**HEALTH FOOD MANUFACTURERS' ASSOCIATION**

**Director: David Adams, 63 Hampton Court Way, Thames Ditton, Surrey KT7 0LT**
**Telephone: 0208 398 4066 Facsimile: 0208 398 5402**
**Email: d.adams@hfma.co.uk Web site: www.hfma.co.uk**

# DG-SANCO DISCUSSION PAPER ON THE SETTING OF MAXIMUM LEVELS

## Response from the UK Health Food Manufacturers' Association: July 2006

1. SUMMARY

I. There is extensive data demonstrating both inadequate micronutrient intakes amongst important population groups in the UK and the potential benefits of supplementation.

II. The UK has the most developed specialist food supplement market in Europe and can demonstrate an outstanding record of safe use of food supplements that has been assisted by cooperation between a responsible food supplement industry and the UK regulatory authorities.

III. The HFMA welcomes references in the Discussion Paper to the need to avoid undue constraints on business and unnecessary overregulation: in addition, we urge the Commission to take full account of the principles of proportionality, subsidiarity and consumer choice.

IV. The HFMA also draws attention to the UK EVM Report, which made evidence-based risk assessments of 34 vitamins and minerals and is used as the basis of risk management in the UK; to the FAO/WHO Model for Establishing Upper Levels that cited options of risk management methods; and to economic impact data that should inform political decision-making.

V. For the setting of harmonised levels, the HFMA fully supports the use of the ERNA-EHPM risk management model that categorises different levels of risk on the basis of rigorous risk assessment and applies a sound methodology to establish maximum levels that takes account of intake from both dietary supplements and fortified foods,

VI. To preserve consumer access to safe, popular supplements in national markets, the HFMA fully endorses the UK Government's position also to permit additional guidance levels to be agreed on a national basis. This would result in a pan-European set of Maximum Levels, based on safety and allowing free trade in these 'harmonised' products, together with an allowance for individual Member States to set higher Maximum Levels, supported by advisory/ warning statements for products marketed within their territory to meet variations in national risk-management policy and population dietary nutrient insufficiencies/deficiencies.

2. HFMA BACKGROUND

The HFMA (Health Food Manufacturers' Association) is a non-profit organisation that was founded in 1965 to represent the interests of manufacturers and suppliers of specialist health products in the UK. Our c.140 member companies include many suppliers of specialist food supplements and health foods.

The HFMA operates three long-standing codes of practice – for GMP, Labelling & Advertising and Upper Safe Levels for Supplements – to ensure that member companies adhere to high standards and offer good quality, safe products to UK consumers.

3. HFMA APPROACH TO SETTING MAXIMUM LEVELS

The HFMA approach is based on longstanding experience in the UK, the most developed specialist food supplement market in the EU:

Safety

The UK has a long history of safe use of dietary supplements. Available data for reported adverse reactions to food supplements show an average of one per annum and most of these reactions have been minor (1)

Industry Approach

The UK Supplements industry has an exceptional record of responsible action to preserve consumer safety, for example:

- The concept of Upper Safe Levels for daily supplementation was developed and first implemented by the HFMA in 1985
- In 2003/4, UK industry bodies agreed the implementation of a system of 'advisory statements' with the UK Food Standards Agency for use on the labels of certain higher dose supplements that may possibly cause consumers to experience mild and reversible side-effects. This system is a mandatory for HFMA Member companies.

Micronutrient Intake Safety

There is no suggestion from the National Diet and Nutrition Survey (NDNS) data for British Adults (2) that intakes of micronutrients from supplements are undesirably high (Annex 1). The NDNS data for older people in Britain (3) also suggests that, in practice, there is no evidence of undesirably high intakes (4).

Evidence of Inadequate Intakes/At-Risk Groups

However, NDNS data shows evidence of micronutrient insufficiency amongst important population groups (Annex 2). There are several important groups known to be at risk of micronutrient insufficiency including women of childbearing age and pregnant women, children and teenagers, young adults, older people, dieters, vegetarians and vegans, ethnic groups, and socially disadvantaged groups. More detailed comments are given in Annex 3.

