GUIDELINE

IMPORT RISK ANALYSIS –
A BASIS FOR BIOSECURIY RISK MANAGEMENT
IN BHUTAN

2022

Coordination & Compilation:
Dr Kinley Penjor, Deputy Chief Regulatory & Quarantine Officer, BAFRA, HQ, Thimphu

Core Contributors:

Contributors	Dr Kinley Penjor, Dy. CRQO, BAFRA, HQ
	Dr N.P Dahal, Specialist, DoL, HQ, Thimphu
	Dr Kuenzang Gyeltshen, Dy. CRQO, BAFRA, Phuentsholing
	Dr Sherub Phuntsho, Dy. CRQO, BAFRA, Samdrup Jongkhar
	Mr. Gem Gyeltshen, Sr. RQO, BAFRA, Wangdue Phodrang
	Mr. Kinley Rabgye, Sr. RQO, BAFRA, HQ, Thimphu
	Mr. Ranjit Rai, Sr. RQO, BAFRA, Phuentsholing
	Mr. Kelzang Tashi, Sr. RQI, BAFRA, Samtse
	Ms. Sonam Choki, Sr. RQI, BAFRA, Thimphu
	Mr. Chimi Dorji, Sr. RQI, BAFRA, Thimphu
Edited by:	Dr Kinley Penjor, Dy. CRQO, BAFRA, HQ, Thimphu
	Dr N.P Dahal, Specialist, DoL, HQ, Thimphu

Published by the Bhutan Agriculture and Food Regulatory Authority (BAFRA)
Copyright © BAFRA, 2022
All rights reserved

For further information, please contact:
Bhutan Agriculture & Food Regulatory Authority
Ministry of Agriculture & Forests
Thimphu, Bhutan
www.bafra.gov.bt
Email: bafraheadoffice@gmail.com
Post Box No. 1071; Tele: +975-2-327032/335540
Toll Free No.1555

Foreword

The Import Risk Analysis Guideline for Animal, Animal Products and animal-related items describe the process the Bhutan Agriculture & Food Regulatory Authority (BAFRA) and relevant public and private agencies needs to follow when conducting an Import Risk Analysis. This is essential to support any Biosecurity decision making process as per the *Biosecurity policy of the Kingdom of Bhutan 2010*, Livestock Act of Bhutan 2001, Livestock Rules and Regulation, the obligations of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement), and the standards developed by the World Organization for Animal Health (OIE) and other Regulations concerning Bhutan's biosecurity.

This guideline describes a structured approach for conducting import risk analysis for animals, animal products and animal related items that is consistent with the legal instrument and obligations of the World Trade Organization (WTO) Agreement on the application of Sanitary & Phytosanitary Measures (SPS) and standards developed by World Organisation for Animal Health (OIE). It further provides valuable practical guidance to BAFRA and relevant public and private agencies in conducting risk analysis on a class of risks posed through imports. By following this guideline, the stakeholders, risk analysts and decision makers can be confident that the disease risks posed have been identified and can be managed effectively. The guideline will also be useful as a training aid to address the critical need for capacity building in this discipline.

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 General
Bhutan Agriculture & Food Regulatory Authority

TABLE OF CONTENTS

Contents

1.Introduction

1.1. The Approach

The Biosecurity Policy of Bhutan 2010, designates Bhutan Agriculture and Food Regulatory Authority (BAFRA) of the Ministry of Agriculture and Forests (MoAF) as the competent authority to safeguard Bhutan's Biosecurity. The policy defines "Biosecurity" as a strategic and integrated approach that encompasses the policy and regulatory frameworks for analyzing and managing relevant risks to human, animal and plant life and health, and associated risks to the environment. Biosecurity can contribute significantly in protecting animals, people and agricultural production system from pests and diseases and facilitating trade. Bhutan is dependent on imports especially livestock and its products and therefore it relies heavily on the biosecurity system to safeguard the health of human, animal, plant and environment and to protect our domestic production and facilitate access to international trade.

The sanitary & phytosanitary (SPS) agreement of the World Trade Organization (WTO) allows members 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 OIE Terrestrial Animal Health Code and the OIE Aquatic Animal Health Code. However, when such standards do not achieve Bhutan'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. BAFRA undertakes a range of risk analyses in response to requests to import goods into Bhutan, where those goods have not been imported before, or have not been imported into Bhutan from a particular country or region. Risk analyses considers the level of biosecurity risk that may be associated with the importation of a good, and identifies appropriate ways to manage these risks. However, the risk analysis in the past was conducted in the absence of an Import Risk Analyses Guidelines.

Risk analysis is a tool intended to provide decision makers with an objective, repeatable and documented assessment of the risks posed by importation of goods. In this regard, the principal

aim of import risk analysis is to provide BAFRA and related public and private agencies 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 or conducted under the supervision of BAFRA. The guidelines will assist the BAFRA in considering the level of biosecurity risk that may be associated with the importation of goods into Bhutan. If the biosecurity risks do not achieve the acceptable risk or appropriate level of protection (ALOP) for Bhutan, risk management measures are proposed to reduce the risks to an acceptable level. If the risks cannot be reduced to an acceptable level, the goods will not be imported into Bhutan, until suitable measures are identified.

