



A Not - For - Profit Health Freedom Organization

***COMMENTS RE.
2006 DISCUSSION PAPER AND NEW WORK
PROPOSAL ON THE APPLICATION OF RISK
ANALYSIS TO THE WORK OF THE CODEX
COMMITTEE ON NUTRITION AND FOODS FOR
SPECIAL DIETARY USES***

JUNE 2006

**P.O. Box 688, Monrovia, CA 91017 ~ 1 (626) 357-2181 ~ Fax 1 (626) 303-0642
Website: www.thenhf.com E-mail: contact-us@thenhf.com**

COMMENTS RELATING TO 2006 DISCUSSION PAPER

A. General Comments

The NHF and its scientific advisors have reviewed the 2006 Discussion Paper on the application of risk analysis to the work of the CCFNSDU and make the following general comments:

- 1. Requirement to better adapt ‘nutritional risk assessment’ methodologies to nutrients.** So-called ‘nutritional risk analysis’ methodologies need to be better adapted from those used for agents which have non-nutritive value in food (e.g., chemical contaminants or toxicants, microbiological agents and non-nutritive food additives), to those used for agents with nutritive value (e.g. nutrients in foods or food supplements). This requires consideration of risk profiles associated with consumption both of excessive and inadequate amounts of specific nutrients across wide dose ranges. The requirement to address risk assessment from both of these perspectives has been addressed in the 2006 Discussion Paper (e.g., Paragraph 25), but this risk-orientated framework nonetheless ignores micro-nutrient intakes that contribute to optimum levels of health¹ in individuals or specific population groups. Accordingly, benefits should be considered alongside risks, and the development of meaningful methodologies for risk-benefit assessment of foods and food ingredients should be prioritised. The European Food Safety Authority has organised a Colloquium on the subject of risk-benefit assessment of food, to be held in Parma on 13-14 July² and outputs from this meeting and other data should inform the development of benefit assessments methodologies that can be compared against risk-assessment data.
- 2. Appropriate identity of agents.** The CCFNSDU needs to clarify the distinction of “biological, chemical, and physical agents” for the first (hazard identification) and second (hazard characterization) steps of risk analysis. At present an agent might be considered to be either a nutrient group (e.g., iron) or a specific nutrient form (e.g., iron sulphate, iron bisglycinate).
- 3. Misapplication of the precautionary principle.** The 2006 Discussion Paper, in addition to the 2006 report by the FAO/WHO nutrient risk assessment project Expert Group³, fails to make reference to the fundamental need to identify nutrient forms as opposed to nutrient groups in the risk-assessment process. With distinction between nutrient forms, risk assessment would, for example, not be conducted on vitamin D as a single “agent” or “substance,”

¹ Ames BN. A role for supplements in optimizing health: the metabolic tune-up. *Archives of Biochemistry & Biophysics*, 2004; 423(1): 227-34.

² Announcement of EFSA Colloquium 6: Risk-benefit analysis of foods: methods and approaches; 13-14 July 2006, Tabiano (Parma), Italy, accessed 31 May 2006 at http://www.efsa.eu.int/science/colloquium_series/risk_benefit_analys_foods/1486_en.html.

³ FAO/WHO *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances*, accessed 31 May 2006 at http://www.who.int/ipcs/highlights/full_report.pdf.

but rather on its distinct forms, such as vitamin D2 and D3, which have significantly different toxicological and pharmacokinetic profiles. The same situation is applicable across a broad range of other nutrients. Policy based on risk assessment of nutrient groups rather than nutrient forms is, *de facto*, an acceptance of the precautionary principle (which, as of 2002, applies to EU food law⁴), despite the precautionary principle having been consistently rejected as a Working Principle for use in risk analysis by a large number of country delegations and NGOs in Codex. This type of *de facto* adoption of the precautionary principle would potentially expose large sectors of the population to ‘nutritional risk’ caused by inadequate consumption of specific nutrient forms. This clear misapplication of the precautionary principle may therefore conflict with other widely adopted principles of food law such as the principle of consumer protection.^{5,6}

