Food Safety Risk Analysis

Part 2
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Setting of International Standards – WHO / FAO

INTERNATIONAL RISK ASSESSMENTS
International Risk Assessments

• Starting point is the relevant food safety policy

• By using Risk Analysis, policy is transferred into:
  • Food Safety objectives (FSO’s)
  • FSO equates with an agreed level of consumer protection
Use of Risk Analysis

Food Safety Policy

Risk Management

Risk Assessment

Risk Communication

Agreed Level of Consumer Protection
Appropriate Level of Protection

- **ALOP**: Results as an output of Risk Assessment
- Takes account of costs
- Level of Hazard present if food at point of consumption at which adverse health impacts are avoided
Food Safety Objective

• *Food Safety Objective*: A government-defined target considered necessary to protect the health of consumers (this may apply to raw materials, a process or finished products).
International RA’s

• FAO and WHO are organisations concerned with food safety at the international level

• Int. Food safety standards established by the Codex (CAC) who delegates development of standards to subsidiary bodies / committees

• Draft standards, guidelines & recommendations for CAC
Process of Setting International Standards

Member countries

- FINAL Standards
- Guidelines
- Recommendation

FAO/WHO

CAC

Codex Committees

JECFA

JMPR

DRAFT Standards
- Guidelines
- Recommendation

Ad hoc
International Criteria (Chemical)

- Setting international criteria for chemicals requires setting a food safety policy
- Policy contains rules, e.g. “carcinogens should be absent from food”
- ALARA principle used - “As Low as Reasonably Achievable”
- Also, an “Appropriate Level of Protection” - ALOP
- Level usually below the No-effect Level
- RA is directed at exposure assessment
- Risk management directed at FSO’s
- Process, product and storage criteria for incorporation into HACCP
International Criteria [Micro]

• At international level no formal Food Safety Policy established
• EU now set criteria
• Micro. Hazards start with a Quantitative Risk Assessment
• ALOP is established and FSO’s are set
• These are incorporated into HACCP plans
• Chemical is more direct.... Micro is more complex
Present and Future Trends

Trends in Food Safety Control (Microbiological):
• Traditionally assessed through testing of randomly selected food samples
• Approach simply confirms meeting of criteria... Limited and not the full picture
• Move towards HACCP and GMP
• Predictive and preventative approach
• This starts with Q Risk Assessment
• Identify hazard
• Characterise hazard
• Exposure estimated
• Risk Management – ALOP at point of consumption
Production of Micro Safe Food

- ALOP
- Customer Req’s
- Food Producer

Risk Assessment

- FSO’s
- Process Criteria
- Process, Product, Storage

Risk Management

- Safety Management Systems
- GMP - HACCP

Verification (and Adjustment)

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Example: *Bacillus cereus in milk*

- Bacillus cereus is a hazard in pasteurised milk
- Potentially pathogenic
- Is found & can multiply in the product
- Associated with foodborne illness resulting from consumption of product
- Some countries have set limit of 10-5 per ml in milk [ALOP]
- To meet this product must be stored at 7oC for 7 days
- Probability of consuming milk with greater than 10-5 is 7% [Notermans et al, 1997]
- Maintaining storage temps and time eliminates risk
Example: Bacillus cereus in milk

RISK MANAGEMENT:

- What determines levels in product?
- Initial levels of contamination
- Storage time \( t \)
- Storage temperature \( T \)
- Producer could do nothing since 7°C storage instructions is adequate
- Not all domestic storage conditions meet this
- Recommend a lower storage temp
- Reduce storage time less than 7 days
- All have issues in reality
Acknowlegdement: Dr. Wayne Anderson [FSAI]

THE EU APPROACH
EU Approach

• Pre-1990’s
• Market concerns outweighed consumer concerns
• BSE and Belgian Dioxin issues changed everything
• Post-1990’s
• Consumer concerns outweighed Market concerns
• EU adopted the Codex model
• General Principles of Food Law established Risk Analysis as bases of decisions
• Established EFSA
• Precautionary Principle
EU Approach to Risk Analysis

CODEX
Consumer, Media, Lobby, Industry, Professionals etc

Risk managers
Risk assessors

EU MODEL
Consumer, Media, Lobby, Industry, Professionals etc

Risk managers
THE COMMISSION
Risk assessors
EFSA
EU Approach to Risk Analysis

- EFSA – Risk Assessment
- No Management role
- Management conducted by Commission
- Must agree with Parliament and Council on risk management options
- Referred to Member states, e.g. FSAI
- Enforced locally
- Member’s states communicate locally
- F & V Office monitor member states
- All feedback to Commission and EFSA and so on....
Data Sources

• Risk assessment requires sound information
• Information is available from a number of sources
• Information required should be identified
• Information availability is often incomplete
• Few organisations collect pertinent data or structure it so it may be used
• International co-ordinated approach is required to improve data collection and reporting
• Data of distribution of hazards in foods, supply chain operations, process & product criteria, epidemiological reports, etc.
Data Sources


• ICMSF Microbial Ecology of Food Commodities: Microorganisms in Foods. Volume 5, 6

• Food Risk.Org [JIFSAN / University of Maryland]: http://foodrisk.org/
Risk Management: Second Element of Risk Analysis Framework
Risk Management

- *Risk Management*: development of policy, legislation, standards, guidelines, recommendations

- Primary aim of RM associated with food is the protection of public health by controlling risks as effectively as possible

- Achieved through the selection and implementation of appropriate control measures
Risk Management Framework

• Risk evaluation
• Risk management
• Implementation of management decision
• Monitor and review
Evaluation 1

• ID food safety hazard
• Establish risk profile
• Conduct risk assessment
• Consider results of risk assessment
Evaluation 2

- Is zero risk achievable?
- Is level of risk acceptable or not?
- What is the ALOP?
- ALOP assumes there is a single level above which the risk is unacceptable and below which it is acceptable
Risk Management ALARA

- **ALARA**: As Low As Reasonably Achievable
- Concept which links RM with acceptability considerations
- Both the level of risk and the severity of cases are used to categorise risk
Risk Management Option

- ID of available management options
- Selection of preferred management options, including consideration of appropriate food safety standard
- Final management decision
Risk Management Decision

- Liaise with stakeholders – industry, consumers, regulators, scientists, academics, researchers, producers, processors, markets
- Consider cost, feasibility, technical issues
- Consider impact of mitigation measures
- May consider conducting parallel cost benefit analysis prior to selecting final management decision
- Implementation of Management Decision
Monitor & Review

• Essential part of RM is gathering and analysing data to ensure food safety goals are being met

• Continual basis

• Assessment of effectiveness of measures taken

• Review of risk management decision and/or risk assessment as necessary
Barriers

• Transparency
• Bias
• Conflict of interest
• Link between RA and RM
• Involved stakeholders in RM
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