



"Regards Croisés" sur l'Influenza aviaire



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Rencontres scientifiques autour de deux projets de recherche :
Scientific meeting around two research projects

GRIPAVI (CIRAD, MAEE) & ARDIGRIP (AIRD)

Training Workshop : Introduction to Risk Analysis & Social Analysis Network 18 – 19 December 2008 ; Montpellier





Introduction to Risk Analysis: Overview

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





General concepts

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





General concepts

- Risk
 - A situation involving exposure to danger
 - The possibility that something unpleasant will happen

(Compact Oxford English Dictionary of Current English)





General concepts

- **Risk**

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 occurring times the consequence of the event given that it has occurred.

Society for Risk Analysis

http://www.sra.org/resources_glossary





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

- **Zero-Risk approach:**

Zero-risk is the ideal that we should try to achieve

Appealing **but** often not possible (a **chimera**) or not desirable (**unjustifiable** amounts of resources needed).

In animal health, zero-risk approaches may result in excessively stringent measures and may have **undesirable effects** (e.g. increased risk of illegal trade)

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

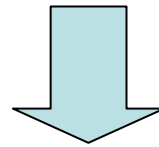




General concepts

Zero risk is often not possible or not desirable

We should try to determine a level of practical achievable control of risk



RISK ANALYSIS





General concepts

- **Risk analysis:**

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.

Society for Risk Analysis

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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

A process that requires multidisciplinary approach within a project team (Epidemiologist, Mathematicians, Infectious disease experts, veterinarians, ecologists...)





General concepts

- **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 Assessment:**

The process of evaluating the risk resulting from a hazard:

Based on how the risk estimate is presented:

- Qualitatively: the evaluated risk is described in words. The estimate of risk is ranked or separated into descriptive categories.
- Quantitatively: the evaluated risk is estimated numerically; numerical expressions of risk are provided.





General concepts

- **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?).





