



Royal Veterinary College
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Introduction to Risk Analysis and Risk Assessment

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Overview

- Concepts:
 - Risk
 - Hazard
 - Risk Analysis and Risk Assessment
- Approaches to Risk Assessment:
 - OIE vs Codex Alimentarius Framework
 - Qualitative vs Quantitative
- Risk Assessment Methodology
 - Requirements
 - Main steps

Concepts

- Risk
- Hazard
- Risk analysis and risk assessment

Concepts

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

Compact Oxford English Dictionary of Current English

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 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.
 - detailed examination including risk assessment, risk evaluation and risk management alternatives, performed to understand the nature of unwanted outcome;

Society for Risk Analysis

http://www.sra.org/resources_glossary

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

Concepts

- Hazard Identification:

Identification of the hazard (something potentially harmful) in the given context.

Can be directly included in the risk assessment.

Concepts

- Risk Assessment:

The process of evaluating the risk resulting from a hazard.

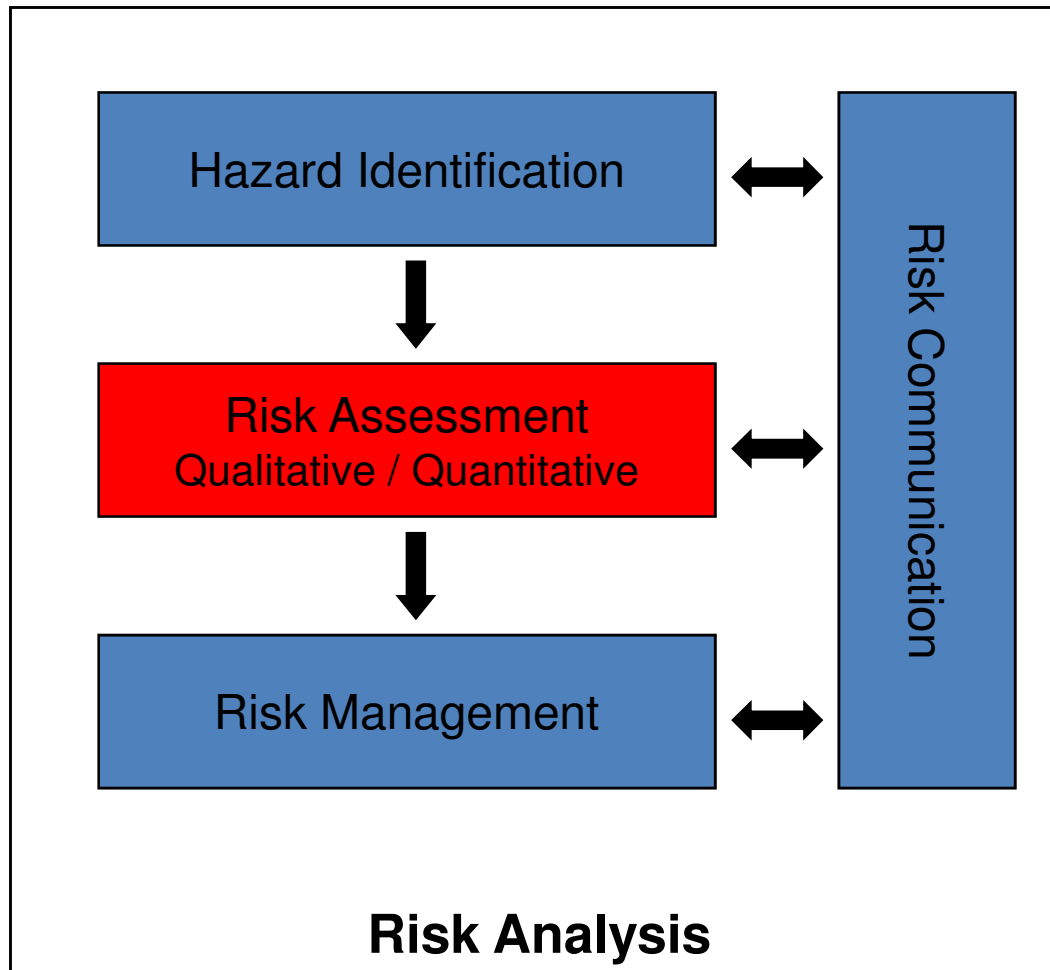
Concepts

- 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.

Concepts

- Risk Communication:
 - Information exchange between risk assessors, risk managers and those affected by both the risk and the decisions taken before the final policy decisions are taken.

