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CENTER**



## Basic Risk Assessment Training

May 27 - 29, 2015 • Bogor, Indonesia

### Module 1B:

# Introduction to Risk Analysis

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### Module 1B:

# Introduction to Risk Analysis

Presented at

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Basic Food Safety Risk Assessment Training  
BPOM RI, ILSI SEAR dan SEAFAST Center  
27 - 29 Mei 2015  
SEAFAST center, IPB, Bogor



## Risk Analysis is NOT really a New Concept?

- **Risk analysis** existed for over a century
- It was widely used in such diverse areas as
  - Insurance
  - Investment
  - Engineering




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## Risk Analysis is NOT really a New Concept?

- It is used to develop an estimate of the risks
- For food safety : risk to human health and safety).




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## Risk Analysis is NOT really a New Concept?

- It is not designed to provide a *decision*




Instead

- It is a tool to support decision - making


Decision concerning

- whether a risk is acceptable, and
- what would be done to reduce or eliminate risk

is taken at a political level









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## Risk Analysis & CODEX ?

- Scientific principles
- *Recommendation on “Joint FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, Rome” (1991) : The CAC and its relevant Committees .... should make explicit the methods they have used to assess risk*



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## Risk Analysis & CODEX ?

- Scientific principles
  - CAC accepted the Conference Recommendation (1991)
  - CAC approved the use of *risk analysis* in Codex work (1993)

FAO/WHO  
guide for application of  
risk analysis principles and  
procedures during  
food safety emergencies

World Health  
Organization

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## Risk Analysis & WTO (SPS) ?

- The SPS Agreement  
Article 5.1

**Members shall ensure that their sanitary and phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life and health, taking into account risk assessment techniques developed by the relevant international organizations**





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## Risk Analysis & WTO (SPS) ?

- The SPS Agreement

Countries may introduce or maintain different standards (measures), based on scientific justification or use a higher level of protection (Article 2.3)

The scientific justification must be based on a risk assessment  
(Article 2.3 and Article 5)



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## Risk Analysis & WTO (SPS) ?


- The SPS Agreement

Food safety measures that conform to the standards elaborated by the Codex Alimentarius Commission are presumed to be consistent with the WTO's SPS Agreement

*This means that no further risk assessment is required: Codex has already provided it*





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## Why Risk Analysis ?

- Hazards and risks are natural part of life (Everyone faces potential hazards and risks every day)



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## Why Risk Analysis ?

- Hazards and risks are natural part of life (Everyone faces potential hazards and risks every day)

Even in a “fun” game :



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## Why Risk Analysis ?

- Hazards and risks are natural part of life (Everyone faces potential hazards and risks every day)
- Risk means different things to different people





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## Why Risk Analysis ?

- Hazards and risks are natural part of life (Everyone faces potential hazards and risks every day)
- Risk means different things to different people
- NEEDS harmonized methods to analyse risk

→ RISK ANALYSIS



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## Risk Analysis to Food Safety

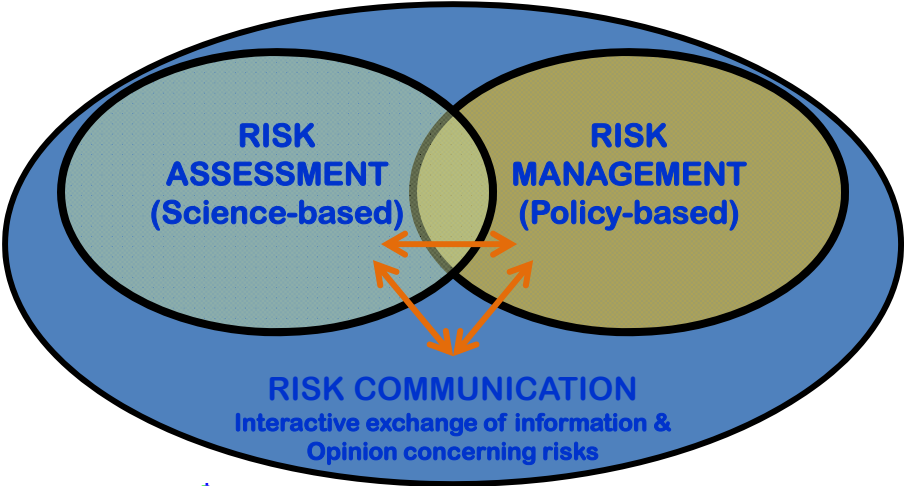
- WHO and FAO are in the forefront of the development of risk-based approaches for the management of public health hazards in food.
- The approach used is called Risk Analysis (RA).
  - RA is made up of three components:
    1. Risk assessment
    2. Risk management
    3. Risk communication




