



Animal Health Matters.
For Safe Food Solutions.



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,
Education and Research EAER

State Secretariat for Economic Affairs SECO



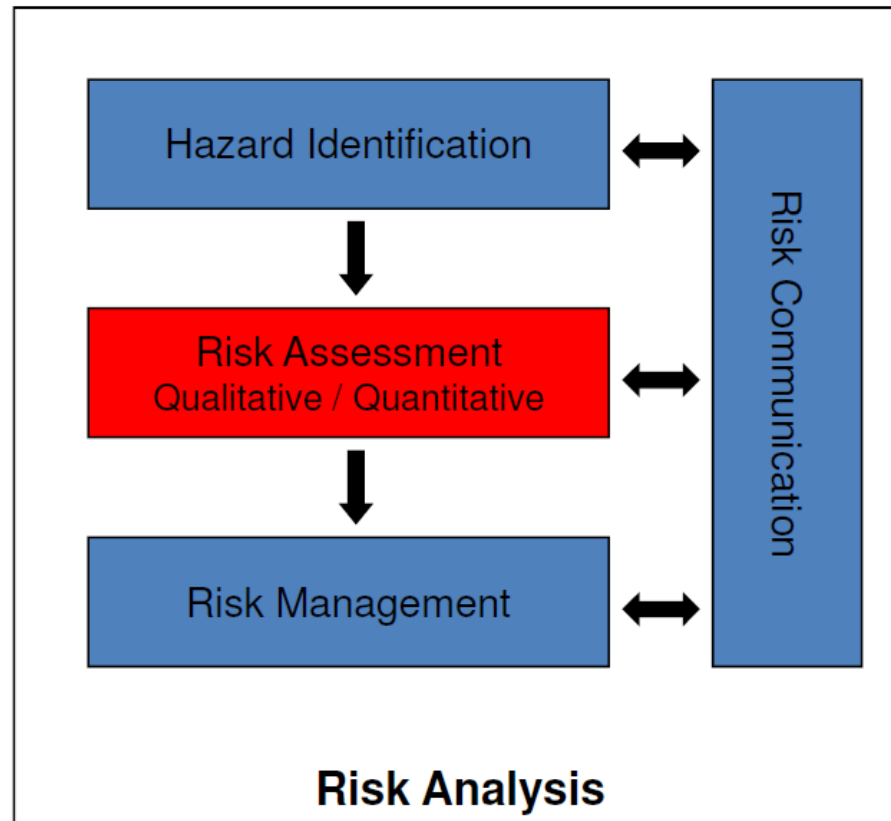
How to conduct a risk assessment

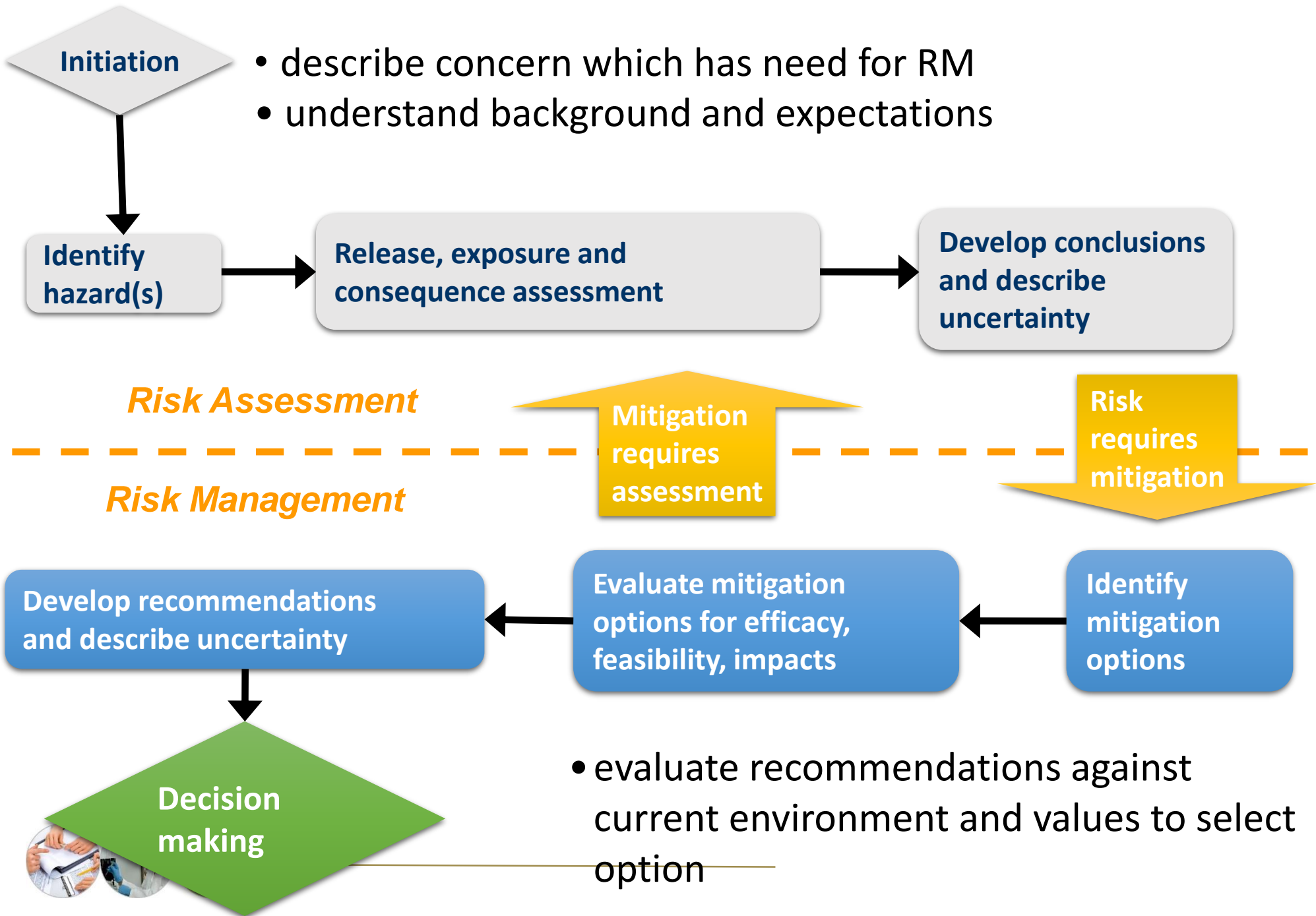
Marco De Nardi (SAFOSO, MSP)



Concepts: risk assessment

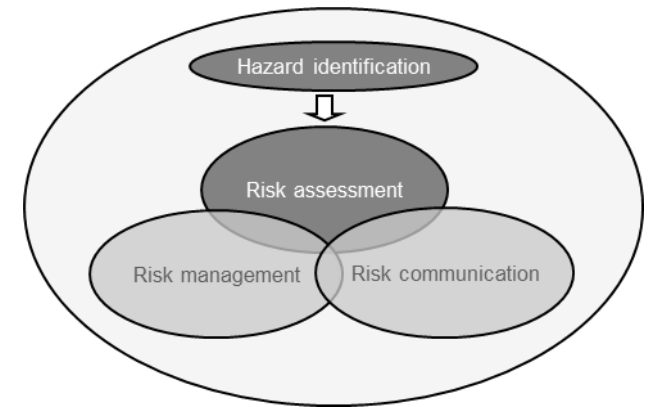
- Risk assessment is only part of the whole process of risk analysis:





Important requirements:

- **Different skills** are required to conduct a risk analysis:
 - Epidemiologists (veterinary, public health)
 - Veterinarians
 - Virologists, microbiologists, laboratory experts
 - Experts on climatology, entomology, ornithology
 - Environmental scientists,
 - Industry technologists,
 - Mathematicians, statisticians
 - Information scientists
 - Economists



Multidisciplinary approach within a project team



Two approaches cont.