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



Approaches to Risk Assessment

- Risk Assessment Systems:
 - OIE vs Codex Alimentarius
- Risk Estimates:
 - Qualitative vs quantitative approach

Approaches to Risk Assessment

- 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:
 - OIE: Versatile, used to address risk questions of different types
 - Codex: Designed to answer questions in relation to maximum levels of substances or pathogens; main focus: microbiological food safety assessment

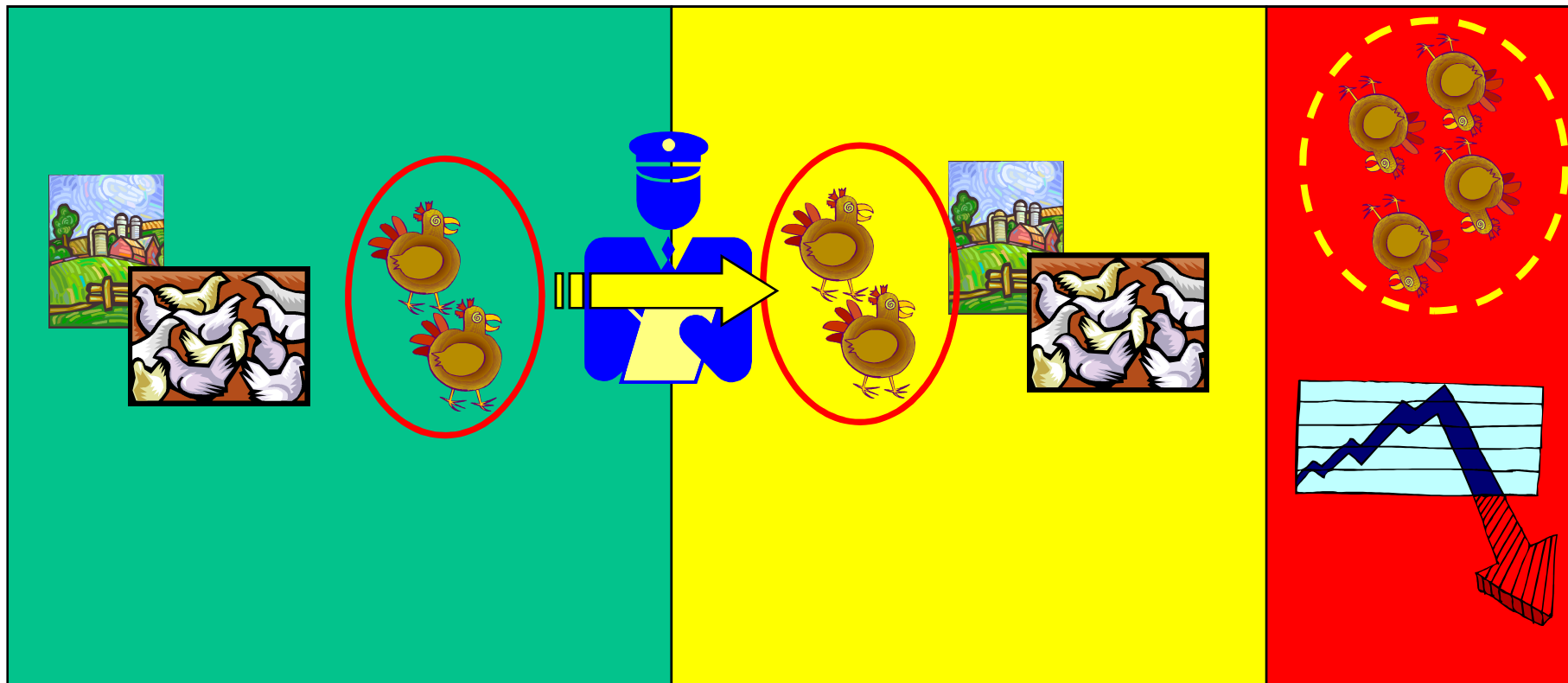
Approaches to Risk Assessment

- **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

Release assessment

Exposure assessment

Consequence assessment



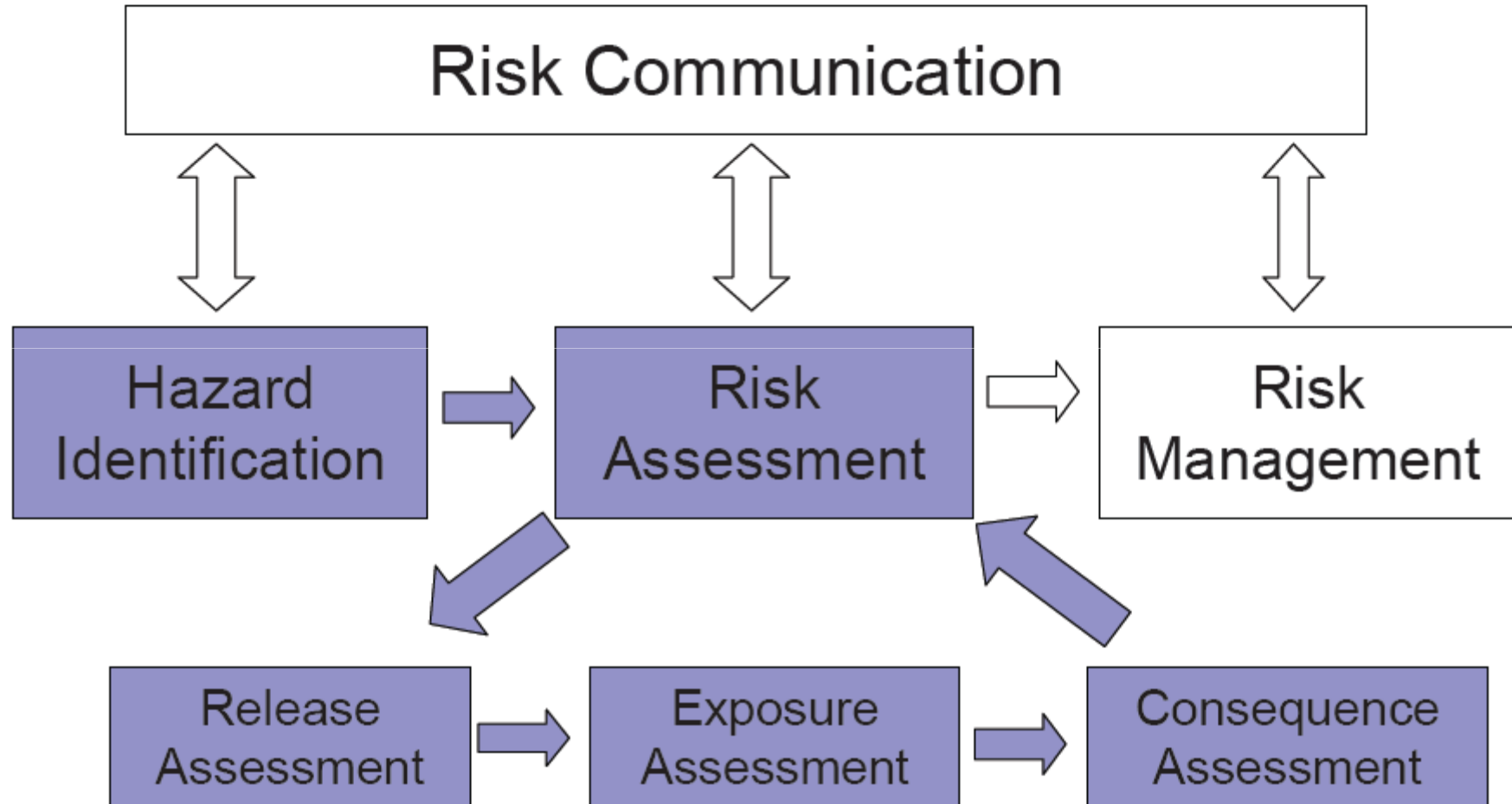
Exporting country

Importing country

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

Risk Analysis Components

(after OIE *International Animal Health Code*)



Approaches to Risk Assessment

- 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 is estimate numerically; numerical expressions of risk are provided.

Approaches to Risk Assessment

■ When:

- As a 1st 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

Risk Assessment Methodology

- Requirements:
 - Clear definition of terms:
 - Risk question
 - Hazard identification
 - Qualitative risk assessment: risk categories and combination matrix
 - Transparency:
 - A risk assessment must be clearly set out, transparent and fully referenced in the resulting report

Risk Assessment Methodology

- The main steps of a risk assessment are:
 - Framing the risk question
 - Identifying the hazard(s)
 - Outlining the risk pathways
 - Identifying data needs
 - Collecting data
 - Assessing the risk

Risk Assessment Methodology

- Framing the risk question:
 - The risk to be assessed should be clearly defined
 - Points to consider:
 - What is the specific hazard of concern?
 - What are the vector/vehicle/of the hazard of concern
 - What specific risk do we want to assess
 - What particular time frame are we interested in?

Risk Assessment Methodology

- 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 / poultry trade / wild bird trade ?) into (wild bird / domestic / human population?) in Kenya?

Risk Assessment Methodology

- Identifying the hazard(s):
 - Hazard may be explicit in risk question
 - Ex: What is the risk of importing Pathogen X in this group of animals?
 - Otherwise full hazard identification must be undertaken

Risk Assessment Methodology

- Outlining the risk pathways:

A Risk pathway is the framework on which to base the risk assessment, describing all stages in the biological process that lead to the outcome of interest.

