Handbook on Import Risk Analysis for Animals and Animal Products

Volume 1

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Introduction and qualitative risk analysis

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Second Edition

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Foreword

The importation of animals and their products involves a degree of disease risk to the importing country. This risk may be presented by one or several diseases or pathogenic agents. The Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) of the World Trade Organization (WTO) allows WTO Members two options in setting sanitary measures to protect against such risks. The SPS Agreement strongly encourages Members to base their sanitary measures on international standards such as the OIE *Terrestrial Animal Health Code* and the OIE *Aquatic Animal Health Code*. However, in the absence of relevant standards or when Members choose to adopt a higher level of protection than that provided by such standards, science-based risk analysis is essential to determine whether importation of a particular commodity poses a significant risk to human or animal health, and if so, what sanitary measures could be adopted to reduce that risk to an acceptable level. Under the SPS Agreement, the level of protection applied to imports should not be stricter than that applied to domestic products that present comparable SPS risks.

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. In this regard, the principal aim of import risk analysis, an important and evolving discipline, is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals and their products.

Volume 1 of this *Handbook* was first published in 2004. It introduced the concepts of import risk analysis and discussed qualitative risk analysis, and Volume 2, also published for the first time in 2004, addresses quantitative risk analysis. In 2009 Volume 1 was updated by an OIE group of internationally recognised experts who were convened to produce a revised second edition. The key issues in the discipline are explained within the frameworks provided by the SPS Agreement and the chapters on risk analysis in the OIE *Codes.* In addition to taking account of relevant new information, the main goal of the revision was to make Volume 1 more suitable for use as a training tool, particularly for veterinarians in developing countries, by the provision of tested practical examples.

This handbook will provide valuable practical guidance to Veterinary Services needing to analyse the risks posed by imports, to ensure that stakeholders, risk analysts and decision makers can be confident that the disease risks posed have been identified and can be managed effectively. The handbook will also be useful as a training aid to address the critical need for capacity building in this discipline.

My sincere thanks go to the experts and the International Trade Department who accepted this task on behalf of the OIE.

In addition to selling the publication, the OIE is publishing the *Handbook* online to ensure that this important information is accessible to Veterinary Services and their stakeholders worldwide.

Dr Bernard Vallat

Director General, OIE

Glossary

Different disciplines may use technical terms with different definitions. For the purposes of this *Handbook*, the following definitions apply:

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

Aquatic Code: The OIE *Aquatic Animal Health Code*.

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

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

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

Entry assessment (formerly known as release assessment): The process of describing the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) pathogenic agents into a particular environment, and estimating the probability, either qualitatively or quantitatively, of that complete process occurring.[1]

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

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

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

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.

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.

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1 The terms 'likelihood' and 'probability' may be used interchangeably. There is a tendency to use the term 'probability' when referring to quantified risk, and 'likelihood' when risk has been assessed qualitatively. However, both terms are correct.

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

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

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

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

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

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

Terrestrial Code: The OIE *Terrestrial Animal Health Code.*

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

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

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

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

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

Abbreviations

AHS	African horse sickness
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
FAO	Food and Agriculture Organization of the United Nations
HACCP	Hazard Analysis Critical Control Points
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
NAS	National Academy of Sciences (USA)
NRC	National Research Council (USA)
OIE	World Organisation for Animal Health
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
WTO	World Trade Organization

Chapter 1
Introduction to import risk analysis

1. Introduction

The objective of this handbook is to provide an international reference text on qualitative import risk analysis for animals and animal products based on the *Terrestrial Animal Health Code* (*Terrestrial Code*) and *Aquatic Animal Health Code* (*Aquatic Code*) (the *Codes*) of the World Organisation for Animal Health (OIE).

Animal health risk analysis is a relatively new and evolving discipline. This *Handbook* outlines the international obligations with respect to the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), and provides a framework for the risk analysis process based on the standards described in the *Codes.* This is intended to ensure that stakeholders, risk analysts and decision makers can be confident that the disease risks posed by imported goods are identified and managed effectively.

The qualitative approach is suitable for the majority of import risk analyses, and is currently the most common type of assessment undertaken to support routine import decision making. However, in some circumstances it may be desirable to undertake a quantitative risk analysis: for example, to gain further insights into a particular problem, to identify critical steps or to compare sanitary measures. Quantification involves developing a mathematical model to link the steps of the risk pathway, which are expressed numerically. The results are also expressed numerically. For a detailed description of quantitative risk analysis, the reader is referred to Volume 2 of this *Handbook* (OIE, 2004).

Animal import risk analysis is concerned with guiding the decision-making process in a structured manner to effectively manage the disease risks associated with the importation of live animals, semen, embryos/ova, biological products, pathological material, and commodities intended for human consumption, for animal feeding, for pharmaceutical or surgical use, or for agricultural or industrial use. In this context risk has two components: one, the likelihood[1] of a disease entering, establishing or spreading in the importing country, and two, its impact on animal or human health, the environment and the economy.

Some form of risk analysis has always been undertaken, or decision makers have used various alternative means of guiding a decision on the feasibility of a particular import. However, it is only since the early 1990s, particularly following the implementation of the SPS Agreement and the recognition of the OIE standards as references for this Agreement, that documented methodologies have been developed and transparent processes have emerged.

The OIE and its sister standard-setting organisations recognised under the SPS Agreement, the International Plant Protection Convention and the Codex Alimentarius Commission, have all developed guidelines on the risk analysis methodology to be used to assist decision makers in answering the following questions:

- What can go wrong?
- How likely is it to go wrong?

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1 The terms 'likelihood' and 'probability' may be used interchangeably. There is a tendency to use the term 'probability' when referring to quantified risk, and 'likelihood' when risk has been assessed qualitatively. However, both terms are correct.

- What are the consequences of it going wrong?
- What can be done to reduce the likelihood and/or the consequences of its going wrong?

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:

1. Determine the scope of the risk analysis;
2. State the question to be answered clearly and explicitly;
3. Assemble the team;
4. Develop a risk communication strategy;
5. Determine the information required;
6. 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;
7. Examine the risk management strategies available;
8. Formulate a programme of risk management measures;
9. Document the assumptions, evidence, data and uncertainties for each variable;
10. Consider how the data and the results should be presented to facilitate communication;
11. Commission a peer review of the risk analysis, and address input;
12. 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. While the focus of this volume, and Volume 2 (OIE, 2004), is on risk analysis with respect to importation of animals and animal products, we hope that the reader will find the techniques described in this *Handbook* useful in all animal health decision making in the face of uncertainty.

2. What is risk?

Risk is usually defined as the chance of encountering some form of harm, loss or damage. For this reason it has two components: the chance, or probability, of something happening; and if it does happen, the consequences. Because of the element of chance, we can never predict exactly what will happen. There is, however, a certain probability of any particular outcome occurring.

In addition to the above, we need to also consider a third element of risk. Many actions are considered to be 'risky', such as, for example, living near a nuclear power plant,

while others, such as walking down a flight of stairs, are not usually considered in the same light. Although the consequences of a nuclear accident could be devastating, the chance of an accident occurring in a modern reactor is probably remote. Similarly, while the consequences of falling down some stairs could be serious for the person involved, the chance of such an accident may also be remote. So why is one of these activities considered to be more risky than the other? The answer lies in the way risk is perceived. Issues such as whether the risk is borne voluntarily, the magnitude of its consequences, its familiarity, to what extent it is dreaded, and how preventable it is, all influence the perception of risk.

3. Approaches to risk analysis

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 qualitative or quantitative assessments of risk, to the resultant management decisions. Import risk analysis also includes communication with stakeholders throughout the process.

The risk analysis process usually comprises four components:

1. Hazard identification
2. Risk assessment
3. Risk management
4. Risk communication.

However, in the biological field, several systems of terminology are in use to describe the process of risk analysis. The system adopted for use in the *Codes* is the one more generally used in the animal health field, and is the one used in this book. It is based on the system first described by Covello and Merkhofer (1993). In this system, risk assessment follows hazard identification, which is considered a separate step and is completed first. This is followed by the four steps of the risk assessment process: entry assessment, exposure assessment, consequence assessment and risk estimation (Fig. 1).

3.1. Codex Alimentarius Commission

Another set of terminology commonly used in biological risk assessment is that of the National Academy of Sciences-National Research Council (NAS-NRC) model (NRC, 1983). This terminology is used by the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) specifically for microbiological food safety risk assessment. The NAS-NRC model and the derived Codex system are briefly described here to avoid confusion, because import risk analysts may encounter these models in other contexts.

The NAS-NRC system divides risk assessment into the following four steps: hazard identification, hazard characterisation, exposure assessment, and risk characterisation. Within the NAS-NRC system, hazard identification is included as a part of risk assessment rather than preceding it as in the OIE system. The exposure assessment in the Codex system includes both the entry assessment and exposure assessment components of the OIE system. The other difference between the two systems is the assessment of consequence, called hazard characterisation in the NAS-NRC framework and consequence assessment in the OIE system (Fig. 2).