OIE method (Covello-Merkhofer)

Hazard identification

Risk Assessment

- Release assessment
- Exposure assessment
- Consequence assessment
- Risk estimation

Risk management

- Risk evaluation
- Option evaluation
- Implementation
- Monitoring and review

Risk communication throughout

Codex Alimentarius method (NAS-NRC)

Risk Assessment

- Hazard identification
- Hazard characterization
- Exposure assessment
- Risk characterization

Risk management

- Risk evaluation
- Option assessment
- Monitoring and review

Risk communication throughout



Risk assessment: key aspects

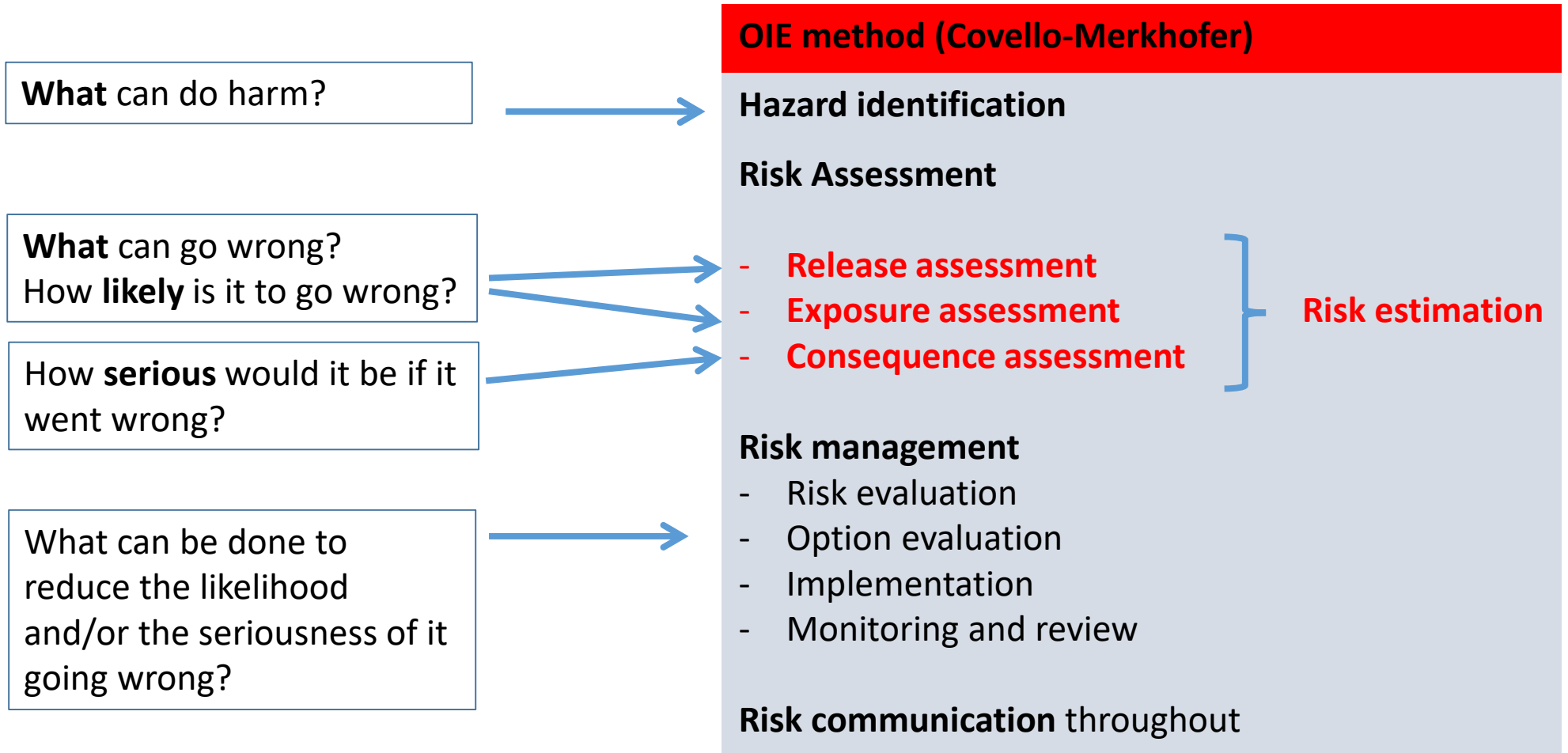


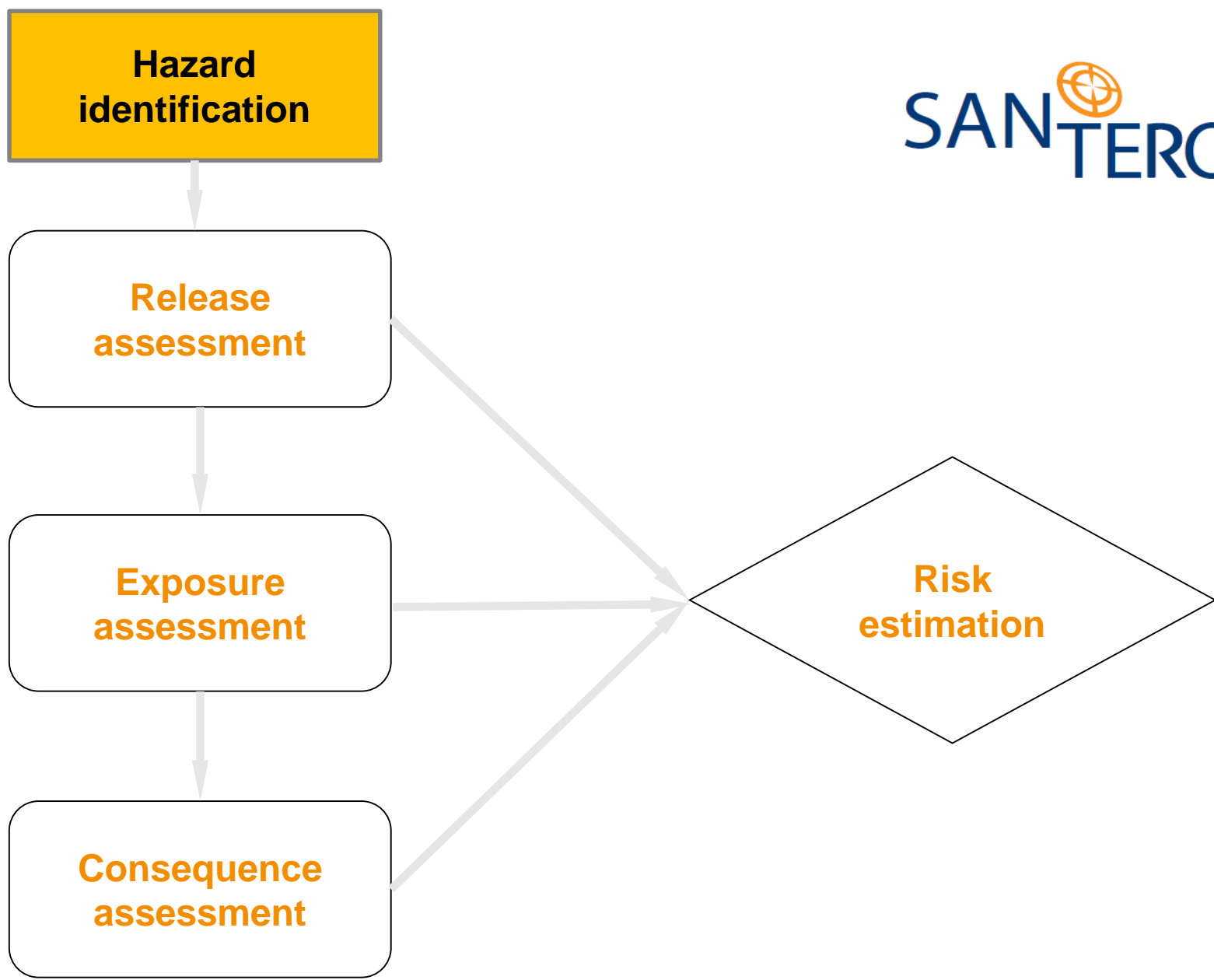
A risk assessment must determine:

- **What** can do harm?
- **What** can go wrong?
- How **likely** is it to go wrong?
- How **serious** would it be if it went wrong?
- What **can be done** to reduce the likelihood and/or the seriousness of it going wrong?



Steps in Risk Analysis - OIE





Risk Assessment - OIE

- 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



Adapted from RVC, Introduction to Risk Analysis and Risk Assessment . Solenne Costard (ILRI, Nairobi, 2nd and 3rd October 2008)

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



Qualitative vs. quantitative RA

Qualitative

■ Advantages

- Often sufficient
- Less resources required
- May be easier to communicate

■ Disadvantages

- Subjectivity hard to avoid
- Uncertainty difficult to integrate
- Less standardised
- Hard to teach!

Quantitative

Advantages

- Mathematically robust
- Uncertainty more formally integrated

Disadvantages

- Resource intensive
- Time
- Data (quantity and quality)
- Capacity
- May imply certainty
- May be difficult to communicate

Qualitative risk estimation

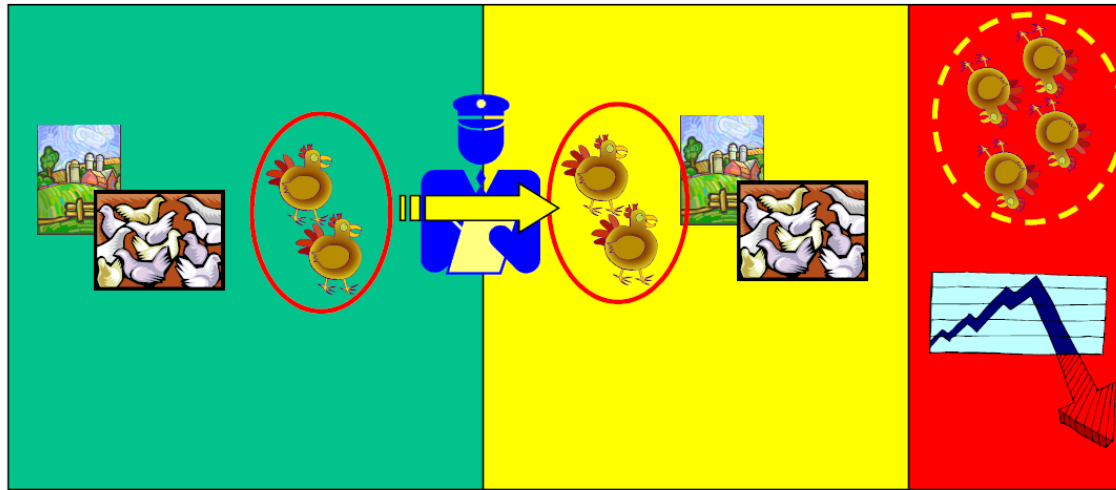
Likelihood	Description
Very high	The event occurs almost certainly.
High	The event occurs very often.
Medium	The event occurs regularly.
Low	The event is rare but does occur.
Very low	The event is rare but cannot be excluded.
Negligible	The event is so rare that it does not merit to be considered.



