GUIDELINE FOR IMPORT RISK ANALYSIS –
A BASIS FOR BIOSECURITY RISK MANAGEMENT IN BHUTAN

Bhutan Food and Drug Authority (BFDA)

Ministry of Health

2024

Adapted from Handbook on Import Risk Analysis for Animals and Animal products

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Foreword

The Import Risk Analysis Guidelines for Import of Animal and Animal Products delineates the procedures for conducting Import Risk Analysis by the Bhutan Food and Drug Authority (BFDA) and related agencies. This process is pivotal for informed biosecurity decision-making in line with the Biosecurity Policy of the Kingdom of Bhutan 2010, the Livestock Act of Bhutan 2001, and the Livestock Rules and Regulation of Bhutan, 2017. Additionally, it complies with the World Trade Organization's (WTO) SPS agreement and standards set by the World Organization for Animal Health (WOAH), incorporating other relevant Bhutanese biosecurity legislations.

The guideline presents a structured method for import risk analysis consistent with the obligation of the WTO SPS Agreement, and WOAH standards, offering practical guidance to BFDA and concerned agencies. Implementation of the guideline will ensure stakeholders, risk analysts, and decision-makers confidently identify and manage disease risks, maintaining an appropriate level of protection (ALOP). Moreover, it serves as a valuable training resource to enhance capacity in this field.

This guideline is a dynamic document and amendments will be made to it as and when deemed necessary. Any major review of the guidelines shall involve consultations of all relevant stakeholders.

Director
Bhutan Food and Drug Authority
Ministry of Health

Abbreviations used

ALOP	Appropriate Level of Protection
BFDA	Bhutan Food and Drug Authority
DoL	Department of Livestock
IRA	Import Risk Analysis
MoAL	Ministry of Agriculture and Livestock
MoH	Ministry of Health
PABD	Plant and Animal Biosecurity Division
SPS	Sanitary and Phytosanitary
TAG	Technical Advisory Group
WOAH	World Organization for Animal Health
WTO	World Trade organization

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Import Risk Analysis Guidelines for Import of Live Animals and Animal Products into Bhutan

1. Introduction

Bhutan's agricultural sector engages around 80% of its population primarily in integrated agricultural farming systems, mostly incorporating subsistence-level crop and animal husbandry. Given Bhutan's dependence on imports, particularly of livestock and its products, ensuring an effective biosecurity system is of paramount importance to safeguard the health of human, animal and environment, and to protect our domestic production. Furthermore, having an effective biosecurity is crucial for gaining access to international markets.

The Biosecurity Policy of the Kingdom of Bhutan 2010, designates Bhutan Food and Drug Authority (BFDA) of the Ministry of Health (MoH) as the competent authority to safeguard Bhutan's Biosecurity. Biosecurity can contribute significantly in protecting animals, people and agricultural production systems from pests and diseases, and facilitating trade thereby boosting the economy of the country. The Sanitary and Phytosanitary (SPS) agreement of the World Trade Organization (WTO) mandates member countries the options in setting sanitary measures to protect against such risks. The SPS Agreement strongly encourages members to base their sanitary measures on international standards such as the Terrestrial Animal Health Code and Aquatic Animal Health Code of the World Organization for Animal Health (WOAH). However, when such standards do not achieve one's acceptable level of risk, science-based risk analysis is indispensable to determine whether the importation of a particular commodity poses a significant risk to human or animal health, and accordingly formulate mitigation measures to reduce that risk to an acceptable level. BFDA undertakes a range of risk analysis in response to requests to import animal, animal products and animal related items into Bhutan, where those goods have not been imported before, or have not been imported into Bhutan from a particular country or region. Risk analysis considers the level of biosecurity risk that may be associated with the importation of animal, animal products and animal related items.

It identifies appropriate ways to manage these risks. Bhutan's unique geographical location and biodiversity necessitate a comprehensive approach to biosecurity. This includes stringent measures to prevent the introduction and spread of diseases that could harm human and animal health, and the environmental health including Bhutan's diverse ecosystems and agricultural productivity. Adherence to the stringent biosecurity measures, BFDA is authorized to implement IRA guidelines. This guideline will be a guiding tool intended to provide decision makers with an objective, repeatable and documented assessment of the risks posed by importation of animal, animal products and animal related items. In this regard, the principal aim of the IRA guideline is to provide BFDA and the technical department with an objective and defensible method of assessing the disease risks associated with the importation of animals and their products. All biosecurity risk analysis shall be coordinated by BFDA in collaboration with the technical department.

2. Purpose

- Provide an overall guide in-conducting risk analysis (hazard identification, risk assessment, risk management and risk communication) to BFDA, technical department, and the technical group conducting the import risk analysis (IRA).
- Guide decision makers in adopting appropriate risk mitigation measures, and communicate the findings to interested parties.
- Outline responsibilities for different stakeholders engaged in the risk analysis.

3. Scope

This guideline is designed to guide risk analysts in undertaking the IRA for import of;

- Live animals
- Animal products, and
- Animal related items

into Bhutan. The guideline does not cover conducting IRA for import of pharmaceutical, plant and food products, and the scope included in Biodiversity Act of Bhutan 2003.

4. Import Risk Analysis (IRA)

4.1 Framework for IRA

An IRA framework is a systematic process used to assess the risks associated with importing live animals, animal products and animal related items (referred hereinafter as "high risk goods") to ensure they do not pose a threat to human, or animal health. This process is integral to implementing the agreement on application of SPS measures under the WTO. The IRA guideline will use its structured approach in managing the risk of diseases and pests involving SPS measures applied along the biosecurity continuum (prevention, preparedness, surveillance, and containment) for import of the above mentioned high risk goods.

An IRA will be undertaken when:

- People or organizations submit IRA request forms for import of high risk goods mentioned above where relevant risk management measures have not been established.
- A commodity for which risk management is well established but the likelihood and/or consequences of entry, establishment or spread of the hazard differ significantly from those previously assessed.
- Possible introduction of a new system, process, procedures or new information that could influence a previous decision
- The change in the biosecurity situation in the country or in the exporting country.

An IRA may not be required if the importer abides by the conditions prescribed in the Terrestrial Animal Health Code of WOAH for import of high risk goods, and meets the established appropriate level of protection (ALOP).

The framework typically includes the following steps:

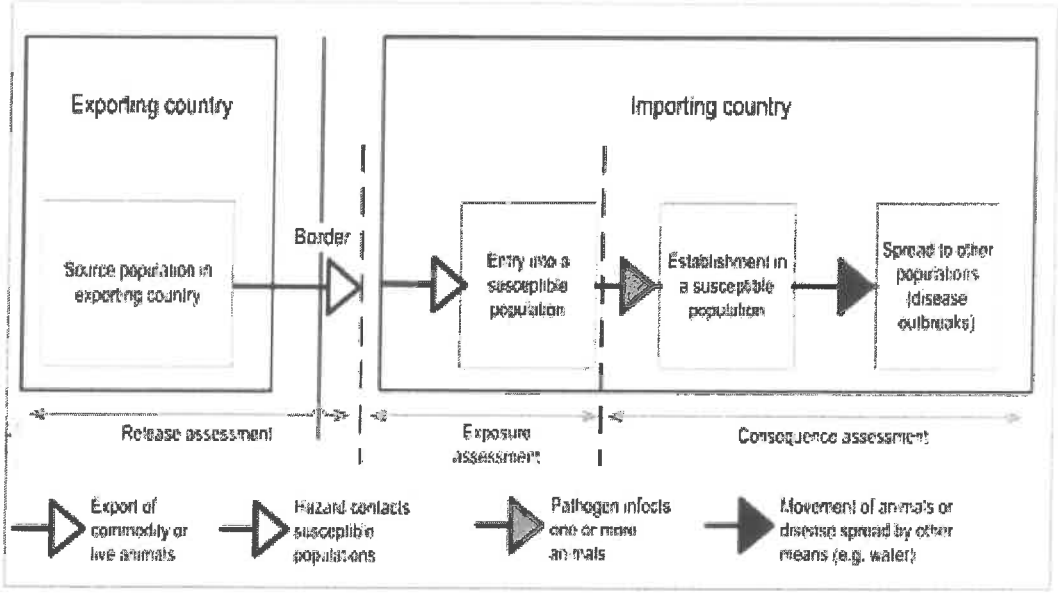
4.1.1 Hazard Identification

Identify potential hazards associated with the import of high risk goods. Hazards could be biological (e.g., pests, pathogens), chemical (e.g antimicrobial), or physical (e.g., contaminants).

