"Regards Croisés" sur l'Influenza aviaire

15-19 / 12 / 2008 • Montpellier • France

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

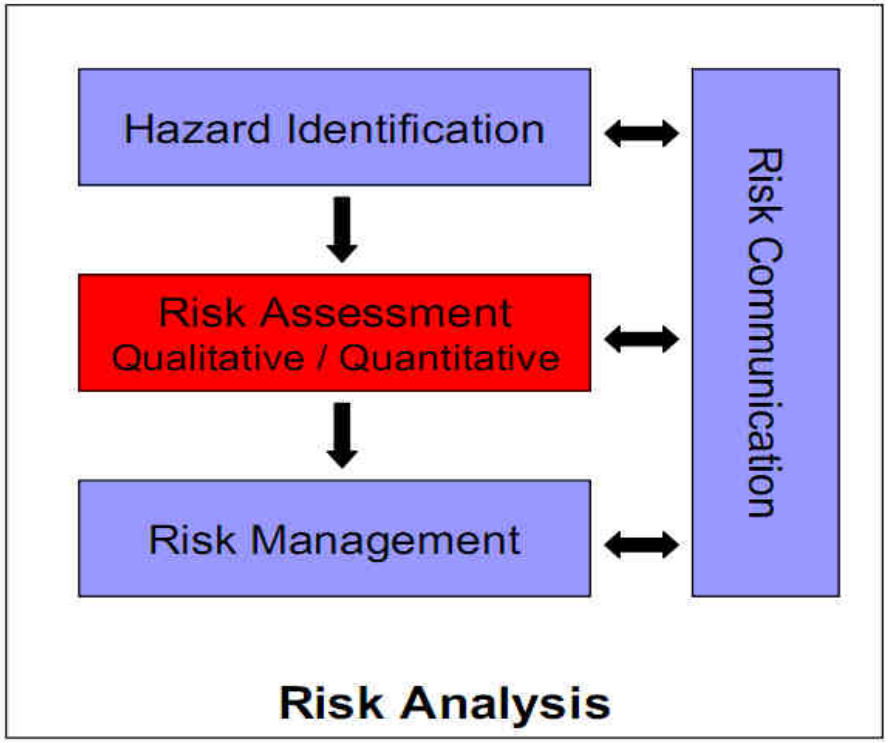
GRIPAVI (CIRAD, MAEE) & ARDIGRIP (AIRD)

Qualitative Risk Assessment

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

Objective



The four components of risk analysis identified in Section 1.3 of the International Animal Health Code (OIE)

To evaluate the risk resulting from a hazard,

Using **words to describe the evaluated risk**

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:**
  - Import policies
  - Surveillance activities
  - Etc.

  → Common approach to support routine decision making

Quantitative 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

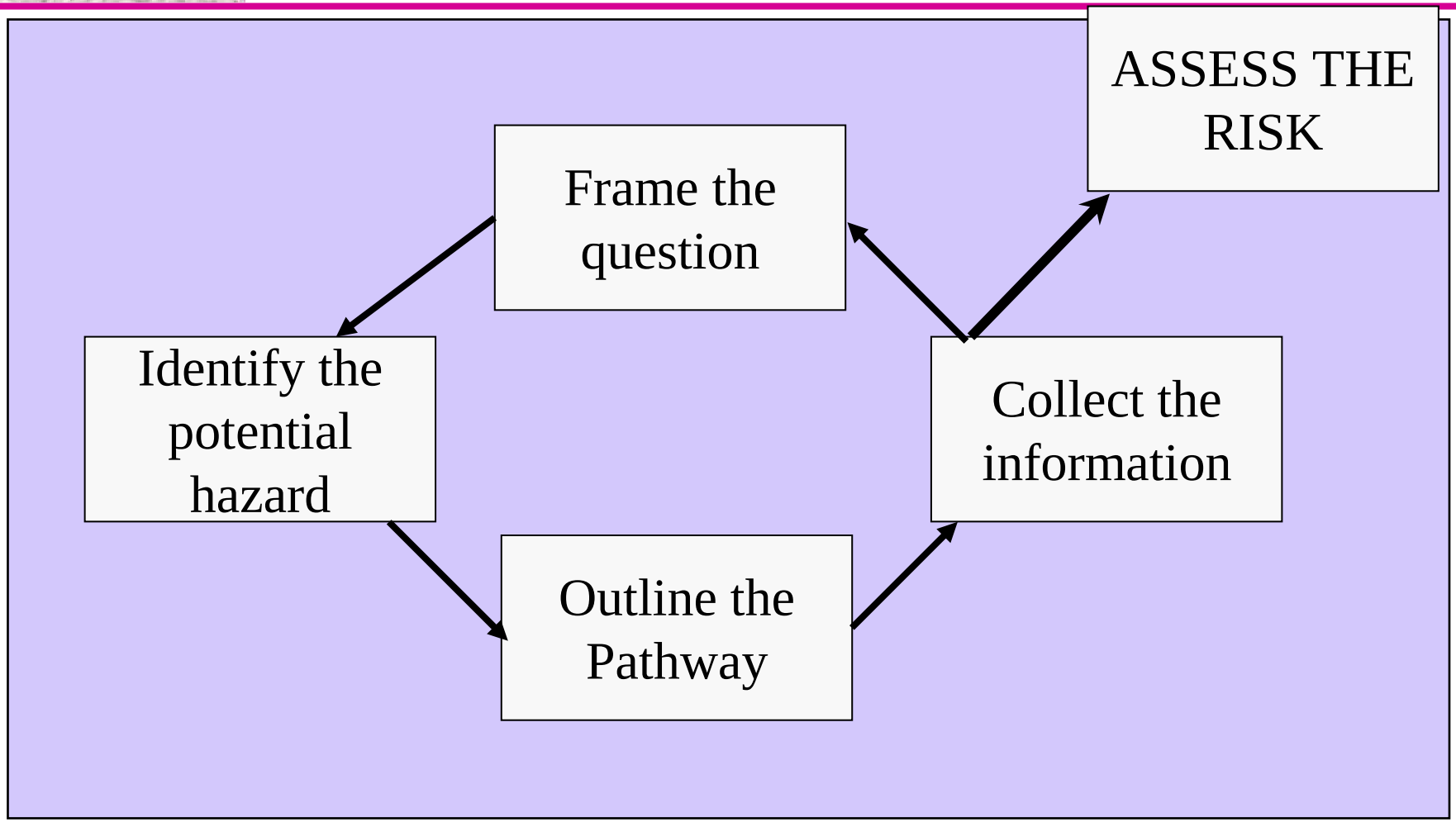
Main steps of qualitative risk assessment

- Frame the risk question
- Identify the hazard(s)
- Outline the risk pathway
- Collect the information
- Assess the risk
  - steps common to both qualitative and quantitative approaches
  - iterative approach

Transparency

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

Undertaking Risk assessment



Main steps of qualitative risk assessment

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

Frame 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
    - Live animals/Products…
  - What specific risk do we want to assess
    - Importation/ Introduction?...
  - What particular time frame are we interested in?
    - Year/Week?...

