Introduction to risk assessment

Flavie GOUTARD – UR AGIRs, CIRAD
goutard@cirad.fr

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Objectives of the lecture

- Be able to explain the key elements of Qualitative Risk assessment
- Be able to develop basic qualitative risk assessment models, given specific questions

Approaches to Risk Assessment

- Different systems used in animal health, food safety, VPH, to answer different types of risk questions:
  - Codex: Designed to answer questions in relation to maximum levels of substances or pathogens, main focus: microbiological food safety assessment
  - OIE: Used to address risk questions mainly for importation / introduction
  - WHO: In order to propose rapid and defensible decision-making about acute public health events

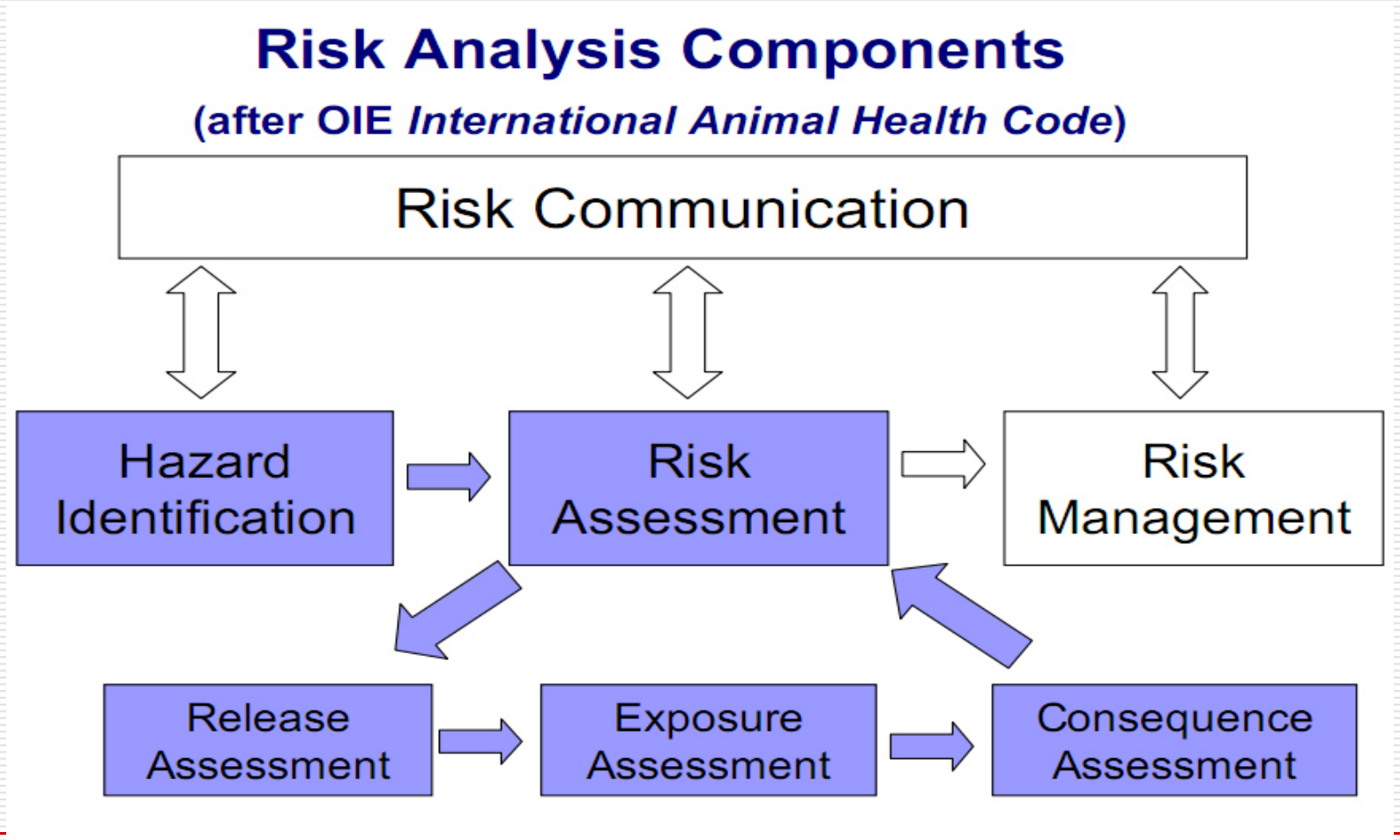
Approaches to Risk Assessment

- **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 adress risk questions of different types, designed to assess the actual magnitude of the risk.

Approaches to Risk Assessment: OIE

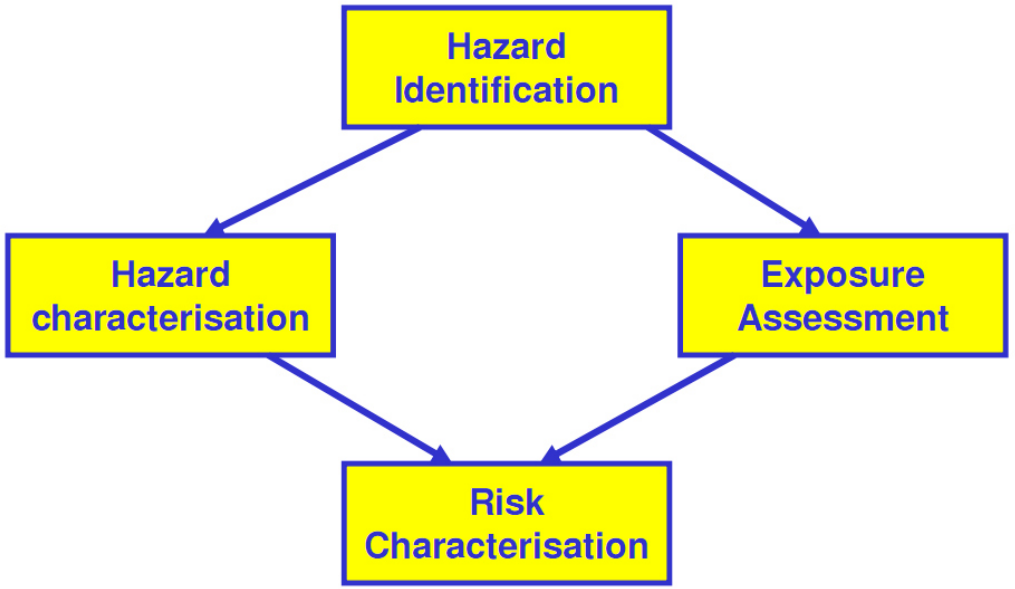
- **Release assessment**: description of biological pathways for release of hazard and estimation of its probability *(infected animal imported)*
- **Exposure assessment**: description of biological pathways necessary for exposure of humans/animals to the hazards released and estimation of its probability *(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



Approaches to Risk Assessment: Codex

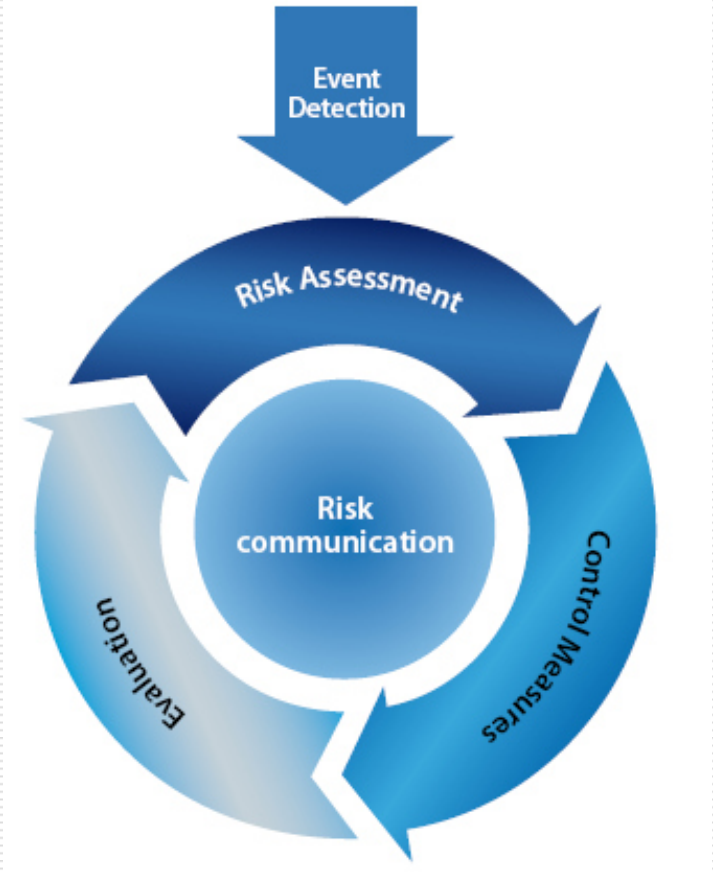
- Designed to answer questions in relation to maximum levels of substances or pathogens; main focus: microbiological food safety assessment.
- Based on the US National Academy of Science model (NAS-NRC)
- Risk Assessment includes:
  - Hazard identification
  - Exposure assessment
  - Hazard characterization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



Approaches to Risk Assessment: Codex

- **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.