1.2. Objective:

The objectives of the guideline are:

1. Provide an overall guide to identifying hazards and conducting risks analysis to BAFRA and all relevant public and private agencies
2. Detail out the procedures and implementation processes for conducting IRA related to importation of animals, animal products and animal related items into Bhutan.
3. Guide the decision makers in adopting appropriate risk mitigation and communication strategies related to IRA.

1.3. Scope of the guideline

This import risk analysis guideline covers details such as the identification of an organisms or diseases potentially associated with biosecurity risks, criteria for determining the methods and instruments in applying IRA and accordingly design risk management measures. The IRA in this guideline is specifically for an import of following items entering Bhutan:

- ✓ Animals
- ✓ Animal products
- ✓ Animal related items

The guideline does not cover import of livestock farm equipment and pharmaceuticals products.

2. Biosecurity risks and framework: Concept, structure & legality

2.1. Biosecurity risks- concept

It refers to the likelihood of a disease incursion, establishment or spread, and the potential for causing harm to health of humans, animals and the environment eventually causing negative implications on the economy of the country.

Import Risk Analysis is conducted as required by the Biosecurity Policy of the Kingdom of Bhutan (policy statement), the Livestock Act of Bhutan (Section 8.2) and the SPS obligation to OIE (OIE chapter 2.1).

For Import Risk Analysis, risk is determined through combination of the likelihood of the entry, establishment and spread of a disease or pest with the consequences. It takes into account the whole of the risk pathways from the identified hazard to the unwanted outcome or consequence. The risk associated with the import commodity is estimated to ascertain that it is within the country's appropriate level of protection (ALOP). Based on the quantum of risk estimated; risk management measures must be put in place.

ALOP is defined as the sanitary and phytosanitary measures (SPS) judged by Bhutan that can provide adequate protection against diseases and pests for animal and public health and environment within its territory. Bhutan will base its risk analysis methodologies and import risk management measures on the standards, guidelines and recommendations set by the OIE. However, when such standards do not achieve Bhutan's ALOP, or relevant standards do not exist, Bhutan will exercise its right to determine ALOP justified on scientific grounds supported by risk analysis.

2.2. Import Risk Analysis framework (structure)

The IRA framework is a multi-layered approach of managing the risk of diseases and pests involving SPS measures applied along the biosecurity continuum (prevention, preparedness, surveillance and containment) for import of animal, animal products and animal related

commodities. The framework outlines the national legal requirements, the international obligations and step wise process of IRA. It also outlines the procedures to adopt and implement IRA decisions.

2.3. LEGAL BASIS

1. Bio security policy of Kingdom of Bhutan, 2010

Bhutan's biosecurity system is built on Biosecurity Policy of the Kingdom of Bhutan, 2010. The policy requires the Ministry of Agriculture & Forests (MoAF) and in particular the Bhutan Agriculture & Food Regulatory Authority of Bhutan (BAFRA) to adopt a risk based transparent approach for all bio security related activities or functions including decision making. To uphold the international obligations, a science-based risk analysis shall be undertaken in accordance with the specific operational standards or procedures developed by international standard setting bodies such as OIE to facilitate safe and sustainable trade.

2. Livestock Act of Bhutan, 2001 & Livestock Rules & Regulation 2017

The Livestock act and its regulation requires legal authorization from BAFRA for the import of animal, animal products and animal related items into the country. The approval of import authorization must be based on the risk based transparent approach so as to provide adequate protection to animal, public health and environment.

3. Biosafety Act of Bhutan, 2015 and Biosafety Rules and Regulation 2018

The act and its regulation prescribethe need for conducting a risk assessment, management and communication according to the standards, procedures and guidelines established for import of a commodity to protect the environment.

4. Food Act of Bhutan, 2005 and Food rules and regulation 2017

The act and its regulation require that the food imported into Bhutan must be certified by the recognized authority in the exporting country and must meet the applicable standards for that particular food established in Bhutan in order to protect the general public health.

5. Administrative documents

BAFRA will use available administrative documents, such as executive orders, codes or standards and guidelines, notifications to regulate imports and undertake all types of IRA activities.

6. International Obligations

Bhutan is a member to International Plant Protection Convention (IPPC), Codex Alimentarius Commission (CAC), and World Animal Health Organization (OIE). Bhutan also serve as the National Enquiry Point for World Trade Organization-Sanitary and Phytosanitary Agreement (WTO-SPS agreement), International Food Safety Authorities Network (INFOSAN) for International Health Regulations (IHR), Cartagena Protocol on Biosafety (CPB) for Convention on Biological Diversity (CBD). Bhutan as the signatory to International organization has obligation to implement SPS arrangements to protect human, animal and environment health and at the same facilitate safe and sustainable trade.

3. Key principles for IRA Framework

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

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

3.2 Comprehensive: That the full range of values, including economic, environmental, social and cultural, are considered when assessing risks and determining mitigation options.

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

3.4 Precautionary: That the risk analyst will incorporate a level of precaution in the import risk analyses to account for uncertainty; for instance, when making a professional judgement 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.

