CPD MODULE ON RISK ANALYSIS IN INTERNATIONAL TRADE OF ANIMAL AND ANIMALS PRODUCTS

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ABBREVIATIONS

ALOP	Appropriate Level of Protection
CBPP	Contagious Bovine PleuroPneumonia
cELISA	Complement-enzyme linked immuno sorbent assay
CL	Confidence limit
Codex Alimentarius Commission	CAC
CPD	Continuing Professional Development
DSB	Dispute Settlement Body
GATT	General Agreement on Tariffs and Trade
IPPC	International Plant Protection Convention
NPV	Negative Predictive value
RRA	Rapid Risk Assessment
Se	Sensitivity
Sp	Specificity
SPS	Sanitary and phytosanitary
TBT	Technical Barriers to Trade
WAHIS	World Animal Health Information System
WOAH/OIE	World Organisation for Animal Health
WTO	World Trade Organization

ACKNOWLEDGEMENTS

This CPD module has been prepared by expert staff from Ethiopian higher education institutes under the supervision of EVA. The module is designed to introduce learners to basic qualitative and qualitative risk analysis. Furthermore, it provides a basic understanding of the Terrestrial and Aquatic Animal Health Code, as well as sanitary and phytosanitary (SPS) measures in international trade that are directly related to risk analysis.

The authors would like to thank the Ethiopian Veterinary Association and Heard Project for allowing them to develop this CPD module.

CPD Module on Risk Analysis in International Trade of Animal and Animals Products

Module objective

The objective of this module is to provide a brief description of qualitative and quantitative risk analysis for international trade of animals and animal products based on the Terrestrial Animal Health Code (Terrestrial Code) and Aquatic Animal Health Code (Aquatic Code) of the World Organisation for Animal Health (WOAH). The module also explains sanitary and phytosanitary (SPS) measures. The module is prepared based on the information provided on the handbook of Import risk analysis for animal and animal products volume 1 and 2, Risk Assessment Methods Approaches for Assessing Health and Environmental Risks book (1-3), and other documents listed in the reference lists.

Module outcome

Upon completion of this module, the learner will be able to

- Define and understand the concept of risk and risk analysis
- Identify and discuss the steps involved in performing a risk analysis
- Perform qualitative and quantitative risk analysis
- understand the terrestrial animal and aquatic animal health codes

1. Introduction to Risk analysis (Section I)

Learning objective of section I

- This section presents definitions, terminologies, and concepts needed for a comprehensive understanding of risk analysis.

Learning outcome of section I

Upon completion of this section, the learner will be able to

- Define risk
- Define the different terminologies of risk analysis
- Identify and discuss the different components of risk analysis

Section I questions

- What are perceptions of risk?
- How does the sensitivity and specificity of the diagnostic test you used could affect the consequence assessment?
- Discuss risk analysis process

1.1. Introduction

Risk analysis is a tool that uses data, information and expert opinions from many disciplines and skills, including pathology, microbiology, virology, epidemiology, statistics, probability modelling and economics. Risk analysis could be qualitative or quantitative. The qualitative approach is suitable for the majority of import risk analyses, and is currently the most common type of assessment undertaken to support routine import decision making. However, no single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances. In qualitative assessments, the likelihood the release and subsequent exposure to a hazard and the magnitude of the resulting consequences are expressed using non-numerical terms such as high, medium, low or negligible, and the qualitative approach has so far proved suitable for the majority of import risk assessments. In some circumstances it may be desirable to undertake a quantitative risk analysis: for example, to gain further insights into a particular problem, to identify critical steps or to compare sanitary measures. Quantification involves developing a mathematical model to link the steps of the risk pathway, which are expressed numerically. The results are also expressed numerically. Risk analysis for Veterinary field focus four areas: (1) Food safety risk assessment for animal source foods (Codex Alimentarius Commission, CAC) (2) Import risk assessment (WOAH) (3) Ecological (Environmental) risk assessment (Environmental Protection Agency, EPA), and (4) Natural disaster risk assessment(UN Disaster Assessment and Coordination, UNDAC).

1.2. What is risk?

Risk is the chance of an undesirable outcome in any given situation. Everyone faces some level of risk on a daily basis (e.g., daily banking, insurance, business operations, buildings, treating animals and humans, importing live animals and their products into one country etc). It has two components: the chance, or probability, of something happening; and if it does happen, the consequences. Because of the element of chance, we can never predict exactly what will happen. There is, however, a certain probability of any particular outcome occurring. In addition to the above, we need to also consider a third element of risk, i.e., risk perception. Many actions are considered to be 'risky', such as, for example, living near a nuclear power plant, while others, such as walking down a flight of stairs, are not usually considered in the same light. Although the consequences of a nuclear accident could be devastating, the chance of an accident occurring in a modern reactor is probably remote. Similarly, while the consequences of falling down some stairs could be serious for the person involved, the chance of such an accident may also be remote. So why is one of these activities considered to be more risky than the other? The answer lies in the way risk is perceived. Issues such as whether the risk is borne voluntarily, the magnitude of its consequences, its familiarity, to what extent it is dreaded, and how preventable it is, all influence the perception of risk.

More formally, we define risk as follows:

Risk: A characteristic of a situation or action wherein two or more outcomes are possible, the particular outcome that will occur is unknown, and at least one of the possibilities is undesired.

1.3. Definition of terminologies as per the risk analysis manual of WOAH terrestrial code??

Acceptable risk: Risk level judged by each WOAHMember to be compatible with the protection of animal and public health within its country.

Commodity: Live animals, products of animal origin, animal genetic material, biological products and pathological material.

Competent Authority: The Veterinary Authority or other Governmental Authority of a Member having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Aquatic and Terrestrial Codes in the whole territory.

Confidence: The degree to which the assessment team is sure of an estimate. It reflects what in some disciplines is referred to as the certainty or uncertainty about an estimate.

Consequence assessment: The process of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the consequences of a given exposure and estimates the probability of their occurring.

Diagnostic sensitivity: The proportion of reference animals known to be infected that test positive in the assay; infected animals that test negative are considered to have false negative results.

Diagnostic specificity: The proportion of reference animals known to be uninfected that test negative in the assay; uninfected reference animals that test positive are considered to have false positive results.

Entry assessment (formerly known as ***release assessment***): The process of describing the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) pathogenic agents into a particular environment, and estimating the probability, either qualitatively or quantitatively, of that complete process occurring. The terms 'likelihood' and 'probability' may be used interchangeably. There is a tendency to use the term 'probability' when referring to quantified risk, and 'likelihood' when risk has been assessed qualitatively. However, both terms are correct.

Exposure assessment: The process of describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) released from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively or quantitatively.

Hazard: a biological, chemical or physical agent in, or a condition of, an animal or animal product with the potential to cause an adverse health effect.

Hazard identification: The process of identifying the pathogenic agents that could potentially be introduced in the commodity considered for importation.

Hazard profile: A concise description of a health problem and its context, the current state of knowledge of the problem and potential risk management options, including health policy that may influence additional possible actions.

Health event: Any event that may have negative health consequences on humans and/or animals.

Impact: The magnitude of the biological and economic consequences of a health event occur, should it occur.

Qualitative risk assessment: An assessment where the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as high, medium, low or negligible.

Quantitative risk assessment: A risk assessment in which the outputs are expressed numerically. It usually involves the development of a mathematical model that links the steps in the risk pathway.

Rapid risk assessment (RRA): The timely assessment of the risk in qualitative terms to animal and human health arising from a health event. An RRA is typically delivered in a few days (24–48 hours) or weeks (1–2 weeks).

Risk: The likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health.

Risk analysis: The process composed of hazard identification, risk assessment, risk management and risk communication.

Risk assessment: The evaluation of the likelihood and the biological and economic consequences of the entry, establishment, and spread of a hazard within the territory of an importing country.

Risk communication: The interactive transmission and exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, risk communicators, the general public and other interested parties.

Risk estimation: The process of integrating the results from the entry assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset.

Risk evaluation: The process of comparing the risk estimated in the risk assessment with the Member's appropriate level of protection.

Risk management: The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.

Risk perception: The judgements that stakeholders and the general public make about the characteristics, likelihood and severity of a specific risk. Addressing people's risk perception is part of the risk communication process

Sanitary measure: A measure, such as those described in various chapters of the Aquatic and Terrestrial Codes, destined to protect animal or human health or life within the territory of the OIE Member from risks arising from the entry, establishment and/or spread of a hazard.

Semi-quantitative risk assessment: A risk assessment in which the outputs are expressed in semiqualitative terms (as scores), associated with numerical ranges of probability and severity of impact. It involves assigning numbers to qualitative estimates by using probability ranges, weights or scores and combining them by addition, multiplication or other mathematical operations.

Transparency: The comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis. Conclusions should be supported by an objective and logical discussion, and the document should be fully referenced.

Uncertainty: The lack of precise knowledge of the input values which is due to measurement error or to lack of knowledge of the steps required, and the pathways from hazard to risk, when building the scenario being assessed.

Variability: A real-world complexity in which the value of an input is not the same for each case due to natural diversity in a given population.

Veterinary Authority: The Governmental Authority of an OIE Member, comprising veterinarians, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Aquatic and Terrestrial Codes in the whole territory.

Veterinary Services: The governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the Aquatic and Terrestrial Codes in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private-sector organisations, veterinarians, veterinary paraprofessionals or aquatic animal health professionals are normally accredited or approved by the Veterinary Authority to deliver the delegated functions.

1.4. The importance of risk assessment

Risk assessment is a means not only to understand the risks that society (or a family or business) faces, with their potential probabilities and impacts, but also to provide a framework to determine the effectiveness of disaster risk management, risk prevention and/or risk mitigation. It would be spurious to pretend that we fully understand all the hazards that society faces and their potential consequences. The process of risk assessment requires a structured approach. Without such a process, risks may be overlooked or implicit assumptions may be made. A risk assessment process requires transparency, opening up assumptions and options to challenge, discussion and review.

1.5. Components of risk analysis

The risk analysis process usually comprises four components:

1. **Hazard identification-** is a pre-risk assessment activity, to determine whether exposure to an agent (biological or infectious agent) might cause an adverse health effect (disease) in animals or in humans.

2. **Risk assessment-** a process to scientifically evaluate the probability of occurrence and severity of known or potential adverse health effect resulting from human exposure to hazards.

3. Risk management- a process to weigh policy alternative in light of the results of risk assessment and, if required, to select and implement appropriate control option.

4. Risk communication- a process to exchange information and opinions interactively among risk assessors, risk managers and other interested parties.

However, in the biological field, several systems of terminology are in use to describe the process of risk analysis. The system adopted for use in the Codes of WOAH is the one more generally used in the animal health field. In this system, risk assessment follows hazard identification, which is considered a separate step and is completed first. This is followed by the four steps of the risk assessment process: entry assessment, exposure assessment, consequence assessment and risk estimation (Fig. 1).

