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 -----
IADSA April 2006
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

- Dr Peter AGGETT, University of Central Lancashire, Preston, United Kingdom
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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

MODEL FOR NUTRIENT RISK ASSESSMENT

- Problem Formulation
- Hazard Identification
- Dietary Intake Assessment
- Risk Characterization
- Hazard Characterization
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

Diagram showing the relationship between intake, dose, and the percentage of the population at risk for deficiency or toxicity. The graph illustrates the distribution of requirements and the risk of deficiency or toxicity as intake and dose increase.
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/