OVERVIEW OF RISK ANALYSIS

APEC workshop: *Hot Issues in Risk Analysis*

August 1, 2009 - Singapore

Risk

- Risk is everywhere
- Some risks more serious than others
- Zero risk is not an option
- Is unavoidable
- Is uncertain

By: Dr. Charles Yoe

Risk Definition

- Risk = probability of an adverse event and the magnitude of the consequences
- Elements of risk:
  - Probability *(or likelihood, chance)*
  - Consequences *(or impact)*
  - Uncertainty
  - Ability to manage

By: Dr. Charles Yoe

Examples

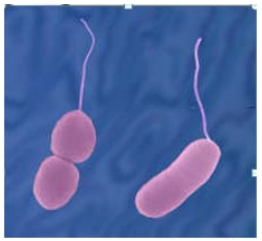
- In animal health:

  Risk = chance of a disease being introduced in a country

- In food safety:

  Risk = chance of getting sick from foodborne pathogens

  = [Hazard] x [Exposure]



Concentration and prevalence of pathogen

x

Number of servings produced

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Food Safety Hazard Concerns

- Misuse of food additives, colors and flavors
- Veterinary drug residues and use of growth promoters
- Animal feed additives
- Fertilizer and growing aids
- Irradiation
- Microbiological contamination
  - Ubiquitous
  - Re-emerging
  - Newly emerging
- Mycotoxins and other naturally occurring food toxicants
- Pesticide residues
- Pollutants
- Defective packaging and labeling
- Adulteration and tampering
- Extraneous matter
- Biopesticides & transgenic insects
- Inspection and sampling

By: Dr. Charles Yoe

Traditional Food Safety System Focus

- Hygiene
- Inspection
- End product testing
- May include food laws & regulations, food control management, inspection & laboratory services, mechanisms for information, education & communication

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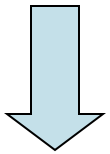
Changes in Food Production and Consumption

- Large scale production
- Global supply chains
- Relentless pressure to lower costs
- Temptation for economic adulteration
- Untrained food workers
- More food consumed outside the home
- More year round foods
- More exotic foods and imports
- Less time for food preparation-microwaves
- More immuno-compromised consumers
- Increasing importance of international trade

By: Dr. Charles Yoe

Science-Based Food Safety System

- We need to. . .
  - Describe the risk (Risk Assessment)
  - Do something about (Risk Management)
  - Talk about it (Risk Communication)



Risk Analysis

By: Dr. Charles Yoe

Risk Analysis

- A systematic way of gathering, evaluating, and recording information leading to recommendations for a position or action in response to an identified hazard
  - applied consistently
  - open, transparent and well documented
  - evaluated and reviewed as appropriate in the light of newly generated scientific data

Risk Analysis

- These principles apply equally to issues of national food control and food trade situations and should be applied consistently and in a non discriminatory manner
- To the extent possible, the application of risk analysis should be established as an integral part of a national food safety system

Why Do Risk Analysis?

- To improve the quality of our thinking before a decision is made — uncertainty is ubiquitous
- To help assure a safe domestic food supply
- To protect human, animal, and plant life and health
- Allow industry to innovate
- It's essential for international trade