3.5 Consistent: That all risk analyses completed by BAFRA 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.

3.6 Transparent: That the reasoning and evidence behind the decisions recommended by the risk analysis, and areas of uncertainty and their possible consequences to those recommendations, are clearly documented and made available to stakeholders.

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

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

3.9 Risk Management: That zero risk is not obtainable and as such risk is managed through deciding in each instance what should be considered an acceptable level of risk.

4. Elements in carrying out an IRA

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 evidences

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

4.1. Hazard identification

Hazard identification involves identifying the pathogenic agents that could potentially produce adverse consequences associated with the importation of a commodity. 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 Bhutan, and whether it is a notifiable disease or is subject to control or eradication in Bhutan 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 programme, 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 is a categorization step, identifying biological agents dichotomously as hazards or not hazards. The risk assessment should be stopped if hazard identification fails to identify hazards associated with the importation.

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

4.2. Risk assessment

Risk assessment should be flexible in order to deal with the complexity of real-life situations. Risk assessment should be dynamic to capture 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.

The risk assessment should be based on the best available information that is in accord with current scientific knowledge. The assessment should be well documented and supported with references to the scientific literature and other sources, including expert opinion.

Risk assessments should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate. In this guideline we have established three major types of risk assessment which are provided in detail below.

Note: The type of risk assessment methods (qualitative and quantitative) shall be decided by the IRA secretariat.

4.2.1 Release assessment

Release assessment consists of describing the biological pathway(s) necessary for an importation activity to introduce a pathogenic agent into a particular environment, and estimating the probability of that complete process occurring either qualitatively or quantitatively. The release assessment estimates the likelihood of the potential hazard being present in the imported commodity under each specified set of conditions with and how these might change as a result of various actions, events or measures.

The kind of information required in the release assessment are:

Biological factors:

- Species, strain or genotype, and age of animal
- Strain of agent–Tissue sites of infection and/or contamination
- Vaccination, testing, treatment and quarantine.

Country factors:

- Incidence or prevalence
- Evaluation of Animal Health Services, surveillance and control programs, and zoning and compartmentalization systems of the exporting country.

Commodity factors:

- Whether the commodity is alive or dead
- Quantity of commodity to be imported
- Ease of contamination
- Effect of various processing methods on the pathogenic agent in the commodity
- Effect of storage and transport on the pathogenic agent in the commodity.

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

4.2.2. 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 identified from a given risk source, and estimating the probability of these exposure(s) occurring, either qualitatively or quantitatively. The probability of exposure to the potential hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure, and the number of species and other characteristics of the animal and human populations exposed.

The kind of information required in the exposure assessment are:

Biological factors:

- Properties of the agent (e.g. virulence, pathogenicity and survival parameters)
- Genotype of host.

Country factors:

- Presence of potential vectors or intermediate hosts
- Human and terrestrial animal demographics (e.g. presence of known susceptible and carrier species, distribution)
- Customs and cultural practices
- Geographical and environmental characteristics

Commodity factors:

- Whether the commodity is alive or dead
- Quantity of commodity to be imported

- Intended use of the imported animals or products (e.g. domestic consumption, restocking, incorporation in or use as animal feed or bait)
- Waste disposal practices.

If the exposure assessment demonstrates no significant risk, the risk assessment may conclude at this step.

4.3. Consequence assessment

Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. The consequence assessment describes the potential consequences of a given exposure and estimates the probability. This estimate may be either qualitative or quantitative. The objective of the consequence assessment is to provide a structured assessment of the consequences if a disease were to enter, establish and spread in post border. The assessment considers direct and indirect disease effects and their economic and environmental consequences.

Examples of consequences include:

Direct consequences:

- Animal infection, disease, production losses and facility closures
- Public health consequences

Indirect consequences:

- Surveillance and control costs
- Compensation costs
- Potential trade losses
- Adverse, and possibly irreversible, consequences to the environment.

Depending on the magnitude, consequences can be estimated at local, regional and national level.

4.4. Risk estimation

4.4.1. Quantitative risk estimation

Risk estimation consists of integrating the results of the entry assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the potential hazards. 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:

- The various populations of animals and/or estimated numbers of animal establishments 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
- 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.

For qualitative assessment, a risk matrix is used to estimate the risk.

4.4.2. Qualitative risk estimation: **The risk estimation matrix**

In qualitative method of risk assessment, risk matrix is used as assessment tool to estimate the risk and it is consistent with OIE risk estimation methods.

A risk estimation matrix is used to combine the likelihood of a disease entering, establishing and spreading in Bhutan with the potential consequences should that occur, and to determine whether specific risk management measures are required to achieve Bhutan's appropriate level of protection.

If the estimated risk does not achieve ALOP, MoAF considers whether sanitary or phytosanitary measures will be considered to manage the risk. ALOP is achieved if the estimated risk is at or below 'very low'.

Table 1: Risk estimation matrix

When interpreting a risk estimation matrix, keep the likelihood of release and exposure to the vertical axis corresponding consequences to the horizontal axis.

4.5. Risk management

It is a process of identifying, selection and implementation of risk management measures to address the risks identified in the risk assessment to achieve ALOP.

