The Language of Risk Analysis

Overview of Risk Analysis

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Food Safety – Potential Risks

- Microbial
  - Bacteria
  - Protozoa
  - Viruses
  - Fungi
  - Algae
  - Parasites (nematodes)
- Chemical
  - Toxic elements
  - Contaminants
  - Naturally-occurring toxins
  - Pesticides
- Allergens
- Physical Objects

Significant Progress

- Refrigeration
- Pasteurization
- Organoleptic inspections
- Improved crop varieties, insecticides, herbicides
- Pesticide regulation
- Food safety laws and regulations
- No misbranded and adulterated foods, drinks, and drugs in interstate commerce
- No color additives to conceal inferiority
- No use of "poisonous" colors
- Require plainly marked contents
- Government food standards
- No food additive shown to induce cancer in humans or animals
- Manufacturers of new food additives & colors must establish safety to regulators' satisfaction

New Problems Arise (Food)

- New hazards
  - Pathogens
  - Chemicals
- New behaviors
  - Supply chain integrity
  - Economic adulteration
    - Horse meat in beef, rat as mutton
  - Food defense

Problems Persist-Global Issue

- ~2.1M children < 5 die of diarrheal diseases attributable to foodborne illness
- ~13M children < 5 die from infections & malnutrition attributable to contaminated food
- Serious & chronic health effects of foodborne illness affect 3 of every 1,000 prenatal infants
- CDC estimates ~1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases annually.
- Aggregated annual cost of illness ~ $77.7 billion in USA

Source: USDA, CDC, WHO

Risk Points

- Risk is everywhere
- Some risks are more serious than others
- Zero risk is not an option
- Risk is unavoidable
- We need to. . .
  - describe them (Risk Assessment)
  - talk about them (Risk Communication)
  - do something about them (Risk Management)

Selling Produce

Risk

- Risk is the chance of an undesirable outcome
  - A loss-illness, death, lost product, financial setback, or any sort of hazard
  - A potential gain that is not realized-new product did not catch on as hoped, health did not improve, costs not reduced, new trade was not established, or any sort of opportunity

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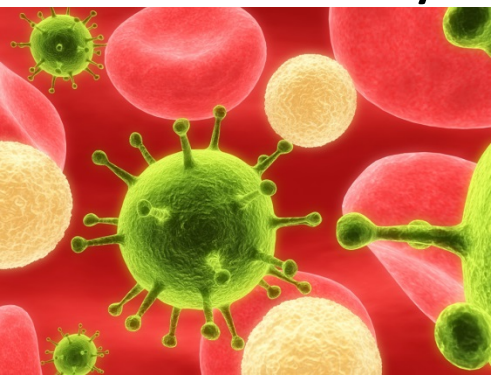


Risk Equation

- Risk = Probability x Consequence
- In food safety

Risk = [Exposure] x [Hazard]