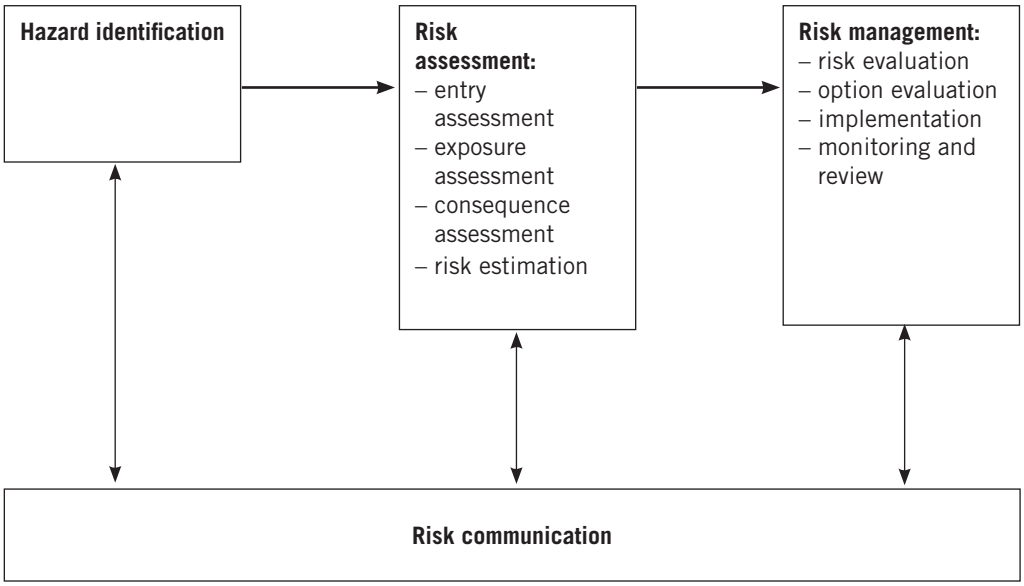

Figure 1 The structure of the OIE risk analysis process

The NAS-NRC system was developed in response to the need to set maximum limits of chemical substances in the environment, food and so on. The risk assessments undertaken using this system were therefore designed to answer the question: 'What is the maximum amount of a substance (or pathogen) to which a person should be allowed to be exposed from a particular source?' The framework used in this model is therefore designed as a regulatory tool for setting allowed, acceptable or tolerable levels of contaminants and pathogens in food, and is the system most frequently used by toxicologists.

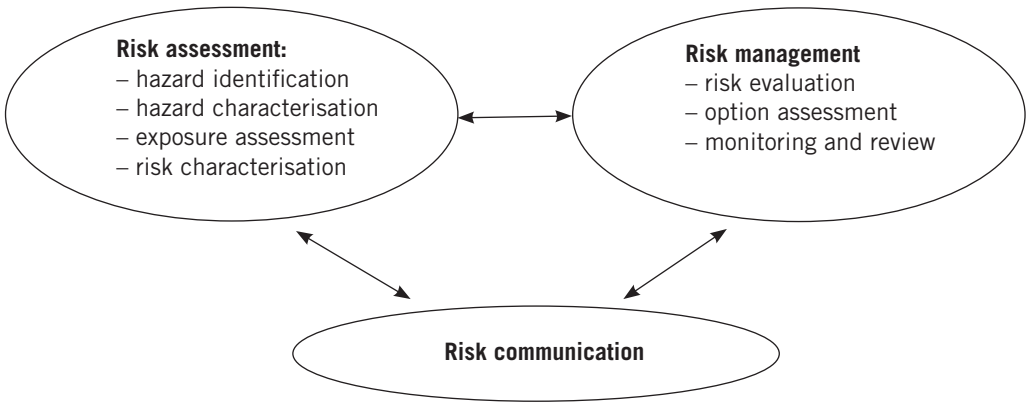

Figure 2 The structure of the NAS-NRC risk analysis process

3.2. International Plant Protection Convention (IPPC)

In the international regulation of matters relating to plant health, the OIE's sister standard-setting organisation is the IPPC. The IPPC is part of the FAO, and is recognised by the WTO under the SPS Agreement as being responsible for developing International Standards for Phytosanitary Measures (ISPMs) to guide governments wishing to protect their plant resources from harmful pests as a result of international trade in plants and plant products. ISPM 11 provides guidelines for the conduct of pest risk analyses (PRAs)

to determine whether a pest is of potential economic importance to an area in which it is not present or is under official control. Such a pest is designated a 'quarantine pest'.

The objectives of a PRA are, for a specified area, to identify pests and/or pathways of quarantine concern and evaluate the risk presented, to identify endangered areas, and if appropriate, to identify risk management options. The PRA process for quarantine pests is defined by three stages (Fig. 3):

- Stage 1 (process initiation) identifies when pest(s) and/or pathway(s) are of quarantine concern and should be considered for subsequent risk assessment;
- Stage 2 (risk assessment) begins with the categorisation of individual pests to determine whether the criteria for a quarantine pest are satisfied. Risk assessment continues with an evaluation of the probability of pest introduction and spread, and of the potential economic consequences;
- Stage 3 (risk management) identifies risk management options for reducing the risks identified at stage 2. These are evaluated for efficacy, feasibility and impact in order to select those that are appropriate.

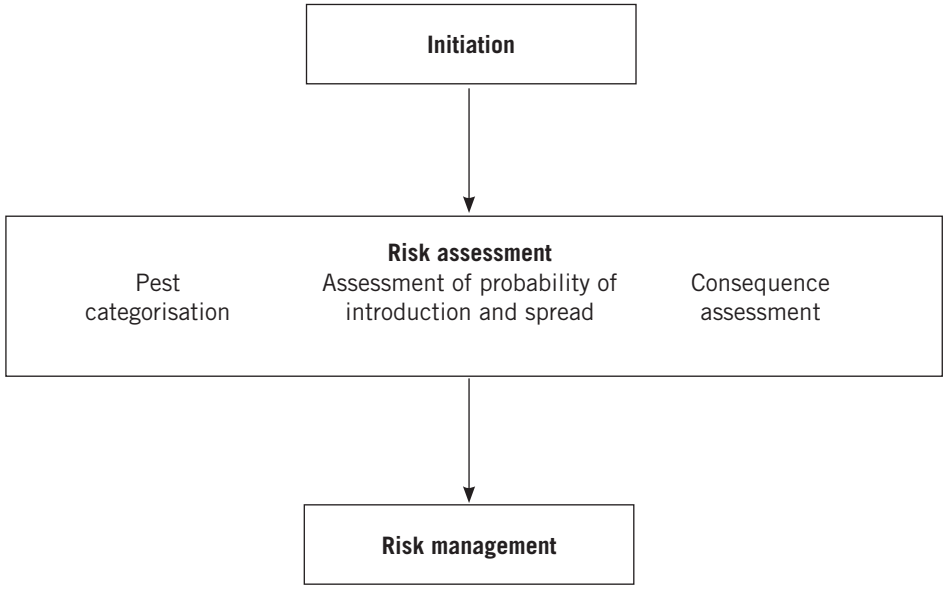

Figure 3 The structure of the IPPC pest risk analysis (PRA) process

The steps in the process are similar to those described in the *Code*, with the main exception being that the IPPC includes pest categorisation (equivalent to hazard identification) within risk assessment, rather than as a separate procedure. The outcomes of IRAs and PRAs are normally described in identical terms.

3.3. World Organisation for Animal Health (OIE)

The Covello and Merkhofer (1993) model for risk assessment, adopted by the OIE, is designed to assess the actual magnitude of the risk for specified consequences in a given situation. It can then be used to decide whether the risk is acceptable as it stands, or whether sanitary measures are required to reduce the risk to an acceptable level. Risk assessments using this system are designed to answer the question: 'What is the likelihood of specified consequences (the adverse human health, animal health, economic or environmental effects of interest) occurring as a result of exposure to a particular

substance or pathogen that came from a defined release source?' This system is more versatile than the NAS-NRC system, and can be applied to various risk questions, making it the system of choice for many risk assessors.

4. Import risk analysis for animals and animal products

The importation of animals and animal products involves a degree of disease risk to the importing country. There may be multiple risks associated with a proposed importation.

The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material. Transparency – that is, the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions – is essential, because data are often uncertain or incomplete, and without full documentation, the distinction between facts and the analyst's value judgements may not be clear. Transparency is also necessary to provide trading partners and stakeholders with clear reasons for the risk management decision.

5. World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures

Members of the World Trade Organization (WTO) have certain rights and obligations. Under the Application of Sanitary and Phytosanitary Measures Agreement (SPS Agreement) (WTO 1994), Members can employ sanitary or phytosanitary measures to the extent necessary to protect human, animal or plant life or health. These measures must not be applied arbitrarily, or result in discrimination between Members where similar conditions prevail, or constitute a disguised restriction on trade.

