SAFOSO

Animal Health Matters.
For Safe Food Solutions.

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An introduction to Risk Assessment principles

Marco De Nardi (SAFOSO, MSP)

Overview

- **Concepts and definitions:**
  - Risk
  - Hazard
  - Risk Analysis and Risk Assessment

- **Approaches to Risk Assessment:**
  - OIE vs Codex Alimentarius Framework
  - Qualitative vs Quantitative

- **How to implement a risk assessment**

- Concepts and definitions

Concepts

- **Risk:**

- a situation involving exposure to danger
- the possibility that something unpleasant will happen

(Compact Oxford English Dictionary of Current English)

- **Risk:**

- A function of the **probability** of an adverse health effect and the severity of that effect, consequential to a **hazard(s)** in food.

(Codex Alimentarious Commission –CAC)

Quiz 1

- How would you define an Hazard?

Concepts

- **Hazards:**

Something that has the potential to have **negative effect** on **our health**. We call that negative effect **unwanted outcome**.

- **Hazards:**

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 an undesirable consequence (*Society for Risk Analysis*)

Concepts

- **Risk vs Hazard:**

– **Hazard**: something with the potential to cause harm.

– **Risk**: the likelihood of occurrence and the magnitude of consequences of a specified hazard being realized.

Concepts

- **Risk Analysis:**
  - analytical process to provide information regarding undesirable events;
  - process of estimating probabilities and expected consequences for identified risks.

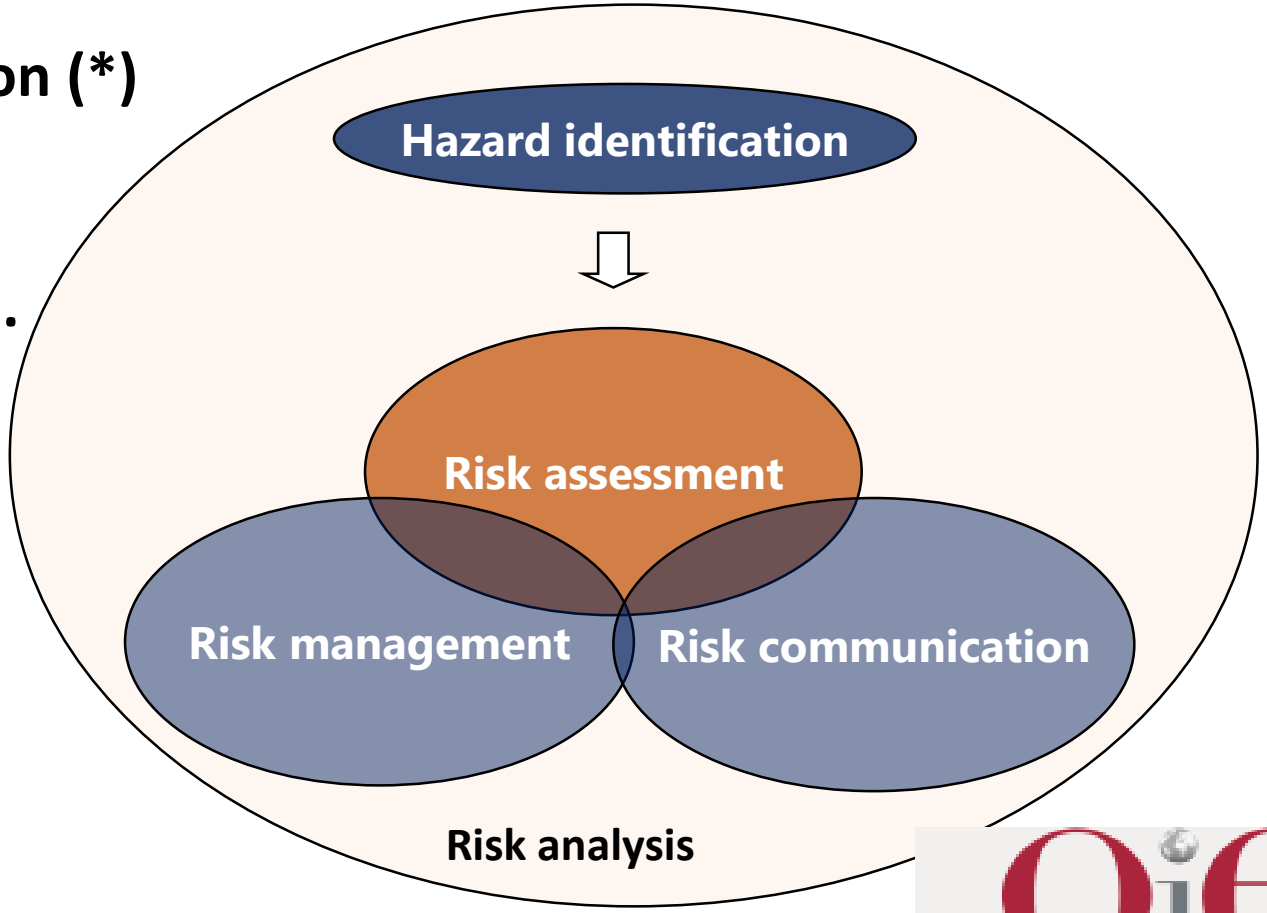
(*Society for Risk Analysis: http://www.sra.org/resources_glossary*)