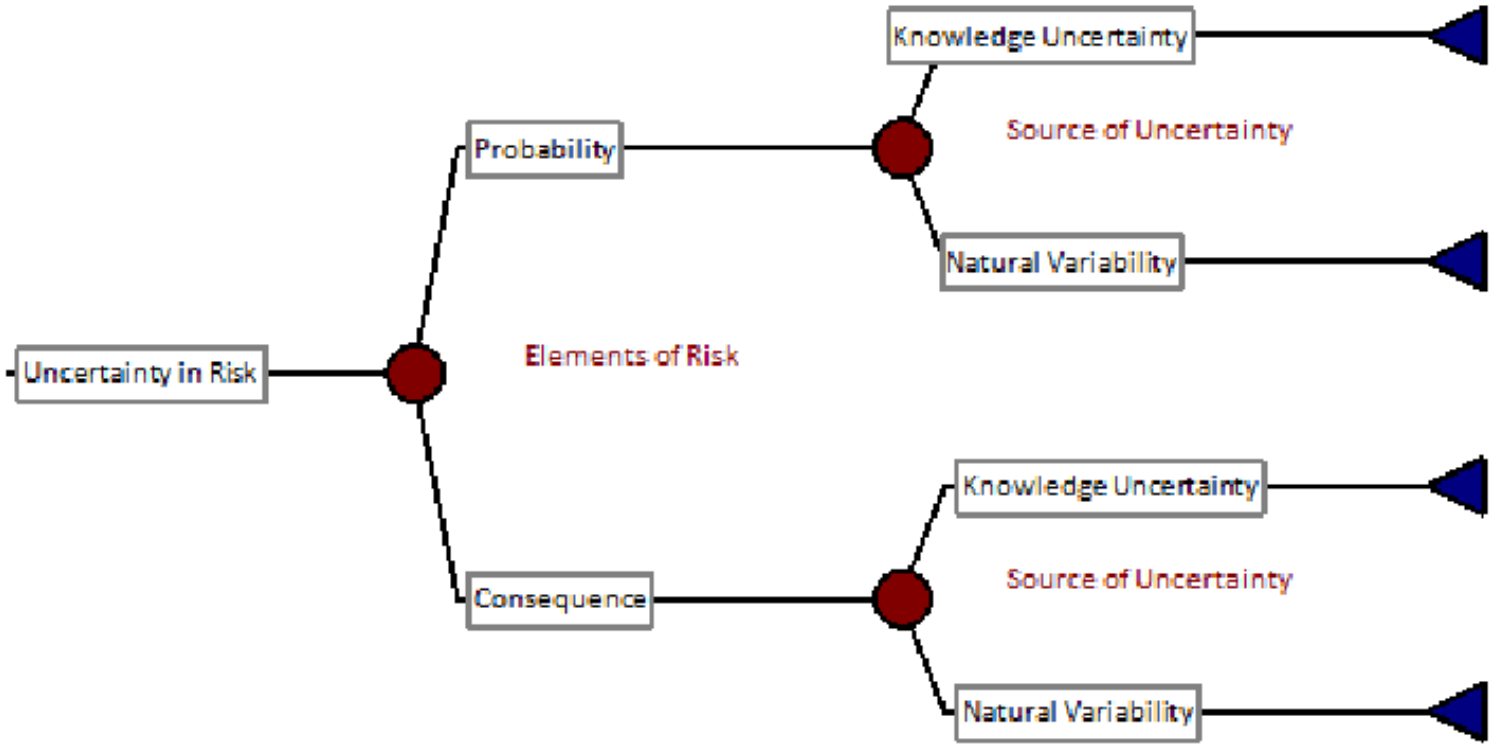
Number of servings produced

x

Concentration and prevalence of pathogen

Why Are There Risks?

- In a word, "uncertainty"
  - Knowledge uncertainty
  - Natural variability



THE RISKS ARE SERIOUS

Traditional Food Safety System Focus

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

Traditional Approach May Rely On

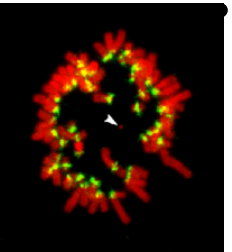
- Precedent
- Trial and error
- Expert opinion
- Compromise
- Safety assessment
- Precautionary principle
- Professional judgment
- Inspection
- Zero tolerance
- Ignorance

Many of these are not very scientific!