WHO: Risk management cycle



Risk management cycle as defined by WHO (2012)

Risk asssessment is only part of the whole process of risk management cycle (risk analysis)

- **Control measures:** ranked by priority, likelihood of sucess, feasability and consequences

- **Evaluation**: continuous monitoring

- **Risk communication**: ongoing to every stakholders in order to support control measures

Qualitative vs Quantitative approach

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

Qualitative risk assessment comprises

- Collection of information
- Arrangement of information in a logical manner
- Deduction from that information the likely magnitude of risk
- Identification of unwanted consequences

Context of use - Applications

- **When:**
  - As a first step, before quantitative approach

  Results → rule out some pathways, identify non-negligible risk requiring quantification, or gaps in knowledge, etc.
  - When numerical data is not available
  - When risks perceived do not justify time and effort required with the quantitative approach…
- **What:**
  - Outbreak investigation
  - Surveillance activities
  - Etc.

⇨ Common approach to support routine decision making

Steps of qualitative risk assessment

- Assembling the risk assessment team
- Frame the risk question
- Outline the risk pathway
- Collect the information
- Assess the risk

- steps common to both qualitative and quantitative approaches
- iterative approach

Transparency

- Describe and evaluate information sources
- identify processes/methods
- provide rationale for conclusions and decisions
- describe uncertainty and identify data gaps or areas for additional research
- peer review

Steps of qualitative risk assessment

- **Assembling the risk assessment team**
- Frame the risk question
- Outline the risk pathway
- Collect the information
- Assess the risk

Assembling the risk assessment team

- Context:
  - Hazard unknown
  - Not an infectious agent
  - Associated with sickness in animals
  - Associated with food, chemical, radionuclear accident
- Additional expertise
  - Toxicology
  - Animal health
  - Food safety
  - Radiation protection
  - …
  - **Communication specialist**

Framing the risk question

- The risk to be assessed should be clearly defined
- Points to consider:
  - What is the specific hazard of concern?
    - Pathogen X/ Long list of pathogens
  - What are the vector/vehicle of the hazard of concern
    - Persons/Products…
  - Who is likely to be affected?
    - Young/oldest…
  - What specific risk do we want to assess
    - Spread / emergence?...
  - What particular time frame are we interested in?
    - Year/Week?...

Framing the risk question

- If not specific enough, a risk question can be interpreted in different ways:
  - Ex: What is the risk for the introduction of HPAI H5N1 (through migratory birds / formal poultry trade/ informal poultry trade…) into population (wild birds/backyard/commercial/human…) in Ethiopia?
- Sometimes several questions are relevant (one pathway for one question)

Framing the risk question

Question A

- Importing a group of cattle: what is the risk of this group passing on any infectious pathogen to indigenous livestock?

- Risk for this import group only
- Risk of infection from any infectious pathogen
- Risk to any indigenous livestock

Framing the risk question

Two deaths and 16 suspected cases of cholera in a camp for internally displaced persons in a particular district.

- What are the risk and the consequence that cholera will spread outside this particular district in a week period?

Framing the risk question

Paediatric analgesic syrup formulated with diethylene glycol is identified after a cluster of deaths in children.

- What are the risk and the consequence that this product will be marketed abroad formally?
- What are the risk and the consequence that this product will be marketed abroad unformally?

Framing the risk question

An outbreak of hand, foot and mouth disease (HFMD) in nursery school children in one of 14 regions in a country.

- What are the risk and the consequence that HFMD will spread outside this particular regions in a week period?
- What will be the effect on this risk if implementing quarantine measures?

Outline risk pathway

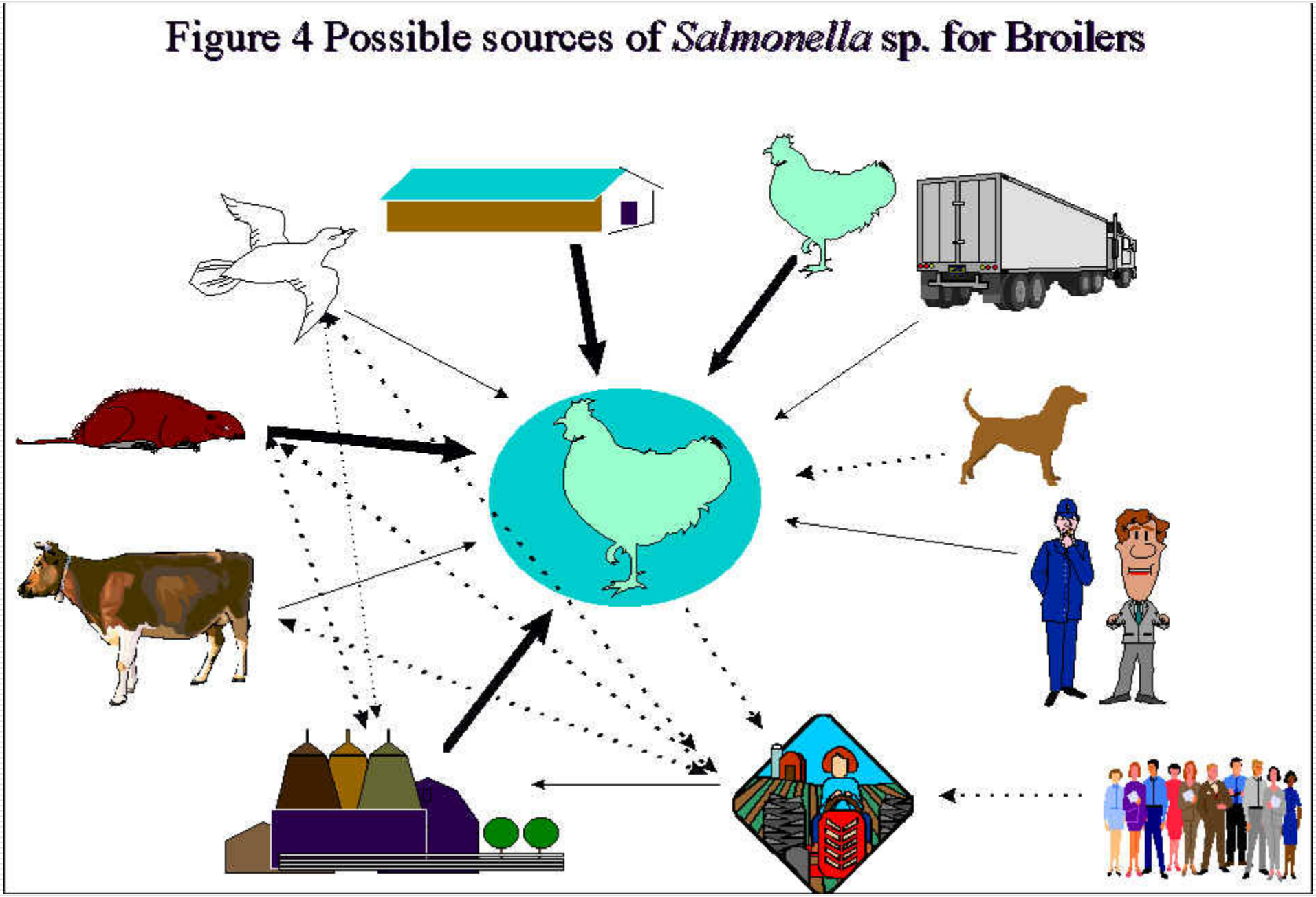
Risk pathway: Framework on which to base the risk assessment, describing all stages in the biological process that lead to the outcome of interest

