Comments to the questions of the European Commission –

referenced in
http://ec.europa.eu/food/food/labellingnutrition/supplements/discus_paper_amount_vitamins.pdf

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?

No upper levels should be set.
Reason: Those nutrients that do not have a scientifically established numerical tolerable upper intake level are generally those where data on toxicity of excess intake have not been found. Where there is no problem, there is no reason to "fix it".

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 it necessary to set maximum levels for these vitamins and minerals?

There is no reason to set upper limits in these cases.
Reason: Where there is no problem, there is no reason to "fix it". But see also the "general comments" at the end of this message.

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 definitely should be set separate levels for fortification and for food supplements.
Reason:
Supplements are conscious-choice products used by people to supplement their diet in a general way, but also to intervene in a preventive way with higher doses. Preventive use of supplements is directed not against deficiency diseases but against the very prevalent *degenerative diseases*, which form a second layer, a second stage of deficiency. Example: While 60 mg of vitamin C is generally enough to protect against scurvy, large doses of the vitamin (one gram or more a day) have a protective effect against cardiovascular problems and other degenerative conditions.
Fortified foods, being "normal" foods for all intents and purposes, are consumed with the stilling of hunger in mind, that is, not generally making a conscious choice of increasing consumption of micronutrients.
Alternative: Set no limits for supplements or fortification, but make sure the content of vitamins and minerals, if added, is clearly stated on the label, including the form of the added vitamin/mineral. In this case, fortified foods should have a PROMINENT notice on the label that the particular food is fortified and with what quantity of what form of vitamin/mineral. This may not be acceptable in the EU regulatory climate that requires close government supervision of the minute details of our lives, but it would certainly be more in line with

letting people be responsible for their own health, rather than blindly following government prescriptions and inevitably falling ill when the prescriptions do not take into account the individual circumstances of the person.

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.

Detailed intake data may have value as background information, but should not influence the setting of maximum levels. When a survey was conducted on nutrient intake data in Italy, the writer of these comments was one of the heads of family asked for data. The collection of data on foods consumed was perfunctory, asking only if any foods were specifically excluded, with NO questions on supplementation, and none on specific foods consumed. It would seem that the accuracy of these official consumption statistics is questionable.

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 data should not be used to lower allowable levels of dosage of supplements.
Reason: As per number 4 above, the reliability of the data is questionable. But more importantly, the *availability of nutrients for individual choice,* as in supplements, should not be scaled down to the lowest common denominator of those who may have a more sensitive reaction (as already taken into consideration in the risk evaluation that precedes the setting of upper levels). Otherwise, what will be created is a *new risk* of blunting public participation in taking care of one's health in a pro-active way, based on personal preference.

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

No, it should not. See answer to point 5 above.

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?

PRIs/RDAs should be taken into account only where needed to make sure that
a) fortification is roughly in line with the recommended amounts or a multiple of these and
b) lower limits on supplement dosage are - if instituted - measured against PRI/RDA.

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?

No different minimum amounts should be set.
Reason: We may think today that regulating both minimum and maximum is a good idea, but perhaps new data will show tomorrow that a very small amount of some nutrient has a different action than the RDA amount, for instance. However, once amounts are set in law, it will be very difficult to change the rules, so the minimum of rules - not setting too many parameters - would be preferable.

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?

Link any minimum amounts - if they HAVE to be set - to the labeling amounts.
Reason: Consumers are quite capable of distinguishing what they are looking for. More "protection from above", will engender less personal responsibility for health, and in the final analysis more illness rather than less. It would be vastly preferable if no minimum amounts could be set.

General Comments:

Supplements should be kept separate from fortification (addition of nutrients to foods), for reasons explained in number 3 above. Our comments, where not specifically stated, relate to supplements, rather than food fortification.

While fortification may require restrictions and rules, supplements as a conscious-choice group of products, should be burdened with as little regulation as possible.

We have argued for little or no regulation on supplements during the approval process of the supplements directive. See letter to members of the European Parliament Environment Committee.

Preventive potential on high dose nutrients

One point that has been constantly overlooked in the discussions leading to the approval of the supplements directive and that is still overlooked during this period of implementation, is the following:

Prevention of illness is most effective when based on supplemental nutritional intervention.

The dosages used in preventive nutrition, often under the supervision of nutritional specialists, are high when compared with the minimal amounts required to avoid deficiencies (RDA/PRI).

There are no provisions for making sure these high dose nutritional products are going to continue to be available. Certainly pharmaceutical manufacturers have little or no interest in manufacturing and making available products that compete with their big sellers, the pharmaceutical medicines.

For this reason, you may be eliminating the basis for preventive nutrition, prohibiting the manufacture and sale of the products used in active nutritional prevention.

Danger of stimulating a black market

The result of regulations limiting nutrient availability may be two-fold:

a) There will be *less prevention and consequently more illness* - exactly the contrary to the stated goal of supplements legislation which, at least in part, is the protection of public health.

b) Consumers who are using nutrition for preventive purposes will not stop to do so because there is a new law from the Brussels Bureaucrats. Instead, *a black market for supplements will form*, just as currently there is a black market for drugs.

Precaution can be overdone

The European legislation on food supplements and especially the setting of dosage limits for supplements is often justified with the precaution that must be taken by legislators and regulators to protect public health. But precaution is not a one-sided affair. It must take into account both the utility of food supplements in helping people protect their health and the

dangers of food supplements providing "too much of a good thing", which - in the rarest of cases - may lead to adverse reactions.

For now, the precaution is taking only into account the - largely exaggerated - dangers of "too much" while completely ignoring the dangers of eliminating supplements to bettering the health of consumers and thereby *eliminating the major tool for prevention*, which is nutritional supplementation.

A discussion of this dilemma can be found in the following recent article:
The Dark Side of Precaution: Preventing Prevention

Respectfully submitted
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