



OVERVIEW OF RISK ANALYSIS IN THE CONTEXT OF FOOD SAFETY AND CODEX ACTIVITIES

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CONTENT

Role of science and risk analysis in Codex (milestones in Codex work)

Elements of risk analysis (risk assessment, risk management and risk communication)

Trends and challenges of risk analysis in Codex

HISTORY

Codex has been implementing risk analysis since its creation in 1961-63, then came ...

1991 FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade

1980s Uruguay Round of the Multilateral Trade Negotiation and creation of WTO (1995) and the SPS Agreement



WORLD TRADE ORGANIZATION

The WTO Agreements Series
Sanitary and
Phytosanitary Measures



Sanitary measures applied by WTO members should be based on scientific principles (art. 2.1) and on risk assessments (art. 5.1)

Sanitary measures conforming to international standards (as defined in Annex A) are deemed necessary to protect human health (art. 3.2)

ROLE OF SCIENCE

“The ... Codex Alimentarius shall be based on the principle of **sound scientific analysis and evidence**, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.”
(CAC decision 1995)

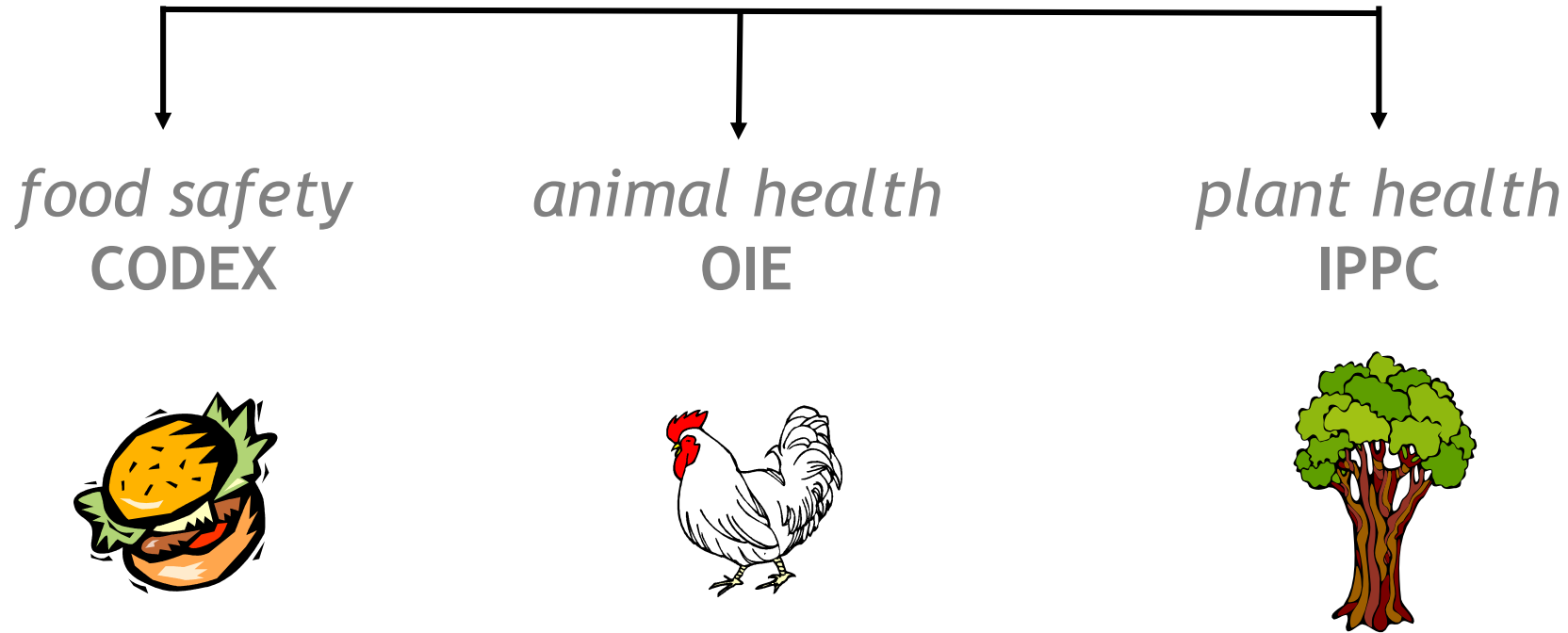
THE SPS AGREEMENT



defines *International standards, guidelines and recommendations*:

“for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice” ; (Annex A,3.a)

THE 3 SISTERS AND THE SPS AGREEMENT



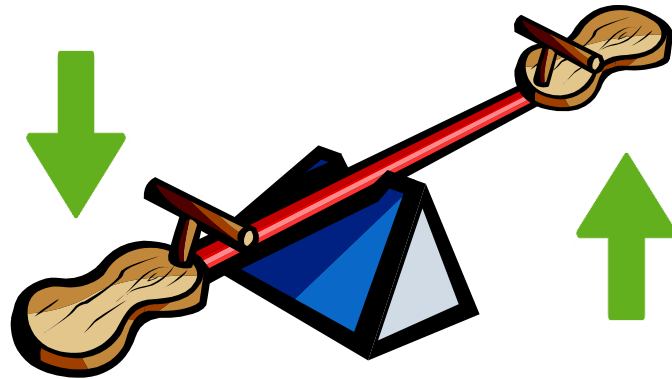
Standards, guidelines and recommendations specifically recognised in the SPS Agreement as the references for international trade

SAFETY AND RISK

- Safety means “no harm”
- 100% safety does not exist
- There is always a chance that a certain harm is caused by a specific pathogen/food combination (i.e. no zero risk)
- Risk assessment estimates this chance (including severity)
- Risk analysis provides a framework for managing the risk