4.1.2 Risk Assessment

Risk assessment consists of three steps.

a. *Release assessment* - to evaluate the likelihood of the hazard entering the country via the imported high risk goods.
b. *Exposure assessment* - to determine the likelihood of the hazard establishing and spreading within the country.
c. *Consequence assessment* - to assess the potential impact of the hazard on human health, animal health, and the environment.



4.1.3 Risk Management

Measures should be developed for implementation to manage and mitigate identified risks. The measures might include:

a. Quarantine procedures
b. Treatment requirements
c. Inspection and sampling protocols
d. Import bans or restrictions

4.1.4 Risk Communication

Communicate risk assessment findings and risk management decisions to stakeholders, including importers, exporters, regulatory authorities, and the public. It is also to ensure transparency and provide opportunities for stakeholder input.

4.1.5 Review and Monitoring

Regularly review and update risk assessments and management measures based on new scientific evidence, changes in trade patterns, or the emergence of new hazards. Continuously monitor the effectiveness of risk management measures and adjust as necessary.

4.2 Import Risk Analysis Process

Each type of IRA has a unique set of circumstances and requirements. While the overarching risk analysis methodology follows international principles, the specific methodology may vary between IRAs so that it is appropriate to the circumstances. Each IRA report will detail the technical methodology used to conduct the analysis.

The IRA process evaluates the likelihood of the entry, establishment or spread of a disease or pest and the magnitude of potential consequences in a defined area, using biological or other scientific and economic evidence.

The following provides a step wise approach to conduct an IRA.

4.2.1 Determining the scope of the risk analysis

Determining the scope of the risk analysis requires that the high risk goods that are subject to the risk analysis be defined as precisely as possible. This includes;

- the nature, source country, and intended use of the risk goods;
- methods of production, manufacturing, processing, or testing that are normally applied including quality assurance programs; and then
- draft a suitable title for the risk analysis.

4.2.2 Stating the purpose of the risk analysis clearly

Once the scope of the risk analysis is determined, clearly stating its purpose is crucial. This ensures that both the analysts and stakeholders understand its objectives and the nature of the risk being assessed. This clarity often requires interactive discussions with those requesting the analysis. If the purpose is vague, problems can arise, such as dissatisfaction due to the analysis not adequately addressing the full risk continuum or estimating the potential consequences of a hazard spreading or becoming established.

4.2.3 Developing the risk communication strategy

Risk communication is the process by which information and opinions regarding hazards and risks are gathered from stakeholders 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 stakeholders 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. A risk communication strategy should:

- identify stakeholders,
- determine when it is necessary to communicate with them,
- determine the appropriate means of communication.

4.2.4 Identifying the sources of information for the risk analysis

Information to assist in identifying hazards, assessing risks and exploring risk management options can be found in a variety of sources, including the WOAH website and other sites devoted to diseases of livestock, aquatic animals, and wildlife, as well as scientific journals, textbooks and import risk

analyses undertaken in other countries. Assistance and advice can also be sought from subject matter specialists. Data on historical trade may provide valuable insights into whether or not imports of a particular commodity are likely to pose a risk of introducing specific diseases. In those situations where information is scarce or lacking, a subjective approach utilizing expert opinion may be needed.

4.2.5 Identification of hazard likely to be associated with the risk goods under consideration

Hazard identification involves identifying the pathogenic agents that could potentially produce adverse consequences associated with the importation of high risk goods. The 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 necessary to identify whether each hazard is already present in the importing country, and whether it is a notifiable disease or is subjected to control or elimination or eradication in the importing country, and to ensure that import measures are not more trade restrictive than those applied in the country. Further, the evaluation of the animal health services, surveillance and control program, and zoning and compartmentalization systems are important inputs for assessing the likelihood of hazards being present in the animal population of the exporting country.

Hazard identification begins with the development of a list of pathogenic agents that are appropriate to the species being imported, or from which the commodity is derived. The WOAH list of diseases should be used as a starting point when developing these lists, but pathogens not included in the WOAH list should also be considered, where appropriate. Each pathogenic agent should be dealt with separately, with a reasoned, logical and referenced discussion of its relevant epidemiology, including an assessment of its likely presence in both the importing and exporting countries. A conclusion is then reached on whether or not the commodity under consideration is a potential vehicle for the introduction of the pathogenic agent into the importing country. If it is, the pathogenic agent is classified as a hazard for further consideration. If no hazard is identified, the risk analysis can be concluded at this point.

A number of important questions and steps, as outlined in *Annexure I*, must be considered when determining whether or not a pathogenic agent can be identified as a hazard (also refer figure 1 below). When preparing a list of hazards, the template in Table I, which includes some examples, can be used to provide a useful summary. The latest taxonomy and nomenclature should be used.

Table 1: An example of a list of hazards

Common name	Scientific name	Exotic	Free compartments, or official control programmes	More virulent strains in other countries	Identified as a hazard
Foot and mouth	Family *Picornividae*, genus *Apthovirus*, FMD virus A, Asia 1, C, O, SAT 1, SAT 2, SAT 3	Yes	n/a	n/a	Yes
Bovine tuberculosis	*Mycobacterium bovis*	No	Yes	No	Yes

Note: Bhutan may decide to permit the importation using the appropriate SPS measures recommended in the WOAH Terrestrial Animal Health Code, thus eliminating the need for a risk assessment.