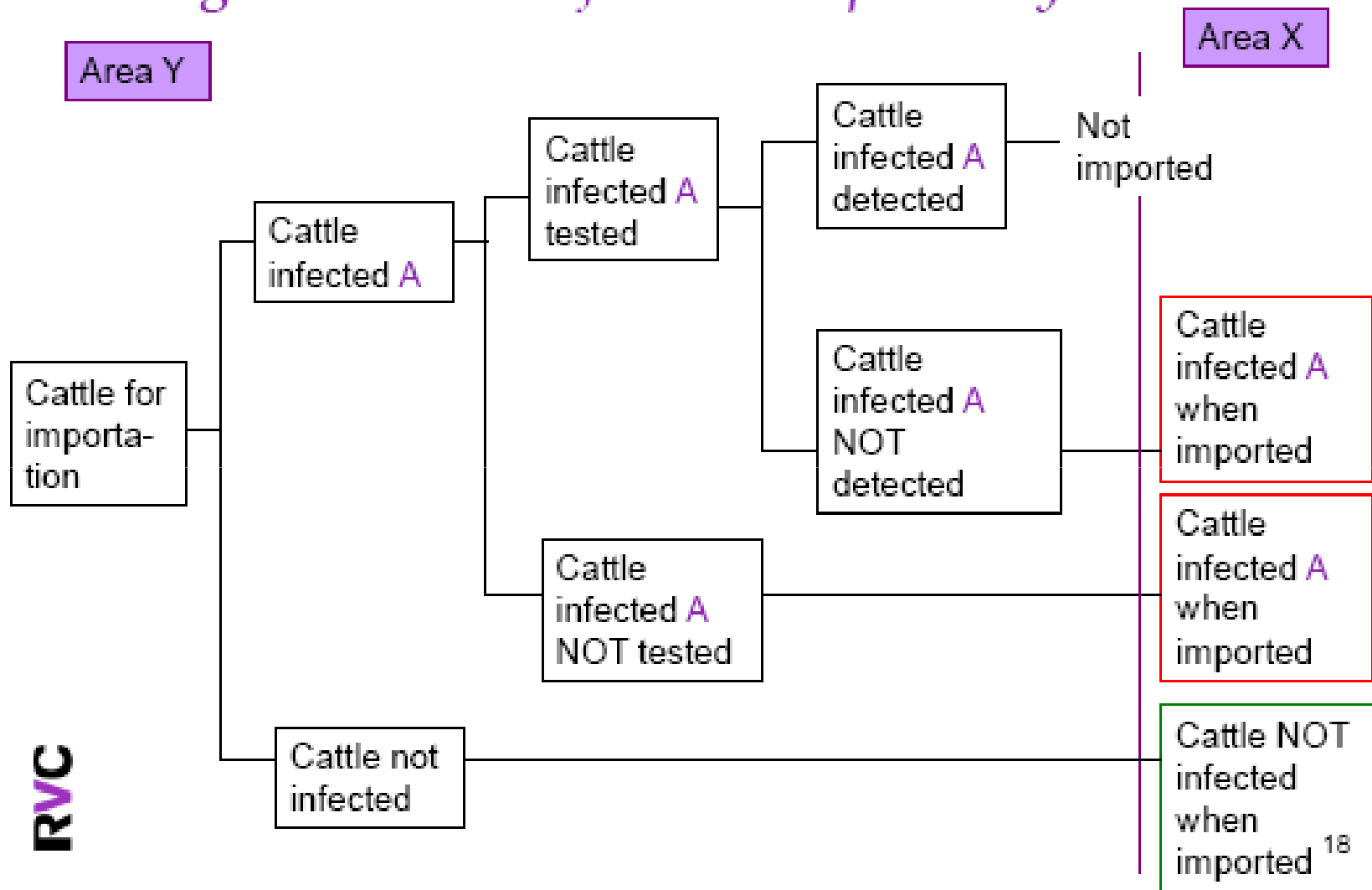
- list all steps required for the risk to occur, differentiating release, exposure and consequence
- Important: report your underlying assumptions

Risk Assessment Methodology

- What is the risk for the introduction of HPAI H5N1 through migratory birds into wild bird population in Kenya?

	Definition	Steps of pathway
Release assessment	Likelihood of entry	<ul style="list-style-type: none">• Migratory bird infected• Migratory bird enter Kenya
Exposure assessment	Likelihood of target population to be exposed	<ul style="list-style-type: none">• Infected migratory bird in resting sites• Contact with local wild birds in resting sites
Consequence assessment	Consequences + likelihood of occurrence and magnitude	<ul style="list-style-type: none">• Local wild bird infected• Local wild bird spread disease among pop.

