NHF NATIONAL HEALTH FEDERATION

A Not - For - Profit Health Freedom Organization

National Health Federation Comments re. EC Discussion Paper on the Setting of Maximum and Minimum Amounts for Vitamins and Minerals in Foodstuffs

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EXECUTIVE SUMMARY

The National Health Federation believes that no upper levels should be set for those nutrients that do not yet have a scientifically established numerical tolerable upper intake level. There is no scientifically valid reason to set maximum levels when the risk of adverse effects is low, and all levels of all nutrients should be given the status of "innocent until proven guilty". Intake from different population groups should be taken into account when setting any maximum levels of vitamins and minerals, as the "one-size-fits-all" approach is seriously flawed. PRIs/RDAs should not be taken into account, however, as they were never intended for such purposes. Current PRIs/RDAs were compiled - badly in our opinion - to address needs, not safety. Restrictions upon the minimum level of each nutrient contained in a vitamin and mineral supplement are impractical and unnecessary.

Finally, and as described in the Annex, we consider that the majority of current proposed models for nutrient risk assessment, centering as they do on the No Observable Adverse Effect Level (NOAEL), are outdated. In this respect we believe that the key issues to be addressed in order to correct this are: the need to consider individual Nutrient Forms, as opposed to Nutrient Groups; the need to consider Benefits in assessing Safe Upper Levels (SULs); the need to start with a Prioritization Model; and the need to establish a proper Evidence-Base for Assessments. Failure to fully address these issues will result in scientifically flawed risk assessments, and the maximum permitted amounts for vitamins in minerals in foodstuffs being scientifically invalid.

ANSWERS TO QUESTIONS ON WHICH THE COMMISSION SEEKS COMMENTS:

Q1 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?

NHF: There should not be any upper levels set for such nutrients. All levels of all nutrients should be given the status of "innocent until proven guilty". Moreover, placing restrictions upon the maximum levels for nutrients when there are no scientifically established tolerable upper intake levels risks harming consumers by excluding products from the marketplace and thus limiting people's ability to attain optimum health. This, in turn, will inevitably result in a continuation of the current skyrocketing cost of pharmaceutically-based healthcare systems, and an unnecessary and totally unsustainable economic drain on Member States' economies.

Q2 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?

NHF: There is no scientifically valid reason to set maximum levels when the risk of adverse effects is low. As described under Q1, placing restrictions upon the maximum levels for nutrients when the risk of adverse effects is extremely low or non-existent risks harming consumers by excluding products from the marketplace and thus limiting people's ability to attain optimum health. This, in turn, will inevitably result in a continuation of the current skyrocketing cost of pharmaceutically-based healthcare systems, and an unnecessary and totally unsustainable economic drain on Member States' economies.

Q3 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?

NHF: Contrary to received wisdom, and judging from what we know about our membership, people who use supplements on a daily basis frequently avoid fortified foods. Moreover, the levels of supplementary nutrients added to fortified foods are mostly so low as to not to be worth worrying about, and the sources of nutrients used in such products are mostly of low bioavailability.

Q4 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.

NHF: What little information that is available is mostly based upon cross-sectional national surveys. These generally consist of weighed intake records collected for between four and seven days. Such data are notoriously unreliable, and depend for their accuracy upon the diligence of the participants. In addition, and to correct the oft-heard adage, we are not what we eat, but what we absorb. The efficiency of people's digestive systems varies widely, and, as such, it is ultimately futile to compile information on intakes of nutrients and assume that the participants all absorb them equally efficiently.

Moreover, food composition tables, such as 'McCance and Widdowson's The Composition of Foods', show that the nutrient content of foods in the UK has declined precipitously over the past 60 years or so.[1][2][3][4] This phenomenon is not unique to the UK however, as similar data is available regarding the nutrient content of foods in the United States,[5][6][7][8] Canada[9][10] and Germany. As such, any decisions taken based upon assumed current intakes of vitamins and minerals are likely to be increasingly inaccurate with the

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[1] McCance and Widdowson. 1940 1st Edition. "The Chemical Composition of Foods". Published by Medical Research Council: Special Report Series No: 235.

