

# **A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances**

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**Report of a Joint FAO/WHO Technical Workshop  
on  
Nutrient Risk Assessment**

**WHO Headquarters, Geneva, Switzerland  
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*----- Christine Taylor, WHO -----*  
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# Background: Nature of Report

- FAO/WHO Technical Workshop
- Focus → upper levels of intake of nutrient substances
- "Manual" for conducting nutrient risk assessment

# Background: Nature of Report

- Outlines scientific process
- Does not specify upper levels of intake
- International in scope

# Background: 'Drivers' for Report

- Codex Alimentarius
  - Request for scientific advice
  - Codex Committee on Nutrition & Foods for Special Dietary Use
    - Focus on risk assessment approach
    - Debate on establishing guidance for upper 'limits' on food/supplement products

# Background: 'Drivers' for Report

- WHO interest to harmonize risk assessment approaches
  - Absence of an international model
- Member country interest
  - Increasing availability of fortified foods and supplements

# Context for Report: Starting Point

- Non-nutrient risk assessment approach
- 3 comprehensive national/regional reports
  - **European Union**, EFSA (SCF)
  - **United Kingdom**, Expert Group on Vitamins and Minerals
  - **United States & Canada**, Institute of Medicine

# Context for Report: Special Challenges

- Requires 'marriage' of nutrition and toxicology
- Diverse expertise

# Process for Report Development: Initiation of Project

- FAO/WHO announcement
- Background paper and request for input
- Qualified experts encouraged to 'self-apply'

# Process for Report Development: Pre-Workshop

- Discussion papers
- Telephone conference calls
- Development of context paper

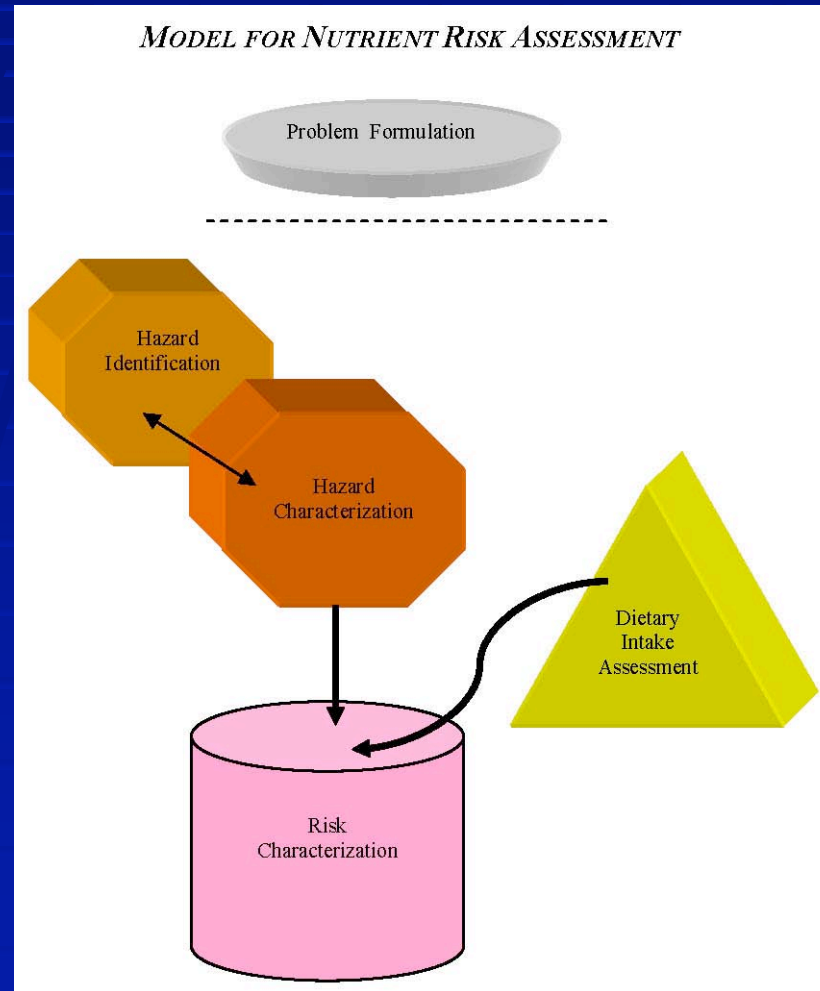
# Process for Report Development: Participants

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# Process for Report Development: Funding

- **Australia**, Food Standards Australia New Zealand and Australian Department of Agriculture, Fisheries and Forestry (Canberra)
- **Canada**, Health Canada (Ottawa)
- **European Commission** (Brussels)
- **Republic of Korea**, Korea Food and Drug Administration (Seoul)
- **United States of America**, National Institutes of Health: National Institute of Environmental Health Sciences (Research Triangle Park) and Office of Dietary Supplements (Bethesda)