SCIENCE CAN HELP

Food Hazard Concerns –List growing/changing

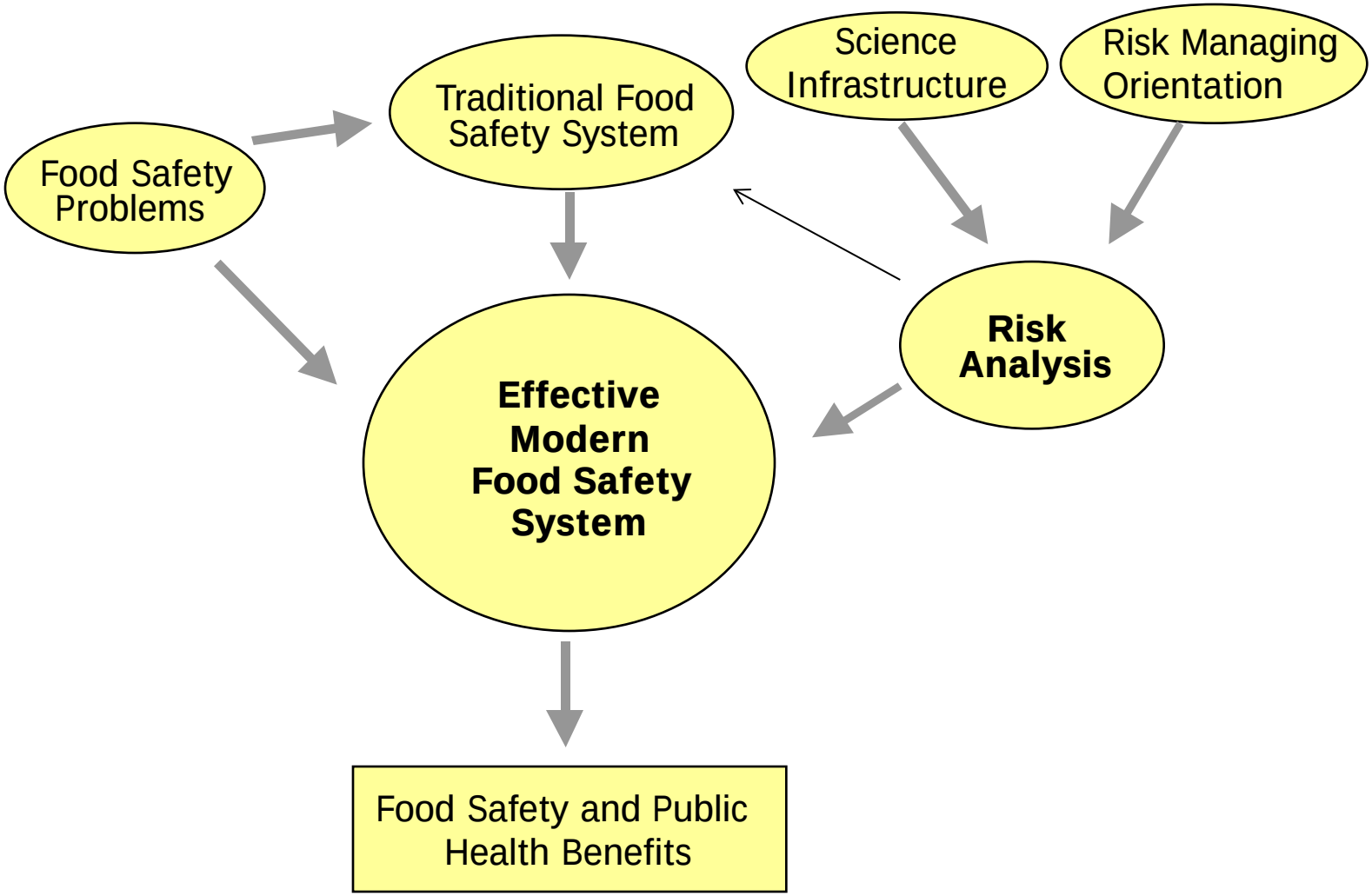
- Misuse of food additives, colors and flavors
- Veterinary drug residues and
  use of growth promoters
- Animal feed additives
- Fertilizer and growing aids
- Irradiation
- Microbiological contamination (last 15 yrs)
  - Ubiquitous
  - Re-emerging
  - Newly emerging
- Mycotoxins and other naturally occurring food toxicants
- Pesticide residues
- Pollutants
- Defective packaging and labeling
- Adulteration and tampering
- Extraneous matter
- Inspection and sampling
- GMO's (new technologies)



Changes in Food Production and Consumption

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

Science-Based Food Safety System



Risk Analysis

- Anintegrated, system-wide approach to managing food safety risk that uses science-based standards and decision criteria
- Risk is organizing principle for food safety regulatory systems
- Answers call for modernization

Examples of Science-Based Risk Analysis Activities

- Implementation of Hazard Analysis and Critical Control Point ***(HACCP)*** systems
- Establishment of ***acceptable daily intakes*** for chemical additives in food
- Estimation of ***maximum allowable exposure*** levels to pesticides
- Use of ***labeling*** to warn consumers about potential ***food allergens***