[2] McCance and Widdowson. 1978 4th Edition. "Composition of Foods". Published by Medical Research Council/HMSO.

[3] McCance and Widdowson 1991 5th Edition. "The Composition of Foods". Published by RSC/MAFF.

[4] Meat and diary: where have all the minerals gone? Food Magazine 72, pub. by The Food Commission, UK. Jan/Mar 2006. http://www.foodcomm.org.uk/PDF%20files/meat_dairy2.pdf

[5] Composition of Foods (Raw, Processed, Prepared): Agriculture Handbook No. 8. USDA Agricultural Research Service. 1963.

[6] U.S. Department of Agriculture, Agricultural Research Service. 2005. USDA National Nutrient Database for Standard Reference, Release 18. Nutrient Data Laboratory Home Page. http://www.nal.usda.gov/fnic/foodcomp

[7] Vegetables Without Vitamins. Life Extension magazine, March 2001. http://www.lef.org/magazine/mag2001/mar2001_report_vegetables.html

[8] Changes in USDA Food Composition Data for 43 Garden Crops, 1950 to 1999. Donald R. Davis, PhD, FACN, Melvin D. Epp, PhD and Hugh D. Riordan, MD. Journal of the American College of Nutrition, Vol. 23, No. 6, 669-682 (2004). http://www.jacn.org/cgi/content/abstract/23/6/669

[9] Nutrient Changes in Vegetables and Fruits, 1951 to 1999. Compiled by Jeffrey Christian. http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/20020705/favaro_nutrients_chart_020705

[10] Apparent Nutrient Changes in Government Data for a Selection of Fruits & Vegetables: 1951 vs 1999. L. A. Piché PhD RD, Associate Professor, Nutrition Program, Brescia University College. http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/20020705/favaro_nutrients_analysis_020705?s_name=&no_ads=

passage of time unless the aforesaid decline in the nutrient content of foods can be brought to an end.

Finally, available information on intakes of vitamins and minerals does not take account of biochemical individuality. Every individual is genetically unique, and this also applies to his or her need for nutrients. As such, setting maximum amounts for vitamins and minerals prevents consumers from addressing their own individual needs.

Q5 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?

NHF: Existing data are notoriously unreliable, as described above, and diets across the 25 European Union Member States vary widely. As such, in no way can it be considered to be even remotely valid, scientifically speaking, to use data based upon the assumed intake in some Member States to set maximum levels at a European level.

Q6 Should the intake from different population groups be taken into account in the setting of maximum levels of vitamins and minerals?

NHF: Yes, however the very fact that the Commission is even asking this question demonstrates that a “one-size-fits-all” approach is seriously flawed.

Q7 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?

NHF: PRIs/RDAs should not be taken into account, as they were never intended for such purposes. Current PRIs/RDAs were compiled - badly in our opinion - to address needs, not safety.

Q8 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?

NHF: Setting minimum amounts of vitamins and/or minerals for fortified foods serves no useful purpose. However, we would agree that minimum amounts could be set in terms of the significant amount required to be present for a claim and/or declaration of the nutrient in nutrition labelling

Q9 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?

NHF: Restrictions upon the minimum level of each nutrient contained in a vitamin and mineral supplement are impractical in the case of some minerals because of the limitations of tablet/capsule size. If the Commission were to insist upon a uniform minimum percentage level for each nutrient contained in a vitamin and mineral supplement, some manufacturers might choose to not include some important minerals in their multivitamin/mineral products on the grounds that tablets/capsules containing them would be difficult to swallow (and hence difficult to sell). Such an eventuality would not be in the best interests of public health or consumer safety.

In fact, by mandating any minimum levels of vitamins and minerals, the Commission would be ***jeopardizing*** the health of consumers because: (a) manufacturers will in many instances have to replace the small additional vitamins and minerals that would have been added to a capsule or tablet with useless inert fillers and excipients; and (b) minimum levels will prohibit those special formulations that make synergistic use of vitamins and minerals in smaller-than-minimum-level amounts.

The smarter and more pragmatic approach would be to simply prohibit any claims for those vitamins and minerals present in amounts below the threshold minimum level.