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

Available online at www.sciencedirect.com

ScienceDirect

PREVENTIVE
VETERINARY
MEDICINE

Preventive Veterinary Medicine 86 (2008) 43–56

www.elsevier.com/locate/prevetmed

ELSEVIER

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 Rodríguez^a



- How to implement a risk assessment



Important requirements:

- **Clear definition of terms:**
 - Risk question
 - Hazard identification
 - Qualitative risk assessment: risk categories and combination matrix
- **Always report information sources**
 - Systematic review
- **Provide rationale for conclusions and decisions**
- Describe **uncertainty** and identify **data gaps** or areas for additional research
- **Quality assurance**
 - Publication
 - Peer review



Adapted from RVC, Introduction to Risk Analysis and Risk Assessment . Solenne Costard (ILRI, Nairobi, 2nd and 3rd October 2008)

How to do a risk assessment

- The main steps of a risk assessment are:
 1. Identifying and prioritize the **hazard(s)** of interest
 2. Framing the **risk question** (identify the unwanted outcome)
 3. **Characterize** the hazards (if CAC)
 4. Outlining the steps necessary (**risk pathways**) to get from hazard of interest to unwanted outcome in the target population
 5. Identifying **data** and **information** needs
 6. **Collecting data** and information to estimate the probability of each event in the pathway
 7. **Assessing the risk**
 - *Qualitatively*
 - *Quantitatively*



1) Hazard identification



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Hazard identification

- Essential first step in RA
- Process of identifying **all potential hazards** associated with the species from which the commodity (e.g. milk) is derived (e.g. pathogenic agents)
- Based on a number of **criteria**, determining whether or not the can be classified as hazards for further consideration in RA
 - Good knowledge of animal diseases, patterns of disease and pathogenic agent is compulsory
 - Critical for the risk analysis/assessment
 - No hazard → no risk!
 - If one hazards is missed → results of analysis will be false



Hazard identification

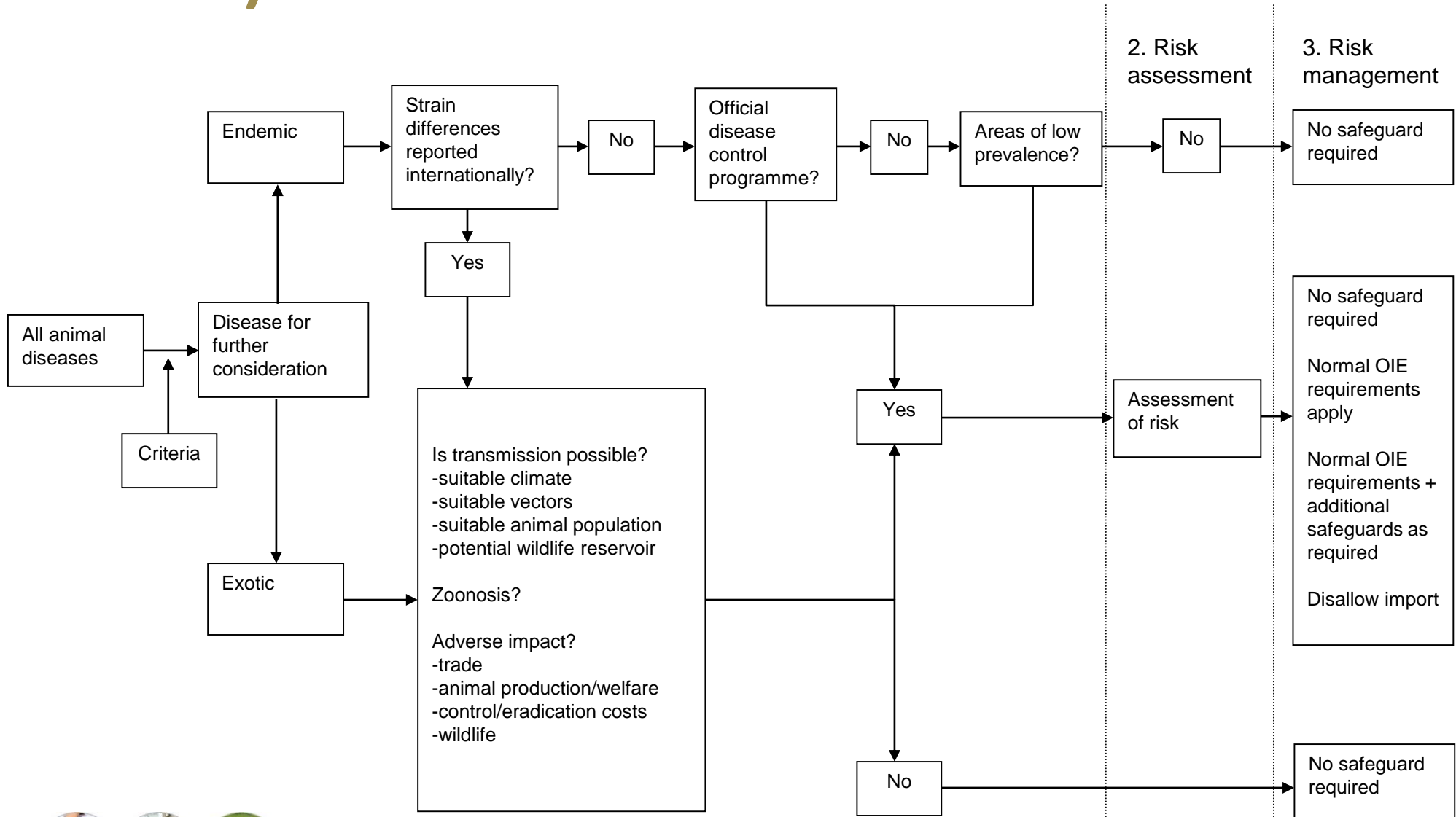
- Hazard may be **explicit** in risk question

Ex: - What is the risk of importing **ASF** in Ukraine from neighboring countries?
- What is the risk of infection with **M. Bovis** by milk consumption?

- Otherwise **full hazard identification** must be undertaken
 - List all potential disease agents (OIE list, other diseases)
 - Categorise disease agents (hazard yes/no), given:
 - Species affected
 - Type of commodity
 - Country of origin/destination
 - Use existing analyses as examples



Decision tree for shortening disease list (life animals)



Examples of Hazards in dairy products



Contents lists available at [ScienceDirect](#)

 **ELSEVIER**

International Dairy Journal

journal homepage: www.elsevier.com/locate/idairyj



Review

A review of the microbiological hazards of dairy products made from raw milk  CrossMark

C. Verraes ^{a,*}, G. Vlaemyck ^b, S. Van Weyenberg ^b, L. De Zutter ^{c,d}, G. Daube ^{c,e},
M. Sindic ^{c,f}, M. Uyttendaele ^{c,g}, L. Herman ^{b,c}

- **Listeria monocytogenes** (cheese, raw milk butter and cream)
- **Verocytotoxin-producing Escherichia coli (VTEC)** (cheese, raw milk butter and cream)
- **Staphylococcus aureus** (cheese, raw milk butter and cream)
- **Salmonella** (cheese)
- **Campylobacter** (cheese)
- **Brucella spp.** (raw milk dairy products)
- **Mycobacterium bovis** (raw milk dairy products)



Examples of Hazards in dairy products

Zoonoses and Public Health

ORIGINAL ARTICLE

A Qualitative Risk Assessment Approach for Swiss Dairy Products: Opportunities and Limitations

S. Menéndez González^{1*}, S. Hartnack^{2†}, T. Berger³, M. Doherr^{2*} and E. Breidenbach¹

- **Listeria monocytogenes**
- Shiga toxin-producing **Escherichia coli** (STEC)
- **Staphylococcus aureus** enterotoxin
- **Salmonella** spp.
- **Campylobacter** spp.



Hazards identification

- The **hazard/s** should be described in details and its description should be provided in the RA report
- This information will help in defining the **risk pathways** and assessing the **data needs** and gaps
- Pathogen characterists
- Clinical signs
- Epidemiology
- Diagnostic
- Control measures
- Etc.....



