Introduction to risk analysis

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Overview

- General concepts
- Areas of application of Risk Analysis
- Approaches to Risk Assessment
- Public health scenarios

General concepts

- Risk
- Hazard
- Zero-risk approach
- Risk analysis

General concepts: Risk

- *Compact Oxford English Dictionary of Current English*
  - A situation involving exposure to danger
  - The possibility that something unpleasant will happen

- *Society for Risk Analysis* *http://www.sra.org/resources_glossary*

  The potential for realization of unwanted, adverse consequences to human life, health, property, or the environment; estimation of risk is usually based on the expected value of the conditional probability of the event occuring times the consequence of the event given that it has occured.

General concepts: Risk

- Chance of encountering some form of harm, loss or damage
  - → Probability of something happening, something going wrong, and, if it does happen, the resulting consequences
- Requires the existence of a hazard
- Different possible outcomes, one or more of these outcomes are unwanted

General concepts

- **Hazard**

  A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect *(Codex Alimentarius Commission)*

  A condition or physical situation with a potential for undesirable consequence *(Society for Risk Analysis)*

General concepts

- Hazard → something with the potential to cause harm
- Risk → the likelihood of harm, usually estimated as the combination of likelihood and consequence of a specified hazard being realized.
- No hazard – no risk!

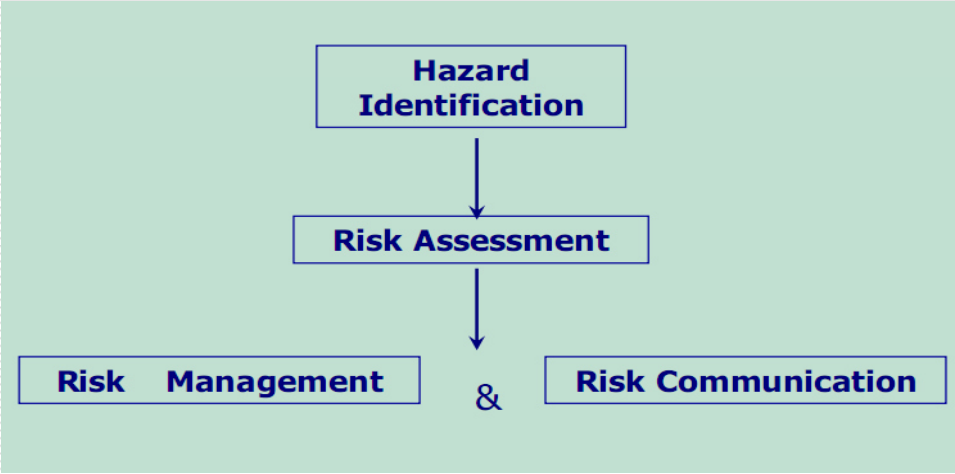
General concepts: Risk analysis

- *Society for Risk Analysis* http://www.sra.org/resources_glossary

  A detailed examination including risk assessment, risk evaluation, and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment; an analytical process to provide information regarding undesirable events; the process of quantification of the probabilities and expected consequences for identified risks.

General concepts: Risk analysis

- A process undertaken to deal with matters which pose a potential danger, managed according to certain standard procedure and that involves:
  - Hazard Identification
  - Risk Assessment
  - Risk Management
  - Risk Communication



Systematic approach to deal with risks

General concepts: Risk analysis

- Different skills are required:
  - Epidemiologists
  - Virologists, microbiologists
  - Experts on climatology, entomogly, ornithology
  - Environmental scientists,
  - Industry technologists,
  - Mathematicians, statisticians
  - Information scientists
  - Economists
- → Multidisciplinary approach within a project team

General concepts: Risk analysis

Risk analysis assists the decision maker:

- What can go wrong?
- How likely is it to go wrong?
- What are the consequences of it going wrong?
- What can be done to reduce the likelihood of it going wrong?