Frame risk question

- Which information are available?
  - Scientific report (internal and external → expert committees)
  - Brainstorming and discussions
- Quality and quantity of data that will be needed to answer the question?
- Can we do something? If not reframe the question
- Sometimes several questions are relevant (one pathway for one question)

Framing the 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

CIRAD

Main steps of qualitative risk assessment

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

Identify hazard(s) of concern

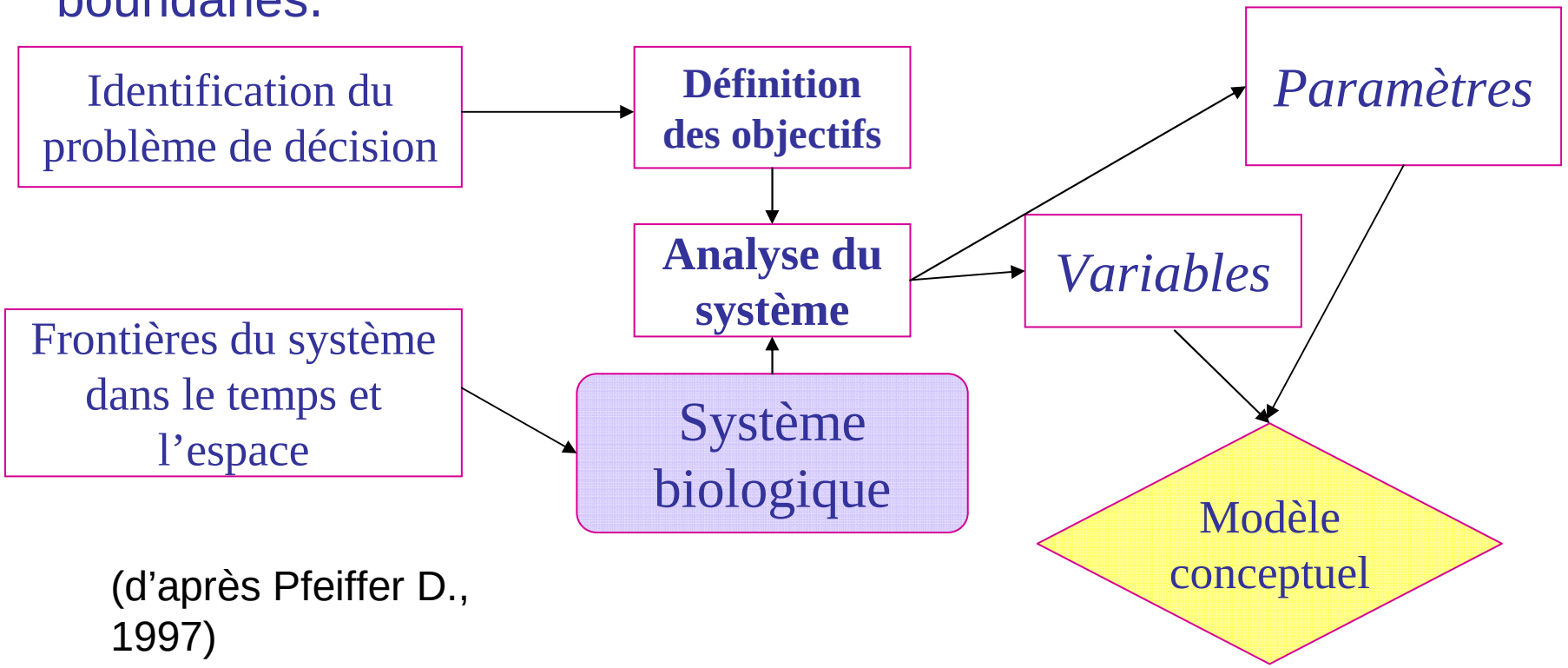
- Hazard **may be explicit** in risk question
  - What is the risk of importing Pathogen X in this group of animals?
    - Pathogen X
- **Otherwise full hazard identification** must be undertaken
  - What is the risk of importing disease in this group of animals
    - Long list of pathogens

Main steps of qualitative risk assessment

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

Conceptual model

- Need to have an overall description of the system studied (exhaustiveness) – Conceptual model: highlight question boundaries.



(d'après Pfeiffer D., 1997)

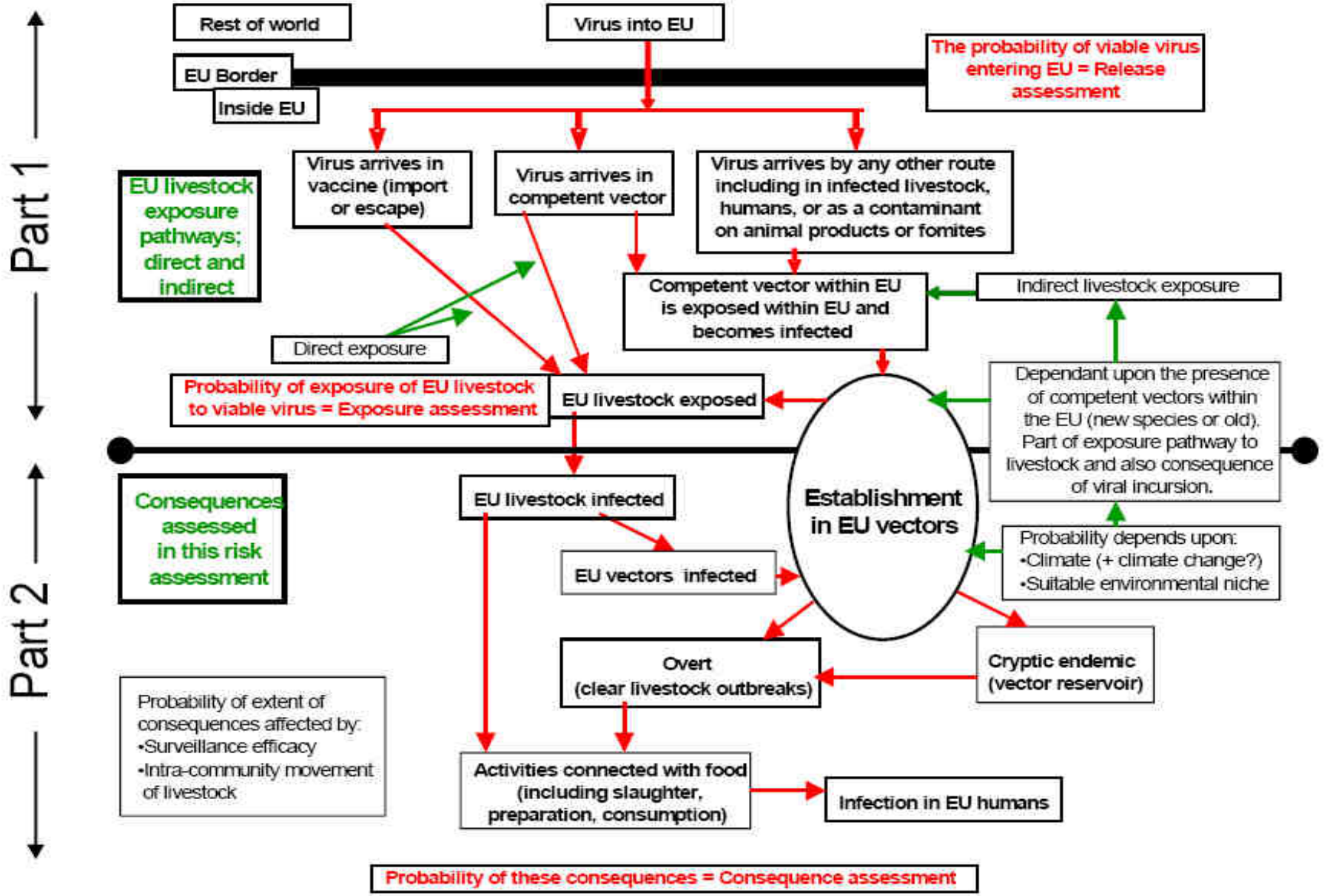


Figure 3: Diagrammatic summary of potential exposure and consequence assessment pathways after an entry of RVF virus to the EU (note: this includes all pathways which were considered in the risk assessment prior to making a decision about their importance)