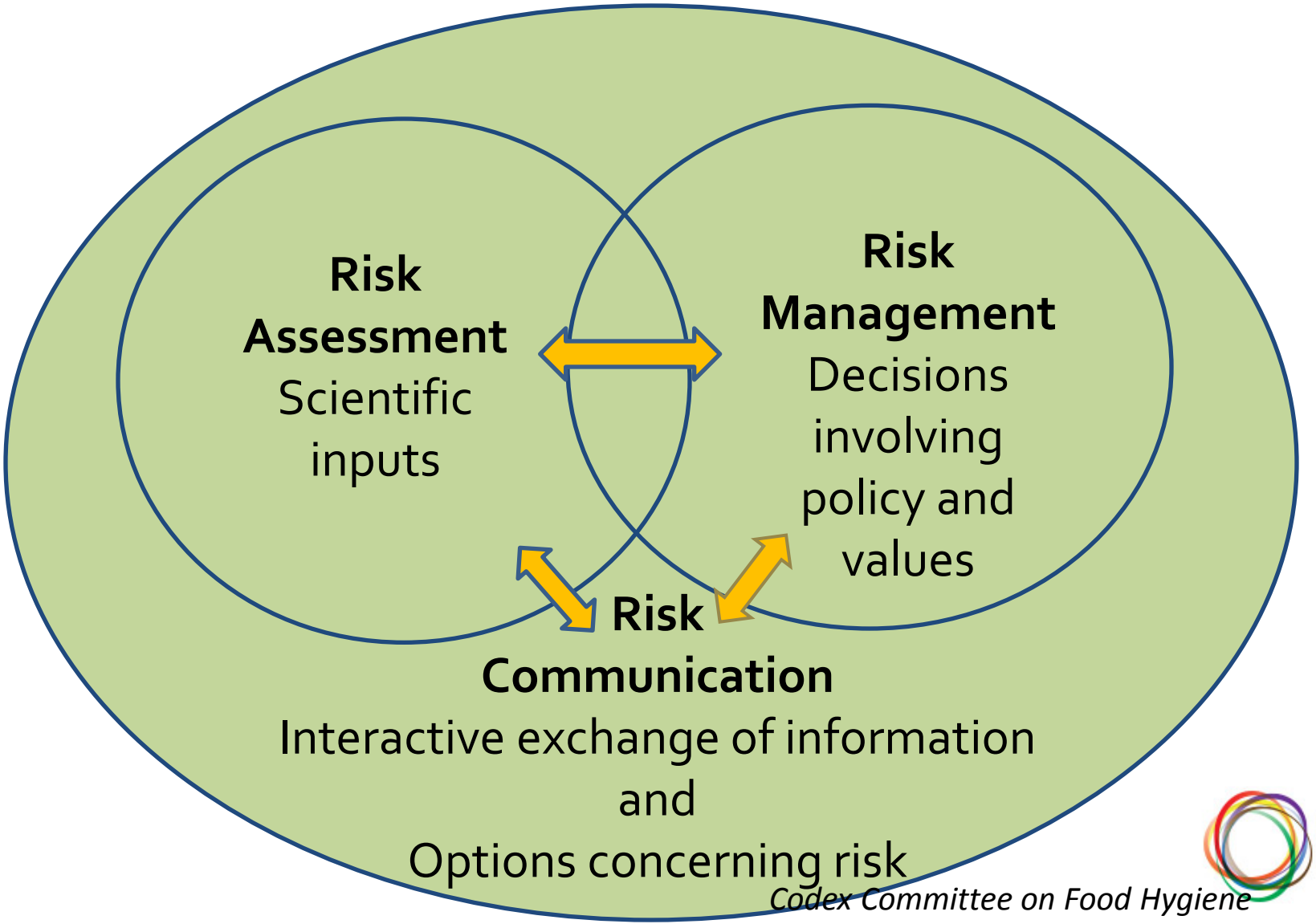
Examples of Science-Based Risk Analysis Activities

- Use of ***risk assessment*** to support food safety regulations
- Establishment of product safety standards, performance ***standards*** and specifications for use in international trade
- Resolution of trade disputes based on the WTO Sanitary and Phytosanitary ***(SPS)*** Agreement

Requirements of Risk Analysis Approach

- Effective data collection
- Scientific methods for assessing risks
- Regulatory mechanisms that respond to risk
- Administrative and analytical capacity to use risk information in program management

Risk Analysis Framework



Codex Committee on Food Hygiene

What Makes Risk Analysis Different

- It is a way of thinking about things and organizing to solve problems (paradigm)
- It is science-based but not science
- It is the interface between science and values
- It is for making decisions under uncertainty

What Makes Risk Analysis Different

- Its purpose is to find right problem
- Copes well with soft data
- Seeks needed information from a variety of sources
- Involves many people (is a team)

What Makes Risk Analysis Different

- Tolerates ambiguity
- Flexible, updateable
  - Has a future-focused vision
  - Because of uncertainty it's open to next solution as well as this one
- Designed for continuously improving decisions

