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Regulatory Affairs

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To whom it may concern

Basel, September 25, 2006

Comments to

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

by DSM Nutritional Products Europe Ltd

Introduction

DSM welcomes the Commission discussion paper and the consultation of stakeholders as the basis for setting maximum levels for food supplements and fortified foods. We have always supported the setting of safe maximum amounts based on scientific risk assessment principles and would like to provide the following specific comments to the Commission`s questions:

1. **Where there is not yet a scientifically established 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?**
   The nutrients, for which EFSA has not set an upper level because no evidence of adverse effects at current levels of intake has been noted, are vitamins B1, B2, B12, biotin, pantothenic acid, vitamin K and trivalent chromium. These do not represent a risk to human health at current levels of intake and do not in principle require a maximum level for fortification or food supplements. For the sake of consistency however the nutrient should be included in any annexe listings with a clear note “No evidence of risk at current intake levels”. Failing that, if an upper level is to be set, the views of other scientific groups such as the US FNB[i], the UK EVM[ii] , ERNA[iii], ILSI[iv] and AFSSA[v] in France could be taken into account. Where some evidence of risk at excessive intake exists, but no EFSA upper level has been set, international risk assessments and upper levels could be taken into consideration and a guidance level set on a case-by-case basis, and reviewed if new evidence materialises.

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?**
   In principle there is no need to set upper levels for these nutrients. If however a decision is made to set a level, that level should be set on the basis of evaluating the findings of other scientific groups as in paragraph 1.

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 public health and the legitimate expectations of the various food business operators?**
   A pragmatic approach would be to collect data on maximum highest intakes (97.5th percentile figures) from food and fortified foods, which is normally done anyway by several Member States and subtract this from the known upper safe level for intakes from all sources to give a maximum level for supplementation. It should be noted that if vitamin and mineral intakes from foods and fortified foods increase by 10% at mean intake level, this is unlikely to increase 97.5th percentile intake figures by as much as 10%, as the 10% growth is likely to be via new users rather than existing users.
   Evidence exists to show that vitamin and mineral intakes from foods and fortified foods grow in one Member State where fortification is freely practiced at about 1% per annum for vitamins and 0.7% for minerals[vi].
   Evidence also exists[vii] that fortification accounts for only 3% of an individual's intake in Europe generally and only 10% in the case of extreme intakes, and is generally carried out at no more than 50% of an RDA per daily serving, often for organoleptic and nutritional rationale reasons.

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 levels.**
   The Seneca study (published 1994) looked at dietary intakes in the Elderly at European level but did not break out vitamin and mineral levels. The EU funded DAFNE project (ongoing)also summarized food intakes across 16 EU Member States and is being expanded to 20 Member States and can be used as a cross reference for say comparative food and vegetable intakes as a reality check re nutrient intakes.
   National dietary surveys are also known to exist in Ireland, Germany, Italy, France and Spain but they use different methodologies. There is an obvious need for co-coordinated EU data. EUROFIR is ongoing and will aim to harmonize food composition tables in use across the Member States.
   Data on population sub-groups at EU and country level is however generally inadequate, non-existent, or not comparable, particularly on the smaller groups such as pregnant women (circa 1% of the population) and should be improved before it can be used. This could take several years so should not be a part of short term policy.

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?**
   Diets across Europe vary more in terms of cooking style and presentation rather than in actual composition. It can be shown[viii] that approximately 75 % of the diet in each of the Member States France, Germany, Italy, Spain and the UK consists of twelve basic foods i.e. fruit and vegetables, meat and fish, bread, milk, carbonated soft drinks, mineral water, tap water, wine, coffee, juices, canned foods, and cheese, in quantities of similar magnitudes. Thus in the absence of comprehensive EU data, national surveys will continue to be useful for setting maximum levels until such a time as comprehensive EU data becomes available, at which point the levels could be reviewed. UK NDNS data is interesting because that data reflects intakes of nutrients in a market place where fortification and supplementation have co-existed for several decades.

6. **Should the intake from different population groups be taken into account in the setting of maximum levels of vitamins and minerals?**
   In general, little data exists in most Member States on intakes in population sub-groups, and so this question is largely premature until that data becomes available.
   The derivation of UL`s for the essential nutrients for adults is based on the principle that the most sensitive members of the general population must be protected from adverse dietary effects on health. Therefore the UL is adequate for these groups.
   There is a case for setting maximum levels for two groups, notably adults and young children. Requirements across the adult population are broadly of similar magnitude, but in children, body weight and metabolism considerations could be included.
   As the SCF has already recommended safe upper levels for children as well as adults this should not be logistically complex.

