Risk Assessment use in the public and private context

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Outline

- Microbiological Risk Assessment (MRA)
- Examples of Government use of Microbiological Risk Assessment
- Use of MRA technology for Exposure Assessment in an Industry context
Microbiological Risk Assessment (MRA)
“Risk Management” drives Risk Analysis

Risk manager owns issue:
- Decides on need to deal with the issue
- Risk Assessment as appropriate
- Decisions on mitigation options

Iterative interaction with:
- Risk assessors
- Risk communicators
- Stakeholders / interested parties
Microbiological Risk Assessment: purpose?

To provide a basis for decision-making by the risk manager

- By systematically assessing the level of risk associated to pathogenic microorganisms in foods.
- By making an inventory of “typical” risk contributing factors.
- By elaborating possible risk mitigation options/strategies (“what if”).
Microbiological Risk Assessment is a science-based procedure driven by governments to assess the safety of foods consumed in their population.

MRA is most valuable when:
- Highly complex situation
- Variability in operational chains
- Variability within population
- Uncertainty, incomplete knowledge
Microbiological Risk Assessment is performed for pathogen/food combinations that are associated with foodborne illness.
Microbiological Risk Assessment evaluates the relevant steps of a (typical) food chain, between primary production to consumption or part thereof.
Microbiological Risk Assessment

- Microbiological Risk Assessment takes into consideration **all foods consumed in a specific country**, whether produced in that country or imported.

- It is about the population **exposed** to the hazard.
MRA outcome: *Risk estimates*

- **Population level**
  - Estimated *number of cases* of illness per year per population (e.g. 100,000 persons) caused by a micro-organism present in a particular food or food group (*risk for population*)

- **Consumer level**
  - Chance of illness due to consumption of a specific food-product to which a particular hazard can be associated (*risk for individual consumer, “per serving”*)
MRA outcome: *other outcomes*

- A **ranking** of foods according to the risk they pose to consumers
  - A specific type of food, different hazards
  - Grouping of foods according to risk categories for one hazard
- **What-if scenarios** for impact of mitigation measures
- **Insight** in the impact of processing, handling, distribution and preparation scenarios on risk
- **Insight** in consumer use and abuse (misuse)
Examples of Government use of Microbiological Risk Assessment
Global Food Standard Setting level

JECFA, JMPR, JEMRA, ad hoc expert Consultations

Member Countries

WTO Agreements

Needs, feasibility, inputs, etc.

International trade agreements

Data, expertise

Scientific advice

Standards, guidelines, related texts

Requests for advice, risk assessment

International risk manager

CODEX ALIMENTARIUS

Scientific advice

Benchmark standards
Providers of scientific advice to Codex

JEFCA

Chemical hazards

JMPR

Ad hoc consultations

biotechnology

probiotics

micronutrients

e tc..

JEMRA

Microbial hazards
International “risk managers” and “risk assessors”:

- **Risk Managers:**
  - Codex Committee on Food Hygiene (CCFH), i.e. Codex Member States (input: FAO & WHO, Observer organizations)

- **Risk Assessors:**
  - JEMRA (Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment), selected experts in microbiology (ecology, public health, epidemiology, statistics, etc.)
Risk assessments of Salmonella in eggs and broiler chickens

INTERPRETATIVE SUMMARY

CX/FH 04/10/Add.3

Codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
WORLD HEALTH ORGANIZATION

Agenda Item 10 (c)

CX/FH 04/10/Add.3
December 2003

Joint FAO/WHO food standards programme

Codex committee on food hygiene
Thirty-sixth session
Washington DC, United States of America, 29 March – 3 April 2004

Discussion paper on risk management strategies for Salmonella spp. in poultry

Prepared by Sweden with the assistance of Australia, Brazil, Canada, China, Czech Republic, Denmark, France, Germany, Netherlands, New Zealand, Thailand, USA, the European Commission and ALA

Background

At its 34th session in Bangkok, the Codex Committee on Food Hygiene was informed about the outcome of the FAO/WHO expert consultations on risk assessment on Listeria and Salmonella. It was noted that there was a need to develop a discussion paper on Risk Management Strategies for Salmonella spp. in broilers based upon the risk assessment document (FAO Food and Nutrition Paper 72). The committee agreed that a drafting group, led by Sweden should develop a discussion paper to be considered at its next Session. The drafting group met in Uppsala, Sweden, the 25-26th of February 2002.
JEMRA Reports & Guidelines

MRA reports

“how to” guidelines

Guidelines on principles/process
JEMRA MRAs

- *Salmonella* spp. in broiler chickens and eggs
- *Listeria monocytogenes* in ready-to-eat food
- *Campylobacter* spp. in broiler chickens
- *Vibrio* spp. in seafood for the
- *Cronobacter* spp. in powdered infant formula

Codex Codes

- Risk management strategies for *Salmonella* spp. in poultry
- General principles of food hygiene for management of *L. monocytogenes*
- Risk management strategies for *Campylobacter* spp. in poultry
- Risk management strategies for *Vibrio* spp. in seafood
- Recommended international code of practice for foods for infants and children

