

**Codex Food Safety Risk Analysis Framework**  
**FAO/WHO Development of Scientific Advice**

David James

**This talk...**

- Introduction
- Risk Analysis
- Risk Management
- Risk Assessment
- Risk Communication
- FAO/WHO Development of Scientific Advice

**WTO/SPS Agreement (1995)**

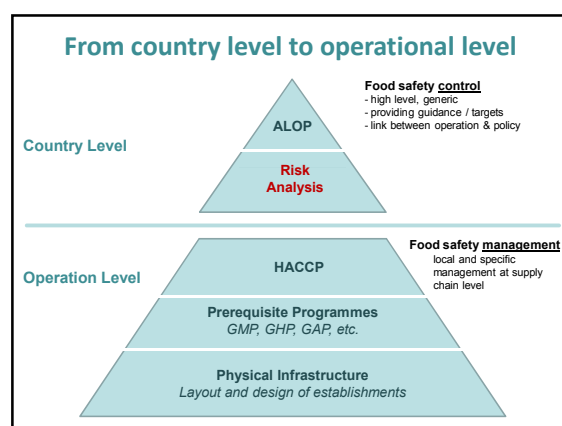
- This agreement is the starting point...
- Food can be freely imported if that does not endanger the country's **Appropriate Level Of Protection (ALOP)**
- **Risk assessment** is an important tool for assisting in the elaboration of food safety measures.

**Appropriate Level Of Protection**

- Level of protection deemed appropriate by a member (country) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.
- Country should not be endangered by imported foods

**But remember...**

- Although defining an acceptable level of risk is exceedingly difficult, it is important to communicate that a **level of zero risk cannot be attained or expected.**
- In the context of food safety, an ALOP is a statement of the degree of public health protection that is to be achieved by the food safety systems implemented in a country.



### Risk Analysis

- Overall objective of risk analysis in food safety is to ensure human health protection
- Is the link between food safety objectives at a country or international level, and
- The operational procedures at company level (based on PRPs and HACCP) that are needed to ensure that food safety is maximised for society

### Codex Definitions

- Risk
  - A function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s) in food.
- Risk Analysis
  - A process consisting of three components: risk assessment, risk management and risk communication.

### Risk Analysis Components

- Risk Management
  - What can we do about the risk?
  - Political process
- (Quantitative) Risk Assessment
  - How big is the risk, what factors control the risk?
  - Scientific process
- Risk Communication
  - How can we talk about the risk with affected individuals?
  - Social and psychological process

### Risk analysis should be:

- Applied consistently
- Open, transparent and documented
- Evaluated and reviewed as appropriate in the light of newly generated scientific data

### The Risk Analysis Process



### Risk management

- Process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options
- Implementation of risk management decisions at national level should be supported by an adequate food control system

### Risk assessment

- The scientific evaluation of known or potential adverse health effects resulting from human exposure to food borne hazards, consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization
- The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties.

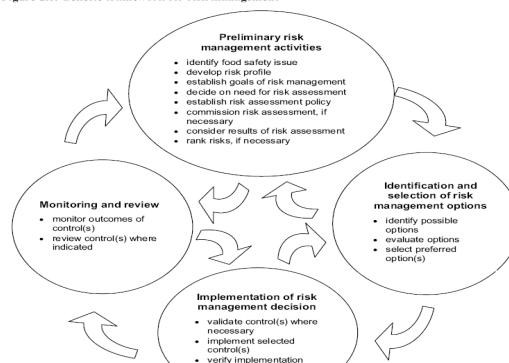
### Risk Communication

- Means the interactive exchange of information and opinions throughout the risk analysis process as regards **hazards and risks, risk-related factors and risk perceptions**
- Among **risk assessors, risk managers, consumers, feed and food businesses, the academic community** and other interested parties
- Including the explanation of **risk assessment** findings and the basis of **risk management** decisions

### Codex Principles of Risk Management

- **Principle 1:** Risk management should follow a structured approach.

Figure 2.1. Generic framework for risk management



### Codex Principles of Risk Management

- **Principle 2:** Protection of human health should be the primary consideration in risk management decisions.
- **Principle 3:** Risk management decisions and practices should be transparent.
- **Principle 4:** Determination of risk assessment policy should be included as a specific component of risk management.

### Codex Principles of Risk Management

- **Principle 5:** Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment.
- **Principle 6:** Risk management decisions should take into account the uncertainty in the output of the risk assessment.

### Codex Principles of Risk Management

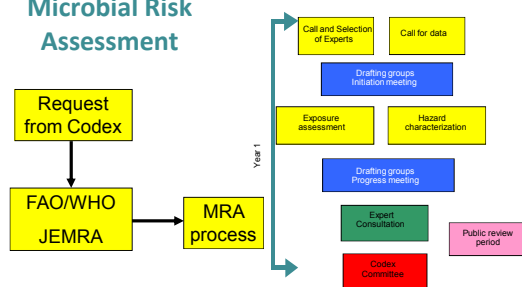
- **Principle 7:** Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process.
- **Principle 8:** Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions.

