Primary author:

Stephen Cobb BSc(VetSci) BVM&S MRCVS, Director, SRC Associates

Stephen@SRCAssociates.org
www.SRCAssociates.org
This page is intentionally blank
Contents

Introduction to import risk analysis ................................................................. 3
   What is risk? ................................................................................................. 3
   Use of risk analysis as an objective and defensible tool.............................. 6
   Terminology used ....................................................................................... 6

Risk assessment vs risk management ......................................................... 8
   The difference between risk assessment and risk management and why is this important? ........... 8
   The need for dialogue and discussion between risk assessors and risk managers ................. 9

Transparency .......................................................................................... 10
   What does this mean and why is transparency essential? .......................... 10

Uncertainty and variability .................................................................. 11
   The difference between uncertainty and variability .................................. 11
   Communication of uncertainty ................................................................ 12

Qualitative and quantitative approaches .............................................. 13

Risk analysis and the WTO SPS Agreement ........................................... 14
   SPS Agreement ....................................................................................... 14
   WTO notification ..................................................................................... 14
   Communication and consultation with international counterparts .......... 15

OIE risk analysis framework and how this is applied in New Zealand .... 16
   The OIE risk analysis framework ............................................................ 16
   Hazard identification ............................................................................... 16
   Risk assessment ...................................................................................... 17
   Risk management ................................................................................... 17
   Risk communication .............................................................................. 18

Determining the scope of a risk analysis .............................................. 19
   Importance of clearly defining the scope of a risk analysis ...................... 19
   Examples of risk analysis commodity definitions ................................... 20

Hazard identification ........................................................................... 21
   Process to compile a list of pathogenic agents appropriate for the species and commodity ...... 21
   Identification of hazards from this list of pathogens .................................... 21
   Sources of information for hazard identification .......................................... 23

Risk assessment .................................................................................... 24
   An overview of the process to be followed for each identified hazard ......... 24

Entry assessment .................................................................................. 25
   Factors that must be considered in the entry assessment .......................... 25
      Biological factors: .................................................................................. 25
      Country factors .................................................................................... 26
      Commodity factors ............................................................................... 26
   Sources of information for entry assessment ............................................ 28
Exposure assessment........................................................................................................... 29
  Matters that need to be considered including biological, country and commodity factors........ 29
    Biological factors: ........................................................................................................ 29
    Country factors: ......................................................................................................... 29
    Commodity factors: .................................................................................................... 30
  Sources of information for exposure assessment .............................................................. 31

Consequence assessment .................................................................................................. 32
  Direct consequences ....................................................................................................... 32
  Indirect consequences .................................................................................................... 32
  Sources of information for consequence assessment ....................................................... 34

Risk estimation ................................................................................................................ 35
  Risk estimation decision steps ........................................................................................ 35

Risk management ............................................................................................................. 36

Risk communication ........................................................................................................ 38
  Developing a risk communication strategy ...................................................................... 38
  Who is involved in the risk communication process? ....................................................... 38
  Factors to be considered when developing a risk communication strategy ..................... 38
  The goals of risk communication .................................................................................... 38

Peer review and consultation ............................................................................................ 40

CONCLUSIONS ................................................................................................................ 41

Further reading ................................................................................................................ 42

Appendix 1 – Glossary of terms ....................................................................................... 43


Appendix 3 – Checklist for import risk analysis ............................................................... 53
Introduction to import risk analysis

What is risk?

Risk has two components; the **likelihood** (or probability) of a disease entering, establishing or spreading in the importing country and its **impact** on animal or human health, the environment and the economy.

Risk analysis assists the decision maker by answering the following questions:

- What can go wrong?
- How likely is it to go wrong?
- What are the consequences of it going wrong?
- What can be done to reduce the likelihood or the consequences of it going wrong?

Risk is usually defined as the product of two components: the chance, or probability, of something happening and, if it does happen, the resulting consequences.

Terminology varies across disciplines and countries regarding the meaning of ‘risk analysis’. For some, the process of estimating the probability and impact of a particular risk is termed ‘risk analysis’. In the context of import risk analysis this process is referred to as ‘risk assessment’, while the term ‘risk analysis’ refers to a wider process which embraces a series of steps from hazard identification, through assessments of risk, to any resulting management decisions. ‘Risk analysis’ also includes communication with stakeholders throughout the process.

The risk analysis process consists of four components (see Figure 1):

- hazard identification
- risk assessment
- risk management
- risk communication.

Several systems of terminology are in use to describe the process of risk analysis. That risk analysis process adopted in the Code is the one more generally used in the animal health field and is the one used here.
Figure 1  The structure of the OIE risk analysis process

HAZARD IDENTIFICATION
Is the organism likely to be associated with the commodity?
Is the organism present in the importing country?
Is there a control programme in the importing country?
Are there different strains overseas?
Is the organism identified as a hazard?

RISK ASSESSMENT
Entry assessment. Likelihood of organism entering on the pathway
Exposure assessment. Likelihood of exposure and establishment
Consequence assessment. Likely impact on economy, environment, and human health
Risk estimation. Is the organism assessed to be a risk?

RISK MANAGEMENT
What are the options available to manage the risk?
What is the effect of each measure, alone or in combination, on the level of risk?

RISK COMMUNICATION
Figure 2 Risk analysis process applied in New Zealand

HAZARD IDENTIFICATION

- List of organisms and diseases of concern
  - Is the organism likely to be associated with the pathway? (no)
  - Is the organism present in New Zealand? (yes)
  - Is there a control programme in New Zealand? (no)
  - Are there different strains overseas? (no)
  - Would the organism increase the existing exposure in NZ? (no)
  - Could the organism bring a pathogen/disease not present in New Zealand? (yes)

- Hazard in this risk analysis

RISK ASSESSMENT

- Entry Assessment: Likelihood of hazard entering New Zealand on the pathway (negligible)
- Exposure/Establishment Assessment: Likelihood of exposure and establishment in NZ (non-negligible)
- Consequence Assessment: Likely impacts on the economy, environment and human health in NZ (negligible)
- Risk estimation: Organism/disease is assessed to be a risk in this risk analysis (non-negligible)

RISK MANAGEMENT OPTIONS

- What options are available to manage the risks?
- What is the effect of each measure on the level of risk?
Use of risk analysis as an objective and defensible tool

Import risk analysis provides importing countries with an objective and defensible method of assessing the disease risks associated with an imported commodity.

Transparency is essential, because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst’s value judgements may blur. Transparency also provides an exporting country with clear reasons for the risk management decision.

This course outlines the international obligations with respect to the WTO SPS Agreement and provides a framework for the risk analysis process based on the standards described in the Code.

Terminology used

N.B. Appendix 1 of these notes provides a comprehensive glossary.

The terminology outlined in the Code should be used and the introduction of new terms, or terms from other disciplines, should be avoided.

Care must be exercised when using various terms to estimate or describe risk; certain WTO Panels and Appellate Bodies, convened under the terms of the SPS Agreement, have emphasised the importance of the correct use of terms such as likelihood and potential.

Most import risk assessments on animals or animal products are concerned with evaluating the likelihood of entry, establishment or spread of a disease, as well as the associated potential biological and economic consequences. It is not sufficient to conclude that there is a possibility of entry, establishment or spread. Instead the likelihood, which may be expressed qualitatively or quantitatively, must be evaluated. Similarly, as the ordinary meaning of ‘potential’ relates to possibility, the likelihood of possible consequences must be evaluated. For this reason it is important to use appropriate terms when describing a likelihood. Table I gives examples of terms which are acceptable and ones to be avoided; these definitions are taken from the Concise Oxford Dictionary, other dictionaries may give different definitions. It should be noted that the common dictionary definitions for some terms may not be precise enough to be useful in a risk analysis; for example ‘possible’ and ‘possibility’ in this table.