The SPS Agreement requires WTO Members to base their sanitary measures on international standards, guidelines and recommendations, where they exist. However, Members may choose to adopt measures that result in 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 is 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 published in the *Terrestrial Code* (for mammals, birds and bees) and the *Aquatic Code* (for amphibians, crustaceans, fish and molluscs).

5.1. Types of risk analysis addressed in the SPS Agreement

The SPS Agreement applies to SPS measures, which are defined as measures that are applied to address:

- animal or plant health risks arising from pests or diseases
- human health risks from diseases carried by animals, plants or their products
- human or animal health risks arising from food or feed safety risks
- the risk of other damage arising from pests.[2]

These measures must be based on either an international standard or a risk assessment (SPS Agreement Articles 3.1, 3.3, 5.1).

The SPS Agreement contains two definitions of the term 'risk assessment', one for food safety risks and one for pest or disease risks (SPS Agreement Annex A, paragraph 4). According to these definitions, food safety risk assessments should address 'the potential for adverse effects on human or animal health from the presence of pathogenic agents, additives, contaminants or toxins in foods, beverages or feedstuffs'. Food safety risk assessments are not considered further in this *Handbook*.

Pest or disease risk assessments are defined as:

> The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences (SPS Agreement Annex A, paragraph 4).

5.2. Factors to take into account in a risk analysis

Members should take into account the risk assessment techniques developed by the relevant international organizations, including the OIE (SPS Agreement, Article 5.1).

According to the jurisprudence coming from cases brought to the WTO dispute settlement system, risk assessments should include the following three steps (WTO, 1998a, 1998b):

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

In addition, the SPS Agreement (SPS Agreement, Article 5.2) identifies the following scientific and biological factors to be taken into account:

- available scientific evidence
- relevant processes and production methods
- relevant inspection, sampling and testing methods
- prevalence of specific diseases or pests
- existence of pest- or disease-free areas
- the existence of eradication or control programmes
- relevant ecological and environmental conditions
- quarantine or other treatment.

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2 SPS Agreement, Annex A, paragraph 1. 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 labeling requirements directly related to food safety.

The relevant economic factors to consider are (SPS Agreement, Article 5.3):

- potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease
- costs of control or eradication
- relative cost-effectiveness of alternative approaches to limiting risks.

5.3. Evaluating risk

A disease or pest risk assessment requires an evaluation of the likelihood of entry, establishment or spread of a disease, and of the associated biological and economic consequences. The OIE has developed standards (the *Codes*) that require the risk to be expressed in terms of probability, rather than mere possibility. For this reason, it is not sufficient to conclude that there is a possibility of a risk arising. An evaluation of the likelihood of the risk, which may be expressed qualitatively or quantitatively, must be undertaken.

It is very difficult to prove that a risk does not exist. However, purely hypothetical risks should not be considered in an import risk analysis (WTO, 1998a). Such risks, however, may need to be addressed through risk communication.

5.4. Evaluating disease or pest risks individually

A risk assessment must identify risk on a hazard-specific basis. That is, it has to identify separately the risk for any given hazard of concern, not simply address the overall risk related to the combination of all hazards. This is because each hazard is likely to behave differently. However, some of the elements of a risk assessment related to one hazard might be applicable to the assessment of the risk posed by another hazard, so that hazard-by-hazard assessments may overlap. A specific assessment for one hazard of concern may select a sanitary measure which, incidentally, is sufficient to address a range of hazards. In such a case, there may be no need to conduct a full assessment of the risks posed by the other hazards (WTO, 1998b). That is, a relatively short risk assessment may suffice to demonstrate that the sanitary measure selected for one hazard addresses all the hazards.

5.5. Evaluating disease or pest risks according to the measures that might be applied

The SPS Agreement requires that a disease or pest risk assessment evaluate the likelihood of entry, establishment or spread of disease according to the SPS measures that might be applied. For this reason, it is not acceptable simply to identify a range of measures that might reduce the risks. There must be a rational relationship between the measures and the risk assessment, so that the results of the assessment support the measures chosen. Each measure must be evaluated either singly or in combination with other measures to determine its relative effectiveness in reducing the overall disease risk (WTO, 1998a).

5.6. Striving for objectivity in a risk analysis

While a risk analysis inevitably includes subjective elements, there are a number of factors within the SPS Agreement, including ‘risk assessment techniques developed by the relevant international organisations’, ‘available scientific evidence’ and ‘scientific principles’, which

should be used to maximise objectivity. The level of objectivity must be such that a relatively high degree of confidence is achieved in the evaluation, particularly in the assessed levels of risk (WTO, 2000).

5.7. Dealing with insufficient information

Where scientific evidence is insufficient, according to Article 5.7 of the SPS Agreement measures may be adopted provisionally on the basis of available pertinent information. However, additional information should be sought to allow a more objective risk assessment within a reasonable period of time (WTO, 1994). While the so-called 'precautionary principle'[3] has not been written into the SPS Agreement as a ground for justifying measures that are otherwise inconsistent with the Agreement, it finds reflection inter alia in Article 5.7. The precautionary principle does not override the SPS Agreement's requirement that sanitary or phytosanitary measures be based on either an international standard (in this case the *Codes*) or a risk analysis that takes into account available scientific evidence (WTO, 1998c).

5.8. Equivalence

Issues of equivalence arise frequently in import risk analysis. Equivalence is the capability of different sanitary measures to meet the same objectives. The SPS Agreement requires that Members accept the sanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member demonstrates objectively to the importing Member that its measures achieve the importing Member's appropriate level of sanitary protection (SPS Agreement Article 4).[4]

5.9. Regionalisation

Article 6 of the SPS Agreement deals with the concept of regionalisation. This places an obligation on Members to adapt their sanitary measures to the sanitary characteristics of the area – whether all of a country, part of a country, or all or parts of several countries – from which the product originated and to which the product is destined. Assessments of sanitary characteristics should take into account, inter alia, the prevalence of specific diseases, the existence of eradication or control programmes and relevant OIE standards.

Determination of disease-free areas and areas of low disease prevalence should be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary controls.

Exporting Members wishing to use the regionalisation principle should provide relevant evidence to support their claims and should give trading partners reasonable access for inspection, testing and other relevant procedures.

The WTO-SPS Committee has published guidelines on implementing Article 6 (G/SPS/48, 16 May 2008), and the *Codes* contain standards for the guidance of Members wishing

3 Principle 15 of the Rio Declaration on Environment and Development (United Nations, 1992) is often referred to as the precautionary principle. It states that 'in order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'

4 The SPS Committee has adopted a 'Decision on the Implementation of Article 4 of the SPS Agreement' (G/SPS/19/Rev.2).

to apply the concepts of zoning and compartmentalisation. The latter concept is similar to regionalisation. Both concepts are based on the establishment of a sub-population of animals with a different health status from that of the general population. In the case of zoning, this separation is based mainly on physical factors, such as geography and physical barriers. In the case of a compartment, the separation is based mainly on management factors. However, in both zones and compartments, biosecurity is of fundamental importance to prevent the movement of the specified pathogen from the population of lower health status into the sub-population of higher health status.

In any risk assessment, the disease status of the source of the animals/products is a key element in evaluating the probability that a disease agent may be present. In the event that the assessment deals with animals or products originating from an officially recognised country, region, zone or compartment with a defined disease status, the risk assessor should take account of the provisions in Article 6 of the SPS Agreement and of relevant OIE standards and recommendations.

5.10. Notifying other WTO Members

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 can put a measure in place without notifying their trading partners first, but they are still required to notify (after the fact) with a brief indication of the objective and the rationale of the measure, including the nature of the urgency, allow other Members to comment, and take the comments into account (SPS Agreement Article 7 and Annex B).

6. Obligations under other international agreements and under domestic legislation

The risk analyst may also have obligations under international conventions and agreements ratified by their own country, such as the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES, 1973), the Convention on Biological Diversity, or other conventions related to protection of the environment or biodiversity. Preliminary guidelines on the conduct of risk analysis with reference to invasive alien species are available from the Secretariat of the Convention on Biological Diversity (CBD, 1993).

The risk analyst may have specific obligations under domestic legislation. These may apply either directly to imports of animals and animal products, or indirectly to, for example, public health risks, environmental protection, plant health and biological control agents. Relevant analyses in these areas of concern may be carried out by government agencies other than the Veterinary Services.

7. The *Terrestrial Animal Health Code* and *Aquatic Animal Health Code*

The *Terrestrial Code* and *Aquatic Code* document the standards referred to in the SPS Agreement that are relevant to import risk analysis for animals and animal products.

The *Terrestrial Code*, prepared by the OIE Terrestrial Animal Health Standards Commission, contains standards, guidelines and recommendations designed to prevent the introduction of pests and diseases into the importing country during trade in animals, animal genetic material and animal products, while the *Aquatic Code* is a companion publication prepared by the Aquatic Animal Health Standards Commission.