e.g. Scenario tree for release pathway



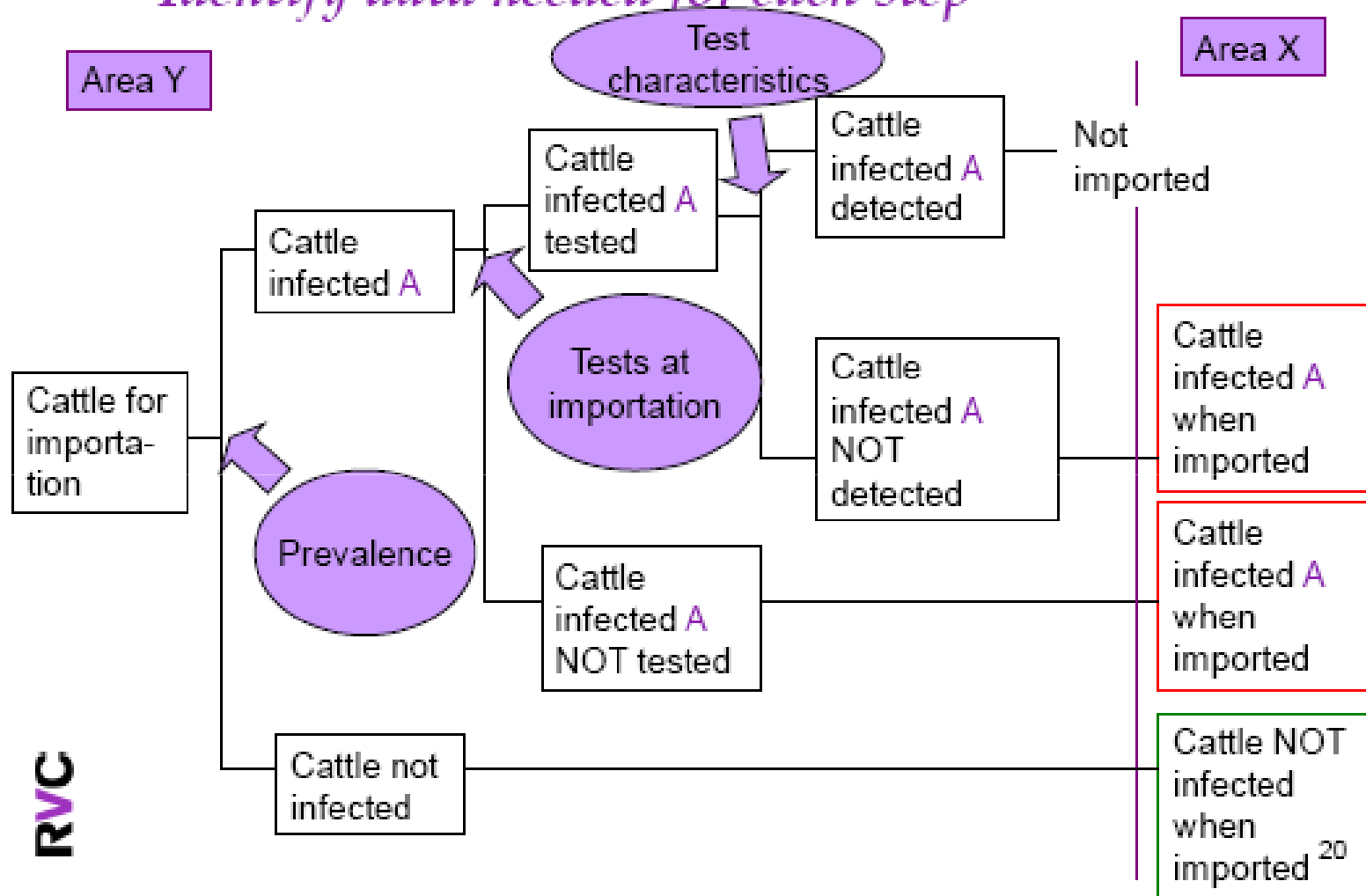
Risk Assessment Methodology

- Identification of data needs:
The data required to assess the likelihood of occurrence of each step of the pathway must be identified

Risk Assessment Methodology

	Step of pathway	Data needs
Release assessment	<ul style="list-style-type: none">• Migratory bird infected• Migratory bird enter Kenya	<ul style="list-style-type: none">• Flyways• Species• Susceptibility
Exposure assessment	<ul style="list-style-type: none">• Infected migratory bird in aggregation sites• Contact with local wild birds in aggregation sites	<ul style="list-style-type: none">• Resting sites / water points<ul style="list-style-type: none">- for migratory birds- for local wild birds• Virus survival
Consequence assessment	<ul style="list-style-type: none">• Local wild bird infected• Local wild bird spread disease among pop.	<ul style="list-style-type: none">• Type of contact, susceptibility, shedding..

Identify data needed for each step



Risk Assessment Methodology

- Collecting Data Required:
 - Number of sources:
literature, experimental, expert opinion...
 - Consider validity:
Most up-to-date
Estimates of prevalence from surveillance systems, Expert opinion
=> Best available data should be used
 - Fully referenced (transparency)
 - For Qualitative approach, no new data collected;
identification gaps in knowledge / data

Organize information collected

Table : Data required and data obtained for each step of the release assessment

Risk pathway step	Data needed	Data obtained	Source
Risk of cattle from area X being infected	Prevalence data in cattle in area X	10 %	Xxxxx et al. 2008
Risk of cattle not being tested before importation	Control at importation ? Frequency ?	Serological test 0.1% animals tested	Expert opinion
Risk of a positive animal is not detected	Test characteristics	Se 99% Sp 95%	Xxxx et al. 2005

RVC

To be done also for the exposure and consequence

Risk Assessment Methodology

- Assessing the risk:

Once the relevant information for the different steps is collected the overall risk is assessed in terms of the probability of occurrence of the unwanted outcome.

- For qualitative risk assessments a logical overall conclusion will be reached based on the probability of occurrence of each of the individual steps. The final risk estimate would be expressed in words:

Example AI-RA EFSA migratory bird

Probability category	Interpretation
Negligible	Event is so rare that it does not merit to be considered
Very low	Event is very rare but cannot be excluded
Low	Event is rare but does occur
Medium	Event occurs regularly
High	Event occurs very often
Very high	Event occurs almost certainly

- For quantitative risk assessments: An overall probability of the unwanted outcome will be given in mathematical terms.