Potential Benefits of Supplementation

There is considerable scientific evidence that food supplements provide significant benefit in supplementing the diet. To take just two examples:

(i) Folic acid

- There is conclusive scientific evidence that additional folic acid around the time of conception reduces the risk of neural tube defects in the foetus
- In the UK, women are recommended to consume an additional 400µg folic acid per day at this time and into the first 12 weeks of pregnancy
- It is difficult to achieve this magnitude of increased intake by the selection of folate-rich foods
- FSA-funded research has shown higher absorption of the form of folic acid used in supplements and added to food compared with the more complex forms of folate present in food. Folate in food is also subject to substantial cooking losses, depending on the method of preparation (5)
- Hence the valuable role of folic acid supplements and foods with added folic acid is recognised.

(ii) Vitamin D

- Vitamin D is essential for calcium homeostasis
- Vitamin D deficiency can result in rickets in children, and in osteomalacia in adults. Low vitamin D status is a risk factor for osteoporosis, a widespread and growing public health problem across Europe
- A key lifestage to maintain adequate vitamin D status is during older age, when there is risk of osteoporotic fractures
- Dietary reference values in the UK for adults aged 65+ years are set at 10µg vitamin D per day, in order to maintain similar vitamin D status to that found in younger adults
- As there are few good dietary sources of vitamin D, it is well recognised that supplementation with vitamin D is an effective means of maintaining adequate vitamin D status
- The value of vitamin D supplementation during pregnancy is also well recognised to ensure adequate maternal and neonatal vitamin D status.

Health Claims

Many helpful health claims for food supplements will be substantiated to EFSA's satisfaction and used throughout Member States following implementation of the Nutritional and Health Claims Regulation. Failure to allow, let alone encourage, consumers to take advantage of the benefits offered by safe, informed supplementation would threaten to undermine 'the high level of human health' that the Treaty sets as DG-SANCO's policy objective (para 14).

The HFMA welcomes references in the Discussion Paper to:

- The need to avoid 'undue constraints of business' (para 21) and the implicit risk of adverse economic impact
- The need to avoid 'unnecessary overregulation' (para 22)
- Infringement of EU Law by adoption of non-safety based approaches as recognised in cases C-192/01, C-387/99 & C-150/00 (para 41).

However, we are disappointed that there is no reference to:

- The very important principles of proportionality, subsidiarity and consumer choice
- The FAO/WHO 2006 publication: A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances (6) and, in particular:
  - Examples of risk management options which include the use of warning labels, information on safe use, and dialogue with industry
  - The recommendation of an iterative process between risk managers and risk assessors
- The UK EVM report (7) that is the basis of the safe and pragmatic UK system of using advisory statements on labels of supplements at selected high doses. Since the upper levels set for dietary supplements represent doses that can be taken daily over a life-time, some vitamins and minerals could be taken in larger amounts over a shorter timescale provided consumers are advised of potential mild and reversible adverse effects. This approach upholds the principle of informed consumer choice and ensures continued access to safe, popular supplements.

In addition, a comprehensive economic impact assessment is required to provide context for the political aspects of decision-making once safety criteria have been satisfied.

4. KEY PRINCIPLES FOR EVALUATING SETTING MAXIMUM LEVELS

The HFMA has assessed the Discussion Paper against application of the following principles:

- Consumer safety
- Consumer choice
- Proportional interpretation of data and application of scientific principle
- Avoidance of overregulation
- Avoidance of adverse economic impact
- Recognition of alternative risk management stratagems
- Recognition of the principle of subsidiarity

5. RESPONSES TO SPECIFIC QUESTIONS

Question 1 (page 11)

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

It is important to distinguish between vitamins and minerals for which there is evidence that high intakes are not associated with adverse effects and those for which there is inadequate evidence to set a firm upper level.

HFMA supports the ERNA-EHPM approach of setting an upper level via a qualitative risk characterisation on the basis of the available risk assessment by EFSA/SCF (8), which gives indications of the nature of the adverse effects and the potential risks in relation to existing patterns of intake. It would also be appropriate to base this qualitative assessment on the findings of other high quality risk assessments such as the UK EVM report (7) and the US FNB assessments. This approach has been used in at least three of the five examples of risk management models provided in the discussion document.

Question 2 (page 11)

- *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?*

There is no reason to apply a risk management measure (i.e. set maximum levels) for these vitamins and minerals since the scientific risk assessment shows no evidence of risk to human health.

Question 3 (page 11)

- *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 at a high level of public health protection and the legitimate expectations of the various food business operators? Are there alternatives?*

Where the PSI (Population Safety Index) is close to the RDA, it is appropriate to set maximum amounts on a case-by-case basis, and this could potentially include separate levels for dietary supplements and foods. However, for vitamins and minerals with low risk of exceeding the upper levels there is no need to set separate maximum levels for supplements and foods, and where risk is non-existent (as in Q2) there is no justification for setting any maximum levels.