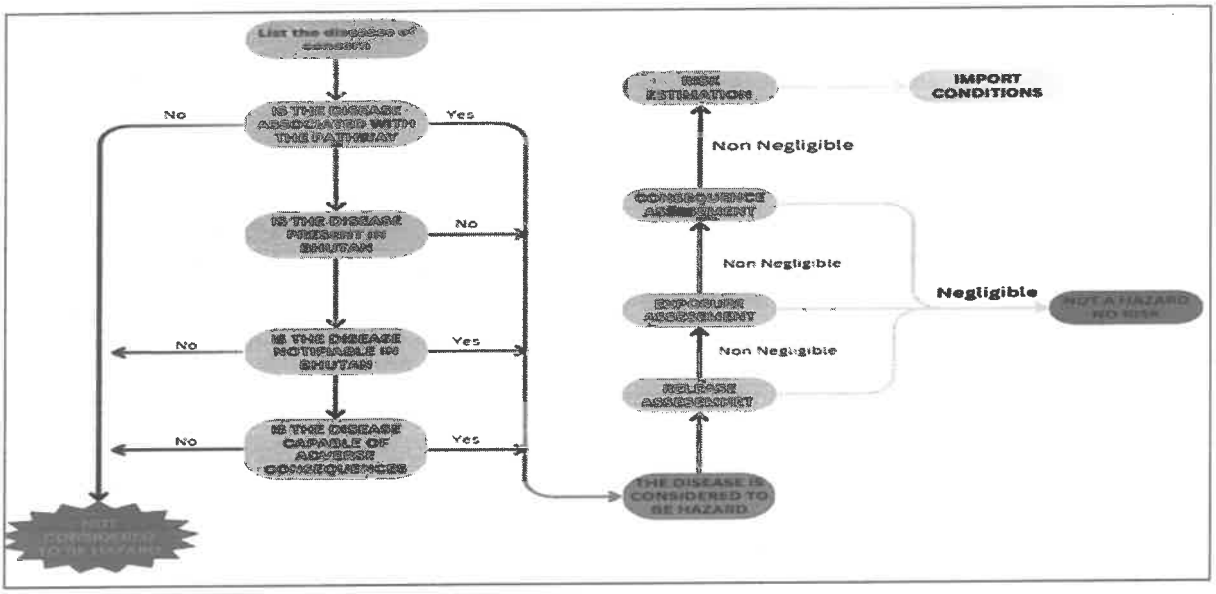


Figure 1: Flowchart used to identify hazards

4.2.6 Determine whether or not the WOHA Code recommends sanitary measures for the hazards in the risk goods under consideration

It is important to determine whether the WOAH Code provides sanitary measures for any of the hazards that have been identified in the commodity under consideration. If it does, these measures should be applied, unless domestic legislation, policy or other considerations require a complete risk analysis to be undertaken.

In the situation where measures are not prescribed by the code or it is decided to adopt a higher level of protection than that provided for in the code, a risk analysis will need to be undertaken to either determine the need for and type or measures, or to justify the imposition of measures that result in a higher level of protection.

4.2.7 Conducting risk assessment for each hazard

A risk assessment evaluates the likelihood and the biological, environmental and economic consequences of the entry, establishment or spread of a hazard within the importing country. The commodity under consideration, which may act as a vehicle for the hazard, must be evaluated in the form in which it is intended to be used, processed or sold when imported.

4.2.7.1 Identify the populations of interest

Once the hazards associated with the commodity under consideration have been determined, potentially susceptible species need to be identified. This will ensure that all the appropriate biological pathways are considered in the risk assessment. Susceptible species include terrestrial and aquatic animals that are reared on farms or in captivity, or are in the wild, as well as humans if the hazard has zoonotic potential.

4.2.7.2 Draw a scenario tree for each hazard

Prior to embarking on the risk assessment itself, it can be helpful to draw a scenario tree for each hazard under consideration to facilitate the identification of the various risk pathways leading to:

- the commodity harbouring the hazard when imported,
- susceptible animals and/or humans being exposed,
- potential outbreak scenarios.

A scenario tree assists in conveying the range and types of pathways considered in a simple, transparent and meaningful fashion. Scenario trees are an appropriate and effective way of depicting risk pathways. They provide a useful visual representation to:

- identify pathways,
- identify information requirements,
- ensure a logical chain of events in space and time,
- assist with communicating the import risk analysis,
- clarify ideas and understanding of the problem,
- assist with identifying sanitary measures and risk management in general,
- assist with determining the likelihood of occurrence and subsequent consequences,
- provide a framework for the later development of a quantitative model, should this be required.

A scenario tree starts with an initial event, for example selecting some animals from a herd that is potentially infected. It then outlines the various risk pathways leading to:

- the animals or animal products harbouring the hazard when imported (release/entry assessment),
- susceptible animals and/or humans being exposed to the hazard (exposure assessment).

4.2.7.3 Dealing with uncertainty and variability

It is important to distinguish between uncertainty and variability in the context of an animal health import risk analysis. Uncertainty is used to reflect a lack of understanding or incompleteness of knowledge or information about a particular thing. Variability, on the other hand, reflects the heterogeneity that naturally exists within any biological system, whether we have a good understanding of that system or not. So while uncertainty is reduced as knowledge increases, variability remains the same. In most, if not all situations, it is likely that the varying degrees of uncertainty that exist at different points in the risk pathway will be of more concern than variability. How then can we determine the impact of these uncertainties on the final risk estimate? Fortunately, risk analysis provides us with a tool that enables the inevitable uncertainties to be considered in context. For example, it could turn out that, while considerable uncertainty exists at one point in the risk pathway, its overall contribution to the final risk estimate is inconsequential. In such circumstances it is important not to over-emphasize the uncertainty but to provide appropriate perspective.

4.2.7.4 Qualitative risk assessment

No single method of import risk analysis has proven applicable in all situations, and different methods may be appropriate in different circumstances. A qualitative assessment is essentially a reasoned and logical discussion of the relevant commodity, epidemiological and economic factors associated with a hazard, in which the likelihood of its release and exposure, and the magnitude of its consequences, are expressed using non-numerical terms such as high, medium, low or negligible. It is however essential that there is consensus amongst risk assessors and risk managers on the use and meaning of these or any other non-numerical terms used.

A scenario tree may be used to depict the relevant factors and assist with the understanding of the logic. The qualitative approach is suitable for majority of import risk analyses, and is the most common type of assessment undertaken to support routine import decision making.

In some circumstances it may be desirable to undertake a quantitative analysis. However, for the import risk analysis of import of high risk goods into Bhutan, qualitative approach would be adopted, unless otherwise deemed necessary by the Technical Advisory Group.

4.2.7.5 Release/Entry assessment

An entry assessment estimates the likelihood of an imported high risk goods being infected or contaminated with a hazard. It also describes the risk pathways necessary for that hazard to be introduced into the country. For each step, it lists the relevant risk, country or commodity factors considered. Each hazard should be dealt with separately, with a reasoned, logical and referenced discussion of its relevant epidemiology to:

- describe the risk pathways necessary for the high risk goods to become infected or contaminated. A scenario tree provides a useful conceptual framework to assist in identifying and describing pathways.
- estimate the likelihood of the high risk goods being infected or contaminated when imported.

The risk assessment may be concluded at this point if there is a negligible likelihood of the commodity being infected or contaminated with the hazard when imported.