4. **Scientific evidence used in risk analysis.** The 2006 Discussion Paper does not include reference to the importance of proper selection of data and evidence to be used in the risk identification and characterisation process. Lack of clarity over study selection criteria has led to different national and regional bodies using different studies, resulting in different interpretations of risk, a point well made in the FAO/WHO nutrient risk assessment report (pp. 35-39). Many previous risk assessments on nutrients have been characterised by the frequency of absent data. A systematic approach is clearly required, as stressed in the FAO/WHO report, and this issue should be included in Discussion Paper under ‘Factors to Consider in Nutritional Risk Assessment’ (p. 15). Moreover, the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* indicate that “Risk assessment should be based on all available scientific data.” This implies that the data should not exclusively be sourced from peer review journals, which typically exclude important clinical and other evidence.
5. **The need for a prioritization model.** The 2006 Discussion Paper should be modified to include addition of some type of prioritization system to ensure risk assessment is prioritized for nutrient forms with the greatest potential to cause harm at either inadequate or excessive levels of intake. Conversely, limited resources should not be wasted on risk assessment of nutrients known to be safe at even very high levels of intake. Decision criteria for categorisation of low, medium and high priorities for risk assessment were considered in the consultation response by the Alliance for Natural Health to

⁴ Council Regulation (EEC) 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1–24.

⁵ JC Hanekamp, G Frapporti, K Olieman. Chloramphenicol, food safety and precautionary thinking in Europe. *Environmental Liability*, 2003; 6: 209-21.

⁶ JC Hanekamp. The precautionary principle: a critique in the context of the EU Food Supplements Directive. *Environmental Liability*, 2006; 2: 43-51.

the FAO/WHO nutrient risk assessment project.⁷ Prioritization models are widely used in other areas of complex risk assessment.⁸

B. Specific comments by section of 2006 Discussion Paper

SECTION 1

The NHF supports the terminology changes made in the 2006 Discussion Paper, but, in addition, supports the inclusion of the five key points made above.

Suggested revisions/additions are indicated in **bold** below for specific paragraphs:

NHF proposed revision 1

39. *Hazard Identification:* The identification of **distinct** biological, chemical, and physical agents in, or condition of, food, capable of causing adverse health effects and which may be present in a particular food or group of foods.

NHF proposed revision 2

40. *Hazard Characterization:* The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with **distinct** biological, chemical and physical agents in, or a condition of, food, which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

NHF proposed revision 3

41. *Dose-Response Assessment:* The determination of the relationship between the magnitude of exposure to, or intake of (dose) a **distinct** chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

NHF proposed revision 4

The NHF proposes insertion of a new paragraph 59, under a proposed new subheading **Risk-benefit assessment**, viz.

59. When a food or food substance is associated with both potential health risks and benefits, and particularly when the levels of intake associated with risk and benefit are close, there is a need to define an intake range within which the balance of risk and benefit is acceptable for risk-management purposes. However there is currently no agreement on the

⁷ Alliance for Natural Health submission to FAO/WHO nutrient risk assessment project, 2003, accessed 31 May 2006 at <http://www.who.int/ipcs/highlights/alliancefornathealth.pdf>.

⁸ Salvito, Daniel T., Senna, Ronald J., Federle, Thomas W. A framework for prioritizing fragrance materials for aquatic risk assessment. *Environmental Toxicology and Chemistry*, 2002; 21: 1301-1308.

general principles or approaches for conducting a quantitative risk-benefit analysis for food and food ingredients. One of the main challenges of such an exercise is to define a common scale of measurement for comparing the risks and the benefits. Such principles are under development and the CCNFSDU should adopt risk-benefit assessment as soon as such principles, where applicable to food and food substances, are finalised.

