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An introduction to the OIE's Risk Analysis Framework



**Regional training course (Africa)
Import risk analysis for African swine fever
9 November – 14 December 2021**



Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

Objectives

- to develop a greater appreciation of
 - what is meant by risk and how it is characterised
 - dealing with incomplete information (uncertainty)
 - the importance of adequately scoping a risk analysis
 - the OIE's Risk Analysis framework and the role that it plays in facilitating safe international trade
 - striving for objectivity through transparency and peer review

Why undertake an import risk analysis?

- to identify and examine the disease risks associated with international trade
- to develop conditions that allow trade to proceed safely
 - guidance is provided by
 - World Organisation for Animal Health (OIE)
 - Terrestrial and Aquatic Animal Health Codes (see Chapter 2.1)
 - Handbook on Import Risk Analysis for Animals and Animal Products. Introduction and Qualitative Risk Analysis. Vol.1. 2nd Edition. 2010.
 - World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement). 1995

Risk analysis is a structured way of thinking ...

... that provides a framework for identifying, assessing and managing risks

- what can go wrong
- how likely would it be 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

Risk is a function of ...

... probability and magnitude

– the probability (chances or likelihood) of something happening

- a disease outbreak

– the likely magnitude of its consequences

- the scale of an outbreak and its associated costs of control and/or eradication, trade losses, sociological and ecological impacts, etc

When communicating about a risk ...

- ... it is important to understand how it may be perceived
 - perception is influenced by many factors, including
 - beliefs, attitudes, judgements, feelings
 - whether it is voluntary, individually controlled, familiar, fairly distributed, memorable, natural or catastrophic
 - perception determines how upsetting a risk might be

How a risk is perceived...

... does not justify the imposition of measures to manage political expectations or appease stakeholder concerns

- there are many examples of trade disputes arising as a result of attempts to manage perceptions
- the resulting measures
 - fail to respect international obligations and standards
 - are inevitably arbitrary and discriminatory
 - are disproportionate to the likely level of risk

An important obligation...

- WTO SPS Agreement
 - there should be no restrictions (sanitary measures) on international trade in animals and animal products unless it is likely that a disease may enter, establish or spread and lead to unacceptable biological and economic consequences

So, for the purposes of international trade ...

- ... it is necessary to evaluate risk as a function of
 - the probability (chances or likelihood) of something happening
 - the likely magnitude of its consequences

Risk analysis provides a tool to ...

... deal with incomplete information, for example

- prevalence of disease
- survival of viruses and bacteria when subjected to freezing, pH changes, cooking
- it is a structured process to aid decision making in the face of inevitable uncertainties

What's the difference between uncertainty and variability?

- uncertainty
 - a lack of understanding or incomplete knowledge
- variability
 - the heterogeneity that naturally exists within any biological system
- while uncertainty is reduced as knowledge increases, variability remains a constant

A risk analysis is like building a jigsaw puzzle ...

... there are lots of disparate pieces of information that we need to bring together to evaluate the overall situation

- it could turn out that, while considerable uncertainty exists at one point in a risk pathway, its overall contribution to the final risk estimate is inconsequential
- in such circumstances it is important not to overemphasise the uncertainty that exists but to provide appropriate perspective

Dealing with uncertainty – an example (1)

- Suppose we want to estimate the likelihood of an outbreak of FMD associated with imported goat's cheese
- for this scenario to unfold
 - there must be an outbreak of FMD in the exporting country that results in at least one goat shedding FMD virus in its milk
 - the virus must survive pasteurisation, the cheese manufacturing process, storage and transportation
 - a susceptible animal must ingest discarded cheese, become infected and pass it on to other animals

Dealing with uncertainty – an example (2)

- Information available
 - very good information exists on the survival of FMD virus in pasteurised milk
 - limited information on the occurrence of FMD in the exporting country
 - virtually no information on the likelihood of susceptible animals ingesting cheese scraps in the importing country
 - we conclude that there is significant uncertainty in the occurrence of FMD in the exporting country and in the exposure of susceptible animals in the importing country

Dealing with uncertainty – an example (3)

- we need to consider the impact of these uncertainties on the overall risk estimate
 - if pasteurisation effectively kills FMD virus, the impact is insignificant

but

- if there is significant variability in the efficacy of pasteurisation as a result of heat tolerant strains of FMD virus, these uncertainties become much more important

Where there is significant uncertainty ...

- ... a precautionary approach may be adopted
 - however, the measures selected must still be based on a risk assessment that takes account of the available scientific information
 - the measures should be
 - reviewed as soon as additional information becomes available
 - be consistent with other measures where equivalent uncertainties exist
 - it is not acceptable to simply conclude that, because there is significant uncertainty, measures will be based on a precautionary approach
 - the rationale for selecting measures must be made apparent

Before embarking on a risk analysis ...

... it is essential that risk assessors and risk managers as well as other stakeholders have a clear understanding from the very beginning of the questions(s) being posed as well as the purpose and scope of the analysis

Does the following “request” provide sufficient background and scope to embark on a risk analysis?

- What is the risk of importing sheep or goat meat?
 - What else would you like to know?

Scoping should be an iterative process ...

- ... involving at least the risk manager and risk assessor
 - if a request is vague, ill-defined and poorly thought through it will inevitably lead to a report that no-one is satisfied with
- the risk analysis should not begin until all involved agree on the scope and purpose

Determining the scope ...

- ... requires that you define as precisely as possible the animals or animal products which are the subject of the risk analysis, including
- the nature, source(s) (including country) and intended use(s)
 - the scientific names when describing the animal species or disease agent
 - the relevant methods of production, manufacturing, processing or testing that are normally applied including quality assurance programs (such as HACCP)

Options for scoping a risk analysis ...

- Commodity
 - a particular commodity (chicken meat)
 - a category of commodities (live viral vaccines)
- Species
 - a single animal species (pigs)
 - a group of similar species (ruminants)
- Diseases
 - a particular disease (FMD)
 - a group of diseases with similar epidemiological characteristics (orbiviruses)
- Country
 - a single country - bilateral (Canada)
 - a group of countries -multilateral (European Union)
 - any country (generic)

State the purpose of the risk analysis clearly ...

- To identify and assess the likelihood of (*the hazard(s)*) being introduced and spreading or becoming established in (*your country*) together with the likelihood of and the likely magnitude of their potential consequences for animal or human health as a result of importing (*the commodity*) for (*intended use*).
- To recommend sanitary measures, if appropriate.

Scoping a risk analysis – an example (1)

- A request has been received to import sheep and goat meat from countries where peste des petits ruminant virus (PPRV) is endemic.
 - use scientific names when describing the animal species or disease agent
 - domestic sheep (*Ovis aires*)
 - domestic goats (*Capra hircus*)
 - PPRV (*Paramyxoviridae*; Genus: *Morbillivirus*; Species: *Peste des petits ruminants virus*)
 - describe the nature, intended use(s) and source(s) of the commodity
 - chilled or frozen sheep or goat meat for human consumption from a country where PPRV is endemic