FOOD SAFETY AND RISK

By reducing
the probability and
severity of harm



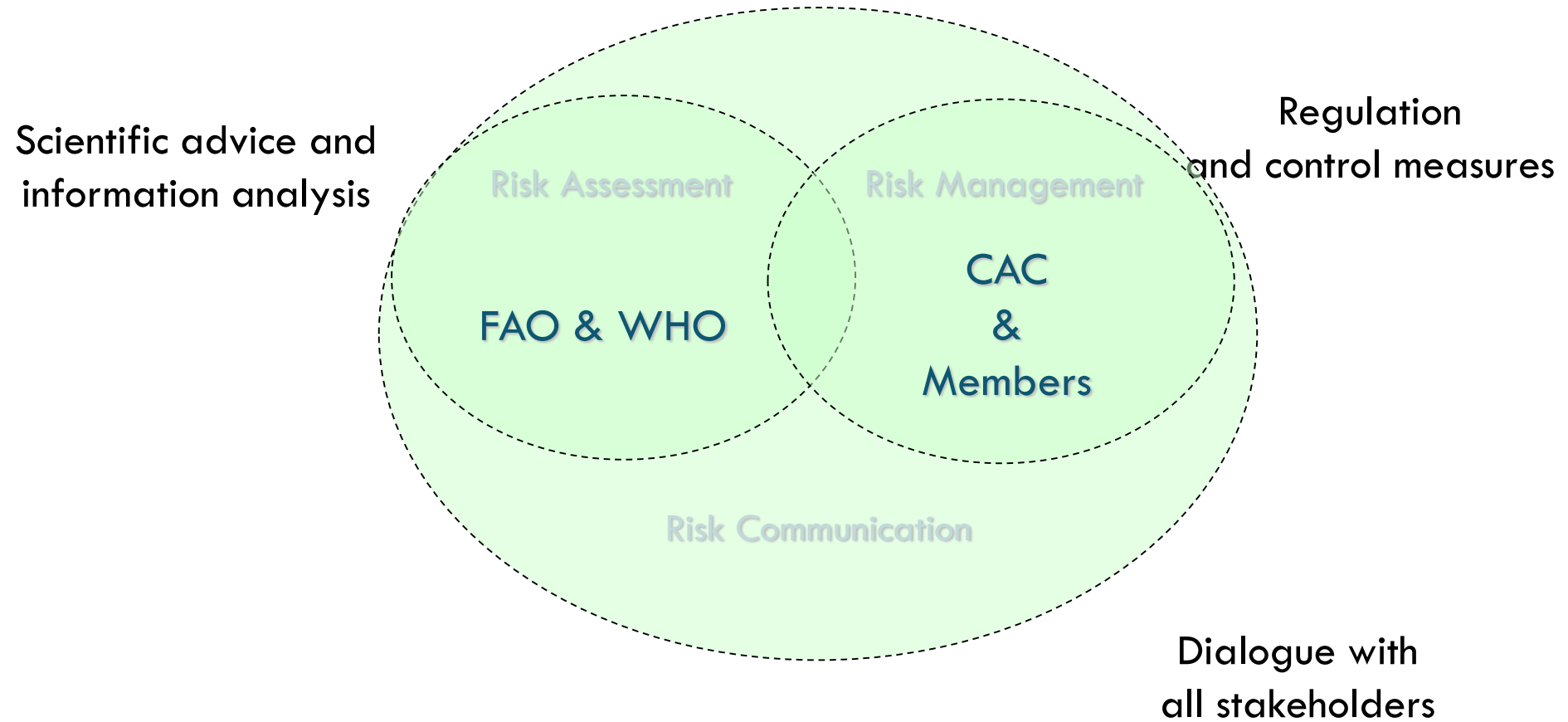
The safety of food is
increased



ELEMENTS OF RISK ANALYSIS



RISK ANALYSIS PARADIGM



RISK ASSESSMENT

The scientific evaluation of known or potential adverse effects resulting from human exposure to foodborne hazards

