Overview of Risk Analysis Process

Shashi Sareen
Senior Food Safety & Nutrition Officer
FAO Regional Office for Asia and the Pacific
Bangkok, Thailand
Coverage

• Background and importance of risk analysis
• Hazards and risks
• Risk analysis and Codex
• Components of risk analysis and a conceptual model
• Features and benefits of food safety risk analysis
KOREANS NAME FOOD SAFETY AS BIGGEST HEADACHE

A survey released yesterday said food safety is more of a concern for Koreans than national security, with 60 percent of the people believing social issues are a greater worry. The Korea National Statistical Office said 42,000 people were surveyed and 20,000 said food safety was a concern.

Chinese milk powder contaminated with melamine sickens 1,253 babies

Chinese hospitals are fighting to save the lives of some of the 1,253 babies who have fallen sick after they were fed milk powder with melamine. Two children have already died, and a woman used to make milk powder and drinking the formula that killed her children.

Improvements in food safety urged

Salmonella outbreak exposes food-safety flaws

The twisting road that led federal investigators to announce Monday that they found a single contaminated jalapeño pepper grown in Mexico appears to have started with a distribution center in New York City.

Vietnam to intensify food safety

Education and media campaigns on ensuring food safety must be raised, local news said. An order must be enforced on suspected offenders, and an independent inspection must be made.

Source of tainted tomatoes may stay a mystery

The Food and Drug Administration may never be able to pinpoint the origin of salmonella-tainted tomatoes that have sickened hundreds of people, the agency's official said Wednesday. "We may not ultimately know where these came from," Dr. David Acherson, the agency's associate commissioner for food, said. "We're not going to be realistic. The agency is invested in disclosure of the chain."

Consumer group seeks ban on some food dyes

A New York company is voluntarily recalling about 286,000 pounds (129,700 kg) of fresh chicken and pork products that may be contaminated with salmonella-tainted tomatoes linked to a number of illnesses.

Mums-to-be warned of fish danger

Mums-to-be and those planning to have children should avoid eating too much fish as it may contain excessive levels of mercury, the Centre for Disease Control and Prevention said.

U.S. company recalls meat

The European Commission warned Italian authorities it could join Japan and South Korea's import ban on mozzarella imported from the United States because of contamination.

Salmonella-infected tomatoes linked to markets, restaurants

Health group urges overhaul of US food safety system

Food safety and Olympic challenge for Beijing Games

CHINA REPORTS BIG RISE IN FOOD-POISONING DEATHS
Some recent food safety examples

- **Melamine** Contamination of Infant Formula in 2008
- **E.coli O104:H4** (in 2011) in northern Germany
  - serious outbreak of foodborne illness (characterized by bloody diarrhoea, serious complications)
- **Dioxin** contaminated Irish pork in 2008
- **radionuclide** contamination of food items from Japan
- **Pesticide residues** found by EU in vegetable consignments from Thailand in 2009-11
- **Influenza A (H7N9)** virus in poultry in China
Factors driving changes in food safety systems

- Innovations in food industry/new technologies
- Greater public demands for health protection
- Increasing population/urbanization & demand for food
- Scientific research outcomes
- Changing agricultural practices & climate
- Consumer, Media
- Imported food failures
- Globalization & increasing volume/diversity of trade in food
- Food Incidents
Some Data on Foodborne Illnesses

- WHO estimates that foodborne and waterborne diarrhoeal diseases cause ~2.2 m deaths worldwide annually (1.9 m children)

- US – around 1 in 6 Americans (or 48 million people) gets sick, 128,000 hospitalized, 3,000 die of foodborne diseases (20% known pathogens & 80% unknown agents) (Source CDC)

  Top five - Norovirus, *Salmonella* nontyphoidal, *Clostridium perfringens*, *Campylobacter spp*, *Staph aureus*

- Australia – 5.4 million cases/ year of gastroenteritis

- **Data from Asia/ SAARC ??**
Foodborne Risks

• Arise from hazards – chemical, microbiological & physical (familiar & new)

• Hazard and Risk

• 2 important aspects to deal with risks
  – What is the nature and magnitude of the health risk?
  – How should the risk be managed and communicated to those affected?