For vitamins and minerals with low risk of exceeding the upper levels the following points are relevant:

  - Since Article 2 of Directive 2002/46/EC states that ‘food supplements means food stuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect…..’, food supplements should by definition provide higher levels of specific vitamins and minerals than are provided by individual foods.
  - The EHPM-ERNA approach to risk management, which HFMA supports, allows for increasing dietary intakes over time, including the potential for higher intakes from fortified foods.
  - For most micronutrients, the UK EVM report (7) provides an upper safe level or a guidance level for supplemental intake alone. This is because the scientific trials on which the risk assessments are made have investigated the effects of high doses of micronutrients in supplement form. Hence the potential for adverse effects relating to issues such as the form of the nutrient being different to that present in foods, the timing of ingestion, the amount consumed at one time, and the bioavailability, have been accounted for by the nature of the study undertaken. Also the trials have not always specified the level of the nutrient present in the diet background, which is likely to have included some fortified foods.
  - In the few cases where separate maximum levels may need to be set for fortified foods and supplements, it should be recognised that supplements are clearly labelled as unit doses but

that consumers will have difficulty in calculating intake from different-sized portions of fortified foods. Hence levels in the latter should be low.

- Since consumers are advised to eat a varied diet, micronutrient intake from fortified foods will vary from day to day. Similarly consumers' use of food supplements is often irregular and the products they take vary over time. In the EVM report, the derivation of SULs or guidance levels was on the basis of daily life-long intake and in the UK it is recognised that excursions above the maximum levels for short periods of time do not present a serious risk, provided consumers are advised of the potential adverse effects. This approach enables consumers to make an informed choice.
- Since the levels of micronutrients added to foods are generally restricted to the minimum amounts needed to make either a 'source' or a 'rich' claim, it is unlikely that in practice there will be a general increase in levels added to foods.
- The potential for crossover between consumption of high dose supplements and individual highly fortified (functional) foods is likely to be low. Functional foods will attract significant price premia that will deter consumers who have already purchased supplements and this situation can be managed by use of advisory label statements and consumer education messages.
- Monitoring foods with added nutrients will be possible through the notification procedure outlined in the *Addition of vitamins and minerals and of certain other substances to foods regulations*, and consumer research or focused dietary surveys could be used to assess consumer behaviour and levels of intakes, should there be a significant increase in the marketing of highly fortified foods.

Question 4 (page 12)

- *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.*

The UK National Diet and Nutrition Surveys provide nutrient intake data across a range of population groups (adults, older people, 1½ to 4 year olds, and 4 to 18 year olds). However, even the best sources of dietary survey data have inherent weaknesses and there is variation in the standard and availability of intake data between Member States. These differences include the age/population groups surveyed (whole population, adults, adult men), the nutrients for which intakes have been assessed, different methodologies for collecting the food consumption data, whether intake from added vitamins and minerals and from supplements is included in the data, and the percentile used to assess intakes at the upper end of the range. These practical differences are documented in Flynn et al 2003 (9), who found that nutrient intakes are not directly comparable between different National surveys. It was therefore not possible to derive fully valid pan European estimates of 95$^{th}$ percentile intakes from non-fortified foods based on the data currently available.

Also data in the food composition databases that are used to determine intakes do not have a very high degree of precision due to the natural variation in nutritional composition of foods, and the use of different analytical techniques. Food composition databases also vary between countries regarding the types of foods and the range of micronutrients included. Indeed the EU-funded pan European project EUROFIR recognises the limitations of current databases and aims to harmonise and improve food composition data across Europe.
It is therefore important in the future to undertake improved dietary surveys that include estimation of the contribution of vitamins and minerals from food supplements and from fortified and functional foods.

Question 5 (page 12)

- *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?*

No. In addition to weaknesses of the dietary survey data overall and variation in the standard and availability of survey data between Member States, there is also huge variability of dietary intakes between different Member States, This is due to variation in food cultures, activity patterns and hence overall food intakes, the stage of advancement of the food and food service industries, prevalence of home cooking, consumption of convenience and fortified food, and health and dietary awareness, which affects food consumption patterns and use of supplements in different member states. It is therefore difficult to accurately extrapolate micronutrient intakes between member states.