---

1the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions

### Table 1  Terminology for describing likelihood

<table>
<thead>
<tr>
<th>Term</th>
<th>The Concise Oxford Dictionary definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Terms to avoid</strong></td>
<td></td>
</tr>
<tr>
<td>Chance</td>
<td>When used in a singular context it indicates a possibility</td>
</tr>
<tr>
<td>Could</td>
<td>Past of can, where can means to be potentially capable of</td>
</tr>
<tr>
<td>Might</td>
<td>Expressing a possibility based on a condition not fulfilled</td>
</tr>
<tr>
<td>Potential</td>
<td>When used as a noun means possibility</td>
</tr>
<tr>
<td>Possibility</td>
<td>A thing that may exist or happen</td>
</tr>
<tr>
<td>Possible</td>
<td>That is likely to happen; whatever is likely</td>
</tr>
<tr>
<td><strong>Acceptable terms</strong></td>
<td></td>
</tr>
<tr>
<td>Chances</td>
<td>In its plural form chance indicates a probability</td>
</tr>
<tr>
<td>Likelihood</td>
<td>Probability; the state or fact of being likely</td>
</tr>
<tr>
<td>Likely</td>
<td>Probable; such as well might happen or be true; to be reasonably expected</td>
</tr>
<tr>
<td>Probability</td>
<td>The likelihood of something happening; mathematically it is defined as the extent to which an event is likely to occur, measured by the ratio of the favourable cases to the whole number of cases possible</td>
</tr>
<tr>
<td>Probable</td>
<td>May be expected to happen or prove true; likely</td>
</tr>
<tr>
<td>Would</td>
<td>To express probability (I guess she would be over 50 by now); past of Will: expressing a wish, ability, capacity, probability or expectation.</td>
</tr>
<tr>
<td><strong>Term (suite)</strong></td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>The usual amount, extent, rate</td>
</tr>
<tr>
<td>Extremely</td>
<td>Outermost, furthest from the centre; situated at either end; utmost; the highest or most extreme degree of anything</td>
</tr>
<tr>
<td>High</td>
<td>Extending above the normal or average level</td>
</tr>
<tr>
<td>Highly</td>
<td>In a high degree</td>
</tr>
<tr>
<td>Insignificant</td>
<td>Unimportant; trifling</td>
</tr>
<tr>
<td>Low</td>
<td>Less than average, coming below the normal level</td>
</tr>
<tr>
<td>Negligible</td>
<td>Not worth considering; insignificant</td>
</tr>
<tr>
<td>Significant</td>
<td>Noteworthy; important; consequential</td>
</tr>
<tr>
<td>Remote</td>
<td>Slight, faint</td>
</tr>
</tbody>
</table>
The difference between risk assessment and risk management and why is this important?

Risk assessors provide independent scientific advice on potential threats. Risk managers use this advice as a basis for making decisions to address these issues.

Figure 3  European Food Safety Authority (EFSA) infographic summarising the difference between risk assessment and 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 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).

**The need for dialogue and discussion between risk assessors and risk managers**

A close relationship between the risk assessors and risk managers is essential as there must be a rational relationship between the outcome of the risk analysis and the sanitary measures chosen. **The risk analysis should precede the decision, rather than being commissioned to support a decision already made.**

The formulation of import conditions is not always a purely technical process. The inputs into the conditions for importation include:

- the outcomes of the risk analysis
- experience of import/export staff
- consideration of the importing country’s ALOP
- availability of the sanitary measures and their practicality, feasibility and cost.

The outcomes of the risk analysis are aids in decision making. The decision maker must also take into account these other factors. Nevertheless, the outcomes of the risk analysis should be the most significant basis upon which the decision maker makes his or her decision.
Transparency

What does this mean and why is transparency essential?

The Code defines transparency as 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.

Transparency is essential to ensure:

- fairness and rationality
- consistency in decision making
- ease of understanding by all the interested parties
- assumptions are documented
- uncertainties are dealt with appropriately
- reasons for conclusions and recommendations are obvious
- stakeholders are provided with clear reasons for the imposition of sanitary measures or refusal to import.

The risk analysis must be well documented and supported with references to the scientific literature and other sources, including expert opinion, where used. There must be comprehensive documentation of all data, information, assumptions, methods, results, and uncertainties.

To facilitate risk communication it is essential that the risk analysis focus on information directly relevant to the logic chain of the analysis. Each disease should be discussed only to the extent necessary to enable the reader to gain an appreciation of likelihood of the entry, establishment or spread of hazard(s) and of their associated consequences. If, for example, it is concluded that the likelihood of a hazard being released into the importing country is negligible, there is no need to undertake an exposure and consequence assessment and explore risk management options.
Uncertainty and variability

The difference between uncertainty and variability

Incomplete knowledge or a lack of understanding of a pathogen will result in uncertainty, which is likely to be present in any risk analysis. This must be distinguished from the natural heterogeneity inherent in any biological system that will result in variability in a risk pathway.

Risk analysis is essentially a tool aimed at predicting the future. For example, we might want to predict the weight of a weaner pig chosen at random. We know from our own observations that there is a great deal of natural variation between individual pigs of this age. Such variability is a biological reality. While we might have a good ‘feel’ for what the range and average might be, it is only by weighing several pigs that we can begin to make some accurate predictions. As more data are collected, more knowledge is acquired, and we can describe the variation in the weights of weaner pigs with increasing certainty, enabling us to be increasingly confident of our predictions. If we weighed all pigs in the population we would have a perfect understanding of the average weight and how much variation exists and there would be no uncertainty. Obviously, this is impractical and we need to achieve a balance between acquiring perfect knowledge and obtaining reasonable estimates upon which we can base our predictions with a reasonable level of confidence.

Uncertainty may be thought of as a measure of the incompleteness of one's knowledge or information about an unknown quantity. It is important to remember that even with complete knowledge (that is, no uncertainty) variability still exists.

These ideas can be extended to import risk analysis where, for example, we want to predict the likelihood of an outbreak of foot and mouth disease in ‘Country A’ following the importation of goat cheese from ‘Country B’. For an outbreak to occur a complex chain of events needs to take place beginning with:

- an outbreak of FMD in ‘Country B’ that results in at least one infected goat shedding FMD virus in its milk
- the virus surviving pasteurisation, the cheese manufacturing process, storage and transportation to ‘Country A’
- a susceptible animal ingesting discarded cheese in ‘Country A’, becoming infected and transmitting the virus to other animals.

There may be some very good information on the survival of FMD virus in pasteurised milk, some limited information on the occurrence of FMD in ‘Country B’ and virtually no information on the likelihood of susceptible animals ingesting cheese scraps in ‘Country A’. A prediction in these circumstances will be based on information ranging from poor to excellent. As a result we could conclude that there is significant uncertainty in the estimates for the occurrence of FMD in ‘Country B’ and the exposure of susceptible animals in ‘Country A’. The impact of these uncertainties on the overall estimate of risk needs to be carefully considered. For instance, the impact is likely to be insignificant if pasteurisation is predicted to effectively kill FMD virus. On the other hand, if pasteurisation cannot be relied upon because FMD virus is either heat tolerant or there is significant variability in its effectiveness, the impact of these uncertainties becomes much more important.
Communication of uncertainty

Overall uncertainty in a risk assessment should be characterised in terms of how different the assessment outcome might be and how likely that is. There are several ways in which the contribution of the additional uncertainties can be quantified and incorporated into the assessment.

The clear and unambiguous communication of scientific uncertainty is an enabling mechanism, providing decision-makers with the scientific grounds for risk-based decision-making. It increases transparency both of the assessments and of the resulting decision-making, ensuring that confidence in the scientific assessment process is not undermined.

The EFSA Scientific Committee draft guidance on uncertainty in EFSA scientific assessment explores various approaches that can be taken to characterise and communicate uncertainty.
Qualitative and quantitative approaches

A qualitative assessment is essentially a reasoned and logical discussion of the relevant commodity factors and epidemiology of 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. 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 the majority of import risk analyses and is currently 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 as an adjunct to a qualitative assessment, for example, to gain further insights into a particular problem, to identify critical steps or to compare sanitary measures. Quantification involves developing a mathematical model to link the steps of the risk pathway, which are expressed numerically. The results, which are also expressed numerically, invariably present significant challenges in interpretation and communication.

Although a quantitative analysis involves numbers, it is not necessarily more objective, nor are the results necessarily more ‘precise’ than a qualitative analysis.

Since both qualitative and quantitative analyses are inevitably subjective, how can the degree of objectivity be demonstrated? The solution lies, not in the method chosen, but in ensuring that the analysis is transparent. All the information, data, assumptions, uncertainties, methods and results must be comprehensively documented and the discussion and conclusions supported by a reasoned and logical discussion. The analysis should be fully referenced and subjected to peer review.
Risk analysis and the WTO SPS Agreement

*SPS Agreement*

Under the SPS Agreement[^3] WTO Members can employ sanitary or phytosanitary measures[^4] to the extent necessary to protect human, animal or plant life or health. These measures must not be applied arbitrarily, nor result in discrimination between Members where similar conditions prevail, nor constitute a disguised restriction on trade.

