Risk Assessment in Chemical Food Safety

Dept. of Food Safety and Zoonoses (FOS)
http://www.who.int/foodsafety/en/
Risk Analysis Paradigm

Internationally

Scientific data analysis

Risk Assessment
WHO & FAO

Risk Management
Codex & Member States

Risk Communication

Dialog with all stakeholders

Regulation and control
Risk Assessment: A Scientific Process

Problem Formulation

- Hazard Identification
- Hazard Characterization

Risk Characterization

Exposure Assessment

Risk = Hazard x Exposure

World Health Organization
Example of chemical risk assessment
Main Question in Food Safety

What is a „safe” human exposure over lifetime?

e.g. a dose with ”no appreciable or a negligible risk”

BUT: for some scenarios/compounds also acute risks relevant
General considerations re. RA

- Identify problems - prioritization
- Define the scope
- Relevant expertise
  - chemists, toxicologists, epidemiologists, modellers/statisticians, veterinarians, etc.
- Interaction between risk assessor and risk manager
  - common understanding of problem
- Recognise limitations in data, resources - be transparent
- Take the whole database into account - integrate results
WHO Hazard Assessment

Key NOAEL

Uncertainty factors

Safety standard

(Health based guidance value)
e.g. ADI=NOAEL/Ufs

Exposure Assessment

Chemical analysis

Food consumption

Exposure

Safety assurance:

Exposure < ADI → ✔
Exposure ≥ ADI → ✗

Management Decision
Hazard Assessment

A process to determine possible adverse effects of a chemical on the organism\(^1\)

- hazard identification
- hazard characterization

\(^1\) adapted from: EHC 240: Principles and methods for the risk assessment of chemicals in food. Annex 1 Glossary of terms, FAO/WHO 2009
http://apps.who.int/iris/bitstream/10665/44065/13/WHO_EHC_240_13_eng_Annex1.pdf?ua=1
Hazard Assessment

Assessment Procedure

- Identification of critical endpoint/effect and critical study/data set
  - most sensitive species, most sensitive endpoint of relevance to humans, most relevant epidemiological study
- Dose-response analysis (Point of Departure)
  - No/Low Observed Adverse Effect Level (N/LOAEL), Benchmark Dose (BMD, BMDL)
- Identification of uncertainties, assignment of uncertainty/safety factors

Outcome

Health based guidance value (ADI; TDI; ARfD);
quantitative risk at specific exposure;
qualitative descriptor; other guidance to risk manager (e.g. MOE)
“… the qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food …”¹.

¹ The Codex Alimentarius Commission’s (CAC) Procedural Manual (FAO/WHO, 2008a)
Dietary Exposure Assessment

Combining food consumption data with occurrence of chemical in food

- Deterministic approach (point estimate)
- Probabilistic approach (distribution)

Outcome

- Estimated mean and high dietary exposures
- Identification of specific sub-groups
- Identification of key exposure sources

Types of Risk Assessment

- Rapid risk assessment – emergencies
- Qualitative RA – due to lack of data or lack of health concern
- Quantitative RA – derivation of guidance value, or full expression of probability of adverse health outcome at defined level of exposure
Hazard assessment

- Biochemical data
  - Absorption, distribution, excretion, metabolism, effects on enzymes

- Toxicological data
  - Acute, short-term, long-term toxicity & carcinogenicity (mainly rats and mice, sometimes dogs)
  - Genotoxicity (in vitro and in vivo)
  - Reproductive and developmental toxicity (mainly rats)
  - Special studies (e.g. immunotoxicity, cardiovascular effects, thyroid function)

- Observations in humans

*Independant of geographic origin*
What are 'data'? 

**Exposure assessment**

- Food consumption data  
  - Average, high consumption, different age groups

- Occurrence data  
  - Amount in food (raw, processed...)

*Country, region, dietary habit specific*
Where do data come from?

- Regulatory data submission by manufacturer
  For compounds intentionally added to foods

- Data from governments
  - Monitoring data; epidemiological data; research data

- Open scientific literature
  - Experimental research, human data
General procedure and interaction

ADI/TDI
Level of health concern
Sources of exposure

Toxicology & Epidemiology (WHO)
Chemistry, Analytics (FAO)

JECFA

Codex Alimentarius Commission
Prioritization

Standards Recommendations

FAO/WHO Secretariat to schedule meetings;
Call for data
Call for experts
Scientific advice work feeds into:

- Codex standard setting process
- National/regional risk assessments and food legislation

WHO programmes:
- INFOSAN – rapid risk assessment, information notes
- drinking water guidelines
- WHOPES (public health use of pesticides)
- Children's environmental health
- Global Alert and Response

International RA method development and harmonization
EHC 240: Principles and methods for the risk assessment of chemicals in food, WHO 2009

- Risk assessment guidance for all food chemicals
- Guidance on interpretation of studies, and general assessments
- Descriptive guidance, not prescriptive
- Electronic publication in individual chapters – for update

WHO databases

http://www.who.int/foodsafety/databases/en/

Databases

Scientific advice is based on recognized expertise, robust methodologies and international data. WHO collects data and information both from national competent institutions and from FAO/WHO scientific committees. According to a recent resolution of the World Health Assembly, WHO is facilitating the data access to experts and food safety professionals.

FOSCOLLAB

By integrating multiple sources of reliable data, FOSCOLLAB helps overcome the challenges of accessing these key sources in a timely manner. It allows for better risk assessment and decision-making by food safety professionals and authorities.

Access the chemical overview dashboard

The Chemical Overview Dashboard integrates summary elements from three separate sources: JECFA Evaluations Database, GEMS/Food Contaminants database and the WHO Collaborating Centres Database. Note: 1. Hazards evaluated by the JECFA from 1995 onwards are selectable. 2. A blank chart indicates no data available in the GEMS/Food contaminants database. For more details, please visit the source databases themselves by following the links at the bottom of the dashboard.

JMPR database

The database contains basic information (ADI, ARID, CAS number etc) for all pesticides evaluated by the Joint Meeting on Pesticide Residues (JMPR) as well as...
JECFA and JMPR databases


http://apps.who.int/pesticide-residues-jmpr-database

Inventory of evaluations performed by the Joint Meeting on Pesticide Residues (JMPR)

This inventory summarizes evaluations of pesticides that have been performed by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). It does not include the maximum residue levels (MRLs) that have been recommended by JMPR.

Maximum residue limits adopted by Codex Alimentarius Commission are available on: www.codexalimentarius.org/standards/pesticide-mrls/
JECFA and JMPR databases - FAO


AGP - List of Pesticides evaluated by JMPS and JMPR

List of Pesticides evaluated by JMPR and JMPS - A

Below is a list of pesticides that have been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the Joint Meeting on Pesticide Specifications (JMPS).

The pesticides are listed alphabetically: in the JMPR report and evaluation column, click on Report to download either the Toxicological or the Residue Evaluation in the JMPR Report in the related year, and click on Evaluation to download the Residue Evaluation in the related year.

In the specification column, click on the year indicated in each cell to download the latest specification evaluated by the JMPS.

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>JMPR Report and Evaluation</th>
<th>Specification</th>
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Thank you

Question ?