The purpose of the *Codes* is to ensure the sanitary safety of international trade in animals and animal products so as to avoid the transfer of disease agents that are pathogenic for animals or humans. The standards published in the *Codes* are developed using the principles of risk analysis, and are subject to scientifically based peer review by experts in OIE Member Countries and Territories. This is an important concept that should be considered before a decision is made to conduct an import risk assessment, as the standards in the *Codes* themselves present the outcome of a risk assessment, whether it is to render certain commodities safe for trade purposes, even in the presence of a certain disease in a country, or whether it is to recommend certain risk mitigation measures that need to be applied by the exporting country to certify a commodity safe for trade.

Proposals from OIE Members for the development of new standards or the revision of existing standards are addressed by the relevant OIE Specialist Commission. A new or revised standard may be drafted by a Member, an OIE *ad hoc* working group of experts convened for the purpose, or the specialist Commission itself. The draft standard is then circulated to all Members for comment and initial discussion by the OIE World Assembly of Delegates. The specialist Commission examines the draft, taking into account comments received, and revises the text for adoption at the next meeting of the World Assembly of Delegates. Once formally adopted, the standard is made available for implementation by Members.

7.1. Structure of the Terrestrial Code *and commodities considered to be safe for trade*

Volume 1 of the *Terrestrial Code* contains 'horizontal' texts on:

- animal disease diagnosis, surveillance and notification
- risk analysis
- quality of Veterinary Services
- disease prevention and control
- trade measures, import/export procedures and veterinary certification
- veterinary public health
- animal welfare.

In Volume 2 of the *Terrestrial Code*, OIE-listed diseases are addressed in separate 'vertical' chapters structured as follows (although some chapters do not yet contain all listed elements):

a) a brief description of the disease

b) a list of 'safe commodities', that is, those that are considered not to require any disease-specific measures, irrespective of the status of the exporting country for the disease

c) a list of commodities that are considered to require the measures described later in the chapter, with the understanding that an importing country should not impose additional measures for such commodities

d) a list of the factors that should be taken into account in assessing the risks presented by the exporting country for that disease

e) lists of the requirements that should be met by a country/zone/compartment to achieve a specified disease status, for example 'disease-free country', 'free zone with vaccination', 'moderate risk', or 'free flock'

f) articles containing the recommended health measures to be applied to commonly traded commodities, taking into account the likelihood of the pathogen being transmitted through that commodity and the disease status of the exporting country.

Where an animal product is listed as a safe commodity, no specific measures other than the general requirements provided in the *Terrestrial Code* need be applied, and there is no need to conduct a specific risk analysis.

Where there is no recommendation for a particular commodity in the *Terrestrial Code*, it means that OIE experts have not yet developed relevant health measures. In this case, an OIE Member should base its import health measures for the commodity on a scientific risk analysis.

7.2. Structure of the Aquatic Code *and commodities considered to be safe for trade*

Sections 1 to 7 of the *Aquatic Code* contains 'horizontal' texts on:

- aquatic animal disease diagnosis, surveillance and notification
- risk analysis
- quality of Competent Authorities
- disease prevention and control
- trade measures, import/export procedures and health certification
- veterinary public health
- welfare of farmed fish.

In Sections 8 to 11 of the *Aquatic Code*, OIE-listed diseases are addressed in separate 'vertical' chapters structured as follows:

a) definition of the pathogen/disease

b) a list of susceptible species

c) a list of 'safe commodities', i.e. those that are considered not to require any disease-specific measures, irrespective of the status of the exporting country for the disease

d) a list of 'safe' products that have been prepared and packaged for retail trade, i.e. those products that have been prepared and packaged for retail trade and do not require disease-specific measures, irrespective of the status of the exporting country for the disease

e) lists of the requirements that should be met by a country/zone/compartment to achieve a specified disease status, for example 'disease-free country', 'free zone', 'free compartment'

f) recommendations for importations of aquatic animal commodities from a country, zone or compartment declared free of the specified disease.

g) recommendations for importations of aquatic animal commodities from a country, zone or compartment not declared free of the specified disease.

Where an aquatic animal product is listed as a safe commodity, no specific measures other than the general requirements provided in the *Aquatic Code* need be applied, and there is no need to conduct a specific risk analysis.

Where there is no recommendation for a particular commodity in the *Aquatic Code*, it means that OIE experts have not yet developed relevant health measures. In this case, an OIE Member should base its import health measures for the commodity on a scientific risk analysis.

7.3. Useful documents

The current *Codes* are available on the OIE website (www.oie.int) and hard copies are updated annually.

Other relevant documents on the OIE website cover:

- The production and implementation of OIE Standards (OIE, nd)
- The rights and obligations of OIE Members for International Trade (OIE, 2009a)
- Application of the *Code* Recommendations for trade in animal products ('commodities') (OIE 2009b).

Chapter 2
Applying the OIE risk analysis framework

This chapter takes the reader step by step through the risk analysis framework. Throughout this chapter an example of an import risk analysis for the importation of horses potentially infected with African horse sickness (AHS) virus is used to illustrate various steps involved in undertaking a risk analysis. An additional example of an import risk assessment for the introduction of live carp is provided in Appendix 2. This example uses an aquatic animal, and although simpler in approach is equally of value.

1. The OIE risk analysis framework

Both the *Terrestrial Code* and the *Aquatic Code* have dedicated chapters that provide recommendations and guidelines for import risk analysis. Several other horizontal chapters, including the quality of Veterinary Services or Competent Authorities, zoning and compartmentalisation, and surveillance, as well those chapters dealing with specific diseases, are important reference sources for import risk analysis.

According to the *Codes* 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 *Codes* identify four components of a risk analysis: hazard identification, risk assessment, risk management and risk communication (Fig. 4), and provides a list of terms and corresponding definitions. This chapter provides detailed explanations, guidelines and recommendations for each component of a risk analysis, together with a worked example to demonstrate how the OIE framework is applied in practice.

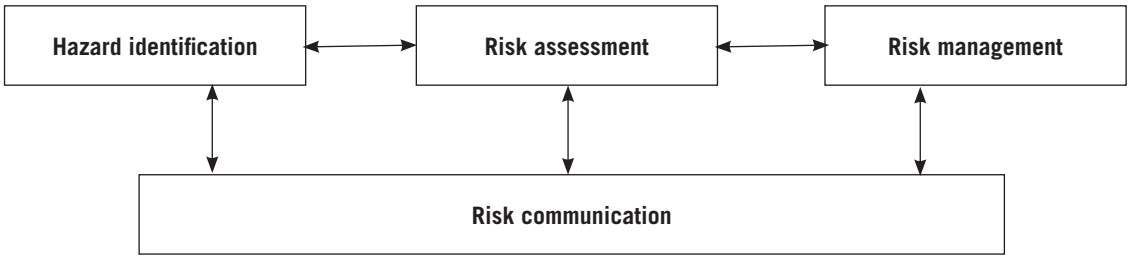

Figure 4 The four components of risk analysis

2. Resource issues and the team approach

Before proceeding with a detailed explanation of the risk analysis process it is worth reflecting on a number of resource-related issues.

2.1. The type of skills required

At a minimum, the basic skills for undertaking a risk analysis consist of epidemiology, the ability to think critically, and a good understanding of the country's domestic legislation and the SPS Agreement, together with well-developed communication skills.

Depending on the commodity being considered and the scope of the analysis, additional skills may be required, including those of pathologists, virologists, microbiologists, parasitologists and economists. In some instances it may be necessary to seek advice from experts as diverse as climatologists, entomologists, ornithologists, environmental scientists and industry technologists. In addition, where it is decided to undertake a quantitative assessment, mathematical modellers and statisticians may also need to be involved.

2.2. The project team approach

Considering the range and types of skills required to undertake a risk analysis, it is unlikely that all this expertise could ever be incorporated into a single risk analysis unit, even in the most developed countries. Depending on its complexity a risk analysis may need to be undertaken by a project team with individuals who have the necessary skills being brought into the team as appropriate. Members of the team do not need to be located at the same site.

2.3. Collaboration between countries

A project team approach may not be possible in many countries, as limited resources and ready access to appropriate skills sets are inescapable realities. In such cases it is important to identify whether there are opportunities for collaboration between countries, for example, where several countries have common concerns and face the same or similar risks.

2.4. Adapting risk analyses undertaken in other countries

Another option worth considering is to adapt risk analyses undertaken elsewhere provided they have been adequately peer reviewed and are relevant to the import scenario under consideration.

2.5. Setting timelines

It is important to appreciate that a good risk analysis requires adequate time.

2.6. Undertaking training

A suitable formal course in import risk analysis is the best method for learning how to do risk analysis. Such courses may be available through an OIE Collaborating Centre (www.oie.int/eng/OIE/organisation/en_listeCC.htm), an OIE Regional Representation (www.oie.int/eng/Divers/en_weboie.htm?e1d13), at tertiary education institutions or from specialists in the field.

In the absence of a suitable formal course in risk analysis, and because import risk analysis is a specialised application of epidemiology, the best training that can be provided for staff embarking on import risk analyses is the discipline of epidemiology. Indeed, it has been said that 'risk analysis is to epidemiology what weather forecasting is to meteorology'.