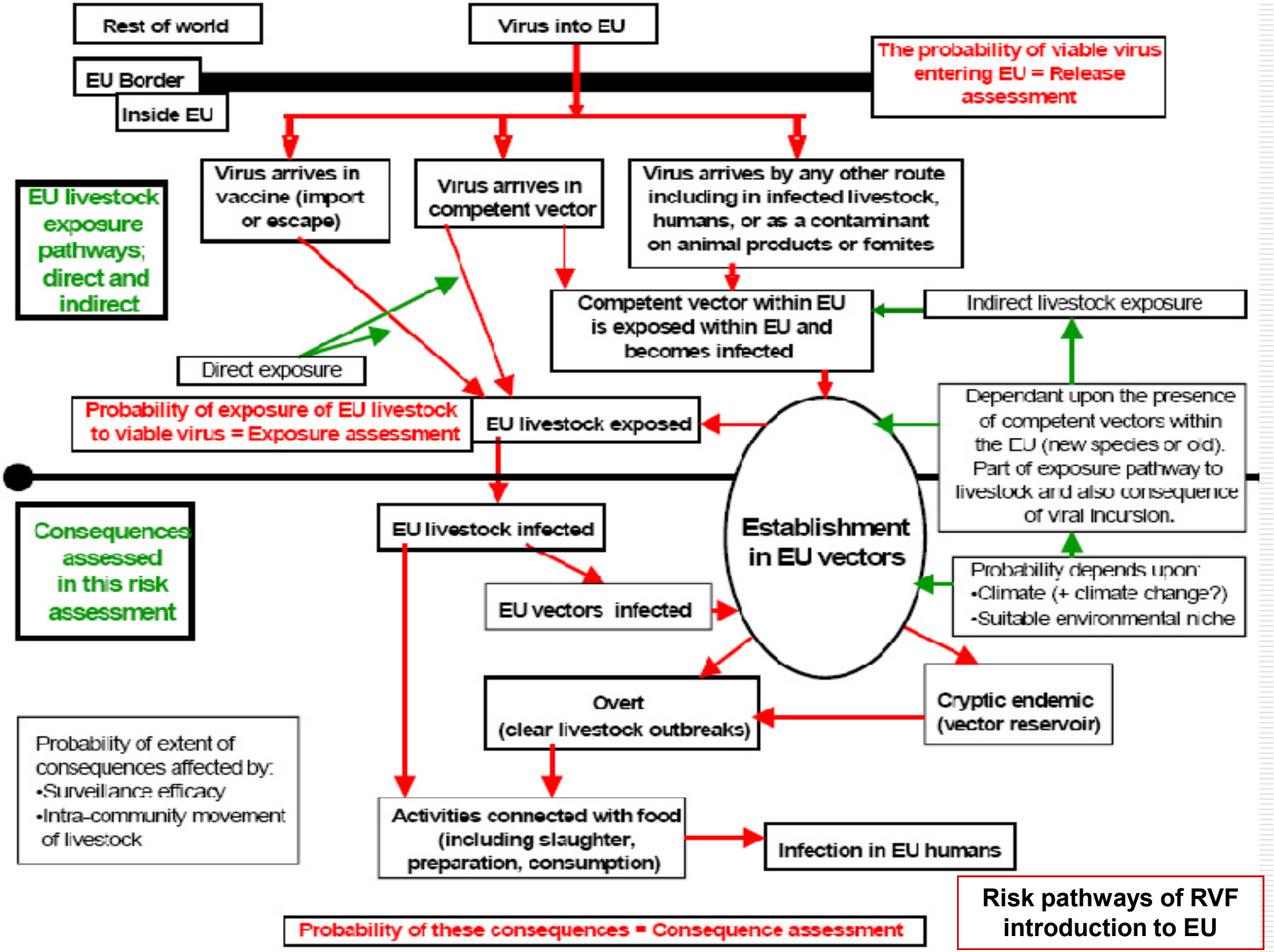
- List all steps required for the risk to occur
- Important to report your underlying assumptions

Pathways analysis steps

- **Step 1:**
  - Establish an understanding of host, agent, and environmental interactions for the disease in question based on **scientific** literature, expert opinion, personal experience or other sources of information.
- **Step 2:**
  - Develop a list of potential pathways for entry/dissemination of the disease agent into a susceptible livestock and/or human population
- **Step 3:**
  - Evaluate the feasibility of each pathway
- **Step 4:**
  - Identify the populations at-risk for each feasible pathway that the disease agent follows to enter/disseminate in the environment.

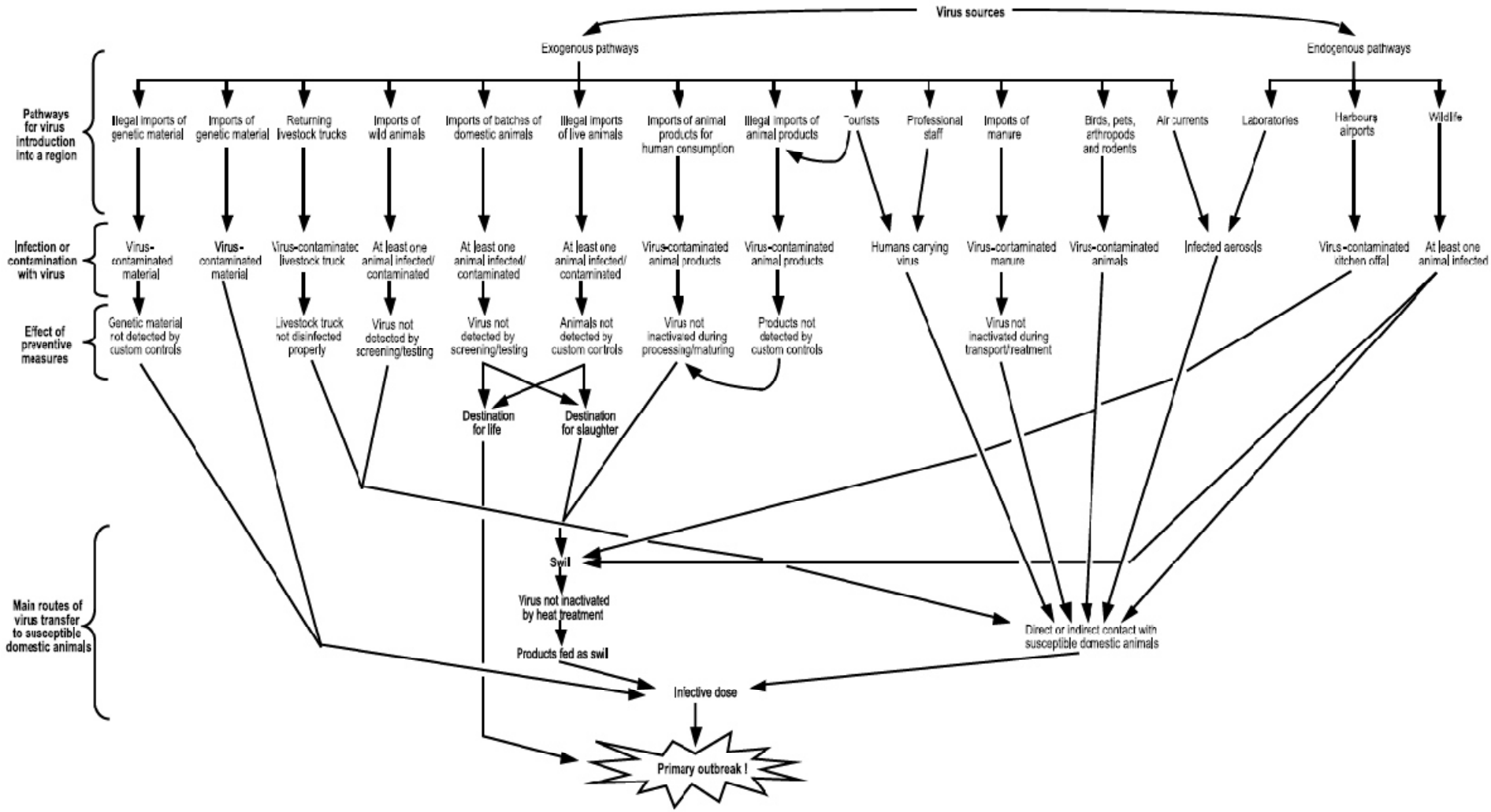
Figure 4 Possible sources of *Salmonella* sp. for Broilers