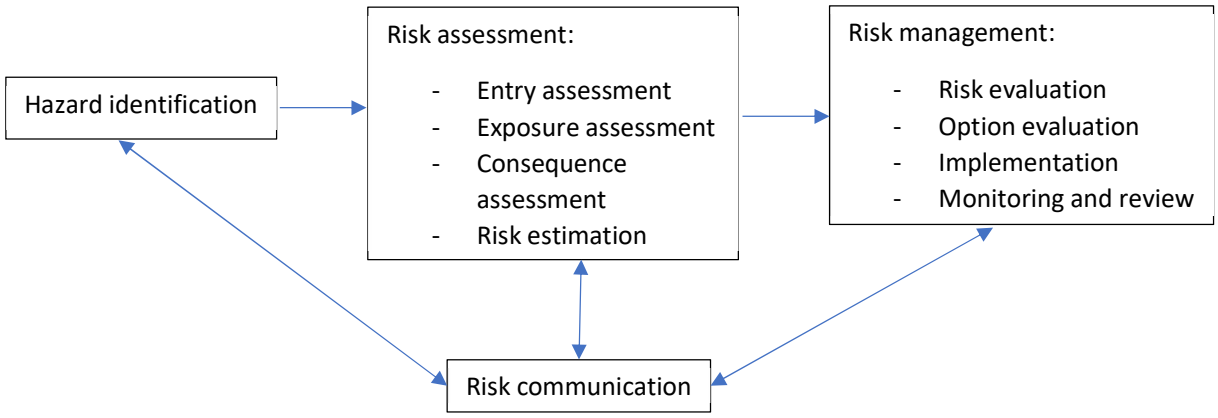


Figure 1: The structure of the WOAH risk analysis process

***Note**: In animal health, the Covello and Merkhofer (1993) model for risk assessment, which is adopted by the WOAH, is commonly used to assess the actual magnitude of the risk for specified consequences in a given situation.*

2. Imports risk analysis for animals and animal products (Section II)

Adapted from Terrestrial Animal Health Code chapter 2 (https://www.woah.org/fileadmin/Home/eng/Health_standards/tahc/2018/en_chapitre_import_risk_analysis.htm)

Learning objective of section II

- This section presents the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological materials.

Learning outcome of section II

Upon completion of this section, the learner will be able to

- Identify the different hazards
- Know the principles and steps of risk assessment, risk management and risk communications
- Conduct risk assessment, risk management and risk communications

Section II questions

- What is hazard?
- What activities should be conducted during the hazard identification step of the risk assessment?
- What is the risk assessment steps in the import risk analysis?
- Are the people/animal really exposed to the hazard?
- What are the most significant factors in the entry assessment?
- If so, how long will it take to determine the amount of exposure?
- Is there evidence to prove that exposure occurred or is occurring?
- Given the information collected, is there a risk of adverse health effects from an exposure?

2.1. Introduction

Different types of animal disease can be spread through the importation of animals or animal products. Thus, importation of animals and animal products directly relates to degree of disease risk to the importing country. This risk may be represented by one or several diseases, infections or infestations.

The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material. Transparency – that is, the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions – is essential, because data are often uncertain or

incomplete, and without full documentation, the distinction between facts and the analyst's value judgements may not be clear. Transparency is also necessary to provide trading partners and stakeholders with clear reasons for the risk management decision.

The components of risk analysis include hazard identification, risk assessment, risk management and risk communication (Figure 1). The risk assessment is the component of the analysis which estimates the risks associated with a hazard. Risk assessments may be qualitative or quantitative. For many diseases, particularly for those diseases listed in this Terrestrial Code where there are well developed internationally agreed standards, there is broad agreement concerning the likely risks. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances.

The process of import risk analysis usually needs to take into consideration the results of an evaluation of Veterinary Services, zoning, compartmentalization and surveillance systems in place for monitoring of animal health in the exporting country.

2.2. Import risk analysis methodology

An import risk analysis begins with a description of the commodity proposed for import and the likely annual quantity of trade. It must be recognized that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the risk estimate, it may not be readily available, particularly where such trade is new.

Hazard identification is an essential step which must be conducted before the risk assessment.

The risk assessment process consists of four interrelated steps. These steps clarify the stages of the risk assessment, describing them in terms of the events necessary for the identified potential risk(s) to occur, and facilitate understanding and evaluation of the outputs. The product is the risk assessment report which is used in risk communication and risk management.

The relationships between risk assessment and risk management processes are outlined in Figure 2.

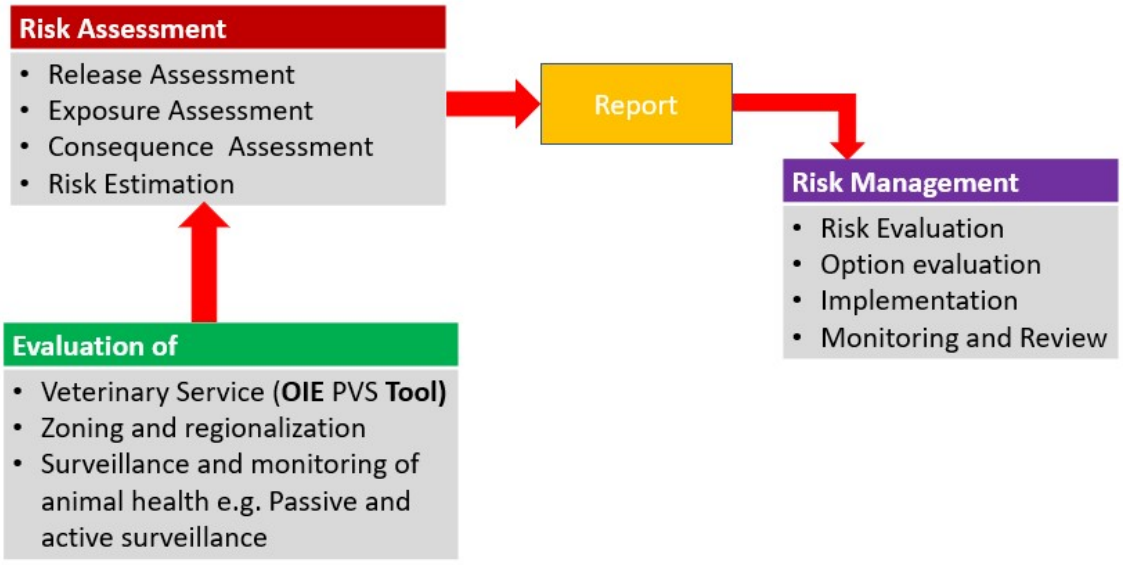


Figure 2: The relationship between risk assessment and risk management processes

2.2.1. Hazard identification

The hazard identification involves identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a commodity. As defined in the Terrestrial Code, a 'commodity' means 'animals, products of animal origin intended for human consumption, for animal feeding, for pharmaceutical or surgical use or for agricultural or industrial use, semen, embryos/ova, biological products and pathological material. The potential hazards identified would be those appropriate to the species being imported, or from which the commodity is derived, and which may be present in the exporting country. It is then necessary to identify whether each potential hazard is already present in the importing country, and whether it is a notifiable disease or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

Hazard identification is a categorization step, identifying biological agents dichotomously as potential hazards or not. The risk assessment may be concluded if hazard identification fails to identify potential hazards associated with the importation. The evaluation of the Veterinary Services, surveillance and control programmes and zoning and compartmentalization systems are important inputs for assessing the likelihood of hazards being present in the animal population of the exporting country.

An importing country may decide to permit the importation using the appropriate sanitary standards recommended in the Terrestrial Code, thus eliminating the need for a risk assessment.

2.2.2. Risk assessment

2.2.2.1 Principle of risk assessment

1. Risk assessment should be flexible to deal with the complexity of real-life situations. No single method is applicable in all cases. Risk assessment must be able to accommodate the variety of animal commodities, the multiple hazards that may be identified with an importation and the specificity of each disease, detection and surveillance systems, exposure scenarios and types and amounts of data and information.
2. Both qualitative risk assessment and quantitative risk assessment methods are valid.
3. The risk assessment should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.
4. Consistency in risk assessment methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.
5. Risk assessments should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate.
6. Risk increases with increasing volume of commodity imported.
7. The risk assessment should be amenable to updating when additional information becomes available.

2.2.2.2 Risk assessment steps

Entry assessment/Release assessment

Entry assessment consists of describing the biological pathway(s) necessary for an importation activity to enter (that is, introduce) pathogenic agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The entry assessment describes the probability of the 'entry' of each of the potential hazards (the pathogenic agents) under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the entry assessment are:

1. Biological factors
    - species, age and breed of animals
    - agent predilection sites

- vaccination, testing, treatment and quarantine.

2. Country factors
    - incidence/prevalence
    - evaluation of Veterinary Services, surveillance and control programmes and zoning systems of the exporting country.
3. Commodity factors
    - quantity of commodity to be imported
    - ease of contamination
    - effect of processing
    - effect of storage and transport.

If the entry assessment demonstrates no significant risk, the risk assessment does not need to continue.

Exposure assessment

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) released from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

The probability of exposure to the identified hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure (e.g. ingestion, inhalation, or insect bite), and the number, species and other characteristics of the animal and human populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

1. Biological factors
    - properties of the agent.
2. Country factors
    - presence of potential vectors
    - human and animal demographics
    - customs and cultural practices
    - geographical and environmental characteristics.
3. Commodity factors
    - quantity of commodity to be imported
    - intended use of the imported animals or products
    - disposal practices.

NOTE: If the exposure assessment demonstrates no significant risk, the risk assessment does not need to continue.

Consequence assessment

Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring (analysis the consequences identified risks). This estimate may be either qualitative (in words) or quantitative (a numerical estimate). Examples of consequences include:

1. Direct consequences
    - animal infection, disease and production losses
    - public health consequences.
2. Indirect consequences
    - surveillance and control costs
    - compensation costs
    - potential trade losses
    - adverse consequences to the environment.

Risk estimation

Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset. Thus, risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

- estimated numbers of herds, flocks, animals or people likely to experience health impacts of various degrees of severity over time;
- probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates;
- portrayal of the variance of all model inputs;
- a sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output;
- analysis of the dependence and correlation between model inputs.

Table 1. Example of Risk assessment steps: 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	• Migratory bird infected • Migratory bird enters Kenya
Exposure assessment	Likelihood of target population to be exposed	• Infected migratory bird in resting sites • Contact with local wild birds in resting sites
Consequence assessment	Consequences + likelihood of occurrence and magnitude	• Local wild bird infected • Local wild bird spread disease among pop. • Economic effects on markets (suspension of poultry trade) • Poses a public health threat • May create devastating effect on the biodiversity of our ecosystems

2.2.3. Risk management

2.2.3.1 Principles of risk management

1. Risk management is the process of deciding upon and implementing measures to achieve the Member's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimized. The objective is to manage risk appropriately to ensure that a balance is achieved between a country's desire to minimize the likelihood or frequency of disease incursions and their consequences and its desire to import commodities and fulfil its obligations under international trade agreements.
2. The international standards of the OIE are the preferred choice of sanitary measures for risk management. The application of these sanitary measures should be in accordance with the intentions in the standards.

2.2.3.2 Risk management components

1. Risk evaluation - the process of comparing the risk estimated in the risk assessment with the Member's appropriate level of protection.
2. Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures in order to reduce the risk associated with an importation in line with the Members appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse health and economic consequences. Evaluating the

efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options.

3. Implementation - the process of following through with the risk management decision and ensuring that the risk management measures are in place.
4. Monitoring and review - the ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended.