3. Steps involved in undertaking a risk analysis

Summary

In developing an import risk analysis there are a number of important steps to work through systematically. These are outlined in Figure 5 with a detailed template provided in Appendix 1. The steps, which are discussed in depth in this section, include:

1. Determining the scope of the risk analysis;
2. Stating the purpose of the risk analysis clearly;
3. Developing a risk communication strategy;
4. Identifying sources of information for the risk analysis;
5. Identifying hazards likely to be associated with the commodity under consideration;
6. Determining whether or not the *Code* recommends sanitary measures for the hazards in the commodity under consideration;
7. Conducting a risk assessment for each hazard:
   i) identifying the populations of interest
   ii) drawing a scenario tree to identify the various biological (risk) pathways leading to the commodity harbouring the hazard when imported; susceptible animals and/or humans being exposed; and potential 'outbreak' scenarios
   iii) dealing with uncertainty
   iv) choosing a qualitative or quantitative approach
   v) using appropriate terminology
   vi) conducting an entry assessment to estimate the likelihood of the commodity introducing the hazard into the country
   vii) conducting an exposure assessment to estimate the likelihood of susceptible animals or humans being exposed to the hazard
   viii) conducting a consequence assessment to estimate the likely magnitude of potential biological, environmental and economic consequences associated with the entry, establishment or spread of the hazard and the likelihood of their occurrence
   ix) summarising the conclusions of the entry, exposure and consequence assessments to provide an overall risk estimation;
8. Determining whether sanitary measures are warranted (risk management):
   i) evaluating the risk to determine if the risk estimate is greater than the country's acceptable risk level
   ii) evaluating animal health options to effectively manage the risks posed by each hazard as well as ensuring that the options chosen are consistent with the country's obligations under the SPS Agreement
   iii) conducting a scientific peer review of the overall risk analysis
   iv) implementing the sanitary options by making a final decision on the measures selected
   v) monitoring and reviewing factors that may impact on the conclusions of the risk analysis and/or the implementation of the sanitary measures.

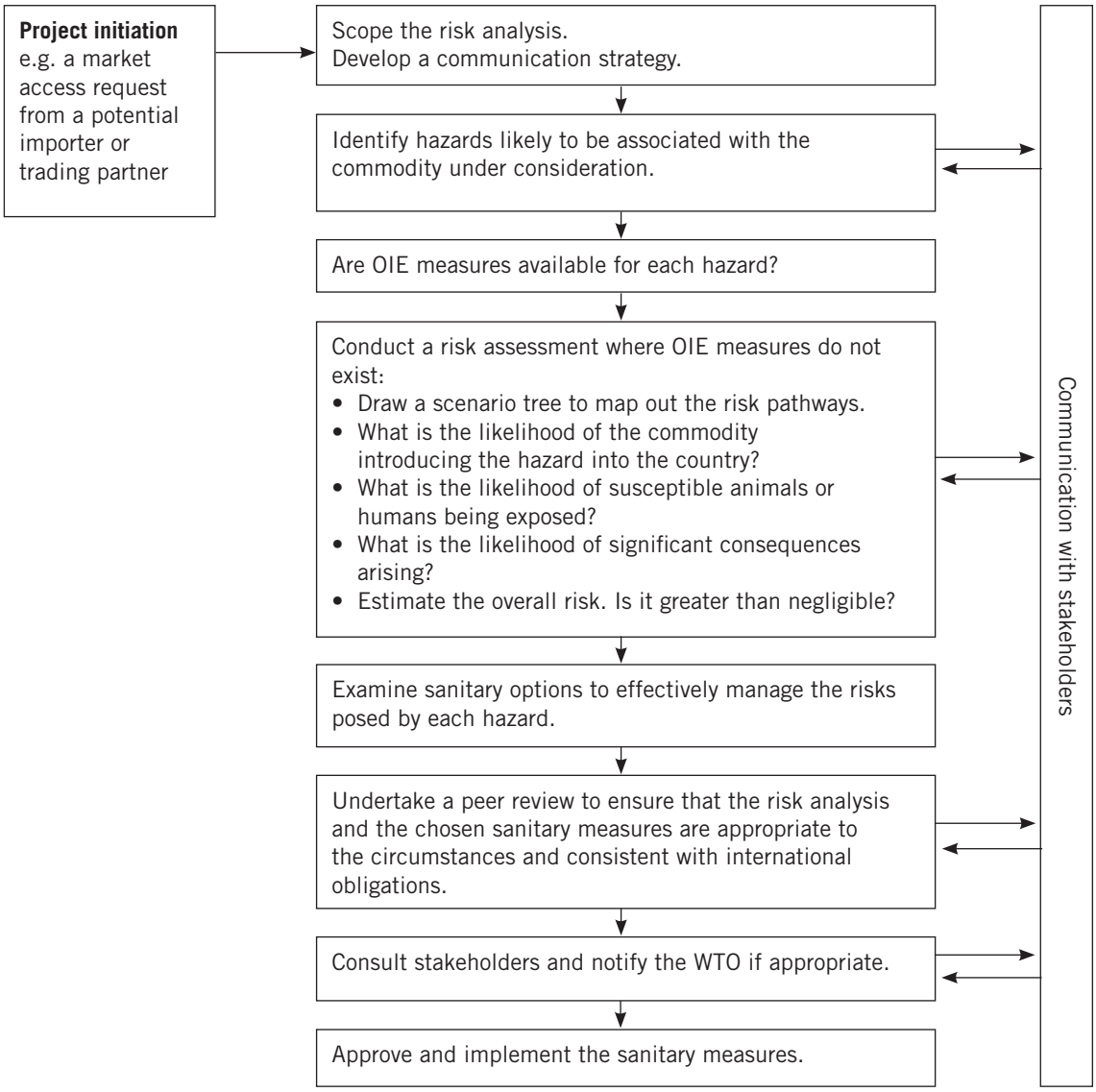

Figure 5 A flowchart for a risk analysis

3.1. Determine the scope of the risk analysis

Summary

Determining the scope of the risk analysis requires that the animals or animal products that are the subject of the risk analysis be defined as precisely as possible. This includes:

- the nature, source(s) (including country) and intended use(s) of the animals or animal products
- the scientific name(s) of the animal species
- the relevant methods of production, manufacturing, processing or testing that are normally applied including quality assurance programmes (such as HACCP)
- an estimate of the likely annual volume of trade if possible
- drafting a suitable title for the risk analysis (based on the above).

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 a clear definition of what commodities are covered.

There are a number of options to choose from when deciding on the scope of a risk analysis. Each has its own advantages and disadvantages. Market access requests, reviewing existing sanitary measures, ensuring consistency, and resource constraints all influence which option is chosen. 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 commodity-based (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, a risk analysis for the importation of eggs would need to clarify:

- the species (does it cover just hens' eggs, or eggs from other species of poultry?)
- the type of eggs (hatching eggs, table eggs, processed egg product?)
- whether the analysis is specific to eggs from a single country, or several countries, or eggs as a commodity regardless of the country of origin (a generic risk analysis).

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. Box 1 provides a checklist for determining the scope of a risk analysis.

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.

Box 1 Checklist: determining the scope of a risk analysis

- 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*);
- 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 USA for human consumption, live viral vaccines for administration by injection;
- 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;
- 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 packing houses;
- Estimate the likely annual volume of trade, as far as possible.

c) Generic risk analysis on [commodity]

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.

Some commodities, such as live animals, could harbour pathogenic agents that may affect plant health; for example, weed seeds trapped in wool or passed in faeces, and soil contaminated with fungal spores on an animal's legs or feet. The potential for these commodities to introduce such pathogenic agents needs to be considered. However, it is beyond the scope of an animal health import risk analysis. Other groups within the government service usually have the appropriate expertise and responsibility for biosecurity issues related to plant health. For this reason, if the commodity under consideration is likely to harbour plant pathogens or pests, an appropriate plant health risk analysis may need to be undertaken by those with the relevant responsibility before the risk analysis for the commodity can be considered complete.

Similarly, the potential for an imported species to be invasive (as defined under the Convention on Biological Diversity) may be the subject of a specific assessment. This would normally be conducted by the agency of government with responsibility for protection of the environment. Preliminary guidelines on the conduct of risk analysis with reference to invasive alien species are available from the Secretariat of the Convention on Biological Diversity (CBD, 2008).

3.2. State the purpose of the risk analysis clearly

Summary

The purpose of the risk analysis should be stated in an appropriate form, for example:

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

Once the scope of the risk analysis has been determined it is important that its purpose be stated clearly, to ensure that those undertaking the analysis as well as potentially affected and interested parties (stakeholders) have a clear understanding of its overall objectives, including the nature of the risk being estimated. This is a critical step, and one that inevitably involves an interactive discussion with those requesting the analysis. Often they only have a general appreciation of the attendant issue, and if the purpose is vague or ill-defined from the outset, problems will inevitably arise. For example, dissatisfaction may arise because the analysis has not adequately addressed the risk continuum by failing to include an estimate of the consequences likely to arise from the spread or establishment of a particular hazard.