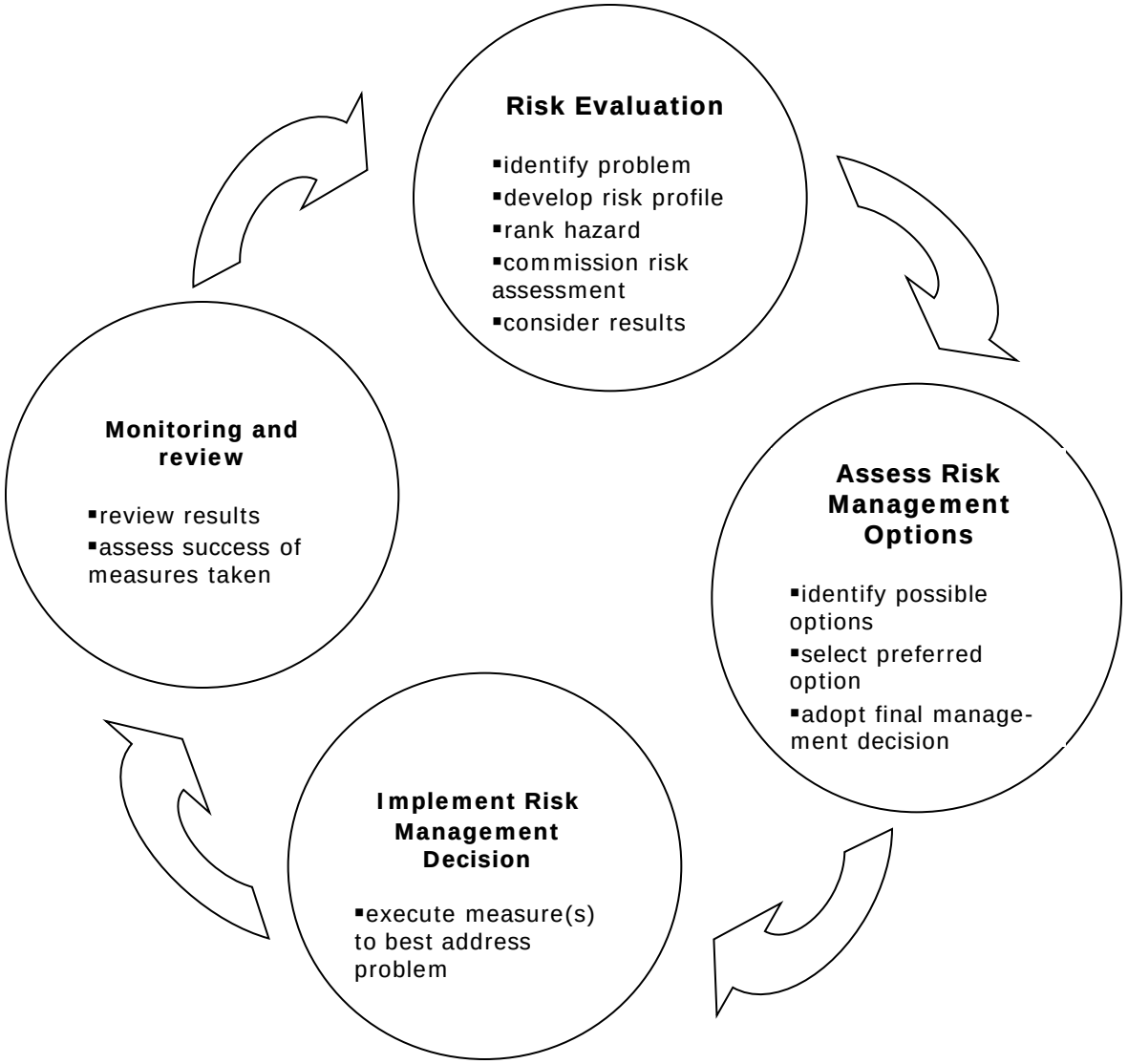
Risk Management-Informal

- What's the problem?
- What questions do we want risk assessment to answer?
- What can be done to reduce the impact of the risk described?
- What can be done to reduce the likelihood of the risk described?
- What are the trade-offs of the available options?
- What is the best way to address the described risk?
- Is it working?

Codex Definition – Took years to agree

- 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.

Risk Management



Risk Assessment

- What can go wrong?
- How can it happen?
- What are the consequences?
- How likely are they?