An entirely appropriate way of dealing with such variability is to permit individual member states to allow higher levels of nutrients if accompanied by informative advisory statements approved by national experts. This would be consistent with the principles of consumer choice, proportionality and subsidiarity.

Question 6 (page 12)

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

Even in the best sources of survey data the sample sizes of particular population groups are very small and therefore the information is unlikely to have a high degree of precision. It is therefore difficult to extrapolate this data to population sub-groups in different countries, particularly as they will also have different cultural and other influences on food intake. Therefore, until better survey data are available, we do not agree that intake data from different population groups should be taken into account.

Overall there should be one main set of maximum levels, although it may also be appropriate to set a separate set of maximum levels for supplements for children aged 3 - 7 years. Setting maximum levels of vitamins and minerals for a range of population sub-groups would be complex to apply, particularly in the case of fortified foods but also for various dietary supplements, as many products are not targeted at specific population groups.

Question 7 (page 14)

- *Taking in to account all the above-mentioned considerations, how far should PRIs/ RDAs be taken into account when setting maximum levels for vitamins and minerals?*

PRIs/RDAs are a useful tool for assessing the risk of exceeding the upper levels of intakes but should not form the basis on which maximum levels are set.

PRIs/RDAS are therefore useful to categorise vitamins and minerals for which there is 1) a non-existent risk of exceeding the upper levels, i.e. no maximum levels as required in Q2; 2) a low risk of exceeding the upper levels; and 3) a potential risk of exceeding the upper levels, i.e. those vitamins and minerals for which there is a small dietary space for additional intakes above the PRI to the TUL as discussed in para 42 of the Discussion Paper. The appropriate approach for the small number of nutrients in category 3) is detailed in the ERNA-EHPM Risk Management Model – setting the MSL should take into account the RLV, the risk of deficiency and the risk of excessive intake on a case-by-case basis.

Please note that para 37 is incorrect in describing PRIs as ‘optimal’: they represent ‘minimal’ intake.

Question 8 (page 15)

- *Should the minimum amount of a vitamin or a mineral in a food to which these nutrients are added be the same as the significant amount required to be present for a claim and/or declaration of the nutrient in nutrition labelling? Should different minimum amounts be set for certain nutrients in specific foods or categories of foods? If yes, on what basis?*

The answer to the first part of this question is yes. Adding nutrients and making claims go hand-in hand, and food manufacturers tend only to add up to the minimum amount in order to make a claim (there are costs involved in adding higher levels, yet no advantage in communication terms).

Different (i.e. lower) minimum amounts could be set for certain nutrients, particularly those at high risk of exceeding the upper safe levels.

Question 9 (page 15)

- *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 they should they be set in a different way?*

Since the Nutrition Labelling Directive 90/496/EC, which sets significant amounts for labelling purposes (currently based on 15% of the RDA per 100g or per 100ml), does not apply to food supplements, there is currently no legal basis for the label declaration of minimum quantities of vitamins and minerals in food supplements.

Therefore, for food supplements the minimum amount present and the significant amount for labelling purposes should be set at the same level. However, this may be different to the significant amount for claims.

Where dietary supplements contain low levels of vitamins and minerals this is usually due to technological reasons (it is not always possible to add higher levels). However these amounts can still be a useful addition to the diet. In this case, subject to the minimum levels, these amounts should be allowed to be added and to be labelled in the nutrition panel even though they may not meet the significant amounts for making claims.

Article 5 of the Food Supplements Directive (2002/46/EC) requires that the maximum and minimum amounts relate to the daily portion of consumption. We would suggest that the minimum amounts for addition and for labelling purposes should be set at 7.5% of the RDA per daily portion of consumption and that this is distinct from the significant amount for making claims. In future, should RDAs be set for different population groups such as children, the minimum amounts for products targeted at such groups should relate to the RDA appropriate for that group.

A level of 7.5% RDA is based on practice in the UK over the past 20 or so years where, for the label declaration of nutrients in food supplements, HFMA has advised a level of 7-8% of the RDA, or 15-17% RNI or UK safe level where no RDA exists.

NB The annex of nutrition claims in the Nutrition and Health Claims regulation only refers to claims for source of vitamins and minerals on the basis of the significant level as specified in 90/496/EC (i.e. % per 100g/ml). The nutrient levels provided per daily consumption of dietary supplements will generally exceed these levels on a per 100g basis, but not always on a daily intake basis. There needs to be an appropriate revision of that regulation to be applicable to food supplements.