Note - The international standards of the OIE are the preferred choice of SPS measures for risk management

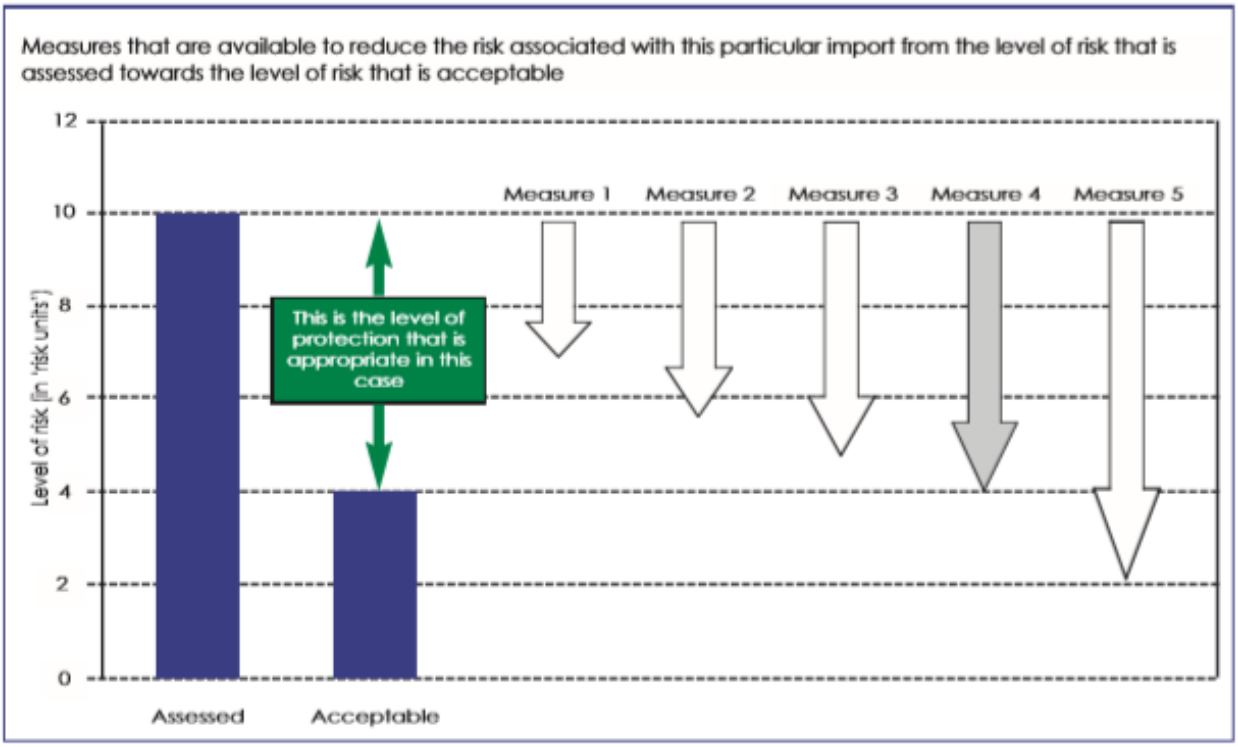


Figure1: Relationship between of risk management options and ALOP

Risk management components are:

a) **Risk evaluation**

The process of comparing the risk estimated in the risk assessment with the reduction in risk expected from the proposed risk management measures.

b) Option evaluation

The process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the risk associated with an importation. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse health and economic consequences to ALOP. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options.

c) **Implementation**

The process of following through with the risk management decision and ensuring that the risk management measures are in place.

d) **Monitoring and review**

The ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the ALOP.

5. Instruments and approaches for IRA

5.1. Procedure for Import Risk Analyses

This section describes how the biosecurity risk is assessed in relation to the importation of commodity listed in the scope of this document.

5.1.1. Role of BAFRA:

All biosecurity risk analysis shall be coordinated by or conducted under the supervision of BAFRA. BAFRA shall conduct IRA if the technical competencies are within the BAFRA or within the ministry. In absence of technical competencies within BAFRA or ministry, BAFRA will outsource IRA. The livestock section under BAFRA will serve as the secretariat to conduct IRA. The secretariat will be responsible to carry out the following functions:

- Contact point for IRA inquiries
- Propose the members for co-opt technical committee members based on the scope of the IRA.
- Publish IRA notification to the proponent, public and technical committee.
- Coordinate consultation meetings wherever required
- Provide regular updates, including clarifying information, throughout the IRA process
- Coordinate the outcomes of IRA
- Management of IRA documents
- Liaise with authorities of the exporting country for information and data exchange
- Ensure that BAFRA field offices are taken on board wherever their involvement is required
- Ensure implementation of risk management measures
- Any requested comments and findings given by the group must be considered by BAFRA in preparing the final IRA report and for the purpose of policy decision.

5.1.2. Role of IRA TechnicalCommittee

At any stage in the process of conducting an IRA, BAFRA may in writing request the committee to examine and provide comments on any aspect of the IRA. The committee must then complete an examination of the requested aspect, and give its comments and findings to BAFRA.

To ensure consistency between IRAs, the ministry will establish three permanent member committee as the IRA technical committee. This will include specialist/experts from the following areas:

- Animal health Specialist
- Risk analyst
- Regulatory &Quarantine Specialist.