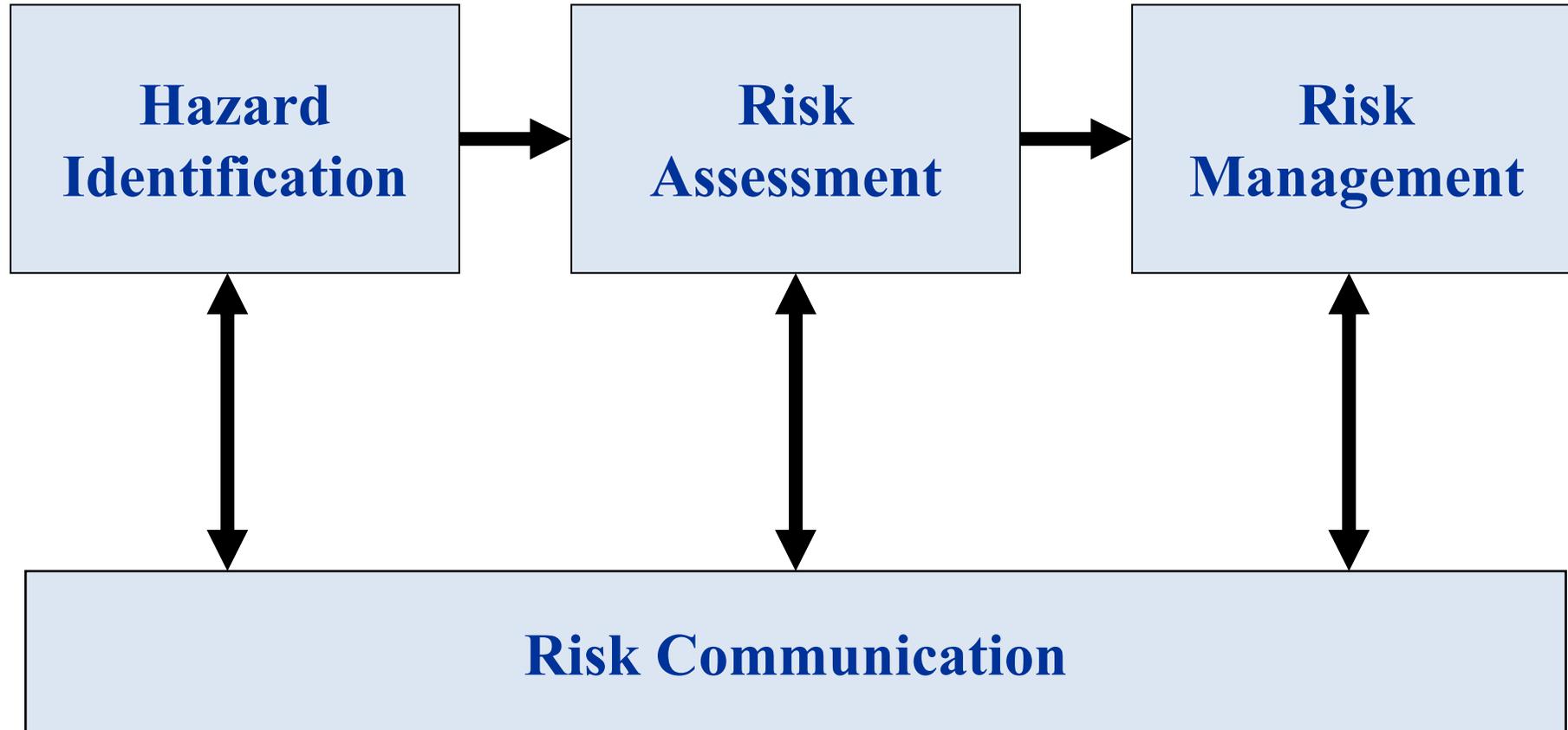
Scoping a risk analysis – an example (2)

- describe the relevant methods of production, manufacturing, processing or testing that are normally applied
 - e.g. chilling, freezing, cooking, curing, irradiation
- describe any quality assurance programs that may apply and how they are verified
 - e.g. HACCP programs for the production of pig meat
- estimate the likely annual volume of trade
 - may not be readily available

Scoping a risk analysis – an example (3)

- clearly state the purpose
 - to assess the likelihood of PPR virus (*Paramyxoviridae*; Genus: *Morbillivirus*; Species: *Peste des petits ruminants virus*) spreading or becoming established in [*your country*] and its likely consequences as a result of importing chilled or frozen meat for human consumption derived from domestically reared sheep (*Ovis aires*) and goats (*Capra hircus*) in a country or zone where PPRV is endemic
 - to recommend sanitary measures if appropriate
- draft a suitable title
 - Import risk analysis: Chilled or frozen sheep and goat meat from a country or zone where PPRV is endemic

OIE Risk Analysis Framework



The principal aim of the OIE's risk analysis framework is ...

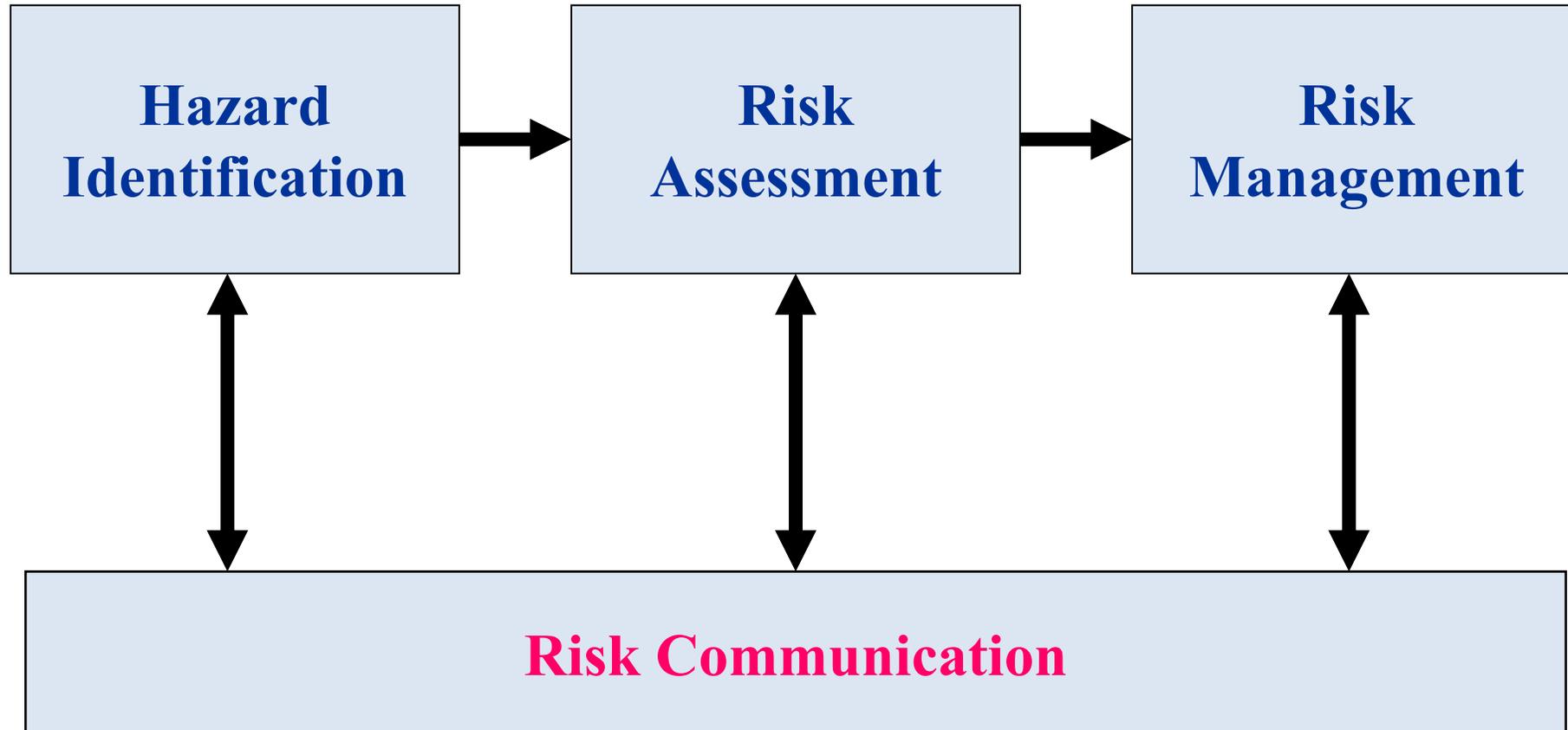
... to assess disease risks objectively and transparently to ensure

- the sanitary safety of terrestrial and aquatic animals and animal products
- that sanitary measures are justified and appropriate to the circumstances

The best outcome of a risk analysis

- reduces risk(s) to an acceptable level
- avoids disputes and disagreements
- minimises the measures required to effectively manage risk
- may not resolve all differences with stakeholders, but may lead to a better understanding of the rationale for a particular decision