Attributing risk for each step: Example (release pathway)

Table : Data required, data obtained and qualitative evaluated risk for the release assessment

Step of risk pathway	Data needed	Data obtained	Source	Evaluated risk
Risk of cattle from area X being infected	Prevalence data in cattle in area X	10 %	Xxxxx et al. 2008	Moderate
Risk of cattle not being tested before importation	Control at importation - frequency	0.1% animals tested	Expert opinion	High
Risk a positive is not detected	Test characteristics	Se 95% Sp 99%	Xxxx et al. 2005	Low

	<i>Parameter 1</i>			
<i>Parameter 2</i>	Negligible	Low	Moderate	High
Negligible	Negligible	Low	Low	Moderate
Low	Low	Low	Moderate	Moderate
Moderate	Low	Moderate	Moderate	High
High	Moderate	Moderate	High	High

Dealing with uncertainty

Qualitative categories for expressing uncertainty in relation to qualitative risk estimates

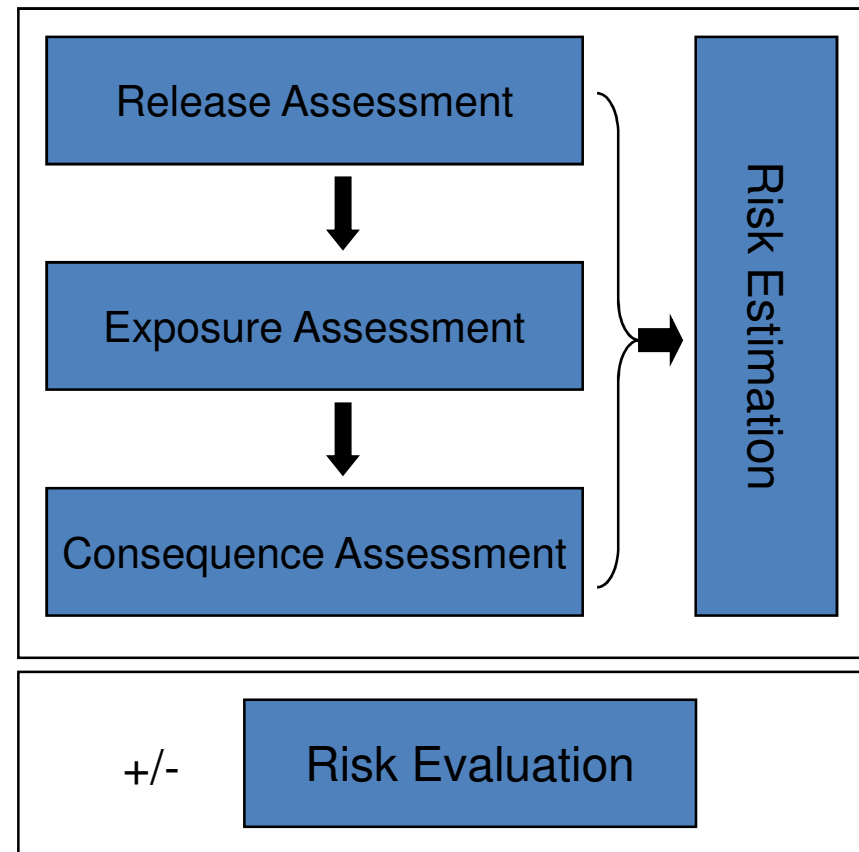
Uncertainty category	Interpretation
Low	Solid and complete data available; strong evidence provided in multiple references; authors report similar conclusions
Medium	Some but no complete data available; evidence provided in small number of references; authors report conclusions that vary from one another
High	Scarce or no data available; evidence is not provided in references but rather in unpublished reports, based on observations, or personal communication; authors report conclusions that vary considerably between them