For each hazard gather information about growth, inactivation and survival parameters; disease features; habitat, transmission, occurrence in humans, animals and dairy products.



2) Risk question

The main steps of a risk assessment are:

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 - *Qualitatively*
 - *Quantitatively*



Risk question

- Risk to be assessed must be clearly defined
- Multiple different risk questions can be asked for the same hazard!
- If not specific enough, a risk question can be interpreted in different ways:

Ex: What is the risk for the introduction of Avian Influenza into susceptible population in Kenya?

OR

Ex: What is the (yearly) risk for the introduction of (HPAI or LPAI) Avian Influenza H5N1 (through migratory birds / poultry trade / wild bird trade ?) into (wild bird / domestic / human population?) in Kenya?



Risk question

- **The risk question should be as clear as possible**
 - Specific hazard?
 - Pathogen X or list of pathogens
 - Which are vectors/fomites to consider?
 - Live animals
 - Products
 - Which specific risk will be estimated?
 - Introduction
 - Infection by drinking milk
 - Time frame?
 - Risk per year/month?
 - Location?



Risk Question

Zoonoses and Public Health

ORIGINAL ARTICLE

A Qualitative Risk Assessment Approach for Swiss Dairy Products: Opportunities and Limitations

S. Menéndez González^{1*}, S. Hartnack^{2†}, T. Berger³, M. Doherr^{2*} and E. Breidenbach¹

‘What is the risk to human health from the consumption of Swiss dairy products taking into account the kind of product consumed and the type of dairy where it was produced?’.

Swiss legislation defines **microbiological limits** (threshold values) beyond which a product is considered hazardous for human health.



3) Characterizing the hazards



The main steps of a risk assessment are:

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 - *Qualitatively*
 - *Quantitatively*



Hazards characterization (CAC)

- "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, biological or physical agents**, a **dose-response assessment** should be performed.
- Dose-Response assessment: the determination of the relationship between the magnitude of exposure (**dose**) to a hazard (chemical, biological or physical agent) and the severity and/or frequency of associated adverse health effects (**response**)



Hazards characterization (CAC)

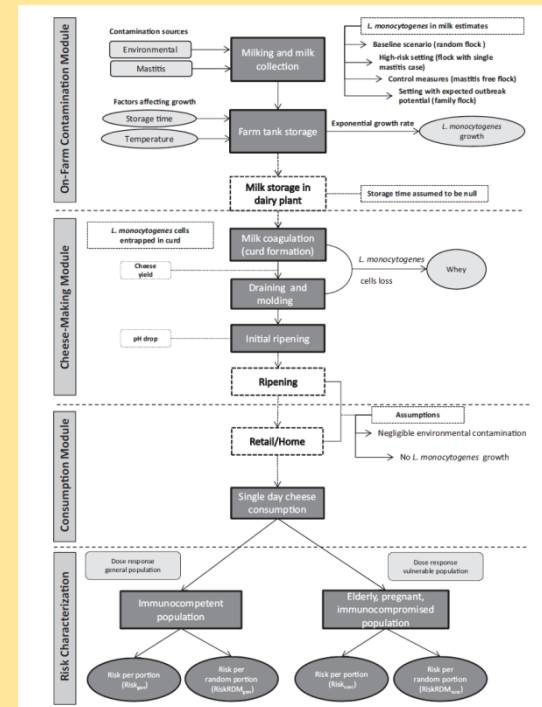
- Emphasis on the impact of adverse health effects
- Qualitative or quantitative description of the **severity** and **duration of adverse effects** that may result from the ingestion of a microorganism or its toxin in food
- Also check for threshold values etc. in OIE code, EU regs and Codex Alimentarius



4) Risk pathways

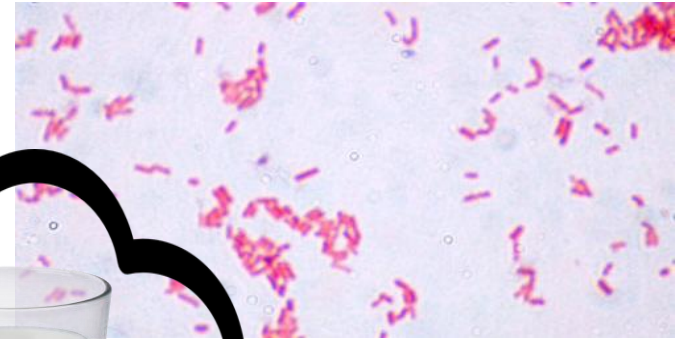
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Risk pathway

How do we get from hazard...



... to unwanted outcome?

Risk pathways

- A risk pathway is a **flowchart**, a schematic representation of a series of events
- A risk pathway shows all stages in the biological process of how a **hazard could reach a susceptible host/a country/a product leading to the outcome of interest.**
- It helps you to **structure** your work and to answer the risk question



Risk pathways: example

N. 0

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A Qualitative Risk Assessment Approach for Swiss Dairy Products: Opportunities and Limitations

S. Menéndez González^{1*}, S. Hartnack^{2†}, T. Berger³, M. Doherr^{2*} and E. Breidenbach¹

- **Release assessment:** it considered the influence of consecutive steps along the food chain on the **presence/absence of contamination** and its magnitude until the products reached the consumers.

These steps were

- (i) the prevalence of the hazards in bulk milk,
- (ii) the manufacturing process,
- (iii) the influence of the type of dairy.

The **release likelihood (RL)** was estimated as the generic likelihood of exceeding the microbiological limit value in the final product for each combination hazard/product/type of dairy.



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S. Menéndez González^{1*}, S. Hartnack^{2†}, T. Berger³, M. Doherr^{2*} and E. Breidenbach¹

- **Exposure assessment** was based on production data corresponding to 2006 and classified per product and type of dairy.
- **Exposure likelihood (EL)**, that is, the relative likelihood of consumer's exposure to a certain product from a certain type of dairy.



Risk pathways

- A risk pathway should be complete
- If it is not in the pathway, it is not considered in the risk assessment
- Therefore, developing a risk pathway requires knowledge about the hazard and possible routes of transmission
- List all steps required for the risk to occur,
 - differentiating release, exposure and consequence



Risk pathways: example N 1 H5N1 introduction in Kenya

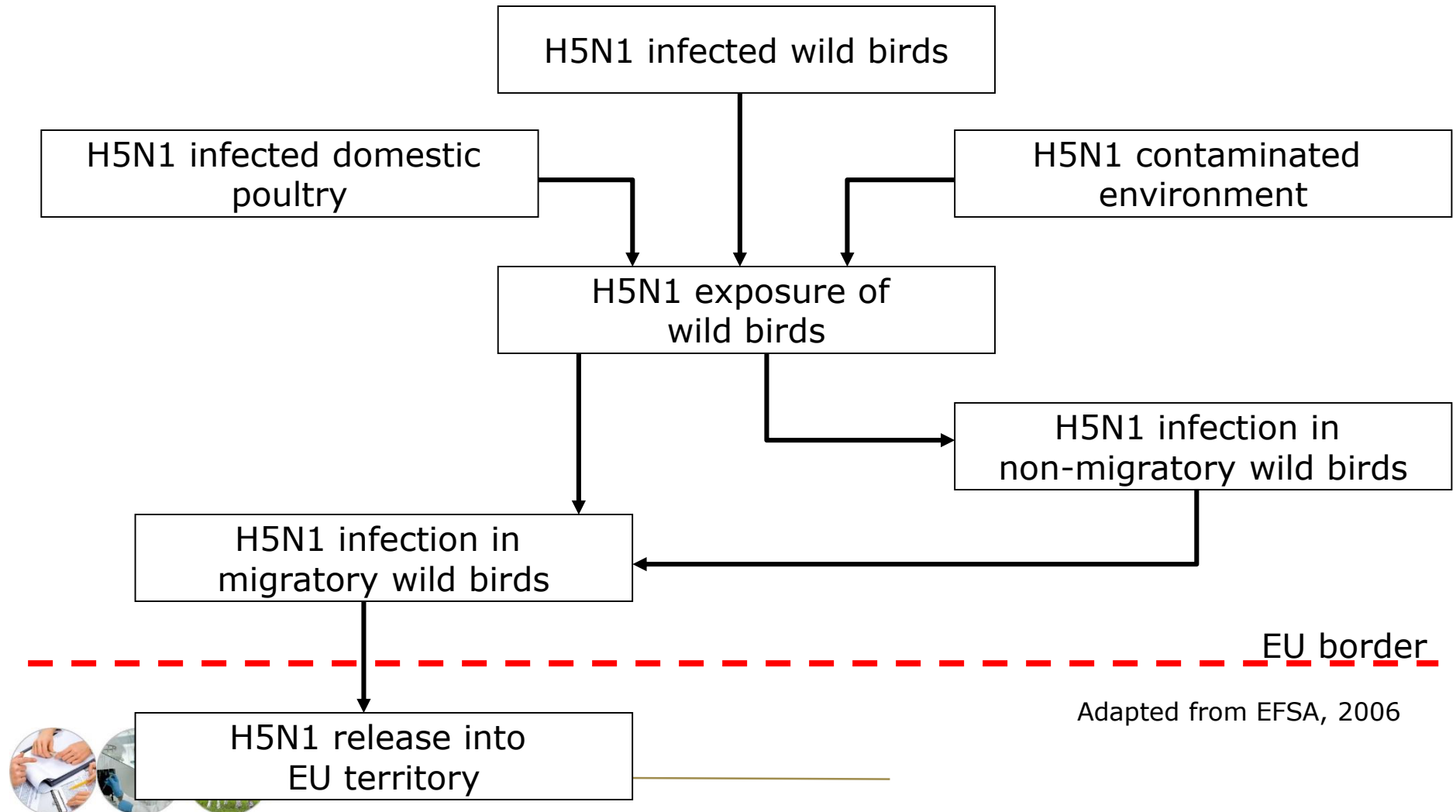
- What is the risk for the introduction of HPAI H5N1 through migratory birds into wild bird population in Kenya?