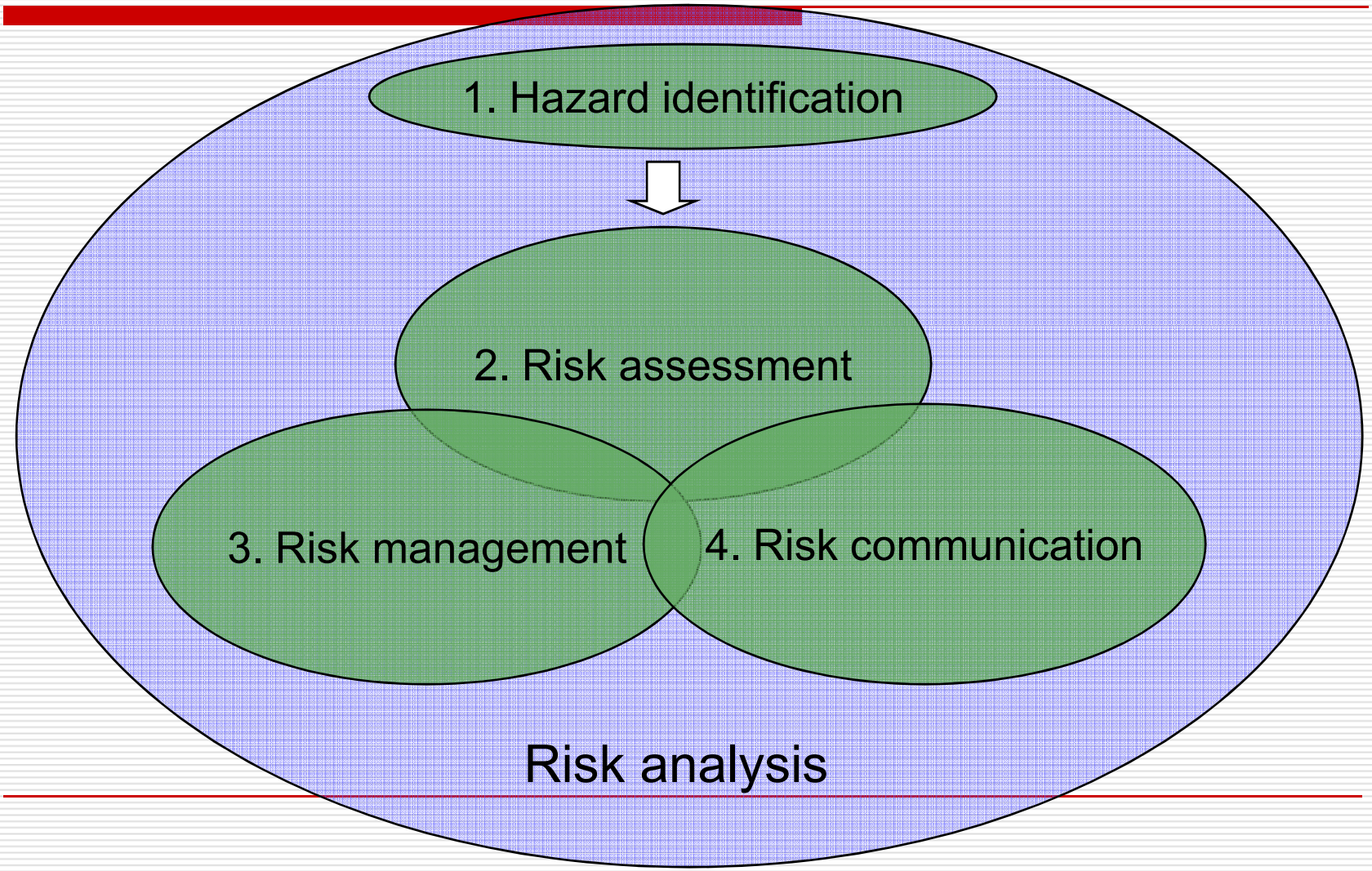
General concepts: Why no zero risk approach?

Zero-risk is the ideal that we should try to achieve
Appealing **but** often not possible or not
desirable (**unjustifiable** amounts of resources needed).

In human health, zero-risk approaches may
result in excessively stringent measures and may have
undesirable effects

Alternative: **trying to determine a level of practical achievable control of risk.**

General concepts: Risk analysis components

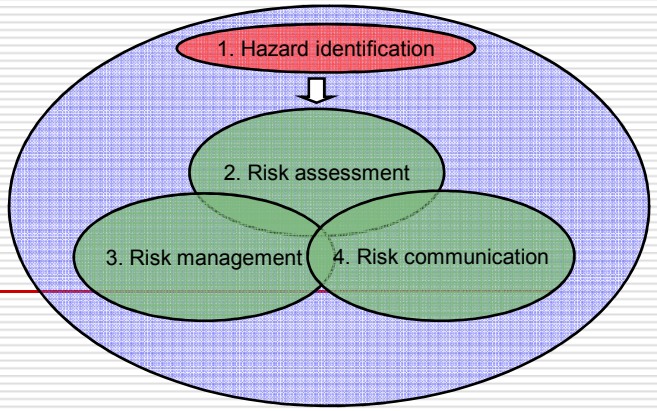


General concepts: risk analysis components

- **Hazard Identification:**

  Initial step of the risk analysis: Identification of the hazard (something potentially harmful).

  In some cases the step of hazard identification is incorporated within the risk assessment



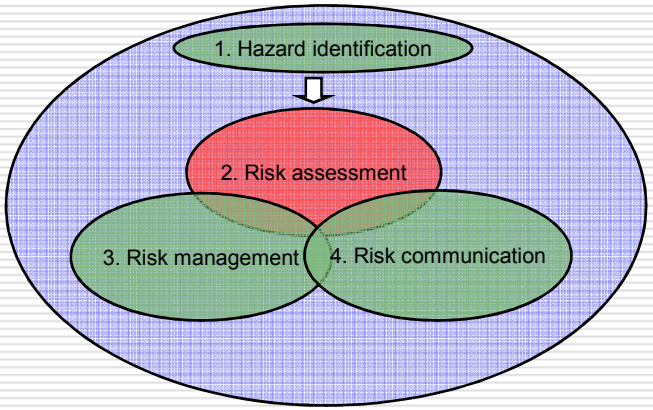
General concepts: Risk analysis components

- **Risk Assessment:** process of <u>evaluating the risk</u> resulting from a hazard
- The evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within the population of interest

• Based on how the risk estimate is presented:

<u>*Qualitatively*</u>: the evaluated risk is described in words. The estimate of risk is ranked or separated into descriptive categories.