## 6. COMMENTS ON THE EXAMPLE RISK MANAGEMENT MODELS

Some specific comments on the examples shown are:

French Agency of Food Safety (AFSSA)

HFMA has concerns about the French approach, particularly to supplements, as this uses RDIs as a basis for setting the maximum levels rather than using the basis of scientific risk assessment.

German Federal Institute for Risk Assessment (BfR)

Several aspects of this approach are unnecessarily restrictive including:

- The arbitrary basis for division between foods and supplements of the amount of a nutrient available for addition to the diet
- The use of a Multi-Exposure Factor (MEF) which potentially over-emphasizes the unlikely potential for crossover between consumption of high dose supplements and highly fortified (functional) foods. Functional foods will attract significant price premia that will deter consumers who have already purchased supplements and this situation can be reinforced via advisory label statements and consumer education messages.

Further, since the model was not applicable to a large number of micronutrients, it is not a practical basis for risk management.

ILSI Europe

The ILSI approach is focused on setting levels for fortified foods and, in developing its model, does not consider intakes from dietary supplements. The approach does not reflect market forces where the minimum levels to make claims generally govern the levels of additions of nutrients to foods. While the paper comments that consumers who use fortified foods and supplements may have a reduced margin of safety between intake from all sources and the UL for some micronutrients, the potential for crossover of consumption of high dose supplements and highly fortified foods with high levels of added micronutrients is unlikely. The potential for this to occur can be monitored and managed in alternative ways than by setting overly restrictive maximum levels that will present undue constraints for businesses.

Danish Institute of Food and Veterinary Research

This is based on the ILSI approach outlined above. While a key difference is the inclusion of the common use of micronutrient supplements, the approach only takes account of micronutrient intake from a standard vitamin/mineral supplement based on 100% of ADT and therefore does not reflect the situation where upper safe levels from supplements are based on a risk assessment (resulting in higher intakes). The model also introduces age-differentiated upper levels for children and adolescents. However, setting maximum levels for different age groups will be difficult to apply in practice, as many foods are not targeted at specific population groups.

ERNA-EHPM

HFMA supports the EHPM-ERNA risk management model for setting harmonized maximum amounts for food supplements, and which has proposed realistic upper levels. The model proposes that no maximum level is warranted where there is no risk of exceeding the UL. Where there is a potential risk of exceeding the UL the maximum level should take account of the label reference value, the risk of deficiency and the risk of excessive intake (i.e. set on a case-by-case basis). Where there is low risk of exceeding the UL the maximum level should take account of changing dietary patterns and is based on a multiple (150% for vitamins and 110% for minerals) of the mean highest intake subtracted from the UL. This model therefore takes account of the future potential for increased marketing of food products with added vitamins and minerals by factoring in a multiplier to allow for changing dietary patterns.

The HFMA also points to the following:

Report of the UK Expert Group on Vitamins and Minerals (EVM) (7)

This report includes evidence-based risk assessments of 34 vitamins and minerals, setting Safe Upper Limits (SUL) or Guidance levels depending on the available data, and expressed as either total dietary intake or as intake from supplements. The risk assessments are based on scientific trials that have investigated the effects of high doses of micronutrients presented in supplement form. The EVM report is currently used as the basis of risk management in the UK where the levels of most dietary supplements on the UK market are well below the SULs. However, since the safety levels set for dietary supplements represent doses that can be taken daily on a life-long basis they tend to be conservative and some vitamins and minerals could be taken in larger amounts over a shorter timescale provided consumers are advised of potential mild and reversible adverse effects, enabling them to make an informed choice.

This latter point is reflected in the exemplary record of safety of vitamin/mineral supplements in the UK (FSA data: 11 reported adverse reactions to food supplements in 11 years – (1)).

The FAO/WHO 2006 publication: A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances (6)

While essentially focused on risk assessment this report makes a number of important points regarding risk management and details risk management options that include the use of warning labels, providing education and information on safe use, and dialogue with industry.

Potential Economic Impact

Whilst the Discussion Paper is concerned with the scientific aspects of risk management, in practice the setting of maximum levels will involve political decisions.

FSA (Food Standards Agency)-commissioned research published in June 2006 shows that the UK market for ‘higher dose’ supplements (defined as at or above the upper or guidance levels in the EVM Report) is worth £25-33 million per annum. The research identified 31 companies supplying 744 products in that category. In practice, many SMEs were not covered by the Survey.