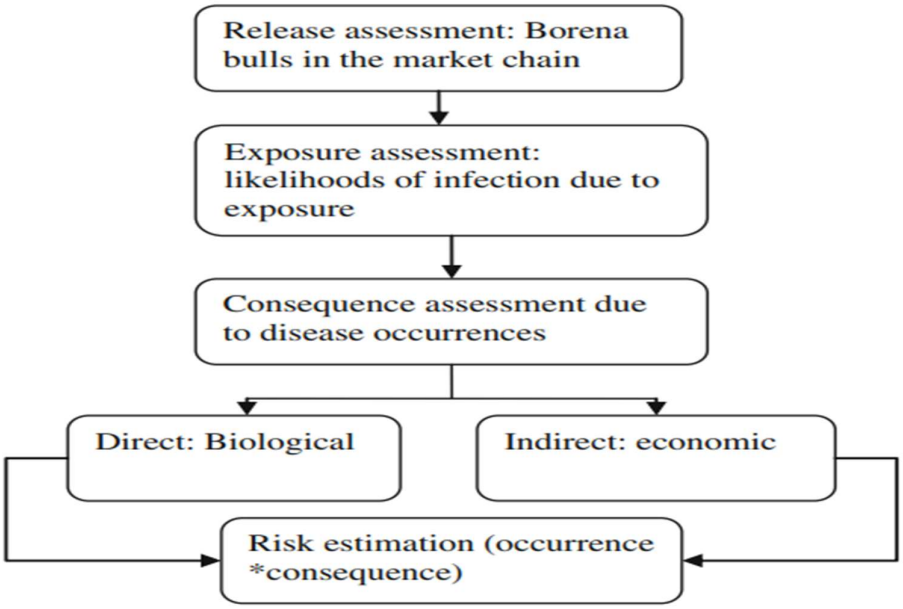
2.2.4 Risk communication

Principles of risk communication

1. Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties in the importing and exporting countries. It is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout. Simply it is an interactive process of exchange of information and opinion among individuals, groups and institutions.
2. A risk communication strategy should be put in place at the start of each risk analysis.
3. The communication of the risk should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.
4. The principal participants in risk communication include the authorities in the exporting country and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.
5. The assumptions and uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated.
6. Peer review is a component of risk communication in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.

Example of qualitative risk assessment:

Risk assessments of lumpy skin diseases in Borena bull market chain and its implication for livelihoods and international trade. Gezahegn *et al.* conducted the study in 2012 with the aim of assessing the risks of lumpy skin disease (LSD) introduction into the market chain and its consequences. This study used the framework that has been recommended by the OIE (2004) for risk analysis. The framework outlines four key steps that should be covered systematically (as shown in figure below).



The identification of hazards is the first step in risk analysis. The authors defined LSDV as the hazard in this risk assessment. The probabilities, their description, and interpretation have been given in the methodology section of this risk assessment, as shown below.

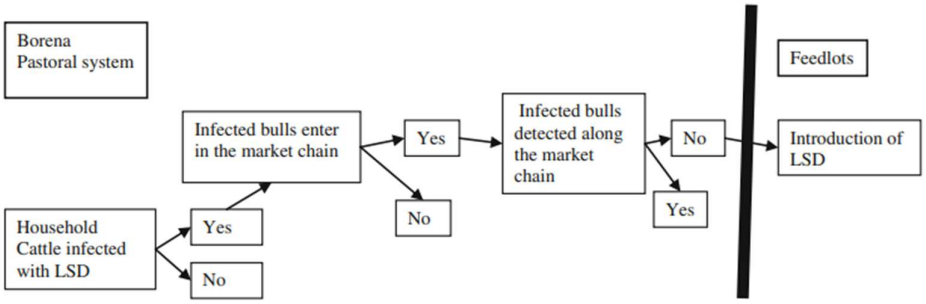
Probability category	Interpretation
Negligible	Event is so rare that does not merit to be considered
Very low	Event is very rare but cannot be excluded
Low	Event is rare but does occur
Medium	Event occurs regularly
High	Event occurs very often
Very high	Event occurs almost at certainly

Adapted from EFSA (2006)

What were the components of risk analysis in this study?

1. Release assessment

The risk question posed for release was "What is the probability of introduction of lumpy skin disease into feedlots by Borena bull moving along market chain?" Scenario tree was designed to describe and evaluate the pathway of introduction of LSD through traded bulls from the point of production until the feedlots in Central Ethiopia. Scenario trees contain nodes that describe the events from which probabilities of an event derive (see the figure below). The authors implicated the overall risk for the release of LSDV in feedlots is estimated to be high (medium uncertainty). Release pathway probabilities vary from high to very high (as shown below). Therefore, the probability of LSDV release into feedlots by traded bulls in the market chain occurs very often.



Fugure: Scenario tree outlining LSD pathway along the Borena bull market chain

Risk pathway	Risk category	Uncertainty
Probability of Borena bull in the market chain infected with LSD	High	Medium
Probability of infected Borena bull not detected while passing along the market chain	Very high	Low
Probability of lack of biocontainment of the virus within the facility along the value chain	High	Low
Overall risk estimate for release	High	Medium

Table: Summary of release assessment for LSD in Borena bull market chain

2. Exposure assessment

The authors clearly demonstrated how bulls in feedlots could be exposed to LSDV (see figure below). The report discusses two paths of exposure in depth. The first pathway involves bulls being exposed to LSDV via blood-feeding arthropods, whereas the second involves bulls being exposed to LSD via equipment. Finally, the overall probabilities of exposure were estimated as shown in table. Accordingly, the probabilities in the pathways range from high to very high. The overall risk estimate for exposure of bulls is thus very high (medium uncertainty). Therefore, exposure of bulls to LSDV occurs almost certainly.

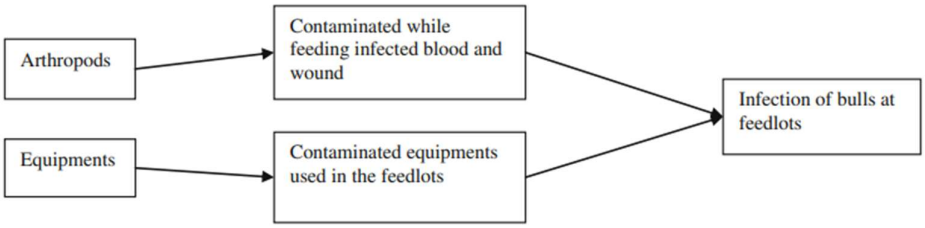


Fig. Exposure pathway of LSD in feedlots

Risk pathway	Risk category	Uncertainty
Probability of infection of bulls in the feedlots after exposure to LSDV from contaminated blood-feeding arthropods	Very high	Medium
Probability of infection of bulls in the feedlots after exposure to LSDV from contaminated equipments	High	Low
Overall risk estimate for exposure	Very high	Medium

Table: Summary of exposure assessment for LSD in Boren bull market chain

3. Consequence assessment

The direct economic loss associated with LSD was calculated using the LSD mortality rate, rejection rate, and total number of bulls at risk of LSD in and near Adama feedlots during an outbreak. The authors of the study looked at a direct loss of 667,785.6 USD.

4. Risk estimation

For overall risk estimation, the authors combined entry assessment, exposure assessment, and consequence assessment (see the figure). Risk assessment result revealed that likelihood of introduction of LSD to feedlots from infected bull passing along market is high. The likelihood of infection, as a consequence of exposure, is considered to be very high. Therefore, the probability of LSD occurrence in the feedlots from the release and exposure is also considered to be high. Therefore, the overall prevalence of LSD is more than negligible that needs control intervention along the value chain.

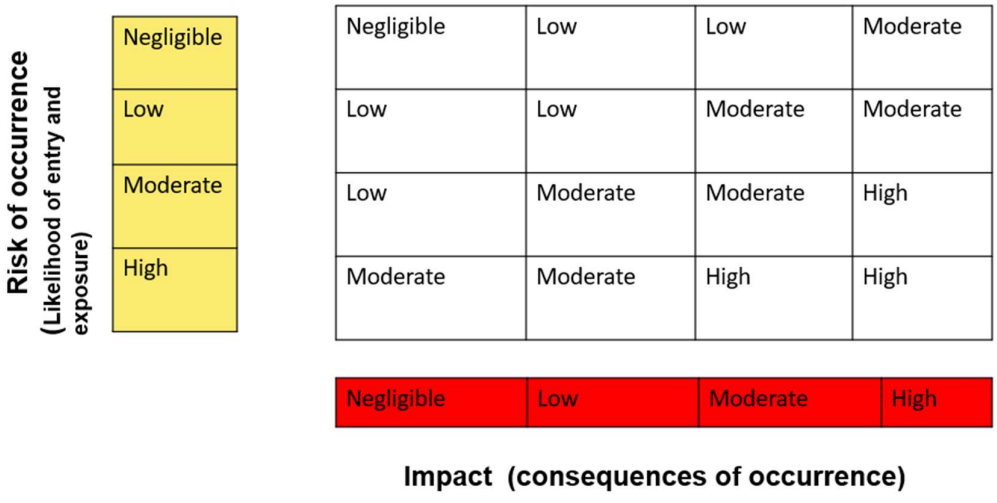


Figure: Risk estimation interpretation

Finally, the researchers published their findings in *Trop Anim Health Prod.* Publication as part of risk communication. To sum up, in qualitative and quantitative risk analysis, all components of risk assessment such as entrance (release) assessment, exposure assessment, consequence assessment (biologic, economic), and risk estimation must be taken into account in the research.

Exercise 1: Read and identify components of risk assessment (release assessment, exposure assessment, consequence assessment and risk estimation) of the paper " Chazya, et al., (2014). A qualitative assessment of the risk of introducing peste des petits ruminants into northern Zambia from Tanzania. *Veterinary medicine international*, *2014*. The article can be found at https://www.hindawi.com/journals/vmi/2014/202618

HINT: see figure below.

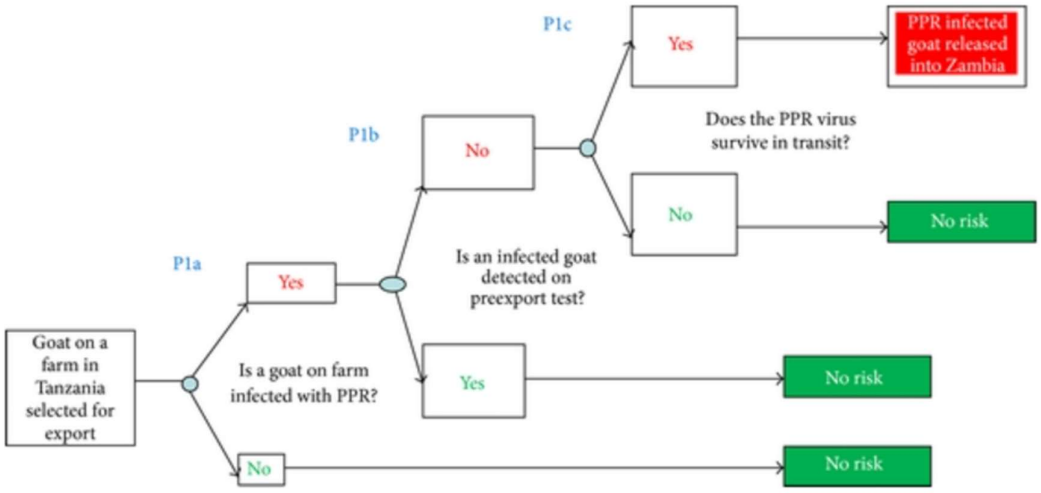


Figure: Scenario tree for PPR exposure to goats in Northern Zambia.