The SPS Agreement[^5] requires WTO Members to base their sanitary measures on international standards, guidelines and recommendations, where they exist. However, Members may choose to adopt a higher level of protection than that provided by these texts if there is scientific justification or if the level of protection provided by measures prescribed in the relevant text are considered insufficient. In such circumstances, Members are obliged to base such measures on a risk assessment and to adopt a consistent approach to risk management.

The SPS Agreement recognises the OIE as the international organisation responsible for the development and promotion of international standards, guidelines, and recommendations for animal health and zoonoses. The relevant international standards for trade in live animals and animal products are the *Terrestrial Animal Health Code* (for mammals, birds and bees) and *Aquatic Animal Health Code* (for fish, molluscs and crustaceans).

**WTO notification**

Once the recommendations of the import risk analysis have been accepted by the Veterinary Administration or Competent Authority, and a schedule of the proposed sanitary measures has been drawn up, a WTO Member must notify other Members of:

- measure(s) where an international standard, guideline or recommendation does not exist or
- measure(s) that are not substantially the same as an international standard, guideline or recommendation and that may have a significant effect on the trade of other WTO Members.

Except in urgent circumstances, sufficient time should be allowed for comments to be taken into account, amendments to be introduced and exporters to adapt. The usual period for consultation before the proposed sanitary measures come into force is sixty days. Where circumstances are urgent, the proposed sanitary measures must still be notified with a brief indication of the objective and rationale of the measure(s), including the nature of the urgency. Members must be extended the opportunity to comment and their comments should be taken into account.

[^4]: These measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety
Communication and consultation with international counterparts

WTO Members are required to notify other Members when they propose to introduce a new measure or make changes to an existing measure affecting international trade, particularly where the measure is not substantially the same as an international standard, guideline or recommendation. Except in urgent circumstances, sufficient time should be allowed for Members’ comments to be taken into account, amendments to be introduced and exporters to adapt. Where circumstances are urgent, Members are still required to notify with a brief indication of the objective and the rationale of the measure, including the nature of the urgency, and allow other Members to comment and take the comments into account\(^6\).

---
The OIE risk analysis framework

The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material. The analysis should be transparent. This is necessary so that the exporting country is provided with clear reasons for the imposition of import conditions or refusal to import.

The Code identifies four components of a risk analysis: hazard identification, risk assessment, risk management and risk communication and provides a list of terms and corresponding definitions.

Hazard identification

Hazard identification involves identifying pathogenic agents that could potentially produce adverse consequences associated with the importation of a commodity\(^7\). To classify an agent as a hazard the following criteria need to be fulfilled:

---

\(^7\) Commodity means animals, products of animal origin intended for human consumption, for animal feeding, for pharmaceutical or surgical use or for agricultural or industrial use, semen, embryos/ova, biological products and pathological material
the agent must be appropriate to the species being imported, or from which the commodity is derived

it may be present in the exporting country. The evaluation of the Veterinary Services, surveillance and control programmes and zoning and regionalisation systems are important inputs for assessing the likelihood of hazards being present in the animal population of the exporting country

if present in the importing country it must be a notifiable disease\(^8\) or be subject to control or eradication.

A risk analysis may be concluded at this stage if the hazard identification step fails to identify hazards associated with an imported commodity. If hazards are identified and an importing country decides to apply the sanitary measures recommended for those hazards in the Code, there may be no need to conduct a full risk assessment.

**Risk assessment**

Risk assessment is the process of estimating the likelihood and biological and economic consequences of entry, establishment or spread of a hazard within the territory of an importing country. It consists of four inter-related steps:

- entry assessment, which consists of determining the likelihood of an imported commodity being infected or contaminated with a hazard and describing the biological pathway(s) necessary for that hazard to be introduced into a particular environment
- exposure assessment, which consists of describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards identified and estimating the likelihood of those exposure(s) occurring
- consequence assessment, which consists of describing the relationship between exposures to a hazard, the consequences of those exposures and their likelihood
- risk estimation, which consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce summary measures of the risks associated with the identified hazards.

**Risk management**

Risk management is the process of determining and implementing measures to achieve the importing country’s ALOP or ‘acceptable risk’, while at the same time ensuring that negative effects on trade are minimised.

Four components are identified:

- risk evaluation where the estimated risk is compared with the importing country’s appropriate level of protection
- option evaluation where measures are identified, evaluated and selected to effectively manage the risks in line with the importing country’s appropriate level of protection
- implementation where selected measures are applied
- monitoring and review where measures are audited to ensure that they are achieving the results intended.

---

\(^8\) Notifiable disease means a disease listed by the Veterinary Authority, and that, as soon as detected or suspected, must be brought to the attention of the Veterinary Authority
**Risk communication**

Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties (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 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.
Determining the scope of a risk analysis

Importance of clearly defining the scope of a risk analysis

Each risk analysis should be appropriate to the commodity under consideration. An analysis of the risks posed by trade in a highly processed commodity from a single country is likely to be a simpler and smaller analysis than one dealing with live animals from a diverse range of countries.

It is important at the outset of the risk analysis that there is clear definition of what commodities are covered.

A risk analysis may be based on a particular commodity, a category of commodities such as live virus vaccines or animal serum, an animal species or group of similar species such as ruminants, or a particular disease. The analysis may apply to a particular exporting country (bilateral) or a trading block, such as the European Union (multilateral) or, in some cases it may not apply to any particular country, in which case it is referred to as a generic risk analysis. Regardless of which option is chosen it is important to define the scope of the analysis and document the rationale for choosing a particular one.

As an example, in a risk analysis for the importation of eggs, one would need to clarify:

- the species (does it cover just hens’ eggs, or all commercial poultry)
- the type of eggs (hatching eggs, table eggs, processed egg product)
- whether the analysis is specific to eggs from a single country, or is generic to groups of countries?

The appropriate scientific name should be used when reference is made to an animal species or pathogenic agent. Where it is relevant, the nature, source(s), intended use(s) and the likely annual quantity of trade of the commodity should be detailed. A description of the relevant methods of production, manufacturing or processing normally applied, such as cooking, curing, irradiation, filtration and tests for sterility or freedom from contamination, should be included as well as any quality assurance programmes, such as Hazard Analysis Critical Control Points (HACCP), and how they are verified. While an accurate estimate of the anticipated quantity of trade is desirable, it may not be readily available, particularly where such trade is new. It is important to appreciate that a commodity definition or description does not, in itself, constitute a sanitary measure. It merely represents the starting point for a risk analysis.

---

9 A commodity, as defined by the Code, means animals, products of animal origin intended for human consumption, for animal feeding, for pharmaceutical or surgical use or for agricultural or industrial use, semen, embryos/ova, biological products and pathological material
The following checklist provides guidance on crafting a commodity definition:

a) Use scientific names when reference is made to an animal species or disease agent
   - e.g. sheep (*Ovis aries*), cattle (*Bos taurus*), Nile perch (*Lates niloticus*), Newcastle disease (Family *Paramyxoviridae*, genus *Paramyxovirus*, avian PMV-1), bovine tuberculosis (*Mycobacterium bovis*).

b) Describe the nature, source(s) and intended use(s), where relevant, of the commodity
   - e.g. frozen chicken (*Gallus gallus*) meat and chicken meat products from the United States of America for human consumption, live viral vaccines for administration by injection.

c) Describe the relevant methods of production, manufacturing, processing or testing that are normally applied
   - e.g. cooking, curing, irradiation, filtration, tests for sterility and freedom from contamination.

d) Describe any quality assurance programmes that may apply and how they are verified
   - e.g. in the production of vaccines or other biologicals, HACCP programmes in meat packhouses.

e) Estimate the likely annual volume of trade, so far as possible.