ANNEX

COMMENTS AND RECOMMENDATIONS ON THE SETTING OF MAXIMUM AND MINIMUM AMOUNTS FOR VITAMINS AND MINERALS IN FOODSTUFFS VIA PROCESSES INVOLVING SCIENTIFIC RISK ASSESSMENT

The shortcomings of most current proposed models

The National Health Federation considers that the majority of current proposed models for nutrient risk assessment, centering as they do on the No Observable Adverse Effect Level (NOAEL), are outdated, Moreover, the basis upon which the NOAELs would be determined is fraught with uncertainty; largely subjective; and would result in reducing considerably the likely safe dosage of nutrients for the bulk of the population. We therefore believe it to be of paramount importance that any models to be adopted take full account of the latest developments in the rapidly expanding field of risk assessment, which now regard basic high-dose, threshold/ NOAEL/Uncertainty Factor models as out-of-date and no longer state-of-the-art.

Along with our numerous collaborating organizations, including the Alliance for Natural Health, we uphold that risk-assessment and -management principles need to be developed for nutrients from scratch. To adopt principles that were essentially developed with respect to food additives, other environmental toxins, or food-borne disease organisms, and then apply these to nutrients, will cause such fundamental problems that nutrient risk-assessment methods based on these principles will be scientifically flawed. This will result in inappropriate risk management that could severely restrict research and the development of appropriate preventative health strategies based on nutrition. Furthermore, any unnecessary restriction on international trade that results from inappropriate risk management, based in turn on flawed risk assessment, may lead to an expensive and time-consuming WTO trade dispute and subsequent challenge of the procedure used in the development of any risk assessment guidelines subsequently developed through, or in collaboration with, the Codex Alimentarius Commission.

We therefore consider that it is vital to field and receive input on risk-assessment methods from independent specialists in the field of risk assessment, prior to the agreement of protocols for risk assessment, management, or communication. In particular, views should be sourced or commissioned from the HAN Foundation[11] and the US-based Toxicology Excellence for Risk Assessment (TERA)[12] as well as any other competent, scientific organizations.

[11] HAN Foundation website (English language): www.stichting-han.nl/english

[12] TERA website: www.tera.org

The four key issues that must be addressed

1: The need to consider individual Nutrient Forms, as opposed to Nutrient Groups

Assessments should be carried out on nutrient forms, not nutrient groups; otherwise, properties specific to a toxic member of one group, say iron sulphate, are applied to all other members of the same group, for example iron bisglycinate.

Stated another way, if risk assessment is undertaken on members of a nutrient group (e.g., different forms of vitamin D, selenium, zinc, or iron), then there is a tendency for the toxicity profile of the ***least safe*** member of the group to be applied to other members of the same group.

Given that the toxicity of a nutrient compound is a function of both the nutrient itself and salts, ligands or other substances with which the nutrient is bound, such a system is scientifically irrational and, if implemented in policy, would certainly prevent consumer access to safe and beneficial levels of a wide range of nutrients.

This problem is depicted conceptually in Figure 1 below.

