

Patron	Her Royal Highness The Princess Royal KG GCVO
Honorary President	Professor Dame Barbara Clayton MD PhD HonDSc FRCP
Honorary Vice-Presidents	Mr IGT Ferguson CBE Professor A Shenkin PhD FRCP FRCPATH
Director-General	Professor RS Pickard PhD CBiol FIBiol
Education Director	Miss SJ Valentine MA DipEd DipAdDev FRSA
Science Director	Professor JL Buttriss PhD BSc RPHNutr
Company Secretary	Mr PD Leigh MIAP ANZIPM



7th September 2006

**By email to: SANCO-VITAMINS-AND-MINERALS@EC.EUROPA.EU
cc Food Standards Agency**

Dear Sirs

EUROPEAN COMMISSION'S DISCUSSION PAPER ON THE SETTING OF MAXIMUM AND MINIMUM AMOUNTS FOR VITAMINS AND MINERALS IN FOODSTUFFS.

The British Nutrition Foundation (BNF) is a not-for-profit organisation with charitable status that promotes the wellbeing of society through the impartial interpretation and effective dissemination of scientifically based nutritional knowledge and advice. It works in partnership with academic and research institutes, the food industry, educators and government.

This response deals specifically with the questions raised by the Commission.

Commission's Questions

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

In BNF's view, in such circumstances the upper safe intake level should be the highest level considered to be without risk of adverse effects. For this purpose, use could be made of the guidance levels set by the UK Expert Group on Vitamins and Minerals (EVM, published by the Food Standards Agency). Given that new evidence emerges from time to time that may trigger a need for re-evaluation of these guidance levels, a review mechanism needs to be in place.

2. For some vitamins and minerals the risk of adverse effects, even at high levels of intake 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?

BNF supports the need to set maximum levels (even if they are very high) for all vitamins and minerals that are included in the Food Supplements Directive and the forthcoming Regulation on the Addition of Vitamins and Minerals. This could build on the risk-based approach taken by the EVM and also that adopted by FAO/WHO (2006) [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: May 2005.] Within this approach, it should be possible to make a distinction between nutrients for which data demonstrate that there is no hint of a problem and those for which there is simply no data. As above, a review mechanism needs to be in place so that account can be taken of new information as it emerges.

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

The approach in the UK to date (the EVM recommendations) has been to set a single amount that could be consumed safely, without distinguishing between fortified foods and supplements. Dietary patterns vary across Europe, as does the availability of fortified foods, and these differences are inevitably reflected in differences in intakes of individual nutrients. The situation is made still more complex by the emerging markets for various 'functional' foods within Europe. It would therefore be very difficult to establish separate maximum levels for provision via foods and via supplements. But should this be attempted, recognition needs to be taken of the likelihood, in some countries at least, that provision via food fortification may continue to increase, and the quantity that can be provided by supplements could be capped accordingly. Capping should primarily be directed towards supplements because nutritionists generally recommend that the first route for supplying nutrient requirements is the diet, including foods subjected to restoration, substitution or fortification of nutrients as appropriate. But if capping of fortification of foods with particular nutrients is also considered as a secondary measure, this could be linked to the criteria for the 'high in' claim in the forthcoming Nutrition and Health Claims Regulation.

4. 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.

In the UK, information on intakes of vitamins and minerals at the individual level (mean intakes and ranges) is available from the National Diet and Nutrition Survey (NDNS) programme, a series of cross-sectional surveys of diet and nutritional status covering the whole population, split into 4 age groups, from age 1½ years upwards. These data are based on weighed intake records collected for four or seven days, and information is provided for food sources only and food sources plus dietary supplements. In due course the current methodology is to be replaced by a rolling programme of diet and nutrition surveys that will provide more regular data on each population age group. In addition, publication is imminent of the findings of a survey of the diet and nutritional status of low income people in the UK (covering both adults and children).

The UK has a long history of provision of detailed food composition data that are needed to support such surveys, i.e. McCance and Widdowson's *The Composition of Foods*. This is complemented by the FSA's programme of analytical surveys of food composition, which are further supplemented with manufacturers' data and recipes.