**Examples of risk analysis commodity definitions**

Some examples of appropriate titles for a risk analysis include:

a) Bilateral risk analysis
   - import risk analysis: fresh or frozen sheep semen (*Ovis aries*) imported from Australia

b) Multilateral risk analysis
   - import risk analysis: live cattle (*Bos taurus* or *Bos indicus* or crossbred animals derived from these species) imported from the European Union
   - import risk analysis: frozen Nile Perch (*Lates niloticus*) skinless, boneless fillets imported from Uganda, Kenya or Tanzania for human consumption

c) Generic risk analysis
   - import risk analysis: chicken (*Gallus gallus*) meat and chicken meat products for human consumption
   - import risk analysis: foot and mouth disease (family *Picorniviridae*, genus *Apthovirus*, foot and mouth disease virus A, Asia 1, C, O, SAT 1, SAT 2, SAT 3) in live ruminants
   - import risk analysis: live viral vaccines for administration by injection
   - import risk analysis: sera for administration to animals.
Hazard identification

Compiling a list of pathogenic agents appropriate for the species and commodity

To effectively manage the risks associated with imported commodities, any organisms that could potentially cause harm and could be introduced into the importing country must be identified. The potential hazards identified are those associated with the species being imported, or from which the commodity is derived, and which might be present in the exporting country. It is then necessary to identify whether each potential hazard is already present in the importing country, and whether it is subject to control or eradication in the importing country and to ensure that import measures are not more trade restrictive than those applied within the importing country.

Hazard identification also needs to consider whether strains of a potential hazard found in the importing country are likely to be less virulent than those reported internationally or in the exporting country, or if the proposed import will increase the exposure to a potential hazard in the importing country.

Depending on the nature of the commodity or the degree of processing, some categories of pathogenic agents may be excluded from consideration. For example, arboviruses such as West Nile virus, which replicate in bloodsucking arthropods and are transmitted by bite to a vertebrate host, need not be considered in a risk analysis for fresh or frozen meat or meat products.

The methods of production, manufacturing, or processing might also exclude certain categories of pathogenic agents.

Provided details of these production methods and a verifiable quality control programme, which includes testing, are included as part of a commodity description, these pathogenic agents do not need to be considered individually in a risk analysis. Where categories of pathogenic agents are excluded, a description of the category and the justification for their exclusion should be included as part of the hazard identification process. For example, provided meat and meat products have been derived from animals that have been subject to ante-mortem and post-mortem inspection in slaughter and processing plants, which operate effective Good Manufacturing Process (GMP) and Hazard Analysis and Critical Control Point (HACCP) programmes, then parasites restricted to the intestinal tract do not need to be considered as potential hazards in these commodities.

If hazard identification fails to identify any potential hazards associated with the imported commodity, then the risk analysis can be concluded at this point. If the importing country adopts international standards recommended in the OIE Terrestrial Animal Health Code, then there is also no need to continue a risk analysis beyond this point.

Identification of hazards from this list of pathogens

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 OIE list should be used as a starting point when developing these lists, but pathogens not included in the OIE list should also be considered, where appropriate.

Depending on the nature of the commodity or the degree of processing, some categories of pathogenic agents may be excluded from consideration. For example, gastro-intestinal parasites need not be considered in a risk analysis for semen or embryos as it is biologically implausible that these commodities would be potential vehicles for such pathogenic agents. The methods of production, manufacturing or processing may also exclude certain categories of pathogenic agents. Highly processed commodities, such as live virus vaccines or hormonal products derived from sera are not likely to be contaminated with certain bacteria or viruses because of their method of production. Provided details of these production methods and a verifiable quality control
programme, that includes testing, are included as part of a commodity description, these pathogenic agents would not need to be considered individually in a risk analysis. Hormonal products, for example, may undergo a number of filtration steps that would exclude bacteria and viruses of a certain size. Where categories of pathogenic agents are excluded a description of the category and the rationale for their exclusion should be included as part of the hazard identification process.

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 the exporting country. A conclusion is then reached as to 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 in a risk assessment. If no hazard is identified, the risk analysis should be concluded at this point.

A number of important questions must be considered when identifying hazards:

- Is the commodity under consideration a potential vehicle for the pathogenic agent?
- Is the pathogenic agent likely to be present in the exporting country?
- Is there sufficient evidence to conclude that the pathogenic agent is absent from the exporting country?

The evaluation of the Veterinary Services, surveillance and control programmes and zoning and regionalisation systems are important inputs for assessing the likelihood of hazards being present in, or absent from, the animal population of the exporting country.

- Is the pathogenic agent exotic to the importing country?
- Is the pathogenic agent notifiable in the importing country?
- Is the pathogenic agent subject to an official control programme in the importing country?
- Are there zones in the importing country that are free of the pathogenic agent or where its prevalence is low?

This criterion would apply if there are zones established under a national or regional disease control programme and where the movement of animals or animal products into the zone is under statutory control. It would also apply where natural boundaries prevented the spread of disease and this could be documented appropriately.

- If the pathogenic agent is present in the importing country, are the local strains likely to be less virulent than those reported internationally or in the exporting country?
The following steps are required to determine if a pathogenic agent is identified as a hazard:

1. If the commodity is a potential vehicle for the pathogenic agent proceed to step 2, otherwise the pathogenic agent is not a hazard.

2. If the pathogenic agent is exotic to the importing country but likely to be present in the exporting country it is classified as a hazard.

3. For a hazard reported in both the exporting country and the importing country
   if  
   a) there are documented free zones or zones of low prevalence in the importing country,
   or  
   b) the pathogenic agent is subject to an official control programme in the importing country,
   or  
   c) there is a more virulent strain in the exporting country,
   then the pathogenic agent may be classified as a hazard.

It is often wise for the risk analysts to consult with stakeholders on the list of hazards which have been identified before starting a risk assessment. This helps to ensure that the list is as complete as possible and is appropriate to the particular importing country.

Sources of information for hazard identification

The sources of information used should be clearly described in a risk analysis. Sources of information for conducting the hazard identification step will be found in scientific journals, textbooks and websites devoted to diseases of livestock, wildlife and zoo animals. These include:

1. OIE website: www.oie.int
2. OIE publications such as World Animal Health and Bulletin
3. OIE Terrestrial Animal Health Code
Risk assessment

An overview of the process to be followed for each identified hazard

Risk assessment consists of four steps:

- entry assessment
- exposure assessment
- consequence assessment
- risk estimation.

Entry and exposure assessments require the skills of a veterinary epidemiologist. When assessing the risks posed by vector-borne diseases there may be a need for input from entomologists, parasitologists and climatologists. Consequence assessment will require the skills of a veterinary epidemiologist and in some cases the skills of an economist. The requirement for access to sources of data and information may also call for the skills of the information specialist. In addition, the knowledge of experts in the relevant industries will be required.
Entry assessment

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

a) describe the biological pathway(s) necessary for the commodity to become infected or contaminated

*Note: a scenario tree provides a useful conceptual framework to assist in identifying and describing pathways.*

b) estimate the likelihood of the commodity 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 5 Scenario tree for an entry assessment for the likelihood of imported pigmeat harbouring porcine reproductive and respiratory syndrome virus (PRRSV).**

**Factors that must be considered in the entry assessment**

**Biological factors**

- The influence of age, breed, and sex of animals on the susceptibility to the potential hazard. For example, only Muscovy ducks and their hybrids are susceptible to Derzsy’s disease so the likelihood of entry for this disease is negligible for meat commodities derived from other duck species.

- Means of transmission (horizontal or vertical) of the hazard. For example, provided OIE guidelines on breeding flock hygiene are followed, of the OIE-listed avian diseases, only highly pathogenic avian influenza (HPAI), Newcastle disease, and avian mycoplasmosis have a non-negligible likelihood of entry in poultry hatching eggs.
• **Infectivity, virulence, and stability of the hazard.** *Chlamydia psittaci* is an obligate intracellular organism that depends on living host cells for high-energy metabolites, so will not be viable in meat.

• **Routes of infection** (oral, respiratory, etc). Inoculation of ducks with *Riemerella anatipestifer* via the intravenous or subcutaneous routes results in significant mortality at all challenge doses, whereas very high doses are needed to cause harm by oral challenge.

• **Agent predilection sites.** Studies have shown that low pathogenicity avian influenza (LPAI) cannot be transmitted to susceptible birds by feeding meat derived from an infected bird because virus replication is largely limited to the respiratory tract. LPAI has a negligible likelihood of entry in imported poultry meat. In contrast, HPAI replicates in a much wider range of tissues and feeding meat from an infected bird is known to transmit virus to a susceptible bird.