OIE Risk Analysis Framework



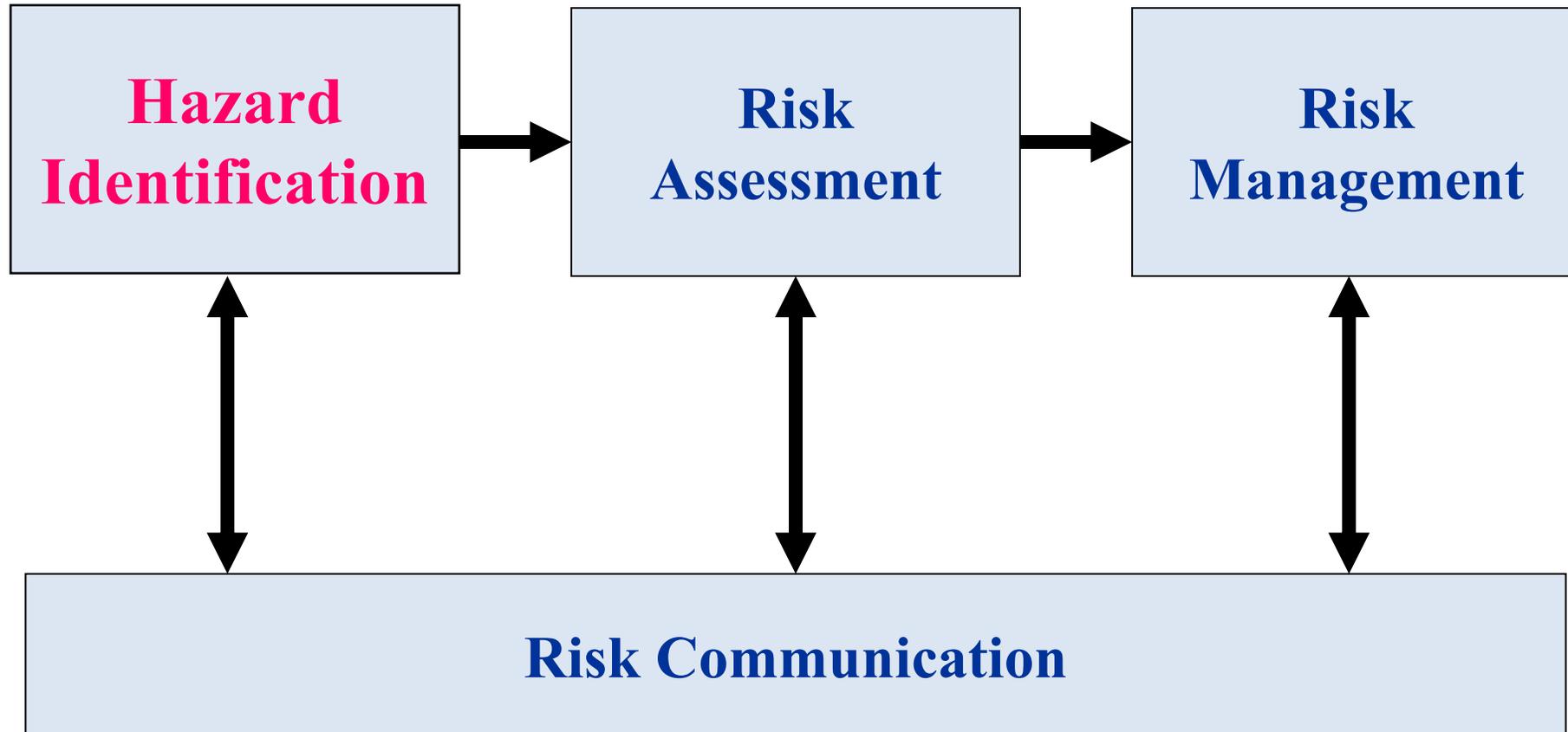
OIE defines risk communication as ...

- a process involving an open, interactive, iterative and transparent exchange of information on hazards and their associated risks, together with proposed mitigation measures

Risk communication involves ...

- an exchange of
 - information and opinions regarding hazards and risks
 - the results and conclusions of a risk analysis
 - proposed measures
- amongst potentially affected and interested stakeholders, including
 - authorities in the exporting country, domestic consumers and livestock producers and the SPS committee
- a communication strategy should ideally be established at the start of each risk analysis and continue throughout

The OIE risk analysis framework



Hazard identification

- The essential 1st step in a risk analysis
- Identifies pathogens
 - which could potentially produce adverse biological, environmental or economic consequences
 - known to affect the animals being imported, or from which the commodity is derived
- If you don't identify a hazard you can't assess or manage it!

Draw up a comprehensive list ...

... of all the pathogens associated with the commodity

- start with the diseases listed by the OIE
- add others as appropriate
- consult with stakeholders as necessary to refine the list

Some categories of pathogenic agents may be excluded ...

... from consideration depending on the nature of the commodity or the methods of production, manufacturing or processing

- gastro-intestinal parasites are not relevant for semen or embryos
- Arboviruses such as bluetongue virus, which are transmitted by vectors, do not need to be considered for meat and meat products
- highly processed commodities such as gelatine are not likely to be contaminated with bacteria or viruses
- document the rationale for exclusion

Safe commodities

- some disease-specific chapters in the Terrestrial Code list commodities determined to be safe for international trade
 - specific measures for these commodities should not be required regardless of the status of the exporting country, for example
 - Chapter 8.11 (Infection with *M tuberculosis* complex)
 - fresh meat and meat products originating from animals that have been subjected to ante- and post-mortem inspections as described in Chapter 6.2
 - cured hides, skins and trophies
 - gelatine, collagen, tallow and meat-and bone-meal

Hazard identification

- Is the commodity under consideration a potential vehicle for the pathogen?
 - assess the relevant epidemiology as well as the methods of production, manufacturing or processing normally applied to determine if the commodity being considered is potentially capable of harbouring the pathogen

Hazard identification

- Is the pathogen considered to be exotic to your country or region?
- Is the pathogen likely to be present in the exporting country or region?

Is the Competent Authority ...

... of either country able to satisfactorily substantiate any claims regarding the status of the pathogen?

- the likelihood of pathogenic agents being present in, or absent from the animal population of a country or subpopulations is assessed through an evaluation of
 - the quality of the Veterinary Service
 - identification and traceability of animals and/or animal products
 - surveillance and monitoring programmes
 - official control programmes
 - zones and/or compartments

Hazard identification

- Is the pathogen present in your country or region?
 - it should not be considered any further unless
 - it is subject to an official control programme
 - there are zones or compartments of different animal health status
 - the local strains are likely to be less virulent than those reported in the exporting country

In summary ...

- if the commodity is a potential vehicle for the pathogen
and
 - the pathogen is likely to be present in the exporting country
and
 - the pathogen is exotic to your country, or
 - present in your country, but subject to official control, or
 - there are zones or compartments of different animal health status, or
 - it is more virulent than strains reported in your country
- ... the pathogen is classified as a hazard
- transparently document the rationale for the conclusions reached

Does the Code provide sanitary measures ...