<u>*Quantitatively*</u>: the evaluated risk is estimated numerically; numerical expressions of risk are provided.



General concepts: Risk analysis components

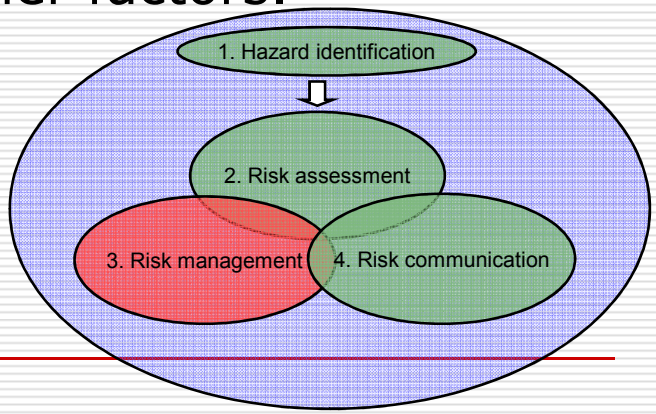
- **Risk Management:**

Based on the results of the risk assessment and the judgement of the 'risk managers' decisions are taken and policy is formulated.

Risk management is the process of weighting policy alternatives in consultation with all interested parties considering risk assessment and other factors.

→ potential benefits?

→ implementing sanitary measures?



General concepts: Risk analysis components

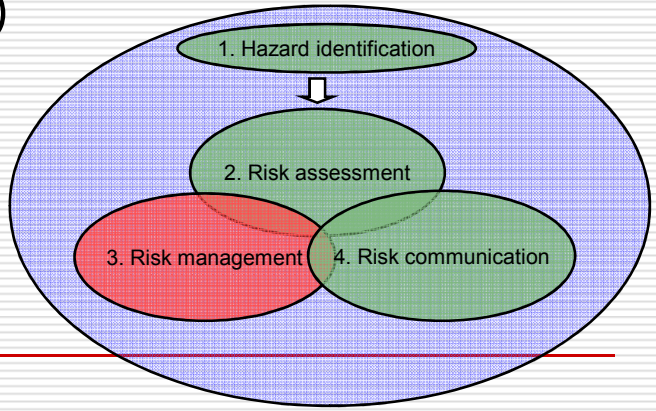
- **Risk Management:**

Effect of consequences:

- assessed risk low + severe consequence
  = usually unacceptable (not always)

- assessed risk high + trivial consequence
  = usually acceptable (not always)

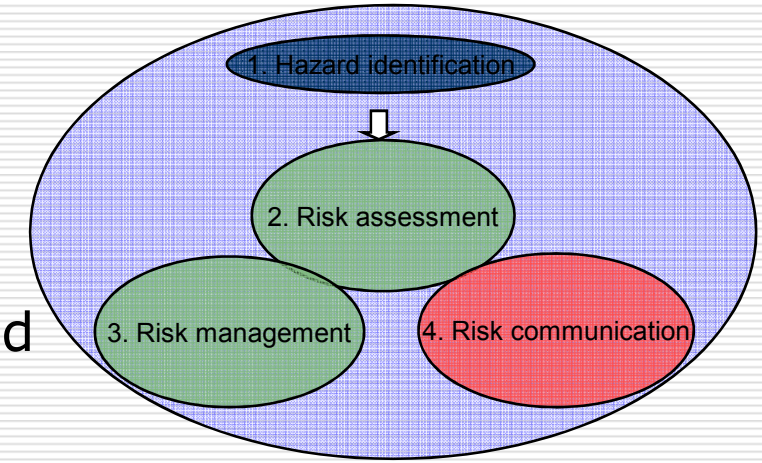
Level of acceptable risk?