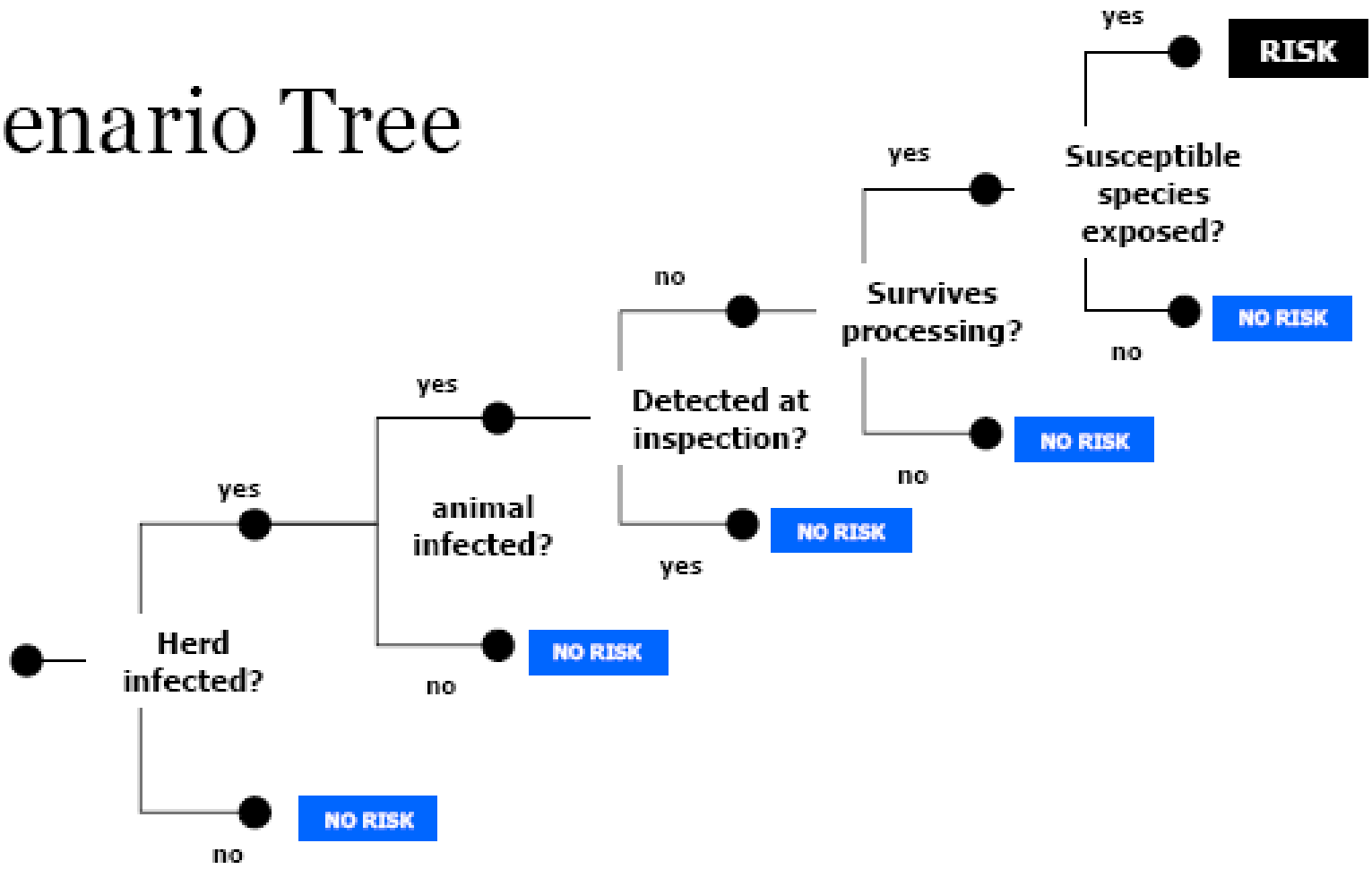
Risk pathways of RVF introduction to EU

Pathway diagram containg all the pathways to contribute to the likelihood of Classical Swine fever introduction in European Union



De Vos C. J. et al., 2003. The risk of the introduction of Classical Swine fever at regional level in the European Union: conceptual framework. Rev. sci. tech. Off. int. Epiz., 2003, 22(3), 795-810.

Scenario Tree



Steps of qualitative risk assessment

- Frame the risk question
- Identify the hazard(s)
- Outline the risk pathway
- **Collect the information**
- Assess the risk

Collect information

- For each step on pathway
- Number of sources
  - Literature, experimental, expert opinion…
- Consider validity
  - Most up to date
  - Estimates of prevalence from surveillance systems, Expert opinion
- Fully referenced (transparency)

Steps of qualitative risk assessment

- Frame the risk question
- Identify the hazard(s)
- Outline the risk pathway
- Collect the information
- **Assess the risk**

Assessing the risk

Qualitative risk assessment:

Evaluation, in non numerical terms, of the overall probability of the pathway of events from hazard to outcome

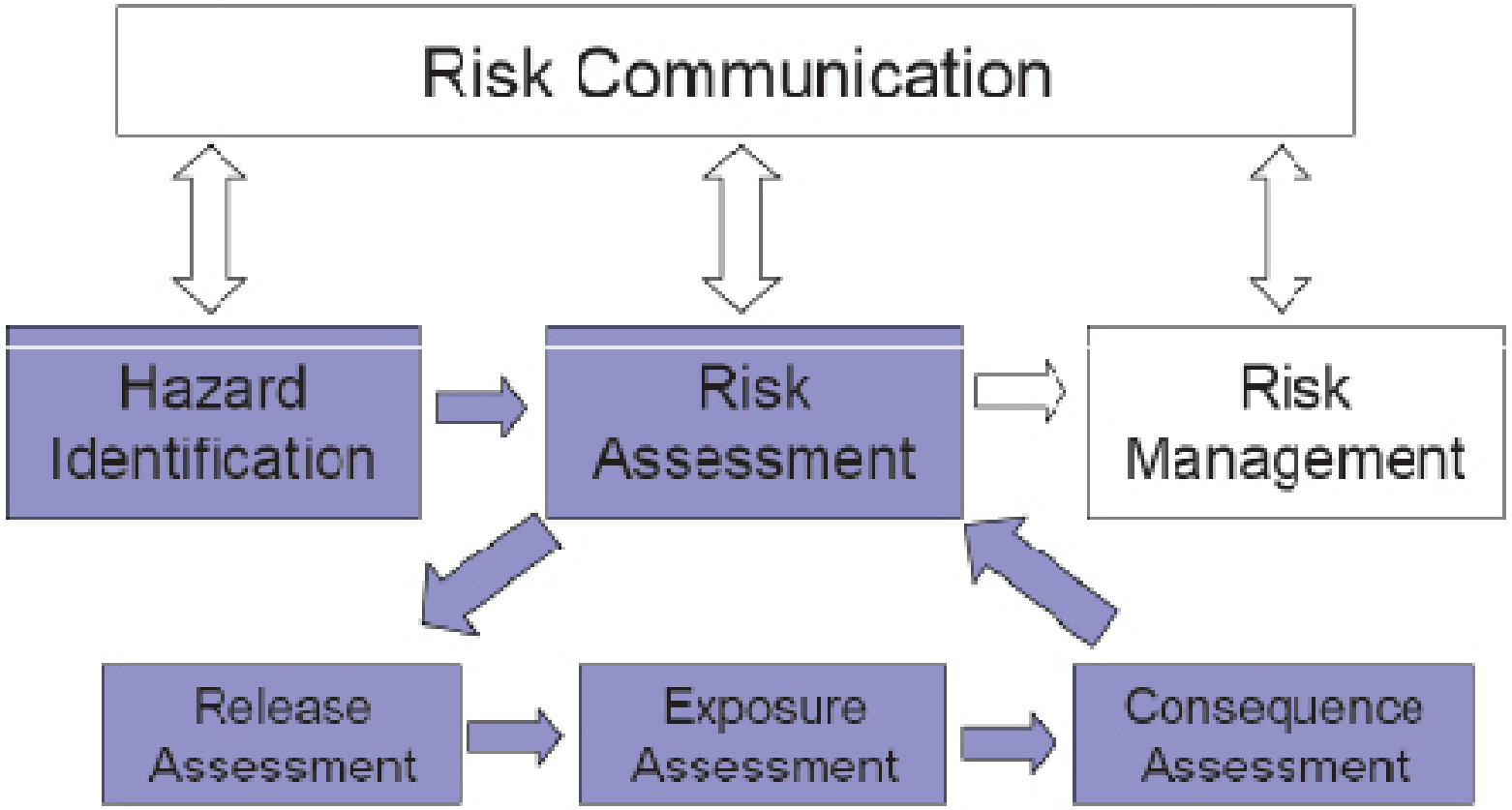
- The result of a qualitative risk assessment is a probability, described by words
- The risk can be estimated as:
  - **Negligible.**
  - **Low.**
  - **Moderate.**
  - **High.**