By: Dr. Charles Yoe

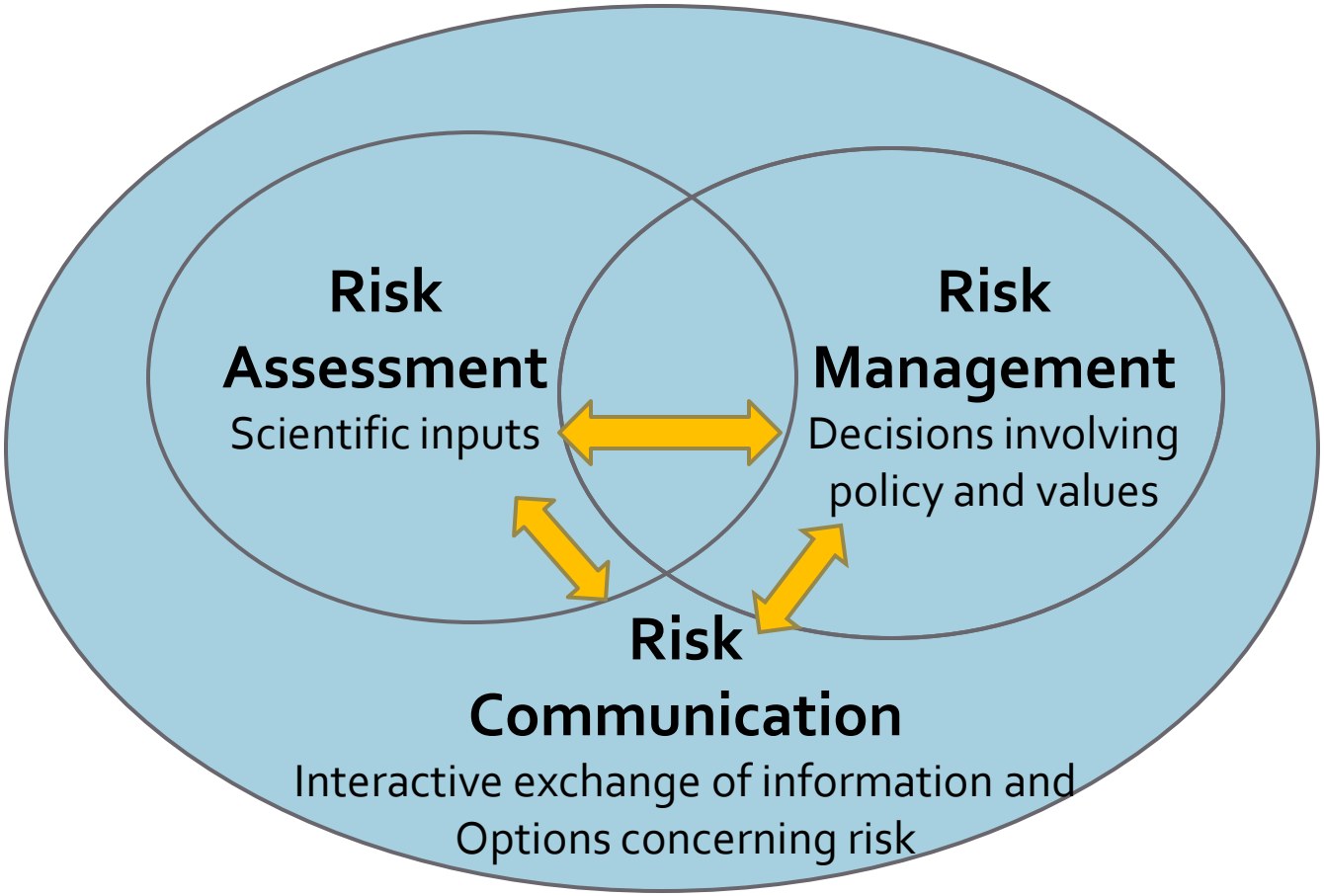
International Trade – WTO

- World Trade Organization (WTO)
  - Established in 1995 to facilitate international trade by serving as a
    - forum for negotiating trade agreements
    - place to settle trade disputes
    - system of trade rules
  - Relevance for Food Safety
    - Sanitary and Phytosanitary (SPS) Agreement

Risk Analysis and WTO/SPS

- WTO members shall: *(in the context of food safety)*
  - Ensure that any measure applied only to the extent necessary to protect human life and health
  - Base their measures on risk assessment, taking into account the techniques developed by international organizations
  - Implement a measure that differs from international norms where a higher appropriate level of protection is a legitimate goal
  - Apply the principles of equivalency where a different measure in an exporting country achieves their appropriate level of protection
- Risk assessment as the system to develop and apply standards for foods in international trade

Risk Analysis framework



Codex Committee on Food Hygiene

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."