Outline risk pathway

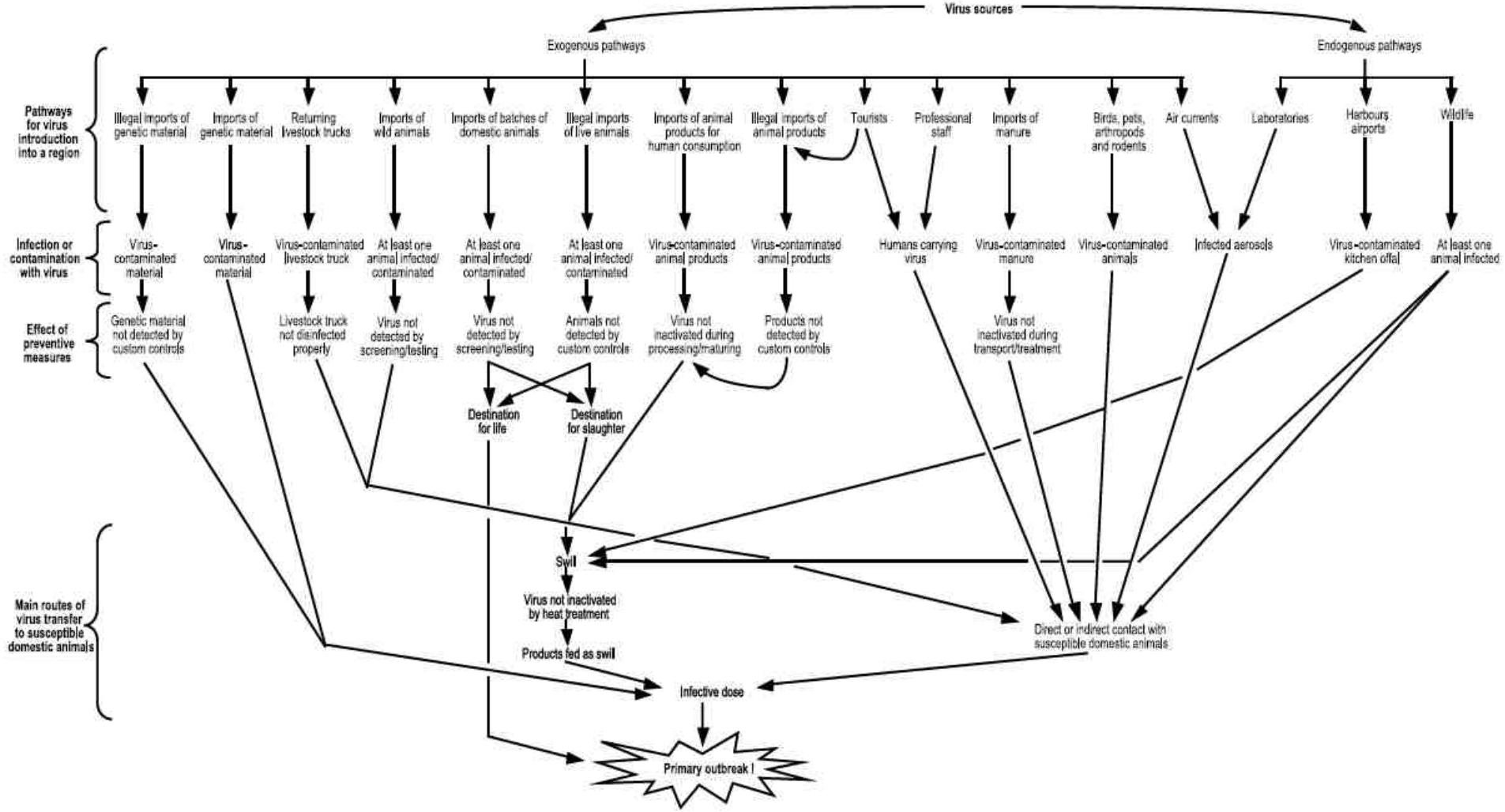
Risk pathway: Framework on which to base the risk assessment, describing all stages in the biological process that lead to the outcome of interest

- 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.

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.