In addition to the permanent members, 2 co-opt members shall be included in the committee depending on the scope of the IRA and technical expertise that is relevant to the class of commodity being analyzed in the IRA. There will not be a pre-determined number of people who can be appointed to the group.

Suggestions for additional members will be sought from other stakeholders prior to the commencement of any new IRA.

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. Overseas experts may be appointed as members of the group.

6.2. Conflict of Interest and Confidentiality

BAFRA recognizes that depending on the particular IRA being conducted that there may be limited scientific/technical expertise available to draw from. As such it is anticipated that conflicts of interest may arise from time to time. Any conflicts of interest must be assessed by thesecretariat and shall be documented as per the prescribed format. (annexed)

All members will be required to sign confidentiality agreements (Annexed). However, BAFRA will make the final decision on the composition of the group.

It is also important to note that the group is not the final decision maker and can only make recommendations to the ministry.

The committee may be asked to examine or provide comment on any aspect of the IRA. This includes examining or providing comment on issues that have arisen during the development of the IRA.

The group will be asked to examine and provide comments on the draft and provisional IRA reports. The group may be asked to consider whether:

- Technical submissions received from stakeholders in response to the draft IRA report have been properly considered
- All relevant matters relating to the likely economic consequences of a disease or pest incursion have been properly considered, and
- The conclusions of the draft IRA report and provisional IRA report (are scientifically reasonable, based on the material presented.

6.3. Initiation of IRA

Upon receiving an import proposal from government authorities of the exporting country in the form of a market access request, or when people or organizations want to import commodity), BAFRA request for submission of documents along with the import application. Risk analyses can also be initiated to identify appropriate measures for import health standard development, or for risk assessments to support surveillance and response or pest management activities as indicated by the technical Departments.

An import proposal is a generic term used to describe a proposal to import animals, animal products or animal-related items into Bhutan in circumstances where import conditions have not been established. The proponent should complete the import application form annexed.

- commodity origin

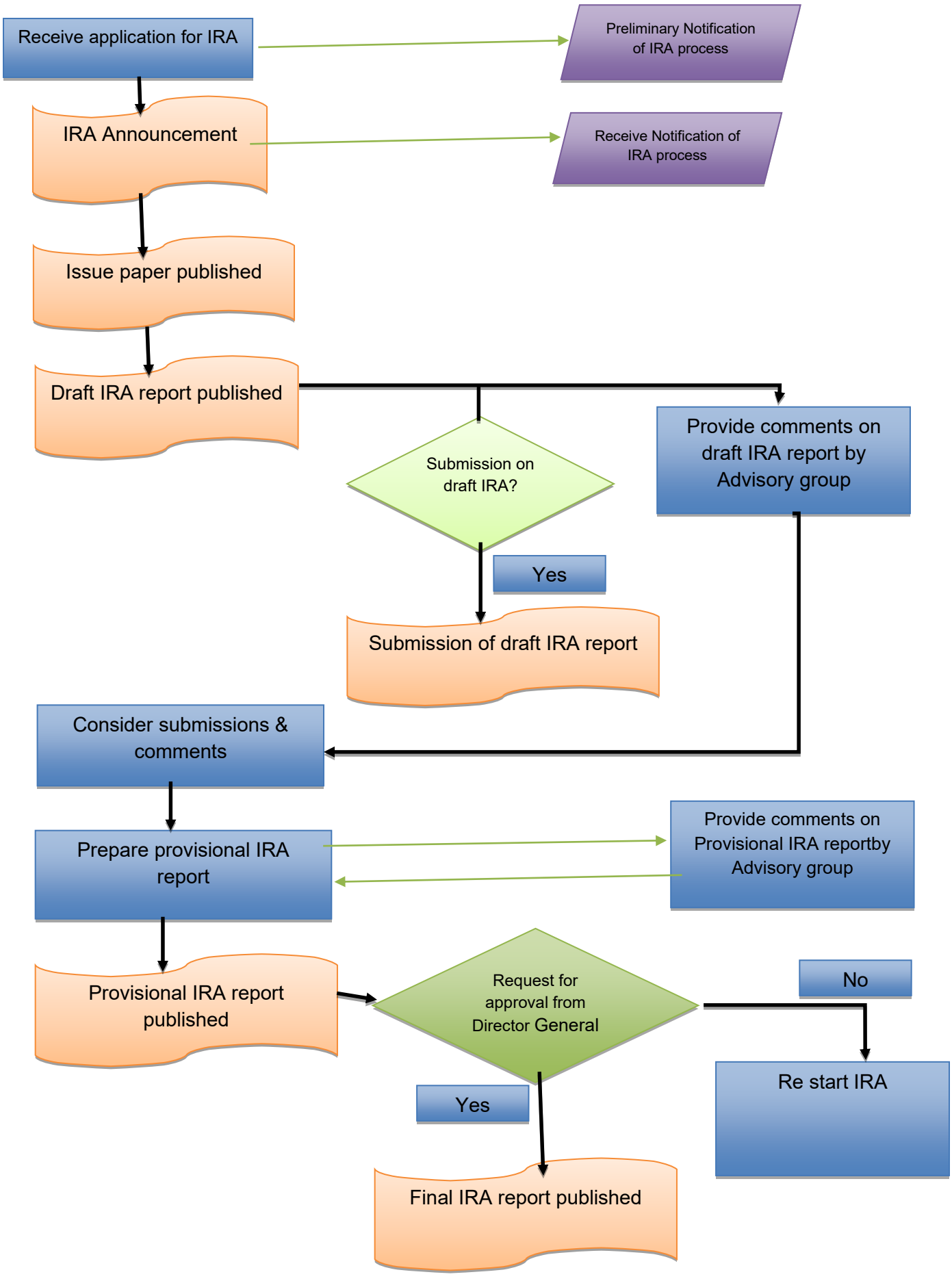
  The IRA secretariat may consult with the proponentwhere required, to confirm the scope of the request and to ensure that any required information has been provided to support their request.