# Components of the Approach



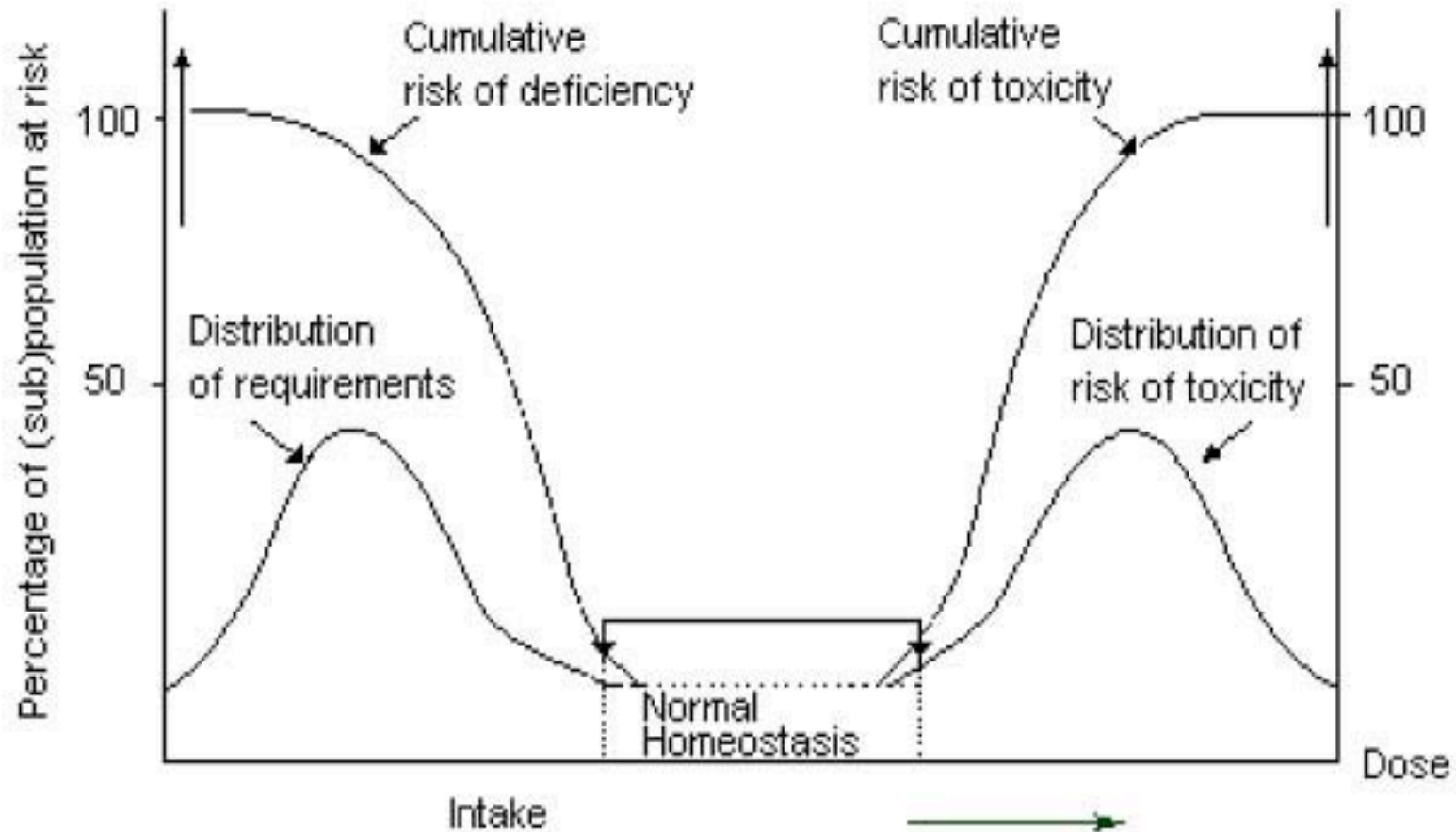
# Components of the Approach

- Hazard Identification and Characterization
  - Data review strategies
  - Derivation of the upper level
- Dietary Intake Assessment
  - Harmonizing methodologies
  - Combining data to estimate total intake
- Risk Characterization
  - Role of Assessor versus Manager
  - Clear communication / Iterative Process

# General Observations

- Continued emphasis on separation between assessment and management
- Many similarities to non-nutrient risk assessment, but .....
  - Lacks 'organized' generation of data
  - Special homeostatic mechanisms
  - Dual risk curves – deficiency & overage

# Nutrient Substances: Dual Risk



# Overarching Conclusion: Transparency & Documentation

- Review of differences among existing reports on nutrient risk assessment revealed .....
  - Lack of transparency in decision-making
    - Need to use scientific judgment does not preclude need to explain it
  - Lack of documentation regarding the process
- → Ensure transparency and documentation

*Highlights:*  
**Special Populations**

- Model is appropriate for use with special populations
  - Inadequately nourished
  - Diseased
- BUT data for special populations will reflect metabolic differences, therefore....  
...ULs will be different than those for normal, generally healthy populations

# Next Steps

- Research needs and data gaps
- Funding limited....
  - Case study(ies)
  - Dialogue and additional science conferences
    - Explore areas of model that need further specification
  - Application of model to specify ULs
- Dissemination of report
  - Europe
  - Asia
  - North America
  - WHO and FAO channels

# Real World Impact?

- "Long march"
- Harmonization possibilities
- Facilitate trade
- International UL possibilities
- Better dietary intake methodologies

# Thank you

Available hardcopy 28 April

Available on website

[www.who.int/ipcs/methods/en/](http://www.who.int/ipcs/methods/en/)