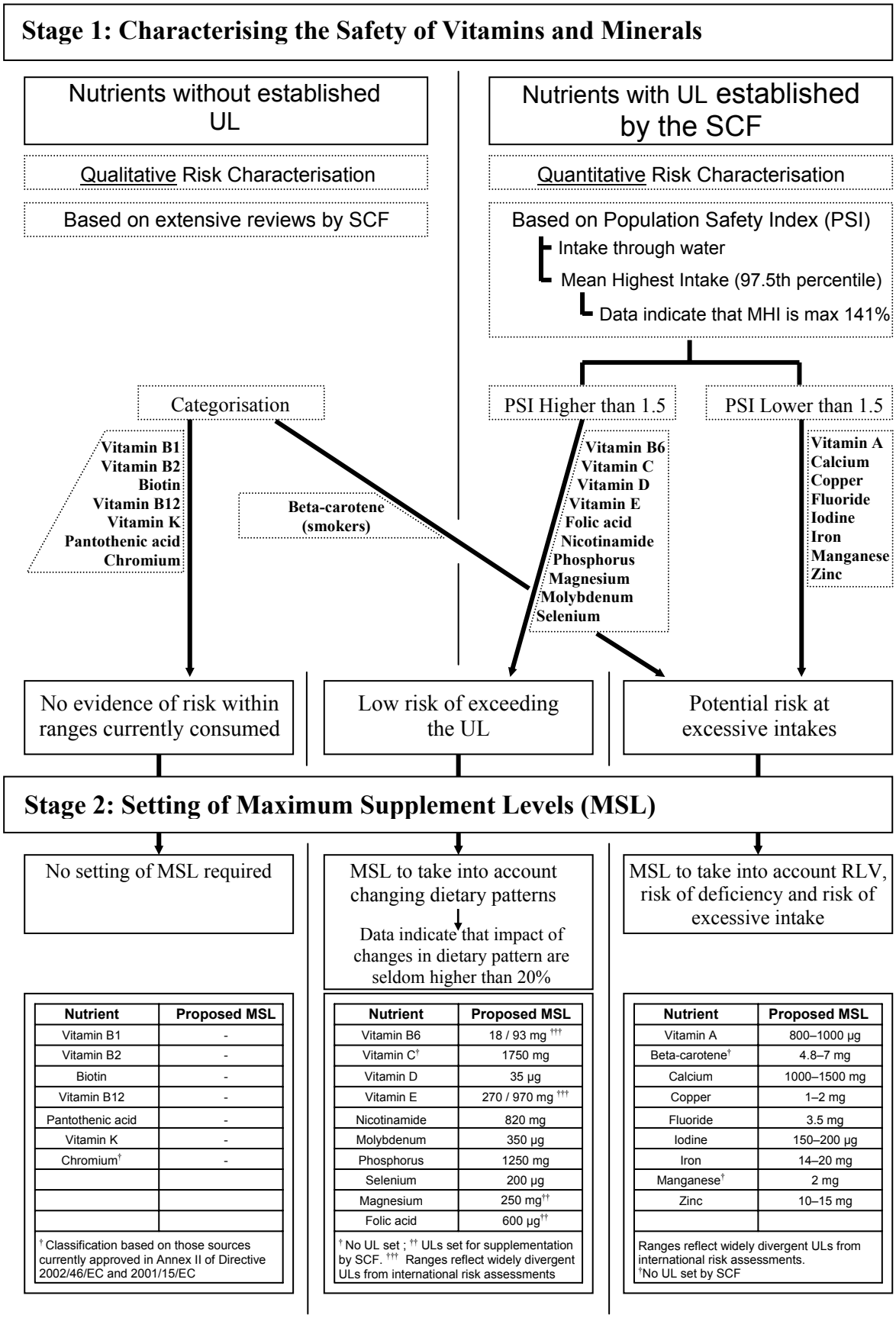
For vitamins
Show increase of intake more than 20 % only for Vitamin B6 and C.
A precautionary risk management factor of 50% to take into account potential changes in dietary pattern.
MSL = UL – (MHI x 150%)

For minerals
For technical and taste reasons, mineral fortification is self-limiting.
Therefore a factor of 10% could be set.
MSL = UL –[(MHI x 110%) + IW]

C: Potential risk of exceeding the UL
Vitamin A, Beta-carotene (smokers), Calcium, Copper, Fluoride, Iodine, Iron, Manganese, Zinc
→ **MSL to take into account RLV, risk of deficiency and risk of excessive intake**

[1] ERNA: European Responsible Nutrition Alliance; EHPM: European Federation of Associations of Health Product Manufacturers.
[2] UL: Intake levels that can be consumed daily over a lifetime without being likely to pose a risk to health according to available evidence.

GENERAL SUMMARY



Nutrient	Proposed MSL
Vitamin B1	-
Vitamin B2	-
Biotin	-
Vitamin B12	-
Pantothenic acid	-
Vitamin K	-
Chromium†	-

† Classification based on those sources currently approved in Annex II of Directive 2002/46/EC and 2001/15/EC

Nutrient	Proposed MSL
Vitamin B6	18 / 93 mg †††
Vitamin C†	1750 mg
Vitamin D	35 µg
Vitamin E	270 / 970 mg †††
Nicotinamide	820 mg
Molybdenum	350 µg
Phosphorus	1250 mg
Selenium	200 µg
Magnesium	250 mg††
Folic acid	600 µg††

† No UL set ; †† ULs set for supplementation by SCF. ††† Ranges reflect widely divergent ULs from international risk assessments

Nutrient	Proposed MSL
Vitamin A	800–1000 µg
Beta-carotene†	4.8–7 mg
Calcium	1000–1500 mg
Copper	1–2 mg
Fluoride	3.5 mg
Iodine	150–200 µg
Iron	14–20 mg
Manganese†	2 mg
Zinc	10–15 mg

Ranges reflect widely divergent ULs from international risk assessments.
†No UL set by SCF