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## Risk Analysis to Food Safety



**RISK ASSESSMENT**  
 (Science-based)

**RISK MANAGEMENT**  
 (Policy-based)

**RISK COMMUNICATION**  
 Interactive exchange of information & Opinion concerning risks




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**Risk Analysis to Food Safety:**

**1 Risk Assessment**

**So .. What is Risk?**

- Risk is a measure of the likelihood of a hazard occurring.
- A food safety hazard is a biological, chemical or physical problem with food that can **potentially** cause a health problem.




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**Risk Analysis to Food Safety:**

**1 Risk Assessment**

**So .. What is Risk?**

- Risk is associated with “negative” (“unwanted” adverse effect)
- Risk is composed of two main elements:
  1. Probability or likelihood of an adverse effect occurring
  2. Magnitude of the consequences (severity)

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## Risk Analysis to Food Safety:

### 1 Risk Assessment

A scientifically based process consisting of the following steps:


- (i) hazard identification,
- (ii) hazard characterization,
- (iii) exposure assessment, and
- (iv) risk characterization

**Science-based Activities:  
By Risk Assessor**





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## Risk Analysis to Food Safety:

### 1 Risk Assessment

(i) **Hazard identification**

- Is there a problem?
- What is it: pathogen? associated food?

(ii) **Hazard characterization**


- What happens when pathogen is ingested?
- How much of it causes illness?

(iii) **Exposure assessment**

- What is the probability of eating contaminated food?
- How many pathogens are likely to be in the food when you eat it?

(iv) **Risk characterization**

- What are the nature and likelihood of the health risk?
- Who is likely to become ill? How many?
- What are the sources of variability and uncertainty in the information used?




## Risk Analysis to Food Safety:

### 1 Risk Assessment -- illustration

Likelihood	High	3	6	9	
	Medium	2	4	6	
	Low	1	2	3	
		Lowest Risk	Low	Medium	High
					Severity

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## Risk Analysis to Food Safety:

### 1 Risk Assessment -- illustration

In walking across the street

- the probability of being hit by a pedestrian
- the probability of being hit by a bicycle, or
- the probability of being hit by a car

And

- The consequences of being hit by a pedestrian
- The consequences of being hit by a bicycle, or
- The consequences of being hit by a car

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## Risk Analysis to Food Safety:

### 2 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

**Policy-based Activities:  
By Risk Manager**



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## Risk Analysis to Food Safety:

### 2 Risk Management

Four major elements of risk management as follows:

- risk evaluation;
- risk management option assessment;
- implementation of management decision; and
- monitoring and review.



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## Risk Analysis to Food Safety:

### 3 Risk Communication

The interactive exchange of information and opinions throughout the risk analysis process concerning **hazards and risks, 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

**By Risk Communicator**



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## Risk Analysis to Food Safety:

