Food Safety Risk Analysis

Part 1
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INTRODUCTION TO RISK ANALYSIS
Introduction to Risk Analysis

- Risk Analysis Framework consists of 3 activities:
  - Risk Assessment
  - Risk Management
  - Risk Communication

- The main goal of Food Safety Management is the reduction of the incidents of food-borne illness to the lowest practical level

- This can only be achieved by taking steps at each point of the food chain where hazards can occur

- Limited resources at regulatory and local level mean decisions must be taken regarding which actions are prioritised

- Risk Analysis is the tool used to determine such actions
Risk Analysis Framework

- Simple Module
- At EU Level it is more complex in reality
- The scientific element is risk assessment
- Risk management uses the output from the assessment to put in place actions to control hazards
- Risk communication is the dialogue between interested parties regarding the outputs of the above
HISTORY AND EVOLUTION OF FOOD SAFETY RISK ANALYSIS
History of "safe" food

• Preoccupation of humans
• Community based food production 17,000 years ago – barley in Egypt
• Dry storage improved preservation
• Other methods developed
• Honey, olive oil, heating and salting
History of "safe" food

- In time humans learned to identify safe food
- Trial and error – adverse health effects
- Lessons found expression in religious taboos
- Eating pigs in Jewish and Muslim religions
- Hygiene – eating ‘unclean’ foods in India
- E.g. Foods ‘sniffed by dog or cat’
- Early example of banning of foods
History of "safe" food

• However – lack of understanding of causes of food poisoning
• Illness persisted
• Scientific understanding commenced in 1795
• French Government offered reward of effective method of food preservation
• Nicolas Appert stuffed food into wide mouth jar, sealed and placed in boiling water for 6 hours
History of "safe" food

• 1810 Englishman – Durand:
  • Method using tin cans
  • Knew How but not Why
  • Both unaware of the discovery of “little heat sensitive animalcules” by Leeuwenhoek in 1677

• Not until 1854 was the scientific basis for thermal preservation understood

• Louis Pasteur showed that certain bacteria caused food spoilage or poisoning

• Commercial heat treatment of wine was introduced, i.e. Pasteurisation
History of "safe" food

- Link established
- Food hygiene control introduced
- Standards established
- Early laws based on *Prohibition*
- Eventually prevention was introduced
- 1922 process criteria for low acid canned foods
- 1960’s introduction of Good Manufacturing Practices (GMP)
- 1971 principle of identifying and controlling critical steps in process was introduced. HACCP – Pillsbury in the U.S.
Origin of Quantitative Risk Analysis

• Since 1955, systematic risk analysis has been used by the FAO / WHO
• Evaluation of the levels of food additives
• Est. Expert Committee JEFCAn
• 1962 Codex Alimentarius Commission CAC est.
• Intergovernmental committee responsible for establishing food safety standards
## Origins of Quantitative Risk Analysis Framework

- 1995 first FAO/WHO Expert Consultation on Application of Risk Analysis in Food Safety

<table>
<thead>
<tr>
<th>Year</th>
<th>FAO / WHO Risk Analysis Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>Application of risk analysis to food standards issues</td>
</tr>
<tr>
<td>1997</td>
<td>Risk management and food safety</td>
</tr>
<tr>
<td>1998</td>
<td>The application of risk communication to food standards and safety matters</td>
</tr>
<tr>
<td>1999</td>
<td>Risk Assessment of microbiological hazards foods</td>
</tr>
<tr>
<td>2000</td>
<td>The interaction between assessors and managers of microbiological hazards in food</td>
</tr>
</tbody>
</table>
Why is risk important in food safety?