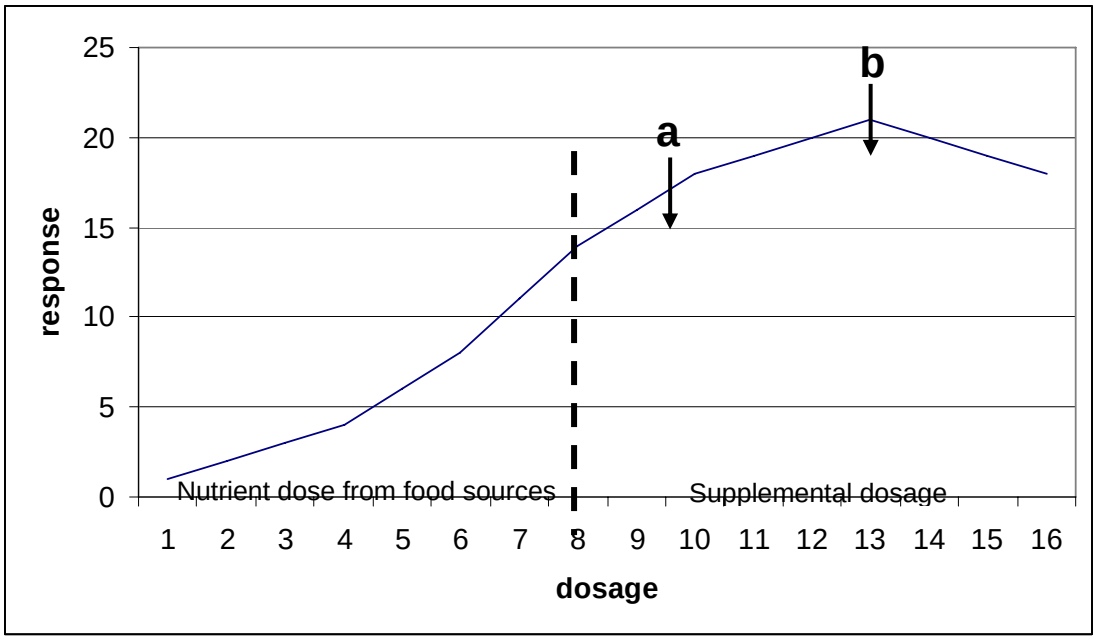


Figure 1. *Conceptual model depicting discrepancy between Upper Level and optimal dosage for members of the same nutrient group (where* ***a*** *= Upper Level and* ***b*** *= optimal dosage for nutrient within the same 'group')*

2: The need to consider Benefits in assessing Safe Upper Levels

Risk assessments should take into account benefits so as to avoid situations where inappropriate science establishes upper levels that are lower than those levels well known to offer considerable health benefits.

The "nutrient group approach" presently used by a range of health authorities around the world (e.g., the U.S. Institute of Medicine, the U.K. Expert Group on Vitamins and Minerals, and the E.U. Scientific Committee on Food) ignores the health benefits of particular nutrients. Although such an approach appears rational for any risk assessment of environmental chemicals, contaminants, and other such substances that confer no benefit to human health, a risk/benefit assessment approach would be much more compatible with the assessment of nutrients and establishment of their safe upper levels (*see* Figure 1 above).

3: The need to start with a Prioritization Model

A prioritization model should be developed so that high-quality scientific assessment can be focused on those nutrient forms in which either physicochemical properties or other evidence suggests greater risk to public health.

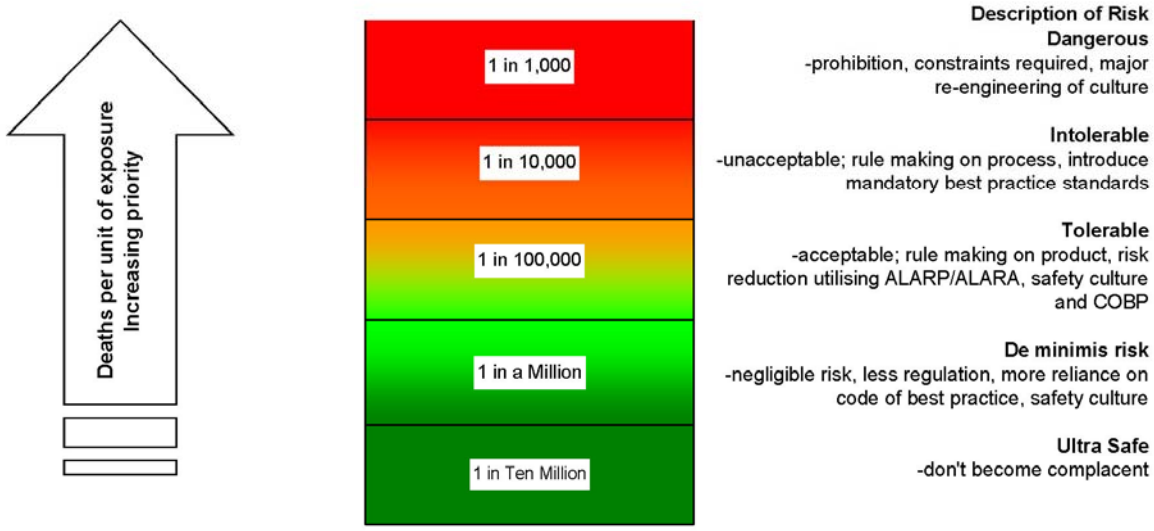
There has been a tendency to consider risk assessment on nutrient groups rather than on individual forms owing to the large number of risk assessments that would be required if nutrient forms were analyzed separately. In the case of the most commonly regarded essential vitamins and minerals, a "nutrient group approach" necessitates just 28 assessments (13 vitamin, 15 minerals), whereas a "nutrient forms approach" would require over 305 assessments (35 vitamin forms and over 270 mineral forms).