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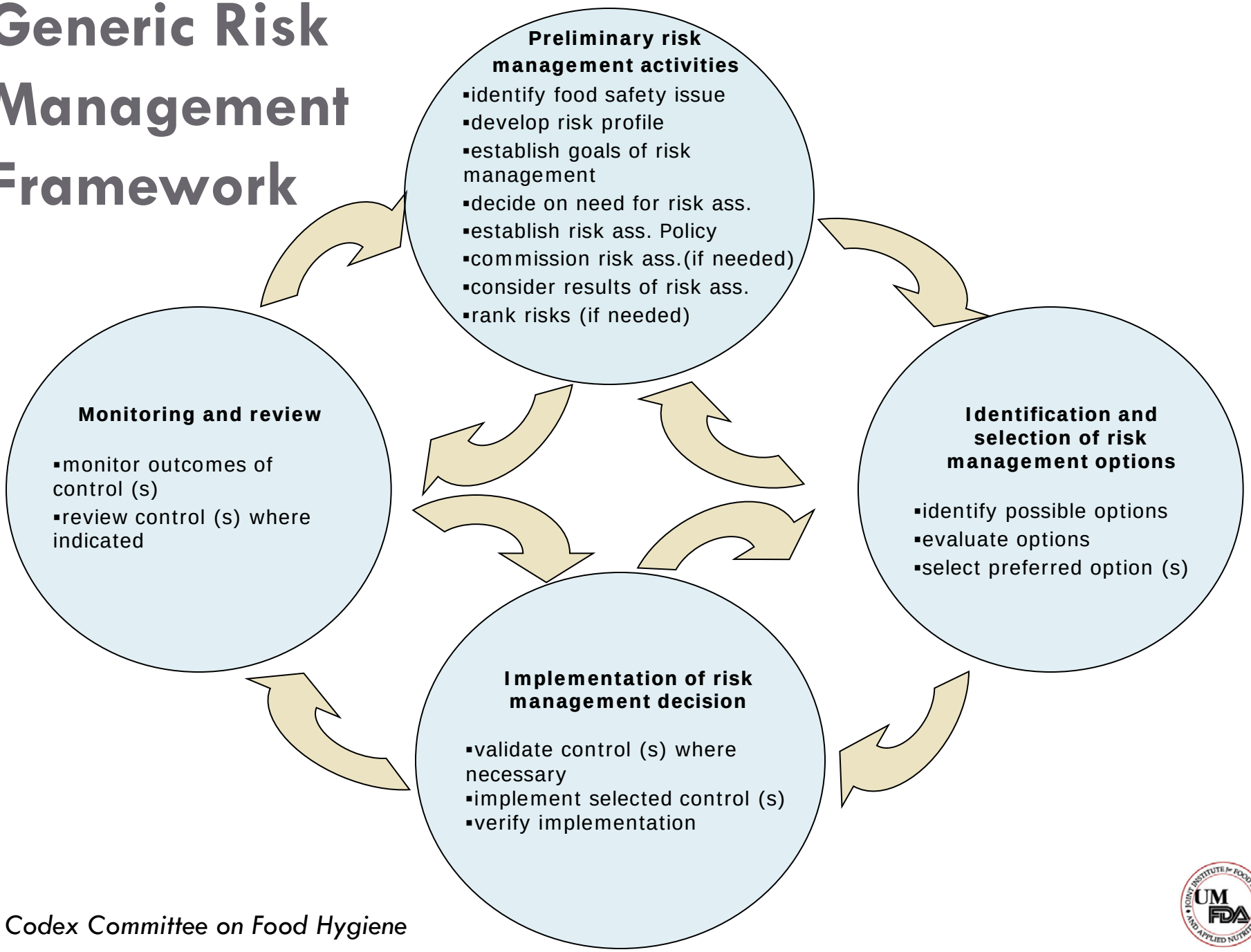
Generic Risk Management Framework