WHAT IS RISK?
Definition of food

• **Food:** Any substance whether processed, semi-processed or raw which is intended for human consumption, including drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of food but excluding cosmetics, tobacco and substances used as drugs.
Definition of hazard

• *Hazard:* A biological, chemical or physical agent in or property of food that may have adverse health effects.
Nature of risk

• Risk is part of everyday life
• Getting out of bed, driving, etc.
• Elimination of risk is either impossible or impractical
• We make judgements daily regarding risk and what is acceptable
• “Taking risks” is an essential part of a normal and fulfilling life
• Balance - risk vs. reward
Nature of risk

- Understanding of risk analysis requires an understanding of the concept of risk itself.
- Encompasses a large element of human psychological responses.
- Perception and understanding varies.
- Some languages do not discriminate between *hazard* and *risk*.
- Perception often based on person or group.
- E.g. age, gender, social class, etc.
# Risk of death

- Risk of death defined as a probability

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Risk of death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking 10 cigarettes a day</td>
<td>1 in 200</td>
</tr>
<tr>
<td>Influenza</td>
<td>1 in 5,000</td>
</tr>
<tr>
<td>Accident at home</td>
<td>1 in 26,000</td>
</tr>
<tr>
<td>Salmonella in poultry</td>
<td>1 in 5,000,000</td>
</tr>
<tr>
<td>Nuclear power station radiation leak</td>
<td>1 in 10,000,000</td>
</tr>
</tbody>
</table>
Nature of risk

• In Food Safety Management
• An understanding of RISK is one of the most important skills you will learn
• Specifically – how to assess risk and make effective management decisions based on this assessment
• Poor understanding of risk (including perception & communication) leads to poor decisions, e.g. BSE, German Bean Sprouts?
Nature of risk

- Impossible to eliminate risk of food safety hazards in food
- Objective - reduction to acceptable levels
- To do this criteria must be employed
- This is conducted at international, national, agency and processing level
Definition of risk

- A function of the probability of an adverse effect and the magnitude of that effect, consequential to hazard(s) in food

\[ \text{RISK} = \text{LIKELIHOOD} \times \text{IMPACT} \]

- How likely is the hazard to occur [high / medium / low] and what is the impact should it occur [mild illness/ severe illness, death]
Risk Assessment: First Element of Risk Analysis Framework
Risk Assessment

- Risk Assessment: Process of identifying a hazard and estimating the risk presented by that hazard
4 Steps of Risk Assessment

1. Hazard Identification
2. Hazard Characterisation
3. Exposure Assessment
4. Risk Characterisation
Risk Assessment

- It may be quantitative or qualitative
- Quantitative RA’s are preferred (or semi-quantitative)
- Detailed quantitative RA is not always available
- Risk Assessment is more often characterised by what we don't know than what we do know
Risk Assessment

- Structured
- Assists decision makers – RM tool
- Initiates interventions
- Actions – Regulatory, voluntary activities and / or educational initiatives
- Takes account of various factors such as quality, acceptable risk, technical feasibility, cost
- Develop more effective HACCP plans
Risk Assessment

• Contributes to better understanding of whole food systems

• RA’s can be used to study proposed changes

• RA’s can be updated to take account of new data

• RA’s may be used to compare risks between foods or various hazards within the same food
Risk Assessment

• RA plays role in international food trade
• Provides tool to determine equivalent levels of public health protection between countries
• Establish scientifically based food safety requirements
Qualitative Risk Assessment

• Qualitative Risk assessment based on qualitative data or giving a qualitative result

• Results are often stated in an estimate range – there is a high, medium or low risk of certain outcome occurring
Quantitative Risk Assessment

• Risk assessment that uses modelling to determine the probability of what can go wrong, how likely it is to happen and how severe are the likely health impacts

• Results are stated in numerical terms

• 42% probability that a certain illness may occur from eating a serving (g) of food X with a certain health outcome
Why Risk Assessment?