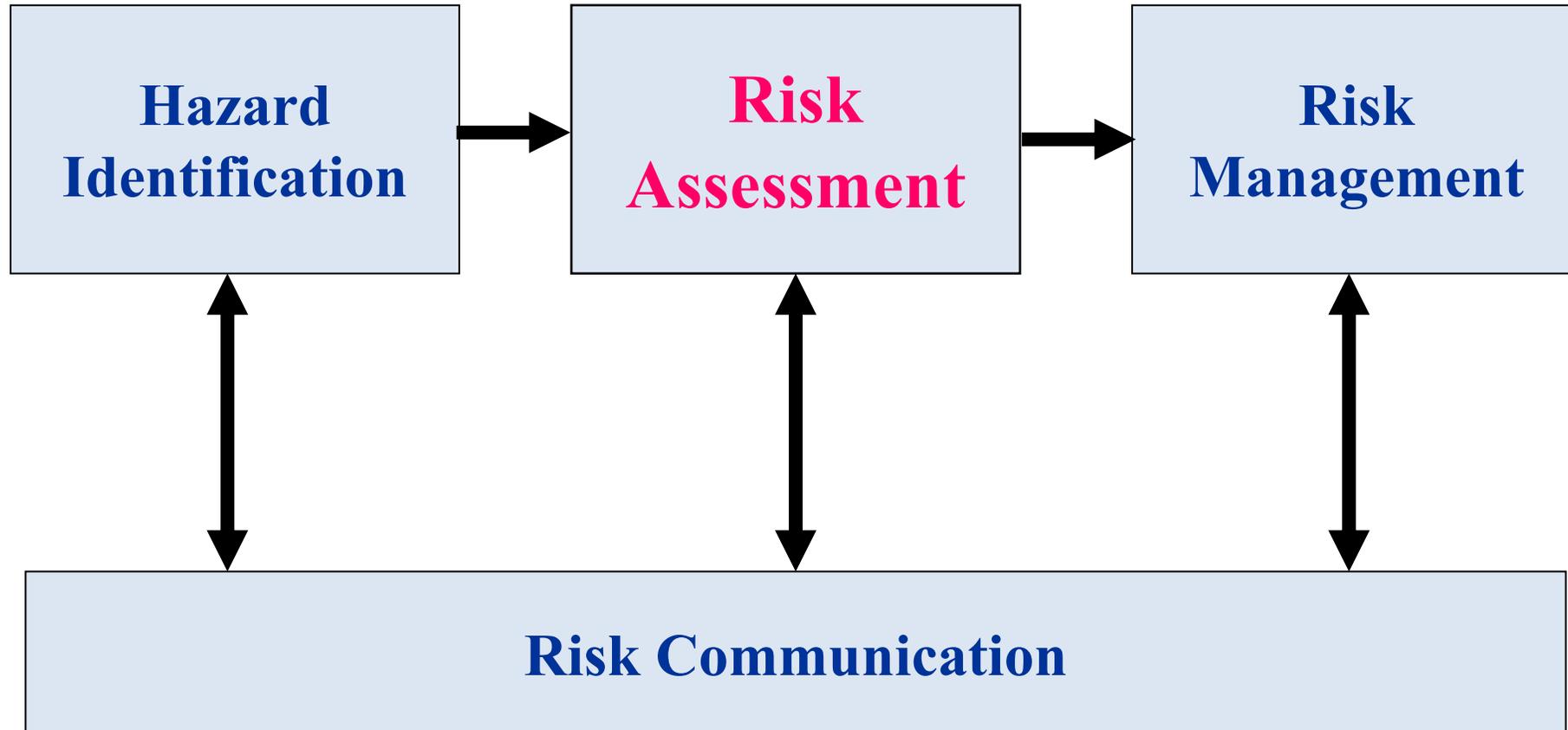
... for the hazards in the commodity under consideration?

- if so, apply the relevant measures
 - this is the preferred course of action unless domestic legislation, policy or other considerations require a complete risk analysis be undertaken

A risk analysis may be concluded ...

- if hazards are not identified, or
- if measures recommended in the OIE *Code* are applied to each hazard