3. An introduction to quantitative risk analysis (Section III)

Learning objective of section III

- This section addresses uncertainty and variability and illustrates how point estimation is calculated. A discussion of how uncertainty and variability are applied to each of the stages of the risk-assessment process and definitions for key terminology related to uncertainty and variability are also addressed in this section.

Learning outcome of section III

Upon completion of this section, the learner will be able to

- Understand the concept of quantitative risk analysis
- Discuss the steps in quantitative risk analysis
- Understand the various types of quantitative risk analysis
- Understand and discuss variability and uncertainty
- Discuss about 'parameter', 'variable', 'input' and 'model'
- Discuss about deterministic (point estimate) risk assessment
- Calculate point estimate for import risk analysis
- Distinguish the advantages and disadvantages of quantitative risk analysis

Section III questions

- What is the difference between variability and uncertainty?
- What factors contribute to variability and uncertainty in exposure assessment?
- How do variability and uncertainty affect risk assessment?
- How can an exposure assessment be designed to ensure variability is well-characterized and uncertainty is limited?
- How are variability and uncertainty addressed in risk assessment?

3.1. Introduction

Previously, we stated that no single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances. In qualitative assessments, the likelihood the release and subsequent exposure to a hazard and the magnitude of the resulting consequences are expressed using non-numerical terms such as high, medium, low or negligible, and the qualitative approach has so far proved suitable for the majority of import risk assessments. However, in some circumstances it may be desirable to undertake a quantitative analysis, for example, to gain further insights into a particular problem, to identify critical steps or to compare sanitary measures.

A quantitative risk assessment is a mathematical model where the inputs and outputs are expressed numerically and is methodology used to organize and analyse scientific information to estimate the probability and severity of an adverse event. In its simplest form, commonly referred to as a deterministic or point estimate analysis, both the inputs and outputs are expressed as single numbers or point values. These may represent a 'best guess', the 'average' or 'expected case' or perhaps the 'worst case'. When one wants to determine the impact of one or more of the input values on the output, one simply substitutes a new value into the model. This is effectively a 'what if', or scenario, analysis. For simple models with few inputs, this type of analysis can be easily undertaken using a calculator.

For more complex models, or in situations where one has more data to work with, probabilistic risk assessments are preferable. In these, inputs are described as probability distributions and a computer is essential for constructing the risk assessment model. Quantification involves developing a mathematical model to link the steps of the risk pathway, which are expressed numerically. The results, which are also expressed numerically, invariably present significant challenges in interpretation and communication. This is beyond the scope of this module. Interested readers could consult the Handbook on Import Risk Analysis for Animals and Animals Products, Volume 2.

3.3. Uncertainty in risk analysis

Total uncertainty is traditionally split into two components: variability and uncertainty. When modelling risks, it is common to keep both components apart (although, strictly speaking, there is no absolute difference between them and the distinction here is only made to be in line with most of the literature). The most common mistake in risk analysis is not to include or underestimate uncertainty.

Variability: Variability is the effect of chance and is inherent to the system. It is also called aleatory uncertainty, stochastic uncertainty, stochastic variability and inter-individual variability. It is said to be irreducible and can only be decreased by changing the system (note however that this is philosophy rather than science). The sensitivity and specificity of a diagnostic test is typical examples. Test sensitivity is defined as the probability of a positive test result when an infected individual is tested. It is a probability; it is impossible to predict the result for any individual animal. We can make a statement about the average number of positive test results in a certain population of infected animals, but the test has to be performed before we can make a statement about an individual.

Uncertainty: Uncertainty in this narrower sense is the lack of knowledge about a parameter's true value (e.g. uncertainty about the exact value of the sensitivity of a diagnostic test). It is reducible through further study or through the inclusion of expert opinion. Uncertainty is also called fundamental uncertainty, epistemic uncertainty, degree of belief. Uncertainty is in principle

subjective.

3.4. Common terms in quantitative risk assessment

The terms ‘parameter’, ‘variable’, ‘input’ and are often used in quantitative risk assessments.

Parameter: In experimental statistics the term parameter represents a numerical descriptive measure that characterizes a population, for example the population mean (μ), the population standard deviation (δ) and the binomial proportion (p). In spread sheet computer software, it is often used to represent the arguments of mathematical, statistical or probability distribution functions such as the values required to define the shape of a Beta distribution or the mean and standard deviation of a normal distribution.

Variable: A variable is any characteristic that has a different value for different subjects or objects. If it can take on a different value as a result of a random process it is called a random variable. It can either be discrete, where it can only take on a limited number of values, or continuous, where it can take on any value within a given range. Examples of discrete variables include the number of infected animals, the number of test positive animals or the number of piglets in a litter, while examples of continuous variables include bodyweight or blood copper levels.

Inputs: An input is any information that is fed into a model. As a result, parameters and variables, together with data and distributions, can be considered as inputs as they provide information that is used in a quantitative risk assessment model.

Model: A model is a simplified representation of the real world. Most models are symbolic because symbols represent properties of the system. In this handbook, a ‘model’ is a representation of an importation scenario in graphical or mathematical form where equations are used to simulate the biological processes under study and the impact of risk management options.

3.6. Deterministic (point estimate) risk assessment

Quantification of risk begins with considering an experiment, or trial with only two possible outcomes: success or failure. The trial may be repeated a number of times. For example, a trial may be a single embryo transfer from an infected animal to a susceptible recipient. A ‘success’ in this case would be where the infection is transmitted while a ‘failure’ would be a transfer where infection is not transmitted. If we observe no successes after ten transfers (trials) we may begin to suspect that the probability of transmitting infection by embryo transfer is low. As more transfers are undertaken without transmitting infection, the more confident we become that transmission is unlikely. This is shown in Table 2, where confidence intervals have been determined by consulting the statistical tables.

Table 2. Probability of transmitting infection following embryo transfer from a viremic donor

Number of transfers (n)	Number of Infected recipients (I)	Probability of transmitting infection ($P_t = \frac{r}{N} * 100$)	Lower 95% confidence limit	Upper 95% confidence limit
10	0	0.00	0.00	30.85
20	0	0.00	0.00	16.84
30	0	0.00	0.00	11.57
40	0	0.00	0.00	8.81
100	0	0.00	0.00	3.62
1000	0	0.00	0.00	0.37

If 100 experimental transfers were undertaken without transmitting infection, we could reasonably conclude, using the upper 95th percent confidence interval, that the probability of transmitting infection for each embryo transferred from an infected donor is 'at worst' 3.62%.

If we plan on undertaking an embryo transfer program we might like to estimate the probability that at least one recipient becomes infected or, alternatively, the average number of infected recipients we could expect.

To calculate the probability that at least one recipient becomes infected we proceed as follows:

- the probability of transmitting infection (a success) is p_t the probability of not transmitting infection (a failure) is 1- p_t
- the probability that none of the recipients become infected is $(1- p_t)^e$, where e refers to the number of recipients (trials)
- so, the probability that at least one recipient becomes infected is $1-(1- p_t)^e$
- the probability is expressed in mathematical notation as $P(x \geq 1)$, where P refers to probability and x refers to the outcome, that is, an infected recipient
- and the final equation is then written as:

$$P(x \geq 1) = 1-(1- p_t)^e \qquad \text{Equation 1}$$

To calculate the expected number of infected recipients we multiply the probability of transmitting infection p_t, by the number of recipients e:

$$\text{expected number of infected recipients} = p_t * e \qquad \text{Equation 2}$$

If we assume a situation where the probability of transmission equals 3.62% (n=100) and the number of embryos transferred equals 30, we could determine the probability that at least one recipient becomes infected (Table 3). For simplicity, we will assume that each recipient is implanted with only one embryo and that each donor produces a single transferable embryo. As a result, the number of recipients equals 30.

$P(x \geq 1) = 1-(1-0.0362)30 = 0.6692 = 66.92\%$

expected number of infected recipients = 0.0362 □ 30 = 1.086

This scenario is essentially a 'worst case' as we have assumed that all the donors are infected. If we had some information on the prevalence of disease among the donors, we could incorporate this into the model. Suppose a survey had been recently undertaken in a donor flock of sheep and 5 animals out of 100 (n) tested were found to be infected. By consulting the table of exact binomial confidence limits from internet we could estimate that the true disease prevalence, with a 95% level of confidence, is likely to be between 1.64% (lower 95% confidence limit) and 11.28% (upper 95% upper confidence limit) with an expected value of 5%. We could include these estimates of disease prevalence in the model to determine three possible outcomes (Table II) using the following formulae:

$P(x \geq 1) = 1- (1-p * p_t)^e$ Equation 3

expected number of infected recipients $= p*p_t*e$ Equation 4

where: p = prevalence,

p_t = probability of transmitting infection and

e = number of recipients.

Table 3. Probability of transmitting infection to at least one recipient and the expected number of infected recipients if thirty embryos are transferred

Scenario	p = prevalence in the flock of origin	p_t = probability of transmitting infection via embryo transfer	Probability ≥ 1 recipient infected (Equation 3)	Expected number of infected recipients (Equation 4)
Minimum	1.64% (lower 95% CL*)		1.77%	0.017 (17 out of every 1,000)

Most likely	5% (expected value)	3.62% (upper 95% CL)	5.28%	0.054 (54 out of every 1,000)
Worst case	11.28% (upper 95% CL)		11.55%	0.122 (122 out of every 1,000)

* CL = confidence limit

After considering the probabilities that one or more recipients would become infected, we might consider that the likelihood is too high and that some risk management measure is desirable. So, we might then decide to test the donors and discard any that are positive. If we test a potential donor, chosen at random, we could calculate the probability that it is infected D^+, given that it is test negative T^-. This is a conditional probability, which is expressed as $P(D^+ | T^-)$. For a perfect test, this probability would be zero. However, since all tests are imperfect (with a sensitivity of less than 1), we can expect that the test will fail to detect some infected animals. In addition, some uninfected animals will be incorrectly classified as positive, since the specificity will also be less than 1. In these circumstances we calculate the $P(D^+ | T^-)$ by firstly determining the predictive value of a negative test *NPV* and then calculate its complementary probability (1-*NPV*). This represents the prevalence of infection within the group of donor animals we accept. That is, the prevalence of infection amongst the test negative animals as a result of discarding test positive animals.