Components of Risk Assessment

- OIE International Animal Health Code
- The risk assessment includes the following components:
  - Release assessment
  - Exposure assessment
  - Consequence assessment
  - Risk estimation

Risk Analysis Components

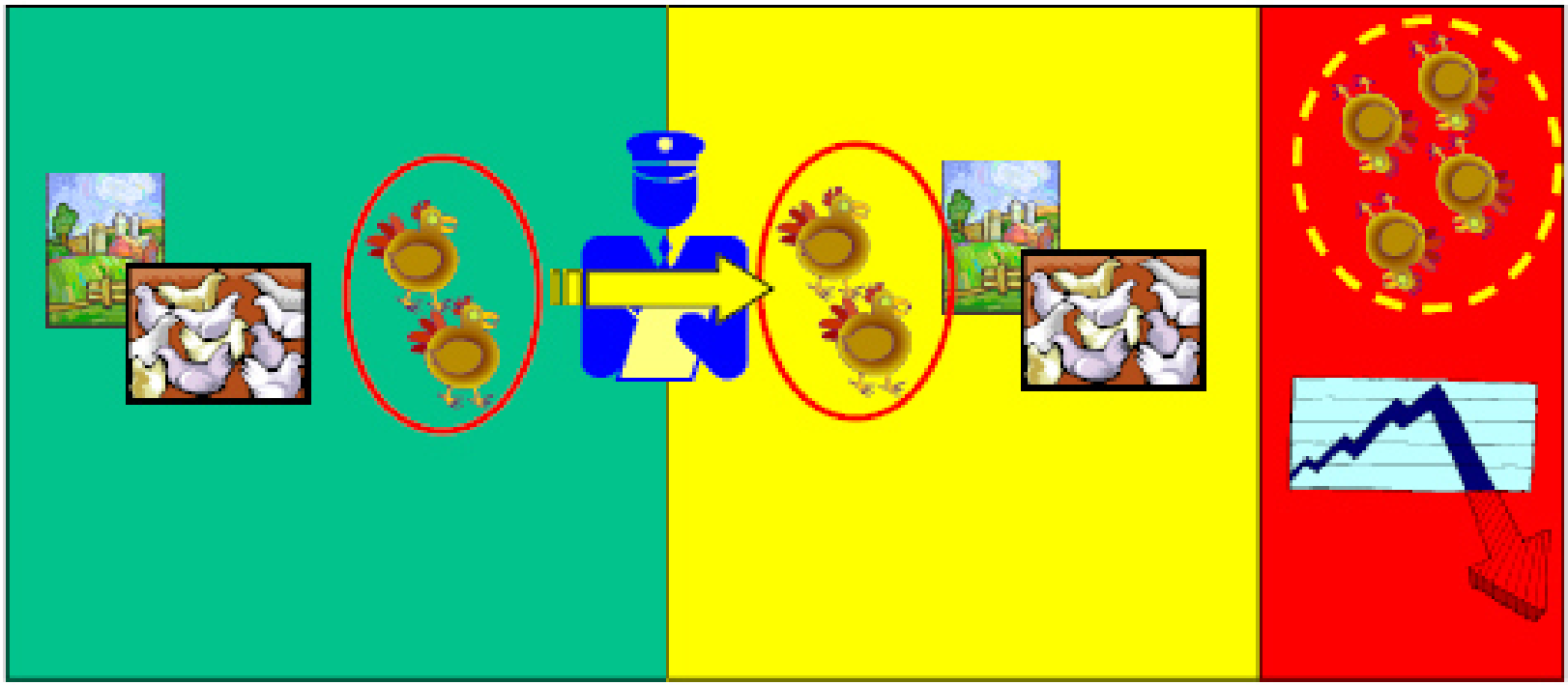
(after OIE *International Animal Health Code*)



Release assessment

Exposure assessment

Consequence assessment



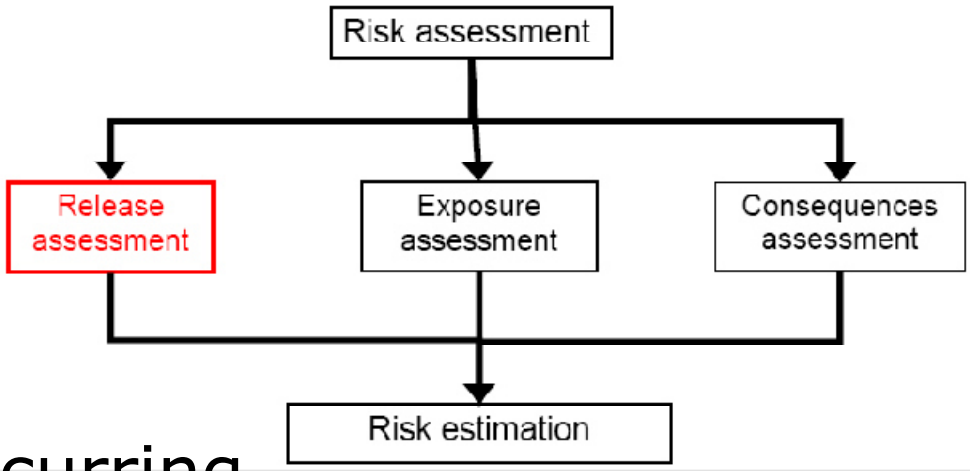
Exporting country

Importing country

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

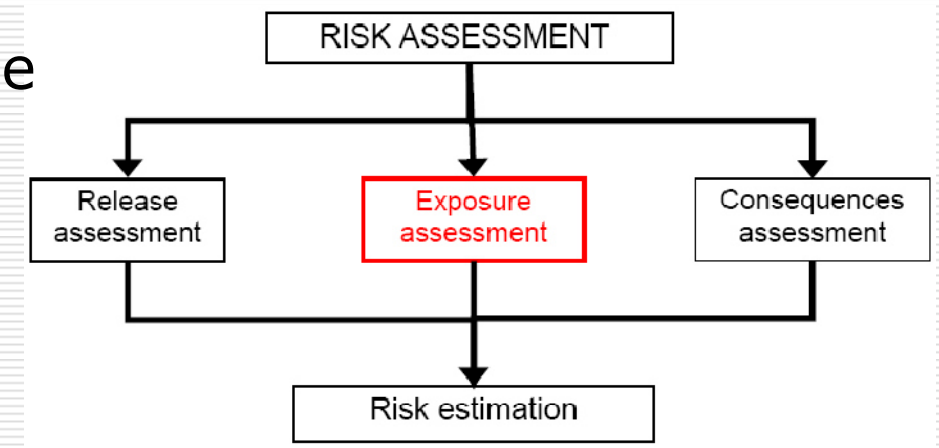
Release assessment

- Describes the biological pathway(s) necessary for an importation activity to 'release' (introduce) a pathogen into a particular environment
  - Pathways analysis
- Estimates the probability of that complete process occurring