General concepts

- **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

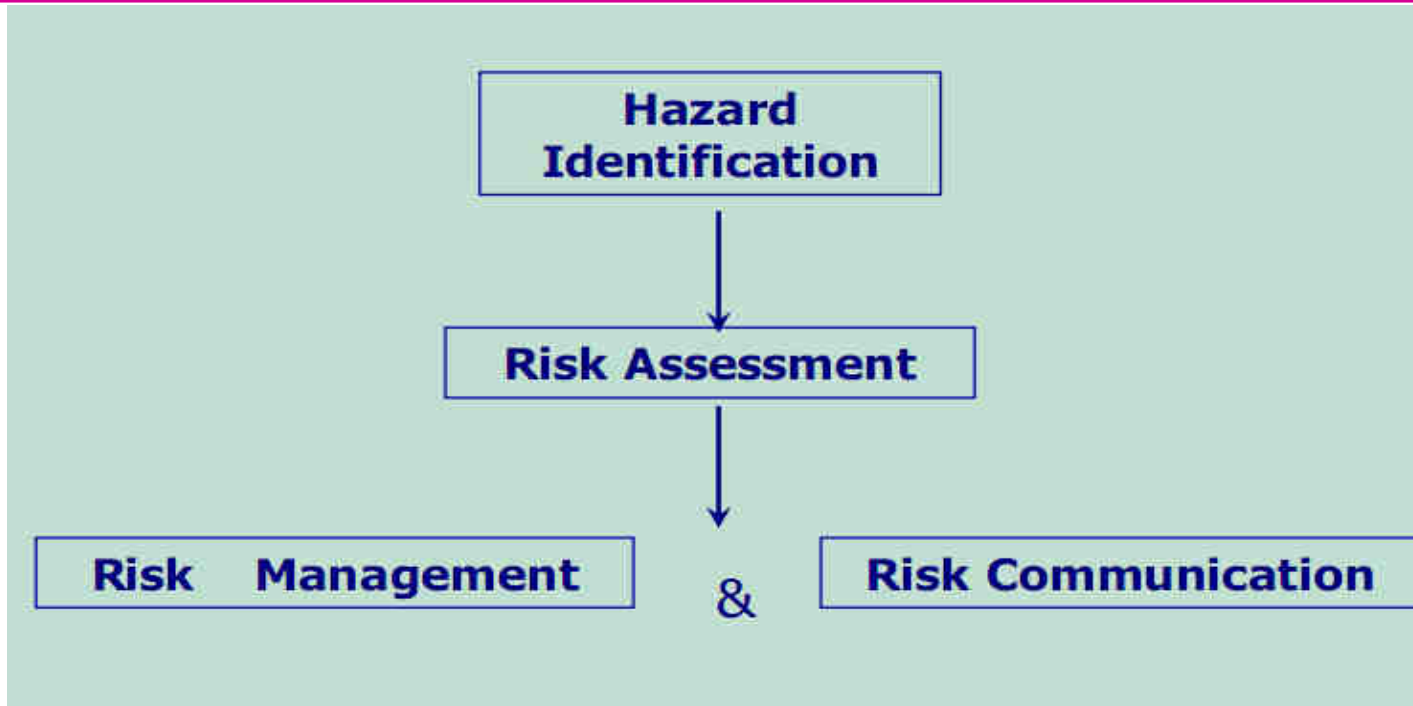
- **Risk communication:**

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.





General concepts



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





Areas of Application

- Food safety
- Animal health and trade
- Human health
- Environmental impact
- Agriculture
- Engineering
- Financial Management
- Security against terrorism
- ...





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.





Areas of Application

- **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.





Areas of Application

- **Financial Management**

Howard C. Kunreuther, Joanne Linnerooth-Bayer (2003)
**The Financial 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.





Approaches to Risk Assessment

- Risk assessment systems
- Risk assessment methodology





Approaches to Risk Assessment

- **Risk Assessment Systems**

Main systems used in animal health, food safety, veterinary public health:

- OIE International Animal Health Code
- Codex Alimentarius Commission

Different systems, developed to answer different types of risk questions.





Approaches to Risk Assessment

- **OIE International Animal Health Code**
 - Based on the Covello Merkhofer model
 - Risk assessment includes the following steps:
 - Release assessment
 - Exposure assessment
 - Consequence assessment
 - Risk estimation
 - Versatile, used to address risk questions of different types, designed to assess the actual magnitude of the risk.





Approaches to Risk Assessment

- OIE International Animal Health Code
 - **Release assessment:** description of biological pathways for release of hazard and estimation of its probability (*infected animal imported*)
 - **Exposure assessment:** description of biological pathways necessary for exposure of humans/animals to the hazards released and estimation of its probability (*indigenous animals exposed*)
 - **Consequence assessment:** description of relationships between exposures to hazards and consequences of those exposures (*death, illness of animals*)
 - **Risk estimation:** Integration of results from previous 3 steps to produce overall measures of risk associated with the hazards