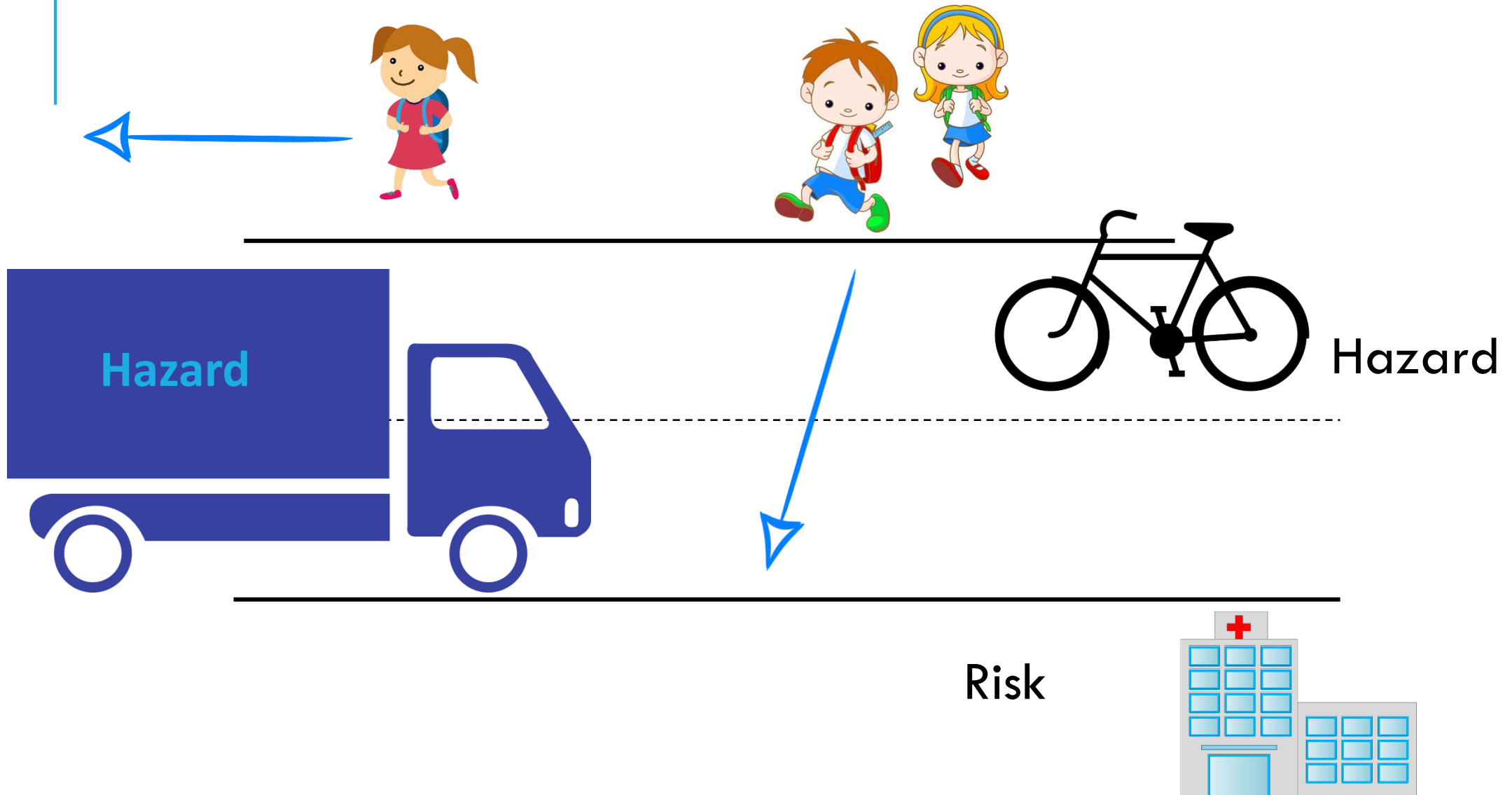
RISK \neq HAZARD

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 and the severity of that effect, consequential to a hazard(s) in food.