6.4. Criteria for an IRA

An IRA will be undertaken when:

- When people or organizations submit import proposal for import of commodity where relevant risk management measures have not been established.
- For a commodity whose risk managements are well established but the likelihood and/or consequences of entry, establishment or spread of diseases could differ significantly from those previously assessed.
- An import of organism for selection and scientific research
- Possible introduction of a new system, process, procedures or new information that could influence a previous decision
- The biosecurity situation in Bhutan changes or political boundaries have changed.

Summary of IRA steps


Receive application for IRA
Preliminary Notification of IRA process
IRA Announcement
Receive Notification of IRA process
Issue paper published
Draft IRA report published
Submission on draft IRA?
Provide comments on draft IRA report by Advisory group
Yes
Submission of draft IRA report
Consider submissions & comments
Prepare provisional IRA report
Provide comments on Provisional IRA reportby Advisory group
Provisional IRA report published
Request for approval from Director General
No
Re start IRA
Yes
Final IRA report published

6.Implementation elements in carrying out IRA

6.1.IRA Process

This section describes the steps to be undertaken in conducting IRA.

1. BAFRA must establish a scientific advisory group.
2. BAFRA, must publish a notice on the website stating:
    - That an IRA is commencing
    - The opportunities for consultation that will occur during the IRA process.
    - BAFRA must prepare an issue paper and publish it on BIAFRA's website. The issue paper will set out background information about the request, the commodity/goods and some of the main matters that will be considered during the analysis.
3. The person responsible in BAFRA for IRA must:
    - Prepare a draft IRA report
    - Publish on BAFRA's website the draft report and an invitation to the public to provide submissions about the assessment of the level of biosecurity risk associated with the relevant goods or class of goods including proposed risk measures for the goods to achieve acceptable limits within a period specified in the invitation.
    - The consultation period must be at least 15 working days, including the day the invitation is published.
    - BAFRA must prepare a provisional IRA report and publish it on BAFRA's website.
4. The final IRA report must be published within 15 working days from the day the notice announcing the IRA was published, unless specific circumstances apply.
5. BAFRA must publish a notice on the website of the result of the IRA.

Fig 2: Continuum of Import Risk Analysis

6.2. Assessment of biosecurity risk

This section describes how the biosecurity risk is assessed in relation to the importation of animals and its products. BAFRA will evaluate the likelihood of entry, establishment and spread of a disease and the magnitude of potential consequences in a defined area, using biological or other scientific and economic evidences. The evaluation follows internationally agreed principles and standards relating to import risk analysis.

6.2.1. Role of BAFRA:

IRA and other types of risk analysis is conducted by staff with technical and scientific expertise relevant to the biosecurity risks under consideration or question. The focal for the livestock section under BAFRA will serve as the secretariat to conduct IRA. The secretariat will be responsible to carry out the following functions

- The IRA Liaison Officer (secretariat) will be the first point of contact for IRA inquiries when an IRA is underway
- Compilation of required data/information
- Liaise with committee members to carry out IRA
- Ensure that BAFRA field offices are taken on board wherever their involvement is required
- Coordinate consultation meetings with committee members and stakeholders wherever required:
    I. Notifying identified stakeholders that a IRA is going to be conducted

II. Informing relevant stakeholders of the issues that will be considered in the IRA
III. Providing regular updates, including clarifying information, throughout the IRA processes
IV. Communicating the timing of a IRA, including when submissions can be made
V. Providing information from domestic stakeholders to the department
VI. Communicating the outcomes of the IRA process
VII. Organizing and coordinating face-to-face meetings and teleconferences as and when required
VIII. Continuing to provide support after the completion of the IRA, up until first import (if relevant)

- Liaise with authorities of the exporting country for information and data exchange
- Coordinate risk communication meetings with stakeholder
- Ensure implementation of risk management measures

Note: The BAFRA should ideally have technical competencies in animal health (terrestrial and aquatic), environmental science, geospatial analysis, microbiology, quantitative science, etc.

6.2.2. Role of external expertise (technical committee)

BAFRA will use external resources in addition to the scientific advisory group whenever necessary. For example, BAFRA may request for an advice or information from relevant technical or scientific experts (technical departments, universities and industries) to access the technical expertise needed for a particular risk analysis.

Sometimes the department needs to validate complex or contentious science, or there may be uncertainty about critical aspects of science. In these cases, the department may organise formal meetings or workshops with scientific and technical experts.

