

DRAFT**RESPONSE TO THE EUROPEAN COMMISSION'S DISCUSSION PAPER ON THE SETTING OF MAXIMUM AND MINIMUM AMOUNTS FOR VITAMINS AND MINERALS IN FOODSTUFFS****Background**

The Food Standards Agency (FSA) has been considering issues related to vitamins and minerals for some time. This includes the FSA Board accepting the report from the Expert Group on Vitamins and Minerals (EVM) in 2003 and the need for advice for consumers, and the discussion by the FSA Board on maximum levels in food supplements in September 2005.

EVM

In 1998 the Expert Group on Vitamins and Minerals (EVM) was established to advise on safe levels of intakes of vitamins and minerals in food supplements and fortified foods. The EVM comprised experts in all relevant disciplines, including nutrition, toxicology, epidemiology and medicine and a non-specialist member to represent consumer interests. The report from this risk assessment was published in May 2003 and is available from the Agency's web site at the following address: www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf

The EVM specifically considered amounts that could be provided by supplements and future fortification, taking into account other dietary sources, which included those fortified foods already on the UK market. Where the data were not sufficient to set an upper level, the EVM gave guidance on the level that was not expected to result in harmful effects.

The FSA and UK stakeholders, including consumers, health interest groups and different sectors of the supplements industry, support the approach taken by the internationally recognised UK Expert Group on Vitamins and Minerals (EVM) in setting safe upper levels and guidance levels for intakes of vitamins and minerals, and recommend that this approach should also be used in setting maximum levels of vitamins and minerals in fortified foods and food supplements. This approach is also supported by the UK independent Scientific Advisory Committee on Nutrition (SACN) and the independent Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT).

In comparison, the Scientific Committee on Food (SCF) and the European Food Safety Authority (EFSA) mainly considered the tolerable upper levels for total dietary intake. They did not advise on how the margin between these upper limits and the EU dietary intake should be allocated to supplements and fortified foods. In many instances SCF/EFSA found the available data insufficient to set an upper level.

The EVM approach is consistent with the model recommended in the recent report of the joint FAO/WHO technical workshop on nutrient risk assessment¹, and notably with respect to two areas not addressed by the SCF/EFSA opinions:

- making efforts to establish upper levels if at all possible even when data are limited (FAO/WHO report - point 2, page xv),
- exposure/intake assessment is dependent on the types of food and supplements consumed and on dietary patterns within a region or nation-state (FAO/WHO report -section 3.1, page 15).

Furthermore, in clarifying the uncertainty associated with vitamins and minerals for which a tolerable/safe upper level could not be established, EVM noted two distinct scenarios, which specifically relate to questions 1 and 2 in the Commission document. Officials from the Food Standards Agency would welcome the opportunity to present the work of the EVM to the Commission and member states.

FSA Board

The FSA Board discussion in September 2005 focussed on setting maximum levels of vitamins and minerals in food supplements and this predates the Commission's discussion document. In the absence of any formal Commission proposals the Board agreed a two-tier approach. This approach supported common maximum safe levels for individual vitamins and minerals being established across the EU for the purposes of intra community trade based on the recommendations from the European Food Safety Authority (EFSA). In addition, a second tier of higher maximum levels for each vitamin and mineral could be set at a national level in individual member states where there was evidence that dietary intake levels at a national level were lower than the figure used across the EU, or a national expert opinion supported safe supplemental intakes. The FSA Board did not address the question of setting maximum levels of vitamins and minerals for fortified foods.

The Board has more recently agreed 4 principles on which discussion should be based on setting levels for vitamins and minerals in foodstuffs and these are as follows:

- Consumers have a right to make an informed choice
- 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

¹ 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, published 2006.