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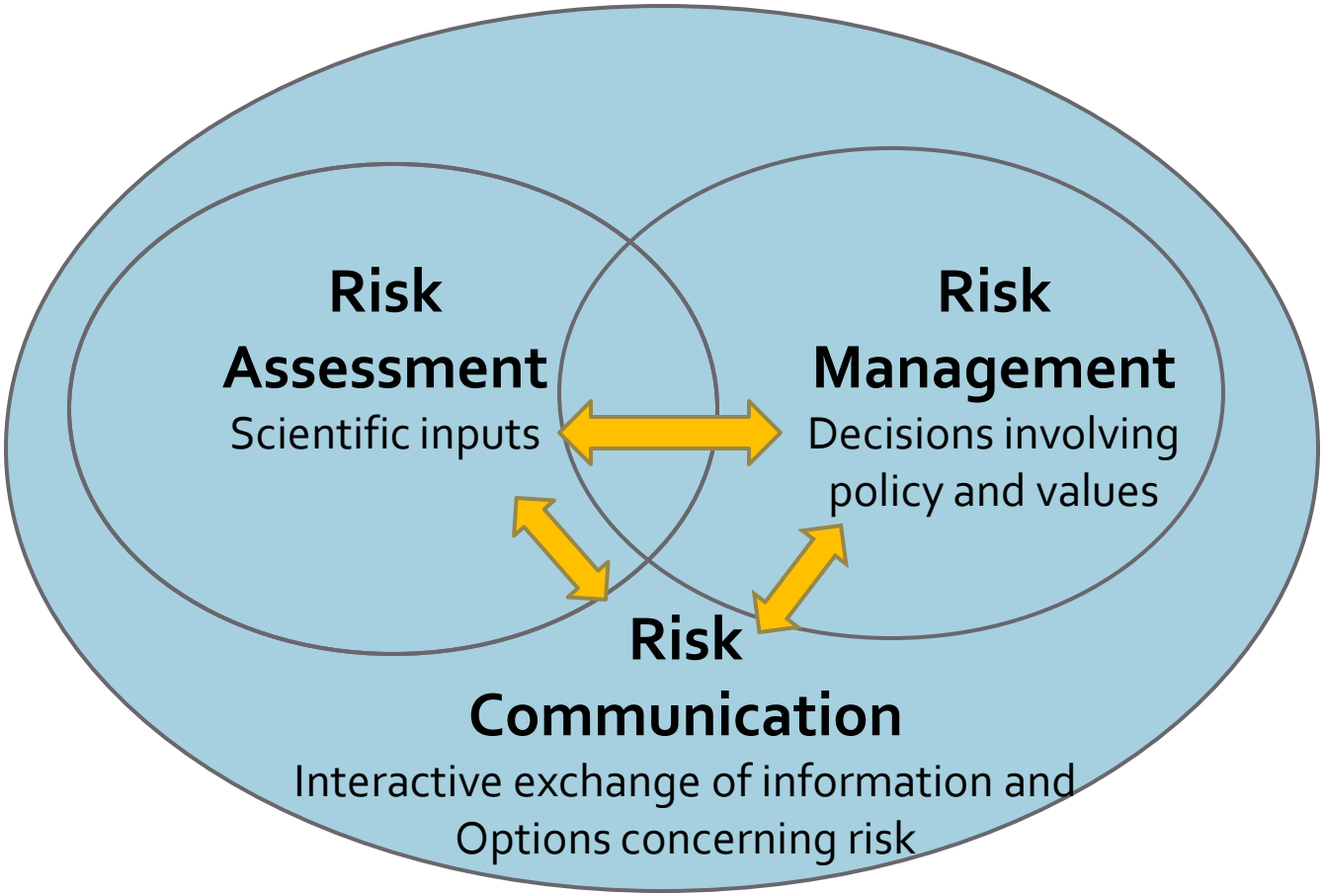
Risk Analysis framework



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Risk Assessment

"A scientifically based process consisting of the following steps:"

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

Risk Assessment – Hazard Identification (i)

"The identification of biological, chemical and physical agents, capable of causing adverse health effects and which may be present in a particular food or group of foods"