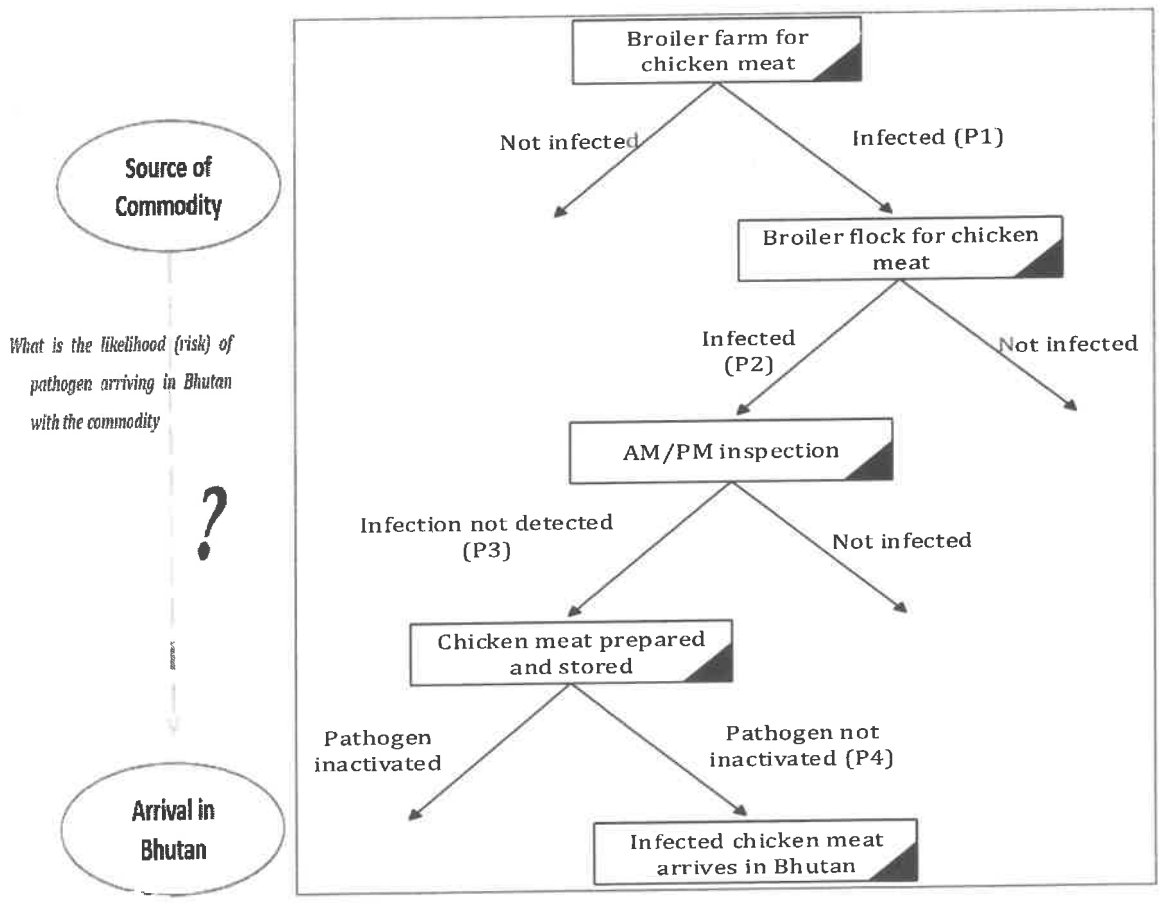


Figure 2: Release assessment (E.g. Risk of Avian Influenza for chicken meat import from Bangladesh)

There are a number of important factors that must be considered in the entry assessment. These include, but are not limited to, the following.

Biological factors

- Susceptibility to the hazard of animals from which the commodity is derived:
- Species and breed
- Age
- Sex
- Means of transmission of the hazard:
  - horizontal transmission
  - direct (animal to animal contact, airborne spread, ingestion, coitus)
  - indirect (mechanical and biological vectors, intermediate hosts, iatrogenic transmission, fomites)
  - vertical transmission
- Infectivity, virulence and stability of the hazard
- Routes of infection (oral, respiratory, percutaneous, etc.)
- Predilection sites of the hazard (for example, muscle, bone, nerve tissue, lymph node etc.)
- Outcome of infection (sterile immunity, incubatory or convalescent carrier, latent infection)
- The impact of vaccination, testing, treatment and quarantine.

Country factors

- Evaluation of the exporting country's Veterinary Service, surveillance, eradication and control programmes, and zoning systems
- Incidence and/or prevalence of disease
- Existence of disease-free areas and areas of low disease prevalence
- Animal demographics
- Farming and husbandry practices
- Geographical and environmental characteristics including rainfall and temperature.

Commodity (high risk goods) factors

- Ease of contamination
- Relevant processes and production methods
- Effect of processing, storage and transport
- Quantity of commodity to be imported.

4.2.7.6 Exposure assessment

Exposure to a pathogenic agent, and the issue of whether or not a susceptible host becomes infected, are two different steps. Exposure is necessary before for infection to occur. However, exposure does not necessarily result in infection. Whether it does so depends on both the dose of pathogen and the degree of susceptibility of the host. This relationship is commonly called as dose response. Infection is a consequence of exposure.

In import risk analysis, primary infection has often been coupled with exposure and evaluated as a part of the exposure assessment. Nevertheless, it should be appreciated that, particularly with contaminated high risk goods, a dose–response effect is likely to play a crucial role in the probability of successful infection. In such cases, it is necessary to separate the two stages, exposure and infection, and assess the probabilities individually.

Each hazard should be dealt with separately, with a reasoned, logical and referenced discussion of its relevant epidemiology, to:

- describe the risk pathways necessary for exposure of animals and humans in the importing country. A scenario tree would provide a conceptual framework to assist in identifying and describing pathways.
- estimate the likelihood of these exposures occurring
- estimate the likely dissemination of the hazard and the population exposed.

The risk assessment may be concluded at this point if the likelihood of exposure is negligible.

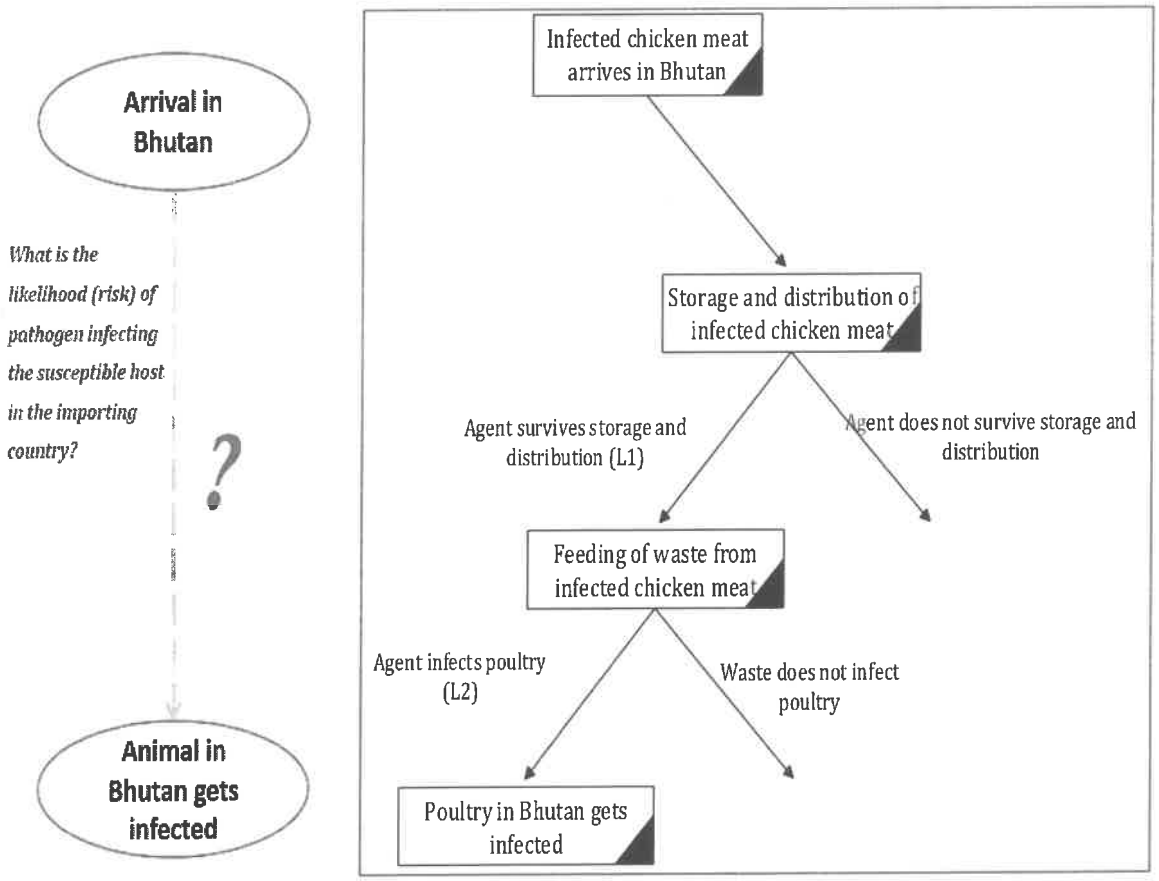


Figure 3: Exposure assessment (E.g. Risk of Avian Influenza for chicken meat import from Bangladesh)

There are a number of factors that might be relevant when considering the exposure assessment. These include, but are not limited to, the following.