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

Introduction

This paper responds specifically to the questions raised by the Commission, recognising that the input to these will inform future proposals from the Commission. It is essential that there is absolute clarity regarding the use of language in our response. EFSA has used the expression ‘tolerable upper level’, and EVM used ‘safe upper level’ or where the evidence base was weak ‘guidance level’ – but these terms essentially have the same meaning. We have defined ‘upper level’ as meaning the total dietary intake level from all sources (foods, fortified foods and supplements) without risk to health. ‘Maximum level’ means the maximum level that should be provided per portion by fortified foods or supplements.

Commission 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?**

Where there are insufficient data to establish a numerical tolerable upper intake level, but there are indications that there may be adverse effects, the upper intake level should be the highest level considered to be safe (without risk of adverse effects). This would be equivalent to the guidance levels set by the UK Expert Group on Vitamins and Minerals-EVM. However, there should be a review mechanism in place to ensure that this level can be amended rapidly if new data become available. The UK could facilitate such a review by means of its national scientific advisory committees.

- 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?**

There are two divergent views from stakeholders regarding the setting of levels, where for certain vitamins and minerals, at even high levels of intake the risk of adverse effects is extremely low or non-existent.

Some stakeholders consider that there is no reason to set levels for these vitamins and minerals and others support a risk categorisation approach for establishing where levels need to be set. Some stakeholders take the view that levels should be set, because, as noted in the FAO/WHO report ¹, the absence of evidence of an adverse effect is not equivalent to evidence of the absence of an adverse effect (point 4, page *xvi*). The EVM took a similar approach to the FAO/WHO and set

guidance levels for upper intake levels at which there is evidence of a lack of adverse effect. The implications of exceeding such a level are uncertain, and it might be possible to have very much larger doses without risk to health.

Some stakeholders expressed the view that consumers may feel more confident if maximum levels are defined for all vitamins and minerals. It was also pointed out that some countries might wish to see maximum levels set in order to facilitate trade.

On balance, after listening to the differing stakeholder views, the FSA opinion is that a risk-based approach is needed and should build on the approach taken by the FAO/WHO and the EVM. The FSA supports the need to set maximum levels for all vitamins and minerals that are included in the Food Supplements Directive and the impending Regulation on the Addition of Vitamins and Minerals and of certain other substances to food. However, consideration should be given to the regulatory status of the maximum levels set for the vitamins and minerals without evidence of adverse effects, for example if these would be viewed as guidance levels rather than regulatory limits. Consideration should also be given to a review mechanism such that the levels can be amended, as new data become available.

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?

Traditional diets throughout the Community are changing and some are being superseded by the trend to convenience foods, sometimes of lower nutritional quality than traditional foods. Changing dietary trends have implications for the nutritional adequacy of the diets throughout the EU and there may be particular concerns in some member states. For example, there is evidence from the UK National Diet and Nutrition Survey that in some cases high consumers of supplements also consume diets naturally high in vitamins and minerals, and may also consume more fortified foods than low intake consumers, as demonstrated by the recent modelling work undertaken by SACN on folates.

In discussions with stakeholders the importance of providing information to consumers and allowing an informed choice was seen as a critical factor rather than defining specific maximum levels for use in supplements and fortified foods. A number of stakeholders also referred to the categorisation of vitamins and minerals in accordance with the upper intake levels identified by risk assessment, and questioned whether upper maximum levels need to be set for all vitamins and minerals.

The question was raised as to whether overages should be taken into account when setting maximum levels and whether there should be an EU agreed approach on analytical measurement of the levels of vitamins and minerals.

There is an increasing interest in healthy eating, and considerable consumer interest in diet and health. The contribution of vitamin and minerals from different foods, fortified foods and food supplements will vary on an individual basis. It would be prudent to consider whether there should be a cap on the levels used in fortified foods. For example, this could be linked to the conditions spelt out for the 'high in' claim in the annex to the Regulation on Nutrition and Health Claims to ensure that consumers are protected from misleading claims. There is clearly a need for further discussion and the views of the food industry should be sought on the practicalities of this.