$$\text{Risk} = \text{Hazard} \times \text{exposure}$$

RISK AND HAZARD

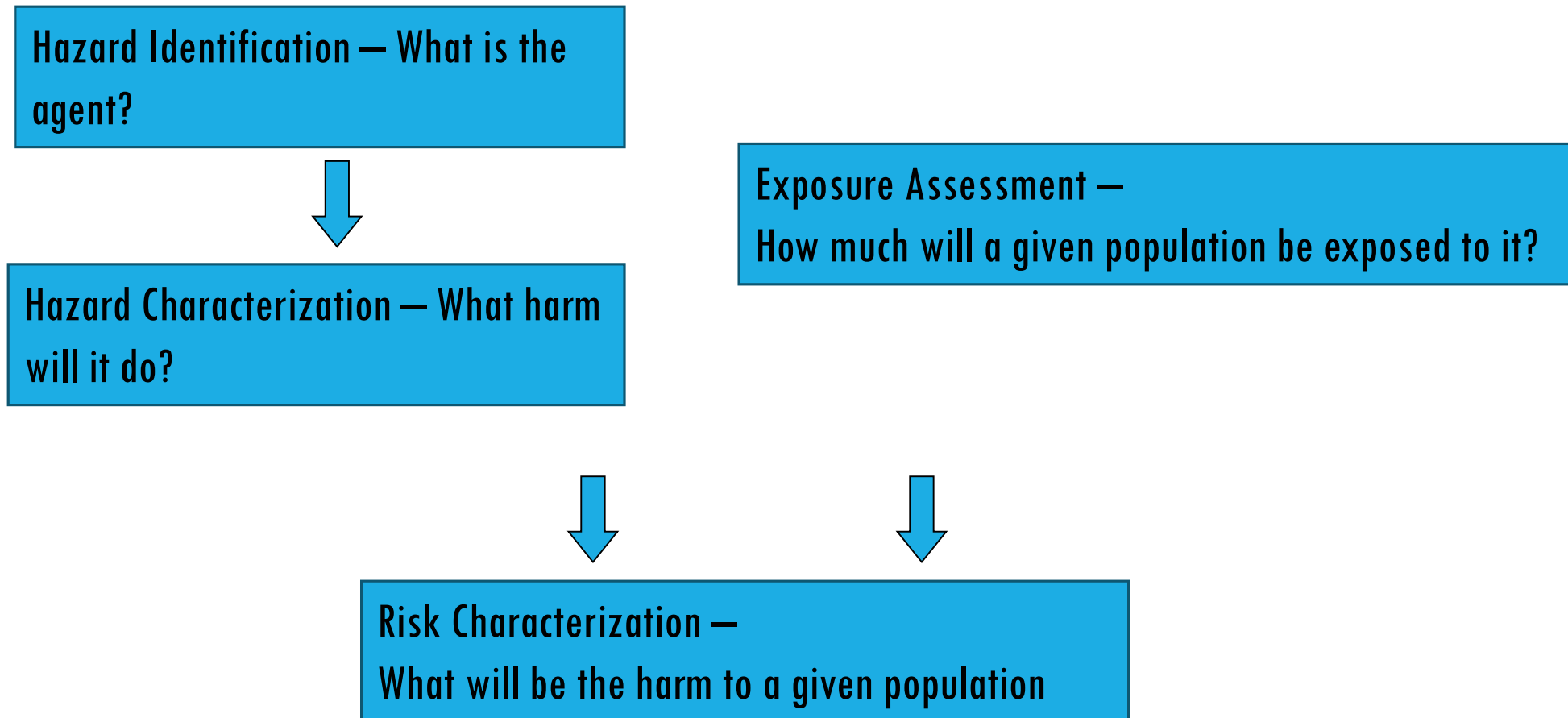


SOUND SCIENTIFIC BASIS AND EVIDENCE

Risk assessment:

- Provides the scientific basis to underpin risk management actions
- A tool to assist risk managers with independent scientific advice related to food and feed safety with respect to public health issues
- Provides a transparent scientific basis to underpin development of standards and regulations
- Enables comparative assessment of different options before implementation

RISK ASSESSMENT ACTIVITIES (FOUR STEPS)



