The role of risk assessment in addressing the safety of foods of animal origin

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What is risk assessment?

- A tool
  - for use in improving food safety

- APPLICATION: To assist risk managers in taking actions that lead to safer food
Risk assessment framework

- Defined by Codex Alimentarius
- A systematic approach for the provision of scientific advice to risk managers

Diagram:
- Hazard Identification
- Hazard characterization
- Exposure assessment
- Risk characterization
Benefits and role of risk assessment?

- Enables a linkage between management action and impact on consumer health
- Provides a transparent science based foundation to underpin risk management actions, standards, regulations
  - Meeting SPS obligations
- Facilitates comparisons of different approaches
  - before implementation (helps in selection of best options)
  - after implementation - establishment of equivalence
Benefits and role of risk assessment

- Not always needed but of particular value when issues are complex
- Facilitates an in-depth look at the food chain of concern – gain greater insight into issues, problems
- Establishment of performance objectives
Risk assessment in an international arena

International risk manager
CODEX

Member Countries

Data, expertise

Scientific advice

Needs, feasibility, inputs, etc.

International trade agreements

WTO Agreements

Standards, guidelines, related texts

Benchmark standards

International risk assessment
JECFA, JMPR, JEMRA, ad hoc expert consultations

Scientific advice

Requests for advice, risk assessment

Interna
tional trade agreements

Scientific advice

Requests for advice, risk assessment
Risk assessment groups at FAO

JEFCA

JMPR

JEMRA

Chemical

Ad hoc consultations

biotechnology

probiotics

micronutrients

eetc..
International risk assessments

- Not a new activity
- JECFA celebrated 50\textsuperscript{th} anniversary in June
- But risk assessment process continues to evolve
- Expands to cover new areas of hazards
  - only began looking at microbiological hazards in 2000
- Undertaken in response to specific requests from Codex and member countries
  - Underpin international standard setting process
  - Provide risk based advice for countries
Areas of risk assessment relevant to foods of animal origin

### Chemical
- Residues of veterinary drugs
- Food additives and flavouring agents
- Pesticide residues
- Naturally occurring toxicants
- Acrylamide
- Dioxins

### Microbiological
- Well known pathogens
  - *Salmonella*
  - *Listeria monocytogenes*
  - *Campylobacter*
  - Enterohaemorrhagic *E. coli*
- Antimicrobial resistant microorganisms

- Foods derived from genetically modified animals
- Lactoperoxidase system
EXAMPLE 1: Residues of veterinary drugs

- The treatment of the animal with veterinary drugs prior to slaughtering

- JECFA establishes
  - Maximum Residue Limits (MRLs)
  - Acceptable Daily Intakes (ADI’s)
  - Principles for evaluating the safety of residues of veterinary drugs in food and for establishing ADIs and MRLs for certain drugs when they are administered to food-producing animals in accordance with good veterinary practices
**EXAMPLE 1: Neomycin**

- **Acceptable daily intake:** The ADI of 0-60 mg/kg bw (established at the forty-seventh meeting of the Committee (WHO TRS 876, 1998)) was maintained.
- **Residue definition:** Neomycin
- **Recommended maximum residue limits (MRLs)**

<table>
<thead>
<tr>
<th>Species</th>
<th>Liver (mg/kg)</th>
<th>Kidney (mg/kg)</th>
<th>Milk (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td>500</td>
<td>10 000</td>
<td>1500</td>
</tr>
</tbody>
</table>

\(^a\)The MRLs of 500 mg/kg for cattle muscle and fat and all other MRLs recommended at the forty seventh meeting of the Committee (WHO TRS 876, 1998) were maintained.
EXAMPLE 1: Impact of no risk assessment

2001/2002 - DISRUPTIONS IN FOOD TRADE CAUSED BY DETECTION OF TRACE AMOUNTS OF CHLORAMPHENICOL AND NITROFURANS IN ANIMAL PRODUCTS

Veterinary drug residues without ADI/MRL

- FAO/WHO meeting, 2004
  - Identified the scientific, technical and regulatory problems
  - Appropriate follow-up steps
    - Analytical methodology – considered measures and made recommendations
    - Recommended that work on international MRLs for veterinary drugs that have been evaluated by national governments and are currently in use is completed within the coming ten years
    - Require innovative approaches to capacity building.

