

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

Dr

First name *

Mariette

Last name *

Gerber

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

Cancer Research Institute

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

Academic

Today's Date *

02/12/2004

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 it is meaningful in that the common approach, which applies to the first 2 steps, will be adapted to the 2 following steps

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.

Once hazard identification and characterization completed based on worldwide scientific data, specific regional and local data on sources and exposure will be collected to achieve risk assessment.

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.

Quality: criteria of scientific validity have been developed . they are described for epidemiological studies in the attachment.

(attachment)

The criteria of selection of analysis are as follows :

- Design of the study: case-control and prospective studies were reviewed.
- Assessment of the exposure: dietary intake, plasma or tissue nutrient concentration. Quality of nutritional data (estimated on number of items of the questionnaire, type of quantitative assessment, and validation of the questionnaire). Quality of biological

measurements was estimated by conditions of storage (-70°C) and of the method used (results based on total anti-oxidant capacity of the plasma were excluded).

- Size of the sample: At least 100 cases for prospective studies and 400 cases in case-control studies for high incidence cancers (lung, breast, colorectal cancers); 50 and 100 cases respectively for less frequent cancers. The studies based on plasma or tissue nutrient concentration may be limited to 50 cases

Rejection of paper will be justified.

All the analysis of data must be based on the actual published report and will be available for the reader.

Evaluation of a set of epidemiological data relevant to a risk will be based on the causal inference criteria as described first by Hill (1965) as follows:

- Consistency of the results
- Strength of the association
- Dose- response
- Biological plausibility
- Analogy

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

consider lifestyle, metabolic and hormonal characteristics of age and gender group

Question 2c: Determination and use of uncertainty factors.

Question 2d: Other

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.

nutritional epidemiology has developed sound protocols of food intake studies, from complete and reliable food composition tables to types of questionnaire and their validation

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.

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.

the risk assessment should be balanced by the presence or absence of benefit

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