	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.

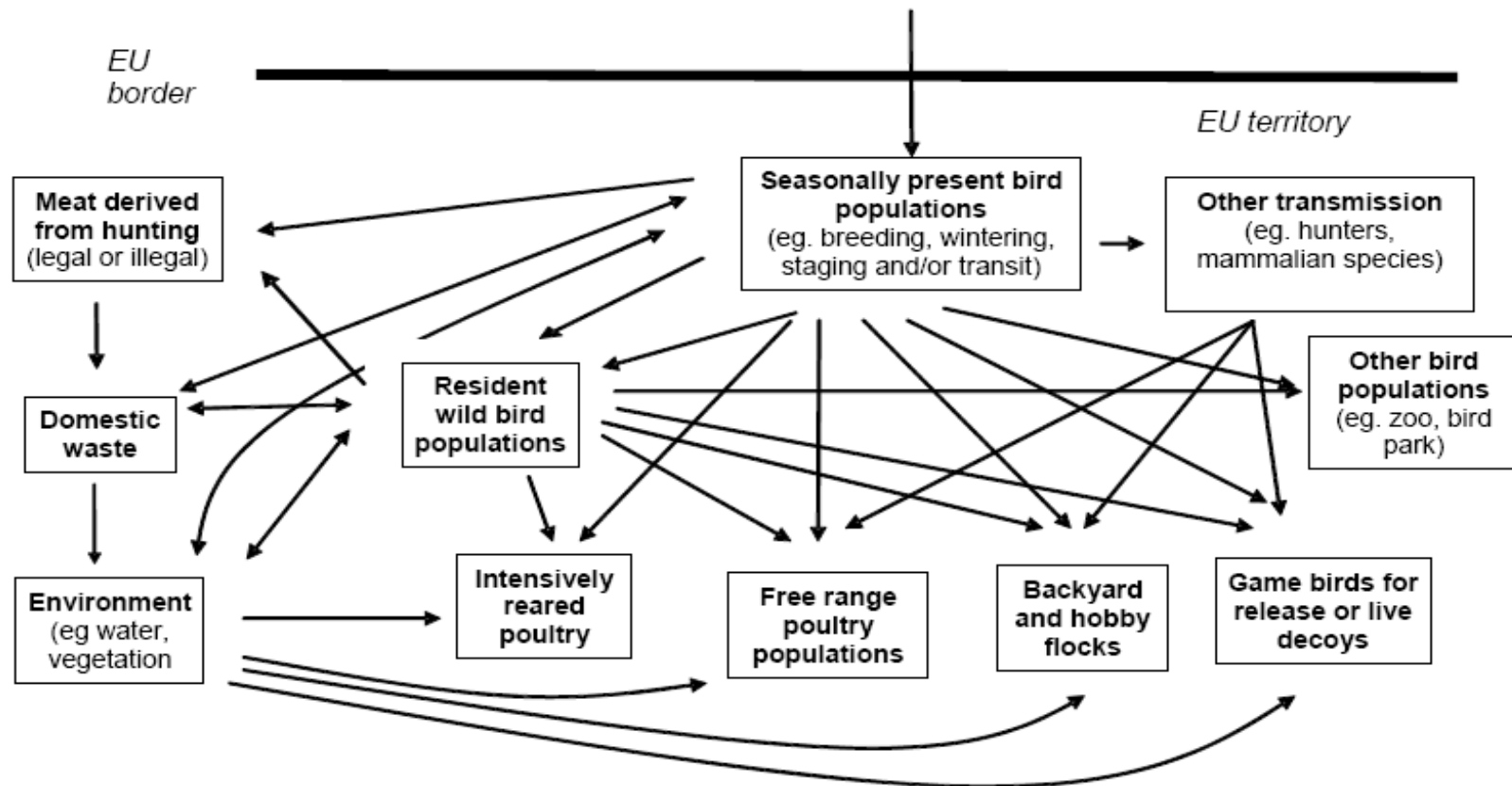
Adapted from RVC, Introduction to Risk Analysis and Risk Assessment . Solenne Costard (ILRI, Nairobi, 2nd and 3rd October 2008)



Risk pathways example N1 : H5N1 release through wild birds



Risk pathways example N 1: H5N1 exposure through wild birds

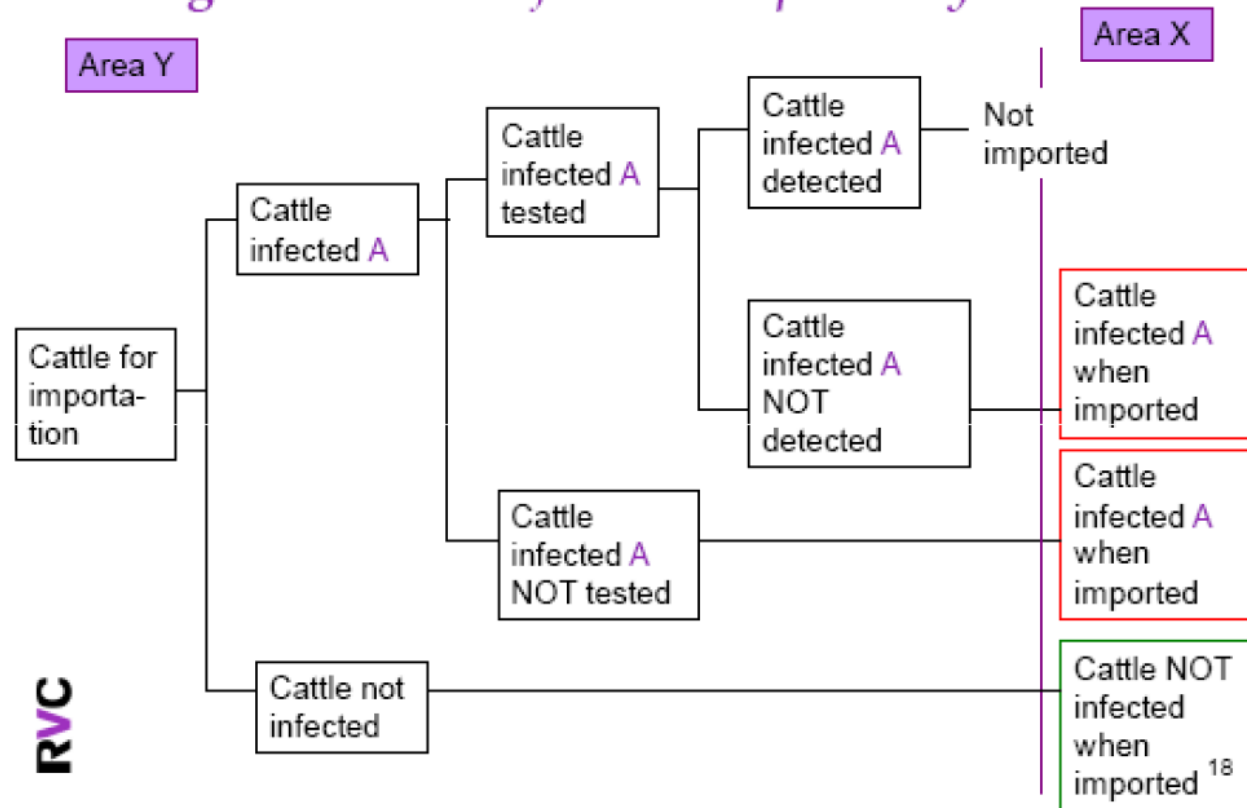


From EFSA, 2006



Risk pathways example N 2: release infected cattle

e.g. Scenario tree for release pathway



Adapted from RVC, Introduction to Risk Analysis and Risk Assessment . Solenne Costard (ILRI, Nairobi, 2nd and 3rd October 2008)

Risk pathways example N 3:

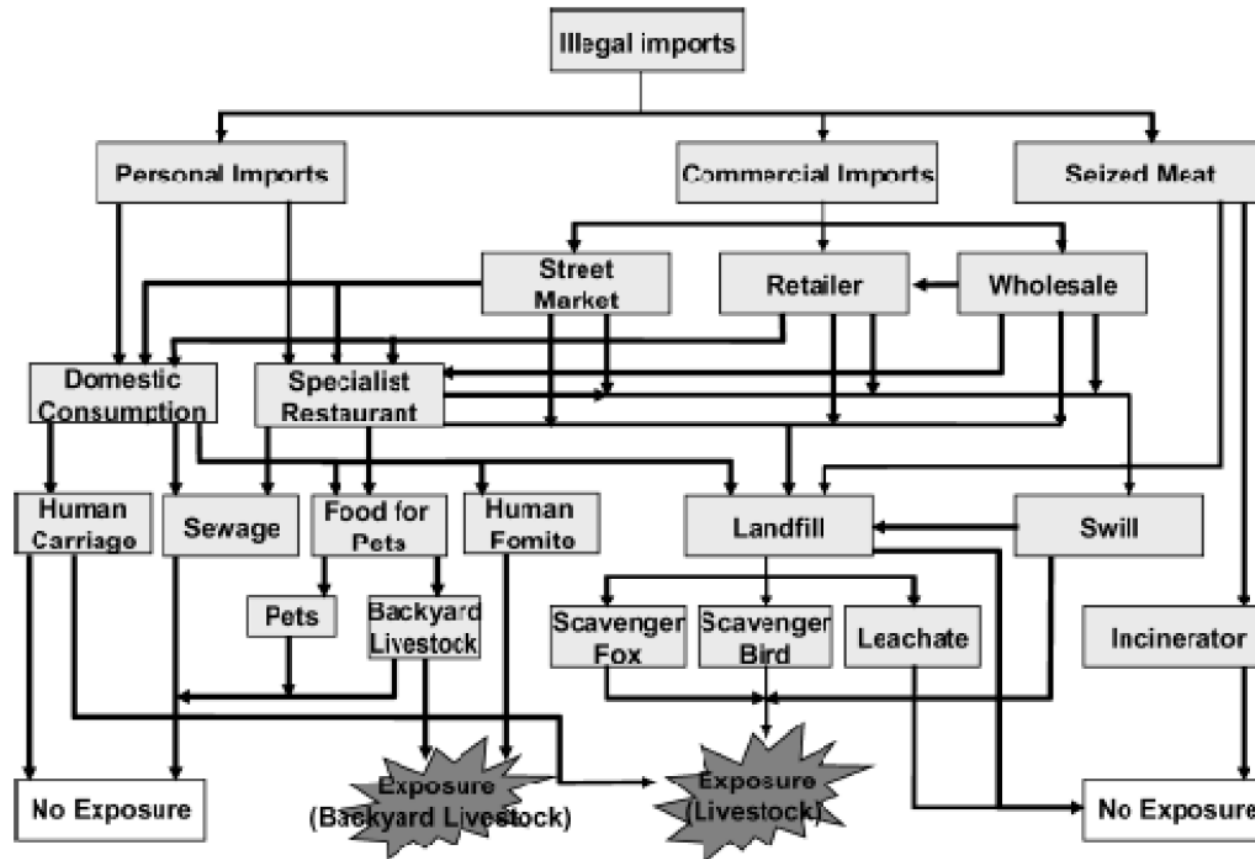
A Quantitative Assessment of the Risks from Illegally Imported Meat Contaminated with Foot and Mouth Disease Virus to Great Britain

**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**

Risk Analysis, Vol 27, num 1, 2007



Risk pathways: example N 3



How to develop a Risk pathway?

- Think about your question: what is the ultimate point of interest?
- That is the endpoint of your risk pathway
- Think about your hazard
- That is the starting point of your risk pathway
- Think about all possible routes how the hazard could reach the endpoint through the animal/commodity of concern
- There must be a (bio)logical explanation for each route



Risk Pathways example N 4:

Risk Analysis DOI: 10.1

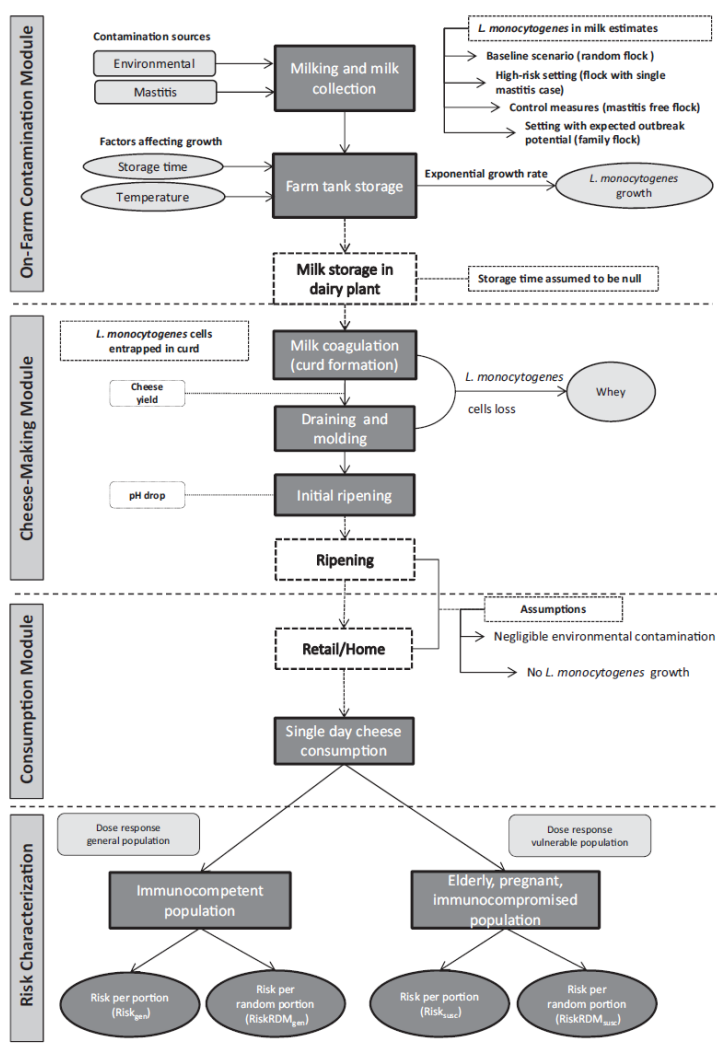
Risk Assessment of Human Listeriosis from Semisoft Cheeses Made from Raw Sheep's Milk in Lazio and Tuscany (Italy)

Roberto Condoleo,^{1*} Ziad Mezher,¹ Selene Marozzi,¹ Antonella Guzzon,² Roberto Fischetti,¹ Matteo Senese,¹ Stefania Sette,³ and Luca Buchini²