Risk Assessment

Hazard Identification

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

Hazard Characterization

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

Exposure Assessment

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

Risk Characterization

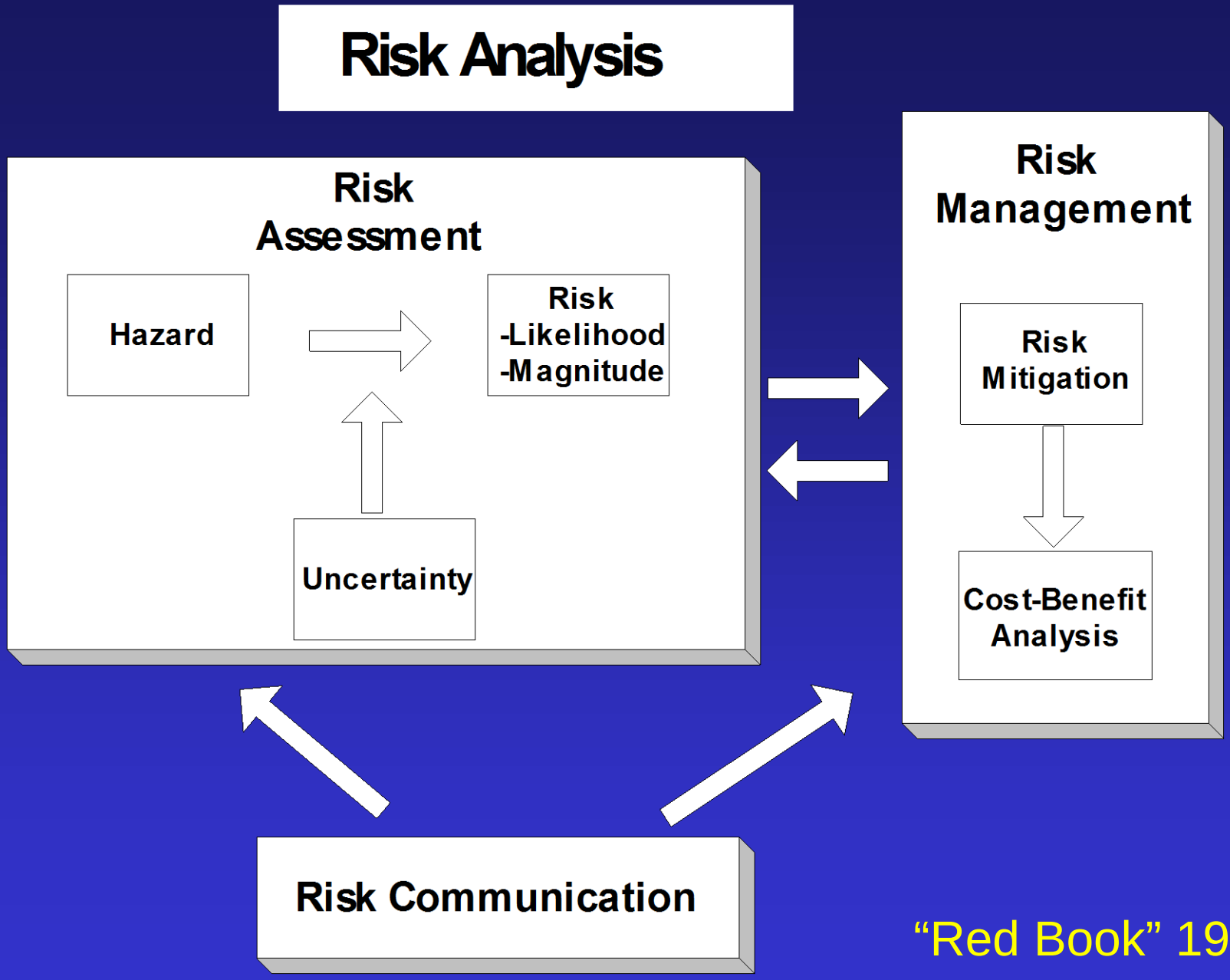
The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment

Risk Communication

- Why are we communicating?
- Who is our audience?
- What do our audiences want to know?
- What do we want to get across?
- How will we communicate?
- How will we listen?
- How will we respond?

Codex Definition

- 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.



"Red Book" 1983

Why Do Risk Analysis?

- Uncertainty is everywhere
- Improve the quality of our thinking before a decision is made.
- Help assure a safe domestic food supply.
- Protect human, animal, and plant life and health.

Why Do Risk Analysis?

- It allows industry to innovate
  - Introduce innovations with a tolerable level of risk.
- Global community uses risk analysis (risk assessment)
  - WTO Risk Assessment
  - Codex Risk Analysis
  - OIE Risk Analysis
  - IPPC Risk Analysis