NPV is calculated as:

$$NPV = P(D^+ | T^-) = \frac{Sp(1-p)}{p(1-Se)+(1-p)Sp} \quad \text{Equation 5}$$

where: p = the prevalence of infection in the flock of sheep

Se = test sensitivity

Sp = test specificity

So the prevalence of infection within the test negative group is calculated as:

$$P(D^+ | T^-) = 1 - NPV \quad \text{Equation 6}$$

If we use a test with a sensitivity of 90% and specificity of 99% and reject any positive animals, we could calculate the probability of infection for a test negative animal by substituting these values into Equation 6 (Table 4):

Table 4. Prevalence of infection among test negative donors

Scenario	p = prevalence in the flock of origin	Se = test sensitivity	Sp = test specificity	Prevalence among test negative donors (Equation 6)
Minimum	1.64% (lower 95% CL*)	90%	99%	0.17%
Most likely	5% (expected value)			0.53%
Worst case	11.28% (upper 95% CL)			1.27%

* CL = confidence limit

- Sensitivity of a test is its ability to correctly classify an infected animal as test positive. It is calculated as the proportion of infected animals that yield a positive test result $P(D^+ | T^+)$
- Specificity of a test is its ability to correctly classify an uninfected animal as test negative. It is calculated as the proportion of uninfected animals that yield a negative test result $P(D^- | T^-)$

Since 1-*NPV* is the prevalence of infection within the test negative group, we can replace 'p' in Equation 3 with '1-*NPV*' to determine the probability of transmitting infection to at least one recipient:

$$P(R^+ \geq 1) = 1(1 - (1 - NPV) * p_t)^e \quad \text{Equation 7}$$

where: R+ = infected recipient

and the expected number of infected recipients:

$$(1 - NPV) * p_t * e \quad \text{Equation 8}$$

The results of these calculations are shown in Table 5

Table 5. Probability of transmitting infection to at least one recipient and the expected number of infected recipients if thirty embryos are transferred

Scenario	(1-NPV) = prevalence in the group of test negative donors (from Table 3)	P_t = probability of transmitting infection via ET	Probability ≥ 1 recipient infected (Equation 7)	Expected number of infected recipients (Equation 8)
Minimum	0.17%	3.62% (upper 95% CL*)	0.18%	0.002 (2 out of every 1,000)
Most likely	0.53%		0.57%	0.006 (6 out of every 1,000)
Worst case	1.27%		1.37%	0.014 (14 out of every 1,000)

* CL = confidence limit

So, by making use of a statistical table and a calculator, we have been able to undertake a simple deterministic or point estimate analysis that has given us a very good idea of the risks we face. We could go on adding to this model, for example by including an estimate of the probability that a randomly chosen flock is actually infected and the effect of quarantining and testing recipients to screen out positive animals.

3. TERRESTRIAL AND AQUATIC ANIMAL HEALTH CODE

Learning objective of this CPD module component

This component of the CPD module comprises of the following three units and introductory topic on terrestrial animal and aquatic animal health codes. The first part is the statement about the aquatic and terrestrial animals' health codes definitions. Unit one deals briefly about terrestrial animal health code, unit two on aquatic animal health code, and unit three commodities considered to be safe for trade. detail concepts are described in each chapter**.**

Learning outcome of this CPD module component

At the end of each chapter the learner be able to identify different codes of Terrestrial and aquatic code animal codes and codes related to commodities considered to be safe for trade as well as the risks and risk identification approaches.

DEFINITION OF HEALTH CODE, WHAT IS TERRESTRIAL AND AQUATIC ANIMAL HEALTH CODE

What is health code?

Definition: Health code is a set of standards established and enforced by an authority for health requirements.

What is terrestrial animal health code?

Definition… *The OIE Terrestrial Animal Health Code (the Terrestrial Code) provides standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide. The health measures in the Terrestrial Code should be used by the Veterinary Authorities of importing and exporting countries to set up measures providing for early detection, reporting and control of pathogenic agents, including zoonotic ones, in terrestrial animals (mammals, birds, reptiles and bees) and preventing their spread via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade…..*

What is aquatic animal health code?

Definition: *…..The OIE Aquatic Animal Health Code (the Aquatic Code) sets out standards for the improvement of aquatic animal health and welfare of farmed fish worldwide, including through standards for safe international trade in aquatic animals (amphibians, crustaceans, fish and mollusks) and their products. The health measures in the Aquatic Code should be used by the Competent Authorities of importing and exporting countries to provide for early detection, reporting and control of agents pathogenic to aquatic animals and to prevent their transfer via international trade in aquatic animals and aquatic animal products, while avoiding unjustified sanitary barriers to trade.*

4.1. Terrestrial Animal Health Code (Section I)

Learning objective of Section I

This topic briefs the learner be about the terrestrial animal health code in relation to diseases outbreak control and prevention, local and transboundary diseases transmission. Further the student will be expected to cover codes related to trade of commodities of animal origin and their safety status.

Learning outcome of this section

At the end of this topic the learner be able to identify different codes Terrestrial animal health code and codes related to commodities considered to be safe for trade.

Session questions

- Which diseases are eligible to be notified to the WOAH?
- Who is authorized to give information to the OIE head quarter in a particular member state?
- How do a member states communicate in case of an event?
- Who is the authorized person to communicate the head quarter of WOAH?
- What are the points to be included in notifying a disease to WOAH?
- What is the name of an online format used to notify an event of animal disease?
- The maximum time gap to notify an event/disease to WOAH after the event occurred in a member state**?**

4.1.1. Notification of Diseases and Provision of Epidemiological Information

Which diseases are eligible to be notified to the WOAH?

Disease termed as listed diseases and emerging diseases are eligible, though member states veterinary authorities/delegates are encouraged to provide the OIE/WOAH with other important animal health information. After notification the WOAH should, communicate/acknowledge the receipt of the information/notification email or through the interface of WAHIS (Article 1.1.5). Further readings are available on (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/id=169&L1&htmfilechapitre_oie_listed_disease.htm).

Who is authorized to give information to the OIE head quarter in a particular member state?

According to article 1.1.1 of the Terrestrial Code and Articles 5, 9 and 10 of the OIE Organic Statutes head quarter have the right to communicate directly with the Veterinary Authority of member states territory or territories. This gives full authority for a member country Veterinary Authority to notify epidemiological information of a disease to the OIE. For example, an outbreak of a disease, eradication of a disease, emergence of a disease etc. Further detail reading on (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-onlineaccess/id169&L1&htmfilechapitre_notification.htm).

How do a member states communicate in case of an event?

In this case member states should notify OIE the presence of an event to minimize the spread (Article 1.1.2.).

This should be done in such a way that

- Members Countries shall comply with the notification requirements specified
- Assist in the clear and concise exchange of information, reports shall conform as closely as possible to the OIE disease reporting format
- The detection of the pathogenic agent of a listed disease in an animal should be reported, even in the absence of clinical signs
- Member countries shall also provide information on the measures taken to prevent the spread of diseases. Information shall include biosecurity and sanitary measures, including restrictions applied to the movement of animals, animal products, biological products and other miscellaneous objects which could by their nature be responsible for the transmission of diseases

Who is the authorized person to communicate the head quarter of WOAH?

According Article 1.1.3 of the animal health code, this should be an individual delegated by the veterinary authority of a member country and he shall send information to the head quarter within 24 hours of the notification of an event. Here disease-specific chapters, notification, through the World Animal Health Information System (WAHIS) or by fax or email. This is followed by weekly, monthly and annual report following an event. The reporting should be done in 24 hours after the event occurrence and the following criteria should be mentioned (Figure 6).

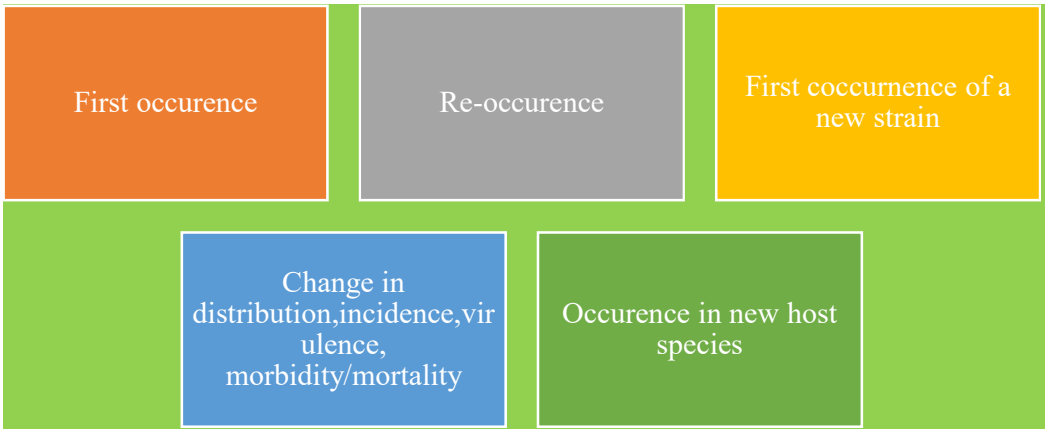


Figure 6: Display of the points to be included in reporting a notification to terrestrial animal's health disease list to WOAH head quarter

The health code also gives responsibility to the Veterinary Authorities of a member state through its delegate to send the notification followed by periodic report to the Headquarters as stated on Article 1.1.4. This should be by WAHIS or by fax or email. The periodic report in this case should be sent until:-

- The infection or infestation has been eradicated; or
- The situation has become stable; OR
- Sufficient scientific information is available to determine whether it meets the criteria for inclusion in the OIE list as described in Chapter 1.2.; 3).

A final report should be sent once the certainty of infestation or infection has been eradicated, the outbreak situation has become stable and scientific information are available to list the disease as WOAH (OIE).

What are the criteria for the inclusion of a disease, infestation or infection in the WOAH list?

According to Article 1.2.2. Animal health code the inclusion criteria are shown in the figure 7. Further reading at (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online access/id169&L1&htm file chapitre_criteria_diseases.htm).

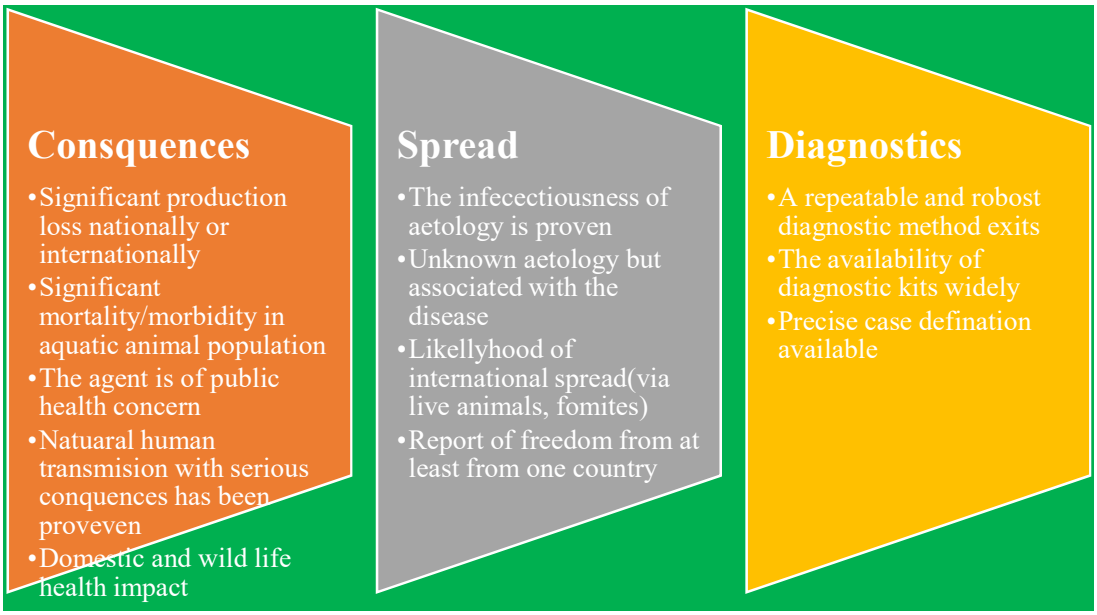


Figure 7: List of criteria for the inclusion of terrestrial animal disease, infestation or infection in the WOAH list

4.1.2. Disease listed by WOAH

The diseases, infections and infestations in chapter 1.3 of the animal health code have been assessed in accordance with Chapter 1.2. and constitute the OIE list of terrestrial animal diseases. In case of modifications of this list adopted by the World Assembly of OIE Delegates, the new list comes into force on 1 January of the following year. This list was adopted in 1976 and recently update adopted in 2022. According to article 1.3 the world organization for animal health (WOAH) listed diseases as follows:

1. Diseases affecting multiple species (subarticle1.3.1full list of the diseases)

2. Diseases affecting cattle (subarticle1.3.2full list of the diseases)

3. Diseases affecting sheep and goat (subarticle1.3.3 full list of the diseases)

4. Diseases affecting equine (subarticle1.3.4 full list of the diseases)

5. Diseases affecting swine (subarticle1.3.5 full list of the diseases)

6. Diseases affecting avian (subarticle1.3.6 full list of the diseases)

7. Diseases affecting lagomorph (subarticle1.3.7 full list of the diseases)

8. Diseases affecting bee (subarticle1.3.8 full list of the diseases)

9. Diseases within the category of other diseases and infections: (subarticle1.39

full list of the diseases)

N: B: For specific diseases consult the following link at (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online access/id169&L1&htmfilechapitre_oie_listed_disease.htm) .