7. **Taking into account all the above-mentioned considerations, how far should PRI`s/RDA`s be taken into account when setting maximum levels for vitamins and minerals?**
   They should not be taken into account when setting maximum levels, as PRI`s/RDA`s are defined as levels to prevent nutritional deficiency whereas maximum levels are defined by risk assessment and the two have no scientific connection. The use of arbitrary multiples of RDA`s to define maximum levels is not scientifically acceptable. RDA`s are a measure of the lowest end of the range of safe intakes.
   PRI`/RDA`s can be used however, as in the ERNA model, to establish the relativity of the RDA and the safe upper level. Where the gap is high, risk is low, and vice-versa and the size of the gap should help to categorise the nutrient in terms of specific risk.

8. **Should the minimum amount of a vitamin or 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 nutritional labeling.**
   In general if a nutritional claim is not made, then no minimum should be required.
   If a nutritional claim is made, then the minimum amount will have to be added according to the Nutritonal Labelling Directive.
   However according to the new EU Health Portal, the Fortification Regulation will permit Member States the right to pursue mandatory fortification where they feel it is necessary. Restoration practices or mandatory fortification carried out at restoration levels are sometimes leading to levels which in some instances may be below the minimum required by the Nutritional Labeling Directive 90/496/EC for a claim to be made. Examples of such practices across Europe should be checked and a mechanism derived, possibly via Nutritional Labelling, or national derogation, to allow such restored product to be differentiated from non-restored product or the consumer could be misled.

9. **Should (a)different minimum amounts be set for certain nutrients in specific foods or categories of foods? If yes, (b)on what basis? Should(c) 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.**
   (a)(i) It should be recognized that vitamins and minerals are generally not added to several major categories such as fruit and vegetables, meat and fish, and tap water for legal reasons but it should be noted that fruit and vegetables are subject to significant storage losses. If vitamins and minerals are added back to the diet to gradually increase

nutrient density to compensate for the current trend of reducing calorific intake, or low fresh food intake in particular circumstances, they can only be added back to those foods which will provide a stable environment for them and which can physically be fortified. An example would be ready meals for the elderly where the gravy, sauce or custard is usually selected as the carrying medium as it is not legal to fortify the fresh components of the meal. Another option would be to fortify the soft drink which accompanies the meal, or the ice cream or dessert which follows the main meal. Thus foods which may give a superficial impression of not being suitable for fortification from a nutrient profile point of view are often the only choice from a pragmatic point of view.

Our opinion is that all foods should be dealt with in the same way on this issue, recognizing that nutrient profiles in the Health Claims Regulation will effectively prevent many high fat, high sugar and high salt products from being fortified as, if a claim cannot be made, the manufacturer will be unlikely to fortify.

(a)(ii) Minimum amounts are set per 100gms of product by the Nutritional Labelling Directive 90/496/EC, but daily serving sizes can be as low as 25-40 gms in the case of margarine and breakfast cereals, implying that to meet the Nutritional Labelling Directive minimum for a nutritional claim only 3.75-6.00% of an RDA needs to be added. This is arguably too low to be deemed significant and a clause should be included to make the declaration per daily serving obligatory in addition to the declaration per 100gms where the daily serving size falls below 50 or 60 gms.

We are in favour of a threshold for nutritional labeling linked to serving sizes rather than weight

(c) The Nutritional Labelling Directive does not apply to food supplements.

A simple declaration of the % of RDA of each nutrient/daily dose should be sufficient information to inform consumers and avoid misleading them.

[i] Food and Nutrition Board of the US National Academy of Sciences
[ii] UK Expert Group on Vitamins and Minerals report “safe Upper levels for Vitamins and Minerals” 2003
[iii] European Responsible Nutrition Association “Vitamin and Mineral Supplements-a risk management model” 2004
[iv] International Life Sciences Europe report “ Vitamins and minerals-a model for safe addition to foods” 2003
[v] Agence Francaise de Securite Sanitaire des Aliments report 2002 on the addition of vitamins and minerals to foods
[vi] UK National Diet and Nutrition Surveys 1986/7 and 2001 comparisons
[vii] D.Godfrey, D.Tennant, and J.Davidson The Impact of fortified foods on total dietary consumption in Europe. Nutrition Bulletin 29 188-198
[viii] Data from The impact of fortified foods on total dietary consumption in Europe. Nutrition Bulletin 29 188-198