A recognised problem in the assessment and comparison of dietary survey data from different countries is the variation in the food composition data used in different countries across Europe. BNF is a partner in the EuroFIR (European Food Information Resource) project, funded by the EU sixth framework programme, which aims to develop and integrate a comprehensive, coherent and validated databank providing a single, authoritative source of food composition data for Europe. A key aim of this project is to address

inconsistencies in the quality and quantity of compositional data, which make it difficult to compare vitamin and mineral intakes between countries.

A new-EU funded project, EFCOVAL (European Food Consumption Validation), also funded under the sixth framework programme, aims to develop and validate a method for assessing food consumption and nutrient intake across Europe. Also, the experience gained in the European Prospective Investigation into Cancer and Nutrition (EPIC) may also be worth considering, as data were collected in 10 countries across the EU (23 centres and half million people) and included collection of information on diet as well as biological samples for analysis of nutritional status.

5. If such existing data refer only to the intake in some Member States, can they be used for the setting of legitimate and effective maximum levels of vitamins and minerals at European level? On the basis of what adjustments, if any?

Presumably, data from individual countries, e.g. the UK, could be used to assess the likely range of intakes. EPIC data may also be helpful (see above), in particular the work that has taken place to attempt to smooth out the disparities in food composition data quality, which is now feeding into EuroFIR.

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

Requirements for some nutrients differ markedly across the population (e.g. children of different ages vs. adults vs. pregnant/lactating women) - an example here would be folate in women planning a pregnancy - and recommendations also vary from country to country. Hence it would be far too complex to attempt to take all this into consideration. However, it may be helpful to take into account the lower needs of young children and any specific data relating to maximum safe intakes in this group. In general, however, the issues of relevance to specific population groups will probably need to be dealt with via clear product labelling and supporting product information, which give contraindications for particular products, e.g. 'not suitable for children under 5'.

7. 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?

BNF believes that maximum levels should be based on risk. RDAs/PRIs are estimates of adequacy (for adults) and so we do not feel they are an appropriate basis for setting maximum (safe) intake levels for vitamins and minerals.

8. 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?

It should be noted that vitamins and minerals are added to foods for several purposes apart from voluntary fortification, i.e. for restoration and substitution and for mandatory fortification which has been in place in the UK for selected nutrients and foods for some time e.g. margarine and bread flour. In such cases, addition of amounts lower than the proposed 'minimum' value may be appropriate and this is allowed for in the proposed Regulation on the Addition of Vitamins and Minerals and of Certain Other Substances to Food.

However, in terms of voluntary fortification of foods, there is an expectation when a claim is made for a vitamin or mineral that the product will make a significant nutritional contribution as part of a balanced diet. It would therefore seem appropriate to use the criteria already established in the proposed claims Regulation

for 'source of' and 'high in'. For foods, the 'source' level (15%) is perhaps the most relevant point of reference for the 'minimum' value.

9. 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?

Yes. The same approach should be taken. If there is a claim on a supplement that a nutrient is present, the expectation is that sufficient is contained (and of appropriate bioavailability) to be effective. Indeed, given that the expectation may be that supplements are providing amounts in excess of what is normally provided by the diet, a figure of 30% (the 'high' level) should perhaps be considered for supplements, rather the 'source of' (15%) level which is probably more appropriate for foods. These could be set in the context of recommended daily dose.

Please contact me if you would like further clarification of any of these points.

Yours sincerely

Professor Judy Buttriss
Science Director, British Nutrition Foundation

THE BRITISH NUTRITION FOUNDATION
REGISTERED IN ENGLAND AS A COMPANY LIMITED BY GUARANTEE NO. 898651
REGISTERED CHARITY NO. 251681 VAT NO. 381 7380 37

REGISTERED OFFICE
HIGH HOLBORN HOUSE
52-54 HIGH HOLBORN
LONDON WC1V 6RQ
Tel: +44 (0) 20-7404 6504
Email: postbox@nutrition.org.uk
Web: <http://www.nutrition.org.uk>