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

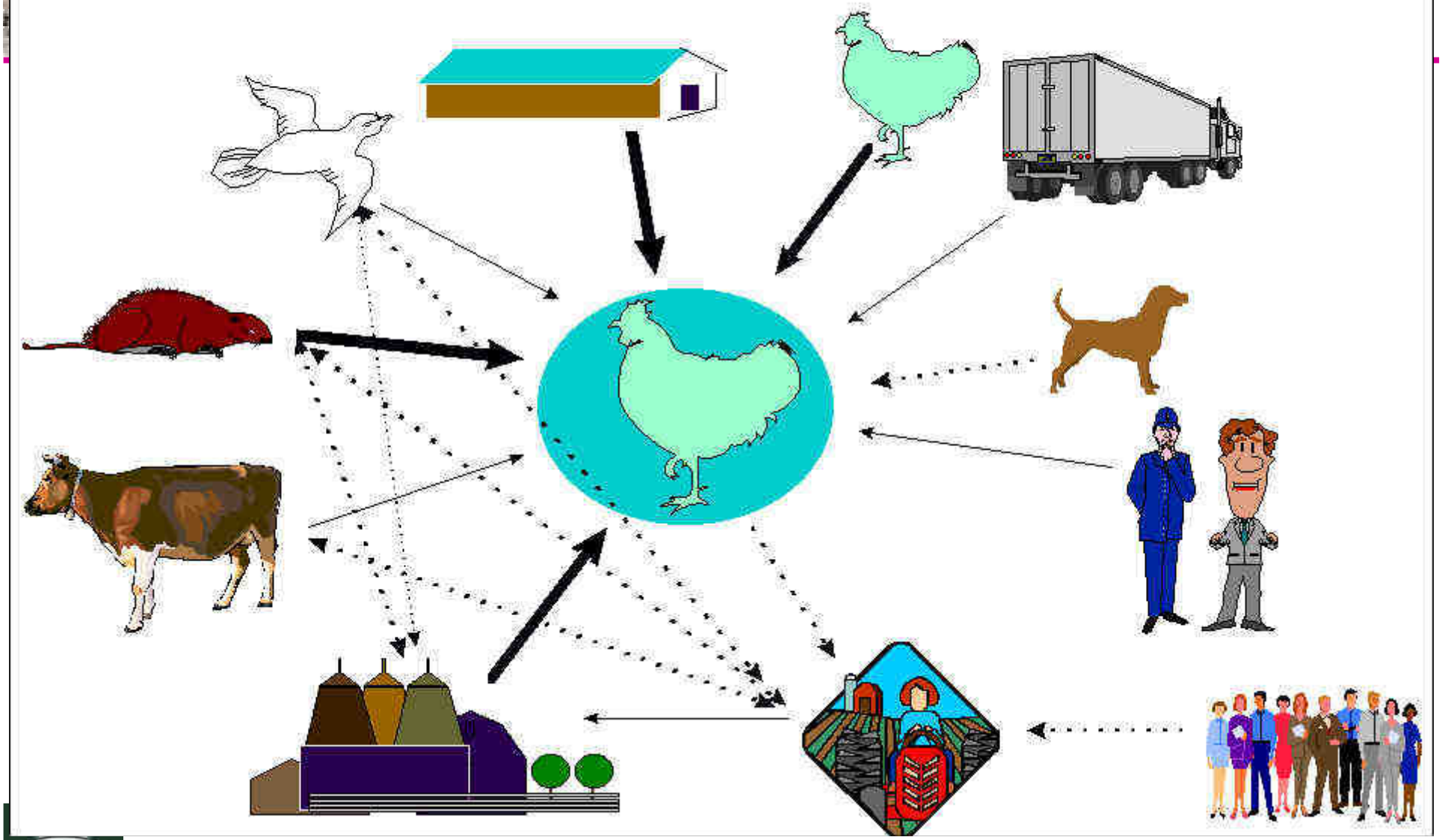
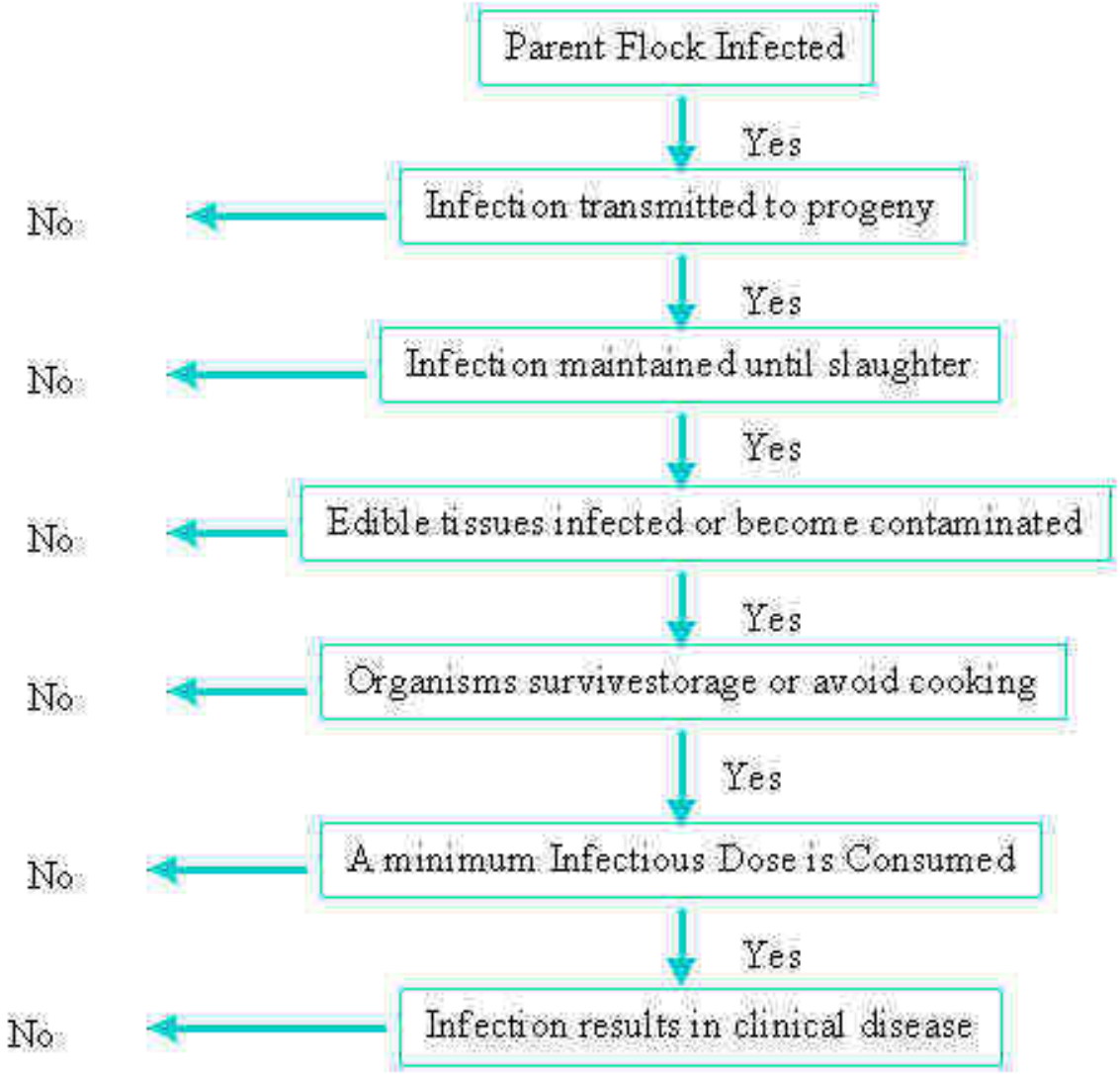
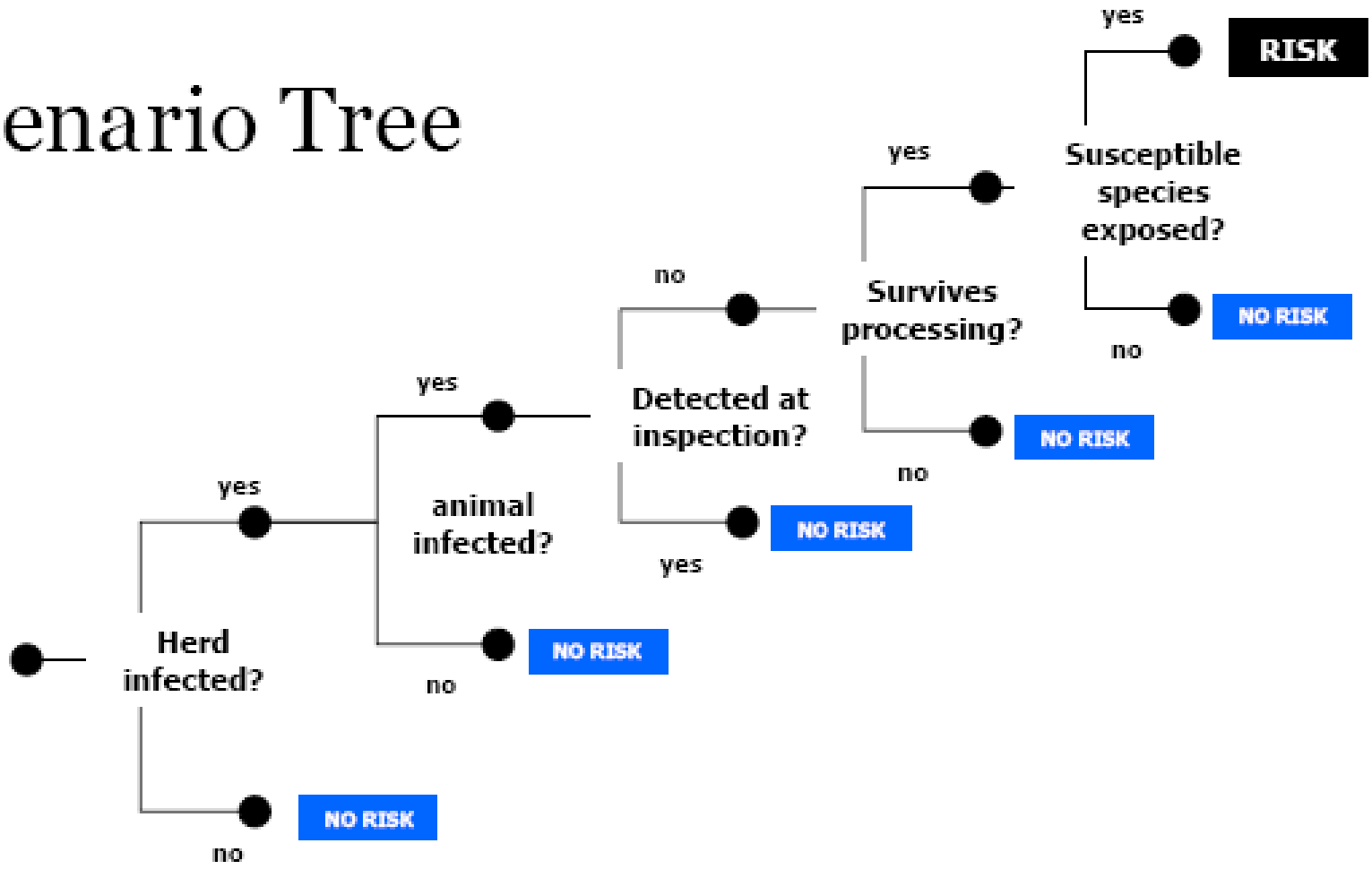