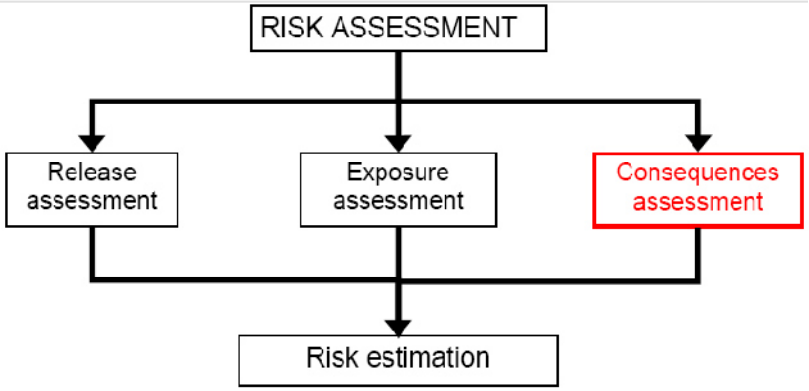
Exposure assessment

- Describes the biological pathway(s) necessary for exposure of animals and humans in the *studied environment* to the *hazards* released from a given *risk* source
- Estimate the probability of the exposure(s) occurring.
  - animal and/or people



Consequence assessment

- Describes the relationship between specified exposures to a biological agent and the consequences of those exposures
  - Direct consequences
    - animal infection, disease, and production losses
    - public health consequences.
  - Indirect consequences
    - surveillance and control costs
    - compensation costs
    - potential trade losses
    - adverse consequences to the environment



Risk estimation

- Integration of the results from:
  - Release assessment
  - Exposure assessment

  Likelihood of occurence

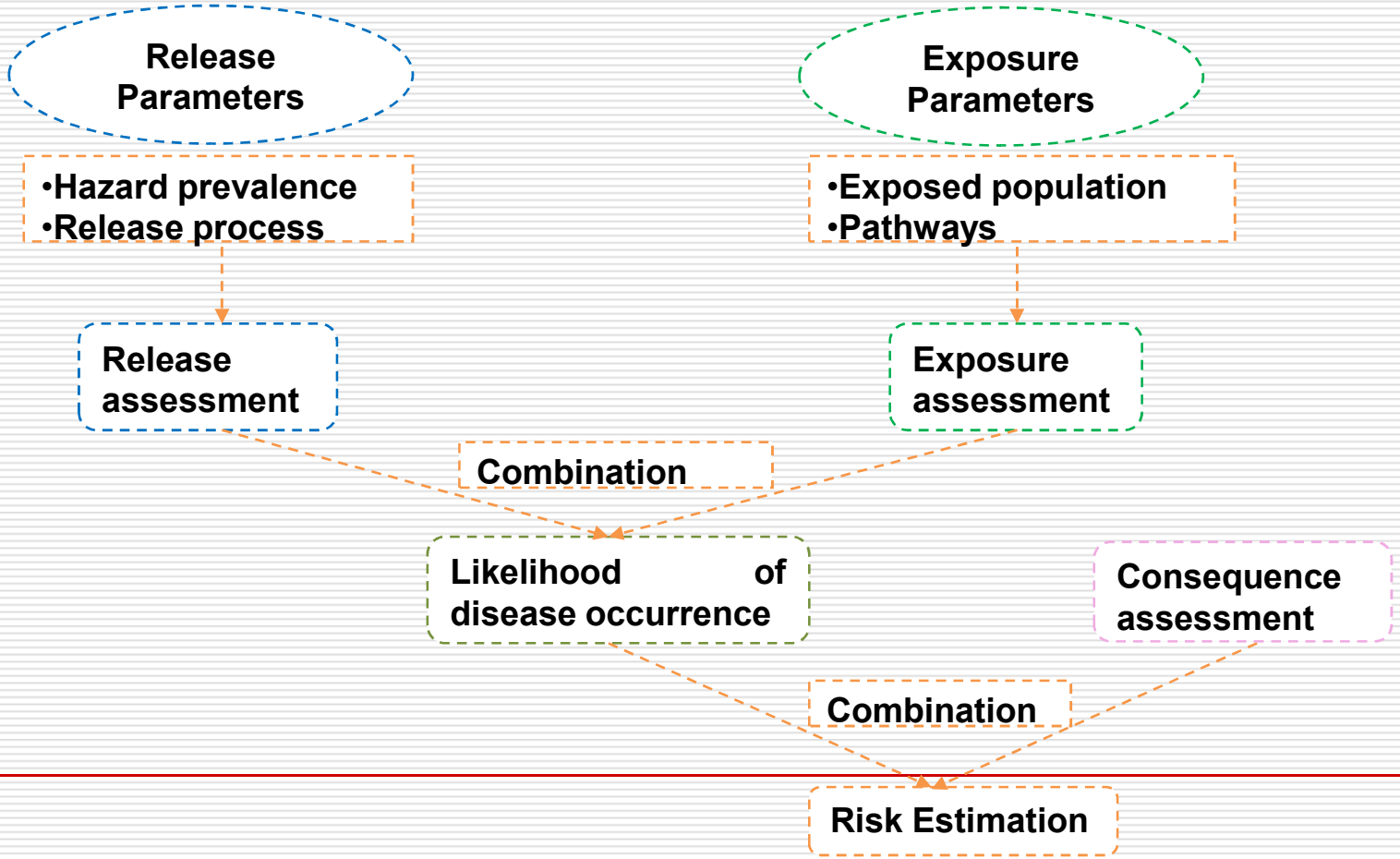
  +
  - Consequence assessment

  = **Risk estimation**

  To produce overall measures of risk associated with the hazards

Risk estimation

- The overall probability is obtained by combining the probabilities of the various consecutive steps:

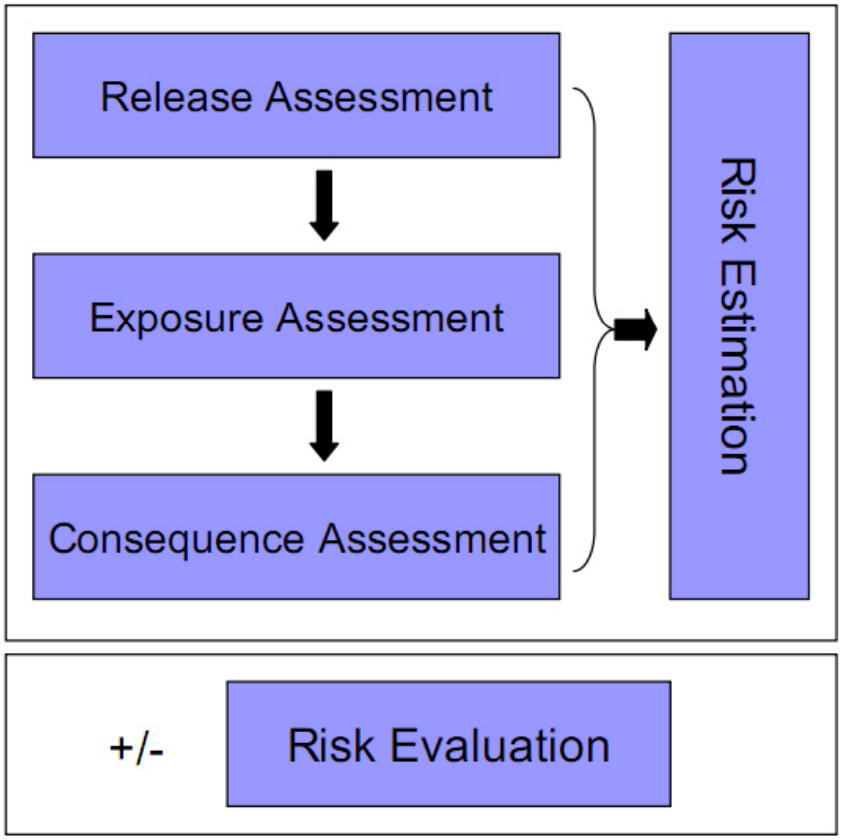


Assessing the risk

- Review information and estimate risk for each step
- Deduct the overall probability of occurrence of the risk of interest and of unwanted consequences
- +/- decide whether this risk is acceptable or not