Some Examples of MRA use

- Pathogens in powdered infant formula
- *Listeria* in Ready-to-eat foods
- *Salmonella* in undercooked chicken
Cronobacter spp. (*Enterobacter sakazakii*) in powdered infant formula

- Associated with sporadic cases or small outbreaks in pre-matures/very young infants
- Primarily associated with consumption of powdered infant formula
- Causes bacteraemia or meningitis in vulnerable infants
- High mortality rate (~10 to 50%) and very delicate “at risk” consumer group
Mitigation need signaled in 2003

Countries / national governments

Codex system

Revise existing standard

Request scientific advice

Resolution on infant and child nutrition

Request for preparation and use guidance
JEMRA & CCFH work done in 2004 - 2008

Revision of Codex standard

Risk Assessment

Web based risk assessment tool

Development of preparation and use guidance
Listeria monocytogenes in RTE foods

- Food-borne - can grow at chill temperatures; ubiquitous
- May cause listeriosis when present in high numbers in food consumed
- Relatively rare, but serious disease
- High-risk groups include pregnant women, newborn babies, immunocompromised
- Incidence is 0.3-10 cases per million persons in Europe, USA, Australia
- Ready-to-eat foods: no “kill-step” after manufacture until consumption

Typical foods
- Soft cheeses
- Meat products
- Smoked fish
- Deli salads
Estimated number of listeriosis cases as a consequence of contamination level*

* at point of consumption
FAO/WHO MRA on *L. m.* in RTE foods

Relationship between exposure and risk

(adapted from T. Ross)
## FAO/WHO MRA on *L. m.* in RTE foods

### Susceptibility of sub-populations

<table>
<thead>
<tr>
<th>Condition</th>
<th>Relative susceptibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transplant</td>
<td>2584</td>
</tr>
<tr>
<td>AIDS</td>
<td>865</td>
</tr>
<tr>
<td>Cancer – pulmonary</td>
<td>229</td>
</tr>
<tr>
<td>Diabetes</td>
<td>25</td>
</tr>
<tr>
<td>&gt; 65 years old</td>
<td>7.5</td>
</tr>
<tr>
<td>&lt; 65 yrs, healthy</td>
<td>1</td>
</tr>
</tbody>
</table>
### FAO/WHO MRA on *L. m.* in RTE foods

Differences in risk estimates

<table>
<thead>
<tr>
<th>Food</th>
<th>Mean cases of listeriosis per 10 million people per year</th>
<th>Mean cases of listeriosis per million servings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk (pasteurised)</td>
<td>9.1</td>
<td>0.005</td>
</tr>
<tr>
<td>Smoked fish</td>
<td>1.6</td>
<td>0.053</td>
</tr>
<tr>
<td>Ice-cream</td>
<td>0.012</td>
<td>0.000014</td>
</tr>
<tr>
<td>Fermented meat</td>
<td>0.00055</td>
<td>0.0000021</td>
</tr>
</tbody>
</table>

Highest in risk ranking

Relative-risk posed by different RTE products

Predicted Cases of Listeriosis per Annum—Total Population in the USA

Estimating effectiveness of Interventions (what if scenarios)

Predicted Annual Mortality

Refrigerator Temperature (°C)

Deli Meat - Elderly

7°C/45°F cut-off

ILSI, 2004
Impact of undercooking

Probability of salmonellosis before and after changing cooking practices

FAO/WHO
Government context use of MRA summary

Risk Analysis in the government context:

- Systematic / structured, transparent and open process
- Objective / based on sound science

Use of Risk Assessment in government context:

- Basis for setting public health goals, risk-based metrics
- Allows for “Informed decision-making” on risk and mitigation options
Use of MRA technology for Exposure Assessment in an Industry context
Does industry need to use Risk Assessment?

– Industry does not need to conduct risk assessments as governments do

– But, Industry needs to ensure that proper food safety management systems (FSMS based on Good Practices and HACCP-principles) are adequately implemented and executed day-by-day

– However, MRA studies may contain valuable information that can help strengthen industry’s food safety management systems
  • How different control measures affect risks
  • What handling increases risks
  • Insight in critical processes
  • Insight in unintended use
Can Industry use of MRA techniques (Exposure assessment)

- Yes, examples in presentation of Judith

- Simulation tool, building on predictive modelling, in areas such as:
  - Simulating consumer safety of complex or radical product innovations
  - Evaluating whether performance standards or risk-based metrics (FSO/PO/…) are met
  - Simulating ‘safe’ changes to reducing heat-processing for quality improvements
Industry context use of MRA summary

Learning from Risk Assessment use by governments
- Learning about factors that increase or reduce risks

Risk Assessment / Exposure assessment
- Systematic/structured, transparent and open process
- Objective / based on sound science

Use of Risk Assessment in government context:
- Simulating changes in product and process design
- Establishing “safety of product design”
- Deciding on management specific measures / HACCP, FSMS
Risk Analysis Pre-requisites

- Data on pathogens & foods (surveillance; incident investigation; epidemiology) - government
- Quantitative methods/approaches for data handling/processing (e.g. Predictive modelling, Risk Assessment; etc)