Figure 5. Broiler Salmonella: A Risk Analysis Pathway



Scenario Tree



Main 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)

Main 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

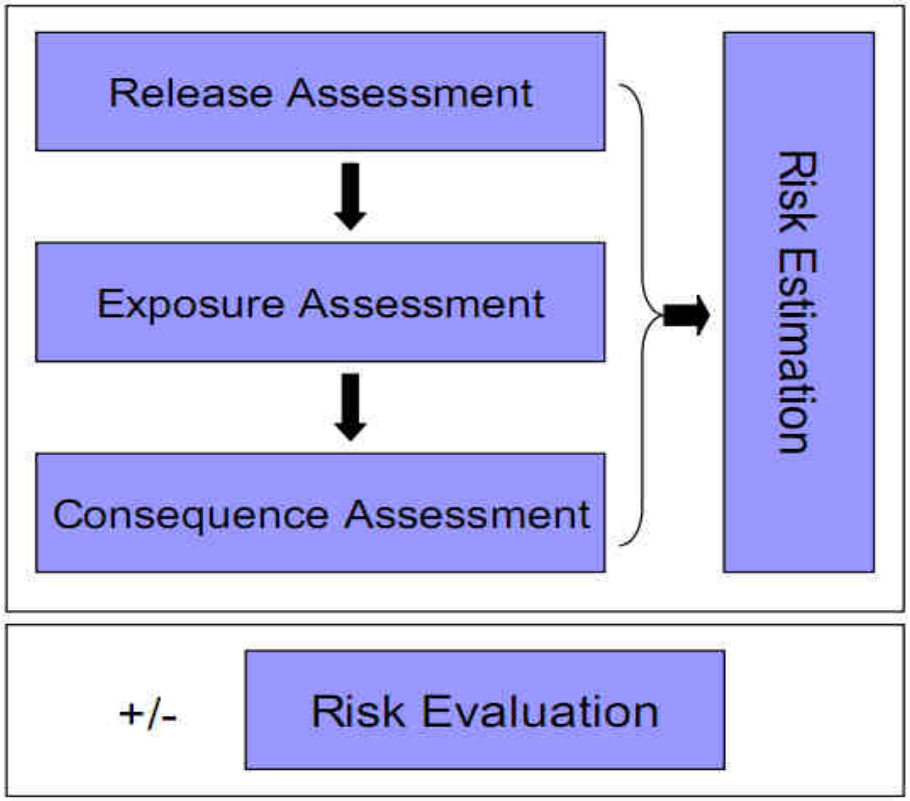
- The result of a qualitative risk assessment is a probability, described by words
- The risk can be estimated as:
  - **Negligible.** Probability of event sufficiently low to be ignored or event only possible in exceptional circumstances
  - **Low.** Occurrence of event is a possibility in some cases
  - **Moderate.** Occurrence of event is a possibility
  - **High.** Occurrence of event is clearly a possibility

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

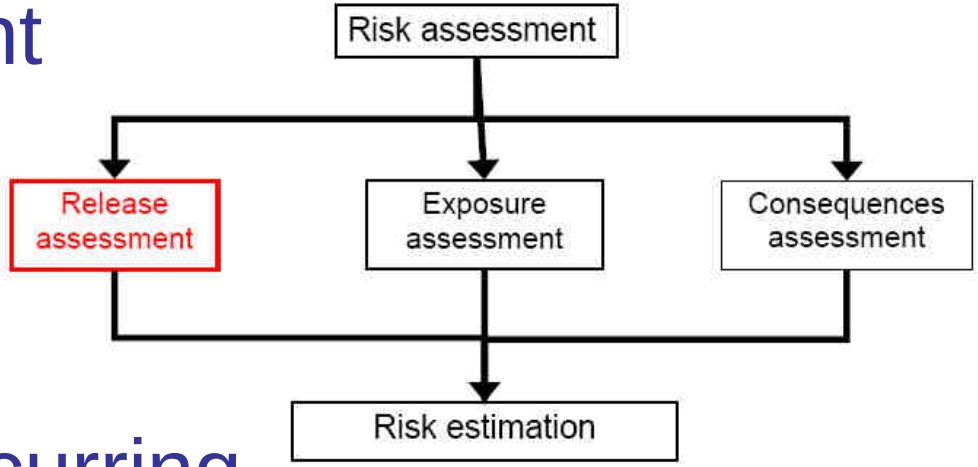
NB: « low » or « negligible » risk does not imply « acceptable risk » (e.g. when severe consequences for human population)

- OIE Framework (Import risk analysis)