4.2. Aquatic Animal Health Code (Section II)

Learning objective Section II

This topic briefs the learner be about the aquatic animal health code in relation to diseases outbreak control and prevention, local and transboundary diseases transmission. Criteria used to list aquatic animal disease in WOAH list. Further the student will be expected to cover codes related to trade of commodities of animal origin and their safety status.

Learning outcome of the section II

At the end of this topic the learner be able to identify different codes for aquatic animal's code and codes related to commodities considered to be safe for trade.

Session questions

- Which aquatic diseases are eligible to be notified to the WOAH?
- Who is authorized to give information to the OIE head quarter in a particular member state about aquatic animal health disease?
- How do a member states communicate in case of an event?
- What are the criteria for the inclusion of a disease, infestation or infection in the WOAH list?

4.2.1. Notification of Aquatic Animal Diseases and Provision of Epidemiological Information

According to article 1.1.1. For the purposes of the Aquatic Code and in terms of Articles 5, 9 and 10 of the OIE Organic Statutes, every Member Country of the OIE shall recognize the right of the Headquarters to communicate directly with the Competent Authority of its territory or territories. All notifications and all information sent by the OIE to the Competent Authority shall be regarded as having been sent to the country concerned and all notifications and all information sent to the OIE by the Competent Authority shall be regarded as having been sent by the country concerned.

This should be done in such a way that (Article 1.1.2.-1.1.6) available at https://www.woah.org/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/?id 169&L 1&htmfile chapitrenotification.htm).

- Information between members countries shall be available through WOAH). This helps minimize the spread of important diseases of aquatic animals and their pathogenic agents and to assist in achieving better world-wide control of these diseases.
- To assist a better world-wide control of the disease member Countries shall comply with the notification requirements specified in Articles 1.1.3. and 1.1.4.
- Reports shall conform as closely as possible to the current WOAH disease reporting format for clear and concise exchange of information.
- The detection of the pathogenic agent of a listed aquatic disease in an animal should be reported, even in the absence of clinical signs
- Member countries shall also provide information on the measures taken to prevent the spread of diseases. Information shall include biosecurity and sanitary measures, including restrictions applied to the movement of animals, animal products, biological products and other miscellaneous objects which could by their nature be responsible for the transmission of diseases

Who is authorized to give information to the OIE head quarter in a particular member state about aquatic animal health disease?

According Article 1.1.3 of the aquatic animal health code, this should be an individual delegated by the veterinary authority of a member country and he shall send information to the head quarter within 24 hours of the notification of an event. Here disease-specific chapters, notification, through the World Animal Health Information System (WAHIS) or by fax or email. This is followed by weekly, monthly and annual report following an event.

The reporting should be done in 24 hours after the event occurrence and the following criteria should be mentioned (Figure 8).

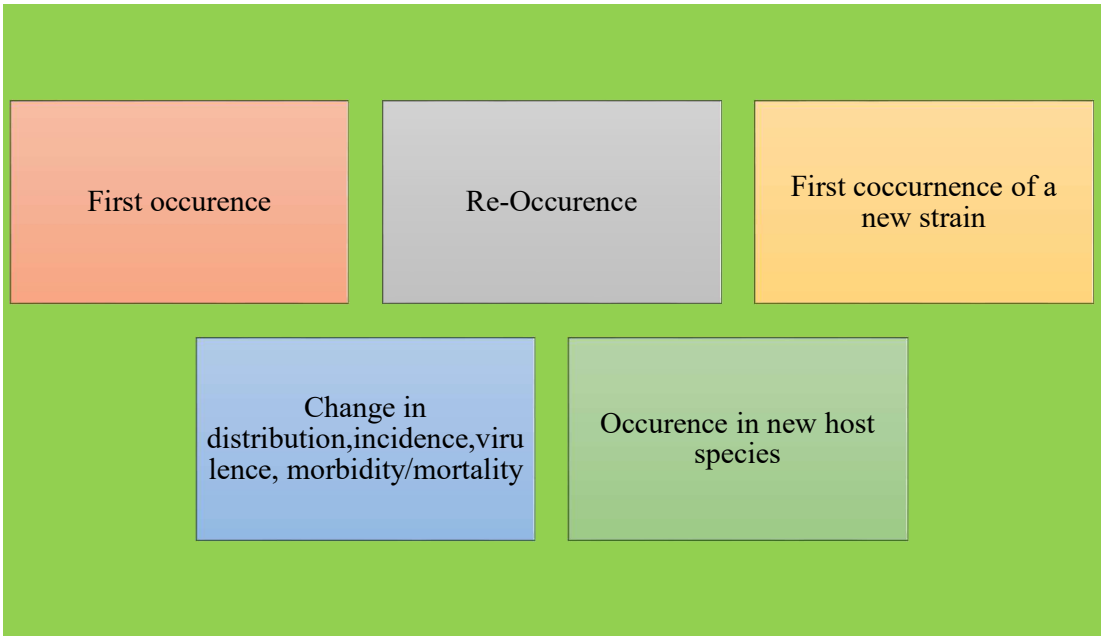


Figure 8: Display of the points to be included in reporting a notification about aquatic animal health listed disease to WOAH head quarter

How do a member states communicate in case of an event?

Similar to the terrestrial animal health code, the aquatic health code also gives responsibility to the Veterinary Authorities of a member state through its delegate to send the notification followed by periodic report to the Headquarters as stated on Article 1.1.4 of the aquatic and terrestrial animal health code. This should be by WAHIS or by fax or email. The periodic report in this case should be sent until: -

- The infection or infestation has been eradicated; or
- The situation has become stable; OR
- Sufficient scientific information is available to determine whether it meets the criteria for inclusion in the OIE list as described in Chapter 1.2.; 3).

A final report should be sent once the certainty of infestation or infection has been eradicated, the outbreak situation has become stable and scientific information are available to list the disease as WOAH (OIE).

What are the criteria for the inclusion of a disease, infestation or infection in the WOAH list?

Article 1.2.1. of the aquatic animal health code describes the criteria for listing diseases in supporting the efforts to prevent the transboundary spread of important diseases of aquatic animals through transparent and consistent reporting. Based on the consequence, spread and diagnostic nature of the aquatic disease criteria are set by the WOAH on article 1.2.2. A disease should fulfill one of the following characteristics to be included in the WOAH list (Figure 9).

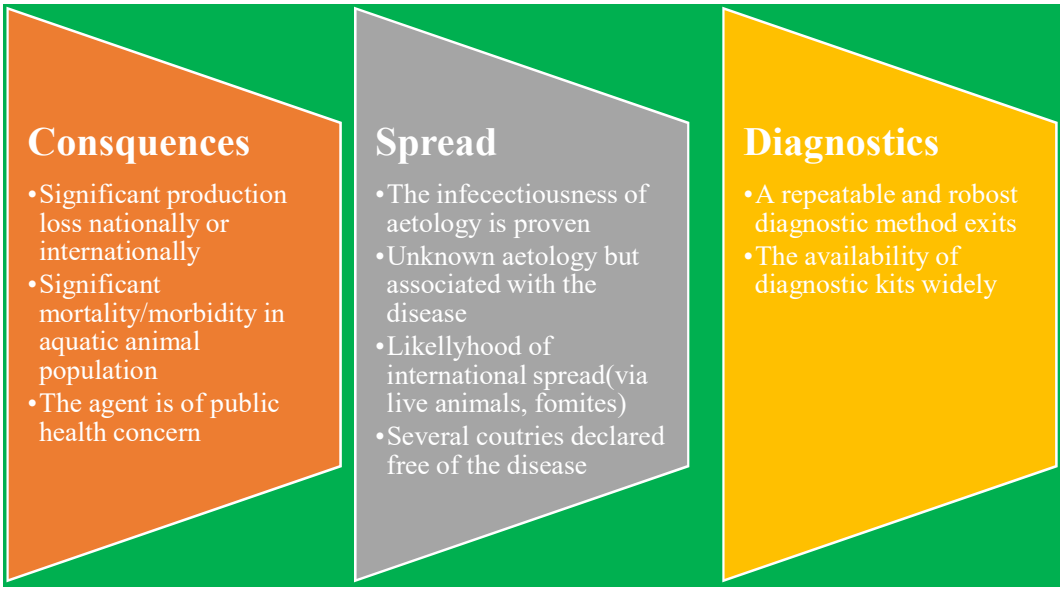


Figure 9: List of criteria for the inclusion of aquatic animal disease, infestation or infection in the WOAH list. Further consult (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/?id 169&L 1&htmfile chapitre_criteria diseases.htm).

4.2.2. Which aquatic diseases are eligible to be notified to the WOAH?

Aquatic Disease listed by WOAH

The WOAH (OIE) listed the following diseases using the criteria list of an aquatic animal disease on article 1.2.2. If modification is needed in the list of aquatic animal diseases the new list comes into force on 1 January of the following year.

This lists are mentioned on Article 1.3.1.,1.3.2.,1.3.3, and 1.3.4. of the aquatic animal health code. The lists are as follows based on the species they affect as diseases of fish, mollusks, crustaceans and amphibians. Further consult at (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/aquatic-code-online access/?id 169&L 1&htmfile chapitre diseases listed. htm).

1. Diseases of fish (Article 1.3.1)

- *Epizootic haematopoietic necrosis*
- *Infection with Aphanomyces invadans (epizootic ulcerative syndrome)*
- *Infection with Gyrodactylus salaris*
- *Infection with HPR-deleted or HPR0 infectious salmon anaemia virus*
- *Infection with salmonid alphavirus*
- *Infectious haematopoietic necrosis*
- *Koi herpesvirus disease*
- *Red sea bream iridoviral disease*
- *Spring viraemia of carp*
- *Viral haemorrhagic septicaemia.*

2. Diseases of molluscs (Article 1.3.2)

- *Infection with abalone herpesvirus*
- *Infection with Bonamia ostreae*
- *Infection with Bonamia exitiosa*
- *Infection with Marteilia refringens*
- *Infection with Perkinsus marinus*
- *Infection with Perkinsus olseni*
- *Infection with Xenohaliotis californiensis*

3. Diseases of crustaceans (Article 1.3.3)

- *Crayfish plague (Aphanomyces astaci)*
- *Infection with yellow head virus*
- *Infectious hypodermal and haematopoietic necrosis*
- *Infectious myonecrosis*
- *Necrotising hepatopancreatitis*
- *Taura syndrome*
- *White spot disease*
- *White tail disease*

4. Diseases of amphibians (Article 1.3.4)

- *Infection with Batrachochytrium dendrobatidis*
- *Infection with ranavirus*

4.3. Commodities Considered to be Safe for Trade (Section III)

Learning objective of section III

This topic briefs the learner be about the commodities considered to be safe for trade mainly of animal products and by products. Approach used to identify and reduce the risk. WTO and its importance in reducing the risks and WTO agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) in WOAH(OIE) list. Further the student will be expected to cover codes related to trade of commodities of animal origin and their safety status.