Biological factors

- Means of exposure to the hazard:
  - horizontal exposure (direct through animal to animal contact, airborne spread, ingestion, or coitus, or indirect via for example mechanical and biological vectors, intermediate hosts, iatrogenic exposure, fomites)
  - vertical exposure during the perinatal period
- Stability, infectivity and virulence of the hazard
- Route of exposure (oral, respiratory, percutaneous)
- Susceptibility of animals likely to be exposed to the hazard (species, age, sex).

Country factors

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

Commodity (high risk goods) factors

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

4.2.7.7 Consequence assessment

A consequence assessment is assessing the consequences of a given exposure to a hazard, and estimates the probability of their occurring. The first consequence of interest is successful infection of at least one animal and/or human.

The consequences to animals, people, the environment and the economy may be direct and indirect, and the probability of a particular outcome will be determined by factors associated with establishment and spread of the disease, assuming exposure of susceptible animals.

When accounting 'relevant economic factors' to consequence assessment, 'direct' and 'indirect' effects of a disease have to be differentiated, and where possible provide examples of factors that will typically be relevant to an import risk analysis. These consequences may be taken into account only to the extent that they are directly or indirectly attributable to the hazard.

Each hazard should be dealt with separately, with a reasoned, logical and referenced discussion to:

- estimate the likelihood that at least one animal will become infected;
- identify the biological, environmental and economic consequences associated with the entry, establishment or spread of the hazard, and their likely magnitude; and
- estimate the likelihood of the occurrence of these consequences.

It is important to note that a causal relationship must exist between exposure to a hazard and an adverse effect. The risk analysis may be concluded at this point if either no consequences are identified or the likelihood for each of the consequences identified is negligible.

A number of factors may be attributable to the hazard. These include:

Direct consequences

- Outcome of exposure in domestic and wild animals and their populations:
  - biological (morbidity and mortality, sterile immunity, incubatory or convalescent carriers, latent infection)
  - production losses
- Public health consequences
- Environmental consequences:
  - physical environment, such as side-effects of control measures
  - impacts on other life forms, biodiversity, endangered species.

Indirect consequences

- Economic considerations:
  - control and eradication costs
  - compensation
  - surveillance and monitoring costs
  - costs of enhanced biosecurity services
  - domestic effects (changes in consumer demand, effects on related industries)
  - trade losses (embargoes, sanctions, market opportunities)
- Environmental:
  - reduced tourism and loss of social amenity.

In order to evaluate the likely magnitude of the consequences, and the likelihood that they will occur at any given magnitude, the risk analyst may identify and describe a small number of 'outbreak scenarios'. The relative likelihood of each of these occurring can then be estimated, along with the likely magnitude of the consequences in each case. For example, in the case of imported live animals, outbreak scenarios might include:

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

Direct and indirect consequences may be estimated at four levels: farm/village, dzongkhag, regional and national. In a qualitative risk analysis, the impact at each level can be described in terms such as *negligible, moderate, significant* or *severe*. When considering the consequences of a disease outbreak, the risk analyst may need to consider the persistence of its effects.

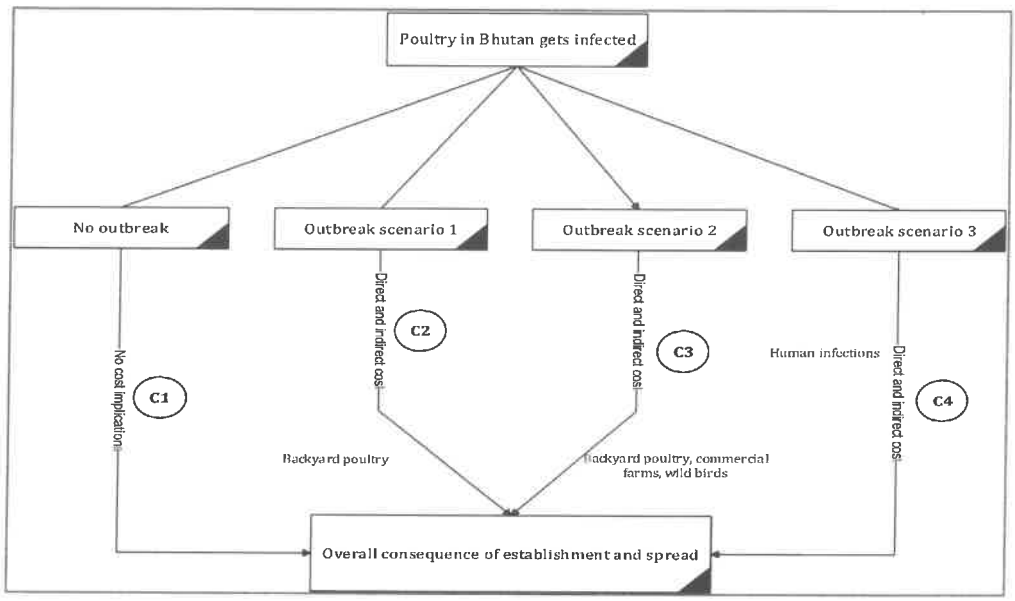


Figure 4: Consequence assessment (E.g. Avian Influenza for chicken meat import from Bangladesh)

4.2.7.8 Risk estimation

Each hazard should be dealt with individually, summarizing the results and/or conclusions arising from the entry, exposure, and consequence assessments to estimate the likelihood of the hazard entering the importing country, becoming established or spreading, and resulting in adverse consequences. It is not sufficient to conclude that there is a possibility of entry, establishment or spread, or that there might be consequences. An evaluation of the likelihood of each of these factors must be undertaken. The decision steps outlined below can be followed to ensure the risk estimate is transparent. If the risk is not estimated to be negligible, the application of sanitary measures may be justified. It is important to remember that risk analyses are all subjective to varying degrees, and the conclusion that a risk is negligible is also the assessor's subjective judgment.

A. Risk estimation decision steps

A1. Entry assessment (likelihood of entry)

Is the likelihood negligible that the high risk good is carrying the hazard when it is imported?

a) If the answer is YES, the risk estimate is classified as negligible;
b) If the answer is NO, then conduct an exposure assessment.

A2. Exposure assessment (likelihood of susceptible animals and/or humans becoming exposed)

Is the likelihood negligible of susceptible animals and/or humans being exposed via each and every exposure pathway?