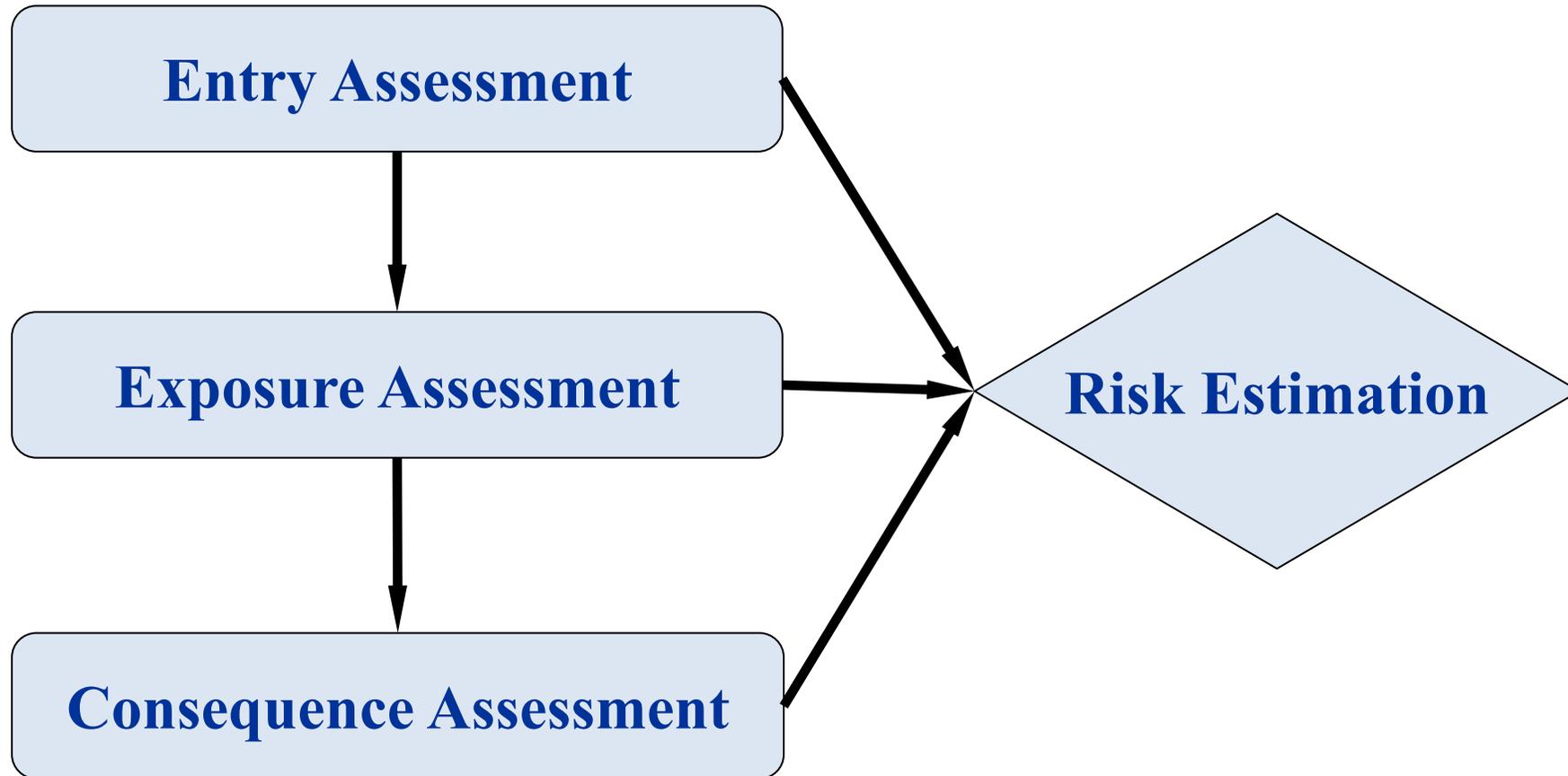
The OIE risk analysis framework



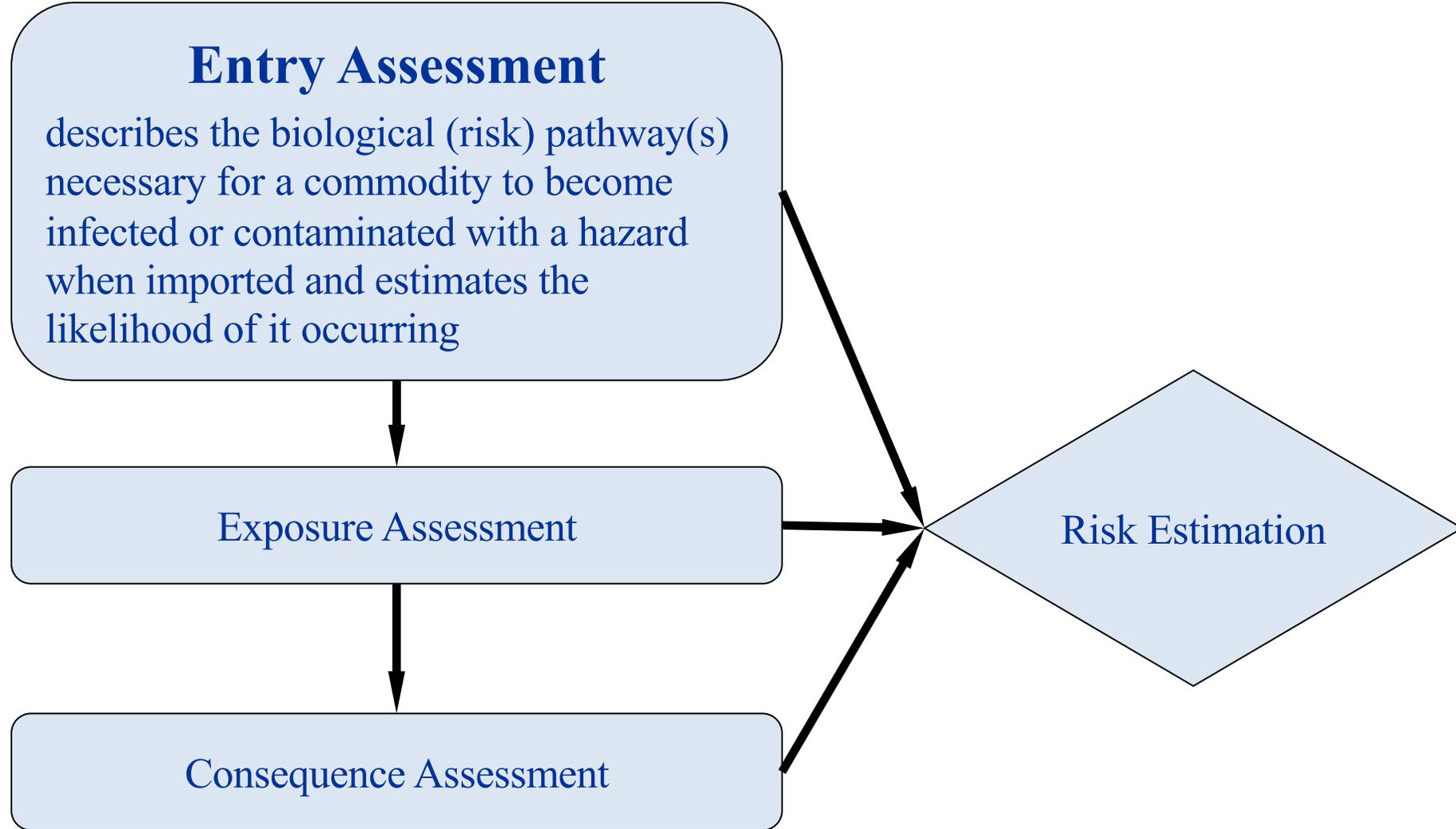
Risk assessment ...

- Evaluates the likelihood and biological, environmental and economic consequences of the entry, establishment or spread of a hazard
 - the commodity under consideration must be evaluated in the form which it is intended to be used, processed or sold

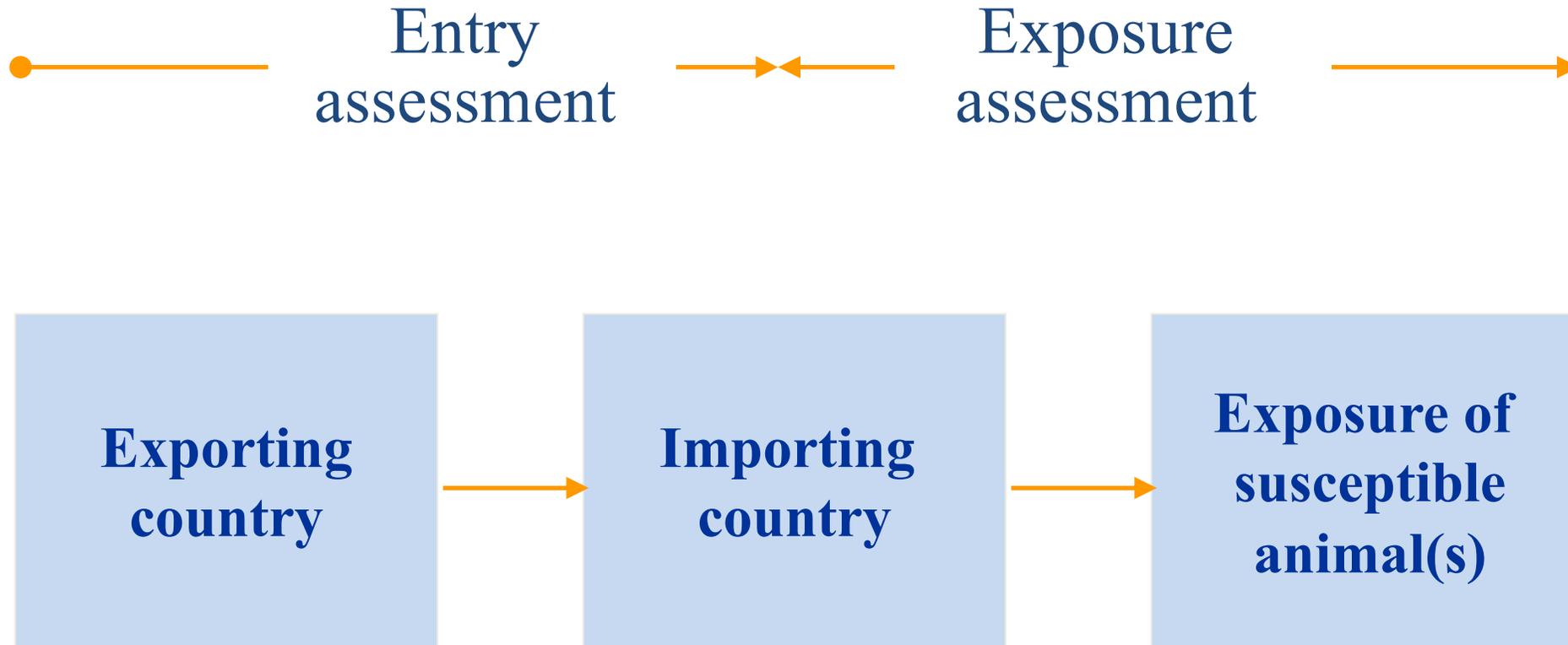
A risk assessment consists of four inter-related steps



Components of a risk assessment



Entry assessment



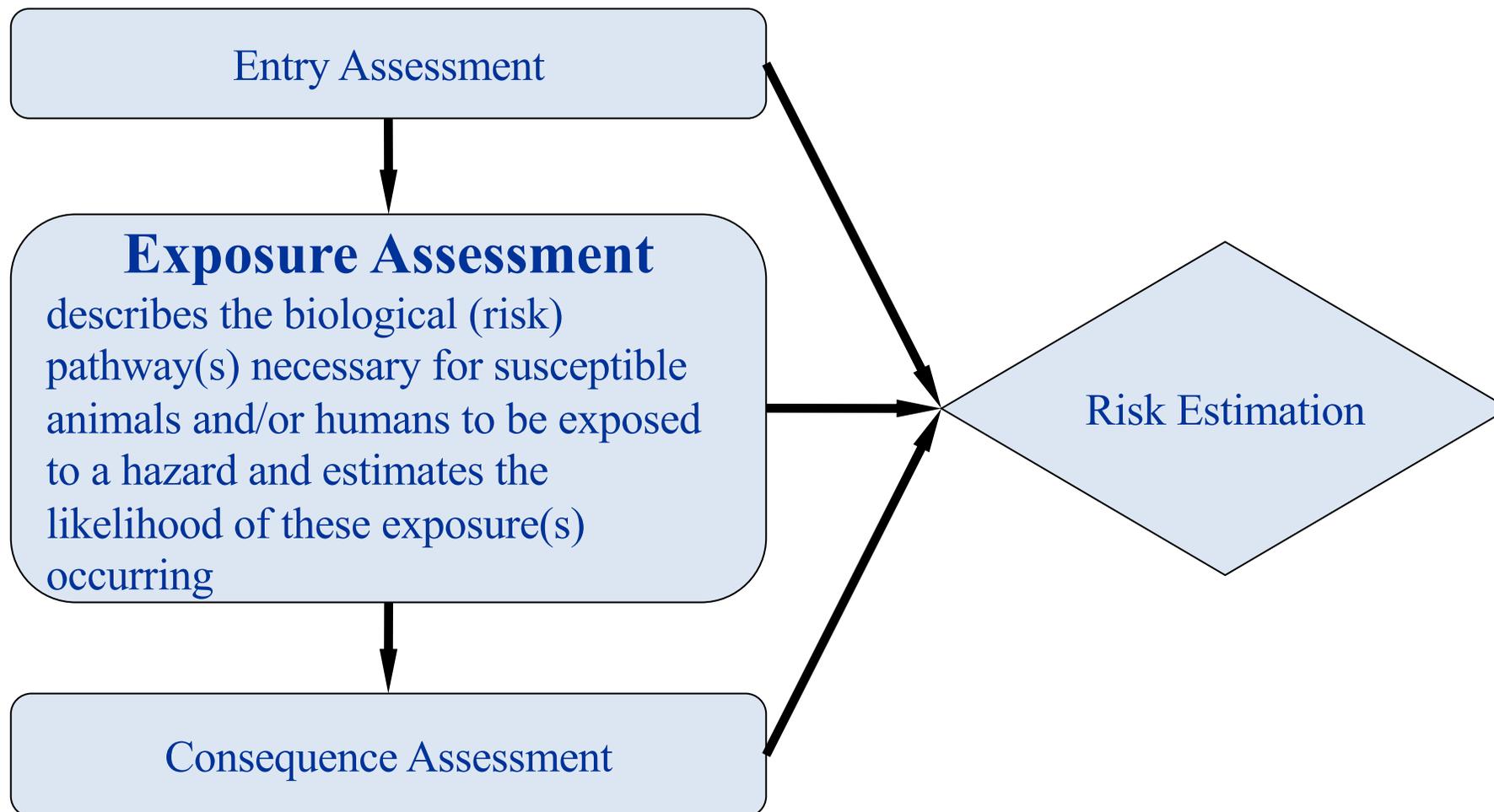
The likelihood of a commodity harbouring a hazard ...