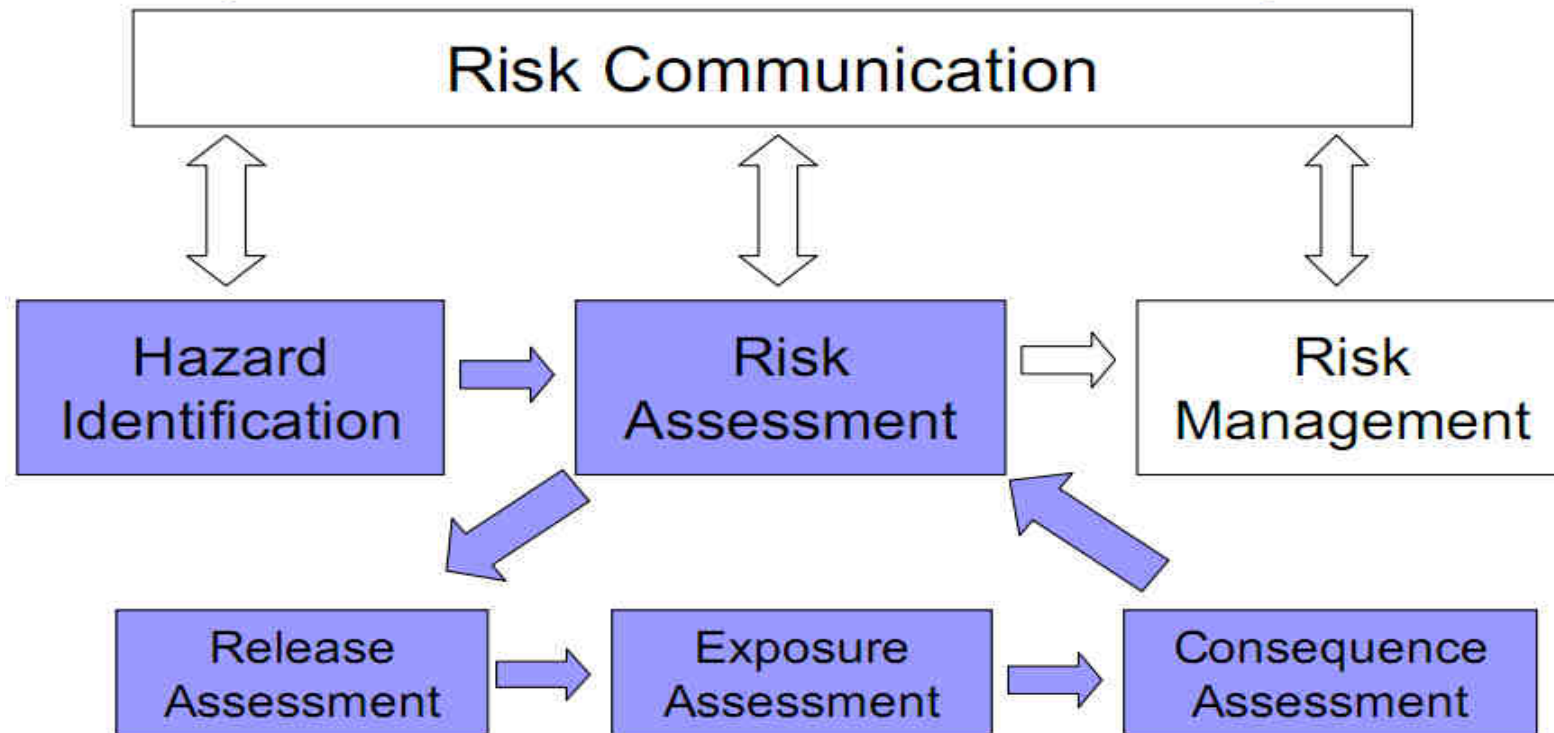




Approaches to Risk Assessment

Risk Analysis Components

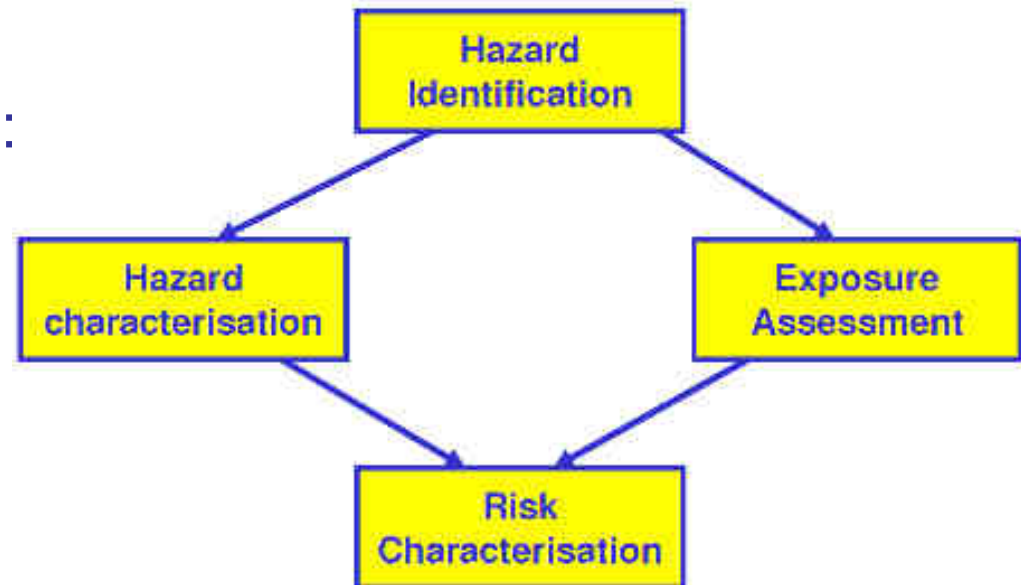
(after OIE *International Animal Health Code*)