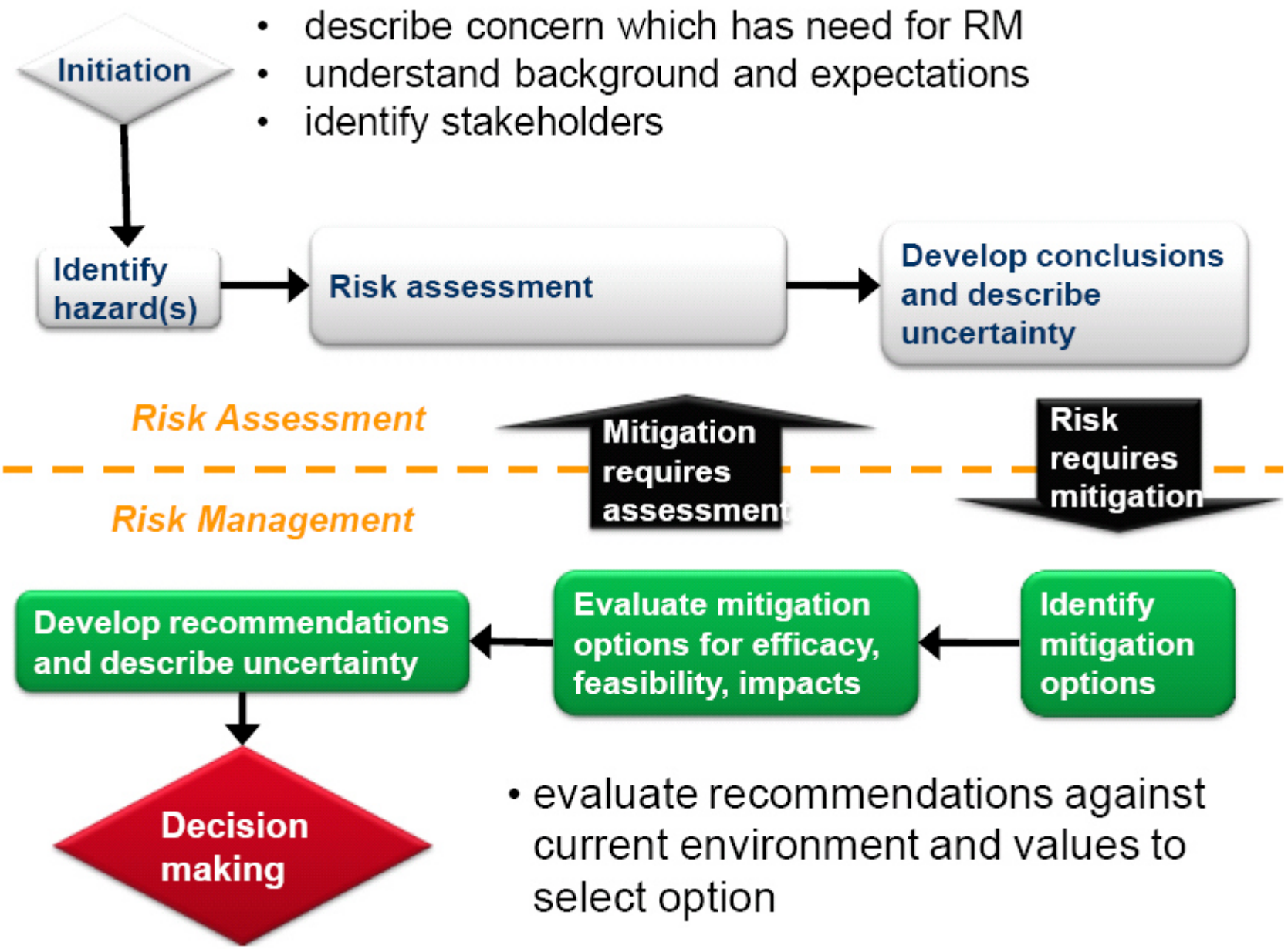
General concepts: Risk analysis components