- Risk profile may be sufficient
- Identify specific risk factors

Risk Assessment – Hazard Characterization (ii)

"The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable"

- Dose-response relationship: levels of exposure to the hazard and the likelihood of different adverse health effects
  - morbidity/hospitalization/mortality/sequelae associated with different doses
- Data: animal toxicity studies, clinical human exposure studies and epidemiological data from investigations of illness

Risk Assessment – Exposure assessment (iii)

"The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures to other sources if relevant"

- Amount of hazard consumed by various members of the population
- [Concentration of the hazard / changes in concentration (increase/decrease)] X [food consumption pattern]

Risk Assessment – Risk Characterization (iv)

"The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment"

- Combines hazard characterization and exposure assessment to generate risk
- Describes uncertainty and variability
- May include comparative rankings

Risk Assessment

- Organizes the relevant science
- Answers risk manager's questions
- Characterizes the risk
- Models of reality
  - Qualitative (descriptive model)
  - Quantitative (mathematical model)
    - Deterministic
    - Stochastic/Probabilistic
- A risk assessment model must fit a purpose

Qualitative Risk Assessment

- The process of compiling, combining and presenting evidence to support a statement about risk
  - Descriptive or categorical treatment of information
  - Is formal, organized, reproducible method based on science and sound evidence
  - Easy to explain to others
  - For routine non controversial tasks
  - When theory, data, time or expertise are limited
  - Good for establishing relative risks or evaluate relative impacts on risk mitigation strategies
  - Supports risk management decision making – but limited in the sense that does not provide a probability

Qualitative Risk Assessment - Example

"What is the probability of introduction and transmission of H5N1 HPAIV into the 1-km buffer zone surrounding a compartmentalised (integrated) poultry farm in Thailand?"

Pathways for introduction	Release		Exposure & Consequence		Overall Risk	
	Risk	Uncertainly	Risk	Uncertainly	Risk	Uncertainly
Wild birds	Very low	Medium	Medium	Medium	Very low	Medium
Live poultry	Very low	High	Very high	High	Very low	High
Free-ranging ducks	Very low	Low	Very low	Very low	Medium	Medium
Fertilizers	Very low	Medium	Very low	Very low	Medium	Medium
Humans	Very low	Medium	Low	Low	High	High

From: Qualitative Risk Assessment of the Risk of Introduction and Transmission of H5N1 HPAI Virus for 1-km Buffer Zones Surrounding Compartmentalised Poultry Farms in Thailand
http://www.research4development.info/PDF/Outputs/HPAI/WP7_090216.pdf

Quantitative Risk Assessment

- Mathematical modeling
  - Deterministic model
    - Assumes inputs are know and fixed values with no randomness
    - A given input will always produce the same output
    - Model can be built using expected value, worst case estimates etc.
    - Difficult to interpret point estimates – there is no probability associated with the outcome
  - Stochastic/Probabilistic model