Concepts

A process consisting of 3-4 components:

hazards identification (*)
risk assessment,
risk management
risk communication.

(*)= only OIE



Concepts

- **Hazard Identification (HI) -** 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
- (HI = included in the Risk assessment component in the OIE framework. As separate component in the CAC framework)

- **Risk Assessment** - The process of evaluating the risk resulting from a hazard. A scientifically based process consisting of the following steps:

  (i) hazard identification,

  (ii) hazard characterization,

  (iii) exposure assessment,

  (iv) risk characterization.

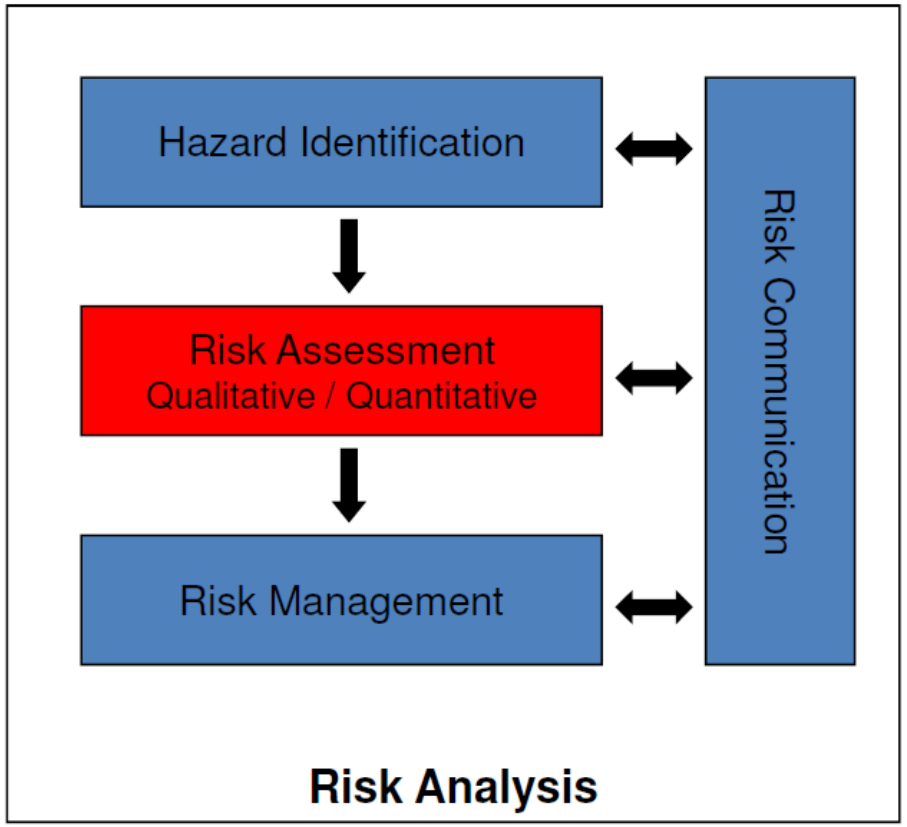
Concepts

- **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 Communication** - The interactive exchange of information and opinions throughout the risk analysis process concerning risk, 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.

Concepts

- Risk assessment is only part of the whole process of risk analysis:



- Approaches to Risk Assessment

Approaches to Risk Assessment

- **Risk Assessment Systems:**

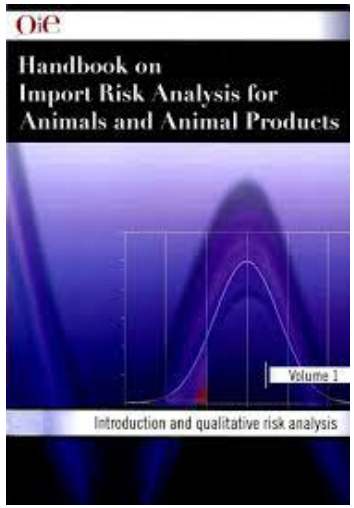
– **OIE** vs **Codex Alimentarius**

- **Risk Estimates:**

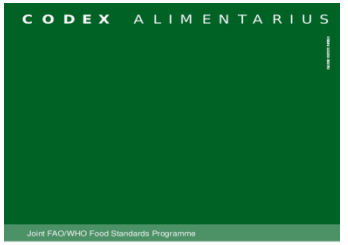
- Qualitative vs quantitative approach

Two approaches to risk analysis

- **OIE Animal Health Code approach**:
  - Based on Covello-Merkhofer model
  - **Versatile methods**. Able to answer risk questions of different types
  - Main focus: risk from importing animals or animal products



- **Codex Alimentarius Commission (CAC) approach**:
  - Based on USA National Academy of Science model (NAS-NRC)
  - Designed originally to answer questions in relation to maximum levels of substances or pathogens in food;