The value of this sector would be lost, and the viability of many SMEs imperilled, if maximum levels were to be implemented even slightly below the EVM levels. However, if the levels were to be set at levels between those shown in the ERNA/EHPM and BfR Reports quoted in the Discussion Paper then, according to separate research conducted amongst member companies within the HFMA, an average loss of approximately 50% of sales of vitamin/mineral supplements would ensue for those companies exclusive of further loss resulting from damage to brand reputation.

Such losses would result in widespread business closure, resultant unemployment and the risk of many UK consumers turning to unregulated sources of supply outside the jurisdiction of the EURO (e.g. via the internet).

Given the exemplary record of safety of vitamin/mineral supplements in the UK (FSA data: 11 reported adverse reactions to food supplements in the past 11 years – (1)), this would be totally unwarranted. It is therefore imperative that the debate on this legislation be informed by rigorous assessment of potential economic impacts.

**The HFMA endorses the FSA/UK Government's position, which supports maximum safe levels based on a scientific risk assessment whilst permitting additional guidance levels to be agreed on a national basis. This evidence-based approach enables consumer protection whilst maintaining consumer choice.**

## *References*


1. UK Food Standards Agency: Food Supplements (England) Regulations 2003 Regulatory Impact Assessment
2. Henderson L *et al*, 2003. The National Diet and Nutrition Survey: Adults aged 19-64 years, London: TSO; vol 3.
3. Finch *et al,* 1998. National Diet and Nutrition Survey: people aged 65 years and over. London: TSO; vol 1.
4. Bates CJ *et al.* 1999. Micronutrients: Highlights and research challenges from the 1994-5 National Diet and Nutrition Survey of people aged 65 years and over. British Journal of Nutrition 82: 7-15.
5. McKillop et al. Brit J Nutr. 2002; 88: 681-688.
6. FAO/WHO 2006. A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. Report of a joint FAO/WHO Technical Workshop on Nutrient Risk Assessment. Geneva Switzerland, May 2005. Published online, January 2006
7. EVM, 2003. Safe upper levels for vitamins and minerals. UK Expert Group on Vitamins and Minerals. Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6BH
8. EFSA. Tolerable Upper Intake Levels for Vitamins and Minerals, Scientific Committee on Food, Scientific Panel on Dietetic Products, Nutrition and Allergies, February 2006.
9. Flynn A et al, 2003. Vitamins and Minerals: a model for safe addition to foods. Eur J Nutr 42: 118-130.

Annex 1

Table 1 compares 97.5 percentile intakes for British adults (1) from all sources (food and supplements) with the EVM SUL and guidance levels (5), and with EFSA Tolerable Upper Levels (TUL) for vitamins and minerals (7).

Table 1: 97.5 percentile intakes in British adults compared with EVM SUL and guidance levels and EFSA TULs

| **Micronutrient** | **97.5 percentile intakes[†] from all sources men / women** | | ***EVM SUL[¶] for intake from total diet*** | ***EFSA/SCF TUL (adults)*** |
|---|---|---|---|---|
| Vitamin A (total) µg | 3922 / 2122 | | 1500 (G) | 3000 |
| Riboflavin mg | 4.77 / 3.91 | | 43 (G) | No limit set |
| Nicotinamide mg | 81.8 / 57.2 | | 560 (G) | 900 |
| Pantothenic acid mg | 14.5 / 13.2 | | 210 (G) | No limit set |
| Biotin µg | 99 / 76 | | 970 (G) | No limit set |
| Folic Acid µg | 680 / 554 | | 1500 (G) | 1000 |
| Zinc mg | 19.6 / 17.3 | | 42 | 25 |
| Iodine µg | 428 / 340 | | 500 (G); 940 (T) | 600 |
| Manganese mg | 7.06 / 5.63 | | 4 (G); 9-12 (T) | No limit set |
| Copper mg | 3.20 / 2.25 | | 10 | 5 |
| | **Dietary intake, all sources** | **Dietary intake, food sources** | **EVM SUL for intake from food supplements** | |
| β-carotene µg | 5774 / 5275 | 5750 / 5186 | 7mg | No conclusion |
| Thiamin mg | 5.38 / 5.17 | 4.0 / 3.90 | 100 (G) | No limit set |
| B6 mg | 6.4 / 5.2 | 5.2 / 3.6 | 10 | 25 |
| B12 µg | 19.7 / 12.8 | 19.6 / 10.7 | 2000 (G) | No limit set |
| Vitamin C mg | 329 / 473 | 217 / 205 | 1000 (G) | No limit set |
| Vitamin D µg | 11.8 / 13.7 | 9.2 / 8.4 | 25 (G) | 50 |
| Vitamin E mg | 29.4 / 42.6 | 21.8 / 15.6 | 540 (G) | 300 |
| Iron mg | 27.5 / 26.7 | 23.4 / 18.1 | 17 (G) | No limit set |
| Calcium mg | 1794 / 1550 | 1783 / 1372 | 1500 (G) | 2500 |
| Phosphorus mg | 2406 / 1764 | 2381 / 1763 | 250 (G) | No limit set |
| Magnesium mg | 528 / 399 | 527 / 377 | 400 (G) | 250 as supplement |