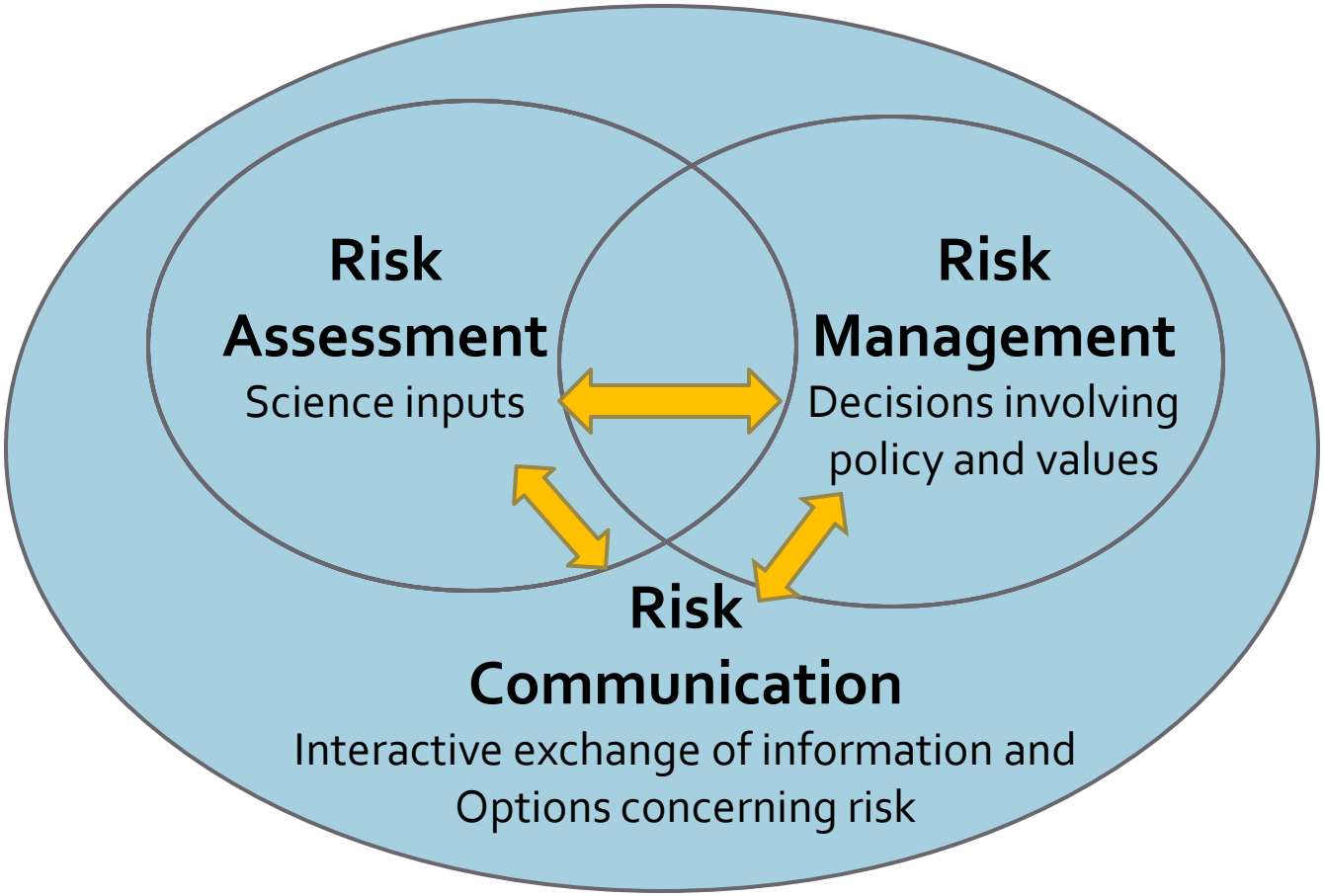
Quantitative Risk Assessment

- Mathematical modeling
  - Deterministic model
  - Stochastic/Probabilistic model
    - Values can be entered as probability distributions - incorporate randomness
    - Monte Carlo simulation allows to simulate uncertainly and variability in the values
    - Outcome has a probability associated with it
    - Allows for Sensitivity analysis – which inputs in your model impact more significantly the output

Risk Assessment

- Uncertainty
  - Reflects the level of knowledge the assessor has regarding the components of the risk assessment
  - More study, research, elicitation reduce uncertainty
- Variability
  - Refers to the fact that natural phenomena have inherent dispersion
  - Irreducible

Risk Analysis framework



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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. "