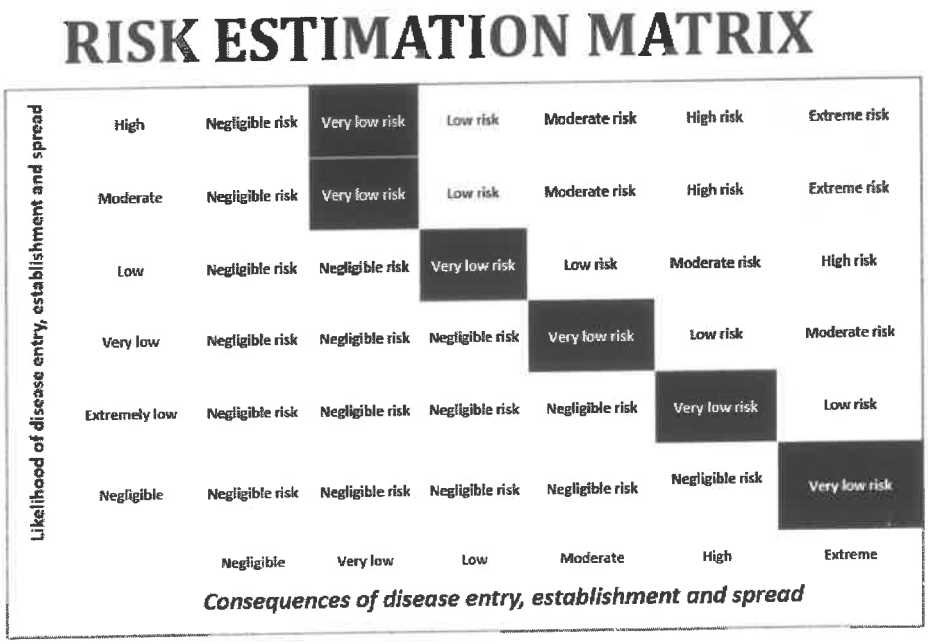
a) If the answer is YES, the risk estimate is classified as negligible;
b) If the answer is NO, then conduct a consequence assessment.

A3. Consequence assessment

Is the likelihood of each and every significant biological, environmental or economic consequence negligible?

a) If the answer is YES, the risk is estimated to be negligible;

b) If the answer is NO, then proceed to risk management.



4.2.7.9 Risk management

Risk management is the process of deciding upon and implementing sanitary measures to effectively manage the risks posed by the hazard(s) associated with the commodity under consideration. It is not acceptable merely to identify a range of measures that might reduce the risks. There must be a reasoned relationship between the measures chosen and the risk assessment, so that the results of the risk assessment support the measure(s).

Where there is significant uncertainty, a precautionary approach may be adopted. However, the measures selected must nevertheless be based on a risk assessment that takes account of the available scientific information. In these circumstances the measures should be reviewed as soon as additional information becomes available. It is not acceptable to simply conclude that, because there is significant uncertainty, measures will be based on a precautionary approach. The rationale for selecting measures must be made apparent.

Each hazard should be dealt with separately using the following framework:

a. Risk evaluation
b. Option evaluation
c. Implementation
d. Monitoring and review.

a. Risk evaluation

In the risk evaluation step, the risk estimate arising from the risk assessment is compared with the importing country's acceptable risk - Appropriate Level of Protection (ALOP). A country's ALOP is a societal or political judgment which needs to be in place before individual decisions on human and animal health risks are made. The level of risk considered acceptable may differ between countries. While there is no unique or defined level of acceptable risk applicable to all countries, it is nevertheless essential that within each country, the ALOP is applied consistently across the various risk pathways associated with the range of commodities imported from different countries and their associated hazards. This will ensure that arbitrary distinctions in the level of protection are avoided.

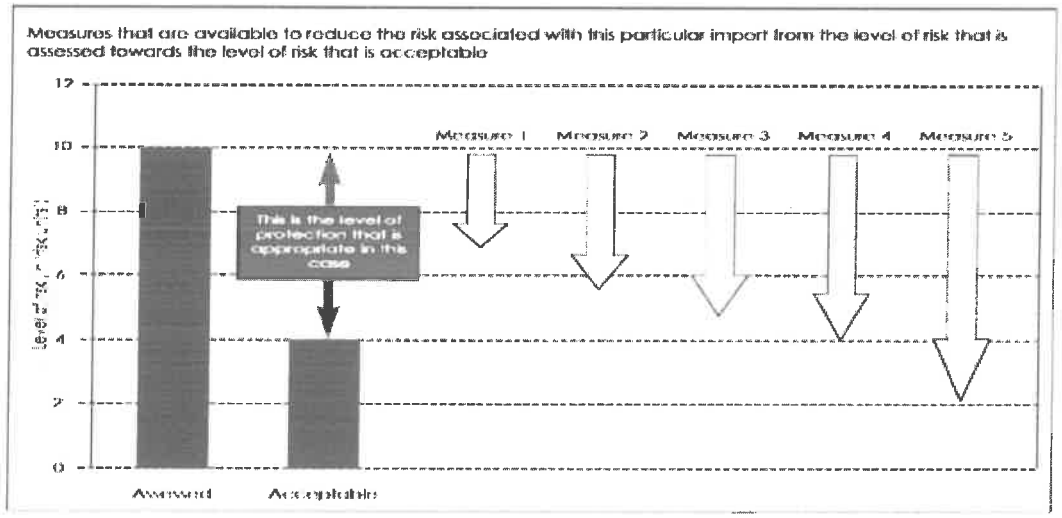


Figure 5: Diagram illustrating ALOP and the options of sanitary measures

If assessed risk is greater than the acceptable risk, sanitary measures may be justified. Acceptable risk reflects the level of risk deemed to be compatible with the dual goal of protecting animal and public health while at the same time fulfilling obligations under the SPS Agreement to minimize disruptions in international trade. Although there is no unique or defined level of acceptable risk applicable to all countries, it is nevertheless an obligation of WTO membership that within each country, it is applied consistently applied across the various risk pathways associated with the full range of imported commodities.

b. Option evaluation step

Where it has been determined in the risk evaluation step that the level of risk posed by a hazard in the high risk good under consideration is greater than the acceptable risk of the importing country, options to manage these risks effectively need to be identified and evaluated.

Where sanitary measures are considered, countries must ensure that the measures finally chosen:

- are based on a risk analysis, not simply selected arbitrarily;
- are applied only to the extent that is necessary to reasonably and effectively manage the overall risk continuum;
- are not disguised restrictions on trade;

- do not result in discrimination between an importing and exporting country, or the granting of preferential treatment to one exporting country over another, where similar conditions (disease status, control programmes, etc.) exist in the exporting countries;
- are consistently applied across a range of commodities likely to contain the same hazard to avoid situations where different levels of protection arise; and
- are technically, operationally and economically feasible

Steps to identify, evaluate and select sanitary measures to effectively manage risks

1) Identify possible options, including any sanitary measures indicated in the WOAH Terrestrial Animal Health *Codes.*
   - To assist in identifying appropriate option(s) it is necessary to formulate an objective that states what these option(s) should aim to achieve in order to manage the risks effectively.

2) Select an option or combination of options that will achieve the acceptable risk of the importing country. The following guidelines should be taken into account when selecting option(s):
   - Ensure that the Code's sanitary measures are considered.
     - if there is a scientific justification that the Code's measure(s) will not effectively achieve the acceptable risk of the importing country, measures that result in a higher level of protection may be applied. Alternatively, measures less stringent than those recommended in the Code may be applied where there is sufficient justification that the risks can be effectively managed using those measures;
   - Ensure that the option(s) are not chosen or applied arbitrarily, but that they are based on scientific principles, which are best elaborated in a risk analysis.
     - evaluate the likelihood of the entry, exposure, establishment or spread of the hazard, together with an estimate of the likely magnitude and likelihood of occurrence of biological, environmental and economic consequences according to the option(s) that might be applied;
   - Ensure that that negative effects on trade are minimized.
     - the option(s) chosen should be technically, operationally and economically feasible, and applied only to the extent necessary to protect human or animal life or health.
     - it is important to avoid situations where some parts of a risk pathway are over-managed. As a result, when deciding upon an appropriate set of sanitary measures it is necessary to consider each one from the overall perspective of the entire risk pathway, not in isolation. If the contribution of a particular measure to the overall reduction in risk is insignificant or negligible, it is effectively redundant and should not be included. Apart from not being a defensible measure, its inclusion could create unnecessary and unjustifiable technical and/or operational challenges as well as an unwarranted inflation in costs. It should be recognized that it is unlikely to be necessary to apply an sanitary measure at each and every step in the risk pathway in order to achieve the acceptable risk for an importing country.
   - Ensure that the option(s) do not result in either discrimination between an importing and exporting country, or the granting of preferential treatment to one exporting country over another, where similar conditions, such as disease status or control programmes, exist in both exporting countries.