• **Impact of vaccination, testing, treatment, and quarantine.** Vaccination against some diseases, such as leptospirosis, might reduce the excretion rate of the organism and, therefore, the contamination of the environment. Vaccination of poultry has been shown to prevent HPAI virus replication in skeletal muscles.

**Country factors**

• **Incidence and prevalence.** The incidence rate of a disease agent affects the probability of a harvested animal being infected. For such information to have value, it should be derived from statistically based surveys reporting the disease prevalence, not just the clinical disease.

• **Evaluation of veterinary services, surveillance and control programmes, and zoning systems of the exporting country.** The quality of information relating to the disease status of a country reflects the standard of veterinary services and the programmes they manage.

• **Existence of disease-free zones and compartments.** If surveillance and disease management procedures allow recognition of such areas, then importation from these reduces the risk associated with that organism.

• **Farming and husbandry practices.** Traceability is recognised as an important food safety issue. Ruminants reared totally on pasture are exposed to risk factors different from those of ruminants spending part of their time housed or confined and fed concentrates. The likelihood of animals in the United Kingdom in the 1980s being exposed to the bovine spongiform encephalopathy agent depended on whether they had been fed meat and bone meal.

**Commodity factors**

• **Risk increases with increasing volume of trade.**

• **Likelihood of contamination.** Only healthy animals should be presented for harvest and the distance travelled before harvest should be minimised. Quality control techniques such as GMP and HACCP will help minimise contamination at harvest. The recovery of *Salmonella* Gallinarum-Pullorum from poultry meat has only been reported in environments with poor hygiene practices.

• **Effect of processing.** The pH of meat drops with rigor mortis. If the pH of meat falls below 6.0, then foot and mouth disease virus (FMDV) is likely to be inactivated. However, the pH might not fall below 6.0 if an individual is stressed prior to harvest and, as a result, FMDV may persist in the carcass. However, even in healthy animals, the pH will not fall
below 6.0 in lymph nodes, blood clots, viscera, and bone marrow, so these tissues pose a risk for the introduction of FMDV.

- **Effect of storage and transport.** Freezing is recognised to inactivate a number of pathogens such as Aujeszky’s disease virus, leptospires, and hydatids. Heat treatment can also be relied on to inactivate a number of pathogens although a few, such as infectious bursal disease virus, are recognised as being able to withstand domestic cooking temperatures.

Several of these factors might be influential in determining the likelihood of a potential hazard entering a country through an imported commodity. Figure 6 illustrates how these factors might impact the likelihood of introducing porcine reproductive and respiratory syndrome virus (PRRSv) in imported pig meat.
Sources of information for entry assessment

Advice on sources of information used to carry out the entry assessment may be sought from epidemiologists, risk analysts, biostatisticians, virologists, microbiologists, parasitologists, laboratory diagnosticians, wildlife specialists, biologists and ecologists. The information may be found scattered throughout the scientific literature, textbooks and other publications on risk analysis and risk assessment and statistical methods. Useful sources include the OIE publications World Animal Health, Bulletin and Manual of Standards for Diagnostic Tests and Vaccines and the OIE website: www.oie.int.

Other sources include import risk analyses carried out in other countries (although care should be taken to ascertain whether these have been peer-reviewed or not).

National disease reports and the veterinary journals of the exporting country are useful, as are any evaluations which may have been made of the veterinary services, monitoring and surveillance programmes and zoning and regionalisation of the exporting country.
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 infection can occur. However, exposure does not necessarily result in infection; it depends both upon the dose of pathogen and the degree of susceptibility of the host. This relationship is commonly called a dose response.

It should be appreciated that, particularly with contaminated commodities, a dose-response effect is likely to play a crucial role in the probability of successful infection. In such cases, it may be 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:

a) describe the biological pathway(s) necessary for exposure of animals and humans in the importing country

b) estimate the likelihood of these exposure(s) occurring

c) 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.

Matters that need to be considered including biological, country and commodity factors

There are a number of factors which may be relevant when considering the exposure assessment. These include, but are not limited to:

Biological factors

a) means of exposure to the hazard:
   – horizontal exposure:
     • direct (animal to animal contact, airborne spread, ingestion, coitus)
     • indirect (mechanical and biological vectors, intermediate hosts, iatrogenic exposure, fomites)
   – vertical exposure

b) stability, infectivity and virulence of the hazard

c) route of exposure (oral, respiratory, percutaneous)

d) susceptibility of animals likely to be exposed to the hazard (species, age, sex).

Country factors

a) presence of intermediate hosts or vectors

b) human and animal demographics

c) farming and husbandry practices

d) customs and cultural practices

e) geographical and environmental characteristics including rainfall and temperature.
Commodity factors

a) intended use of the imported animals or animal products
b) waste disposal practices
c) quantity of commodity to be imported.

The exposure assessment is often the area where there is greatest uncertainty in a risk assessment. For example, for contaminated meat products to serve as vehicles for the introduction of animal disease, the following criteria must be met:

- The pathogen in the meat must be present at an infectious dose.
- Scraps of meat must be fed to a susceptible animal of the appropriate species in the importing country.
- The pathogen must be able to establish infection when given via the oral route.
- If an infection is established in the importing country, local conditions must be such that the disease could spread.

With the exception of pathogens that are able to survive the processes involved in meat and bone meal manufacture, for imported meat to introduce a disease the contaminating pathogen must be able to infect a carnivorous or omnivorous animal when eaten. Ruminants, being herbivores, are extremely unlikely to be infected directly by pathogens carried in meat. The greatest risk of exposure, therefore, occurs in countries with significant pig populations, although imports of poultry meat could expose local poultry to certain disease risks. However, domestic legislation controlling the feeding of waste food to pigs and poultry might have some impact on this risk.

The concentration of the pathogen in meat and the dose of the pathogen required to establish infection via the oral route need to be considered. Continuing the example described in Figure 6 (above) of PRRSv in imported pig meat:

- Meat containing an infectious dose of PRRSv at harvest is likely to come from pigs that are at the peak of viraemia. The mean concentration of PRRSv in the blood of pigs at the peak of viraemia can be estimated from published studies to be approximately $10^{3.38}$ TCID$_{50}$ ml$^{-1}$ blood.
- The residual blood content of lean meat is $2–9$ ml kg$^{-1}$ muscle, so the viral titer of meat after bleeding out will be no more than 0.9% of the peak viraemic titer.
- Maturation and the delay before the product arrives at the point of retail result in a further reduction of the amount of viable virus that can also be quantified using published studies.
- The results of experimental studies published in 2005 have established the dose–response relationship between the oral dose of PRRSv and the probability of infection.

Knowing the likely concentration of virus in imported pork at the point of retail (taking into account the effect of bleeding out, maturation, and refrigeration or freezing), it is possible to predict the probability of a known weight of pork taken from a viraemic individual to contain an infectious dose of virus if fed to a susceptible recipient. Furthermore, as the available evidence suggests that only 1.2% of meat samples taken from pigs at harvest are likely to harbor an infectious dose of PRRSv, one can also estimate the probability of a known weight of pork imported from a country where PRRSv is present to contain an infectious dose of the virus. Such calculations have shown
that 1 kg of pig meat imported from a country with PRRSv has a probability of $1.8 \times 10^{-3}$ of containing an infectious dose of virus. However, caution is needed when extrapolating outside experimental results when using purely mathematical models fitted to experimental data. Because of this, the results reported here should be considered highly conservative (i.e., overestimating the probability of infection). For low-dose calculations, a mechanistic model (e.g., $\beta$-Binomial, $\beta$-Poisson, or Weibull-Gamma) is more plausible. Further discussion of this is beyond the scope of this course.

**Sources of information for exposure assessment**

As with the entry assessment, the starting point for finding the information used in the exposure assessment is the expertise of epidemiologists, risk analysts, biostatisticians, virologists, microbiologists, parasitologists, laboratory diagnosticians, wildlife specialists, biologists, ecologists, livestock industry specialists, field veterinarians and product specialists.

Import risk analyses carried out in other countries may be useful, so long as one can be confident these have been adequately peer-reviewed.

The general and specialist scientific literature, including textbooks, websites and other publications on risk analysis, epidemiology, risk assessment and statistical methods, products and product processing, may be consulted to provide information relevant to particular exposure assessments.
Consequence assessment

Consequence assessment describes the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process should exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socioeconomic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring.