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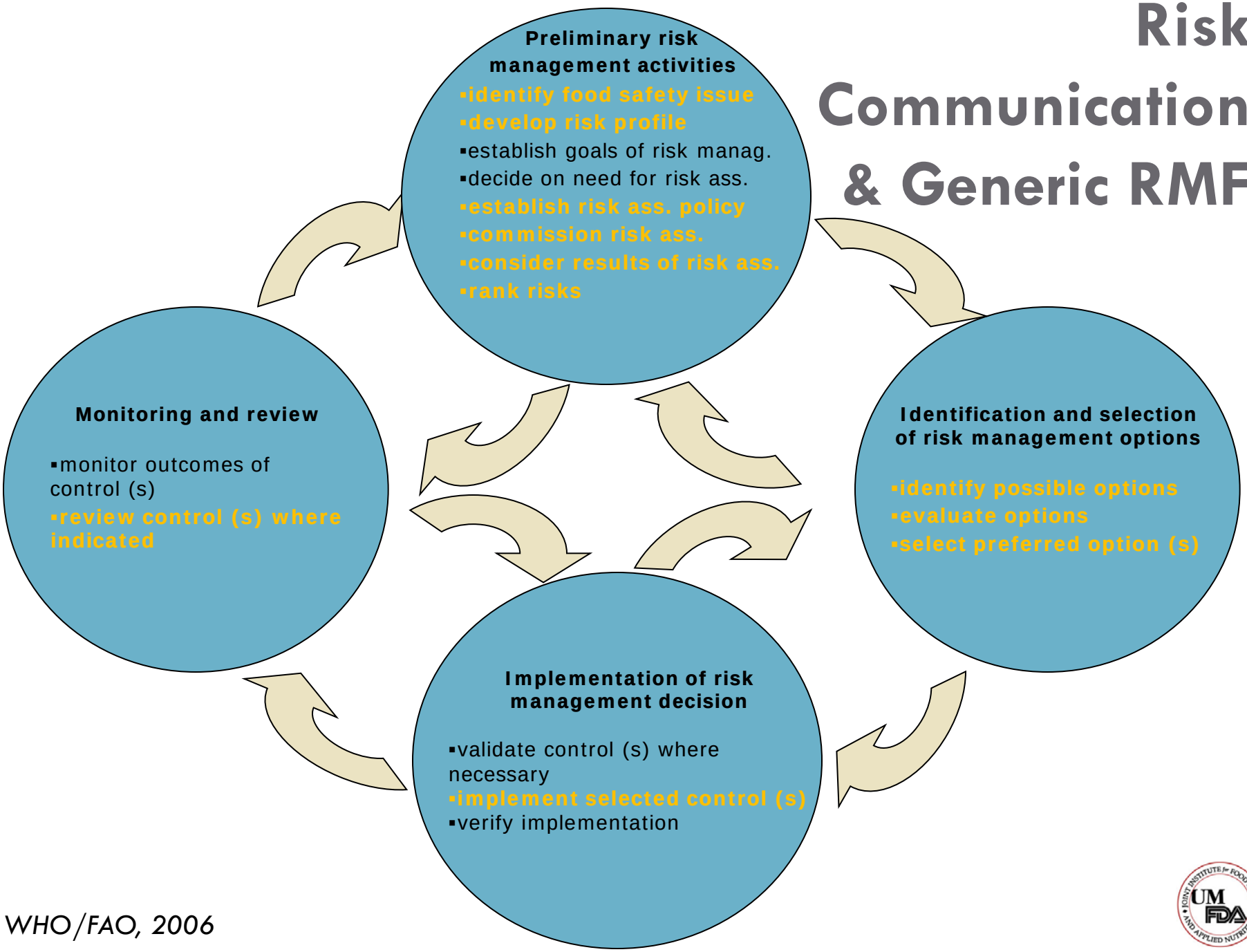
Risk Communication & Generic RMF