Learning outcome of section III

At the end of this topic the learner be able to identify codes related to commodities considered to be safe for trade and safe commodities of animal origin. WTO agreement on the Application of Sanitary and Phytosanitary Measures.

Session questions

- What is safe commodity?
- How can one judge a commodity as safe?
- Is a pathogen classified as a hazard if present in both the importing and the exporting country?
- What is the approach used to classify a commodity as hazard?

4.3.1. Commodities Considered to be Safe for Trade

The exchange of all commodities among countries are traded through the rule and regulations of the World Trade Organization (WTO) legal framework for international trade. Animal products are also commodities that are exchanged between countries and should be abide the rule and regulations of the WTO where the OIE Terrestrial Animal Health Code (Terrestrial Code) provides many options in the selection of health (sanitary) measures. This code provides a sound and reliable basis to facilitate safe trade animals and animal products. This is consistent with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The WTO focuses on Terrestrial code recommendation for health measures relating to the importation of beef, pig meat and poultry meat for human consumption. Additional resources to be consulted in this regard are publication International trade: the rights and obligations of OIE Member Countries, the OIE Handbook on Import Risk Analysis for Animals and Animal Products and the OIE Internet page at www.oie.in (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_import_risk_analysis.htm).

The concept of safe commodity

This concept is a best approach of WOAH (OIE) to facilitate safe trade. An animal product is listed as a safe commodity; when the product will come safe pertinent to all ante mortem and post-mortem inspection of livestock, in accordance with Chapter 6.2 (https://www.woah.org/fileadmin/Home/eng/Health_standards/tahc/2016/en_chapitre_control_bio hazard.htm) and (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/id169&L1&htmfilechapitresecurite marchandise.htm).

What is safe commodity?

Safe commodity means a commodity which in the form normally traded is considered safe for trade with respect to a listed disease. Without the need for specific risk mitigation measures against the listed diseases and regardless of status of the country or zone of origin for that disease. ´

How can one judge a commodity as safe?

In order to judge a commodity to be safe, initially the hazard should be identified. According to the WOAH (OIE) Terrestrial Code, ´hazard identification is the process of identifying the pathogenic agents which could potentially be introduced in a commodity considered for importation´. This is the first step in the development of health (sanitary) measures.

The status of the importing and exporting country with respect to OIE listed diseases need to be compared through six-month report. The OIE World Animal Health Database (WAHID) is a resource for the information of disease reported by the exporting country and other information relevant to the credibility of the national Veterinary Services.

Is a pathogen classified as a hazard if present in both the importing and the exporting country?

It is not considered as hazard but,

If that disease is the subject of an official control or eradication program in the importing country. However, an importing country may be justified in taking measures to prevent the entry of distinct strains or serotypes of a pathogen that are exotic to the importing country and that occur in an exporting country.

Listing hazard is important to set import health measures. For this the following points need to be considered

- If a pathogen is not associated with the commodity in question, it should not be considered as hazard. For example if the trade community is beef, poultry pathogens should not be considered as hazard in beef.
- A pathogen that is found in a species that is naturally ´dead end hosts´ should not be classified as a hazard for the purposes of trade. For example, West Nile fever in Equidae, in this case the Equidae is the dead-end host for West Nile virus where this virus is a not a problem or classified as hazardous agent for the purpose of trade.
- The recommendations on ´safe commodities´ should be respected
- The nature of the commodities being traded has significant bearing risk. If a country is importing processed commodity, the risk classification in this case is lower as compared to live animal's import. In the processed commodity the products should be inactivated.
- Import of embryo should be considered considering the relevant risk as stated in WOAH chapter 4.5-4.11.
- For all trade commodities the exporting country should provide epidemiological evidence that allows the importing country to ´rule out´ a pathogen from consideration as a hazard for the purpose of trade

4.3.2. What is the approach used to classify a commodity as hazard?

A decision tree approach to categorize a pathogen as hazard

In developing a health measure for the purpose of trade in animal products the decision tree method of analysis is a useful approach. This decision tree method/approach is a five-step process where every question is followed by yes or no answer. Based on the approach a pathogenic agent might be considered as hazard or not hazard (Table 6).

Table 6. A decision tree approach method used to develop health measure for the purpose of categorizing a pathogenic agent as hazard or not hazard in commodities of animal origin

Questions	**YES**	**NO**	**Remark**
1. Is the commodity under consideration a potential vehicle for the pathogenic agent?	Proceed to Step 2	The pathogenic agent is not a hazard	Export of the commodity has no danger
2.Is the pathogenic agent present in the exporting country?	Proceed to Step 3	Satisfactorily substantiate a claim that the pathogenic agent is absent	The capacity and capability of the exporting country's Competent Authority
3.Are there zones or compartments from which the commodity could be derived within the exporting country that are free of the pathogenic agent?	The pathogenic agent is not a hazard.	Contact the Competent Authority to seek additional information or clarification and proceed to Step 4.	There is sufficient confidence in the capacity and capability of the exporting country's Competent Authority to satisfactorily substantiate a claim that the pathogenic agent is absent
4.Is the pathogenic agent present in the importing country?	Proceed to Step 5.	Is the Competent Authority of the country able to satisfactorily	**Yes, the pathogenic agent is classified as a hazard** No, proceed to Step 4.

		substantiate a claim that it is absent?	
5.For a pathogenic agent reported in both the exporting and the importing country	IF: a) it is subject to an official control programmer in the importing country, OR b) there are zones or compartments of different animal health status, OR c) local strains are likely to be less virulent than those reported internationally or in the exporting country:		
	THEN the pathogenic agent might be classified as a hazard.		

Color code: Deep Green: the pathogenic agent is not hazard, Light green: Additional information from the competent authority capacity, Yellow: Question on the authority to claim the absentee of the pathogen, Red: the pathogen is classified as hazard.

4.3.3. Criteria Applied by the WOAH for Assessing the Safety of Commodities (Terrestrial and Aquatic Derived)

This was stated on Article 2.2. of the WOAH terrestrial animal health code and under this article sub article 2.2.1. a general provision was stated listed commodities that are safe and can be traded safely. In case of aquatic animals originated commodities article 5.4 of the WOAH code states that commodities that are safe and can be traded safely like the former. Consult further at (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-onlineaccess/?id 169&L 1&htmfile chapiter securite marchandise.htm) for commodities originated from terrestrial animal and (https://www.woah.org/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/?id=169&L 1&htmfile chapitre criteria commodities htm) for commodities originated from aquatic animals.

The criteria for their inclusion in the list of safe commodities are: -

- Absence of the pathogenic agent in the traded commodity (either due to its absence in the tissues from which the commodity is derived or to its inactivation by the processing or treatment that the animal products have undergone).

For an animal product to be considered a safe commodity for international trade as described in the User's guide and Article 2.2.1., it should comply with the following criteria:

1) There is strong evidence that the pathogenic agent is not present in the tissues from which the animal product is derived in an amount able to cause infection in a human or animal by a natural exposure route.
2) If the pathogenic agent may be present in, or may contaminate, the tissues from which the animal product is derived.

The standard processing or treatment applied to produce the commodity to be traded, while not being specifically directed at this pathogenic agent, inactivates it to the extent that possible infection of a human or animal is prevented through its action. These method of inactivation can be one of or a combination the listed:-

a) Physical (e.g. temperature, drying, irradiation)
b) Chemical (e.g. iodine, pH, salt, smoke)
c) Biological (e.g. fermentation)
d) A combination of a) to c) above

5. Sanitary and Phytosanitary (SPS) measure

Learning objective of this section

This section presents the overview of the SPS Agreement and its objectives, scope, main rights, and basic obligations.

Learning outcome of this section

Upon completion of this section, the learner will be able to

- Define SPS
- Understand the concept of sanitary and phytosanitary measures and its application
- Describe the main rights and obligations under the SPS agreement

Section questions

- What does "SPS measure" mean?
- What is covered by the SPS Agreement?
- What is the significance of an SPS agreement?
- What are WTO members' rights and obligations in implementing the SPS agreement?

5.1. What is SPS?

Introduction

Sanitary and phytosanitary (SPS) measures are the laws, rules, standards, and procedures which are applied to protect human, animal or plant life or health from risks arising from the introduction, establishment and spread of pests and diseases and from risks arising from additives, toxins and contaminants in food and feed. E.g. quarantine and biosecurity measures. “Sanitary and phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia* , end product criteria; processes and production methods; testing; inspection; certification and approval processes; quarantine treatments including relevant requirements associated with transport of animals or plants, or with materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.” (SPS WTO, 1995). The SPS Agreement provides a

framework of rules to guide WTO Members in the development, adoption and enforcement of all sanitary (relating to animals) and phytosanitary (relating to plants) (SPS) measures that may have an impact on international trade, either directly or indirectly. Measures that protect animals and plants from pests or diseases are also covered under the SPS Agreement. These regulations serve as the foundation for animal and plant import and export requirements. Thus, SPS Agreement introduces new disciplines that govern trading practices at the international level that prevent or limit damage from the entry, establishment, and spread of pests or disease. All WTO Members are required to uphold the principles and obligations of the SPS agreement. SPS measures must be based on science and applied in a uniform and systematic manner. However, all countries determine their own appropriate food safety levels and animal and plant health protections. In general, the SPS Agreement allows countries to use SPS measures to protect themselves from unwanted pests that may harm human, plant, or animal health, but not in ways that unfairly affect trade.

Accepting the WTO Agreement means governments agree to abide by the rules in all of the multinational trade agreements attached to it, including the SPS Agreement. The SPS Agreement reduces uncertainty for both regulators and traders by providing a common set of rules to help avoid potential conflicts.

5.2. Scope of Application of the SPS Agreement

The SPS Agreement regulates the conditions under which national regulatory authorities may
Set and enforce health and safety standards that directly or indirectly affect international
Trade. In particular, it applies to any measure, regardless of the specific form it may take, which is adopted with the aim to:

- Protect consumers and animals from food- and feed-borne risks.
- Protect consumers, animals and plants from pest- or disease-related risks.

In the case of food safety, for example, the SPS Agreement applies to risks deriving from additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs. It is clear from the above that in order to determine whether a measure falls under the SPS Agreement or under other WTO disciplines, such as the Agreement on Technical Barriers to Trade (TBT) or the General Agreement on Tariffs and Trade (GATT), the basic criterion is the purpose for which the measure is put in place. Measures which address health risks other than those mentioned above (such as a ban on asbestos products) or which are aimed at other policy objectives are not SPS measures. The distinction is significant, since the legal disciplines of the SPS Agreement are substantially different from, and in part stricter than, those applying to technical standards and regulations under the TBT Agreement or generally

Under GATT. Typical policy instruments used to achieve SPS protection are import bans, technical specifications, including process and product standards, and information tools, including labelling requirements. Process standards are the most commonly used SPS measures.
The SPS Agreement sets out both substantive and procedural requirements with the aim of
Preventing food safety and animal and plant health regulations from unnecessarily hindering
International trade and from being misused for protectionist purposes.

