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

- 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.

From country level to operational level
- Country Level
  - ALOP
  - Risk Assessment
- Operation Level
  - HACCP
  - Prerequisite Programmes
    - GMP
    - GHP
    - GAP
  - Physical Infrastructure
    - Layout and design of establishments
- Food safety control
  - High-level guidance
  - Providing guidance / targets
  - Links between operation & policy
- Food safety management
  - Local and specific
  - Management at supply chain level
## 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 Assessment** ("scientific")
  - Hazard identification
  - Hazard characterisation
  - Exposure assessment
  - Risk characterisation + quantification

- **Risk Management** ("policy")
  - Social
  - Economic

- **Risk Communication** (interactive exchange of information and ideas)

## 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
APPENDIX 3

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.

- **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.

- **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.

**Codex Alimentarius Commission**

- International Body for Risk Management
- FAO/WHO Risk assessment bodies
- Risk assessments - scientific process
  - 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**

- Request from Codex
- FAO/WHO JEMRA process
- MRA process
- Call for data
- Exposure assessment
- Hazard characterization
- Review of Expert Consultation
- Drafting groups
- Progress meeting
- Public review period
- Year 1: Request from Codex
- Year 2: Technical report, Interpretative summary
- Year 3: Finalisation of risk assessment documents

**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
### 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...

<table>
<thead>
<tr>
<th>Actual Risk</th>
<th>Risk Factor</th>
<th>Perceived Risk</th>
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</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>microbiological contamination</td>
<td>LOW</td>
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<tr>
<td></td>
<td>packaging failure</td>
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<td></td>
<td>distribution failure</td>
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<tr>
<td></td>
<td>pesticide residues</td>
<td></td>
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<td></td>
<td>biotechnology</td>
<td></td>
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<tr>
<td></td>
<td>food additives</td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>food irradiation</td>
<td>HIGH</td>
</tr>
</tbody>
</table>

But communication to consumers is vital...

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

### 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

### Risk Communication
- The nature of the risk
- The nature of benefits
- Uncertainties in risk assessment
- Risk management options
<table>
<thead>
<tr>
<th>FAO/WHO Development of Scientific Advice</th>
<th>Issues covered</th>
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<tbody>
<tr>
<td>• FAO and WHO offer a neutral, international forum for scientific discussions on food safety and nutrition</td>
<td>• Safety assessment of chemicals in food</td>
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<tr>
<td>• Advice provided by established expert committees (expert bodies) and <em>ad hoc</em> consultations</td>
<td>• Safety assessment of biological agents in food</td>
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<td>• Assessment of production technologies for foods</td>
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<td>• Human nutrition</td>
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</tbody>
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<thead>
<tr>
<th>Joint FAO/WHO Expert Bodies</th>
<th>Other expert meetings and <em>ad hoc</em> consultations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Joint Expert Committee of Food Additives (JECFA) (1956)</td>
<td>• Convened to generate scientific advice or to respond to requests for advice</td>
</tr>
<tr>
<td>• Joint Meetings of Pesticide Residues (JMPR) (1963)</td>
<td>• All experts are selected on the basis of their expertize and in a personal capacity</td>
</tr>
<tr>
<td>• Joint Expert Meetings on Microbiological Risk Assessment (JEMRA) (2000)</td>
<td>• Selection procedures are closely monitored</td>
</tr>
</tbody>
</table>

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