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.

The WTO SPS Agreement states that:

*Members shall take into account as relevant economic factors; the potential damage in terms of loss of production or sales in the event of entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.*

The Code expands on these ‘relevant economic factors’ to differentiate between the ‘direct’ and ‘indirect’ effects of a disease, and to provide examples of factors that will typically be relevant to an import risk analysis. Under the provisions of the SPS Agreement, these consequences may be taken into account only to the extent that they are directly or indirectly attributable to the hazard. Effects not related to the hazard, such as the impact of competition from cheaper imported goods on a particular industry, must not be taken into consideration. In addition, consequence assessments must not consider the benefits, for example to consumers, of trade in a commodity. Each hazard should be dealt with separately with a reasoned, logical and referenced discussion to:

\[a\) estimate the likelihood that at least one animal becomes infected \]
\[b\) identify the biological, environmental and economic consequences associated with the entry, establishment or spread of the hazard, and their likely magnitude \]
\[c\) estimate the likelihood of the occurrence of these consequences. \]

*Note:* a causal relationship must exist between exposure to a hazard and an adverse affect.

The risk analysis may be concluded at this point if consequences are not identified or the likelihood of the consequences is negligible.

A number of factors may be attributable to the hazard.

**Direct consequences**

\[a\) outcome of exposure in domestic and wild animals and their populations: \]
\[\text{– biological (morbidity and mortality, sterile immunity, incubatory or convalescent carriers, latent infection)} \]
\[\text{– production losses} \]
\[b\) public health consequences \]
\[c\) environmental consequences: \]
\[\text{– physical environment, such as ‘side effects’ of control measures} \]
\[\text{– impacts on other life forms, biodiversity, endangered species.} \]

**Indirect consequences**

\[a\) 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)

b) 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:

a) disease does not establish within the exposed population

b) disease establishes within the exposed population, but is quickly identified and eradicated

c) disease establishes within the exposed population and spreads to other populations before eventually being eradicated

d) 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, district, 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.

A detailed analysis of the estimated consequences is not necessary if there is sufficient evidence, or it is widely agreed, that the introduction of a hazard will have unacceptable consequences. In such cases, risk assessment will primarily focus on the likelihood of entry, establishment and exposure. It will, however, be necessary to examine impact factors in greater detail when the level of unwanted consequences is in question, or when the level of unwanted consequences is needed to evaluate the strength of measures used for risk management or in assessing the cost-benefit of exclusion or control.
Sources of information for consequence assessment

The starting point for finding the information used in the consequence assessment is the expertise of epidemiologists, risk analysts, biostatisticians, virologists, wildlife specialists, biologists, ecologists, livestock industry specialists, agricultural economists, field veterinarians and product specialists.

Import risk analyses carried out in other countries may be useful, so long as one can be confident these have been adequately peer-reviewed and care is taken to ascertain that the circumstances pertaining in one country are relevant in another.

The general and specialist scientific literature, including textbooks and other publications on epidemiology, risk analysis and economics may be consulted to provide information relevant to particular exposure assessments.
Risk estimation

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

Each hazard should be dealt with individually, summarising the results or conclusions arising from the release, 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 may 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 judgement.

Risk estimation decision steps

Entry assessment
Is the likelihood negligible that the commodity is carrying the hazard when it is imported?
– if the answer is YES, the risk estimate is classified as negligible
– if the answer is NO, then conduct an exposure assessment.

Exposure assessment (likelihood of susceptible animals or humans becoming exposed)
Is the likelihood negligible of susceptible animals or humans being exposed via each and every exposure pathway?
– if the answer is YES, the risk estimate is classified as negligible.
– if the answer is NO, then conduct a consequence assessment.

Consequence assessment
Is the likelihood of each and every significant biological, environmental or economic consequence negligible?
– if the answer is YES, the risk is estimated to be negligible
– if the answer is NO, then proceed to risk management.
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 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 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:

**Risk evaluation**

If the risk estimate, determined in the risk assessment, is greater than negligible, sanitary measures may be justified.

**Option evaluation**

*a*) identify possible options, including the Code’s sanitary measures, where they are available

To assist in identifying appropriate option(s) it is necessary to formulate an objective which states what these option(s) should aim to achieve in order to effectively manage the risks. The objective needs to be quite specific, for example, to effectively manage the risks of AHS, sanitary measures should ensure that imported horses are not viraemic.

*b*) evaluate the likelihood of the entry, exposure, establishment or spread of the hazard according to the option(s) that might be applied

*c*) select an option or combination of options that will achieve the ALOP of the importing country. The following guidelines must be taken into account when selecting option(s):

- ensure that the option(s) are based on scientific principles
- ensure that the Code’s sanitary measures are considered. If there is a scientific justification that the Code’s measure(s) do not effectively manage the risks, 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 applied only to the extent necessary to protect human or animal life or health
- ensure that negative trade effects are minimised
- ensure that the option(s) are not applied arbitrarily
- ensure that the option(s) do not result in discrimination between exporting countries where similar conditions exist
- ensure that the option(s) are feasible by considering the technical, operational and economic factors affecting their implementation

The objective of risk management is to manage risk appropriately to ensure that a balance is achieved between a country’s desire to minimise the likelihood or frequency of disease incursions
and their consequences, and its desire to import commodities and fulfill obligations under international trade agreements.

Because risk is a function of probability and consequences, risk management may either seek to reduce the probability of an event occurring or the consequences of it occurring. Continuing the example of the risk of PRRSv in imported pig meat, options that could be considered to manage this risk may include:

- **Removal of high-risk tissues.** PRRSv has a high affinity for lymphoid tissues, although replication does not appear to be significant in bone marrow. Therefore, the removal of major carcass lymphoid tissues, especially those of the head and neck, and also the major regional lymph nodes, can be considered to significantly reduce the risk in meat.

- **Stabilised herds.** Pigs that are naturally exposed to PRRSv after having recovered from a previous infection with the same virus strain are known to have a shorter duration of viraemia than naïve animals exposed for the first time, providing the basis for the concept of the ‘stabilised’ herd. Thus, in situations where infection is known to have occurred several months prior to harvest, even if the animals have been recently reinfected, the likelihood of viraemia in harvest age pigs can be considered to be significantly lower than in situations where a herd of naïve animals has been infected just a few weeks prior to harvest.

- **Treatment of pig meat to inactivate PRRSv.** PRRSv is known to be relatively sensitive to pH; outside the range of pH 6.0–7.5, the virus is rapidly inactivated. On this basis, a wide range of salamis can be considered to pose negligible risk of PRRS. Similarly, holding meat chilled for a week has been shown to reduce the level of infectivity present by 90%, so curing for 12 months such as in the production of Parma ham is considered to result in insignificant levels of infectivity. PRRSv has been shown to be inactivated following exposure to 56°C for an hour, so pig meat that is cooked at this level or greater is considered to pose negligible risk.

- **Measures that reduce the likelihood of exposure.** Any form of meat that minimises trimming or cutting during its preparation prior to cooking can be expected to pose a lower risk than whole carcasses because of the lower likelihood that scraps will be generated prior to cooking that might be fed to pigs in the importing country. For example, quantitative modeling in New Zealand has shown that if imports of pig meat are restricted to consumer-ready cuts weighing less than 3 kg, then the probability of a PRRSv incursion would be equivalent to a mean of once every 1227 years.
Risk communication

Risk communication is the exchange of information and opinions with stakeholders during a risk analysis, and the communication of the results of a risk assessment and proposed risk management measures with the decision-makers and interested parties in the importing and exporting countries.

The communication of the risk should be an 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 is a crucial component of risk communication in order to obtain scientific critique and to ensure that the data, information, methods, and assumptions used in a risk analysis are the best available.

Developing a risk communication strategy

It is essential to establish a communication strategy from the start of a risk analysis to ensure that stakeholders are provided with an opportunity to become involved. The strategy must identify the potential stakeholders and aim to be inclusive rather than exclusive. The strategy should also identify various opportunities with which to communicate with stakeholders, for example, official publications, web pages, direct mail-outs and public notices in newspapers.