Doing  
**RISK ASSESSMENTS**

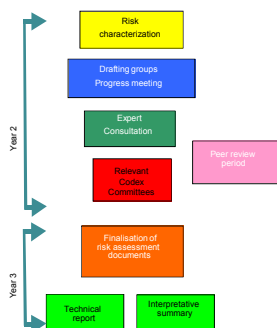
### Codex Alimentarius Commission

- International Body for Risk Management
- FAO/WHO Risk assessment bodies
  - Joint FAO/WHO Expert Committees
  - JEMRA... Joint Expert Meetings on Microbiological Risk Assessment
  - JECFA ... Joint Expert Committee on Food Additives
- Outputs of risk assessments considered by Codex Committees and adopted by CAC

### Microbial Risk Assessment



### Microbial Risk Assessment (continued)



### Case study - Listeria

- *Listeria monocytogenes* identified as a foodborne pathogen
- Zero tolerance in some countries
- FAO Expert Consultation
- Codex Committee on Food Hygiene develops risk assessment questions
- FAO/WHO performs risk assessment
- Results considered by CCFH, criteria developed

The risk assessment was intended to address three specific questions posed by the 37th session of the CCPIB (CAC, 2000) namely:

1. Estimate the risk of serious illness from *L. monocytogenes* in food when the number of organisms ranges from absence to 25 groups to 1000 colony forming units (CFU) per gram or millilitre, or does not exceed specified levels at the point of consumption.
2. Estimate the risk of serious illness for consumers in different susceptible population groups (elderly, infants, pregnant women and immunocompromised patients) relative to the general population.
3. Estimate the risk of serious illness from *L. monocytogenes* in foods that support its growth and foods that do not support its growth at specific storage and shelf-life conditions.

### Summary

- Scientific risk assessments necessary to communicate the risk of illness from foods
- Risk assessments are data and resource intensive
- FAO/WHO risk assessments are important for assisting food safety managers at national level

### The actual risk is the issue...

Actual Risk	Risk Factor	Perceived Risk
HIGH	microbiological contamination	LOW
	packaging failure	
	distribution failure	
	pesticide residues	
	biotechnology	
	food additives	
LOW	food irradiation	HIGH

But communication to consumers is vital...

### Risk Communication

- International Organizations (FAO/WHO, Codex, WTO)
- National Governments
- Industry
- Consumer and consumer organizations
- Academia
- Media

### Risk Communication

- The nature of the risk
- The nature of benefits
- Uncertainties in risk assessment
- Risk management options

### Principles of Risk Communication

- Know the audience
- Involve the scientific experts
- Establish expertise in communication
- Be a credible source of information
- Share responsibility
- Differentiate between science and value judgment
- Assure transparency
- Put the risk in perspective

### FAO/WHO Development of Scientific Advice

- FAO and WHO offer a neutral, international forum for scientific discussions on food safety and nutrition
- Advice provided by established expert committees (expert bodies) and *ad hoc* consultations

### Issues covered

- Safety assessment of chemicals in food
- Safety assessment of biological agents in food
- Assessment of production technologies for foods
- Human nutrition

### Joint FAO/WHO Expert Bodies

- Joint Expert Committee of Food Additives (JECFA) (1956)
- Joint Meetings of Pesticide Residues (JMPR) (1963)
- Joint Expert Meetings on Microbiological Risk Assessment (JEMRA) (2000)
- Joint Expert Meeting on Pesticide Specifications (JMPS) (2002)

### Other expert meetings and *ad hoc* consultations

- Convened to generate scientific advice or to respond to requests for advice
- All experts are selected on the basis of their expertise and in a personal capacity
- Selection procedures are closely monitored

Scientific advice provided to:

- Codex Alimentarius Commission (CAC) and subsidiary bodies
- Member countries
- Other interested parties – industry, consumer groups, research institutes, etc.

### Scientific advice definition:

- The conclusion of a skilled evaluation - taking into account the scientific evidence, including uncertainties (either in the current state of knowledge or adequacy of available data)

### Products of Scientific Advice

- Risk assessments – chemical or microbiological related to food
- Guidelines and resource documents related to food safety and nutrition
- Risk assessment methodology and international harmonization

### Legal framework and core principles

- Legal framework for provision of scientific advice is laid down in basic texts of both FAO and WHO

### Core principles include:

- Soundness – the need for scientific excellence
- Responsibility
- Objectivity – neutrality of both experts and their advice
- Fairness
- Transparency
- Inclusiveness – inclusion of minority scientific opinion

### Procedures for expert bodies and consultations

- Terms of reference exist for expert bodies or are prepared for consultations
- Rosters of experts available for expert bodies
- Call for experts for consultations followed by selection by joint secretariats
- Call for data

### Communication of Scientific Advice

Documented in various forms – monographs, technical reports or publication series (for expert bodies) depending on the target audience