Risk Assessment Methodology

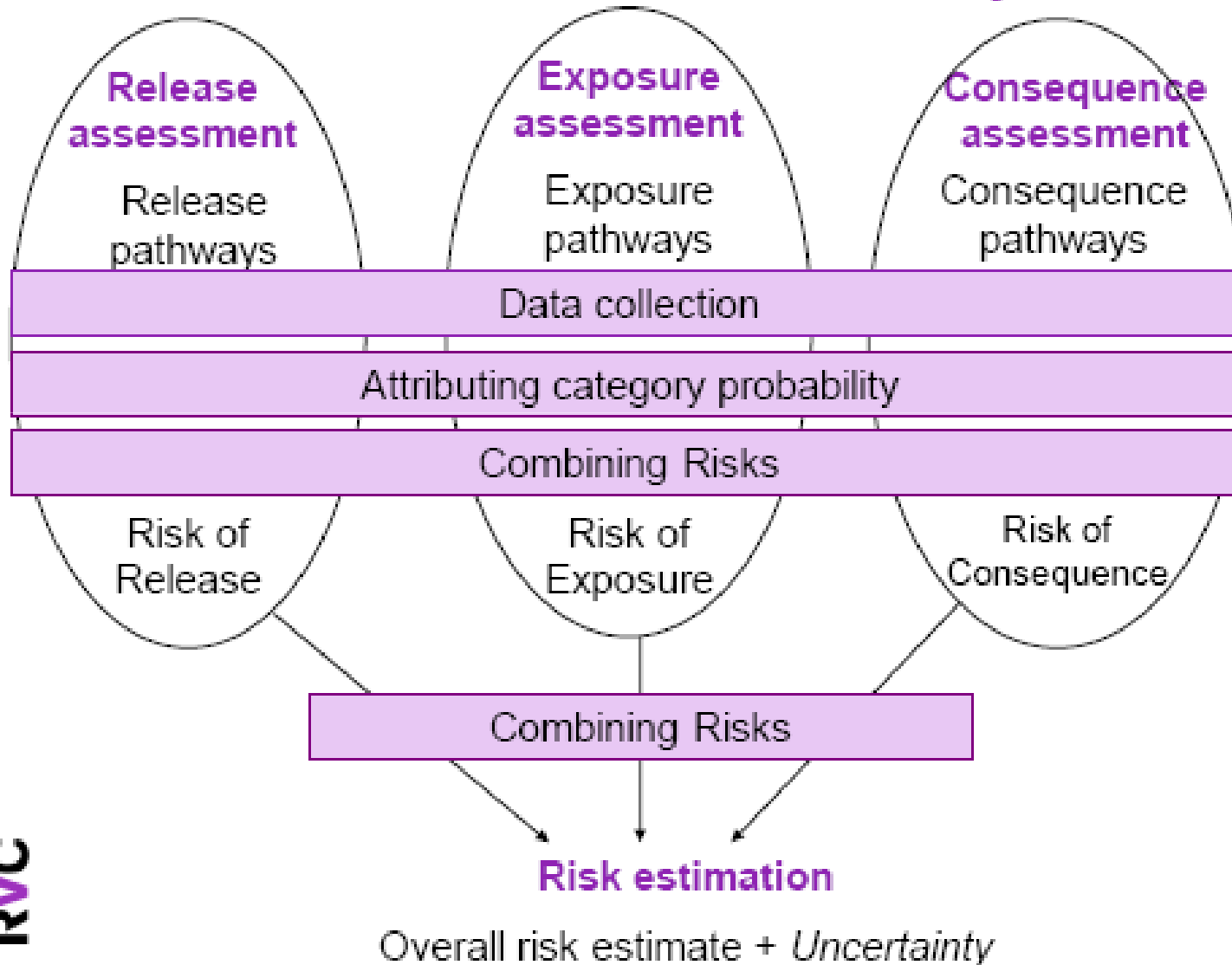
- Qualitative RA:
- Review information available and estimate risk for each step
- Combine risk estimates using pre-defined combination matrix
- Deduct the overall probability of occurrence of the risk of interest and of unwanted consequences
- +/- decide whether this risk is acceptable or not

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

- OIE Framework
(Import risk analysis)



Risk assessment - summary



Examples of risk pathways

- Coburn, H.L., Snary E. L., *et al.* (2005)
Qualitative risk assessment of the hazards and risks from wild games. *Vet record* 157(11):
321-322

Coburn H.L., Snary E.L., *et al.* (2005)

- What is the risk for human health from the handling/consumption of wild games?