Box 2 provides an example of a suitable title and statement of purpose based on an import risk analysis carried out by the New Zealand Ministry of Agriculture and Forestry for domestic horses. It was applicable at the time, for the particular trade under consideration, and may not be universally applicable.

Box 2 An example of a suitable title and statement of purpose for an import risk analysis

Title: Import risk analysis: African horse sickness virus in domestic horses (*Equus caballus*)

Purpose: To identify and assess the likelihood of African horse sickness virus (Family *Reoviridae* Genus *Orbivirus* African horse sickness viruses 1 to 10) being introduced and spreading or becoming established in New Zealand together with the likelihood of and the likely magnitude of its potential consequences for animal or human health as a result of importing domestic horses (*Equus caballus*).

3.3. Develop a risk communication strategy

Summary

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. A risk communication strategy should:

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

Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties (the 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.

Stakeholders' interests or responsibilities may be affected by the findings, recommendations or decisions arising from a risk analysis. Because of this there are greater expectations from various stakeholder groups in many countries that they will be provided with an opportunity for consultation before decisions are made. Today people in general have a high level of education and easy access to an enormous variety of information. They are less reliant on the scientific community or government to evaluate risks and make decisions on their behalf. As a result, 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 should identify potential stakeholders, and aim to be inclusive. The stakeholders consulted may be domestic only, or may include the Competent Authority of the country from which the proposed importation is to occur.

The strategy should also identify various opportunities with which to communicate with stakeholders, for example through official publications, web pages, direct mail-outs and public notices in newspapers. The breadth of groups considered to be stakeholders (including consumers) and the mechanism for consultation may vary between countries and situations.

Risk communication should be an interactive and iterative process involving a two-way dialogue. Stakeholders should be invited to provide comments from the outset. Concerns raised by stakeholders should be considered and timely feedback provided. 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, if they are involved from the outset, appropriately addressed and with their concerns considered, they may have a greater understanding of why a particular decision has been made. Risk communication is dealt with in more depth in Chapter 3.

3.4. Sources of information for a risk analysis

Summary

Information to assist in identifying hazards, assessing risks and exploring risk management options can be found in a variety of sources, including the OIE website and other sites devoted to diseases of livestock, aquatic animals, wildlife and zoo animals, as well as scientific journals, textbooks and import risk analyses undertaken in other countries. Assistance and advice can also be sought from a variety of specialists, ranging from epidemiologists to ecologists to agricultural economists and product specialists. Data on historical trade may provide valuable insights into whether or not imports of a particular commodity are likely to pose a risk of introducing specific diseases. In those situations where information is scarce or lacking, a subjective approach utilising expert opinion may be needed.

Information to assist in identifying hazards, assessing risks and exploring risk management options can be found in a variety of sources. including scientific journals, textbooks and websites devoted to diseases of livestock, aquatic animals, wildlife and zoo animals. Specific examples are:

- OIE website:
  – official country disease status
  – animal disease data
  – *Terrestrial Animal Health Code*
  – *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
  – *Aquatic Animal Health Code*
  – *Manual of Diagnostic Tests for Aquatic Animals*
  – publications and documentation including the OIE *Scientific and Technical Review,* OIE *World Animal Health* and OIE *Bulletin*
  – World Animal Health Information Database (WAHID);
- ProMed-mail;
- FAO EMPRESS (www.fao.org/ag/AGAinfo/programmes/en/empres/home.asp);
- The joint FAO/OIE/WHO global early warning system for major animal diseases including zoonosis (GLEWS) (www.glews.net/);
- The Competent Authority in the exporting country:
  – national disease reports and veterinary journals
  – evaluations of the Veterinary Services including monitoring and surveillance programmes and zoning and compartmentalisation;
- Import risk analyses undertaken:
  – in other countries so long as you can be confident these have been adequately peer reviewed, and care is taken to ascertain that the circumstances of the analysis are relevant in the new context;
  – by private consultants contracted by a would-be importer. The same standards of rigorous analysis, documentation and scientific review must be applied to such externally conducted risk analyses. Since it is the Competent Authority that might have to defend the recommendations of the analysis in the domestic or international arena, it is essential that the Competent Authority has in place its own review mechanism to ensure the quality of such analyses.

Assistance and advice can also be sought from a variety of specialists including epidemiologists, veterinary pathologists, virologists, microbiologists, parasitologists, laboratory diagnosticians, wildlife specialists, biologists, ecologists, entomologists, ornithologists, climatologists, livestock industry specialists, agricultural economists, field veterinarians and product specialists. Where it is decided to undertake a quantitative risk analysis, advice from a mathematical modeller and/or a statistician may be required.

Data on historical trade often provide valuable insight into whether or not imports of a particular commodity are likely to pose a risk of introducing specific diseases. There may be reports in the literature, for example, of a certain pathogen that has sometimes been recovered from a particular commodity, but this does not, of course, necessarily mean that importing that commodity poses a risk of introducing the disease, because there might be no realistic pathways for exposure. A useful first step, therefore, in conducting an import risk analysis can be to obtain trade data on volumes of the commodity that have been exported from countries in which the disease of concern is known to be endemic, to countries where there is surveillance information to support claims of freedom from that disease. An example of this approach is provided in a recent review of disease transmission risks from prawn products exported for human consumption (Flegel, 2009). If large volumes of the particular commodity have been exported from countries where the disease of concern is endemic, yet there have been no reports of the disease being introduced into importing countries, this gives some assurance that such imports pose little risk.

Examinations of historical trade data make it possible to quantify the risk. Once the analyst has obtained data on the volumes of the commodity imported into disease-free countries, whether in kilograms, tonnes or some other units, he/she may use Beta distribution described in Volume 2 of this *Handbook* (OIE, 2004, p. 35) or in other text books (e.g. Vose, 2000). An even simpler method of quantifying risk on the basis of trade data is provided by use of the table of exact binomial confidence limits given in Appendix 1 in Volume 2 of this *Handbook* (OIE, 2004).

In situations where information is scarce or lacking, a subjective approach utilising expert opinion is appropriate for release, exposure and consequence assessments. However, care must be taken when obtaining expert opinions, to avoid bias and to deal with disagreement among experts. Appropriate methods for obtaining expert opinions are discussed in Volume 2 of this *Handbook* (OIE, 2004), pp. 73-76) and in other textbooks (e.g. Vose, 2000).

3.5. Identify the hazards likely to be associated with the commodity

Summary

Hazard identification consists of drawing up a list of pathogenic agents associated with the species from which the commodity is derived, and based on a number of criteria, determining whether or not they can be classified as hazards for further consideration in a risk assessment. The criteria considered for each pathogenic agent include determining whether:

- the commodity under consideration is a potential vehicle
- it is present in the either or both of the exporting and importing countries
- the disease caused by the pathogenic agent is subject to an official control programme, or there are zones or compartments of different animal health status, or local strains are likely to be less virulent than those reported in the exporting country.

A risk analysis may be concluded at this stage if the hazard identification step fails to identify potential hazards.

Hazard identification is the essential first step in a risk analysis. To effectively manage the risks associated with imported commodities, any organisms capable of, or potentially capable of, causing harm and which could be introduced into the importing country must be identified. Such pathogenic agents are referred to as hazards by the *Code,* which defines a hazard as a biological, chemical or physical agent in, or a condition of, an animal or animal product with potential to cause an adverse health effect. Since the WTO recognises the OIE as the reference organisation for international standards for managing animal health and zoonotic diseases, the term 'hazard' should be used. The OIE lists diseases that are significant in international trade.

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, 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. Hormonal products, for example, may undergo a number of filtration steps that will exclude bacteria and viruses of a certain size. 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 all other commodities, 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 of diseases 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. Each pathogenic agent should be dealt with separately,

with a reasoned, logical and referenced discussion of its relevant epidemiology, including an assessment of its likely presence in both the importing and exporting countries. A conclusion is then reached on whether or not the commodity under consideration is a potential vehicle for the introduction of the pathogenic agent into the importing country. If it is, the pathogenic agent is classified as a hazard for further consideration. If no hazard is identified, the risk analysis can be concluded at this point.

A number of important questions and steps, as outlined in Box 3, must be considered when determining whether or not a pathogenic agent can be identified as a hazard.

When preparing a list of hazards, the template in Table I, which includes several examples, can be used to provide a useful summary. The latest taxonomy and nomenclature should be used.