The EVM approach is based on UK dietary intake, and refers to intake from supplements or new sources of fortification without exceeding the safe upper level and without distinguishing between them.

Some stakeholders favoured a cap that gave a greater allocation to fortified foods whereas others felt that this should be given to food supplements. The Food Standards Agency recognises that this is an extremely complex issue and therefore it is difficult to allocate contributions from these two sources. We would welcome a wider EU discussion on the feasibility of allocating levels and the factors that would need to be taken into account. These would include:

- The difficulty on predicting dietary changes, and market development in other member states
- The onus on the consumer to interpret additional information in order to make informed choices
- The requirement to have a monitoring system in place that is both accurate and proportionate.

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.

Information on vitamin and mineral intakes in the UK is available from the National Diet and Nutrition Survey programme, a series of cross-sectional surveys of diet and nutritional status covering the whole population from age 1½ years upwards, split into four separate age groups. These surveys provide nutrient intake data at the individual level including means and distributions of intake for a range of vitamins and minerals, based on weighed intake records collected for four or seven days. Intakes are presented both from food sources only and including the contribution of dietary supplements. The most recent data available on adults was collected in

2000/01 and on children in 1997. The UK is currently setting up a rolling diet and nutrition survey programme to provide more regular data on each population age group. The first tranche of data from this programme is expected in 2008/09. A survey of diet and nutrition of low income consumers in the UK has also been carried out (covering both adults and children). Results are expected in autumn 2006 and will include vitamin and mineral intakes from food and dietary supplements.

Information on the nutrient content of foods used to derive the nutrient intakes is based on a programme of analytical surveys, supplemented with manufacturers' data and recipes. This data can be particularly important when dealing with rapidly changing food compositions. Data from the UK programme of analytical surveys are also disseminated via the UK food composition tables, 'McCance and Widdowson's The Composition of Foods'. These internationally renowned composition tables have, for over 60 years, been an authoritative and widely used source of information about the nutritional value of foods consumed in the UK.

At the European level, the EuroFIR (European Food Information Resource) project, funded by the sixth framework programme, aims to develop and integrate a comprehensive, coherent and validated databank providing a single, authoritative source of food composition data for Europe. In so doing the project aims to address inconsistencies in the quality and quantity of composition data which make it difficult to compare vitamin and mineral intakes between countries. There are also a number of cross European research studies that include dietary intake data that may be useful as well as data from single centre research studies and sales data from companies. However, the validity and applicability of all data would need to be considered on a case by case basis.

An ILSI European Task Force is currently collating intake data for foods and supplements from countries within the EU. The data are expected to be available in spring 2007.

We are not aware of any nutrition surveys conducted at the European level. EFCOVAL (European Food Consumption Validation) a new project funded by the sixth framework programme aims to develop and validate a method for assessing food consumption and nutrient intake across Europe.

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?

The UK data (and other Member States data) could be of use in assessing the potential range of intakes at the EU level. However, as noted above the FAO/WHO report specified that exposure assessment is population-specific, and it is currently unclear how the data could be applied across the EU as opposed to the Member

State level. It should be noted that the nature and timing of the data collected would need to be carefully considered before any inferences were drawn.

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

Clarification is required on the different population groups, which need to be considered, and whether high level intakes can be identified. In addition, nutritional requirements of different sectors of the population vary considerably and need to be borne in mind when fortified foods and supplements are being used to improve the nutritional adequacy of diets. Consideration needs to be given as to how the needs of specific population groups could be factored in to the setting of maximum levels for fortified foods and supplements that are intended for the general population. For example, the needs of these subgroups could be addressed by a more targeted approach through labelling or by individual dietary advice provided by qualified health professionals.

For example, the levels at which some vitamins and minerals have effects on certain subgroups can vary e.g. vitamin A intake and the elderly, and folic acid for women planning to become pregnant. This reinforces the need for clear information to allow consumers to make an informed choice.

