NATIONAL ASSOCIATION OF HEALTH STORES

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Commission Discussion Document on Maximum Levels in Vitamin and Mineral Products

Response from the UK National Association of Health Stores
August 2006

Our bottom line

The NAHS supports the proposal of the UK Food Standards Agency which would create a twin-track approach, allowing the setting of pan-European levels thus establishing a Single Market in nutritional products, but also allow individual Member States (MSs) to set higher levels on a national basis. We feel this is a sophisticated proposal that will not interfere with the creation of a Single Market in food supplements. It meets the need for subsidiarity, consumer choice, protection of consumer health, as well as protection of Small or Medium sized Enterprises (SMEs) from unnecessarily restrictive legislation.

For the setting of the pan-European levels we give qualified support to either the ERNA-EHPM method of calculating upper levels or the UK's Expert Group on Vitamins and Minerals (EVM), published in May 2003. These are the most reasonable out of the risk-managed options published in the Annexes to the Discussion Document.

We also feel that appropriate resources should be made available to the European Food Safety Authority (EFSA) to enable reviews of available research on vitamins and minerals to be evaluated on a **systematic** and **regular** basis. Its track record in evaluating nutrient form dossiers suggests that it may struggle with the workload of administering this Directive.

The NAHS request that the Commission performs a regulatory impact assessment, particularly with regard to SMEs, on any proposals that it brings forward, and follows this up by taking due account of the findings.

About the National Association of Health Stores

The NAHS was founded in 1931 as the representative body for the burgeoning health food store movement in the UK. It currently represents approximately 1,500 independent health stores, all of them SMEs.

The NAHS has taken a particular interest in the Food Supplements Directive (FSD) as it would disproportionately affect our members' businesses, perhaps more so than other stakeholders. The largest market for specialist supplements in the EU is the UK, and the businesses which turnover the highest proportion of food supplements are health food stores.

Our interest in the FSD is not just from the perspective of our businesses. We care strongly for the health of our customers and take a keen personal interest in their wellbeing. We know that many, many people have turned around chronic health problems through use of supplementation and we would be loathed to see that compromised.

In 2003 the NAHS mounted a judicial review of the FSD in the British High Court. Although the decision went against us in the European Court of Justice, we are

keeping our legal options open, particularly if the principles of subsidiarity, proportionality, and consumer choice are not adhered to in the setting of MPLs.

The British Experience

The availability of high potency food supplements commenced in the late 1960s with the arrival of specialist vitamin C and E supplements. The real explosion in products occurred in the 1970s and have been very popular with the public ever since. In total, billions of doses have been consumed and the safety record of the trade has been exemplary.

NAHS member stores typically carry a range of natural, organic foods, nutritional supplements and herbal remedies. They make a positive contribution to their customers and their communities by sharing information on natural health, helping countless millions of people over the years.

The higher margins on supplements underpin the businesses and increase their viability. It is estimated that a typical health food store would stand to lose about 10% of its turnover if potencies were reduced to EU RDA levels excluding the knock-on effects to both credibility and footfall..

Our members tell us that this would have a disproportionate effect by making their businesses less profitable and they would consider closing. This is not taking into account the loss of nutrient forms under the FSD or herbal combinations under the Traditional Medicinal Herbal Product Directive. All in all, a potentially lethal cocktail for our small and specialist businesses.

The NAHS urges the Commission bring forward recommendations for the setting of MPLs that are proportionate and take account of the reality of the British experience of selling specialist supplements for nearly 40 years. This period has been characterised by an outstanding safety record.

Responses to the specific questions posed

1. ***Where there is not yet a scientifically established numerical 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?***

It is easy to lose the context of the word 'scientifically'. If the terms of reference are based on a safety assessment used for toxins and toxic drugs instead of natural and essential foods, then the risk assessment, though a perfectly reasonable procedure within itself, will produce completely different set of criteria and safety factors, reducing the levels to absurdly low levels.