However, the number of risk assessments can be made very manageable by implementing a prioritization model, as utilized widely in other areas where priority was given to those nutrient forms known either as a result of their physico-chemical properties and/or their historical safety profile to present the greatest risks to health when used at "high" dosages.

A prioritization model will allow EFSA and the Commission to economize their expenditures while at the same time maximizing their effectiveness in performing risk-assessment tasks. Importantly, prioritizing so as to focus on those nutrients thought to be most likely to cause harm at high dosage levels will in the end enable EFSA and the Commission to more easily establish nutrient levels that will withstand the expected close scrutiny by the scientific community, affected countries and organizations, and that will ultimately benefit the consuming public.

This problem is depicted conceptually in Figure 2 below.

A Model for Prioritising Risk Management Policy and Resources



Sources: Health Canada, Renshaw, Amalberti, Leape, NZFSA [⁂]

[⁂] http://www.hc-sc.gc.ca/pmra-arla/english/pdf/spn/spn2000-01-e.pdf; Renshaw, F. M. (1990). "A Major Accident Prevention Program." Plant/Operations Progress 9, no. 3 (July), 194-197; Amalberti, R. (2001) Revisiting safety and human factors paradigms to meet the safety challenges of ultra complex and safe systems, In B. Willpert, & B. Falhbruch, Leape cited in Norton et al....Challenges and pitfalls of safety interventions, Elseiver; Leape, L., (2002) Safe Health Care: Are we up to it? http://www.vipcs.org/conf2002/leape.pdf; NZFSA (2000) A Risk Management Framework for Food Safety, http://www.nzfsa.govt.nz/policy-law/harmonisation/rmgmtpr.pdf©
R Law 2004

Figure 2. *Figure 2 shows the range of risks from ultra safe to de minimis to tolerable to intolerable to dangerous, with the risk increasing from bottom to top.*

4: The need to establish a proper Evidence-Base for Assessments

Assessment should take into account all of the available scientific evidence and should not simply restrict itself to peer-reviewed studies only, the latter of which are often not applicable to particular nutrient forms and cannot readily be used comparatively.

Although risk-assessment methods used to-date rightly support the notion of the quality of evidence, the sole source of evidence that is considered are peer-reviewed scientific studies of particular nutrient forms, which are often non-comparable owing to differing experimental designs, subject condition, nutrient forms delivered, and numerous other factors.

For example, it is not rational to base the upper safe level for use of naturally sourced mixed tocopherols (vitamin E) on studies of synthetic dl-alpha-tocopherol, nor is it rational to base upper levels of beta-carotene derived from natural sources on the CARET and ATBC trials conduced on smokers and asbestos workers exposed to high levels of synthetic beta-carotene.

Complete sources of data that should be considered to provide a full evidence-base include:

- Molecular studies: published, peer reviewed research
- Cellular studies: published, peer reviewed research
- Animal studies: published, peer reviewed research
- Controlled clinical studies: published, peer reviewed research
- Uncontrolled clinical studies: published, peer reviewed research
- Epidemiological studies: published, peer reviewed research
- Meta-analyses: published, peer reviewed research
- Government, university or other reports: published / unpublished
- Case reports: published
- Case reports: unpublished
- Commercial data: conference proceedings
- Commercial data: unpublished

By broadening our sources, we will better serve the consuming public and ensure their good and hopefully optimal health.