Note: the text for the above paragraph, with the exception of the last sentence, was derived verbatim from the Background section in the announcement for the proposed Colloquium on risk-benefit assessment, convened by the European Food Safety Authority for July 2006.²

NHF proposed revision 5

The NHF proposes insertion of a second new paragraph before the existing paragraph 59, under a proposed new subheading **Scientific evidence for risk assessment**, viz.

59. It is imperative that a systematic approach to inclusion/exclusion of data for risk assessment is adopted to ensure both the highest possible degree of accuracy and to minimize differences in interpretation between national/regional bodies. Among other things, this systematic approach should utilize all available and relevant peer-reviewed scientific data as well as government and medical records and other meaningful data where these are appropriate.

NHF proposed revision 6

The NHF proposes insertion of a new paragraph 72, as the final paragraph in the existing section entitled “Additional Factors to Consider in International Nutritional Risk Assessment,” viz:

72. Owing to the scale of nutrient risk assessment work, it is appropriate to develop a prioritization model to ensure both that initial risk-assessment efforts are expended on those distinct agents with the greatest potential to cause harm and effort is not wasted on agents (nutrients) that are known to be safe at even very high levels of intake.

SECTION 3

The NHF is concerned about implementation of any of the three proposed approaches given that none at present adequately take into account the fundamental points raised in this document. Risk assessment outcomes will differ substantially in our view for individual nutrient forms depending on whether or not these points are considered.

In order to demonstrate the sensitivity of risk assessment to these points or factors, the NHF urges that the EWG seeks to undertake or commission risk-benefit assessment for a number of key nutrients and forms using conventional as against a modified

method which factors in some or all of the points. For example, the following worked examples are likely to be revealing:

Nutrient group	FAO/WHO risk assessment methodology	Modified methodologies
Carotenoids	Beta-carotene	Synthetic beta-carotene Naturally-occurring mixed carotenoids
Vitamin D	Vitamin D	Vitamin D2 Vitamin D3
Calcium	Calcium	Calcium oxide Calcium citrate
Chromium	Chromium	Chromium (III) chloride Chromium polynicotinate
Iron	Iron	Ferrous sulphate Iron bisglycinate
Selenium	Selenium	Sodium selenite Selenomethionine

COMMENTS RELATING TO NEW WORK PROPOSAL

Proposed revisions by the NHF are indicated in **bold**.

NHF proposed revision 1

1 Purpose and Scope of the Proposed Work

The purpose of the work is to elaborate nutritional risk analysis principles in the first instance, potentially followed by more detailed and operationally focused guidelines as appropriate, to guide the work of the CCNFSDU and other subsidiary bodies in the development and review of Codex texts on nutritional matters. The principles **should be consistent at least with the Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, although additional principles may be added to allow for developments in the emerging field of nutritional risk assessment.**

NHF proposed revision 2

4 Assessment against *Criteria for the establishment of work priorities*

Application of a consistent approach to risk analysis throughout the Codex Alimentarius, including to its work on nutrition and foods for special dietary use, will contribute to the development of appropriately based standards and related texts that serve to protect **or enhance** the health of consumers and facilitate international trade.

NHF proposed revision 3

- 6 Information on the relation between the proposal and other existing Codex documents

The principles and guidelines **should be consistent at least with** the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, **although additional principles may be added to allow for developments in the emerging field of nutritional risk assessment.**

NHF proposed revision 4

- 7 Identification of any requirement for and availability of expert scientific advice

Noting the role of FAO/WHO expert and technical consultations as a primary source of risk-assessment advice for Codex Alimentarius, including CCNFSDU, it will be important for the FAO and WHO to contribute their input to the nutritional risk assessment and communication sections. The recent publication of the Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment is expected to considerably facilitate this process.

Additionally, experts responsible for risk assessment should be selected in as transparent manner as possible, from different regions of the world and from a range of sectors including government, academia, practitioners, and industry.