c. Scientific peer review

Risk analysis as a discipline is based in science, and so risk analyses should be subjected to a process of peer review. Undertaking a scientific peer review of the risk analysis and the sanitary measures is to ensure that the analysis is technically robust and the measures are both appropriate to the circumstances and consistent with international obligations and that the decision makers can be sure that it will withstand criticism by stakeholders opposed to importation or in favour of unrestricted importation, as well as potential challenge under the WTO rules

To ensure the technical robustness of the analysis it should be subject to a process of:

- internal scientific review; and
- external scientific review by selected experts with specialized knowledge in risk analysis and its application to the diseases under consideration.

d. Implementation

The focus of implementation is on reaching a final decision on the sanitary measures to be adopted for the particular commodity under consideration. Once measures have been identified in the option evaluation step, consideration should be given to clearly identify who the decision maker is, and transparently documenting the rationale for any decisions made that are not based on or supported by a risk analysis. The WTO will need to be notified if the measures are not substantially the same as those in the Code and are likely to have a significant effect on international trade. Sufficient time (usually 60 days) should be allowed for comments from WTO members to be taken into account.

e. Monitoring and review of sanitary measures

Once the sanitary measures have been implemented, they will need to be monitored to ensure they are achieving the results intended. This could be achieved through an audit of the various sanitary measures and certification requirements implemented in both the exporting and importing countries. From time to time as new information becomes available or the results from the audit arise, the measures themselves or the underlying risk analysis may need to be reviewed.

The risk associated with importation of animals or animal products is dynamic. Factors that affect the previously determined risk may vary from day to day within and outside the exporting country. Most of this day-to-day fluctuation is compensated for through the risk analysis process. However, there are several factors of major importance that may have an immediate impact on the risk, and these should be monitored. In addition there are specific factors associated with each risk analysis that may need to be reviewed periodically because of their potential effect on the resultant risk estimate.

4.3 Presenting the results in a risk analysis report

4.3.1 Transparency

A transparently documented risk analysis report that provides sufficient details of the analysis, including its scope, purpose, methodology, results and the rationale for the conclusions reached and recommendations made, is an essential prerequisite for the scientific peer review process. It is also needed in order to ensure that effective communication is achieved with all affected and interested parties (in other words, stakeholders), including decision makers and trading partners. Since risk analysis is based in science, the report should be written in a style that reflects this science- based approach.

4.3.2 Information to include in the import risk analysis report

This section provides detailed guidelines that are necessary to facilitate communication of the results of the analysis. A template for an import risk analysis report is attached as *annexure II*

It is important to:

- restate the question that has been asked;
- explain the risk analysis structure clearly, with the aid of appropriate diagrams, such as a scenario tree;
- focus on information directly relevant to the logic chain of the analysis;
- document all the evidence, data and assumptions, including their references;
- use clearly labelled, uncluttered graphs, where appropriate; and
- communicate the results verbally whenever this is reasonably practicable. Verbal communication ensures a better understanding of the problem and the outcome of the risk analysis.

In the interests of transparency, the risk analysis must be well documented and supported with references to the scientific literature and other sources, including expert opinion, where used. The analysis must also provide a reasoned and logical discussion to support the conclusions and recommendations.

4.4 Risk Communication

Risk communication involves the open and transparent exchange of information about hazards and associated risks among risk assessors, managers, and stakeholders in both importing and exporting countries. It reduces risk to acceptable levels while minimizing disputes and enhancing understanding among stakeholders.

Risk communication should begin at the start of risk analysis to involve stakeholders early, and continue throughout the IRA process in both formal and informal ways. A strategy should be developed to identify stakeholders and provide them with information on the scope and preliminary hazards, enabling their input from the outset.

Key stakeholders which may include anyone with an interest in the specific IRA underway viz. the research organizations, farmers, importers, exporters and the general public should be identified, and various communication methods should be used to ensure inclusivity. Information may be disseminated through direct mail, publications, web pages, and meetings, with mechanisms for feedback. Information provision will vary according to stakeholder needs, from detailed technical dossiers to summary leaflets.

The goals of risk communication are to;

- ensure free information exchange through interactive dialogue;
- maximize risk analysis efficiency by allowing stakeholder information sharing;
- provide clear, accurate, and targeted information; and
- promote awareness, consistency, transparency, and public trust in risk management decisions.

5. Roles of the Agencies Conducting IRA in Bhutan

The institutional set up for different stakeholders is as per the arrangements detailed below;

5.1 Role of the Ministry of Health (MoH)

Secretary, MoH

- Provide administrative support to the Technical Advisory Group (TAG) wherever required.

5.1.1 Role of BFDA

a. Director

- Approving authority for co-opt members to support TAG in conducting IRA
- Endorsement to conduct IRA following the request made by the secretariat
- Implement risk mitigation measures relevant to BFDA including resource mobilization

b. Secretariat for IRA

The Plant and Animal Biosecurity Division (PABD) under BFDA will serve as the secretariat for IRA. The Chief of the PABD will be the member secretary to the TAG. The secretariat will be responsible to carry out the following functions:

- Contact point for all IRA inquiries
- Assess the need for IRA in consultation with TAG.
- Notify proponent, public and TAG on IRA needs with respect to the high risk good under consideration.
- Provide regular updates to the interested stakeholders including the proponent on the status of IRA process including the outcome of the IRA.
- Manage data, information and other documents related to the conduct of IRA.
- Communicate with authorities of the exporting country for information and data exchange.
- Follow-up on the implementation of risk management measures as recommended by TAG.
- Propose review of IRA findings, where required.
- Project and propose required resource for the conduct of IRA.
- Coordinate the meetings of TAG.

5.2 Role of the Ministry of Agriculture and Livestock (MoAL)

Secretary, MoAL

- Approval of the TAG members
- Endorsement of recommendations of IRA findings made by the TAG
- Policy directives and approval of IRA decisions for implementation of IRA findings.

5.2.1 Animal Health Division, Department of Livestock (DoL)

- Collaborate and provide technical guidance to the IRA secretariat for coordinating the conduct of IRA.
- Provide administrative or technical clearance (where required) in regard to import of high risk goods before initiation of IRA.
- Implementation of risk mitigation measures.

5.3 Technical Advisory Group and their role

The Technical advisory group will consist of the following permanent members:

- Animal health expert from DoL
- A representative each from PABD, BFDA and Animal Health Division, DoL,
- Regulatory and quarantine expert from BFDA
- Epidemiologist from the National Centre for Animal Health, DoL
- Chief, PABD, BFDA (Member secretary)

In addition to the permanent members, co-opt members shall be included in the group depending on the scope of the IRA and technical expertise that is relevant to the high risk goods for which the IRA is being initiated. There will not be a predetermined number of people who can be appointed to the group. Nominated members should have a proven record of scientific or technical expertise relevant to the IRA or evidence of a significant contribution to the science or technical methods relevant to the IRA. The chairmanship of the TAG will be elected among the permanent members for a tenure of 2 years each. The TAG will meet as and when required or at least once a year.

