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

1. 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?

The lack of scientifically established numerical tolerable upper intake level value indicates the insufficiency of the available data, therefore in these cases the maximum level should be determined very carefully. Maximum levels shall be set taking into account the precautionary principle on the basis of available data. In our opinion, the guidance levels (GL) or observed safe levels (OSL) published in the report of UK Expert Group on Vitamins and Minerals (EVM) in 2003, could be a good source to set maximum levels for these nutrients. Considering, that most of the vitamins and minerals included in this category have pharmaceutical applications as well, the experiences gained from their long-term application should also be taken into account.

2. 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?

In our opinion it is very important to set maximum level for all vitamins and minerals in many ways.

i) In the absence of maximum levels of vitamins and minerals having extremely low risk of adverse effects, the possible risk of interactions with medicinal products is increasing. Scientific opinions raised by SCF and EFSA do not include assessment of the possible contraindications and interactions with medicinal products, although consumption of fortified food, food supplements and taking medicines frequently occurs simultaneously.
ii) In case of long-term and regular consumption, the extremely high intake of vitamins and minerals can influence the human homeostasis in a negative manner, and could result in unnecessary burden for excretory organs.
iii) It is important to give orientation and help to competent authorities with market surveillance activities, and small and medium size enterprises.

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?

To our mind, maximum levels must be set in both cases, separately. These values would be important for both consumer protection and practical considerations (can be used as a basic tool for daily work of competent authorities with market surveillance activities, and small and medium size enterprises). The maximum level could be set using a risk assessment, but the published models contain too much uncertainty, such as the level of reliability and accuracy of nutrient intake data, data and estimates on the

rate and quantity of consumption of fortified foods, food supplements and medicines with the same effective components, their alteration by time, and variability in the member countries. The models do not really include vulnerable groups (like children, pregnant or lactating women, the elderly generation, etc.).
We presume that within the limits (upper level (UL) minus dietary intake from normal foods) the maximum level for food supplements and fortified foods should not be the same from safety point of view. The consumption of fortified food can easily get out of consumer's control, due to taste, appearance, consumption habits etc., which can result in a high dietary intake of that food and an overdose of vitamins and minerals. A lower maximum level would not be disturbing in case of fortified foods, due to the fact that the addition of vitamins and minerals has technological limits and quality aspects as well, such as taste stability and interactions in that food matrix.
The consumption of a food supplement could be kept in a better way under consumer control due to appearance, etc.

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.

A National Population Health Survey (OLEF) was carried out in Hungary in 2003, with 5015 persons initially. A 3-days nutritional questionnaire was used to obtain information on the intake of vitamins and minerals. Finally 1179 persons have participated and has given suitable data for evaluation. The following age groups were analysed: 18-34 years, 35-59 years, and over 60 years. The number of surveyed males was 473 in total, with a distribution of age groups of 136, 199, 138, respectively. The number of females in total was 706, with a distribution of age groups of 176, 295, 235, respectively. The detailed results are under publication, so we attach a short summary of the most relevant results. (see in the attached Excel file).
We also refer to the work of Prof. Elmadfa et. al. „On the Recommended Nutrient and Energy Intakes for the European Community (*Elmadfa I, Anklam E, König JS (eds.): Modern aspects of Nutrition. Present Knowledge and Future Perspectives. Forum Nutr. Basel, Karger, 2003, vol 56, pp94-95).*

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 is rather doubtful that reliable intake data obtained by controlled surveys are available for all Member States. If realistic intake data are required, it is inevitable to initiate a global dietary survey for all Member States, coordinated at European level. However, it is questionable whether the outcome of the huge costs and efforts (to accomplish a global dietary survey) could result in a fundamentally better approach.
Fist of all the available data should be analysed. The extreme high intakes and the size of the population concerned shall be taken into account in a significant way. Usually there are smaller or bigger differences in the dietary habits of member countries, but there could be regions irrespectively from the countries, in which dietary pattern,

habits and lifestyle show close similarities. In case of lack of reliable intake data, the use of the intake data of “similar” countries can not be objectionable.

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

From safety point of view, the intake of different population groups (genders, poor and rich people, the vulnerable groups, like children, elderly people, pregnant and lactating women, etc.) shall be taken into account in the setting of maximum levels of vitamins and minerals. To avoid the overdose of vitamins and minerals, the highest intake and extreme cases should be taken into account in a weighed rate. Nevertheless, at least the differentiation between maximum levels for children (with different age groups) and for adults is essential.

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?

Despite of the fact, that the ruling of the European Court of Justice indicates PRIs/RDAs cannot be solely used for establishing maximum levels, the importance of PRIs/RDAs values have never been questioned. PRIs/RDAs are also key factors in setting the maximum levels, since the application of nutrients at much higher level than the requirements (or at higher level than the usual therapeutic dose of the selected nutrient) definitely increases the risk of unwanted interaction, or contraindicated consumption. The weaknesses of the current SCF/EFSA opinions are that contraindications and interactions have not been evaluated in detail for nutrients, and the assessment has been mainly focusingon toxicity symptoms and adverse effects. Furthermore, if the PRIs/RDAs are not taken into account, it allows the consumer to consume all nutrients at maximum level (which is much higher than the requirement), and without knowing the effect of this extreme load on the organs involved in the metabolism of these nutrients.

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?

From practical point of view and due to transparency, the minimum amount should be set at the same level as the significant quantity required to be present for a claim. For the different vitamins and minerals the same minimum amounts should be set, but it would be important to distinguish specific foods or categories of foods, because their regular consumed portion could be very different. For example: the single portion of a non-alcoholic beverage is about 200- 300 ml. If we insist on keeping 100 g or 100 ml as a benchmark, than 7,5 % RDA vitamin, and/or mineral/100 ml beverage could already be beneficial for the consumer, because one single portion ensures at least 15 % of RDA. In case of sauces, or dressings (ketchup, mayonnaise, different salad

dressings) the situation is totally different. The regular consumed quantity is about 30 – 50 g. To get a significant quantity of vitamins/minerals from a portion is only possible when 30 % RDA of vitamin and/or mineral/100 g product is required.

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?

In the daily dose of food supplements, at least 15 % RDA vitamin and/or mineral as a significant quantity is required. However, in case of multivitamin and/or multimineral preparations, which contain number of vitamins and minerals, it could be questionable to set the 15 % RDA threshold compulsory for each vitamin or mineral compound, or only for a certain number of these materials.