  - Main focus: Emphasis on food safety (**Microbiological Risk Assessment**, concerned with the risk from consuming food products)



Two approaches cont.

OIE method (Covello-Merkhofer)	Codex Alimentarius method (NAS-NRC)
Hazard identification	
Risk Assessment - **Release assessment** - **Exposure assessment** - **Consequence assessment** - **Risk estimation**	**Risk Assessment** - **Hazard identification** - **Hazard characterization** - **Exposure assessment** - **Risk characterization**
Risk management - Risk evaluation - Option evaluation - Implementation - Monitoring and review	**Risk management** - Risk evaluation - Option assessment - Monitoring and review
Risk communication throughout	**Risk communication** throughout

Two approaches cont.

- Altought differences exist both models systems conclude with a step which utilizes the results of the previous steps to give a **final estimate of risk**:

- Risk estimation (OIE)

- Risk characterization (CAC)

- They basically include the **same fundamental steps** even though in a slightly different order

Risk assessment in the veterinary sphere

- **International trade**
  - Import
  - Export
- **Veterinary biologicals**
  - Vaccines
  - GMOs
- **Food safety**
  - Infectious organisms
  - Toxins
- **Disease transmission**
  - Within herds / beetween herd

OIE vs CAC : examples

OIE

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Available online at www.sciencedirect.com
ScienceDirect

Preventive Veterinary Medicine 86 (2008) 43–56

PREVENTIVE VETERINARY MEDICINE

www.elsevier.com/locate/prevetmed

Quantitative risk assessment of foot-and-mouth disease introduction into Spain via importation of live animals

