

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

### SETTING OF MAXIMUM AMOUNTS

#### Establishment of maximum amounts for food supplements and other foods

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

**A.** As per the general food law principles, the setting of maximum and minimum amounts for vitamins and minerals should be proportionate; therefore we believe that where no safety concern has been demonstrated, and no upper intake level (UL) has been established by EFSA, no maximum level should be set.

**Q.** 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?

**A.** Where there is no question of safety, there is no need to set maximum levels for these vitamins and minerals since the scientific risk assessment shows no evidence of risk to human health.

**Q.** 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?

**A.** Fortified foods should not be taken into consideration for vitamins and minerals with low risk of exceeding the upper levels as there is no need to set separate maximum levels for supplements and foods, and where risk is non-existent (as in the previous question) there is no justification for setting any maximum levels.

#### Intake of vitamins and minerals from dietary sources

**Q.** 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.

**A.** 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. It was therefore not possible to derive fully valid pan European estimates of 95<sup>th</sup> 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.

**Q.** 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?

**A.** The extremely varied diets across the EU make it near impossible to compare the vitamin and mineral needs of those consuming a mediterranean diet with those consuming a nutrient deficient ready meal diet, therefore believe that without true data, there can be no true EU benchmark on which to set these levels.

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

**A.** 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.

## Reference intakes of vitamins and minerals

**Q.** 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?

**A.** 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:

- I. a non-existent risk of exceeding the upper levels, i.e. no maximum levels required
- II. a low risk of exceeding the upper levels
- III. 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 paragraph 42 of the Discussion Paper.

Please note that paragraph 37 is incorrect in describing PRIs as 'optimal': they represent 'minimal' intake.

## **MINIMUM AMOUNTS**

**Q.** 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?

**A.** Adding nutrients and making claims go hand-in hand, however due to the size of food supplements in comparison to foods; hence the significant amounts need to be amended to be more relevant to this specialised sector of the food market.

**Q.** 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?

**A.** 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 (ie % 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.