Approaches to Risk Assessment

- **Codex Alimentarius Commission**
- Designed to answer questions in relation to maximum levels of substances or pathogens; main focus: microbiological food safety assessment.
- Based on the US National Academy of Science model (NAS-NRC)
- Risk Assessment includes:
 - Hazard identification
 - Exposure assessment
 - Hazard characterization
 - Risk characterization





Approaches to Risk Assessment

- Codex Alimentarius Commission
- **Hazard identification:** identification of the microorganisms or microbial toxins of concern.
- **Exposure assessment:** assessment of the extent of human exposure.
- **Hazard characterization:** description of the severity and duration of adverse effects that may result from exposure to the hazard.
- **Risk characterization:** integration of the three previous steps to obtain a risk estimate that would provide an estimate of the likelihood and severity of the adverse effects that could occur in a given population.





Approaches to Risk Assessment

OIE vs Codex

- Both are systems of risk assessment, part of risk analysis. Codex system includes hazard identification as part of the risk assessment.
- Exposure assessment (Codex) is equivalent to release assessment + exposure assessment (OIE)
- Assessment of consequences: consequence assessment (OIE) vs. hazard characterization (Codex)
- Final step in both cases is obtaining an estimate of risk: risk estimation (OIE), risk characterisation (Codex)
- Both systems require similar information, in both cases collected and organized in systematic and transparent ways.





Approaches to Risk Assessment

- **Risk assessment methodology**
 - Define and frame the question
 - Identify the potential hazard/s
 - Outline biological pathways
 - Collect information
 - Assess the risk





Approaches to Risk Assessment

- Qualitative vs. Quantitative
 - Define and frame the question, identify the potential hazard/s, outline biological pathways, collect information
 - Assess the risk: → Risk estimate, which can be presented:
 - Qualitatively: the evaluated risk is described in words. The estimate of risk is ranked or separated into descriptive categories.
 - Quantitatively: the evaluated risk is estimated numerically; numerical expressions of risk are provided.





Applications in Animal Health

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





Applications in Animal Health

- Risk analysis in 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>





Applications in Animal Health

- Risk analysis in animal-related trade
- WTO Agreement on Application of Sanitary and Phytosanitary Measures (SPS agreement)

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

WORLD TRADE ORGANIZATION

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Sanitary and Phytosanitary Measures

Problem: How do you ensure that your country's consumers are being supplied with food that is safe to eat — "safe" by the standards you consider appropriate? And at the same time, how can you ensure that strict health and safety regulations are not being used as an excuse for protecting domestic producers?

An agreement on how governments can apply food safety and animal and plant health measures (sanitary and phytosanitary or SPS measures) sets out the basic rules in the WTO.



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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.

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

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Applications in Animal Health

- Risk analysis in animal-related trade
- WTO SPS agreement
 - Scientific basis → regionalisation, risk analysis
 - Trust → harmonization, equivalence, transparency
- OIE International Animal and Aquatic Animal Health Code
 - 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
 - Human health
 - Bioterrorism (anthrax)





Risk-based surveillance

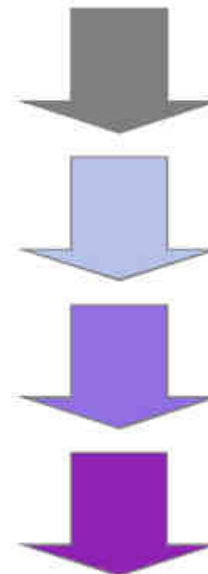
„A surveillance programme in the design of which risk assessment methods have been applied together with traditional design approaches in order to assure appropriate and cost-effective data collection.“