B. Martínez-López [a,*], A.M. Perez [b,c], A. De la Torre [d], J.M. Sánchez-Vizcaíno Rodriguez [a]

CAC

ELSEVIER

Preventive Veterinary Medicine 37 (1998) 129–145

PREVENTIVE VETERINARY MEDICINE

Quantitative risk assessment of human listeriosis from consumption of soft cheese made from raw milk

N. Bemrah[a], M. Sanaa[a,*], M.H. Cassin[b], M.W. Griffiths[c], O. Cerf[a]

[a] *Epidemiology and Animal Health Management Laboratory, Alfort Veterinary School, Maisons-Alfort, France*
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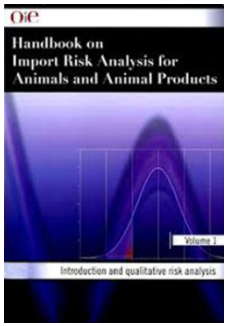
[c] *Department of Food Science, University of Guelph, Guleph, Ontario, Canada*

Quiz 2

- Which approach would you use in the MSP?

➢ **<u>Not really important</u>. The differences are subtle. And whichever system is being used the same kind of information must be collected and organized an similar, transparent ways.**

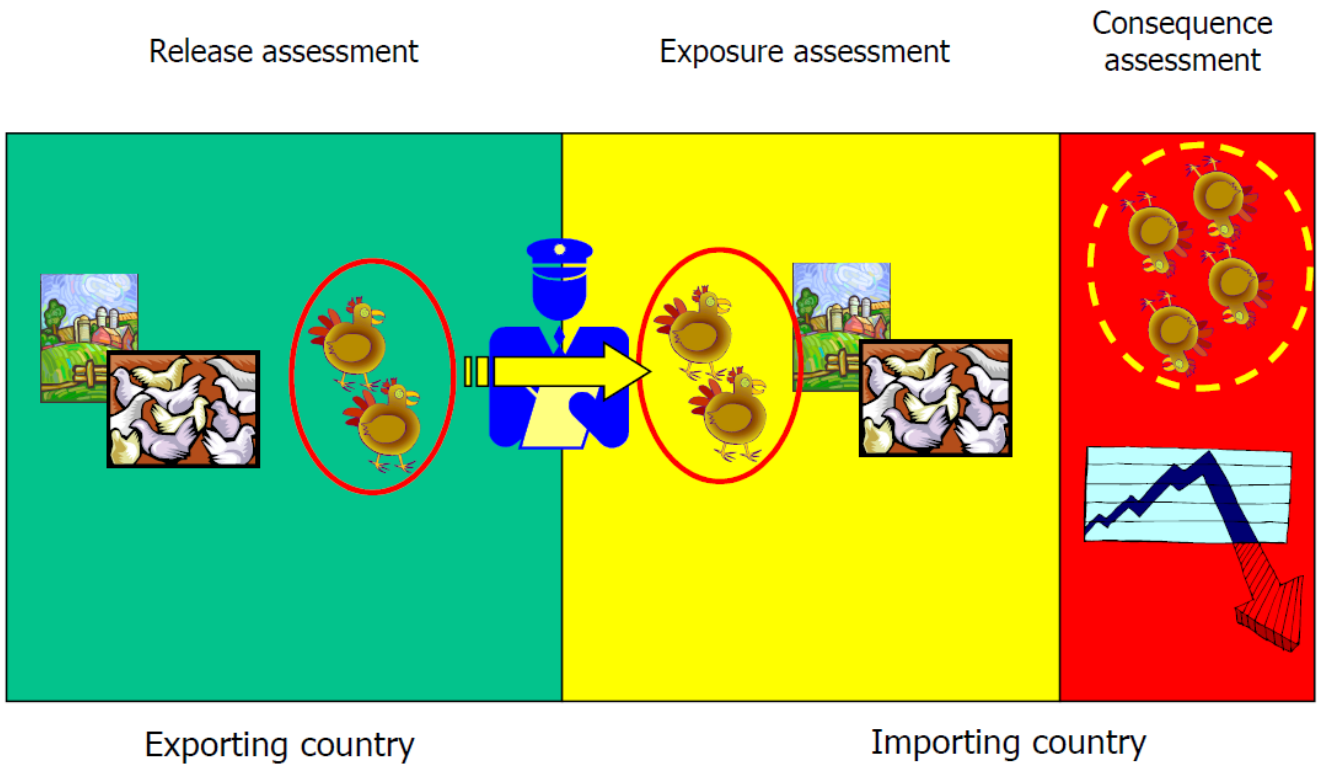
OIE International Animal Health Code



The risk assessment includes the following steps:

- **Release assessment**: description of biological pathways for release of hazard and estimation of its probability.
- **Exposure assessment**: description of biological pathways necessary for exposure of humans / animals to the hazards released and estimation of its probability.
- **Consequence assessment**: description of relationships between exposures to hazards and consequences of those exposures (biological and economic).
- **Risk estimation**: Integration of results from previous 3 steps to produce overall measures of risk associated with the hazards

OIE International Animal Health Code



Cristóbal Zepeda, Centers for Epidemiology and Animal Health USDA-APHIS /Animal Population Health Institute, Colorado State University

Codex Alimentarius Commission (CAC) approach:

- Risk assessment is defined for the purposes of the Codex Alimentarius Commission as "*A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization*."

- **Hazard identification** is "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** is "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."

Codex Alimentarius Commission (CAC) approach:

- **Exposure assessment** is "The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant."

- **Risk characterization** is "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."

  (World Health Organization, 2010)

- How to implement a risk assessment