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,

- selecting appropriate prevention and control options, if needed

Close interaction with risk assessment is essential

PRELIMINARY RISK MANAGEMENT ACTIVITIES

Identification of a problem

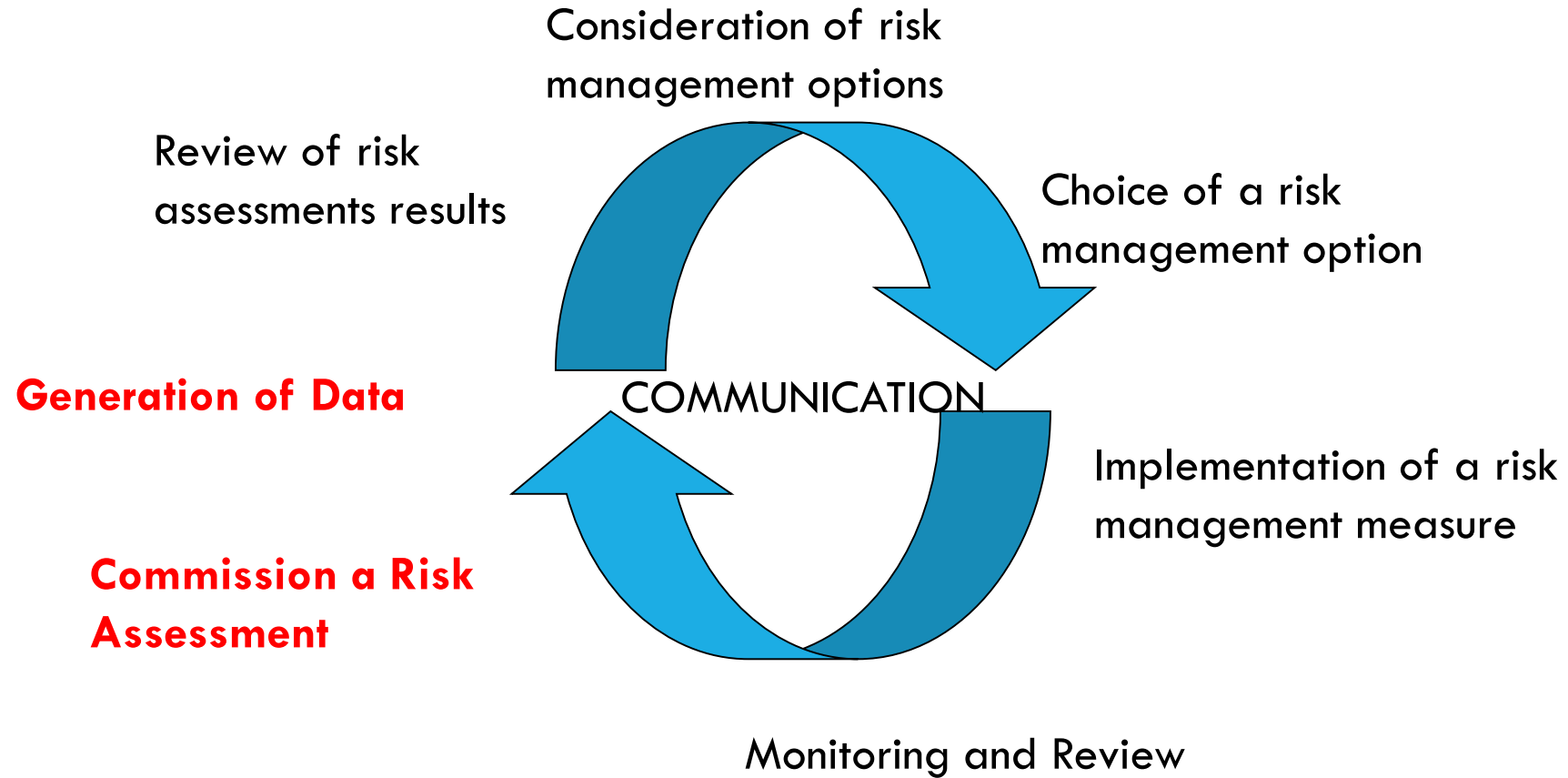
Establishment of a risk profile

Ranking of the hazard for risk assessment and risk management priority

Establishment of risk assessment policy for conduct of risk assessment

Commissioning of risk assessment

RISK MANAGEMENT ACTIVITIES



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

RISK COMMUNICATION

Between risk assessors and risk managers

- Clear definition of the issues to be addressed
- Clear definition of the process
- Transparent and documented procedure

Between risk managers and other relevant stakeholders (including consumers)

- Transparent decision process
- Communicating uncertainties
- Providing immediate communication in case of emergency



GUIDING PRINCIPLES

Know the audience

Involve the scientific experts

Establish expertise in communication

Be a credible source of information

Share responsibility

Differentiate between science and value judgement

Assure transparency and put the risk in perspective

PRECAUTION/UNCERTAINTY ANALYSIS

- Precaution is an inherent element of risk analysis
- The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis
- The risk management options should reflect the degree of uncertainty and the characteristics of the hazard

OTHER LEGITIMATE FACTORS

- Should not affect scientific basis of risk analysis
- Should be accepted on a worldwide basis
- Some legitimate concerns of governments are not generally applicable or relevant worldwide



TRENDS AND CHALLENGES



TRENDS IN RISK ANALYSIS

Risk management

- Clear problem formulation
- Indication of how advice is to be used
- Significance and urgency of the work
- Availability of scientific knowledge and data
- Availability of resources to perform the work
- Cost/benefit analysis

Risk assessment

- Best science available
- Independent advice
- Transparency in the assessment
- Systematic review
- Weight of evidence approach
- Combined exposure to multiple hazards
- Comparison of options

CHALLENGES

- Identification of priorities at international level
- Definition of possible scope of the work and use to be given to results
- Harmonization of risk assessment methodologies based on the Codex principles for risk analysis
- Periodic review of old risk assessment
- Availability and quality of data
- Resources

Thank you for your attention

Now it's your turn for making comments and
asking questions