Table I An example of a list of hazards

Common name	Scientific name	Exotic	Free zones or compartments, or official control programmes	More virulent strains in other countries	Identified as a hazard
Foot and mouth disease	Family *Picorniviridae*, genus *Apthovirus*, FMD virus A, Asia 1, C, O, SAT 1, SAT 2, SAT 3	Yes	n/a	n/a	Yes
African horse sickness	Family *Reoviridae*, Genus *Orbivirus*, African horse sickness viruses 1 to 10	Yes	n/a	n/a	Yes
Bovine tuberculosis	*Mycobacterium bovis*	No	Yes	No	Yes
Newcastle disease	Family *Paramyxoviridae*, genus *Paramyxovirus*, avian PMV 1	Yes	n/a	Yes	Yes
Enzootic bovine leucosis	Family *Retroviridae*, genus '*blv-htlv retroviruses*', type species bovine leukaemia virus	No	No	No	No
Infectious bovine rhinotracheitis	Family *Herpesviridae*, subfamily *Alphherpesvirinae*, genus *Varicellovirus*, bovine herpesvirus 1 (BoHV-1)	No	No	Yes	Yes
Johne's disease	*Mycobacterium paratuberculosis*	No	No	No	No
Biting midges	*Culicoides* spp.	Yes	n/a	n/a	Yes
Listeriosis	*Listeria monocytogenes*	No	No	No	No
Salmonellosis	*Salmonella enterica*, subsp. *Enterica*, serovar Typhimurium DT 104	No	Yes	No	Yes

Notes

The rationale for classifying each hazard according to the criteria and the conclusion reached must be supported by a referenced discussion. This is an actual example carried out by the New Zealand Ministry of Agriculture and Forestry.

n/a: not applicable.

Box 3 Steps to determine whether a pathogenic agent is a hazard

1. Taking account of the methods of production, manufacturing or processing normally applied, is the commodity under consideration a potential vehicle for the pathogenic agent?

   a) If the answer is YES, proceed to Step 2. Otherwise the pathogenic agent is not a hazard.

2. Is the pathogenic agent present in the exporting country?

   a) If the answer is YES, proceed to Step 3.

   b) If the answer is NO, is there sufficient confidence in the capacity and capability of the exporting country's Competent Authority to satisfactorily substantiate a claim that the pathogenic agent is absent?

      – If the answer is YES, the pathogenic agent is not a hazard.

      – If the answer is NO, contact the Competent Authority to seek additional information or clarification and proceed to Step 4. Assume that until otherwise demonstrated, the pathogenic agent is likely to be present in the exporting country.

3. Are there zones or compartments from which the commodity could be derived within the exporting country that are free of the pathogenic agent?

   a) If the answer is YES, is there sufficient confidence in the capacity and capability of the exporting country's Competent Authority to satisfactorily substantiate a claim that the pathogenic agent is absent, and ensure that the commodity is only derived from these zones or compartments?

      – If the answer is YES, the pathogenic agent is not a hazard.

      – If the answer is NO, contact the Competent Authority to seek additional information or clarification and proceed to Step 4. Assume that until otherwise demonstrated, either the pathogenic agent is likely to be present in these zones or compartments, or the commodity is likely to be derived from other areas in the exporting country.

   b) If the answer is NO proceed to step 4.

4. Is the pathogenic agent present in the importing country?

   a) If the answer is YES. proceed to Step 5.

   b) If the answer is NO, is the Competent Authority of the country able to satisfactorily substantiate a claim that it is absent?

      – If the answer is YES, the pathogenic agent is classified as a hazard.

      – If the answer is NO, proceed to Step 4. Assume the pathogenic agent is present, and explore options within a reasonable period of time to ascertain its presence or absence with a sufficient level of confidence.

5. For a pathogenic agent reported in both the exporting and the importing country, IF:

   a) it subject to an official control programme in the importing country, OR

   b) there are zones or compartments of different animal health status, OR

c) local strains are likely to be less virulent than those reported internationally or in the exporting country,

THEN the pathogenic agent might be classified as a hazard.

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

It is often wise for the risk analysts to consult with stakeholders on this list of hazards 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. An example of hazard identification is presented in Box 4. For the purposes of illustration, the import risk analysis upon which this example is based can be assumed to be generic for domestic horses (*Equus caballus*). It was applicable at the time, for the particular trade under consideration, and may not be universally applicable.

3.6. Determine whether or not the Code *provides sanitary measures for the hazards in the commodity under consideration*

Summary

Once a hazard has been identified, determine whether the *Code* provides sanitary measures for that hazard in the commodity under consideration?

a) If the answer is YES, is there a requirement by legislation, policy or other considerations within the country to undertake a complete risk analysis?

- If the answer is YES, conduct a risk assessment;
- If the answer is NO, consider applying the sanitary measures prescribed in the *Code,* as a risk assessment is not necessary to fulfill WTO obligations.

b) If the answer is NO or it is decided to adopt a higher level of protection than that provided by the measures in the *Code*, conduct a risk assessment.

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

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

Although the *Code* provides sanitary measures for AHS, for the purposes of continuing with the worked example, it is assumed that domestic legislation in New Zealand required that a complete risk analysis be undertaken.

Box 4 An example of a hazard identification carried out by the New Zealand Ministry of Agriculture and Forestry

African horse sickness

Aetiological agent

Family *Reoviridae*, genus *Orbivirus*, African horse sickness viruses 1 to 10.

New Zealand's status

African horse sickness (AHS) has never been reported in New Zealand and is classified as an exotic disease.

Epidemiology

AHS is an infectious non-contagious disease of horses and other solipeds (order *Perissodactyla*) caused by an *orbivirus* and transmitted by *Culicoides* midges (Lagreid, 1996). There are nine known serotypes, all of which may cause significant mortality in horses (Coetzer and Erasmus, 1994). AHS is endemic in tropical East and West Africa, from where it regularly spreads to southern, and occasionally northern Africa (Coetzer and Erasmus, 1994; OIE, 1995/2002). AHS occurs seasonally and is influenced by climatic conditions favouring the breeding of *Culicoides* midges (OIE, 1997; Mellor and Wellby, 1998). Most horses are infected between sunset and sunrise when *Culicoides* midges are most active (Coetzer and Erasmus, 1994).

There are four classical forms of AHS: pulmonary, cardiac, mixed and horse sickness fever. The pulmonary form has a short incubation period, ranging from three to five days, and a marked and progressive respiratory involvement leading to death in more than 95% of cases within four to five days. The incubation period for the cardiac form varies from seven to 14 days, followed by clinical disease lasting for three to eight days with death in 50% to 70% of cases. The mixed form is characterised by a combination of respiratory and cardiac involvement, with an incubation period and mortality rate roughly halfway between the pulmonary and cardiac forms. Horse sickness fever is the mildest form, and is frequently overlooked in natural outbreaks. The incubation period varies from five to 14 days and is followed by a low-grade fluctuating fever lasting for five to eight days. All affected animals recover. This form of the disease is usually observed in immune animals infected with a heterologous virus type, or in resistant species, such as the donkey and zebra. Horses are the most susceptible equine species, followed by mules, while most infections in donkeys and zebras are subclinical (Lagreid, 1996; OIE, 1996). In view of the high mortality rate in horses, this species is regarded as an accidental or indicator host (Coetzer and Erasmus, 1994).

The virus is present in all body fluids and tissues from the onset of fever until recovery. Viraemia in horses is of variable duration, typically lasting for four to eight days, but no longer than 21 days, while in donkeys it may last up to 28 days (OIE, 1995/2002). Horses that recover from AHS do not remain carriers. Survivors develop a strong immunity to the particular serotype with which they were infected. While this may confer some cross-protection to infection with other serotypes, a strong challenge may overcome it (Coetzer and Erasmus, 1994).

Two types of vaccine are most commonly used: a polyvalent or monovalent live vaccine and an inactivated monovalent vaccine (OIE, 1996). While both types of vaccine provide protection against clinical disease, vaccinated animals may still develop a viraemia sufficiently high to infect vectors. Problems remain with some live vaccines reverting to virulence, although the opportunity to escape the host would be limited as the viraemia associated with a live vaccine is likely to be of a similar duration to that occurring in a natural infection. Subunit vaccines which are being developed offer the most effective means of inducing protective immunity. They are not subject to reversion or vector transmission (Lagreid, 1996).

Conclusion

While domestic horses that recover from infection do not remain carriers, horses that are either naturally infected or vaccinated with a live vaccine may be viraemic for up to 21 days and therefore potential vehicles for AHS virus. As a result AHS virus is classified as a hazard.

3.7. Conduct a risk assessment

Summary

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

- Entry assessment: consists of determining the likelihood of an imported commodity being infected or contaminated with a hazard, and describing the biological (risk) pathway(s) necessary for that hazard to be introduced into a particular environment;
- Exposure assessment: consists of describing the biological (risk) 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: consists of describing the relationship between exposures to a hazard, the consequences of those exposures and their likelihood;
- Risk estimation: consists of combining the results from the entry assessment, exposure assessment, and consequence assessment to produce summary measures of the risks associated with the identified hazards.

Prior to embarking on the risk assessment, it is important to identify potentially susceptible species and map out the biological pathways that could potentially lead to them being exposed to the hazard, and the associated ‘outbreak’ scenarios that could arise. In addition, consideration needs to be given to how the inevitable uncertainties that arise can be dealt with, whether or nor a qualitative or quantitative approach is to be used, and the most appropriate terminology to use when estimating or describing risk.