6.3. IRA decision

A decision specifies whether trade may be permitted and if so, what conditions, if any, must be applied to the goods to achieve country's ALOP.

BAFRA shall consider the following for makingthe IRA decision:

- The final IRA report and its recommendations
- Any other relevant information, including country's rights and obligations.

Once BAFRA makes a policy determination, it notifies the proposer, registered stakeholders and the WTO secretariat (if required). The policy determination, and information about what occurs after a policy determination, should be made available on the department's website.

A policy determination can be reviewed at any time if relevant new information is received, or a review can be initiated by the department for other reasons.

6.5. Decision to terminate IRA

In most cases, when IRA is started it will be completed. However, there are situations when it is not appropriate, or necessary, to complete an IRA. BAFRA may decide to terminate IRA at any time even if BAFRA has requested information from a person, including an external expert, or has requested the scientific advisory group to examine and provide comments on any aspect of the IRA

BAFRA will consider the requested information or comments received and decide, based on all other available information and evidence, and taking into account international trade obligations, whether terminating the IRA is appropriate.

Including a provision that allows BAFRA to terminate an IRA before it is complete ensures that an IRA is not continued where needs have changed. Some examples of this include:

- Has been given an adequate response to the request and is unsatisfied that there is insufficient reason to complete the IRA,In circumstances where BAFRA is reacting to changing priorities (such as where a country withdraws its request for market access), or
- Where the policy rationale no longer exists for IRA process, or
- Where new science or information has emerged.

in the event of IRA process, the committee member comes into common consensus that the assessment is similar to the one which has already been conducted and approved for importation.

In some of these cases, the IRA may transition into a non-regulated risk analysis.

If BAFRA terminates an IRA, they must publish a notice on the BAFRA's website stating that the IRA has been terminated and cite the reasons for the termination.

Provisional sanitary and Zoo-sanitary measures

Under the SPS agreement, in cases where relevant scientific evidence is insufficient, WTO members may adopt provisional SPS measures on the basis of available relevant information. However, they are required to seek additional information necessary for more objective risk analysis within a reasonable period of time. Where provisional SPS measures have been applied, the IRA report will detail the information on which they are based and undertaken to review the measure within a reasonable period of time.

6.5.Consultation and Communication

Communication with stakeholders

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.

A risk communication strategy should be put in place at the start of each risk analysis.The communication of risk should be open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

The assumptions and uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated. Peer review of risk analyses is an essential component of risk communication in order to obtain a scientific critiqueand to ensure that the data, information, methods and assumptions are the best available.

Engagement with stakeholders is an important part of the IRA process. Stakeholders include anyone with an interest in the specific IRA underway and may include research organizations, farmers, importers, exporters and the general public.

Consultation throughout the IRA process is both formal and informal and aims to seek stakeholder views on technical issues relevant to the risk analysis. Engagement with stakeholders occurs through conversations and meetings, as well as through website updates, publication of biosecurity advice notices and information sent directly to relevant stakeholders.

BAFRA welcomes stakeholder comments or submissions at any time on matters relevant to the IRA or other import conditions.Additional comments can be provided either through the Liaison Officer that is conducting the IRA.

6.6.IRA Technical Committee

BAFRA must institute Biosecurity advisory committee with representation from relevant technical departments/agencies. The approval for nomination of the members should be sought from the Ministry.

At any stage in the process of conducting an IRA, BAFRA may in writing request the committee to examine and provide advice on any aspect of the IRA. The committee must then complete an examination of the requested aspect, and give its comments and findings to BAFRA.

Any requested comments and findings given by the group must be considered by BAFRA in preparing the final IRA report.

6.6.1. Composition

To ensure consistency between IRAs, BAFRA will will seek nominations from ministry three standing members to the committee with relevant experience in risk analysis. This will include

an animal health specialist, a person experienced in risk analysis and specialist in regulatory & quarantine measures.

Outside of the standing members, the composition of the committee will be decided depending upon the IRA to be conducted. Selections will be based on the scientific and technical expertise that is relevant to the class of goods being analyzed in the IRA. There will not be a pre-determined number of people who can be appointed to the group.

Suggestions for additional members will be sought from other stakeholders prior to the commencement of any new IRA.

Nominated members will have a proven record of scientific or technical expertise relevant to the IRA or will have made a significant contribution to the science or technical methods relevant to the IRA. Overseas experts may be appointed as members of the group.

6.6.2. CONFLICT OF INTEREST AND CONFIDENTIALITY

BAFRA recognizes that depending on the particular IRA being conducted that there may be limited scientific/technical expertise available to draw from. As such it is anticipated that conflicts of interest may arise from time to time. Any conflicts of interest must be declared by the committee members and shall be documented as per the prescribed format. (annexed)

All members will be required to sign confidentiality agreements (Annexed). However, BAFRA will make the final decision on the composition of the group.

Intellectual properties (copy right)

It is also important to note that the group is not the final decision maker and can only make recommendations to the ministry.

6.6.3. Role

The committee may be asked to examine or provide comment on any aspect of the IRA. This includes examining or providing comment on issues that have arisen during the development of the IRA.

