European Commission
Health and Consumer Protection
Directorate-General

(SANCO-VITAMINS-AND-MINERALS@EC.EUROPA.EU)

29/09/2006

Dear Sir/Madam

The MRC Collaborative Centre for Human Nutrition Research (HNR) thanks the European Commission for the opportunity to comment on their consultation on the setting of maximum and minimum amounts of vitamins and minerals in foodstuffs (dated June 2006).

This response was prepared by senior staff at HNR and does not necessarily reflect the view of the Medical Research Council.

We hope that these comments will make a useful contribution to this consultation and we would be pleased to offer additional input on specific issues should this be required.

If you have any queries regarding this response then, in the first instance, please address them to me at the address below.

Yours sincerely

Dr Dora Pereira
Research Scientist
Micronutrient Status Research Section

MRC Human Nutrition Research
Elsie Widdowson Laboratory, Fulbourn Road, Cambridge CB1 9NL
Tel: 01223 426356 Fax: 01223 437515 www.mrc-hnr.cam.ac.uk

A response from MRC Human Nutrition Research to the European Commission Consultation on the setting of maximum and minimum levels of vitamins and minerals in foodstuffs (June 2006).

29th September 2006

MRC Collaborative Centre for Human Nutrition Research (hereafter HNR) was established in 1998 to advance knowledge of the relationships between human nutrition and health by providing a national centre of excellence for the measurement and interpretation of biochemical, functional and dietary indicators of nutritional status and health. HNR conducts basic research in relevant areas, focusing on optimal nutritional status and nutritional vulnerability in relation to health, including the development of innovative methodologies. HNR responds to the strategic priorities of the wider scientific community by conducting research projects, within the scope of HNR's activities, in collaboration with, and on behalf of: other MRC establishments and groups, Government departments, industry, national and international agencies, universities, research foundations and charitable organisations. HNR also acts as an independent, authoritative source of scientific advice and information on nutrition and health in order to foster evidence-based nutrition policy and practice.

We are pleased to have the opportunity to comment on this EC consultation concerning the setting of maximum and minimum levels of vitamins and minerals in foodstuffs. We welcome this positive step towards developing a clear European strategy towards vitamin and mineral supplements and food fortification and believe this document provides a systematic and clear framework under which future legislation can be developed.

Comments to the specific questions raised by the commission

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?**

For those vitamins and minerals where there are insufficient data to establish a numerical tolerable upper intake level (UL), the upper safe level should be based on the minimum level of dietary intake considered to be safe (without risk of adverse effects). This could be garnered from the guidance levels set by the UK Expert Group on Vitamins and Minerals-EVM and perhaps by cross-reference to the Dietary Reference Intakes of the Food and Nutrition Board of the Institute of Medicine (USA). However, there should be a review mechanism in place to ensure that this level can be amended rapidly if new data become available. In addition it should be recognised that setting any level, including upper safe levels, based purely upon the 'mass content' of a nutrient is a blunt metric when considering supplements or fortificants because of differences in absorption depending on the form of the nutrient. For example, the trace element silicon, for which there are increasing links with optimal health but very few valuable nutritional data, comes in many different supplemental forms, and typical absorption in humans may vary from <2% to

Elsie Widdowson Laboratory, Fulbourn Road, Cambridge CB1 9NL
Tel: 01223 426356 Fax: 01223 437515 www.mrc-hnr.cam.ac.uk

70%. Similar issues of chemical speciation and bioavailability exist for other micronutrients. The committee should thus consider the form of the added nutrient in order to take account of absorption and other aspects of bioavailability, when extrapolating from the guidance levels for foods.

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?**

Yes. We strongly believe that there is the need to set maximum levels for all the vitamins and minerals approved for use in the manufacture of food supplements in the European Union. There are no good long term (epidemiological or intervention) data analysing the impact of different levels of supplementation on health outcomes. It is therefore not possible to assume that acute observations will be carried through to the long term. Moreover the interactions between some nutrients should be taken in consideration in the assessment of risk for adverse effects. For example vitamin C is often quoted as a micronutrient with minimum adverse risk at high levels of intake. In some arenas 'mega-dosing' has been encouraged. However, vitamin C by increasing the bioavailability of iron from non-animal food sources also increases iron redox cycling in the gastrointestinal lumen and can thus promote intestinal damage. Recent data indicate that just a *two-fold* change in dietary iron levels (luminal iron activity) markedly increases the incidence of cancerous lesions in the colon of rats with chronic ulcerative colitis. As yet, the specific implications of this finding for maximum levels of Vitamin C are unclear, but this is a useful example of the need for constant vigilance where intakes greatly exceed the quantities of a nutrient available in the habitual diet.