- **Risk communication:**

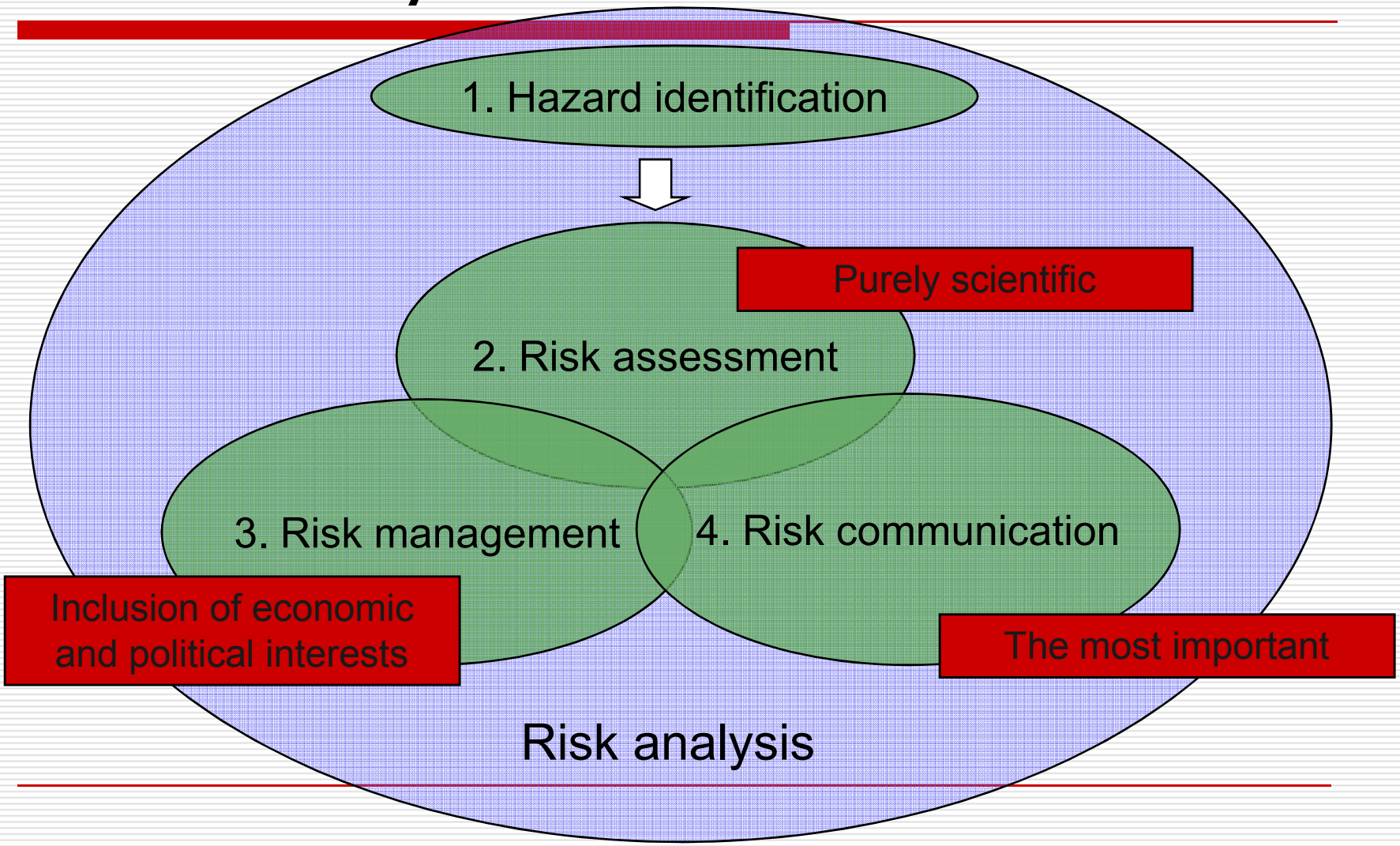
Information exchange between risk assessors, risk managers and those affected by both the risk and the decisions taken (stakeholders) before the final policy decisions are taken.



Risk assessment is **only part** of the whole process of risk analysis which also includes hazard identification, risk management and risk communication!


Initiation
• describe concern which has need for RM
• understand background and expectations
• identify stakeholders
Identify hazard(s)
Risk assessment
Develop conclusions and describe uncertainty
Risk Assessment
Mitigation requires assessment
Risk requires mitigation
Risk Management
Develop recommendations and describe uncertainty
Evaluate mitigation options for efficacy, feasibility, impacts
Identify mitigation options
Decision making
• evaluate recommendations against current environment and values to select option

Risk Analysis



Areas of application

- **Food safety**

  Maarten J. Nauta, Wilma F. Jacobs-Reitsma, Arie H. Havelaar. **A Risk Assessment Model for Campylobacter in Broiler Meat**. *Risk Analysis*

  Fosse J., Seegers H., Magras C. **Foodborne zoonoses due to meat: a quantitative approach for a comparative risk assessment applied to pig slaughtering in Europe.** *Vet. Res*. (2008) 39:01

Areas of Application

- **Animal Health and Trade**

Martinez-Lopez B., Perez A.M., De la Torre A., Sanchez-Vizcaino Rodriguez J.M. **Quantitative risk assessment of foot-and-mouth disease introduction into Spain via importation of live animals**. *Prev. Vet. Med* 86 (2008) 43-56.

Areas of Application

- **Public Health**

  Walter Dowdle, Harrie van der Avoort, Esther de Gourville, Francis Delpeyroux, Jagadish Desphande, Tapani Hovi, Javier Martin, Mark Pallansch, Olen Kew, Chris Wolff (2006) **Containment of Polioviruses after eradication and OPV cessation: Characterizing Risks to Improve Management** *Risk Analysis* 26 (6), 1449-1469.

Areas of Application

- **Environmental impact**

  Christopher Snary (2002) **Health Risk Assessment for Planned Waste Incinerators: Getting the Right Science and the Science Right.** *Risk Analysis* 22 (6), 1095-1105.

- **Agriculture**

  Olurominiyi O. Ibitayo (2006) **Egyptian Farmers' Attitudes and Behaviors Regarding Agricultural Pesticides: Implications for Pesticide Risk Communication** *Risk Analysis* 26 (4), 989-995.

Areas of Application

- **Engineering**

  Alessandro Mazzola (2000) **A Probabilistic Methodology for the Assessment of Safety from Dropped Loads in Offshore Engineering** *Risk Analysis* 20 (3), 327-338.

- **Financial Management**

  Howard C. Kunreuther, Joanne Linnerooth-Bayer (2003) **The Financiel Management of Catastrophic Flood Risks in Emerging-Economy Countries** *Risk Analysis* 23 (3), 627-639.

Areas of Application

- **Security against terrorism**

  Henry H. Willis (2007) **Guiding Resource Allocations Based on Terrorism Risk** *Risk Analysis* 27 (3), 597-606.