• Identify food safety issues
• Set priorities
• Address specific public health food safety problems. Justify or evaluate new of alternative measures, technology or inspection system
• Issues may come from any source:
  • RM, FSO, FSM, Government, Codex, disease surveillance, industry, consumer, new technologies, trade
Risk Assessment 6

- Process initiation?
- Exactly what is being assessed?
- What is being requested?
- By whom?
- What product or commodity?
- Purpose?
- Form of output?
Principle 1

- Purpose and objective
- Questions that RA should answer
- Requires dialogue between assessor and managers
- Independence should be maintained

“An RA should clearly state the purpose of the exercise including the form of the estimate that will be the output”
Principle 2

- All methods, assumptions and judgements should be clearly stated

- Sufficient data should be provided to allow the assessment be challenged

“RA should be transparent”
Principle 3

- Data and data collect should show sufficient quality
  
  “Data should be of sufficient quality and precision”

- Best available information and data should be used

- Efforts to reduce uncertainty and increase reliability
Principle 4

• Describe the limitations of the data, methods or models utilised

“The Risk should contain a description of uncertainty and where the uncertainty arose during the risk assessment process”
Principle 5

• For micro hazards, growth, survival or death should be explicitly considered

• Interaction between human and the agent should be assessed

“Where appropriate, the RA should consider the fate of the hazard(s) in food and the disease process following infection.”
Principle 6

- It should not be a static entity
- Reviews should be conducted as required

"Risk estimates, where possible, should be reassessed over time against independent human illness data and new data as it becomes available."
Hazard Identification

- Identification of agents capable of causing adverse health effects
- Identifies micro-organism, toxin, etc. of concern and evaluates whether it is a hazard

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Hazard Identification

- Output is the hazard(s)
- e.g. *Cl. Botulinum* in low acid canned food
- e.g. BSE prion in beef
- Source of data used
- Gap in data / further data required
Hazard Characterisation

- Assessment of the nature of the adverse health effects associated with hazard.
- Provide an estimate of the nature, severity and duration of effects.
Hazard Characterisation

Adverse health effects depend on:

• The agent
• The individual
• The food
• The consumption pattern
Hazard Characterisation

- Dose–response: Number or quantity of agent that causes adverse response
- Determine different end points
- Range of symptoms
- Duration
- Nature of carriers
Hazard Characterisation

- Micro-organisms:
  - Infectious
  - Toxigenic

- Food Attributes:
  - Food matrix
  - Fatty foods

- Host Sensitivity
Exposure Assessment

- Evaluate the levels of hazardous agent in food at the time of consumption
- This may be actual or anticipated human exposure due to consumption
Exposure Assessment

- Hazard Identification
- Hazard Characterisation
- Exposure Assessment
- Risk Characterisation

- Based on science
- Routes
- Sources of exposure
- Estimate final dose
- Initial levels in raw material
- Effects of production, processing, handling, distribution, preparation, packaging, hygiene conditions, etc.
Exposure Assessment

- Reports
- Existing RA
- Storage test
- Challenge testing
- Performance data
- Micro modelling
- Epidemiological data
- Consumption data
- Uncertainty
- Variability
- 10% of food 0-10 cells / 100g, etc.
Risk Characterisation

- Assessment of the nature of the adverse health effects associated with a hazard which may be present in foods
- Provide an estimate of the nature, severity and duration of the adverse effects
- Brings together data...

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Risk Characterisation

- Qualitative: High, Medium, Low
- Quantitative: 1 in 1 million chance of illness
- Or 10 illnesses per year in a certain group
- Should be useful
- State uncertainty
### Risk Characterisation

- **Hazard Identification**
- **Hazard Characterisation**
- **Exposure Assessment**
- **Risk Characterisation**

**Examples:**

- Risk to public health from food borne Listeria monocytogenes among selected categories of ready to eat foods [US DHHS / USDA]
- Risk assessment on the public health impact of Vibrio para. in raw molluscan shellfish [USFDA]
Risk Assessment Report

- Describe Uncertainty
- Clearly state estimates
- Suggestions for management
- Need for more research
- Methods used
- Who conducted RA
- Sources of information and data [more about this later]
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