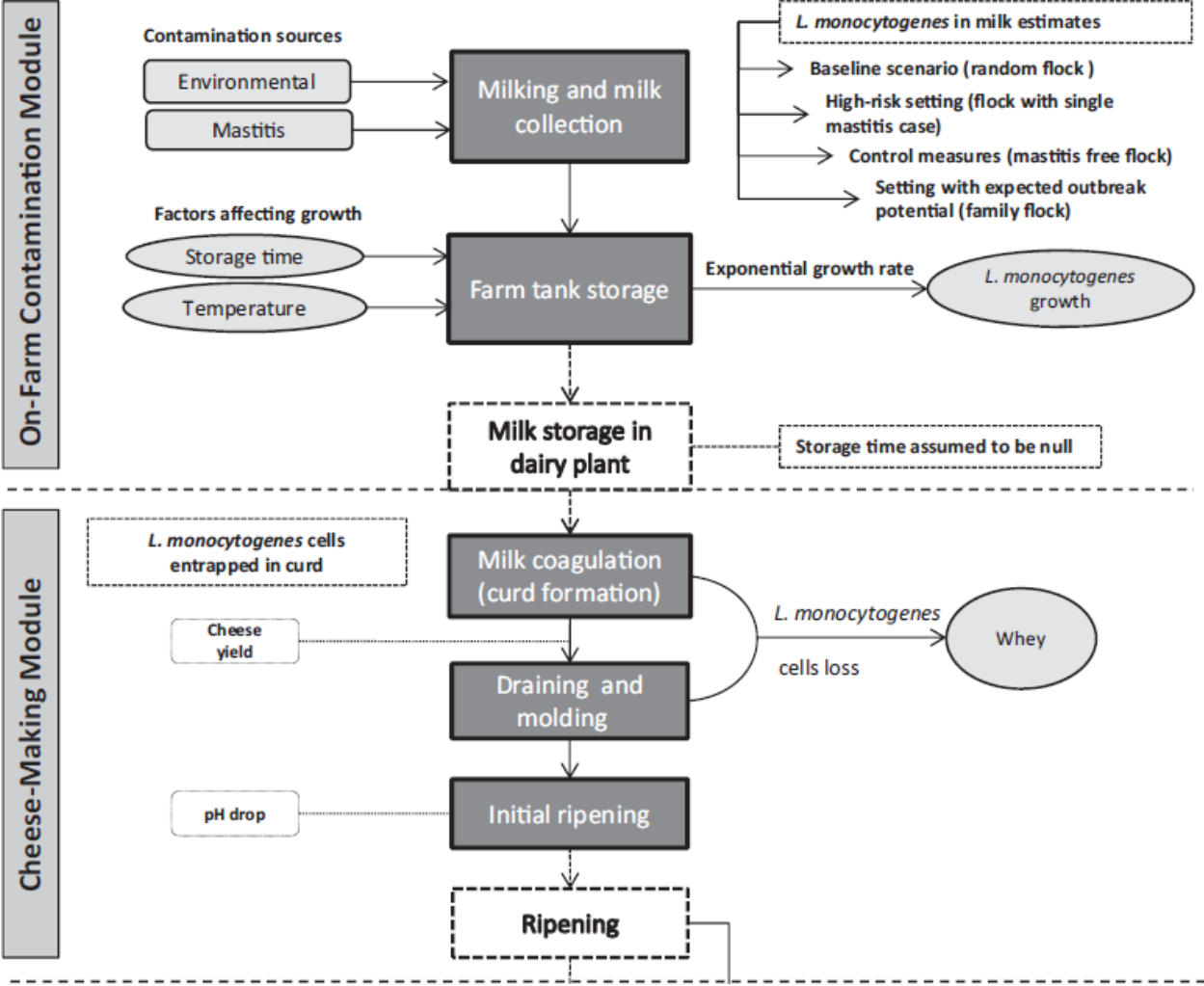
Release

Exposure

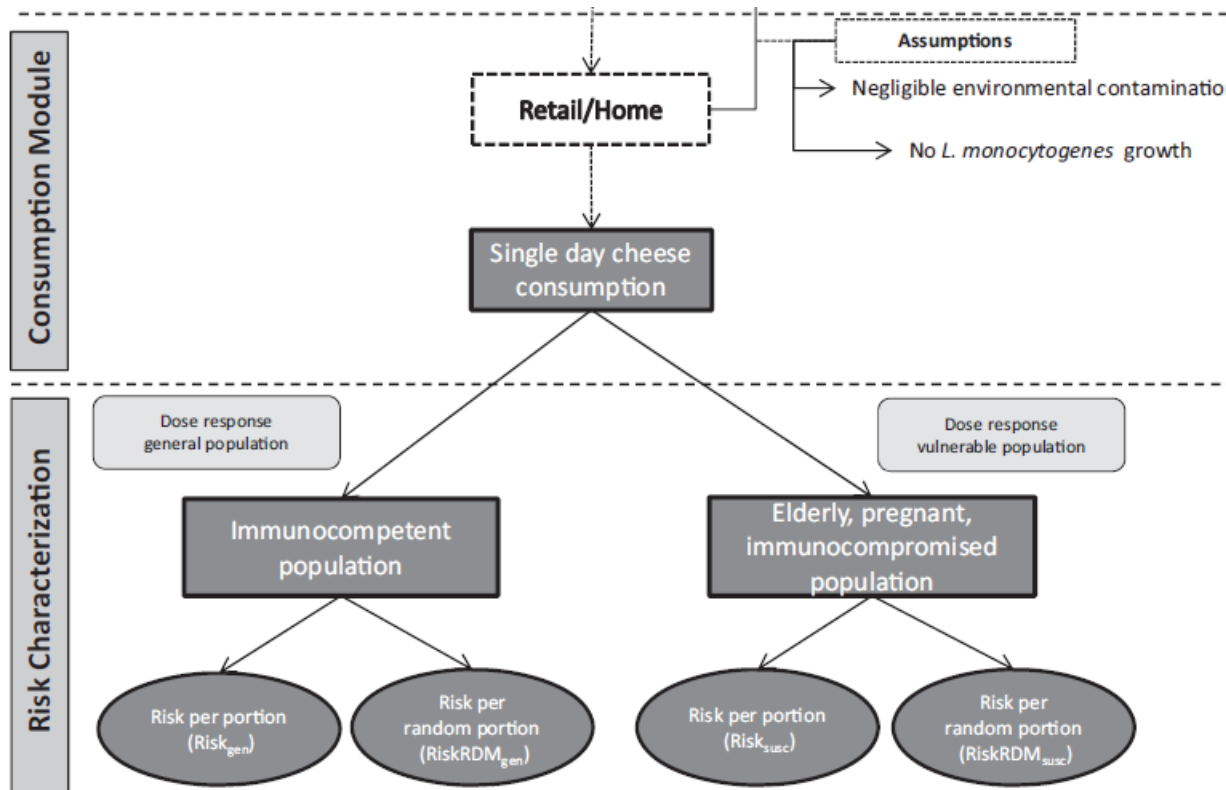
Consequence



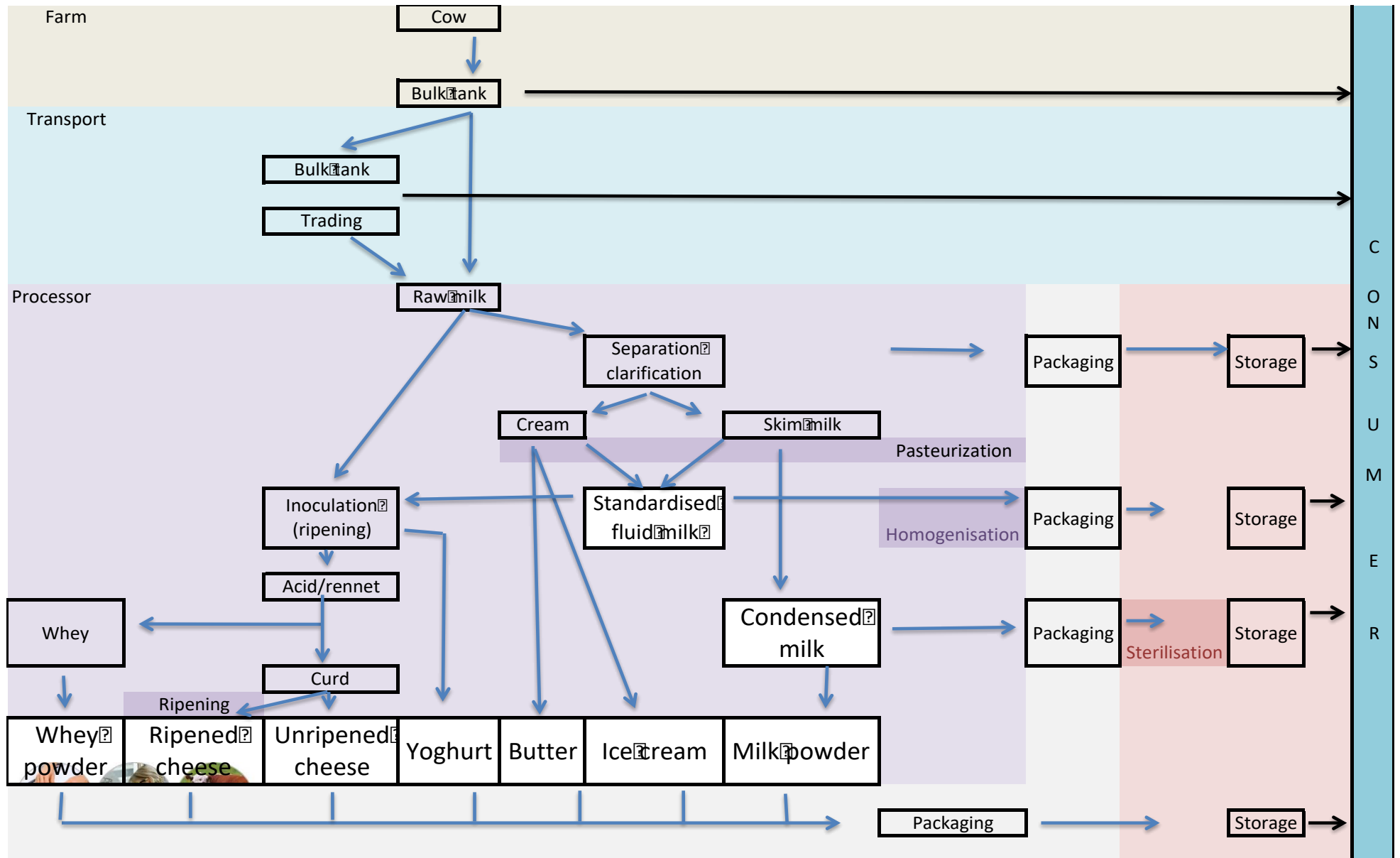
Release



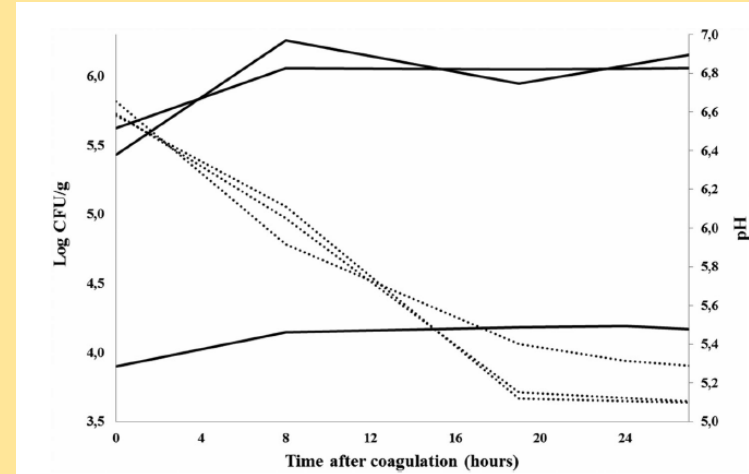
Exposure and consequence



Dairy production chain: a general flow chart



5) Data needs



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 - *Qualitatively*
 - *Quantitatively*