• Risk analysis - A systematic approach to examine and assess public health & safety risks associated with food & identify and implement appropriate measures to manage the risks and communicate with stakeholders on the risks as well as risk mitigating measures
Key concept : Hazard vs risk?

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Risk: A function of the probability of an adverse health effect & the severity of that effect, consequential to a hazard(s) in food.
Example of important Chemical hazards for food safety in the region

• **Metals**
  – Arsenic
  – Cadmium
  – Lead
  – Methyl mercury

• **Mycotoxins**
  – Aflatoxins
  – Zearalenone
  – T2-toxin
  – HT-2 toxin
  – Deoxynivalenol
  – Nivalenol
  – Patulin

• **Marine toxins**
  – Paralytic shellfish poisoning toxins
  – Diarrhetic shellfish poison toxins
  – Ciguatera poisoning toxins
  – Domoic acid
  – Brevetoxin

• **Process contaminants**
  – Acrylamide
  – Polycyclic aromatic hydrocarbons
  – Furan
  – 3-monochloropropane-1,2-diol (3-MCPD)
  – 3-MCPD fatty acid esters

Example of Japanese Case
Example of important Microbiological hazards for food safety in the region

• *Campylobacter*
• *Enterohemorrhagic Escherichia coli*
• *Listeria monocytogenes*
• *Salmonella*
• *Norovirus*
• *Kudoa septempunctata*
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A key discipline to reducing foodborne illnesses and strengthening food safety systems
• Demand for scientific advice has increased

- WTO’s recognition of Codex as benchmarked standards for food safety in international trade (SPS Agreement)

- Increasing accountability demanded of governments & food producers to demonstrate the scientific basis for food safety measures
Rights
• Right to apply sanitary & phytosanitary measures necessary for the protection of human, animal & plant life or health

Obligations
• Apply to the extent necessary
• Measures based on scientific principles
• Non-discriminatory
• No disguised restrictions on trade

Key provisions – Harmonization (Article 3) & Risk assessment (Article 5)
Scientific Justification of SPS Measures

Measures conform to international standards
(Article 3)

Measures based on a risk assessment
(Article 5 & 2)
Strategic Vision Statement

“The CAC envisages a world afforded the highest attainable levels of consumer protection including food safety & quality.

To this end, the Commission will develop internationally agreed standards & related texts for use in domestic regulation & international trade in food that are based on scientific principles and fulfil the objectives of consumer health protection & fair practices in food trade”
Codex & Scientific Advice

- Strategic Goals (Codex strategic Plan 2008-13)
  - Promoting sound regulatory framework
  - Promoting widest & consistent application of scientific principles & risk analysis
  - Strengthening Codex work management capabilities
  - Promoting cooperation b/w Codex & Relevant International organisations
  - Promoting maximum & effective participation of members
Risk analysis Principles in Codex and Components of Risk Analysis
Working Principles for Risk Analysis for Food Safety for Application by Governments

Procedural manual (twenty-First edition)
Chapter 1: An introduction to risk analysis
Chapter 2: Risk management
Chapter 3: Risk assessment
Chapter 4: Risk communication

Annexes
- Glossary
- Case study of Methylmercury in fish
- Case study of *Listeria monocytogenes* in ready-to-eat foods
Components of Risk Analysis
Components of Risk Analysis

Risk Assessment
Science based

Risk Management
Policy based

Risk Communication
Interactive exchange of information & opinions concerning risks
Risk assessment

• A scientifically based process consisting of the following steps:
  
i) hazard identification;

ii) hazard characterization (evaluate nature of adverse health effects);

iii) exposure assessment (likely intake of hazard – presence in food and food consumption);

iv) risk characterization (probability of occurrence & severity of adverse health effects)

Science based (but may also involve judgments and choices that are not entirely scientific!)
Simply......