WHO/FAO, 2006

Risk Communication

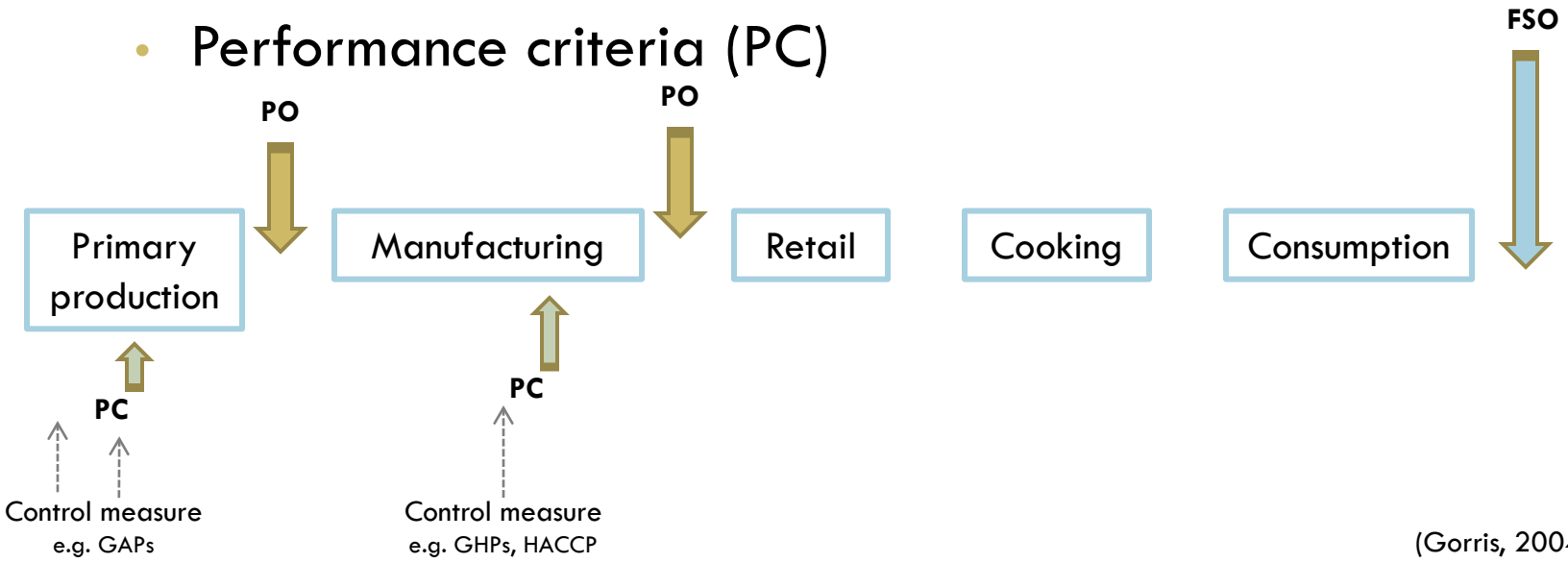
- Contributes to transparency
- Promotes broader understanding and acceptance of risk management decisions
- WTO/SPS Agreement requires governments to:
  - Notify other countries of any new or changed sanitary requirements which affect trade
  - Set up "enquiry points" to respond to requests for more information or new or existing measures

Tools for Risk Analysis

- Capacity building – training online and conventional classroom format
- FoodRisk.org
  - Online resource for food safety risk analysis
  - Risk assessment models
  - Raw data
  - Tools (i.e.: iRisk, food handling model)
  - Relevant literature and documents
  - Tutorials

Hot Issues in Risk Analysis

- Risk-base sampling and inspection
- Development of quantitative microbiological metrics for risk management
  - Food safety objectives (FSO):
  - Performance objectives (PO)
  - Performance criteria (PC)



(Gorris, 2004)

Hot Issues in Risk Analysis

- Risk Prioritization
  - Optimize the use of financial resources by using science-based approach to improve public health and international trade
  - Healthy adjusted life years (HALY):
    - DALY: disability adjusted life years ⟹ Global burden of disease (WHO)
    - QALY: quality adjusted life years
  - Methods to incorporate other measures that impact risk prioritization (e.g.: financial impact on economical sector, consumer perception and acceptance of risk)
    - Multi-criteria decision analysis (MCDA)
    - More transparent and accountable framework

Conclusions - Risk Analysis

- It is a systematic way of thinking about risk and organizing to solve problems
  - It is an ongoing activity
- Purpose oriented to find right problem
- It is the interface between science and values
- Data intensive
- Requires analytical and administrative capacities

Thank you

Questions?

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