Consumers for Health Choice

- A Decade Defending Consumer Choice 1996 – 2006!

Response to the Commission Discussion Paper on the Setting of Maximum and Minimum Amounts for Vitamins and Minerals in Foodstuffs.

Consumers for Health Choice (CHC) welcomes the opportunity to comment on the Commission Discussion Paper.

Background

With over 267,000 registered members, and direct contact through its communications with many millions of supporters throughout the Union, CHC is now the widely accepted voice in Europe of consumers of a wide range of natural health products including vitamin and mineral supplements. We believe that the regulation of such products should accord to the following basic principles:

a. consumers should be able to choose from a wide range of products that are safe and appropriately labelled;
b. supplementation is an accepted approach (by WHO and many other internationally respected bodies) to addressing problems of nutritional deficiency, to achieving and maintaining optimum health, and to reducing the risk of a wide range of serious diseases;
c. the basis upon which the Commission is minded to propose MPLs should be open, transparent, and subject to widespread consultation before final figures are put to the Council; and
d. any restrictions on the sale of supplements for reasons other than a threat to public health constitute an infringement of consumer choice, a distortion of the single market, would be challengeable in the European Court of Justice, and would bring the European Union into disrepute.

The general approach of the Commission to the interpretation and implementation of this legislation should be to provide consumers with accurate information upon which they may make informed, individual choices.

We welcome the very recent commitment of Commissioner Kyprianou who stressed in his letter of 31.07.2006 to Austin Mitchell, a British Member of Parliament, that:

> ***… a main purpose of the legislation is to "provide a wide choice for consumers to supplement their diet".***
>
> ***Commissioner Kyprianou***

We look to the Commission to defend and uphold that principle.

Question 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?

Maximum Permitted Levels for supplements (MPLs) should be set upon the basis of established risk assessment procedures such as those adopted by the United Kingdom's Expert Advisory Group on Vitamins and Minerals. CHC does not accept all the conclusions of the Expert Group Report, as we believe that in the case of some individual nutrients the Group made over-

cautious interpretations and assumptions, but the general approach of the Group commands substantial consensus.

Where the science demonstrates a serious risk of significant adverse effects beyond a certain level of intake, then an appropriate MPL may be set.

Where the science demonstrates only a low risk of minor and reversible symptoms, then there is no need to establish a prohibition on products above that level, but an Advisory Statement might reasonably be issued to guide consumers.

A rapid review process is also absolutely essential to ensure that new scientific data when available can lead to the revision of MPLs. We would ask the Commission to give a guarantee about the processes and timelines for such reviews prior to proceeding to propose any MPLs. This is essential because:

a. the review by EFSA of any new nutrient-related data is likely to be slow given their current and foreseeable workloads; and
b. the low priority and slow speed with which recent experience suggests that the Commission would otherwise bring forward proposals to effect any resulting change.

To provide for the very wide range of nutrient intake from the general diet throughout the Union it is essential that Member States are given flexibility to permit onto their national market products which lie outside the permissive provisions of the MPLs set, provided that where appropriate Advisory Statements are used.

Question 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?

There is no logical reason to call for the setting of maximum permitted levels where risk of adverse effects is "extremely low or non-existent". To suggest otherwise is a distortion and misapplication of the so-called "precautionary principle".

Were there are genuine concerns, based upon signs of suspect adverse behaviour patterns emerging, the principle could possibly be invoked. However, in a situation where many millions of people take food supplements regularly without any evidence of adverse effects over a period of many years there is no case that can be made for such an approach. The same logic would require maximum permitted levels to be set for all foodstuffs, some of which are indeed known to cause problems.

To take such an approach for one category of food product (supplements) but not others would be fundamentally unjust and challengeable in the Court.

Question 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?

No.

There is no evidence to support assertions that consumers are likely to ingest high nutrient levels through both fortified foods and supplements. Evidence from retailers and marketers is that the two groups are not identical, and are also well informed.

Consumers should be empowered by the provision of accurate information and allowed to make their own choice as to whether they receive their nutrients from normal foodstuffs, fortified foods, and/or supplements.

It is important to recall the different reasons for fortification:

a. restoration (simply restoring nutrients to the levels that were present prior to the production processes) which constitute the majority of such products and which will not significantly contribute to high levels of nutrient intake
b. substantial equivalence (adding nutrients to a manufactured product to mirror the nutrient profile of a natural product) which constitute the second largest group and which again will not significantly contribute to high levels of nutrient intake; and
c. specialist fortified products where a higher level of nutrients is intentionally added, but at a price premium. (a much smaller range of specialist products) Consumers of such products tend to seek them and be willing to pay the additional cost as this is their chosen form of enhancing their nutrient intake, so again, this is unlikely to conflict in any way with supplement consumption.

Question 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.

The Commission may find it helpful to view "Status report on the European Commission's Work in the Field of Nutrition in Europe, October 2002", particularly Annex 1 and the Nutritional Challenges in the European Community – pages 25-26.

- Recent dietary surveys suggest that there are continuing problems of deficiencies in micronutrients — in particular iron, iodine and folate — affecting all Member States to various degrees. These deficiencies can cause anaemia, iodine deficiency disorders and congenital deformities.
- Compared with the dietary intake of fruit and vegetables recommended by the Eurodiet project (62), the present consumption of fruit and vegetables is low, especially in the northern part of the Community, and in most socioeconomically disadvantaged groups (63). Fruit and vegetables are valuable sources of vitamins and minerals, and contain dietary fibre and antioxidants.

There is much more material at that source.

Also see answer to Question 7 below identifying sub-groups who have particular nutritional needs.

Question 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?

No. If data exists only for some Member States then clearly it cannot be assumed to apply to the whole of the EU. It cannot, therefore, be used in any formulaic way in calculations of the MPLs to apply to the whole EU.

What can be taken into account, however, is that a substantial number of surveys have shown a large number of groups displaying significant nutritional deficiencies.

Also see answer to Question 7 below identifying sub-groups who have particular nutritional needs.

Question 6

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

The Commission will have more than challenge enough to set general levels without such a range of subsets for different population groups. What is needed is accurate information for consumers who should be free to make their own choices.

Warnings for pregnant women would be sensible where appropriate in this context.

Products aimed directly at children would be a special case but would again raise challenges for enforcement and credibility of message. Such levels if set should be based upon kg of bodyweight not arbitrary and hence unscientific age levels.

Question 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 should be taken into account if, and only if, the calculation of a Maximum Permitted Level suggests a dosage that is below the PRI, thus risking diseases of nutritional deficiency.

The concept of the PRI is particularly outmoded in its relation to "average" requirements because there are so many groups, probably when combined constituting a majority, or at least a very substantial percentage of the population, who need higher than the average or PRI nutrient intake. Such groups would include, but not be limited to:

- People on medicines
- Pregnant women
- People active in sports and fitness regimes
- People on general weight loss diets
- Obese people
- Vegans
- Vegetarians
- Men over 65
- Menopausal Women
- Post menopausal women
- Young women pre-puberty

- Women entering puberty
- Young men pre-puberty
- Men entering puberty
- People with various forms of cancer
- People with diabetes
- People with high cholesterol
- People with arthritis
- People with osteoporosis

The Commission statement in paragraph 37 on page 12 of its Document, that PRIs are "determined on the basis of the concept of optimal nutrition" is incorrect. PRIs are outdated measures of minimum nutrient intake necessary to avoid diseases of nutritional deficiency. They have nothing to do with "optimal nutrition".

Consumers for Health Choice
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