REPORT:
Other residues/chemicals of concern

- Contaminants in animal feedstuffs
  - Mycotoxins
  - Heavy metals
  - Dioxans
  - Pesticide residues

- Growth promoters
  - Antimicrobials - issue of antimicrobial resistance – risk assessment forthcoming
  - Hormones – risk assessments undertaken, some ADI,s established
EXAMPLE 2: Aflatoxin M₁ in milk

- Question from Codex - 0.05 or 0.5 µg/kg?
- JECFA risk assessment
  - Used data from a range of countries
  - Considered susceptible populations (prevalence of Hep B)
  - Looking at risk of liver cancer
  - Risk estimate – worst case scenario
  - Non hepatitis carriers – risk so low impossible to demonstrate
  - With 1% Hep+
    - 0.05 µg/kg – 3.2 cases cancer / 1000 million / year
    - 0.5 µg/kg - 32 cases cancer / 1000 million / year
    - Conclusion – small difference – focus on vaccination and control of hepatitis
EXAMPLE 2: Aflatoxin M<sub>1</sub> in milk

- JECFA risk assessment → CCFAC
- Discussed and debated
- Differing opinions
- Results of risk assessment – scientific advice → 0.5 µg/kg adopted
  - adequate for the protection of consumer health
  - reasonably achievable for all countries
- Implications of lower ML
  - a significant reduction in the availability of milk in developing countries
  - negative implications from a nutritional point of view.
Microbiological hazards in foods of animal origin

- Pathogens can enter at various places along food chain
- Dynamic hazard...can decrease or increase depending on the microorganism
- Risk assessments on
  - *Salmonella* in eggs and broiler chickens
  - *Campylobacter* in broiler chickens
  - *Listeria monocytogenes* in milk, fermented meats
EXAMPLE 3: Listeria monocytogenes (milk, fermented meats)

- Differences in national approaches to addressing the problem of *Listeria* contamination and so difficult for Codex to agree on a management approach
- Risk assessment undertaken from retail to consumption
- Output
  - Predicts that nearly all cases of listeriosis result from the consumption of high numbers of *Lm*.
  - Preventing exposure to high levels has the greatest impact.
  - Most cases of listeriosis are associated with the consumption of foods that do not meet current standards (e.g. absence in 25g, 100cfu/g,........)
EXAMPLE 3: Criteria vs compliance - which is more important?

<table>
<thead>
<tr>
<th>Assumed percentage of &quot;defective&quot; servings</th>
<th>Predicted number of listeriosis cases per year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial standard of 0.04 cfu/g</td>
</tr>
<tr>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td>0.00001</td>
<td>1.7</td>
</tr>
<tr>
<td>0.0001</td>
<td>12.3</td>
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<td>119</td>
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<td>0.01</td>
<td>1,185</td>
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<tr>
<td>0.018</td>
<td>2,133</td>
</tr>
<tr>
<td>0.1</td>
<td>11,837</td>
</tr>
<tr>
<td>1</td>
<td>117,300</td>
</tr>
</tbody>
</table>
EXAMPLE 3: Importance of compliance with established criteria

The rate of defective servings is a more significant risk factor than the numeric value of the criterion within the range that CCFH asked the risk assessment team to consider.
EXAMPLE 4: Salmonella in eggs

- Risk assessment focused on evaluating a range of control measures – comparative assessment

Salmonella in eggs: Shelf-life and cooling scenarios

Probability of illness

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Probability of Illness ($x 10^{-6}$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>3.5</td>
</tr>
<tr>
<td>Shelf-life 14 days</td>
<td>3.0</td>
</tr>
<tr>
<td>Shelf-life 7 days</td>
<td>1.5</td>
</tr>
<tr>
<td>Cooling 7°C</td>
<td>1.1</td>
</tr>
</tbody>
</table>

Baseline Shelf-life: 14 days
Shelf-life: 7 days
Cooling: 7°C
Future work – EHEC’s in meat and meat products

- Addressed by existing approaches – GHP, GMP etc.
- But e.g. July/August 2006:
  - 28 events/outbreaks of *E.coli* 0157:H7 with approx 248 human cases.
  - 8 of these events have led to changes in control measures; 6 recalls; 10 in public education campaigns; and 4 in legal actions.
  - Large economic costs to society
New work – EHEC’s in meat and meat products

- 5 risk assessments developed at national level over a 10 year period
- Learning process – only the most recent had true interaction between risk assessors and risk managers
- Many undertaken as a research exercise
  - But good basis for future work
  - Move in some countries to re-evaluate their measures using risk assessment
Risk assessment integral part of overall system

International level

- Assessment and evaluation
- Guidelines and tools
- Monitoring
- Good practices

National level
For more information

- FAO webpage

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