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?**

There are certain advantages in setting the maximum amounts for vitamins and minerals in fortified foods and food supplements separately because with fortified foods the consumer is not always aware that he/she is taking an extra intake of a nutrient whereas with a food supplement there is a voluntary decision to increase the intake of a particular nutrient and therefore there is more awareness of possible risks. However, if you are to consider them together the labelling in fortified foods should provide enough information to allow consumers, particularly those in vulnerable groups, to be fully aware of the contribution of such foods to their overall intake of a particular nutrient. An example would be food fortification with iron impacting on those carrying the homozygous primary

MRC Human Nutrition Research
Elsie Widdowson Laboratory, Fulbourn Road, Cambridge CB1 9NL
Tel: 01223 426356 Fax: 01223 437515 www.mrc-hnr.cam.ac.uk

haemochromatosis gene mutation, or those with a weak immune system and/or children where iron could increase risk of infection by pathogens and/or inflammation.

Again, as noted in (1) above, different forms of the micronutrients will have different toxicity/safety assessments and therefore should have different settings. An example would be ferrous sulphate and ferric pyrophosphate (both EC approved forms of iron in food supplements and fortificants), where the iron from ferrous sulphate is absorbed but can cause severe gastrointestinal discomfort while ferric pyrophosphate does not have significant reported side effects but iron is very poorly absorbed from this preparation.

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.

We endorse the UK Food Standards Agency reply which is pasted below for ease of reference:

FSA reply

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.

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.

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?

It seems clear that there are major differences in prevalence of particular nutrient (depletion) problems between different EU member states: for instance the prevalence of vitamin D deficiency (especially in the winter months) varies greatly between north and south, thus compensation through dietary means will need to vary in line with this. It should also be noted that some of the newer member states currently may have a large seasonal variation in intakes of nutrients (such as vitamin C) that are derived from fruit and vegetables, since the supply is extremely seasonal. It seems that any legislation needs to be flexible enough to take account of these known differences, and likely projected future changes.

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

Yes, different age groups should be taken into account in the setting of maximum levels of vitamins and minerals in foodstuffs because they will have different requirements for a particular vitamin or mineral. The different groups should be: children, healthy adults, pregnant women, lactating women and the elderly. Beyond this, the label/packaging should provide enough information on possible risks to allow consumers, particularly those in vulnerable groups (e.g people suffering from or at risk of chronic medical conditions), to make an informed choice rather than making recommendations to cover all eventualities.

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?

In the first instance, maximum levels for vitamins and minerals in food supplements and fortified foods should be based primarily on risk (see answer to question 1). There are some arguments to also consider maximum levels in the context of PRIs/RDAs but the uncertainties in setting the current values and the lack of uniformity around Europe limit

MRC Human Nutrition Research
Elsie Widdowson Laboratory, Fulbourn Road, Cambridge CB1 9NL
Tel: 01223 426356 Fax: 01223 437515 www.mrc-hnr.cam.ac.uk

their usefulness. However, we believe in the responsibility of manufacturers to ensure that their supplements and fortified foods are able to deliver absorbable nutrients within the limits.

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?**

Yes. 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. In the case where the vitamin or mineral is added to restore the nutrient value of the product before processing, for example in the case of white wheat flour fortified with iron to the level present in whole wheat flour, there should not be a case for claiming that the product is fortified. These could be labelled as restored or substituted. Only where products are genuinely fortified with a certain vitamin or mineral, that is with one that is either (a) not normally present in the 'natural' product or (b) present at a significantly lower level, should there be a case for claims. In addition, 'claims' must reflect the balance of benefit and risk.

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.

Additional comments

1. One question not addressed here is whether the formulations listed in the positive list of vitamin and mineral substances which may be used in the manufacture of food supplements (Directive 2002/46/EC) are optimal. However this is important. For example, there is increasingly strong evidence to suggest that simple ferrous salts (ferrous sulphate, ferrous fumarate, etc) are toxic to the intestinal mucosa and circulation. Moreover there is no good evidence to suggest that the alternatives listed are better in their lack of toxicity (ferrous carbonate, ferrous citrate, ferric ammonium citrate, ferrous lactate, elemental iron) or in providing absorbable (bioavailable) iron (ferric sodium diphosphate, ferric pyrophosphate, ferric saccharate, elemental iron). Thus we worry that not only may the current list prevent development of better supplements that address these issues, it may be seen to endorse potentially toxic or non-absorbable supplements.

2. The committee could consider legislation so that absorption and basic safety data are provided for supplements/fortificants including those included in the positive list.

MRC Human Nutrition Research
Elsie Widdowson Laboratory, Fulbourn Road, Cambridge CB1 9NL
Tel: 01223 426356 Fax: 01223 437515 www.mrc-hnr.cam.ac.uk