... is influenced by

- disease distribution/status of the exporting country
- susceptibility of animals and the impact of any of disease control programmes on the health status of the animals from which the commodity is derived
- the impact of relevant production, manufacturing and processing methods, storage and transportation on the hazard
- the quality of the Veterinary Service in providing an appropriate level of oversight and in establishing and maintaining confidence in certification

A risk assessment may be concluded if the likelihood of introducing the hazard is negligible

Components of a risk assessment



Exposure to a hazard and the outcome of that exposure are two different steps

- whether or not a susceptible animal or human becomes infected as a result of being exposed to a hazard depends on a range of factors including
 - route of exposure
 - degree of susceptibility of the host
 - level of exposure (dose) and the response of the host
- as a result, infection is a consequence of exposure
 - the likelihood of one or more susceptible animals and/or humans becoming infected, subsequent spread etc. should be considered in the consequence assessment step

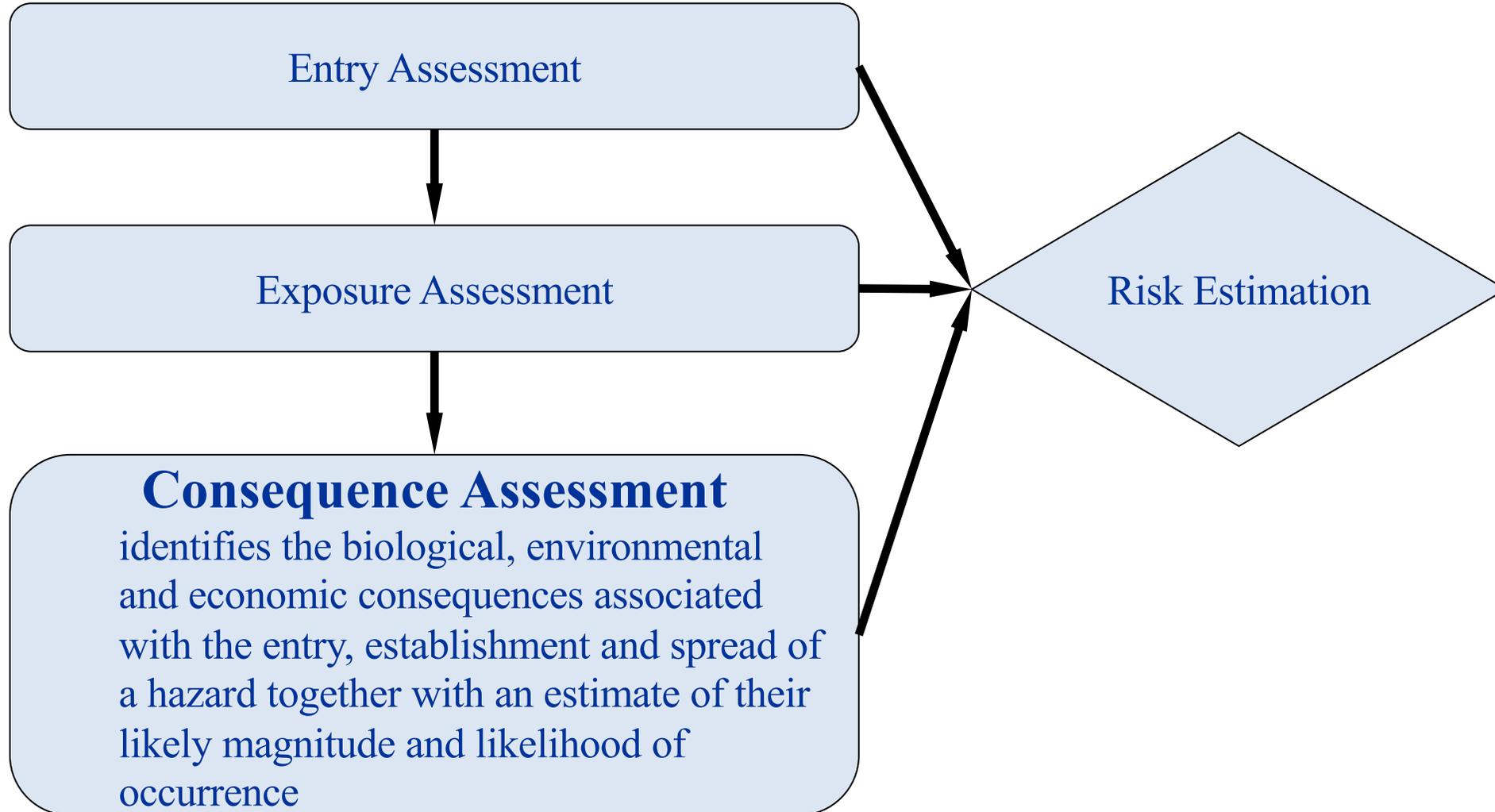
The likelihood of susceptible species being exposed to a hazard ...

... is influenced many factors including

- intended uses of the imported commodity
- the impact of relevant production, manufacturing and processing methods, storage and transport as well as waste and/or effluent disposal
- susceptibility of animals and/or humans likely to be exposed
- presence of potential intermediate hosts or vectors
- human and animal demographics
- farming practices
- customs and cultural practices
- geographical and environmental characteristics such as rainfall and temperature

A risk assessment may be concluded if the likelihood of every exposure pathway is negligible

Components of a risk assessment



A causal relationship must exist ...

... between exposure to a hazard and an adverse effect

- only those consequences directly or indirectly attributable to the hazard should be taken into account
- any positive or negative effects not related to the hazard do not fall within the scope of an animal health risk analysis, such as
 - benefits for consumers through the importation of cheaper goods
 - the impact of these goods on the competitiveness of a particular industry

Potential consequences can be quite broad and include ...

- human health
- animal health and welfare
- social and psychological
- environmental and ecological
- economic
- political
- national security

Consequence assessment – factors to consider (1)

- the likelihood of one or more susceptible animals and/or humans becoming infected and their subsequent outcomes
 - incubatory or convalescent carriers, latent infection, sterile immunity
 - extent of spread/establishment
 - morbidity/mortality rates, production losses
 - animal welfare (e.g. mass culling - humane slaughter, overcrowding, stress, injury, feed restrictions, sanitation)
 - public health
 - environmental/ecological
 - side effects of control and eradication measures (large scale slaughter and mass burial/burning leading to contamination of air, water and soil; decline in tourism and loss of social amenity)
 - impacts on other life forms, biodiversity, endangered species

Consequence assessment – factors to consider (2)

- economic considerations
 - control and eradication costs
 - compensation
 - surveillance and monitoring costs
 - costs of enhanced biosecurity services
 - changes in consumer demand and effects on related industries
 - trade losses (embargoes, sanctions, lost market opportunities)

Consequence assessment – factors to consider (3)

- social and psychological effects (mental health, unemployment, etc.)
- political (e.g. crisis in the EU in 2000 associated with BSE)
- National security
 - the potential to destabilise a society through threats to the food supply, public health etc.