The roles of TAG

- Review and evaluate requests of the secretariat for conducting IRA for import of high risk goods.
- Review and assess technical documents supplied /provided to support conducting IRA.
- Conduct IRA
- Review and evaluate stakeholder feedback on the findings of the IRA, and finalize the IRA report.
- Recommend appropriate sanitary measures to mitigate the risk as per the IRA findings.
- Present the IRA findings along with the recommend appropriate sanitary measures to the Secretaries of MoH and MoAL, and the heads of DoL and BFDA, and seek endorsement of IRA findings and the sanitary measures for implementation.
- Recommend co-opt members to support TAG in conducting the IRA.

6. Conclusions

The IRA guidelines provide a comprehensive framework for assessing and managing biosecurity risks associated with importing live animals, animal products, and related items into Bhutan. In accordance with the Bhutan's biosecurity policies and the international standards, particularly the SPS agreement of the WTO and the WOAH guidelines, the IRA guidelines ensure that hazards are systematically identified, assessed, and mitigated alongside continuous communications with the interested parties. The guideline emphasizes the importance of transparency, stakeholder engagement, and continuous review to adapt to new information or changing circumstances. By adhering to this structured approach, Bhutan aims to protect its biodiversity, human and animal health, and agricultural

productivity while facilitating safe trade. The guidelines is not only a tool for decision-makers but also a dynamic resource that will evolve with emerging biosecurity challenges, ensuring the Bhutan's ongoing commitment to maintaining an appropriate level of protection against potential biosecurity threats.

7. Annexures

Annexure 1: Steps to determine whether a pathogenic agent is a hazard

Steps to determine whether a pathogenic agent is a hazard

1. Taking account of the methods of production, manufacturing or processing normally applied, is the commodity under consideration a potential vehicle for the pathogenic agent?
   a. If the answer is YES, proceed to Step 2. Otherwise the pathogenic agent is not a hazard.

2. Is the pathogenic agent present in the exporting country?
   a. If the answer is YES, proceed to Step 3.
   b. If the answer is NO, is there 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?
      - If the answer is YES, the pathogenic agent is not a hazard.
      - If the answer is NO, contact the Competent Authority to seek additional information or clarification and proceed to Step 4. Assume that until otherwise demonstrated, the pathogenic agent is likely to be present in the exporting country.

3. Are there zones or compartments from which the commodity could be derived within the exporting country that are free of the pathogenic agent?
   a. If the answer is YES, is there 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, and ensure that the commodity is only derived from these zones or compartments?
      - If the answer is YES, the pathogenic agent is not a hazard.
      - If the answer is NO, contact the Competent Authority to seek additional information or clarification and proceed to Step 4. Assume that until otherwise demonstrated, either the pathogenic agent is likely to be present in these zones or compartments, or the commodity is likely to be derived from other areas in the exporting country.
   b. If the answer is NO proceed to step 4.

4. Is the pathogenic agent present in the importing country?
   a. If the answer is YES, proceed to Step 5.
   b. If the answer is NO, is the Competent Authority of the country able to satisfactorily substantiate a claim that it is absent?
      - If the answer is YES, the pathogenic agent is classified as a hazard.
      - If the answer is NO, proceed to Step 4. Assume the pathogenic agent is present, and explore options within a reasonable period of time to

ascertain its presence or absence with a sufficient level of confidence.

5. For a pathogenic agent reported in both the exporting and the importing country, IF:
   c. it subject to an official control programme in the importing country, OR
   d. there are zones or compartments of different animal health status, OR
   e. 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.

Note: The evaluation of the Veterinary Services, the identification and traceability of animals and/or animal products, surveillance, official control programmes and management and husbandry practices related to biosecurity are important inputs for assessing the likelihood of pathogenic agents being present in, or absent from, the animal population of the exporting country or sub-populations within zones or compartments.

Annexure II: A template for an import risk analysis report

A template for an import risk analysis report

1. **Date**:

2. **Title**: Determined from the scoping step by considering the nature, source(s) (including country of origin) and intended use(s) of the animals or animal products; the scientific names of the animal species involved; the relevant methods of production, manufacturing, processing or testing that are normally applied and quality assurance programmes (such as HACCP); and, an estimate of the likely annual volume of trade if possible.

3. **Context**: Provide a brief description of the request.

4. **Purpose**: Clearly state the purpose, for example, 'To identify and assess the likelihood of [*the hazard(s)*] being introduced and spreading or becoming established in [*the importing country*] together with the likelihood of and the likely magnitude of their potential consequences for animal or human health as a result of importing [*the animals or animal products*]; to recommend sanitary measures as appropriate.'

5. **Risk communication strategy**: Provide an overview of who was consulted and when/ how they were consulted.

6. **Executive summary**: Should be simple, concise, complete and contain all the elements needed by the decision maker.

7. **Hazard identification**: List the hazards together with the supporting rationale.

8. **Sanitary measures in the OIE *Code***: Indicate whether OIE measures are available, and whether or not they will be applied, together with any supporting rationale.

9. **Risk assessment**
   a. ***Entry assessment:*** Describe the biological (risk) pathways necessary for each hazard to be introduced into the country. Provide details of the relevant biological, country or commodity factors that have been considered and that support the overall conclusions reached. (Include details of how uncertainty was taken into account and of any assumptions that have been made.)

   b. ***Exposure assessment:*** Describe the biological (risk) pathways necessary for the exposure of susceptible animals and/or humans in the country to each hazard. Provide details of the relevant biological, country or commodity factors that have been considered and that support the overall conclusion reached. (Include details of how uncertainty was taken into account and of any assumptions that have been made.)
   c. ***Consequence assessment:*** Describe the biological, environmental and economic consequences associated with the entry, establishment or spread of each hazard. Provide details of the relevant direct and indirect consequences that have been considered and that support the overall conclusions reached. (Include details of how uncertainty was taken into account and of any assumptions that have been made.)

   d. ***Risk estimation:*** Provide a summary of the results and/or conclusions arising from release, exposure, and consequence assessments.

10. **Risk management:** Discuss the rationale for selecting the chosen animal health options, together with how recommendations from a scientific peer review and feedback from stakeholder consultation have been taken into account.

11. **Conclusions and recommendations:** List the main findings, and include a summary of the sources of uncertainty and of the assumptions that have been made.

12. **References:** List all sources of information used.

Annexure III: Key principles for IRA Framework

Key principles for IRA Framework

The following key principles define the nature and performance of the risk analysis program that shall be adopted in performing IRA.

Compliant: The risk analysis process and methodology meet the needs of and complies with the country's domestic legislation and international obligations.

Comprehensive: While assessing the risks and determining the mitigation options, the range of values that should be considered includes economic, environmental, social and cultural.

Science based: The risk analysis should be based on the best available information that is in accord with current scientific understanding. The process and determination of the appropriate level of protection should not be compromised by pressures of trade or protection.

Precautionary: The TAG will incorporate a level of precaution in the import risk analyses to account for uncertainty; for instance, when making a professional judgment on whether available information is sufficient, when making assumptions, and when selecting risk management options. Where there is insufficient information, provisional measures may be recommended recognizing the obligation to seek additional information.

Consistent: All risk analyses completed by the competent authority achieve the same high level of performance and provide recommendations that deliver to the appropriate level of protection for Bhutan using a common process and methodology.

Transparent: The reasoning and evidence behind the decisions recommended by the technical advisory group and areas of uncertainty and their possible consequences to those recommendations, are clearly documented and made available to stakeholders.

Effective: Each risk analysis accurately measures the risks to the extent necessary and identifies mitigation options that achieve a level of protection appropriate for Bhutan.

Efficient: The risk analysis program avoids duplication and unnecessary use of resources, meets agreed timeframes, and focuses on the areas of highest priority.

Risk Management: Zero risk is not obtainable and as such risk is managed through deciding in each instance considering the acceptable level of risk.