….

Applications in Animal Health

- Animal-related trade
- Food safety
- Others:
  - Risk based surveillance
  - Veterinary biologicals (vaccines, GMOs)

Applications in Animal Health: animal related trade

- WTO Agreement on Application of Sanitary and Phytosanitary Measures (SPS agreement):

  The SPS Agreement is a multilateral framework consisting of rules and disciplines intended to achieve its two-fold objective of ensuring Members' rights to protect health, while aiming to prevent the imposition of arbitrary or unjustified trade barriers.

WTO: http://www.wto.org

SPS agreement:

http://www.wto.org/english/tratop_e/sps_e/sps_e.htm

2.1 Scientific justification

Article 2 of the SPS Agreement stresses that Members have the right to adopt SPS measures to achieve their self-determined health protection level. This level, called the appropriate level of protection (ALOP) or the acceptable level of risk, represents a key feature of the SPS Agreement.

The right to adopt SPS measures to achieve a given appropriate level of protection is accompanied by basic obligations. Essentially, countries may adopt SPS measures provided the measures:

- are applied only to the extent necessary to protect life or health;
- are based on scientific principles and not maintained without sufficient scientific evidence (except emergency or provisional measures); and
- do not unjustifiably discriminate between national and foreign, or among foreign sources of supply.

Members have two options to show that their measures are based on science. They may either:

- base their measures on international standards; or
- base their measures on scientific risk assessment.

http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c2s1p1_e.htm

2.4 Scientific risk assessment

The requirement to base SPS measures on a scientific risk assessment (when they are not based on an international standard), articulated in Articles 5.1, 5.2, and 5.3, is a key component of the SPS Agreement's reliance on scientific evidence for the justification of SPS measures.

Article 5.1 requires that SPS measures be based on an assessment of the risks to human, animal or plant life or health. It does not necessarily require that the importing country itself must do the risk assessment – but the importing country must be able to demonstrate that its measure is based on an "appropriate" risk assessment. Members are to take into account the risk assessment techniques developed by the three sister organizations.

Codex, OIE, IPPC

Article 5.2 explains what kinds of information shall be taken into account when undertaking a risk assessment:

- available scientific evidence;
- relevant processes and production methods;
- relevant inspection, sampling and testing protocols;
- prevalence of specific diseases or pests;
- existence of pest- or disease-free areas;
- relevant ecological and environmental conditions; and
- quarantine or other treatment.

http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c2s4p1_e.htm

Applications in Animal Health

- WTO SPS agreement
  - Scientific basis → regionalisation, risk analysis
  - Trust → harmonization, equivalence, transparency
- OIE International Animal and Aquatic Animal Health Code
  - Former List A and B diseases
  - Guidelines for
    - Risk analysis
    - Regionalization
    - Surveillance
    - Evaluation of veterinary services

Applications in Animal Health

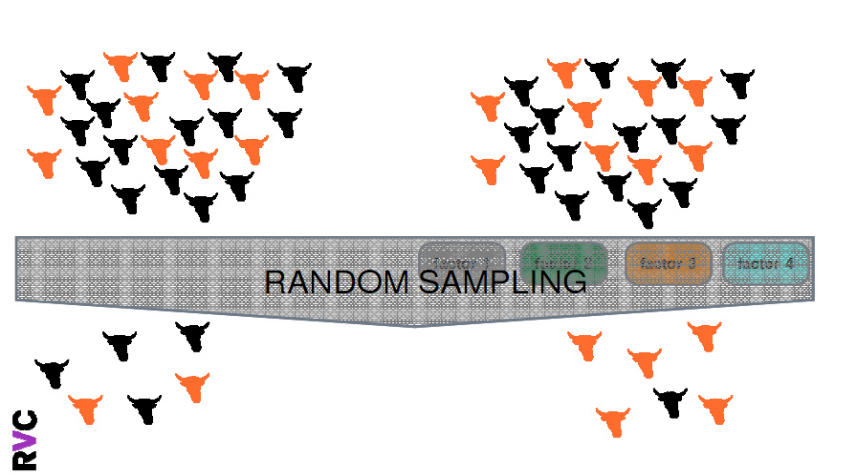
- Risk analysis in food safety
- International standard
  - FAO/WHO *Codex alimentarius*
- Responsible for risk assessment
  - European Food Safety Authority
- Example problems
  - BSE
  - Salmonella
  - Campylobacter
  - Dioxin
  - Antibiotic resistance

Applications in Animal Health

- Risk analysis in other animal-related areas
- Surveillance: Optimised decision making in animal disease control
  - National
  - Individual farm

Risk-based surveillance

- *„A surveillance programme in the design of which risk assessment methods have been applied together with traditional design approaches in order to assure appropriate and cost-effective data collection„*



Risk-based ≠ targeted: a special type of risk-based surveillance design (sampling of high risk strata

Stärk et al., 2006

Applications in Animal Health:

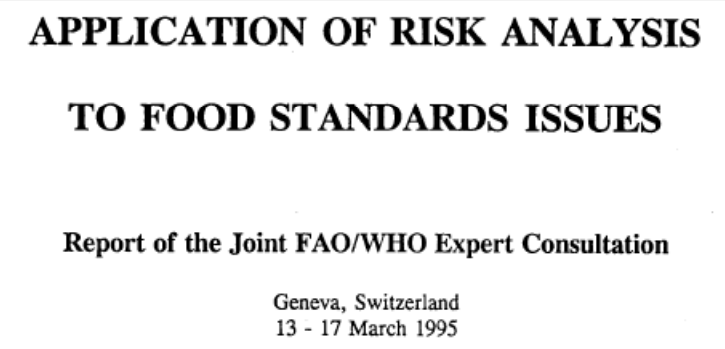
- International trade:
  - Risk of introduction of BSE into Sweden by import of cattle from the UK
  - Global trade in ornemental fish
  - Risk of transmission of FMD, bluetongue and vesicular stomatitis by embryos originating from an area in South America
- Disease spread within a country through 'neighborhood infections'
- Prioritization of pathogens for surveillance

Applications in Public Health

- Food standards & safety issues:
  - *Application of Risk Analysis to Food Standards Issues, a Joint FAO/WHO Expert Consultation,* Geneva, Switzerland, 13–17 March 1995
- Chemical hazards:
  - *WHO Human Health Risk Assessment Toolkit: Chemical Hazards*
- International Health Regulation (2005)
  - Rapid risk assessment of acute public health risks – WHO/HSE/GAR/ARO/2012

Applications in Public Health: Food safety

- International standard
  - FAO/WHO *Codex alimentarius*
- Food standards & safety issues:


APPLICATION OF RISK ANALYSIS

TO FOOD STANDARDS ISSUES

Report of the Joint FAO/WHO Expert Consultation

Geneva, Switzerland
13 - 17 March 1995

Recommendations include:
i) definitions of risk analysis terms,
ii) principles for risk assessment methods
iii) recommendations to promote the implementation of harmonized and transparent risk assessment methods.

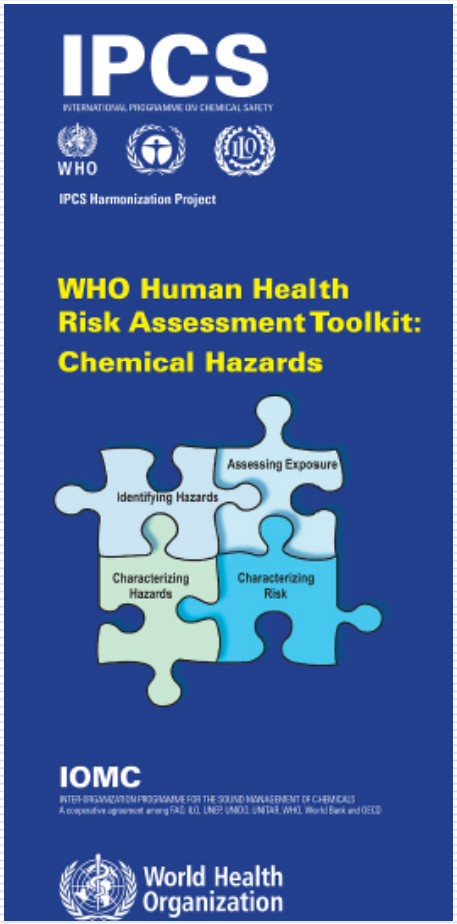
- Codex committees:

Examples:
- BSE
- Salmonella
- Campylobacter
- Dioxin
- Antibiotic resistance

4.1 Food additives
4.2 Chemical contaminants
4.3 Pesticide residues
4.4 Veterinary drug residues
4.5 Biological agents
4.6 Other Codex Committees

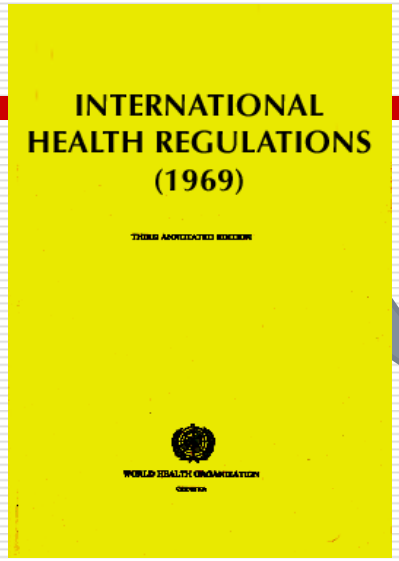
Applications in Public Health: Chemical hazards

- Users:
  - public health and environmental professionals, regulators, industrial managers and other decision-makers
- Purpose:
  - Provide guidance to identify, acquire and use the information needed to assess chemical hazards, exposures and the corresponding health risks at local and/or national levels.
- Examples:
  - Drinking water
  - Respirable particulate Matter (PM10)
  - Pesticides