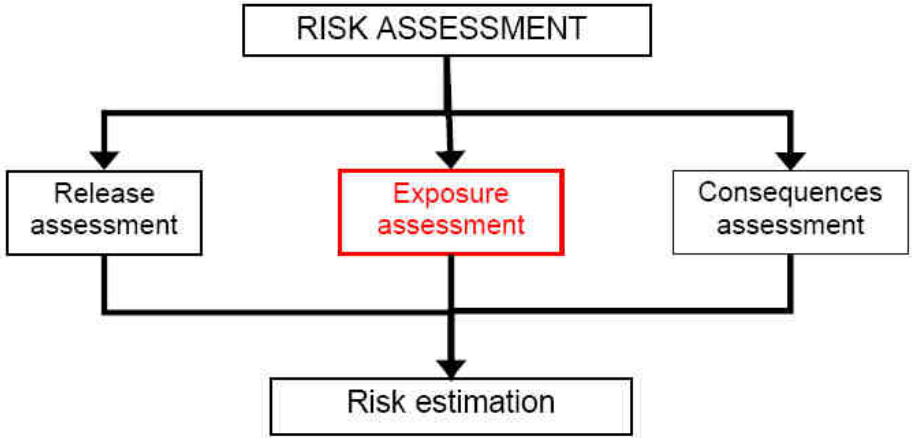
Release assessment

- 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



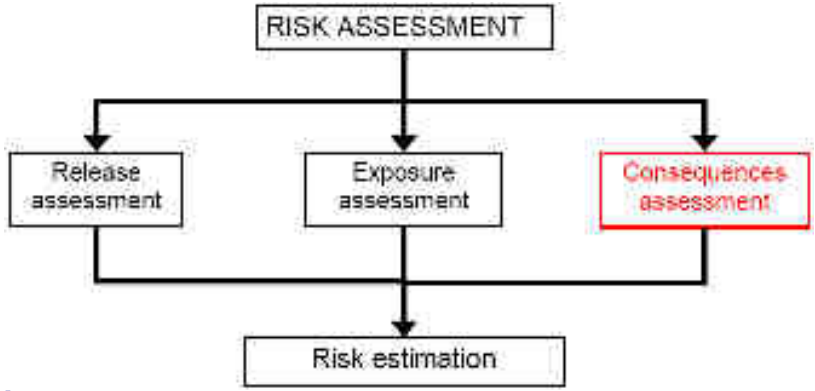
Exposure assessment

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



Consequence assessment

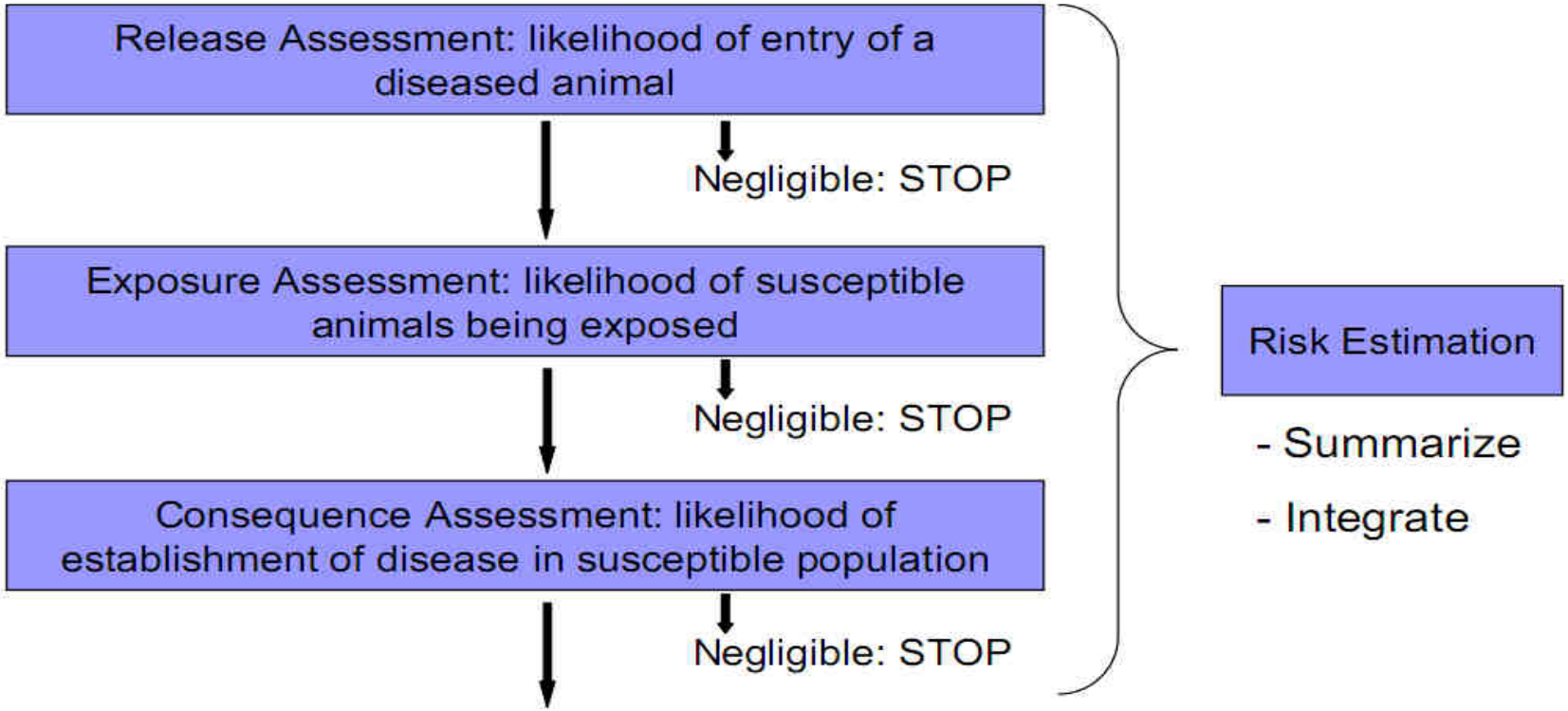
- Describes the relationship between specified exposures to a biological agent and the consequences of those exposures
  - Direct consequences
    - animal infection, disease, and production losses
    - public health consequences.
  - Indirect consequences
    - surveillance and control costs
    -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



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

Assessing the risk

Ex.: risk estimation decision steps for animal import risk assessment



Key points

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

Key points

- Combination of risks (risk estimation)

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

	Parameter 2			
Parameter 1	**Negligible**	**Low**	**Moderate**	**High**
Negligible	Negligible	Low	Low	Moderate
Low	Low	Low	Moderate	Moderate
Moderate	Low	Moderate	Moderate	High
High	Moderate	Moderate	High	High

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, or its real variability in an individual or a group.
- 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

References

- Office International des Epizooties (OIE), 2004. Volume 1. Introduction and qualitative risk analysis
- 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.

"Regards Croisés" sur l'Influenza aviaire

15-19 / 12 / 2008 • Montpellier • France

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

GRIPAVI (CIRAD, MAEE) & ARDIGRIP (AIRD)

Qualitative Risk Assessment: examples

Qualitative risk assessment of the hazards and risks from wild game

H. L. Coburn, E. L. Snary, L. A. Kelly, M. Wooldridge

2005,Veterinary Record 157(11):321-322

THE rules on official controls on wild game meat, currently contained in European Council Directive 92/45/EEC, have been simplified and consolidated into new European Regulations due to come into force on January 1, 2006 (Reg [EC] number 853/2004). In order to inform negotiations on the level of veterinary supervision required at game meat plants, and the postmortem procedures required for the protection of public health, the UK Food Standards Agency (FSA) requested that a qualitative risk assessment be developed to address the following question: 'What is the risk to human health (particularly of human infection with a foodborne pathogen) from the handling/consumption of wild game?'. This short communication describes that risk assessment. The risk was also reassessed for hygiene controls based on hazard analysis critical control points (HACCP) principles, and for veterinary supervision.