Potential consequences attributable to a hazard

Consequences	BSE	FMD	HPAI
Human health	vCJD	X	Strain dependant
Animal welfare	X	mass culling (humane slaughter), overcrowding, stress, injury, feed restrictions, sanitation	
Animal health	limited impact at population level	large scale outbreaks (morbidity, mortality)	
Social & Psychological	individual and community stress, anxiety, depression, shame, stigma, guilt, disintegration of families and communities, unemployment		
Environmental & Ecological	environmental contamination and spill-over into wildlife	large scale slaughter and mass burial/burning leading to contamination of air, water and soil	
Economic	loss of markets, costs associated with control, eradication and production losses		
Political	loss of confidence, voter support		
National Security	X	Threats to the food supply	Significant human-human transmission with a high case fatality rate

Identify potential outbreak scenarios ...

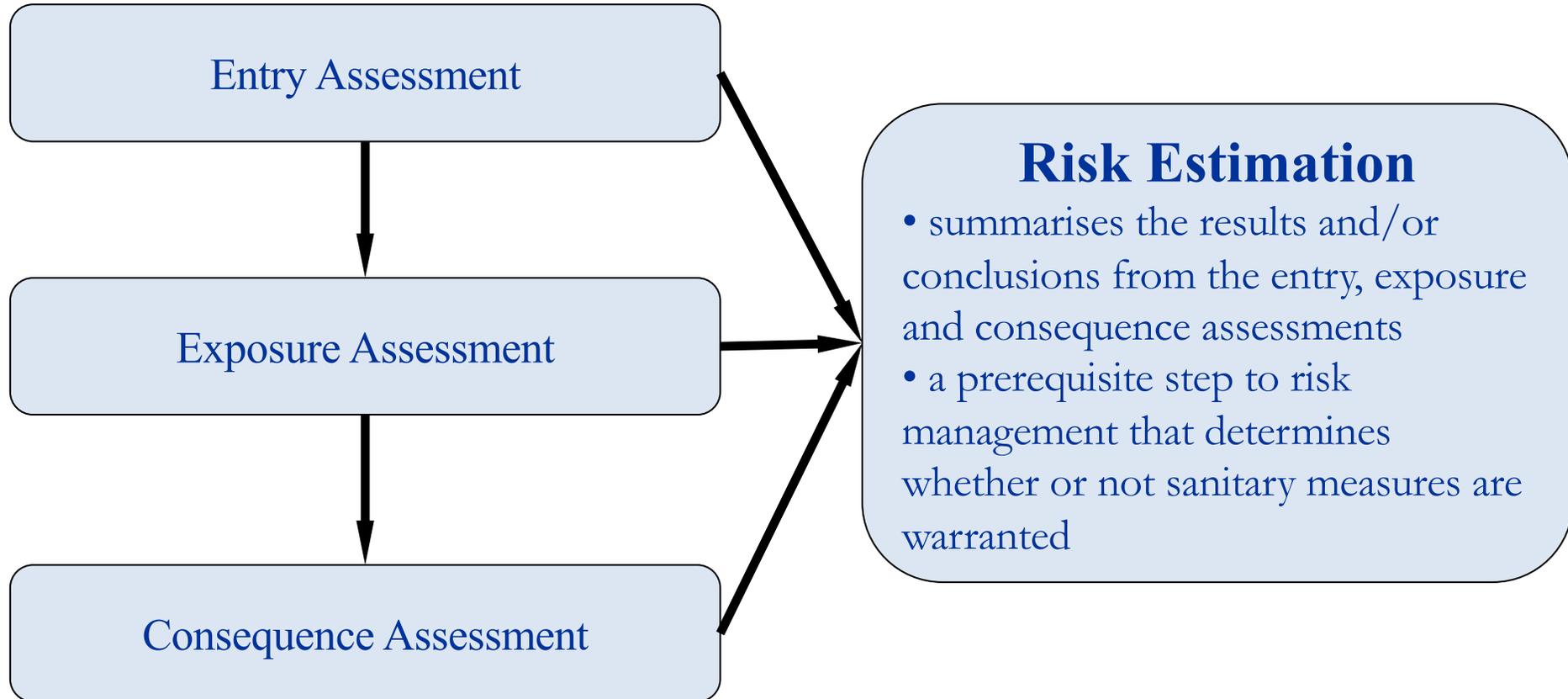
- disease does not spread within the exposed population
- disease spreads within the exposed population, but is quickly identified and eradicated
- disease establishes within the exposed population and spreads to other populations before eventually being eradicated
- disease establishes within the exposed population, spreads to other populations and becomes endemic

Estimate the likelihood of each outbreak scenario and ...

- the likely magnitude of the associated consequences at various levels
 - farm or village
 - district
 - regional
 - Provincial
 - national

A risk assessment may be concluded if either no consequences are identified or the likelihood each consequence is negligible

Components of a risk assessment



It is not sufficient to conclude ...

...that there is a possibility of a hazard entering, susceptible animals and/or humans being exposed and potential consequences arising

- an evaluation of the likelihood of each of these must be undertaken

1. Entry assessment (likelihood of entry)

- Is the likelihood that the commodity is carrying the hazard when it is imported negligible?
 - If the answer is YES, the risk estimate is classified as negligible.
 - If the answer is NO, what are the conclusions from the exposure assessment?

2. Exposure assessment

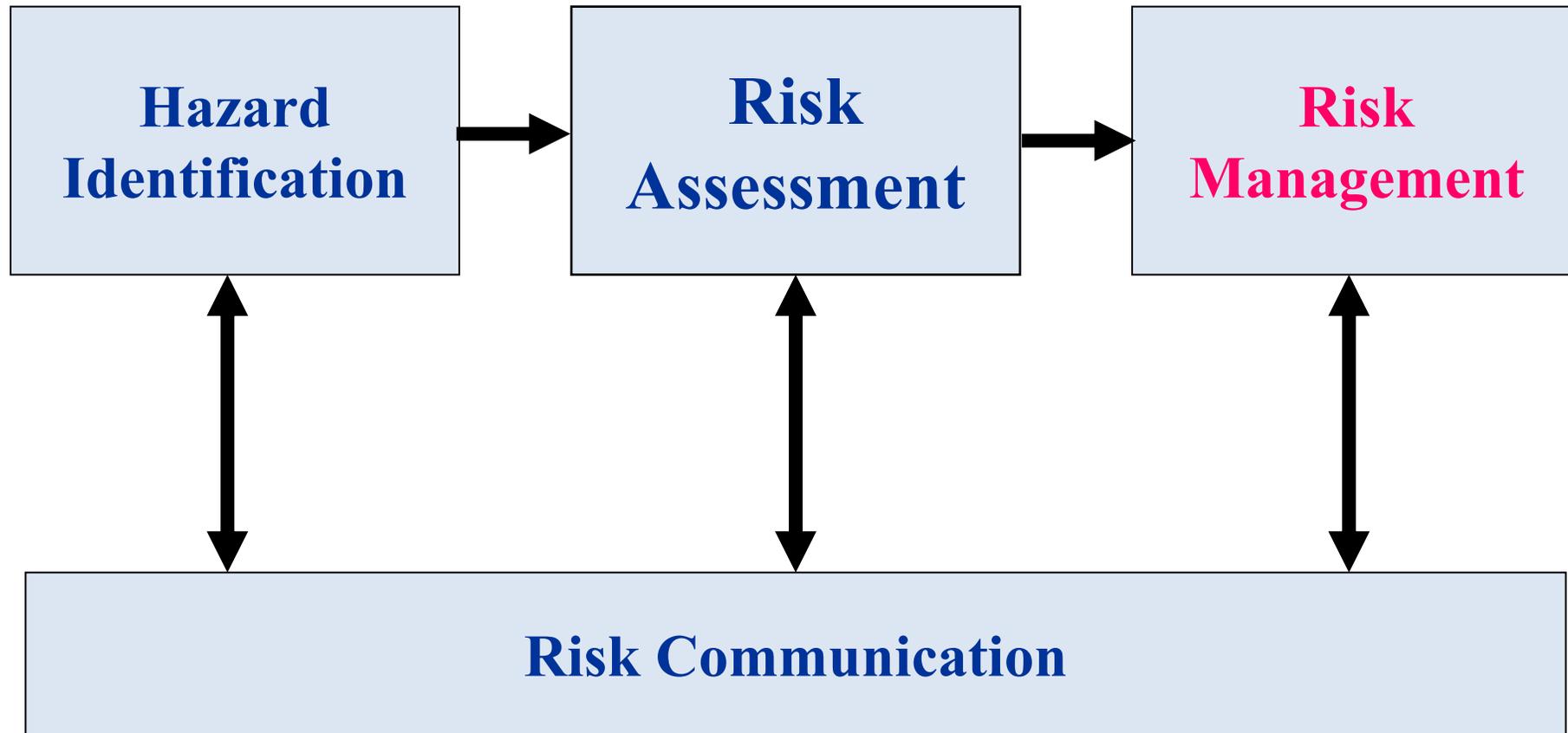
(likelihood of susceptible animals &/or humans being exposed)