Stakeholders should be invited to provide comment from the outset. To ensure that a meaningful dialogue is established, all parties should acknowledge that they have an obligation to provide a reasoned argument that is relevant to the analysis, and a right to propose a contrary view. Once a decision is reached not all stakeholders may agree with it. However, by involving them from the outset, considering their concerns and addressing them appropriately, they may have a greater understanding of why a particular decision has been reached.

Who is involved in the risk communication process?

All the potentially affected or interested parties (stakeholders) in both the importing and exporting countries, including:

- Veterinary Administrations
- the WTO and OIE
- importers and exporters
- producer, farmer and consumer organisations
- academia and scientific institutions
- the media

Factors to be considered when developing a risk communication strategy

Effective risk communication requires the preparation and dissemination of information on the scope of the risk analysis, the hazards to be considered, the risk assessment itself, the proposed risk management measures and the final decision. Stakeholders should be provided with an opportunity to engage in a two-way dialogue with the Veterinary Administration or Competent Authority to ensure that their legitimate concerns and comments are adequately addressed.

The goals of risk communication

The goals of an effective risk communication strategy are:

\( a) \) to exchange information freely by undertaking an interactive and iterative (two-way) dialogue with stakeholders from the outset of a risk analysis
b) to maximise the effectiveness and efficiency of the risk analysis process by providing stakeholders with the opportunity to share information, which may not otherwise be available to:
- risk assessors during the hazard identification and risk assessment steps and
- risk managers when they are identifying and evaluating available sanitary measures

c) to provide information that is meaningful, relevant, accurate, clear and targeted to specific stakeholder groups

d) to promote an awareness and understanding of specific issues

e) to promote consistency and transparency in making and implementing risk management decisions by documenting all the scientific data, information, assumptions, uncertainties, methods, discussion, conclusions and other factors (International agreements, domestic legislation, social, economic, religious and ethical issues, stakeholder perceptions of risk, etc.) that are taken into account in reaching a decision

f) to provide stakeholders with an assurance that their legitimate concerns will be addressed and that feedback will be timely

g) to strengthen working relationships and mutual respect among all participants in the risk analysis process

h) to enhance public trust and confidence in the safety of imported commodities.
Peer review and consultation

Risk analysis as a discipline is based in science, and so risk analyses should be subjected to a process of peer review.

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

- internal scientific review within the Veterinary Service
- external scientific review by selected experts with specialised knowledge in risk analysis and its application to the diseases under consideration.

This is so 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 within the WTO dispute settlement system.

Reviewers are normally chosen on the basis of their status as acknowledged authorities in their field. External scientific review can only be carried out properly when reviewers have a clear idea of what is expected of them. This means the reviewers must be given specific terms of reference. For example:

a) Is the approach biologically and technically sound? Is the logic of the process clear? Can the steps from hazard identification, through the risk assessment to formulation of appropriate sanitary measures be easily followed?
b) Does the document make clear what are data and what are assumptions?
c) Has the literature been cited accurately? Have any important publications been overlooked?
d) Are the references cited appropriate? That is, are the critical epidemiological observations based on secondary sources where it would have been preferable to consult primary sources?
e) Have the relevant international standards been applied appropriately?
f) In those sections where risks have been assessed quantitatively:
  – Is it clear precisely what has been modelled?
  – Have both the scenario being modelled, and the modelling approach, been adequately described in the written text?
  – Is the scenario being modelled plausible, logical and appropriate?
  – Would every iteration of the model give a biologically plausible output?
  – Is the structure of the model appropriate?
  – Are appropriate data used?
  – Is the model mathematically sound and are the formulae used appropriate?
  – Are the distributions used appropriate for the data or information being modelled?
  – Are there any data or information that have been overlooked but which might be appropriate in the quantitative assessment?

Each critique received from the reviewers should be considered carefully by the risk analysts and, where appropriate, incorporated into the analysis. If the reviewers’ suggestions are not adopted, the rationale for this should be fully explained and documented in case the same issue is raised at a later stage in a challenge to the conclusions of the analysis.

Veterinary Administrations and Competent Authorities should expect to pay for the time experts spend reviewing risk analyses.
CONCLUSIONS

Risk analysis is a tool intended to provide decision makers with an objective, repeatable and documented assessment of the risks posed by a particular course of action. Risk analysis is intended to answer the questions:

– What can go wrong?
– How likely is it to go wrong?
– What would be the consequences of its going wrong?
– What can be done to reduce either the likelihood or the consequences of its going wrong?

Qualitative risk assessment is essentially a reasoned and logical discussion of the relevant commodity factors and epidemiology of a hazard in which the likelihood of its release and exposure and the magnitude of the consequences are expressed using non-numerical terms such as high, medium, low or negligible.

The qualitative approach is suitable for the majority of import risk analyses and is currently the most common type of assessment undertaken to support routine import decision-making.

In conducting a qualitative risk analysis, a number of important steps must be worked through in a systematic manner, while keeping the assessment as simple as possible. In summary, these include:

a) determine the scope of the risk analysis
b) state the question to be answered clearly and explicitly
c) assemble the team
d) develop a risk communication strategy
e) determine the information required
f) determine the approach:
   – determine what information is available for each step in the assessment
   – identify the populations of interest
   – estimate the likelihood of the hazard(s) being imported
   – estimate the likelihood of susceptible animals or humans being exposed to the hazards
   – estimate the likely consequences of susceptible animals or humans being exposed to the hazards
   – decide whether risk management measures are warranted
g) examine the risk management strategies available
h) formulate a programme of risk management measures
i) document the assumptions, evidence, data and uncertainties for each variable
j) consider how the data and the results should be presented to facilitate communication
k) commission a peer review of the risk analysis, and address input
l) publish the full risk analysis.

Risk analysis is a structured process designed to aid decision-making in the face of uncertainty. While risk analysis strives for objectivity, essential data are often lacking. Therefore, assumptions are unavoidable and, in the interests of transparency, these must be stated explicitly and justified.
Further reading

The following documents are examples of the application of a risk analysis framework and to provide more discussion and illustration of some of the key principles:


Appendix 1 – Glossary of terms

**Acceptable risk**: A risk level judged by a country to be compatible with the protection of animal and public health within its territory.

**Animal health status**: The status of a country or a zone with respect to an animal disease in accordance with the criteria listed in the relevant chapter of the *Code* dealing with the disease.

**Appropriate level of protection**: The level of protection deemed appropriate by the country establishing a sanitary measure to protect human or animal life or health within its territory.

**Biosecurity**: A set of management and physical measures designed to reduce the risk of introduction, establishment and spread of animal diseases, infections or infestations to, from and within an animal population.

**Biosecurity plan**: A plan that identifies potential pathways for the introduction and spread of disease in a zone or compartment, and describes the measures which are being or will be applied to mitigate the disease risks, if applicable, in accordance with the recommendations in the *Code*.


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

**Compartment**: An animal subpopulation contained in one or more establishments under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.

**Competent Authority**: The Veterinary Authority or other Governmental Authority of a country 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 *Code* in the whole territory.

**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 them occurring.

**Emerging disease**: A new occurrence in an animal of a disease, infection or infestation, causing a significant impact on animal or public health resulting from:
- a change of a known pathogenic agent or its spread to a new geographic area or species; or
- a previously unrecognised pathogenic agent or disease diagnosed for the first time.

**Entry assessment**: The process of describing the biological pathway(s) necessary for an importation activity to introduce pathogenic agents into a particular environment, and estimating the probability, either qualitatively or quantitatively, of that complete process occurring.

**Equivalence of sanitary measures**: The state wherein the sanitary measure(s) proposed by the exporting country as an alternative to those of the importing country, achieve(s) the same level of protection.

**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.
**Free compartment.** A compartment in which the absence of the animal pathogen causing the disease under consideration has been demonstrated by all requirements specified in the Code for free status being met.

**Free zone.** A zone in which the absence of the disease under consideration has been demonstrated by the requirements specified in the Code for free status being met. Within the zone and at its borders, appropriate official veterinary control is effectively applied for animals and animal products, and their transportation.

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

**Hazard identification.** The process of identifying the hazards which could potentially be introduced in the commodity considered for importation.

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

**Importing country.** A country that is the final destination to which commodities are sent.

**Incubation period.** The longest period which elapses between the introduction of the pathogen into the animal and the occurrence of the first clinical signs of the disease.

