Overview on Risk Analysis in Food Safety

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Risk Analysis Framework

Risk Assessment
- Science based

Risk Management
- Policy based

Risk Communication
- Interactive exchange of information and opinions concerning risks
Introduction

- Risk analysis is a systematic, disciplined approach developed in the last 2 decades for making food safety decisions, which includes 3 major components: risk assessment, risk management and risk communication.

- Risk analysis is a powerful tool for carrying out science-based analysis and for reaching sound, consistent solutions to food safety problems.

- The use of risk analysis can promote ongoing improvements in public health and provide a basis for expanding international trade in foods.

Historical Background of Risk Analysis Framework

- First applied in environment hazard control in mid 1900s.
- Begin to be used in food safety control in the 1980s, i.e. Codex standards development.
- Codex adopted the working principles for risk analysis in 2003 and subsequently, specific principles and guidelines were developed by relevant Codex committees (Procedural Manual).
Hazard vs. Risk

A **hazard** is a biological, chemical or physical agent in, or condition of food with the potential to cause harm.

**Risk** is an estimate of the probability and severity of the adverse health effects in exposed populations, consequential to hazards in food.

Risk analysis is used to:

- develop an estimate of the risks to human health and safety,
- identify and implement appropriate measures to control the risks, and
- communicate with stakeholders about the risks and measured applied.
- support and improve the development of standards,
- address food safety issues that result from emerging hazards or breakdowns in food control systems.

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Importance of risk assessment

- As scientific basis for food standard development;
- For setting up priorities in food inspection and control;
- For evaluating the success of various food safety control measures; and
- Important sources of information for risk communication.
Basic components of risk assessment

- Hazard identification
- Hazard characterization
- Exposure assessment
- Risk characterization
Exposure assessment

- Outcomes from risk characterization of chemicals in food are universally applicable, e.g. ADIs, PTWIs, etc. However, it is necessary to conduct exposure assessment by each individual country.

- Exposure assessment

\[
\text{Dietary exposure} = \frac{\sum (\text{Concentration of chemical in food} \times \text{Food consumption})}{\text{Body weight (kg)}}
\]
International Risk Assessment Bodies

- **JECFA** (FAO/WHO Joint Expert Committee for Food Additives) – food additives, contaminants, veterinary drug residues.

- **JMPR** (FAO/WHO Joint Meeting of Pesticide Residues) – pesticide residues.

- **JEMRA** (FAO/WHO Joint Expert Committee for Microbial Risk Assessment) – microbial hazards.

Independent scientific bodies; members serve in their personal capacities, not representing any government, institution or special interest group.
Environmental Health Criteria 240
Principles and Methods for the Risk Assessment of Chemicals in Food

2009

A joint publication of the Food and Agriculture Organization of the United Nations and the World Health Organization
RA agencies in selected countries/regions

<table>
<thead>
<tr>
<th>Country/Area</th>
<th>Organization</th>
<th>Year</th>
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<tr>
<td>EU*</td>
<td>European Food Safety Authority (EFSA)</td>
<td>2002</td>
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<tr>
<td>Canada</td>
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<td>Netherlands</td>
<td>The Food and Consumer Product Safety Authority (VMA)</td>
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<td>Japan*</td>
<td>Japanese Food Safety Commission (FSC)</td>
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<td>Hong Kong, China</td>
<td>Center for Food Safety (CFS)</td>
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<td>China</td>
<td>China National Centre for Food Safety Risk Assessment (CFSA)</td>
<td>2011</td>
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<tr>
<td>USA</td>
<td>FDA, EPA, CDC et al</td>
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* risk assessment only
Relationship between risk assessment and risk management

JECFA

Risk assessment
(expert)

food additives — ADI
contaminants — PTWI
vet. drug res. — ADI

Risk management
(government)

CCFA

food additives — scope and use level

Risk management
(government)

CCCF

Risk management
(government)

contaminants — MLs

CCRVD

Risk management
(government)

vet. drug res. — MLs
Risk Analysis Framework

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Definition of Risk Communication

“The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.”

Risk communication is ...

“An open, two-way exchange of information and opinion about risk leading to better understanding and better risk management decisions.”

Source: USDA, 1992
Risk Communication Gap

- Technical documents
- Scientific journals
- Government reports

The vacuum

- News items
- “Cocktail party” conversations
- Advocacy group reports

Expert risk assessments

Public risk perceptions

From: David Schmidt, IFIC
Case A – a food scary disaster

Duck egg with red yolk in China – adulteration

The case – Illegal use of Sudan Red in duck feed, in order to make the color of egg yolk more appealing.

Risk assessment – Sudan Red is an industrial color, not permitted for feed or food use. It is an animal carcinogen, but no evidence as a human carcinogen (IARC). Sudan Red only occurred in egg yolk with very low levels. Based on the carcinogenic dose in rodents, it was estimated that it may cause adverse health effects in humans, only if one consumes 1000 such adulterated egg every day for a long period.
Case A – a food scary disaster

Duck egg with red yolk in China – adulteration (cont.)

Risk management - Immediate removal of all adulterated duck eggs from the market and the authority re-emphasized that Sudan Red is not allowed to be used in animal feed and human food.

Risk communication – No regulatory agencies make any announcement on the risk assessment and risk management of this case. On the contrast, wide media coverage on the “carcinogenic duck egg event” for 6 weeks, from Mainland to Hong Kong and Taiwan.
Case B – full risk analysis

Melamine in milk (2008) – double adulteration

The case – Melamine was added to raw milk diluted with water, in order to falsely increase the protein content. High melamine content infant formula caused 290,000 cases of urinary tract stone in infants and very young children in China.

Risk assessment in China – Melamine was identified as the cause of the urinary tract illness cases and Sanlu brand infant formula was the causal product. The average melamine intake of these affected cases were approximately 40 times of the melamine TDI proposed by EFSA.
Melamine in milk (2008) – double adulteration (cont.)

Risk management in China – Immediate investigation and inspection to all infant formula and milk powder producers and milk collection stations; all tainted products hold by authorities; responsible producers and related local government officials punished; free medical examination for infants and young children who have consumed tainted products; free medical treatment for the diagnosed patients; action limits for melamine in infant formula and other products were developed and enforced.

Risk communication in China - All risk management measures and inspection results including number of patients and treatment were released timely by relevant authorities through media.
Melamine in milk (2008) – double adulteration (cont.)

International risk assessment – TDI: melamine 0.2 mg/kg bw/day, cyanuric acid 1.5 mg/kg bw/day (WHO Expert Meeting, Ottawa, Canada 1-4 December 2008).

International risk management – Codex MLs for melamine in infant formula and other foods (2011-12).

International risk communication – INFOSAN; scientific papers and media reports on risk assessment and Codex MLs.
For further reading
Summary

- Risk analysis is recognized as the universal framework in dealing with all types of food safety issues, including microbial, chemical and physical hazards in foods.

- Risk assessment is the scientific basis for risk management. However, in certain circumstances, other legitimate factors may supersede science in making risk management decisions.

- Transparent risk communication is critical for the development of correct perception of food safety in consumers.
Thank you!