• RA is a scientific process which consists of determining the likelihood and severity of an adverse health effect in a population exposed to a certain hazard/pathogen-food combination
Risk management

• The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Considers also economic, social, cultural and ethical factors
Risk communication

The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among

– risk assessors,
– risk managers,
– consumers,
– industry,
– the academic community and
– other interested parties,

including the explanation of risk assessment findings and the basis of risk management decisions.
Risk communication

• **Dialog** between risk assessors and risk managers

• **Dialog** between risk managers and stakeholders including consumers
Working Principles for Risk Analysis for Food Safety for Application by Governments
• Risk Analysis: general aspects

- **Overall Objective** - to ensure human health protection.

- **Risk analysis should be:**
  - applied consistently, in a non discriminatory manner (national food control and food trade);
  - open, transparent, documented; and
  - evaluated & reviewed in the light of new scientific data

- **Follow a structured approach** – 3 distinct but closely linked components
• Risk Analysis: general aspects
......Contd

❑ Functional separation - of risk assessment and risk management to the degree practicable

○ What do we mean?
  - Clear delineation between the science and policy
  - Science is undertaken objective manner – without any substantiative input of risk management
  - Maintain transparency

○ Why?
  - ensure the scientific integrity of the risk assessment,
  - to avoid confusion over the functions to be performed by risk assessors & risk managers, and
  - to reduce any conflict of interest
• Risk Analysis: general aspects
   .....Contd

- **Interaction** b/w risk assessors and risk managers is essential

- **Precaution** - is an inherent element of risk analysis. Due to uncertainty and variability

- National governments to take into account guidance/ information from RA activities of Codex, FAO/WHO, others – also share information and experiences with international organizations
Preliminary RM Activities

- Identify FS Problem
- Develop Risk Profile
- Establish RM goals
- Decide on need for RA
- Establish RA Policy (framework)
- Commission RA (if needed)
- Consider results of RA
- Rank risks (if necessary)
- Identify, evaluate, select RM options
- Implement RM decision
- Monitoring and Review

Risk Assessment (RA)

- Hazard Identification
- Hazard Characterization
- Exposure Assessment
- Risk Characterization

Risk Management (RM)

- Risk Communication

Adapted from a model by Dr. Yukiko YAMADA
Risk Assessment Bodies (International)

- JECFA
- JMPR
- JEMRA

Chemical risks

Microbiological risks

Ad hoc consultations
- biotechnology
- probiotics
- micronutrients
- nanotechnology
Risk Analysis & Standards: Inter-relationships International Level

International risk manager
CODEX
International risk assessment
JECFA, JMPR, JEMRA, ad hoc expert consultations

Member Countries

Data, expertise
Scientific advice

Needs, feasibility, inputs, etc.

International trade agreements

Standards, guidelines, related texts

International Level

WTO Agreements

Scientific advice
Requests for advice, risk assessment

Benchmark standards
Government structure to deal with Risk Analysis

- **Risk Management** – number of organizations
- **Risk Assessment** – may have a separate structure/organization (EFSA, China, HK, Japan)
- **Other options** – separate personnel, assembling a multidisciplinary team of scientists, academic institutions designated...
- **Important that specific principles followed** – document, Transparency, expertise, free of conflict of interest, non-biased, based on scientific data...
- **Risk Communication** – to some extent
- **Many countries use international RA** – atleast as a starting point
Food Safety Risk Analysis: Features and Benefits

Internationally recognized
  Adopted by Codex; thus supports international food safety harmonization and thereby trade

Based on science
  Risk assessment and science-based food safety measures are recognised and promoted by WTO

Consumer protection focus
  Provides a scientific evaluation of where in the food chain to take the most effective control steps
Adaptable

Can be applied to address a range of food safety concerns including emerging food pathogens

Inclusive

Promotes stakeholder participation; facilitating balanced decision-making and compliance

Enables tailored decisions

Supports informed decision making and allows consideration of available resources and local situations
THANK YOU

Any Questions??