5.3. Basic Rights and Obligations

The basic rights and obligations provided under the SPS Agreement assure sovereignty but not to the point of discrimination. SPS measures must be applied consistently and cannot be used to discriminate among trading partners or create unnecessary barriers to trade. The following paragraphs address basic substantive provisions of the SPS Agreement. While the Agreement recognises the right of each Member to adopt SPS measures for the protection of human, animal or plant life or health, based on the level of risk each Member deems appropriate, it tries to ensure that these measures are not used for protectionist purpose. It does so by imposing a number of obligations, including:

A. The obligation that any SPS measure must be based on scientific principles and not be maintained without sufficient scientific evidence;
B. The obligation to base SPS measures either on a relevant international standard or on a scientific assessment of the risk;
C. The obligation to apply regulations only to the extent necessary to protect human, animal or plant life or health; and
D. The obligation not to arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.

Other substantive provisions of the Agreement, such as those on recognition of equivalence and regionalization are discussed below.

5.4. Harmonization

One of the main objectives of the SPS Agreement is to further the widest possible use of harmonized measures based on internationally agreed standards so as to minimize the measures' negative impact on international trade. So, the SPS Agreement encourages governments to use international standards, guidelines, and recommendations developed by other WTO Members and international organizations. This is called harmonization. The goal of harmonization is to promote consistency in the application of measures among WTO Members. The SPS Agreement references three standard-setting bodies: the Codex Alimentarius Commission, the World Organisation for Animal Health and the International Plant Protection Convention, so-called "three sister organizations" (figure 10). Members are not obliged to

harmonize their SPS standards. International standards, guidelines and recommendations are, by their very nature, non-binding norms. However, through their explicit recognition in the SPS Agreement, such norms do indeed, acquire a certain force, most importantly, by creating a presumption of WTO/SPS compatibility.

Figure 10: The three SPS standard-setting bodies

5.5. Risk Assessment Obligations

The SPS Agreement allows countries to give food safety and animal and plant health priority over trade, provided there is a demonstrable scientific basis for safety and health requirements. SPS measures must be based on risk. Risk is assessed by collecting and analysing biological and economic information. The application of measures must be based on an assessment of risk. Techniques used to assess risk should take into consideration methods developed by international standard setting organizations (IPPC, OIE, Codex, and WTO). Members are required to ensure that their SPS measures are based on a scientific assessment of the risks involved to human, animal and plant health or life, taking into account risk assessment techniques developed by relevant international organizations. The SPS Agreement encourages both importing and exporting countries to participate in risk assessment. The exporting country should provide relevant information about pest presence, pest distribution, production practices, and inspections. The importing country must justify the application of measures when they are not based on a standard. However, if a provisional measure is used, the importing country is required to provide all proof to support the provisional measures within a reasonable period of time.

Risk Assessment should take into account:

- Available scientific evidence; Scientific evidence does not need to come from peer-reviewed journals, although the reliability of evidence is a very important consideration.
- relevant processes and production methods;
- inspection/sampling/testing methods;
- prevalence of specific diseases or pests;
- existence of pest/disease free areas;
- ecological/environmental conditions;
- Quarantine or other treatment.

Risk assessment for animal and plant life or health should take into account economic factors such as:

- Cost of control or eradication;
- Potential damage or loss of production/sale:
- Cost effectiveness of alternative approaches.

Factors to take into account in a risk analysis

According to the WTO dispute settlement system, risk should include the three steps listed below:

1. Identify the disease whose entry, establishment or spread a member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;
2. Evaluate the likelihood of entry, establishment or spread of this disease, as well as the associated potential biological and economic consequences;
3. Evaluate the likelihood of entry, establishment or spread of this disease according to the SPS measures that might be applied.

5.6. Setting the Appropriate Level of Protection

Under the SPS Agreement, whereas the choice of an appropriate level of protection is regarded as an autonomous right of each Member, the design and adoption of an SPS measure must be based on science, and the applicable disciplines dealing with the process of scientific assessment of the risks are rather strict. Every country has the right to choose the level of protection that is best suited to its needs. This is referred to as an Appropriate Level of Protection (ALOP). That level of protection, however, must be technically justified and applied consistently across Members. Each country has the right to determine what level of food safety, animal and plant health it considers appropriate, based on assessment of the risks involved. Once a country has decided on its acceptable level of risk, there are often a member of alternative measures that may be used to achieve this protection (such as treatment,

quarantine, or increased inspection). In choosing among such alternatives, the SPS agreement requires that a government use those measures that are not more trade restrictive than required to achieve its health protection objectives, if these measures are technically and economically feasible. For example, although a ban on imports could be one way to reduce the risk to the level considered acceptable by the government, this would normally be less trade restrictive requirement.

5.7. Regionalization

Article 6.1 requires members to ensure that their measures are adapted to the SPS conditions of the area from which the product originated and to which the product is destined. Concept of regionalization is stipulated in the international standards such as WTO SPS agreement and OIE codes. Since it is not necessarily appropriate to adopt the same measures to all agricultural products originated from various countries in related to climate, pests or diseases, SPS Agreement provides Member Countries shall adapt their SPS measures to the situations. To implement regionalization, a risk assessment is carried out in accordance with the standard procedure. Regionalization is particularly important for developing countries, especially large developing countries, where conditions vary substantially from region to region. Regional designations of pest/disease presence or absence zones can be used to promote phytosanitary security and facilitate trade can facilitate trade while maintaining low risk (see figure 11).

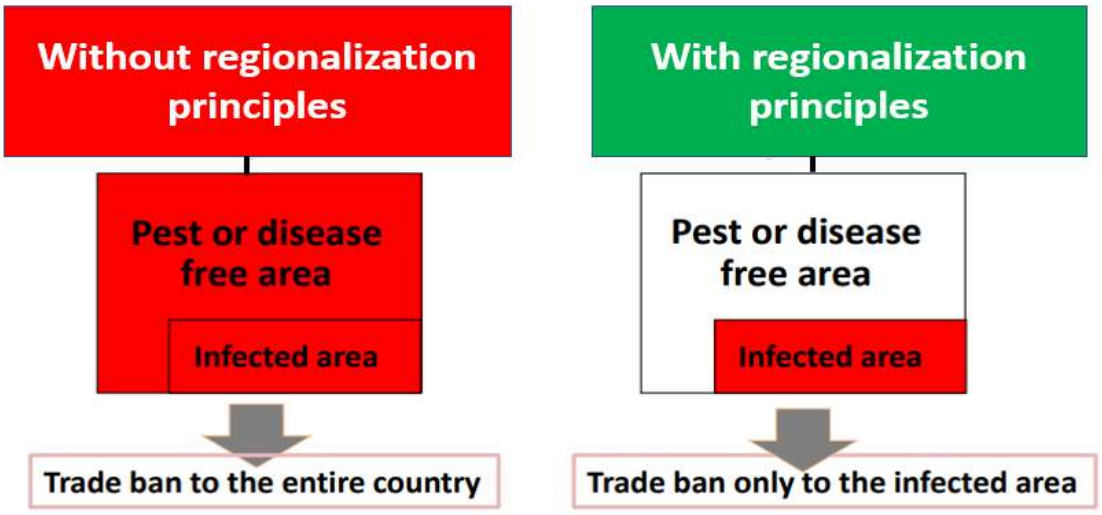


Figure 11: The difference between with and without regionalization

Adapt SPS measures to characteristics of the area (all or part of a country, all or parts of several countries) taking into account

- prevalence of diseases or pests
- existence of eradication or control programs
- criteria/guidelines developed by OIE, IPPC

5.8. Equivalence

The SPS agreement encourages member countries to accept their trading partners' different standards provided these afford a similar level of protection, through equivalence arrangements. The SPS Agreement outlines sanitary and phytosanitary measures for Member countries. However, countries have the sovereign right to choose alternative measures that sufficiently reduce the risk to the same level as an internationally approved measure. This provision provides flexibility to both regulators and trading partners by allowing several ways to achieve the same level of protection. The use of alternative measures does carry restrictions, and Article 4 of the SPS Agreement defines the principles of equivalence. It states that Members shall accept the sanitary and phytosanitary measures of other Members as equivalent, even when these measures differ from their own or from those of other Members trading in the same products, if the exporting country objectively demonstrates to the importing country that its measures achieve the importing country's appropriate level of sanitary and phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

5.9. Transparency Obligations

The correct implementation of transparency and notification obligations is vital for the purpose of facilitating market access and achieving the other objectives of the SPS Agreement. Transparency is a core principle in the WTO. According to Article 7 of the SPS Agreement, members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures. Open communication is especially important when communicating new rules or asking questions about existing policies. Transparency provisions ensure that SPS measures are made known to all potentially interested parties, from the general public to trading partners. In addition to promptly publishing new or altered requirements, countries are responsible for providing an explanation of their reasons for establishing specific SPS measures if requested by another country. In addition to promptly publishing new or altered requirements, countries are responsible for providing an explanation of their reasons for establishing specific SPS measures if requested by another country.

5.10. Dispute Settlement

When trading partners do not agree on the interpretation or application of provisions in the SPS Agreement, they may request resolution by an outside body. A dispute arises when one member government believes another member government is violating an agreement or a commitment that it has made in the WTO. Ultimate responsibility for settling disputes also lies with member governments, through the Dispute Settlement Body (DSB). The DSB is made up of all member governments, which

are usually represented by ambassadors or the equivalent. The DSB has the sole authority to establish panels of experts to consider the case and to accept or reject the finding of the panel or the results of an appeal. It monitors the implementation of the rulings and recommendations, and has the power to authorize retaliation when a country does not comply with a ruling.

The most desirable way of solving a trade dispute under the WTO is for the two parties to reach an agreed solution through bilateral discussions on the issue. Such discussions may be given a more formal character if the complaining party decides to request the other party to enter into official consultations. Once this first stage is reached, WTO rules ensure that the complaining party, if not satisfied with the outcome of the consultations after a certain period of time, has the right, if it so desires, to obtain the establishment of a panel of experts to rule on the issue. The panel's findings may be appealed by either side and, in this case, the final conclusions will be those contained in the report of the Appellate Body. The final report (of the panel, as amended by the Appellate Body) is then adopted by the WTO Dispute Settlement Body (DSB) by "reverse consensus". If the report concludes that the measure at stake violates one or more WTO provisions, the classic recommendation is for the losing defendant party to bring its measure into conformity with its obligations under the relevant WTO agreements. Prompt compliance with the rulings is expected. Should this not materialize within a reasonable period of time, the disputing parties may agree to determine a mutually acceptable compensation (such as tariff reductions in an area of interest to the complaining side). If the parties fail to agree, then the complaining party may request authorization from the DSB to retaliate by suspending concessions or obligations.

5.11. Benefits of the SPS Agreement

How do countries benefit from the SPS Agreement? The transparency provisions in the SPS Agreement are designed to ensure that measures are made known to both domestic and international stakeholders. Because new requirements must be published promptly, and other Members can request an explanation of the reasons for new requirements, trading partners experience much less uncertainty than they would in the absence of such rules. Uncertainty can arise when requirements are not transparent, are not based on risk or scientific evidence, or are applied in a discriminatory manner. By providing risk assessment guidance and a formal means through which disputes can be resolved, the SPS Agreement encourages Members to base requirements on science and to apply them consistently among all trading partners. Trading relationships are more stable when uncertainty is removed, and economic prosperity is more likely in a stable relationship. For this reason, the entire international agricultural community benefits when all countries adhere to the SPS Agreement.

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