[†] Henderson L *et al*, 2003. *The National Diet and Nutrition Survey: Adults aged 19-64 years*, London: TSO; vol 3.

[¶] EVM, 2003. *Safe upper levels for vitamins and minerals. UK Expert Group on Vitamins and Minerals.* Food Standards Agency, London, UK.

(G) – Guidance level; IADSA – International Alliance of Dietary Food Supplement Associations; EHPM – European Federation of Associations of Health Product Manufacturers.

Though the 97.5 percentile intake for total vitamin A exceeds the EVM guidance level for the safe upper level, it should be noted that the safe level is in respect of pre-formed retinol only. High vitamin A intakes are mainly due to the consumption of liver, which provides very high levels of pre-formed retinol. Food supplements containing pre-formed retinol or carotene increased mean daily intake of vitamin A overall by 12% for men from 911µg to 1017µg, and by 19% for women from 671µg to 800µg per day. The contribution from supplements differs by age. Mean intakes from food sources alone were increased by supplements by 3% in 19-24 year old men, and by 26% in women aged 19-24 years. We strongly advise that EFSA assess risk management options relating to the intake of liver meat and related products.

**Annex 2**

| Population Sub-Group | Proportion with intakes below the LRNI (sufficient for 2.5% of the group) |
|---|---|
| **IRON** | |
| 15-18 years | 48% of girls |
| 19-34 years | 40% of young women |
| **CALCIUM** | |
| 11-14 years | 12% of boys and 24% of girls |
| 19-24 years | 5% of men and 8% of women |
| 85+ years | 15% of women |
| Households receiving benefits | 12% of women |
| MAGNESIUM | |
| 11-14 years | 28% of boys and 51% of girls |
| 15-18 years | 18% of boys and 53% of girls |
| 19-24 years | 17% of men and 22% of women |
| 85+ years | 35% of men and women |
| Households receiving benefits | 26% of adults |
| ZINC | |
| 11-14 years | 37% of teenage girls |
| 15-18 years | 42% of teenage girls |
| 19-24 years | 7% of men |
| 85+-years | 10% of women and 15% of men |
| POTASSIUM | |
| 15-18 years | 15% of boys and 38% of girls |
| 19-35 years | 30% of women |
| 85+ years | 57% of women and 34% of men |
| **VITAMIN A** | |
| 4-6 years | 7% boys and girls |
| 7-10 years | 9% boys and girls |
| 11-14 years | 20% of girls and 12% of boys |
| 19-24 years | 16% of men and 15% of women |
| Households receiving benefits | 12% of men and 20% of women |
| **VITAMIN B2** | |
| 15-18 years | 21% of males and females |
| 19-24 years | 13% of young women |
| VITAMIN B2 (Riboflavin) | |
| 11-14 years | 22% |
| 15-18 years | 21% |
| 19-24 years | 13% of young women |
| 25-34 years | 10% of young women |
| Households receiving benefits | 18% of women |
| **Population Sub-Group** | **Proportion with marginal status** |
| FOLATE | |
| 15-18 years | 12% of boys and 14% of girls have marginal status of red cell folate |
| 19-24 years | 13% of men have marginal status of red cell folate |
| Older people | 29% have red cell folate levels indicating marginal status, and 8% have levels indicating deficiency |
| VITAMIN C | |
| 85+-years | 20% of men and 18% of women show vitamin C status that is indicative of biochemical depletion |
| VITAMIN D | |
| 15-18 years | 16% of males and 10% of females |
| 19-24 years | 24% of men and 28% of women |
| 85+-years | 13% of men and 15% of women |
| IRON | |
| 4-6 years | 3% of boys and 8% of girls had haemoglobin |