**Infection.** The entry and development or multiplication of an infectious agent in the body of humans or animals.

**Infective period.** The longest period during which an affected animal can be a source of infection.

**International trade.** Importation, exportation and transit of commodities.

**International veterinary certificate.** A certificate, issued in accordance with Chapter 5.2. of the Code, describing the animal health or public health requirements which are fulfilled by the exported commodities.

**Monitoring and review.** The ongoing process by which the risk management measures are audited to ensure that they are achieving the results intended.

**Official control programme.** A programme which is approved, and managed or supervised by the Veterinary Authority of a country for the purpose of controlling a vector, pathogen or disease by specific measures applied throughout that country, or within a zone or compartment of that country.

**Official Veterinarian.** A veterinarian authorised by the Veterinary Authority of the country to perform certain designated official tasks associated with animal health or public health and inspections of commodities and, when appropriate, to certify in accordance with Chapters 5.1. and 5.2. of the Code.

**Official veterinary control.** The operations whereby the Veterinary Services, knowing the location of the animals and after taking appropriate actions to identify their owner or responsible keeper, are able to apply appropriate animal health measures, as required. This does not exclude other responsibilities of the Veterinary Services e.g. food safety.

**Option evaluation.** The process of identifying, evaluating the efficacy and feasibility of, and selecting measures in order to reduce the risk associated with an importation in line with the country’s appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options.
Qualitative risk assessment: An assessment where the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as ‘high’, ‘medium’, ‘low’ or ‘negligible’.

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

Quarantine station: An establishment under the control of the Veterinary Authority where animals are maintained in isolation with no direct or indirect contact with other animals, to ensure that there is no transmission of specified pathogen(s) outside the establishment while the animals are undergoing observation for a specified length of time and, if appropriate, testing and treatment.

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

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

Risk assessment: The evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard.

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

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

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

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

Safe commodity: A commodity which can be traded without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation and regardless of the status of the country or zone of origin for that disease, infection or infestation.

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

Sensitivity analysis: The process of examining the impact of the variation in individual model inputs on the model outputs in a quantitative risk assessment.

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

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

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

Veterinary Administration: The governmental Veterinary Service having authority in the whole country for implementing the animal health measures and international veterinary certification process which the OIE recommends, and supervising or auditing their application.
**Veterinary Authority**: A Veterinary Service, under the authority of the Veterinary Administration, which is directly responsible for the application of animal health measures in a specified area of the country. It may also have responsibility for the issuing or supervision of the issuing of international veterinary certificates in that area.

**Veterinary Services**: The Veterinary Services comprise the Veterinary Administration and all the Veterinary Authorities.

Chapter 2.1.
Import risk analysis

Article 2.1.1.

Introduction

The importation of animals and animal products involves a degree of disease risk to the importing country. This risk may be represented by one or several diseases or infections.

The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material. The analysis should be transparent. This is necessary so that the exporting country is provided with clear reasons for the imposition of import conditions or refusal to import.

Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst’s value judgements may blur.

This chapter provides recommendations and principles for conducting transparent, objective and defensible risk analyses for international trade. The components of risk analysis are hazard identification, risk assessment, risk management and risk communication (Figure 1).

Fig. 1. The four components of risk analysis

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

The process of import risk analysis usually needs to take into consideration the results of an evaluation of Veterinary Services, zoning, compartmentalisation and surveillance systems in place for monitoring of animal health in the exporting country. These are described in separate chapters in the Terrestrial Code.

Article 2.1.2.

Hazard identification

The hazard identification involves identifying the pathogenic agents which 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 then necessary to identify whether each hazard is already present in the importing country, and whether it is a notifiable disease or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

Hazard identification is a categorisation step, identifying biological agents dichotomously as hazards or not. The risk assessment may be concluded if hazard identification fails to identify hazards associated with the importation.

The evaluation of the Veterinary Services, surveillance and control programmes and zoning and compartmentalisation systems are important inputs for assessing the likelihood of hazards being present in the animal population of the exporting country.

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

Article 2.1.3.

Principles of risk assessment

1. Risk assessment should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Risk assessment should be able to accommodate the variety of animal commodities, the multiple hazards that may be identified with an importation and the specificity of each disease, detection and surveillance systems, exposure scenarios and types and amounts of data and information.

2. Both qualitative risk assessment and quantitative risk assessment methods are valid.

3. The risk assessment should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.
4. Consistency in risk assessment methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.

5. Risk assessments should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate.

6. Risk increases with increasing volume of commodity imported.

7. The risk assessment should be amenable to updating when additional information becomes available.

Article 2.1.4.

Risk assessment steps

1. **Entry assessment**

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

   a. Biological factors
      - species, age and breed of animals
      - agent predilection sites
      - vaccination, testing, treatment and quarantine.

   b. Country factors
      - incidence or prevalence
      - evaluation of Veterinary Services, surveillance and control programmes and zoning and compartmentalisation systems of the exporting country.

   c. Commodity factors
      - quantity of commodity to be imported
      - ease of contamination
      - effect of processing
      - effect of storage and transport.

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

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 (in this case the pathogenic agents) from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

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

a. Biological factors
   - properties of the agent.

b. Country factors
   - presence of potential vectors
   - human and animal demographics
   - customs and cultural practices
   - geographical and environmental characteristics.

c. Commodity factors
   - quantity of commodity to be imported
   - intended use of the imported animals or products
   - disposal practices.

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

3. Consequence assessment

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

a. Direct consequences
   - animal infection, disease and production losses
   - public health consequences.

b. Indirect consequences
   - surveillance and control costs
   - compensation costs
   - potential trade losses
   - adverse consequences to the environment.
4. Risk estimation

Risk estimation consists 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. Thus risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

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

Article 2.1.5.

Principles of risk management

1. Risk management is the process of deciding upon and implementing measures to address the risks identified in the risk assessment, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage risk appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import commodities and fulfil its obligations under international trade agreements.

2. The international standards of the OIE are the preferred choice of sanitary measures for risk management. The application of these sanitary measures should be in accordance with the intentions in the standards.

Article 2.1.6.

Risk management components

1. 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.

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

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

4. Monitoring and review - the ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended.

Article 2.1.7.

Principles of risk communication
1. Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties in the importing and exporting countries. It is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout.

2. A risk communication strategy should be put in place at the start of each risk analysis.

3. The communication of the risk should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

4. The principal participants in risk communication include the authorities in the exporting country and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.

5. The assumptions and uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated.

6. Peer review is a component of risk communication in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.
## Appendix 3 – Checklist for import risk analysis

**Import Risk Analysis**

**File:**

---

### Primary Author

<table>
<thead>
<tr>
<th>Name</th>
<th>Date Initiated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

### Internal Peer Review

1. Risk Assessment only

<table>
<thead>
<tr>
<th>Reviewer(s)</th>
<th>Name</th>
<th>Date</th>
<th>Date Comments Received</th>
<th>Changes Required?</th>
<th>Date Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Risk Management

<table>
<thead>
<tr>
<th>Reviewer(s)</th>
<th>Name</th>
<th>Date</th>
<th>Date Comments Received</th>
<th>Changes Required?</th>
<th>Date Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

### External Technical Review

1. Risk Assessment only

<table>
<thead>
<tr>
<th>Reviewer(s)</th>
<th>Name</th>
<th>Date</th>
<th>Date Comments Received</th>
<th>Changes Required?</th>
<th>Date Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2. Risk Management

Reviewer(s)

<table>
<thead>
<tr>
<th>Name</th>
<th>Date</th>
<th>Date comments received</th>
<th>Changes required?</th>
<th>Date complete</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RELEASE FOR CONSULTATION WITH GOVERNMENT DEPARTMENTS

Sent for consultation

<table>
<thead>
<tr>
<th>Sent to:</th>
<th>Date</th>
<th>Date comments received</th>
<th>Changes required?</th>
<th>Date complete</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTIFICATION OF GENERAL RELEASE

<table>
<thead>
<tr>
<th>Notification type and place</th>
<th>Date of notification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PUBLIC DISTRIBUTION

<table>
<thead>
<tr>
<th>Sent to:</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SUBMISSIONS

Original deadline for submissions: ____________
Extended to: _____________________________
For reason: _____________________________
Submissions received
<table>
<thead>
<tr>
<th>From</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**REVIEW OF SUBMISSIONS**

<table>
<thead>
<tr>
<th>Sent to:</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>