- Is the likelihood of susceptible animals and/or humans being exposed via each and every exposure pathway negligible?
 - If the answer is YES, the risk estimate is classified as negligible.
 - If the answer is NO, what are the conclusions from the consequence assessment.

3. Consequence assessment

- Is the likelihood for each and every significant biological, environmental or economic consequence negligible?
 - If the answer is YES, the risk estimate is classified as negligible.
 - If the answer is NO, the risk is estimated to be non-negligible; proceed to risk management.

The OIE risk analysis framework



Risk management is the process of ...

... identifying, selecting and implementing sanitary measures to effectively mitigate against the risks posed by the hazard(s) associated with the commodity under consideration

- it is not acceptable to simply identify a range of measures that might reduce the risk
- there must be a rational relationship between the measure(s) and the risk assessment so that the results of the risk assessment support the measure(s)

Sanitary measures should be ...

- technically, operationally and economically feasible
- implemented to the extent that is reasonably necessary to protect human or animal health
- consistent with obligations as members of WTO and OIE
- applied consistently across a range of commodities likely to contain the same or similar hazards to avoid situations where different levels of protection arise

OIE standards are the preferred choice

- where OIE standards do not exist, or
- where the proposed measure(s) result in a higher level of protection than that provided by an OIE standard
- the measures must be supported by a risk assessment

Striving for objectivity: transparency and peer review

A risk analysis inevitably includes a degree of subjectivity ...

- the personal opinions and perceptions of analysts, experts and decision-makers are inescapable realities
- to ensure that a reasonable level of objectivity is obtained, it is essential that the analysis is
 - transparently documented
 - subjected to peer review

Transparency ensures ...

- fairness and rationality
- consistency in decision making
- ease of understanding by all the interested parties
- uncertainties are dealt with appropriately
- reasons for conclusions and recommendations are obvious and are supported by a reasoned and logical discussion
- interested parties are provided with clear reasons for the imposition of sanitary measures

Transparency involves ...

... the comprehensive documentation of

- data and information
- assumptions and uncertainties
- methods
- results
- discussion and conclusions
- references

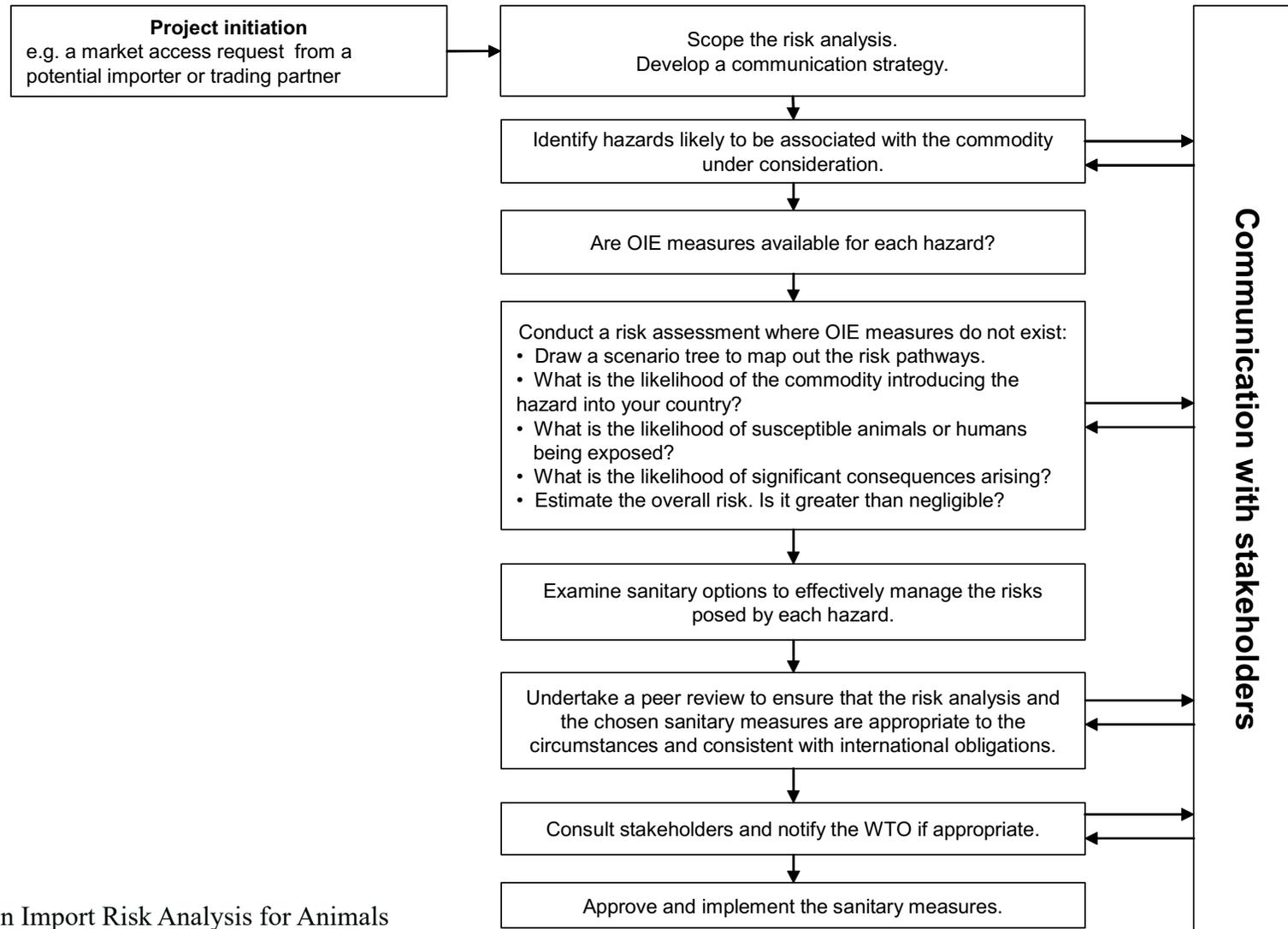
Peer review ensures ...

- the analysis is technically robust
 - the data, information, methods and assumptions are the best available and a reasonable level of objectivity has been obtained
- the measures are both appropriate to the circumstances and consistent with domestic and international obligations

Peer review consists of ...

- a scientific critique of the analysis
 - within the Veterinary Service
 - externally through selected experts with specialised knowledge of risk analysis as well as the particular hazards(s) under consideration
- can only be carried out properly when reviewers have a clear idea of what is expected of them
 - terms of reference are essential
- comments should be incorporated where appropriate, otherwise the rationale for rejecting them should be documented

A flow chart for a risk analysis



Reference: OIE Handbook on Import Risk Analysis for Animals and Animal Products. Volume 1. Introduction and Qualitative Analysis, 2010



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