| | |
|---|---|
| | concentrations indicative of anaemia (by the World Health Organisation cut-off appropriate for their age group) |
| 15-18 years | For 9% of girls haemoglobin was below the adult cut-off indicative of anaemia |
| 15-18 years | Compared with the adult cut-offs there is also evidence of low iron stores in 27% of girls |
| 19 to 49 years | Haemoglobin concentrations indicative of anaemia are evident in 7-10% of women. There is also evidence of low iron stores with 8-16% of women having low serum ferritin values |
| 85+ years | 10% of men and 18% of women have low iron stores as determined by serum ferritin values |
| 85+ years | 37% of men and 16% of women have haemoglobin concentrations indicative of anaemia |

**Annex 3**

## COMMENTS ON GROUPS AT RISK OF MICRONUTRIENT INSUFFICIENCY

### Women of childbearing age and pregnant women

- Pregnancy is a time of increased metabolic demands and particularly during the first trimester inadequate micronutrient intakes can have adverse effects on birth weight.
- Pregnancy increases dietary requirements for thiamin, riboflavin, folate, and for vitamins A, C and D.
- Iron is required by the developing foetus and placenta. While women of child-bearing age should ideally have sufficient iron stores to meet these increased demands, when iron stares are low at the start of pregnancy supplementation with iron is often necessary.
- Adequate nutrition during the pre-pregnancy period is equally critical to that during pregnancy. In addition to the recommendation to take additional folic acid at this time from supplements and fortified foods, it is important to ensure adequate intake of all other vitamins and minerals, particularly as not all pregnancies are planned.

### Children and teenagers

- NDNS data show that vitamin A, riboflavin, iron (girls), calcium, magnesium, potassium and zinc, are the nutrients at risk in the diet of some young children and teenagers
- Adequate micronutrient intake is important for children and teenagers to sustain optimal growth and physiological development as a sound basis for future health. Skeletal development is particularly important for this age group, as development of maximal peak bone mass reduces the risk of osteoporosis later in life

### Young adults

- NDNS data show that Vitamin A, riboflavin, iron, calcium, magnesium, potassium, zinc, are the nutrients at risk in the diet for some young adults. Some young adults also have marginal status of red cell folate (men), vitamin D and iron (women).
- Skeletal development occurs in young adults up to the age of 30, and maintaining adequate calcium intake remains important for this group to achieve optimum bone health.
- Young women who are weight conscious and may be avoiding particular food groups are particularly vulnerable to low micronutrient intakes

### Older people

- NDNS data show that calcium (women), magnesium, potassium and zinc are nutrients at risk in the diet of some older people. Some older people also have poor nutritional status of iron, vitamin D, vitamin C and folate
- To some extent, these deficiencies reflect difficulties that older people have in ensuring adequate micronutrient intakes including reduced levels of absorption, smaller appetite, lower energy requirements, poor dentition affecting food choices, and arthritis and poor eyesight affecting ability to shop for and to prepare food.
- Older age is also associated with a greater incidence of degenerative conditions such as CVD, cancer, and arthritis. Hence the predicted changes to the age structure of the population are also predicted to dramatically increase health care costs in the future unless a greater focus on the prevention of these conditions is achieved

### Dieters

- Unless the diet is very carefully planned, reducing energy intake to lose weight increases the risk of low micronutrient intake. In addition, fad diets may eliminate important food groups, again with risk of inadequate micronutrient intakes

- Therefore, the current emphasis on reducing the incidence of obesity needs to be counter-balanced by strategies to ensure micronutrient sufficiency

### Vegetarians and vegans

- Elimination of meat and fish from the diet increases risk the of low long-chain omega-3 fatty acid intake, and low iron, zinc and vitamin B12 intakes

### Ethnic groups

- The prevalence of rickets has largely declined in Western European countries. However this debilitating disease remains a problem for Asians and Africans living in these countries due to low blood concentrations of vitamin D

**Socially Disadvantaged Groups**

- NDNS data show that in households receiving benefits, the proportion with intakes below the LRNI, for a range of micronutrients, exceeds 2.5% (the proportion of the population for which this level is sufficient).
- Examples are vitamin A, riboflavin, calcium, potassium and magnesium.
- 50% of women aged 19-64 years in households receiving benefits have intakes below the LRNI for iron.
- Adequate nutritional intake can help to reduce health inequalities, where people living in the most deprived areas have a higher prevalence of preventable diseases.