Applications in Public Health:IHR 2005

- The International Health Regulations (2005) IHR - are an international agreement that is legally binding on 194 countries (States Parties), including all WHO Member States
- Purposes:
  - To prevent, protect, and provide a public health response to the international threat and spread of diseases.
  - To avoid unnecessary disruption of international travel and trade



- From **control of borders** to **containment at source**
- From **diseases list** to **all threats**
- From **preset measures** to **adapted and real time response**

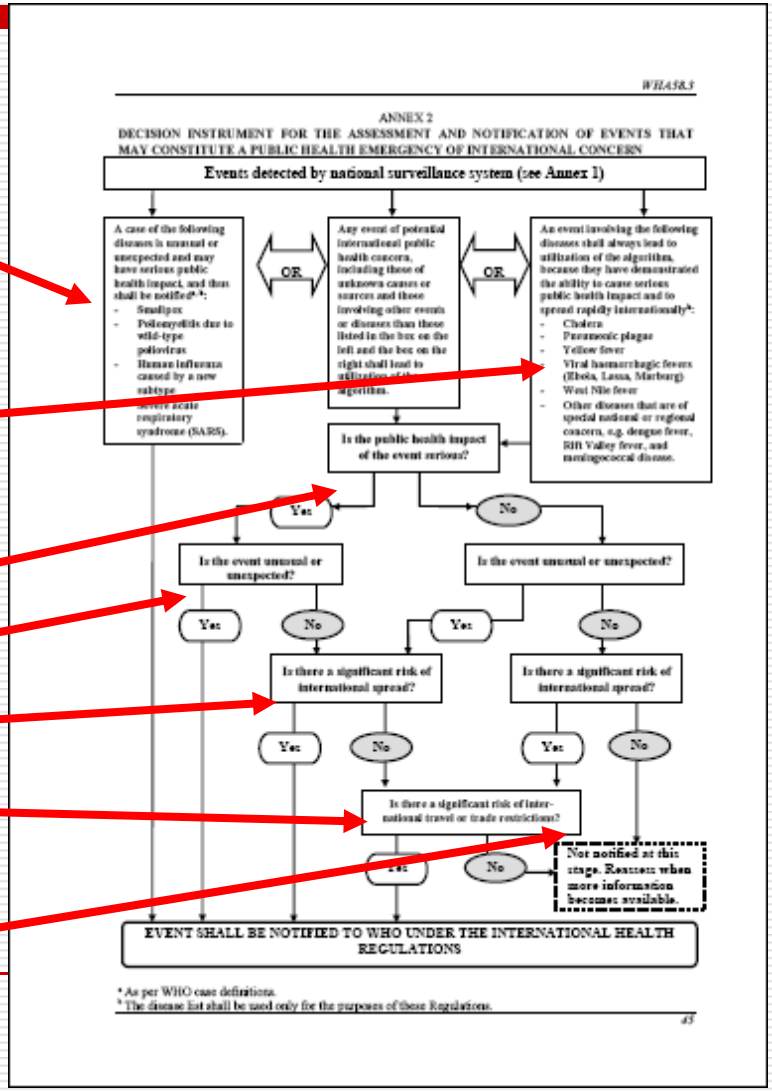
Decision instrument (Annex 2) of IHR (2005) for Assessment and Notification

4 diseases that shall be notified polio (wild-type polio virus), smallpox, human influenza new subtype, SARS.

Disease that shall always lead to utilization of the algorithm: cholera, pneumonic plague, yellow fever, VHF (Ebola, Lassa, Marburg), WNF, others….

Q1: public health impact serious?
Q2: unusual or unexpected?
Q3: risk of international spread?
Q4: risk of travel/trade restriction?

Insufficient information: reassess



Rapid risk assessment of acute public health risks

- To proposed structured steps in order to apply the Annex 2 decision instruments of the IHR
- Purpose:
  - To reduce or prevent disease in affected populations and reduces negative social and economic consequences.
  - Defensible decision-making

  - Implementation of appropriate and timely control measures
  - More effective operational communication
  - More effective risk communication
  - Improved preparedness

Conclusion

Without risk assessment

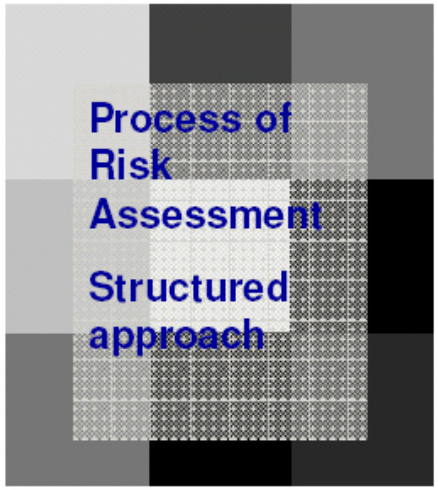
Risk ?

Risk estimation and measures to reduce risk are

not justified, questionable

With risk assessment

Risk ?



Risk estimation and measures to reduce risk are

justified, uncertainties identified, transparent, credible

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