The group will be asked to examine and provide comments on the draft and provisional IRA reports. The group may be asked to consider whether:

- Technical submissions received from stakeholders in response to the draft IRA report have been properly considered
- All relevant matters relating to the likely economic consequences of a disease or pest incursion have been properly considered, and
- The conclusions of the draft IRA report and provisional IRA report (are scientifically reasonable, based on the material presented.

6.6.4. Documentation and Record Keeping

The principle of transparency of the SPS Agreement requires that contracting parties should, on request, make available the rationale for sanitary or phytosanitary requirements. As a prerequisite, the underlying risk analysis should be sufficiently documented. Complete and careful documentation is also a prerequisite to implementing an effective and efficient review process for the risk analysis. When documenting a particular analysis, the entire process from project initiation to the close-out reporting should be sufficiently documented, so that the sources of information and rationale for management decision can be clearly demonstrated.

6.6.5. Records Management

Sound record management practices are not only required to fulfil country's domestic legislative requirements and meet international obligations, but also to provide a readily accessible information recall system that can act as an information resource for future and ongoing work and ensure that issues identified during the development of a risk analysis are recorded and directed to the appropriate business group for action or consideration. The procedural recommendations for this project cover record management associated with the production of import risk analysis after the notification of the final risk analysis. The four main parts of this process serve to ensure that:

1. Hazard information databases are maintained appropriately: Ensure the hazard information are maintained as appropriate with the relevant hazard information developed during the risk analysis processes

2. Literature records referred to by the risk analysis are complete: Full-text references and citations should be stored and be held as a single unit until the process has been completed. After completion, references and citations relevant to particular organisms and diseases and of potential use in other projects should be stored for easy retrieval by future projects.
3. All related files or files developed during the project are complete: All documents related to a project should be easily retrieved as a unit and ensure that all documents relating to the risk analysis process are filed in either the electronic or the hardcopy files established at the initiation of the analysis. Such project-related records or documents include project planning documents, emails and other correspondence, references, submissions, drafts and final risk analysis documents. The completed risk analysis document(s) should be published on the BAFRA's website. The following groups with BAFRA should be notified as appropriate on the outcomes of the risk analysis project.

Other groups or process stakeholders are informed on the outcomes of the risk analysis project.

Process for records management

4. The applicant and other target audience are informed of risk analysis outputs relevant of the risk analysis

The completed risk analysis document(s) should be published on the BAFRA website as *pdf* files and remain on the website indefinitely or until revised. A hardcopy of risk analysis documents should be placed in the risk analysis group library collection for easy access by users.

The availability of risk analysis documents, including the Review of Submissions document, should be advertised. Organisations and individuals that made a submission to the project should be notified individually.

Ensure notifications are completed

The following groups with MoAF should be notified as appropriate on the outcomes of the risk analysis project:

• *Scientific Relevant TECHNICAL Group*, on the outcomes of the risk analysis relevant to the development of operational or regulatory standards;

• *Department of livestock*, on the outcomes of the risk analysis relevant to the management of surveillance, incursion response or pest management activities.

• *Veterinary and border vigilance team,* on the outcomes of the risk analysis relevant to the monitoring of border activities.

There may also be other groups, depending on the scope of the risk analysis project, may also need to be notified of the outcome or aspects of the outcomes of the project. These other groups include the *BCCI, RRCO*, and the various policy and strategy groups directly related to import.

Appendix: Biosecurity contact details

Stakeholders are encouraged to provide any information to BAFRA regarding what may be a biosecurity risk by calling our Toll Free No. 1555.

Officials to be contacted regarding any Animal Biosecurity risk:

kinleypenjor@moaf.gov.bt or

ptamang@moaf.gov.bt

The department's postal address:

Email @ bafraheadoffice@gmail.com

Web @: bafra.gov.bt

Phone No: 325993 / 325790/327031

Fax No: 327032

Postal No: 1071

Glossary:

I. Acceptable risk: Risk level judged by Bhutan to be compatible with the protection of animal and public health within its country. The equivalent term used in the SPS Agreement is appropriate level of protection (ALOP).

II. Aquatic Code: The OIE Aquatic Animal Health Code

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

IV. 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.

V. 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.

VI. 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

VII. 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

VIII. 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.

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

X. 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

XI. Quantitative risk assessment: An assessment where the outputs of the risk assessment are expressed numerically

XII. 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.

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

XIV. 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

XV. 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

XVI. 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

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

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

XIX. 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.

XX. 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

XXI. Import Risk Analysis (IRA): A regulated scientific evaluation of the level of biosecurity risk associated with particular goods, or a class of goods, that may be imported into Australian territory. A BIRA can identify the conditions that must be satisfied to manage the level of biosecurity risk to achieve Australia's ALOP

XXII. International Plant Protection Convention (IPPC): An international plant health agreement established in 1951 that aims to protect cultivated and wild plants from harmful pests that may be introduced through international trade. WTO members are expected to base their phytosanitary measures on international standards developed by the IPPC

XXIII. World Organization for Animal Health (OIE): The intergovernmental organization responsible for improving animal health worldwide. The OIE develops documents relating to rules that WTO members can use to protect themselves from the introduction of diseases and pathogens, without setting up unjustified sanitary barriers

XXIV. The World Trade Organization (WTO): A global international organization dealing with the rules of trade between nations.