### 3 Risk Communication

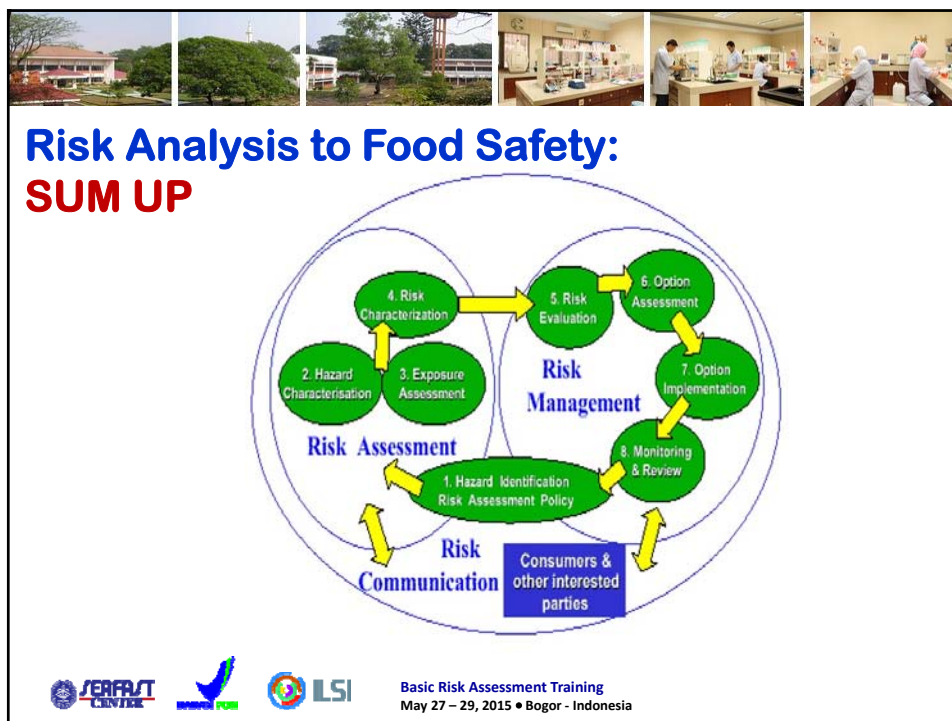
Main components of risk communication include:

- promoting awareness
- promoting consistency and clarity
- providing background information
- explaining risk management decisions to stakeholders
- promoting appropriate involvement from all stakeholders
- exchanging information, perceptions and knowledge



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## Risk Analysis to Food Safety:

### PRINCIPLES (2)

- Precaution is an essential element of risk analysis
  - WHAT IF evidence of a risk to human health exists, BUT scientific data are insufficient or incomplete?
    - May not proceed to elaborate a standard
    - Considers elaborating a related text (Code of Practice?)
      - Such a text should be supported by the available scientific evidence



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## Risk Analysis to Food Safety:

### PRINCIPLES (3)

#### Risk Analysis outcome:

- Quantitative or qualitative estimate of the likelihood of and adverse consequence due to exposure to a hazard to one or more populations
- One or more options to manage risk, and
- Recommendations to communicate the management of the risk to consumer



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## Risk Analysis to Food Safety:

### CONCLUSIONS (1)

1. Risk analysis is a framework for standard development, to facilitate harmonization
2. Report of Risk analysis may be used to establish the *equivalence* of measures or systems designed to address risk
3. Standards, codes and other measures may be assessed to determine if they are equivalent to internationally accepted standards or the standards of their trading partners



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## Risk Analysis to Food Safety:

### CONCLUSIONS (2)

4. Risk Analysis should be used as basis for decision-making in the management of food safety risks
5. Other legitimate factors in decision-making may be considered, but
  - a) they need to be well documented
  - b) should not affect the scientific process
  - c) are not an alternative to the scientific process



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## Risk Analysis to Food Safety:

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## RESOURCES

**CAC**

- <http://www.codexalimentarius.net>

**JECFA Related Information**

- <http://www.who.int/pcs/JECFA/jecfa.htm>

**JMPR Related Information**

- <http://www.who.int/pcs/JMPR/JMPR.htm>

**Expert Consultation Reports**

- <http://www.fao.org/WAICENT/FAOINFO/ECONOMIC/ESN/expertfq.htm>

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## THANK YOU

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