There are some surveys in different Member States that take account of population subgroups, for example, the UK National Diet and Nutrition Survey programme currently provides intakes by age, sex, region and limited information on socio-economic status. However it should be noted that some subgroups of a population, such as vegans, might be hard to characterise due to low representation in national surveys. The UK has also conducted a survey on the nutritional status of low-income groups, which is due to be published in autumn 2006. This additional data should help identify whether there are dietary issues that are of particular concern in this population group.

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?

There are divergent views among UK stakeholders regarding whether PRIs/RDAs should be used for this purpose. On balance the FSA view is that when setting tolerable upper intake levels for vitamins and minerals it is important to ensure that a precautionary approach to lack of data does not result in upper levels that are below the PRI. The Food Standards Agency does not agree that PRIs can be used as the basis for establishing maximum levels for vitamin and minerals in supplements but agree that they should be taken into account when setting minimum levels. We believe that maximum levels should be based on risk.

Paragraph 37 of the discussion document is incorrect. This describes PRIs as 'optimal' when in fact they represent 'adequate' intake.

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 is important to recognise that vitamins and minerals are added to foods for a variety of reasons including restoration and substitution in addition to fortification.

Minimum amounts are foreseen in Article 6 (6) of the proposed Regulation on the Addition of Vitamins and Minerals and of Certain Other Substances to Food, and comments here should be read in this context. Amounts lower than minimum amounts are possible by derogation, which could be important for the addition of vitamins and minerals for restoration and mandatory fortification.

Article 6(6) provides for minimum amounts at the same level as that of a significant amount, where this is defined in the Annex to the nutrition labelling directive 90/496/EEC. It also envisages a lower amount by derogation from the significant amounts in 90/496/EEC. In agreeing a figure for a minimum amount of vitamins and minerals to be present in a food after voluntary addition, the conditions laid down for vitamin and mineral claims should also be taken into consideration. When a claim is made there is an expectation of an effect: that the vitamin or mineral claimed will make a significant nutritional contribution as part of a balanced diet. In the proposed claims Regulation the condition for a 'source of' claim is the same as the significant amount as laid down in the nutrition labelling directive (90/496/EEC). A 'high in' claim is to be twice the significant amount. It would seem sensible to continue to use this linkage with the nutrition labelling directive to ensure claims are not misleading.

The nutrition labelling directive is subject to a forthcoming review. This review should take account of the need for consistency across all the different legislative instruments concerned with labelling of nutrients in foodstuffs. It will be necessary to permit nutrition labelling for all the vitamins and minerals listed in the Annex to the proposed Regulation on the Addition of Vitamins and Minerals and Certain Other Substances to Food. While the lists are identical, nutrition labelling does not apply equally to supplements as it does to fortification of food. For some vitamins and minerals, RDAs have not and possibly cannot be set, which means that a different approach may be needed to setting 'significant amounts'. Where there is a 'significant amount', it might also be judged necessary to revise the 15% figure in some cases. In other cases it might be necessary to take account of consumption patterns of certain foods in which the vitamin or mineral might be used, including portion sizes. An example here would be bottled waters, where larger 'portions' are consumed.

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?

Although the Food Supplements Directive states that the Nutrition Labelling Directive 90/496/EC does not apply to food supplements, certain aspects of 90/496/EEC are applicable, for example, the use of reference values in the annex to the nutrition labelling directive in labelling do apply. It would seem to be appropriate that the minimum amounts should also be linked to the significant amounts in the nutrition labelling directive as these are likely to be relevant also to food supplements, where RDAs can be set. Some stakeholders agreed that there should be a different minimum level for food supplements, others disagreed, stating that the same minimum amounts should pertain in order to protect against consumer fraud. Before any decision is taken on appropriate minimum amounts, consideration would need to be given to whether there are any specific technical issues regarding the inclusion of vitamins and minerals in food supplements.