In summary: how to do a risk assessment

- The main steps of a risk assessment are:

1. Identifying and prioritize the **hazard**(s) of interest

   Define the **unwanted outcome**

   Framing the **risk question**

   Characterize the hazards (if CAC)

2. Outlining the steps necessary (**risk pathways)** to get from hazard of interest to unwanted outcome

3. Identifying **data** and **information** needs

4. **Collecting** data and information to estimate the probability of each event in the pathway

5. **Assessing the risk**

   - *Qualitatively*

   - *Quantitatively*

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Qualitative vs. Quantitative

- The **qualitative** risk assessment gives output in words: the risk is high, low, negligible. Its simpler, quicker and cheaper, and can be done where information is missing.

- The **quantitative** risk assessment gives a mathematical output. Its more complex, time-consuming and requires more data and information.

Qualitative risk estimation

Likelihood	Description
Very high	The event occurs almost certainly.
High	The event occurs very often.
Medium	The event occurs regularly.
Low	The event is rare but does occur.
Very low	The event is rare but cannot be excluded.
Negligible	The event is so rare that it does not merit to be considered.

Quiz 3

Try to fill the gaps:

Identifying the hazard(s) of interest: ……..

Define the unwanted outcome: ……

Framing the risk question: ……..

Quiz 3

Try to fill the gaps:

Identifying the hazard(s) of interest: *Brucella abortus*

Define the unwanted outcome: **Human infection** with *Brucella abortus* from consumption of raw or pasteurized milk/milk products

Framing the risk question: What is the probability per year of human infection resulting from *B. Abortus* in raw or pasteurized milk/milk products produced and consumed within Ukraine?

Today's job

- The main steps of a risk assessment are:

1. Identifying and prioritize the **hazard**(s) of interest

   Define the **unwanted outcome**

   Framing the **risk question**

   Characterize the hazards (if CAC)

2. Outlining the steps necessary (**risk pathways)** to get from hazard of interest to unwanted outcome
3. Identifying **data** and **information** needs
4. **Collecting** data and information to estimate the probability of each event in the pathway
5. **Assessing the risk**
   - *Qualitatively*
   - *Quantitatively*

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Thanks