Risk assessment to select hazards to be surveyed

Risk assessment to select strata to be surveyed

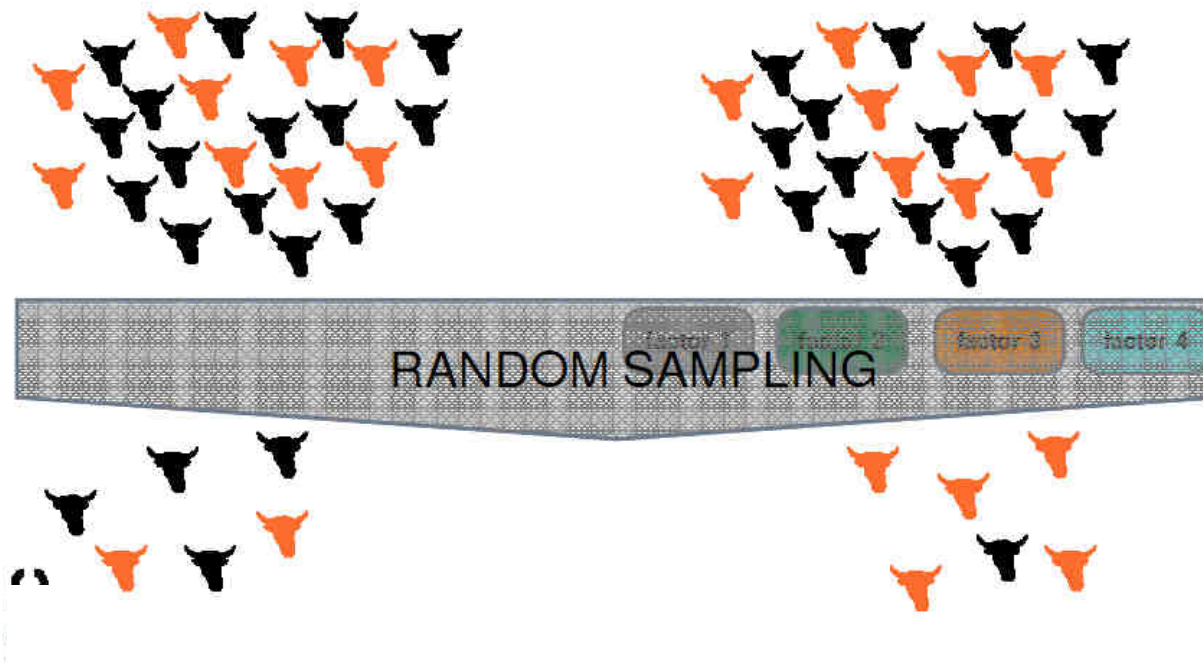
Risk assessment to select product to be surveyed

Random sampling





Risk-based surveillance



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





Applications in Animal Health

- Search in PVM for articles with ‘risk analysis’:
 - International trade:
 - Risk of introduction of BSE into Sweden by import of cattle from the UK
 - Risk of introduction of BSE into Japan by importation of cattle from UK and Germany
 - Global trade in ornamental 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 Animal Health

- **References**

- Guidelines for Risk Analysis. Chapter 1.4.2. In: OIE International Animal Health Code. Eight edition, 1999.
- Principles and Guidelines for the conduct of microbiological risk assessment. Codex Alimentarius Commission. 1999.
- Wooldridge M. Risk assessment applied to antibiotic resistance. Proceedings OIE European Scientific Conference on the use of antibiotics in Animals. Ensuring the protection of public health. 1999.
- Zepeda C., Salman M., Thiermann A., Kellar J., Rojas H., Willeberg P. The role of veterinary services in complying with the World Trade Organization SPS agreement. *Prev Vet Med* 2005; 67(2-3):125-40.