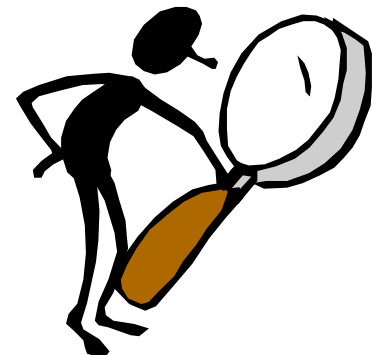


Data needs

- A risk assessment requires lots of data: the data required to assess the **likelihood of occurrence** of each step of the pathway must be identified
- How to determine **which data** precisely?
 - The data should help to answer the question
 - The risk pathway helps to determine what kind of data you need

Data needs

- Each statement made in the risk assessment should be supported by evidence
 - Documented evidence
- Each step or transmission route in the risk pathway leads to subquestions
 - The subquestions are answered via the collection of appropriate data



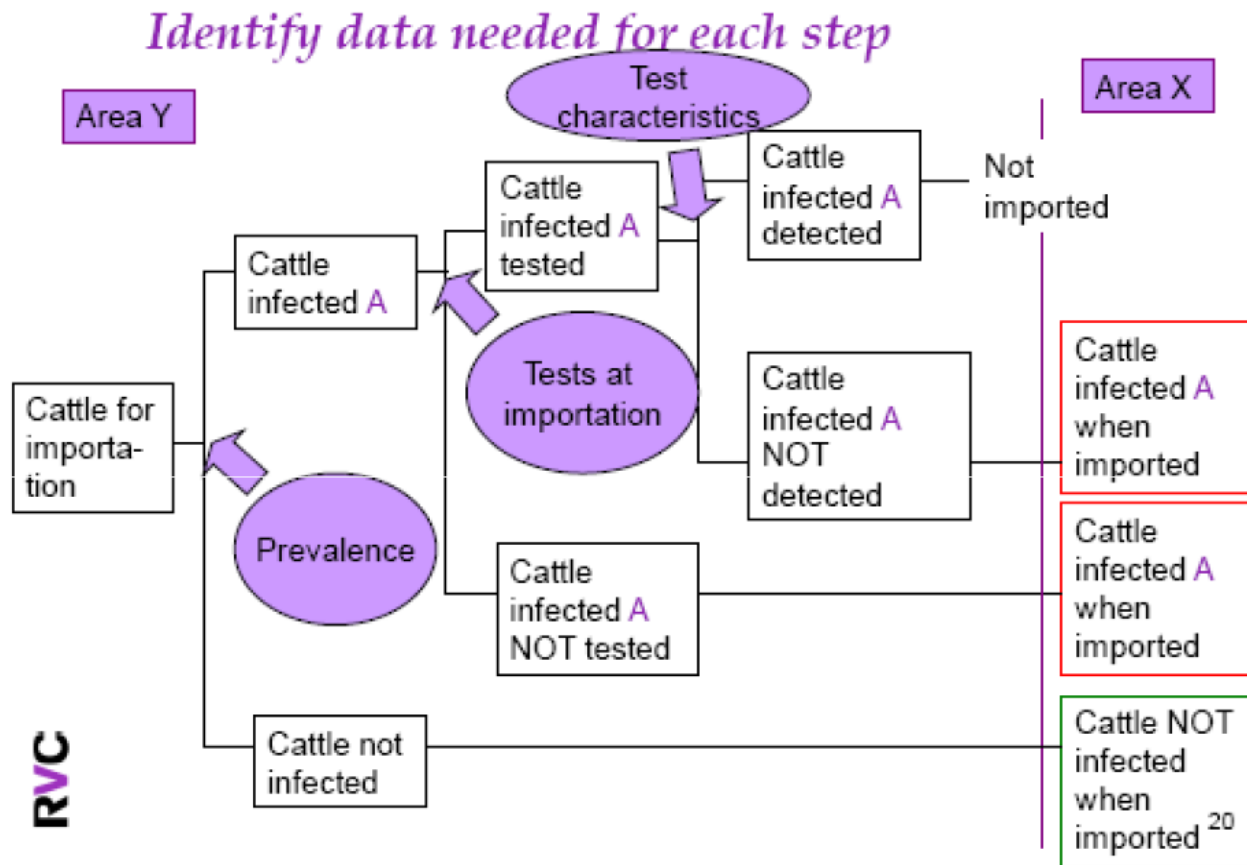
Data needs: example N 1 H5N1 introduction in Kenya

	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..



Adapted from RVC, Introduction to Risk Analysis and Risk Assessment (ILRI, Nairobi, 2nd and 3rd October 2008) Solenne Costard

Data needs example N 2: release infected cattle



Adapted from RVC, Introduction to Risk Analysis and Risk Assessment . Solenne Costard (ILRI, Nairobi, 2nd and 3rd October 2008)



A. Release assessment

- Biological factors to be considered
 - Susceptibility to the hazard of animals from which the commodity is derived (species, breed, age, etc)
 - Means of transmission of hazard (horizontal, direct, indirect, vertical)
 - Infectivity, virulence and stability of hazard
 - Routes of infection (oral, respiratory, etc.)
 - Impact of vaccination, testing, treatment and quarantine
 - Outcome of infection (immunity, latent infection, carrier)
 - Predilection sites of the hazard



A. Release assessment

- Country factors to be considered
 - Incidence and/or prevalence of disease
 - Existence of disease-free areas or low prevalence
 - Animal demographics
 - Farming and husbandry practices
 - Geographical and environmental characteristics, incl. rainfall and temperature



A. Release assessment

- Commodity factors to be considered
 - Ease of contamination
 - Relevant processes and production methods
 - Effect of processing, storage and transport
 - Quantity of commodity to be imported/introduced



C. Exposure assessment

Country factors to be considered

- Presence of intermediate hosts or vectors
- Human and animal demographics
- Farming and husbandry practices
- Customs and cultural practices
- Geographical and environmental characteristics



C. Exposure assessment

Commodity factors to be considered

- Intended use of the imported animals or products
- Waste disposal practices
- Quantity of commodity to be imported



Exclusions – Data missing

- It is sometimes necessary to exclude certain sub-pathway from the risk assessment
 - E.g. all illegal actions are excluded from the risk assessment
- Such exclusions should clearly be stated
- The validity of the risk assessment is influenced
 - The findings of the risk assessment are only valid for those areas that were included

Exclusions – Data missing

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

Adapted from RVC, Introduction to Risk Analysis and Risk Assessment . Solenne Costard (ILRI, Nairobi, 2nd and 3rd October 2008)



5) Source of data



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 - *Qualitatively*
 - *Quantitatively*



Source of data

- **Number of sources:**

- literature, experimental, expert opinion...

- **Consider validity:**

Most up-to-date

- **Fully referenced** (transparency)

- For **Qualitative approach**, no new data collected;

- identification gaps in knowledge / data



Source of data

- A risk assessment requires lots of data
- The data you need will be distributed over many different sources
 - Some sources you already know
 - Some other sources are still unknown to you

What are typical sources of data and information?

Scientific literature	Generally accepted and reviewed Publication bias
Surveillance data	Best information regarding disease status Sampling and test protocols may be ill-standardized Reports depend on quality of veterinary/plant health services May be out-of-date
Trade documents	Best information regarding trade Reports depend on quality of trade statistics
Industry documents	Best information about industry May be difficult to get
Expert opinion	May be the only option Is subjective in nature

Where to get data?

- When data has been published already:
 - Internet
 - Libraries
 - Inspection reports
 - Proceedings from scientific meetings
 - Request from the source (government agencies, authors, trading partner, etc)
- When data has not yet been published:
 - Conduct surveys, studies, questionnaires, etc

Where to get data?

- There is no fixed recipe where you will find the data you need
- Each country is structured differently
- Activities may be carried out by different bodies (e.g. government/private, research/industry)
- You have to be creative and persistent!



How do you find these sources?

- Start with sources you know
- Ask people:
 - If they have the information
 - If they know who may have the information
- Spend some time on the internet and search for information
- Check references of useful publications

When data are not available

- Conduct your own study, for example:
 - Questionnaires
 - Sample collection and testing
 - Expert workshops
 - Participatory rural appraisals



Animal Health Matters.
For Safe Food Solutions.



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,
Education and Research EAER

State Secretariat for Economic Affairs SECO

Thanks