



A Not - For - Profit Health Freedom Organization

**Comments of the National Health Federation on the Report of
a Joint FAO/WHO Technical Workshop on Nutrient Risk
Assessment held at WHO Headquarters, Geneva, Switzerland
2-6 May 2005.**

The shortcomings of the workshop's proposed model

In short, we consider that the workshop's proposed model, centering as it does on the No Observable Adverse Effect Level (NOAEL), is outdated. Moreover, the basis upon which the NOAEL would be determined is fraught with uncertainty, and is thus largely subjective. As such, the workshop's proposed model would have the unfortunate effect of reducing considerably the likely safe dosage to the bulk of the population.

The National Health federation therefore believes it to be paramount that any risk-assessment system to be adopted takes full account of the latest developments in the rapidly expanding field of risk assessment, which now regards basic high-dose, threshold/NOAEL/Uncertainty Factor models as out-of-date and no longer state-of-the-art.

The National Health Federation's recommendations

The National Health Federation, and numerous collaborating organizations including the Alliance for Natural Health, 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 of paramount importance 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 Foundation¹ and the US-based Toxicology Excellence for Risk Assessment (TERA)² as well as any other competent, scientific organizations.

As such, our recommendations to the workshop can be summarised via the following four key issues:

¹ HAN Foundation website (English language): www.stichting-han.nl/english

² TERA website: www.tera.org

Issue No. 1: The need to consider individual Nutrient Forms, not 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.

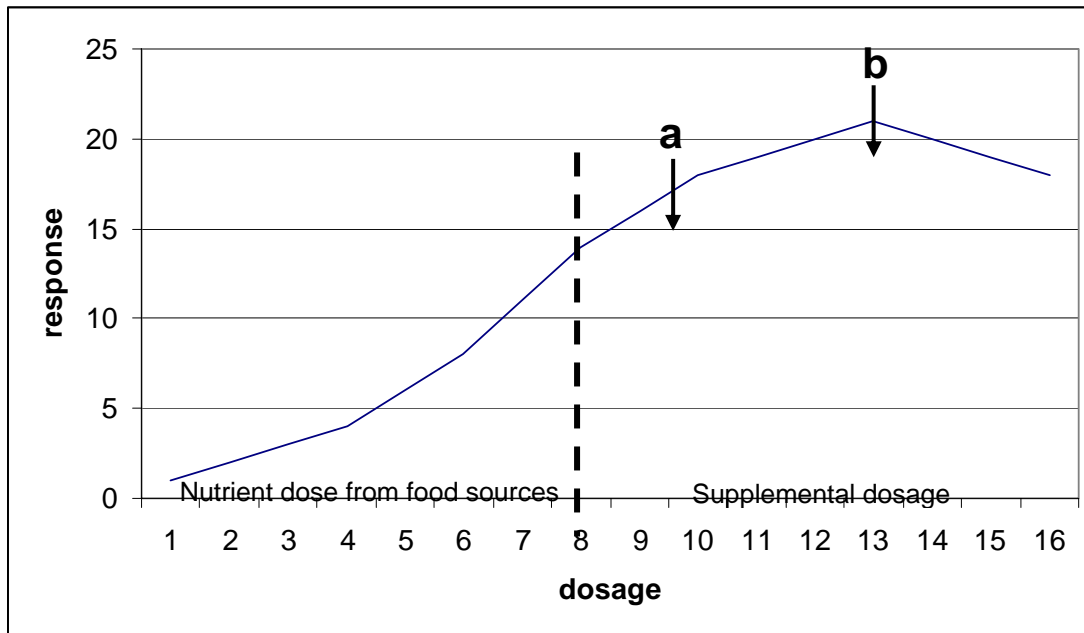


Figure 1. Conceptual model depicting discrepancy between Upper Level and optimal dosage for members of the same nutrient group (where **a** = Upper Level and **b** = optimal dosage for nutrient within the same ‘group’)

Issue No. 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 Institute of Medicine, Expert Group on Vitamins and Minerals, and the 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).

Issue No. 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.

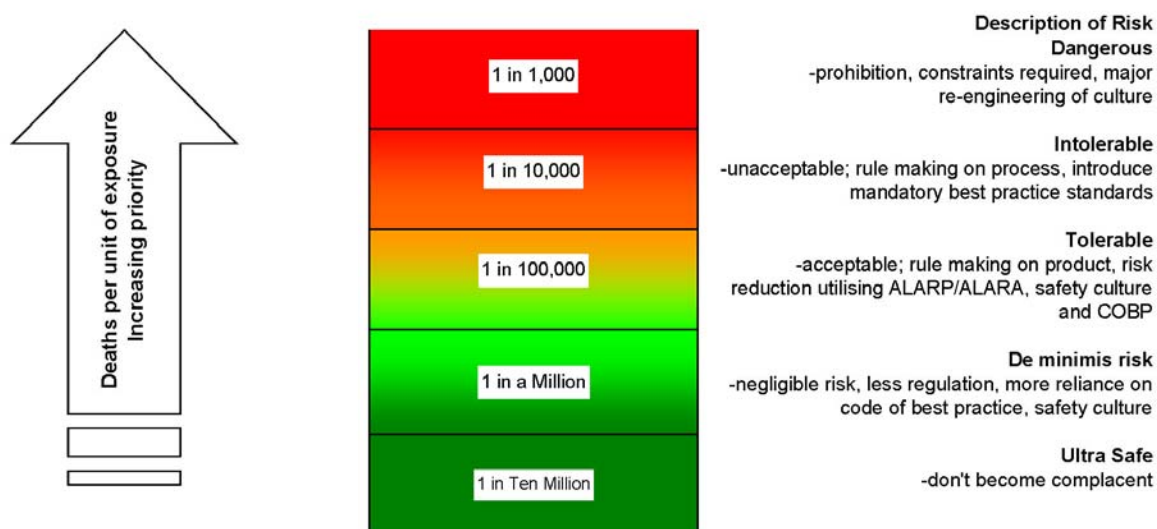
There has been a tendency to consider risk assessment on nutrient groups rather than on individual forms owing to the large number of risk assessments that would be required if nutrient forms were analyzed separately. In the case of the most commonly regarded essential vitamins and minerals, a “nutrient 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 Codex to economize its expenditures while at the same time maximizing its 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 the Committee 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, Elsevier; 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.

Issue No. 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 conducted 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.