NB: « low » or « negligible » risk does not imply « acceptable risk » (e.g. when severe consequences for human population)

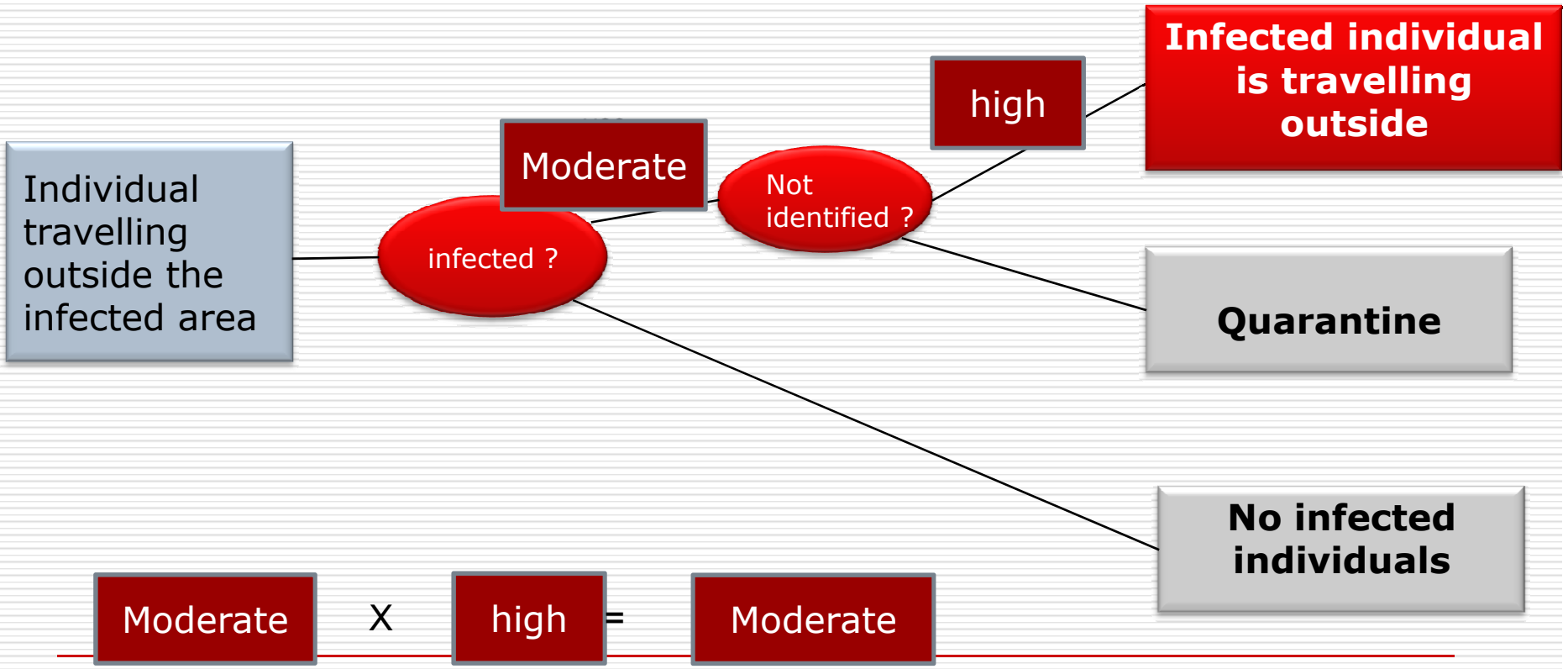
- OIE Framework (Import risk analysis)



Key points

- Combination of risks (risk estimation)

  No consensus → Important to define method selected for combining levels of risks



Example: Decreasing risk along the pathway

This matrix assumes that the risk cannot increase along the risk pathway: cascade of events, each event depends on the outcome of the previous one (similar to multiplying risk estimates in quantitative risk assessment)

Step x * Step y		Risk estimate Y			
		Negligible	**Low**	**Medium**	**High**
Risk estimate X	**Negligible**	Negligible	Negligible	Negligible	Negligible
	Low	Negligible	Low	Low	Low
	Medium	Low	Low	Medium	Medium
	High	Low	Medium	Medium	High

Example: Increasing risk along the pathway

This matrix assumes that if a risk is non-negligible the risk can increase along the risk pathway (non-dependent events), can be suitable in food safety risk assessment (increase of pathogen burden along risk pathway) or to combine release, exposure and consequences.

Overall conservative approach, may lead to overestimation of risk

Step x * Step y		**Risk estimate Y**			
		Negligible	**Low**	**Moderate**	**High**
Risk estimate X	**Negligible**	Negligible	Low	Low	Moderate
	Low	Low	Low	Moderate	Moderate
	Moderate	Low	Moderate	Moderate	High
	High	Moderate	Moderate	High	High

Estimates of consequences

LEVEL	CONSEQUENCES
MINIMAL	Limited impact on the affected population Little disruption to normal activities and services Routine responses are adequate No extra costs for authorities and stakeholders
MINOR	Minor impact for a small population or at-risk group Limited disruption to normal activities and services A small number of additional control measures are required Some increase in costs for authorities and stakeholders.
MODERATE	Moderate impact as a large population or at-risk group is affected Moderate disruption to normal activities and services Some additional control measures will be needed Moderate increase in costs for authorities and stakeholders
MAJOR	Major impact for a small population or at-risk group Major disruption to normal activities and services A large number of additional control measures will be needed Significant increase in costs for authorities and stakeholders
SEVERE	Severe impact for a large population or at-risk group Severe disruption to normal activities and services A large number of additional control measures will be needed Serious increase in costs for authorities and stakeholders

Key points

- Descriptive risk rating:
  - Ex.: negligible < low < moderate < high
  - Must be clearly defined at the beginning of the risk assessment

Risk estimation qualitative RA

Risk category	Interpretation
Negligible	probability of event sufficiently low to be ignored or event only possible in exceptional circumstances (RA can be concluded for pathways with negligible risk)
Low	occurrence of event is a possibility in some cases
Moderate	occurrence of event is a possibility
High	occurrence of event is clearly a possibility

Uncertainty

- Uncertainty is inherent in the process even when using the most accurate data and the most sophisticated models.
- Variability / Uncertainty:
  - "Variability" may be tied to variations in physical and biological processes. Variability can't be reduced with additional research or information, although it may be known with greater certainty
  - "Uncertainty" is a description of the imperfect knowledge of the true value of a particular variable.
- In general, uncertainty is reducible by additional information-gathering or analysis activities (that is,better data or better models), whereas real variability won't change (although it may be more accurately known) as a result of better or more extensive measurements.

Uncertainty

- Uncertainty in qualitative models can be taken into account
  - Different levels of certainty should be defined
  - Uncertainty for each step, then globally (same system of combination can be defined)

  Ex. The risk manager will consider in different ways a risk estimated low but with a high uncertainty and a moderate risk with low uncertainty

Uncertainty

- When you can only present the uncertainty qualitatively, you might consider the possible direction and orders of magnitude of the potential error.

Assessment component		Uncertainty description	Direction of error	Magnitude
Release	DOC import	Offical data available but lack of central recording	Unknown	Medium
	Informal trade	No official data available, estimation through interview and personal observation	Overestimate of risk	High
Exposure	Biosecurity and cleaning measures at farms level	Expert reports. Personal observations	Overestimate of risk	Medium
	Surveillance system	Expert reports. Personal observations	Overestimate of risk	Medium
	Volume of poultry production	Census Expert reports	Underestimate of risk	Low
Consequences	Public health	Previous outbreaks reporting	Overestimate of risk	Low
	Farmer income	Expert report	Underestimate of risk	Low
	Trading	No official data available, estimation through interview and personal observation	Underestimate of risk	High

Pros and Cons

Qualitative RA: logical discussion of the risk being considered using non numerical terms

- Pros:
  - Usually easier and quicker to implement than quantitative approach
  - Does not require quantitative data
  - Results can be used to inform subsequent quantitative RA
- Cons:
  - Risks expressed in words → subjectivity

  But subjectivity also present in quantitative approach (and lack of data or high uncertainty can result in quant. RA with little meaning or validity)

  → Importance: transparency & use of structured framework

Pros and Cons

- Quantitative approaches are not necessarily better than qualitative approaches.
- A quantitative risk assessment that uses poor data or inappropriate techniques can be far less scientific and defensible than a more qualitative assessment.
- A well-structured and timely qualitative assessment is better than an incomplete and late attempt at a more ‘quantitative’ approach.

