

Opportunity to Respond to Questions

This form provides the opportunity to respond to the questions posed in the Background Paper: Joint FAO/WHO Development of a Scientific Collaboration to Create a Framework for Risk Assessment of Nutrients and Related Substances.

Responses may be typed in to the form directly or appended as an 'attachment' to each question (use 'Upload file'). Fields with asterisks are required. Responses and your name/organization will be available for public viewing.

Name/Organization

Title

Mr

First name *

James

Last name *

Gormley

Name of Organization (Use 'None' if none) *

Citizens for Health

Affiliation Category (click on bar to select a sector) *

Non-profit Organization

Today's Date *

10/12/2004

Question 1

The Background Paper discusses the possibility that hazard identification and hazard characterization have global relevance, while exposure assessment and risk characterization are relevant to populations. If such a conceptual framework for the four steps is appropriate, then scientific principles could be organized and considered along these same lines.

Question 1a: Is the distinction between global relevance and population relevance for the four risk assessment steps a meaningful consideration for the purposes of developing an international nutrient risk assessment approach? (Please indicate why or why not)

Yes, but the very model, assumptions upon which it rests and nomenclature ("hazards," "risks") are not appropriate for nutrients, which are inherently benign.

Question 1b: If so, please provide specific suggestions about how best to further articulate and make good use of the differences in identifying the scientific principles for nutrient risk assessment.

First, we should reconsider the nomenclature that is under discussion and the assumptions that may support their use. The very concepts or terms "hazard" and "risk" are not really appropriate for the framework that is under discussion--these concepts/terms apply to industrial chemicals, environmental or physical hazards and toxic agents. We should seriously consider beginning with the following observations and build off them:

- 1) Nutrients (e.g., vitamins and minerals) have been safely consumed by humans since the dawn of civilization and in foodstuffs since the development of agriculture 10,000 years ago. In concentrated form (as dietary supplements), these nutrients have been safely consumed since the late 19th century and in high-potency formulations in modern-day health-food stores that emerged in the early 20th century.
- 2) Modern-day food processing since the 1940s has increasingly stripped food of significant levels of nutrients worldwide. That, combined with nutritionally compromised diets, has created a relative nutritional vacuum globally that should, we can argue, be partly offset via optimal doses of dietary supplements.
- 3) The framework of Upper Safe Limits should be changed to "Recommended Upper Levels" since we are, in the vast majority of cases (with the exception of vitamins A, D, and K, and the minerals selenium and zinc), considering guidelines for nutrients that are inherently and profoundly benign--not inherently dangerous, as are toxic industrial chemicals, for example, which require "hazard" and "risk" models.

Question 2

Hazard identification and characterization involve a number of decision points that require scientific judgment in order to derive a UL. Please provide input as to how

guidelines for these judgments can be developed for the following decision points:

Question 2a: Criteria for the evaluation of the quality and utility of relevant scientific evidence.

In the development of a "Recommended Upper Level" (RUL), the guidelines developed should not be based on what a population generally consumes (since that may be inadequate for proper or optimal health) but upon any relevant safety/toxicological data--if the safety ceiling is so high that it cannot be definitively established, then no upper level should be established, since setting one would then be arbitrary and capricious.

Question 2b: Extrapolation to various age/gender groups.

Conservative recommended upper level (RUL) guidelines should be developed for vulnerable groups, such as pregnant women, children and the elderly, but again as guidelines.

Question 2c: Determination and use of uncertainty factors.

It is crucial that good science reigns when developing a protocol that will be suitable for dietary supplements. I am concerned that the use of uncertainty factors would allow for the application of the precautionary principle when assessing potential risks. The precautionary principle of course holds that when there is reasonable suspicion of harm, lack of scientific certainty or consensus must not be used to postpone preventive action. It is a non-scientific method of ascertaining risk that can be capricious and arbitrary. When applied to supplements, it would empower regulators to limit supplement potencies by citing a lack of scientific certainty of safety even though there is vast epidemiological evidence that supplements sold at present levels are profoundly safe.

Question 2d: Other

n/a

Question 3

The conduct of exposure assessment and risk characterization also requires sound scientific principles that can be applied to the various decision points, including but not limited to compilation and collection of intake data and decision-making for summarizing

the potential for harm.

Question 3a: Please provide input on general scientific principles relevant to the process of determining exposure for a nutrient or related substance.

Assuming that the UN/WHO--and the FAO/CODEX--are at least as concerned with promoting health as preventing disease, then guidelines should be established, not mandated nutrient caps, and these should sufficiently reflect the broad safety of these compounds based on optimal consumption of these nutrients (in food plus high-potency supplements, as appropriate). Again, if the safety ceiling is so high that it cannot be set, then no upper levels should be established or stipulated in those cases. Most certainly the EVM and EFSD documents should not be used since they are overly precautionary and restrictive, respectively.

Question 3b: Please provide input on general scientific principles for the characterization of the severity and the degree to which intakes exceed the UL or other aspects of risk characterization.

Again, I am concerned about nomenclature that is being used and its attendant associations. "Severity" connotes "level of harm" when, in fact, what we are discussing is when dietary intake exceeds the recommended upper level (RUL). Provided there is a wide safety margin--which most assuredly there will be in many if not most cases--consumption over and above the RULs is not really an issue.

And, again, assuming that the UN/WHO--and the FAO/CODEX--are at least as concerned with promoting health as preventing disease, then guidelines should be established, not mandated nutrient caps, and these should sufficiently reflect the broad safety of these compounds based on optimal consumption of these nutrients (in food plus high-potency supplements, as appropriate). Again, if the safety ceiling is so high that it cannot be set, then no upper levels should be established or stipulated in those cases. Most certainly the EVM and EFSD documents should not be used since they are overly precautionary and restrictive, respectively.

Question 4

The Background Paper reflects a 'thought process' and is intended to inform a longer process for the development of a technical expert workshop. Clearly the process will benefit from additional input.

Question 4a: Please provide comments on other general factors or considerations that could be taken into account during the process of identifying principles for nutrient risk assessment.

I would repeat what I submitted above: We should reconsider the nomenclature that is under discussion and the assumptions that may support their use. The very concepts or terms "hazard" and "risk" are not really appropriate for the framework that is under discussion--these concepts/terms apply to industrial chemicals, environmental or physical hazards and toxic agents. We should seriously consider beginning with the following observations and build off them:
1) Nutrients (e.g., vitamins and minerals) have been safely consumed by humans since the dawn of civilization and in foodstuffs since the development of agriculture 10,000 years ago. In

concentrated form (as dietary supplements), these nutrients have been safely consumed since the late 19th century and in high-potency formulations in modern-day health-food stores that emerged in the early 20th century.

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Question 4b: Please provide other comments on the content of the Background Paper.