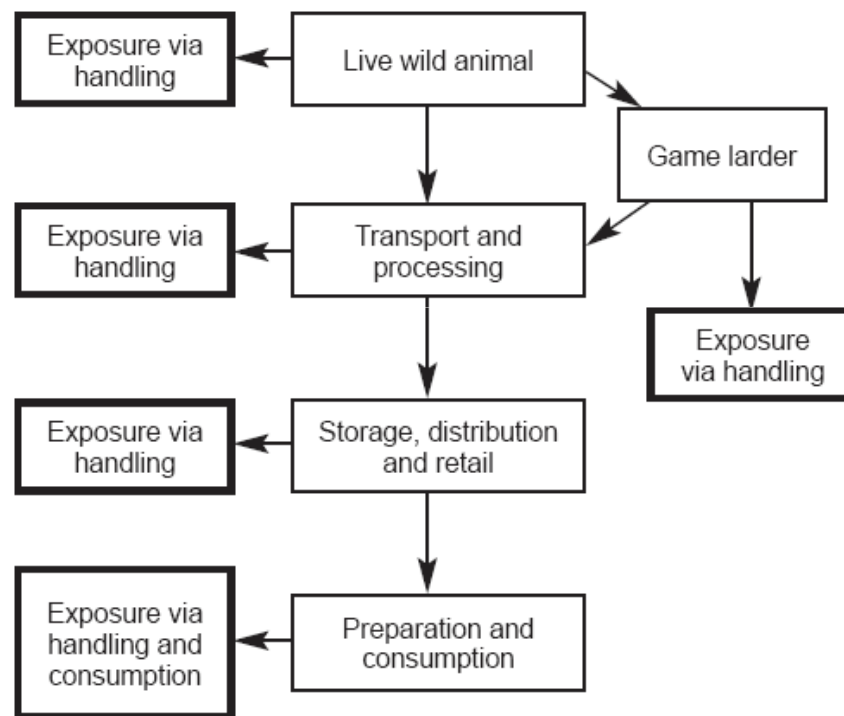


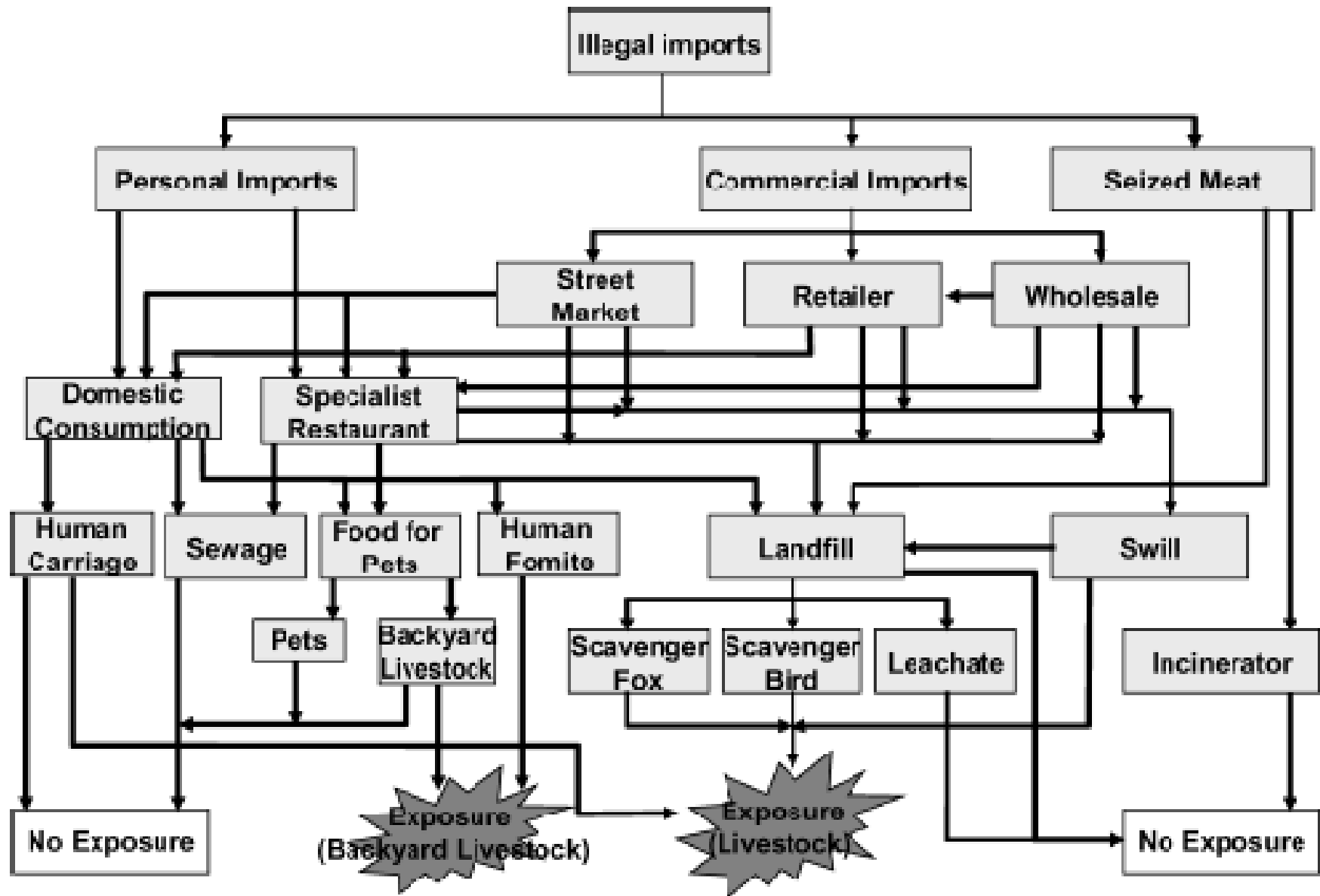
FIG 1: Generic human exposure pathway for hazards from wild game animals

Example 2

A Quantitative Assessment of the Risks from Illegally Imported Meat Contaminated with Foot and Mouth Disease Virus to Great Britain

**Emma Hartnett,^{1*} Amie Adkin,¹ Miles Seaman,² John Cooper,² Eamon Watson,³
Helen Coburn,¹ Tracey England,¹ Christophen Marooney,¹ Anthony Cox,²
and Mavion Wooldridge¹**

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Risk Assessment in context

- Estimation of the overall likelihood of occurrence of the adverse event considered
 - Identification of the steps of the pathways having high risk of occurrence or high impact on overall risk estimate
- => is it worth doing surveillance, and if so, where (on what steps/processes) to focus efforts

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