- **Identify the different key elements of this qualitative risk assessments**
  - **Reason for conductiong RA**
  - **Risk question**
  - **Hazard ientification**
  - **Risk pathway**
  - **Information collected**
  - **Evaluating the risk**
  - **Results**

Key elements

- *Reason for conducting RA:*

  to inform negotiations on the level of vet supervision required at game meat plan, and the post-mortem procedures required for the protection of public health

- *Risk question:* what ids the risk to human health (part. of human infection with a footborne pathogen) from the handling/consumption of wild game?

Codex Alimentarius Framework

Key elements

- Hazard identification:
  - Species: game birds, wild ducks, wild deer, wild lagomorphs.
  - Hazards: bacterial pathogens, parasites, chemicals and foreign bodies.

TABLE 1: Hazards considered for each wild game species

Hazard	Wild game species
Escherichia coli O157	All
Salmonella species	All
Campylobacter jejuni	All
Mycobacterium avium	Gamebirds, wild ducks, wild deer
Chlamydophila psittaci	Gamebirds
Clostridium botulinum	Wild ducks
Mycobacterium bovis	Wild deer
Yersinia pseudotuberculosis	Wild lagomorphs
Lead shot	Gamebirds, wild ducks, wild lagomorphs

- Risk pathway:

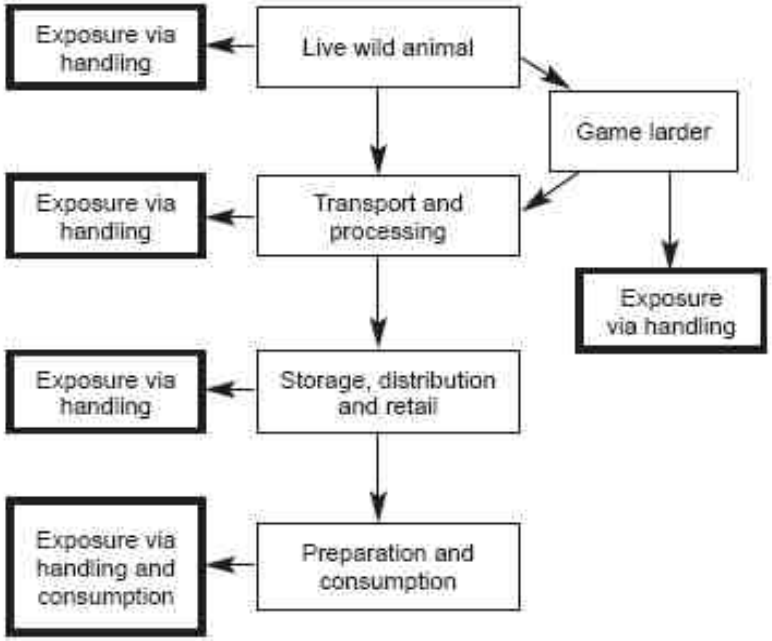


FIG 1: Generic human exposure pathway for hazards from wild game animals

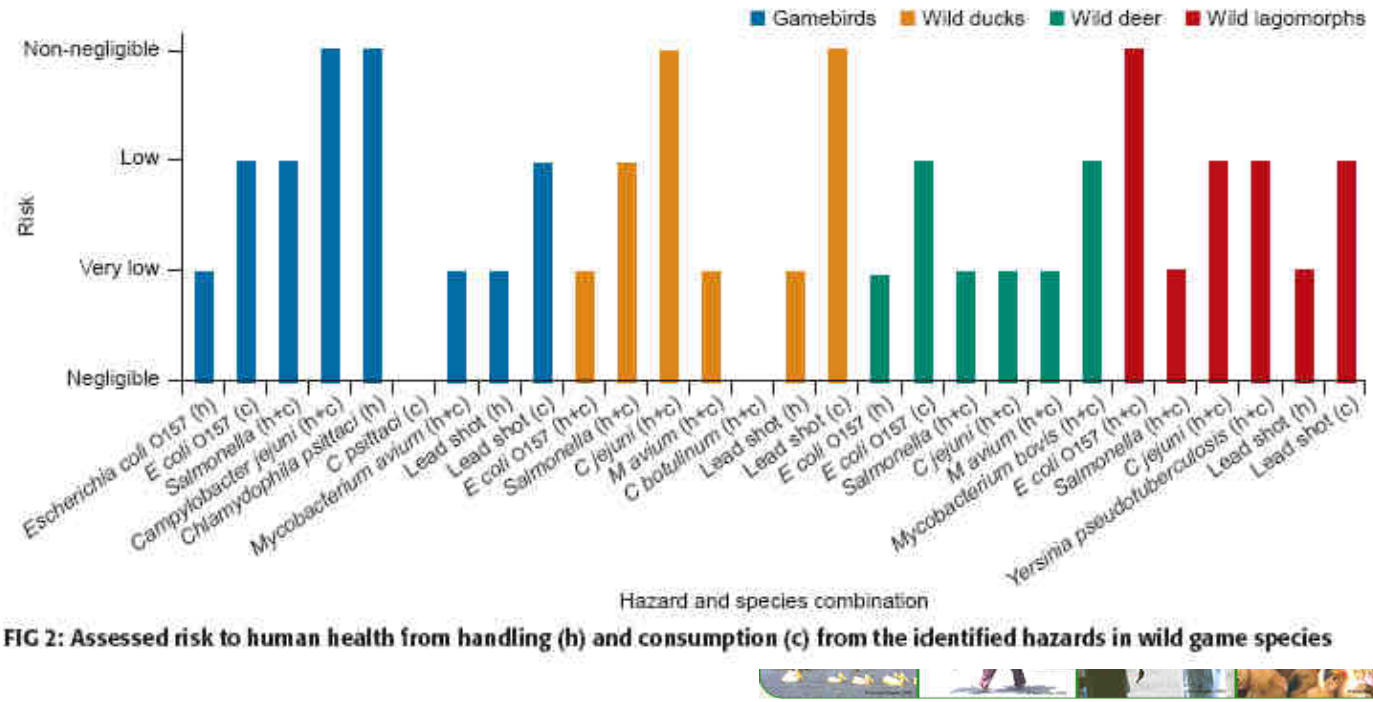
CIRAD

Key elements

- Collect the information:
  - Prevalence of pathogen or other hazard in live animal; survival, gross and cross-contamination during storage in game laders and then during staorage, distribution and retail
  - Data on the number of organisms required to cause adverse effect on human health
  - Source of information:
    - Published and unpublished data
    - Expert opinion when lack of data

Key elements

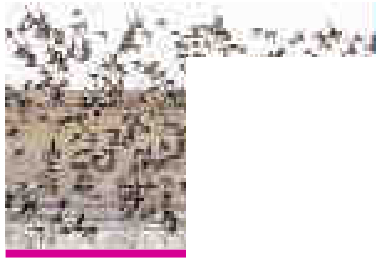
- Assess the risk:
  - For each combination of species and hazard
  - Risk categories (increasing): negligible, very low, low, non-negligible.