References

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- Murray N., 2002. Import risk analysis. Animals and animal products. Ed: New Zealand Ministry of Agriculture and Forestry
- Toma B. et al. Epidémiologie appliquée à la lutte collective contre les maladies animales transmissibles majeures. 2nd edition, 2001. Ed: AEEMA. Pp 495-517.
- Rapid risk assessment of acute public health risks – WHO/HSE/GAR/ARO/2012

CASE-STUDY

A SEMI-QUANTITATIVE ASSESSMENT OF THE RISK OF ACQUIRING ESCHERICHIA COLI O157:H7 FROM CONSUMING INFORMALLY MARKETED MILK IN KENYA

D. Grace[1,2], A. Omore[1], T. Randolph[1] and H. Mohammed[2]
[1]International Livestock Research Institute, Nairobi, Kenya,
[2]College of Veterinary Medicine, Cornell University, Ithaca, USA

Framework

- Codex Alimentarius as a scientifically based process consisting of
- hazard identification
- hazard characterisation,
- exposure assessment
- risk characterisation

Hazard identification

- Milk consumed in households in Africa has a high *a priori possibility of contamination with* ***E. coli O157:H7*** *given the worldwide distribution of the pathogen, and* the low level of refrigeration and pasteurisation and several outbreaks in Africa have been linked with food and water

Hazard characterisation

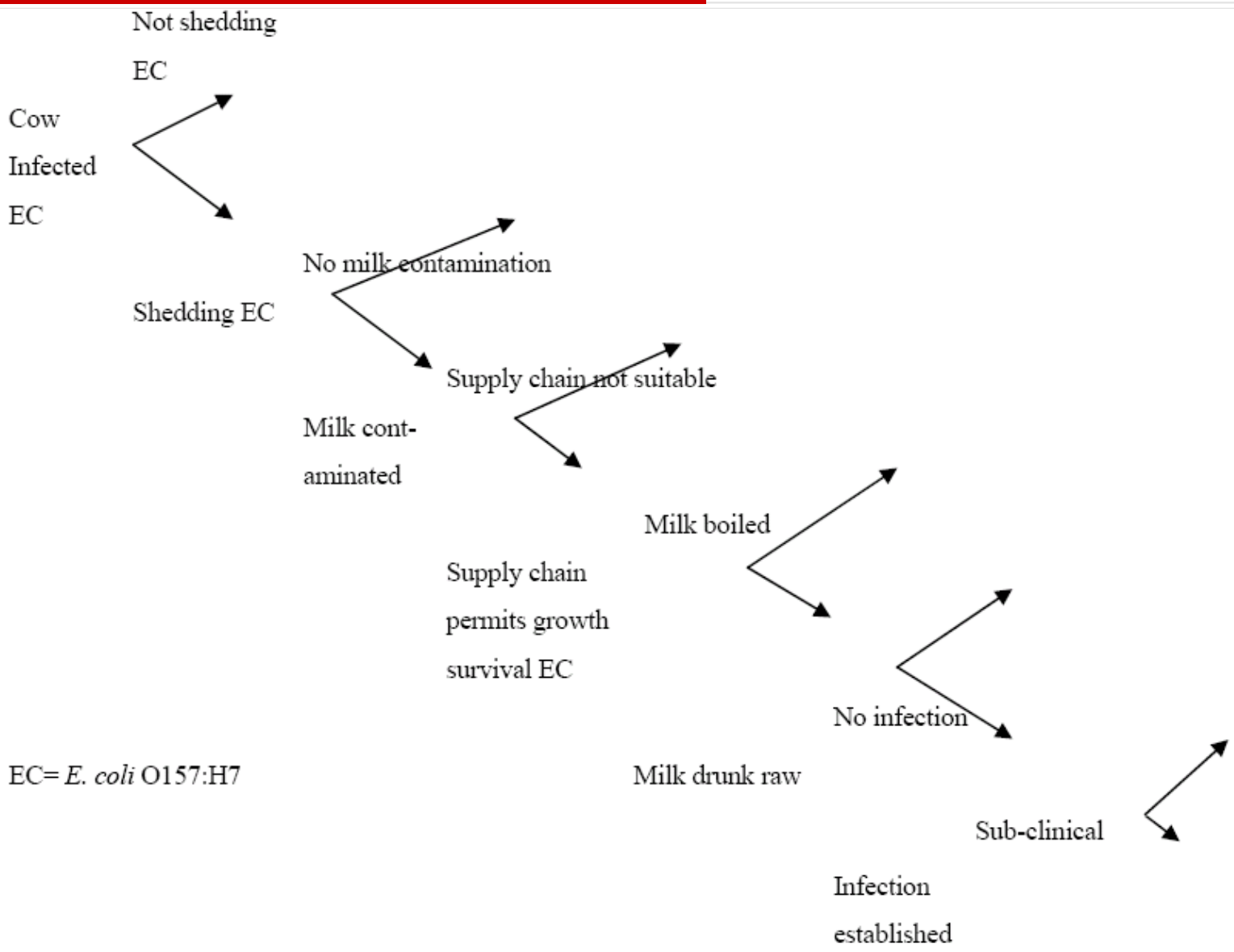
- *Milk from small-scale and large-scale producers:*
  - The infectious dose of E. coli O157:H7 (EC) appears to be very low, probably less than 100 organisms and possibly as low as 10.

Exposure assessment

- To describe the pathway from cow to milk consumer and identify steps where risk amplification or risk mitigation take place.

- The major conclusion was that exposure is likely to be low because smallholder chain offers few opportunities for mixing and growth as milk is partitioned into small volumes and the chain is short.

Event tree



EC= *E. coli* O157:H7

Probability estimation

Event	Factors increasing ri	Factors decreasing risk	Probability
Cow shedding EC		Shedding rates low	V low
EC present in cow milk		Isolation from milk low	V low
Infected milk contaminates other milk farm		Few cows producing low volum so there is little milk to contaminated.	V low
		Hygiene reasonably good	
Substantial EC growth during transpor	No cold chain	Low temperature (night) and sh duration as distances short (20-km)	V low
Substantial mixing with other m during transport		Traders transport small volumes a use small containers	
Growth in household	No cold storage	Milk typically immediate consumed	V low
Pre consumption processes do eliminate		Nearly all milk boiled befc consumption	V low
Many susceptible people	Demography HIV		Low

Source of data

Variable	Source of data
Drink raw milk (proportion)	Three studies giving proportion of urban people drinking raw milk were combined to give the best-guess, and the lowest and highest taken for best and worse case.
Infection (attack) rate	A search (EC, attack) and review (Su & Brandt, 1995) found 5 papers with data on attack rates which were used for best and worst case scenarios.
Susceptible (proportion)	A search (EC, asymptomatic) found 29 papers, 3 of which were combined to give the best-guess, and the lowest and highest taken for best and worse case scenarios.
Proportion households with infected milk	Data were from ongoing studies in Kenya were combined to give the best guess. Literature search d found 3 studies of prevalence in raw milk not associated with outbreaks (0, 0.004, 0.2). These were used for best and worse case.
Number in urban house	Data from study 3 was used as best guess; these were close to the latest official figures are from the Kenya census of 1989. Data from ongoing studies were used for high and low estimates.

(Literature searches carried out on: Medline, AGRICOLA, CAP, Biosis and FSTA)

Risk characterisation

- This analysis suggested that on any given day around 3 in 10,000 consumers will suffer clinical disease from drinking informally-marketed milk.
- Accounting for variation between studies, cases could be as little as 1 in a million or as many as 3 in 1000.
- Deterministic sensitivity analysis suggested that boiling milk has the greatest influence on reducing the number of symptomatic infections

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Flavie GOUTARD – UR AGIRs, CIRAD
goutard@cirad.fr

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