It seems likely that the Commission will prefer a formulaic way of calculating MPLs, rather than the committee structure of the EVM. We would have to say of all the formulae contained in the Annexes to the Discussion Paper, that the

ERNA-EHPM method is the most objective and pragmatic of the approaches and yields the least damaging result to consumer choice in the UK. This becomes even more acceptable if the Commission allows MSs to permit higher levels twinned with label warnings. This will protect existing national markets and allow MSs to make their own adjustments based on national needs.

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. For example, our practical experience shows that peripheral neuropathy caused by excess intake of B6 consumption does not occur in consumers until they get into consumption of hundreds of milligrams over protracted periods of time. As the effects are reversed on cessation of consumption it would seem appropriate to maintain both consumer choice and awareness by Advisory Statements rather than by setting disproportionately low levels.

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?***

No.

Would there be a precedent for restricting consumption of products proved to be non-toxic? To do so would clearly be disproportionate, particularly as it would not apply across all substances consumed by humans.

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.

It is our clear experience, as retailers, that the consumers of high dose supplements are not usually those who purchase fortified foods. Consumers should be made aware that they need to consider their nutrient intake from all sources when buying products and then left to make their own minds up.

The NAHS does not support the fortification of nutritionally bereft foods. We feel that it is a very simplistic way of addressing nutritional deficiencies. For example, white wheat flour is fortified with less nutrients than are lost during processing. By adding a few nutrients back into the product it can give the impression to consumers that it is a healthy food whereas they should be eating unprocessed whole-wheat flour instead.

Some popular foods, medicines, and activities actually create a higher need for nutrients. These include refined sugars, birth control medication, and smoking.

This creates an uneven nutritional playing field for individuals and underlines, again, the need for MPLs to be set based on safety but also flexibility for individuals to address these problems.

We promote the consumption of unprocessed foods in the diet, occasionally combined with supplementation if the need arises. We feel that this is a healthier and more specific way of promoting good health.

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.

No data recommended. See answer 5.

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.

Existing research is often patchy and incomplete. Even if it was complete on an EU-wide basis it would not take account of the wide differences between the needs of individuals. No two people have the same supplementary nutrient requirements (biochemical individuality), and the same applies to nations. This highlights the need for MPLs to be set on a basis that allows all consumers the flexibility to address their individual needs. The FSA proposals will further enhance this.

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

Such information should only be used to inform the Commission that a 'one size fits all' is unrealistic and that a flexible approach is essential. There is a lot of evidence in the FSAs National Diet and Nutrition survey of 2003 that a very large number of people fall below the 2.5% percentile of nutrient consumption. There is no reason to assume that this is much different in other MSs as there is a growing move away from traditional foods to highly processed ones.

In order for these people to remedy the situation with nutritional remedies that have had their potency adjusted based on the average consumption, and then 'risk managed', becomes increasingly impractical and expensive.

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?

RDAs should only be taken into account if, for some reason, the MPLs calculated are below the RDA. Generally, we regard RDAs as outmoded and irrelevant, and many consumers fail to understand what they mean.

This brings us onto the error in the Discussion Document (Para 37, page 12) where RDAs are described as “determined on the basis of the concept of optimal

nutrition". This has never been the case. They were established on the basis of avoiding deficiency syndromes and have nothing whatsoever to do with optimal nutrition.

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?

The NAHS has no firm feelings on this although we feel that there should be some kind of minimum level in order to trigger a claim and for the nutrient to be featured in the main body of the product packaging. It amounts to a fraud on the consumer if a product claims 'Rich in vitamin C' but only contains a couple of milligrams. At levels below the notional limit manufacturers should be confined to listing it only in the list of ingredients.

However, we are philosophically opposed to the fortification of foods which may be nutritionally bereft otherwise, and indeed may contain such high levels of additives, sugars, etc that they in effect become nutrient depleting.

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?

Practically this would not normally occur, but we feel that it would be a fraud on the consumer if a product was marketed as a food supplement which contained only a small proportion of the amount required to avoid deficiency.

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