Risk **FIG 2: Assessed risk to human health from handling (h) and consumption (c) from the identified hazards in wild game species**

Key elements

- Results:
  - Hazards identified, assessment of risk posed to public health;
  - Discussion of hazards where risk could be reduced (HACCP procedures, post mortem inspection).



Early qualitative risk assessment of the emerging zoonotic potential of animal diseases

Stephen Palmer, David Brown, Dilys Morgan

Most new human infections are of animal origin, but there is rarely sufficient evidence to make a risk assessment of the zoonotic potential of emerging animal diseases. An algorithm for early qualitative public health risk assessment has been developed to guide risk management

Department of Epidemiology, Statistics and Public Health, Cardiff University, Cardiff CF4 4XN

Stephen Palmer
Mansel Talbot professor of epidemiology and public health

Health Protection Agency Centre for Infections, London NW9 5HT

David Brown
consultant virologist

Dilys Morgan
consultant epidemiologist

Correspondence to:
S Palmer
palmersr@cardiff.ac.uk

BMJ 2005;331:1256–60

Most newly emerging human infections of global importance are of animal origin,[1 w1] but early accurate predictions of zoonotic risk of emerging animal diseases are difficult, as shown by the epidemic of bovine spongiform encephalopathy and variant Creutzfeldt-Jakob disease in the United Kingdom.[w2] Miscalculation, delays, or poor risk communication can result in failure to protect the public's health and undermine public trust,[2] but overreaction can waste resources and even harm the economy of countries, as in the case of suspected plague in India.[3] The public are increasingly anxious to understand the basis on which a government's decisions on risk management are taken,[w3] but scientists and government may be reluctant to engage with the public at an early stage because of the fear of provoking a public scare. However, since the BSE epidemic, it has been accepted that the criteria used and the evidence considered in risk assessments should be open and explicit.[4 w4 w5]

In this article we describe and illustrate such an approach, one that explicitly distinguishes evidence of lack of zoonotic potential from lack of evidence. The algorithm, endorsed by the UK government's Zoonoses Group[w6] and by the National Expert Panel on New and Emerging Infection,[w7] is being used by the Human and Animal Infections and Risk Surveillance Group of the Health Protection Agency.[5]

Box 1: Levels of confidence of risk of zoonotic transmission of animal diseases

Level 0: Not zoonotic—Evidence of lack of zoonotic potential. Good grounds for not taking further action

Level 1: Potential zoonosis—Possibility of human pathogenicity not excluded. Work needed on biomarkers of infection and pathways of exposure

Level 2: Potential zoonosis—Serological evidence of infection, or human exposure has occurred but surveillance not sufficiently reliable. Enhanced surveillance needed

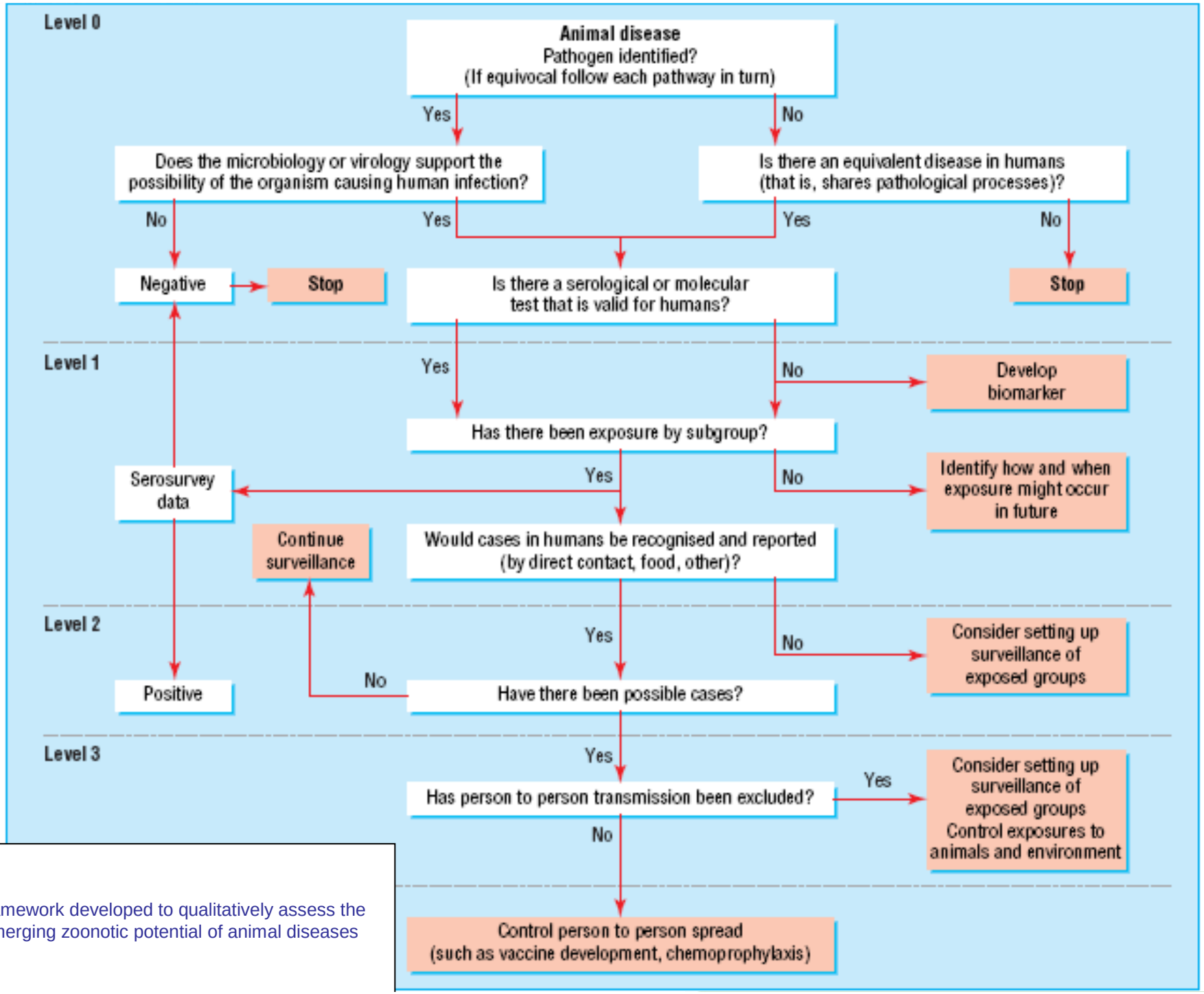
Level 3: Confirmed zoonosis—Human cases have been reported, but evidence against person to person spread. Enhanced surveillance needed. Control exposure of humans to animals and environmental sources

Level 4: Confirmed zoonosis—Human cases have occurred, with subsequent person to person spread not excluded. Control of direct or indirect person to person spread needed

Worked examples

The algorithm was applied to five emerging animal diseases of concern to public health authorities. A possible link between porcine dermatitis and nephropathy

2005, British Medical Journal 331 (7527): 1256-1260.



Framework developed to qualitatively assess the emerging zoonotic potential of animal diseases

Thank you

- Acknowledgements:
  - Agnes Waret
  - Solenne Costard
  - Eric Etter
  - François Roger
  - Dirk Pfeiffer