3.7.1. Identify the populations of interest

Summary

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

3.7.2. Draw a scenario tree for each hazard

Summary

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

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

A scenario tree is a graphical depiction of the biological pathways by which a hazard might be introduced into an importing country. It provides a useful conceptual framework. A scenario tree assists in conveying the range and types of pathways considered in a simple, transparent and meaningful fashion. Scenario trees are an appropriate and effective way of depicting biological pathways. They provide a useful visual representation to:

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

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

- the animals or animal products harbouring the hazard when imported (entry assessment) [Note: 'entry assessment' was formerly known as 'release assessment'.]
- susceptible animals and/or humans being exposed to the hazard (exposure assessment).

By convention events are described in boxes or nodes, while the probability of an event is described by a line or arrow drawn from the box or node (Fig. 6). Three examples of scenario trees are presented in Figures 7 through 9.

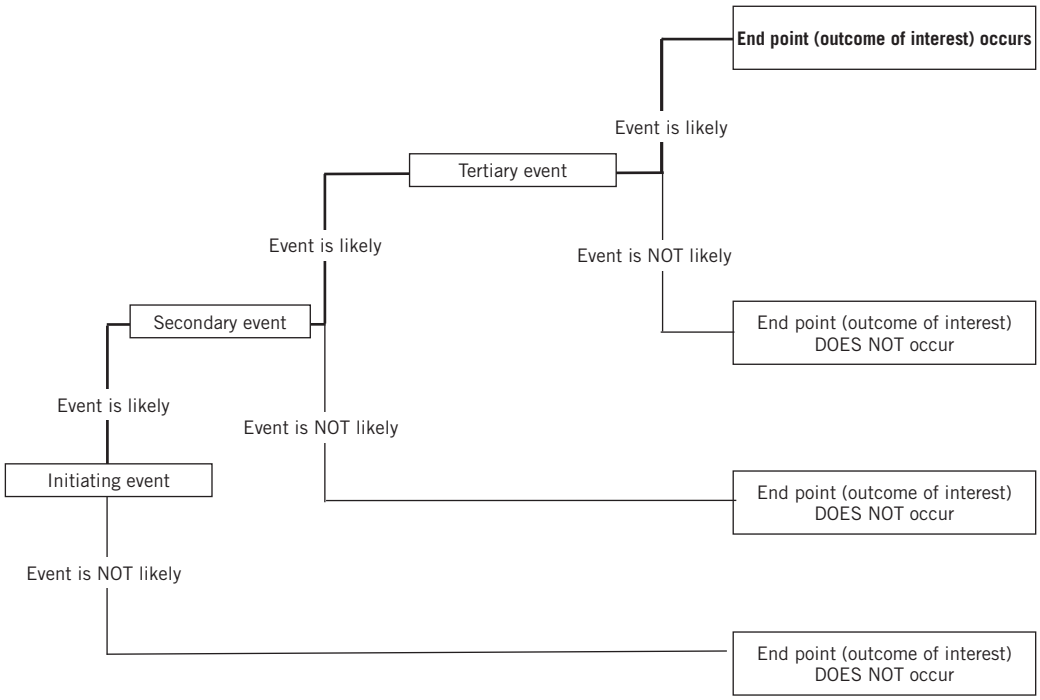

Figure 6 Generalised framework for a scenario tree where probabilities are examined

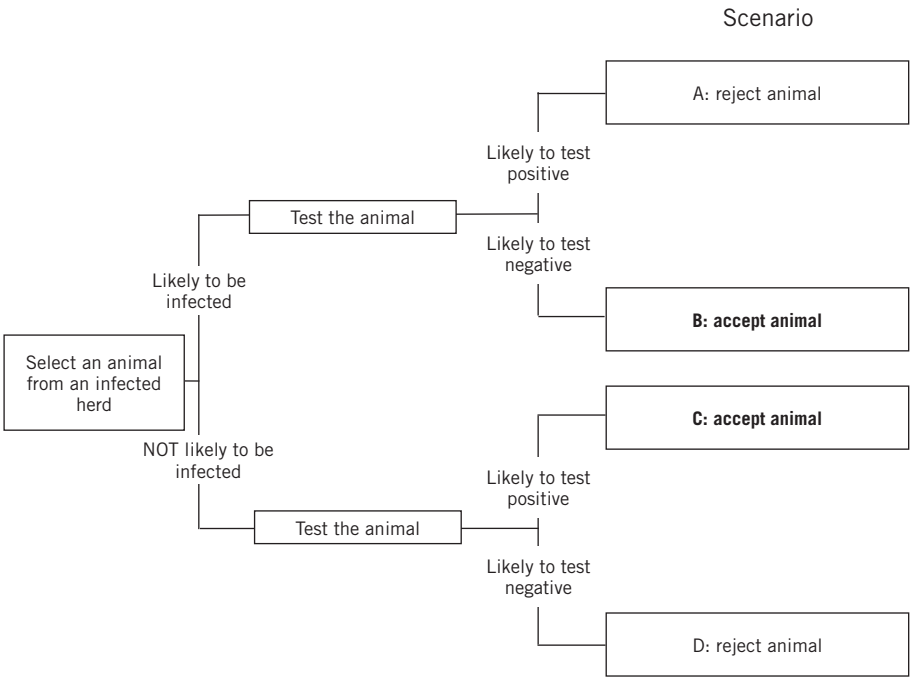

Figure 7 A scenario tree outlining the biological pathways leading to an animal, selected from an infected herd, being either accepted or rejected after it has been tested

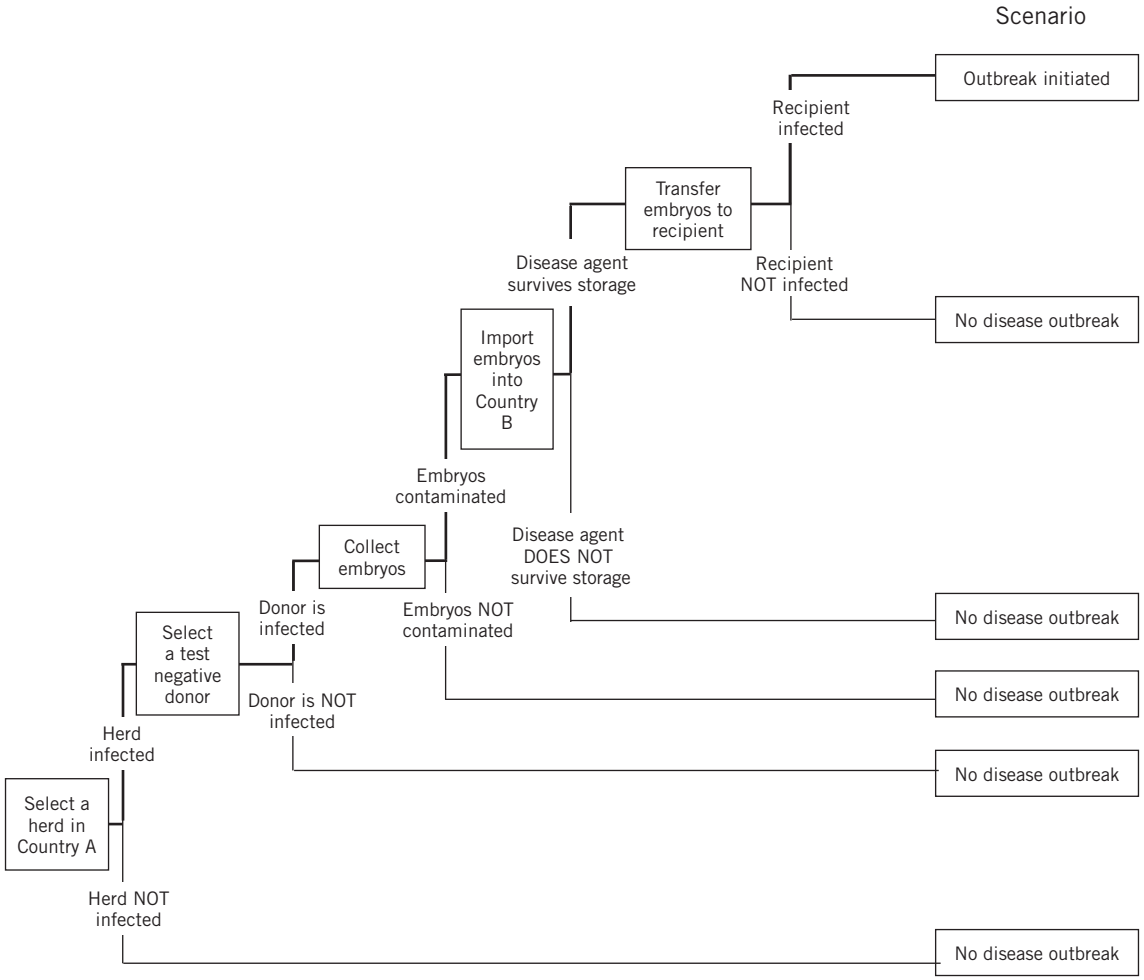

Figure 8 A scenario tree outlining some pathways leading to a disease outbreak following the importation of embryos

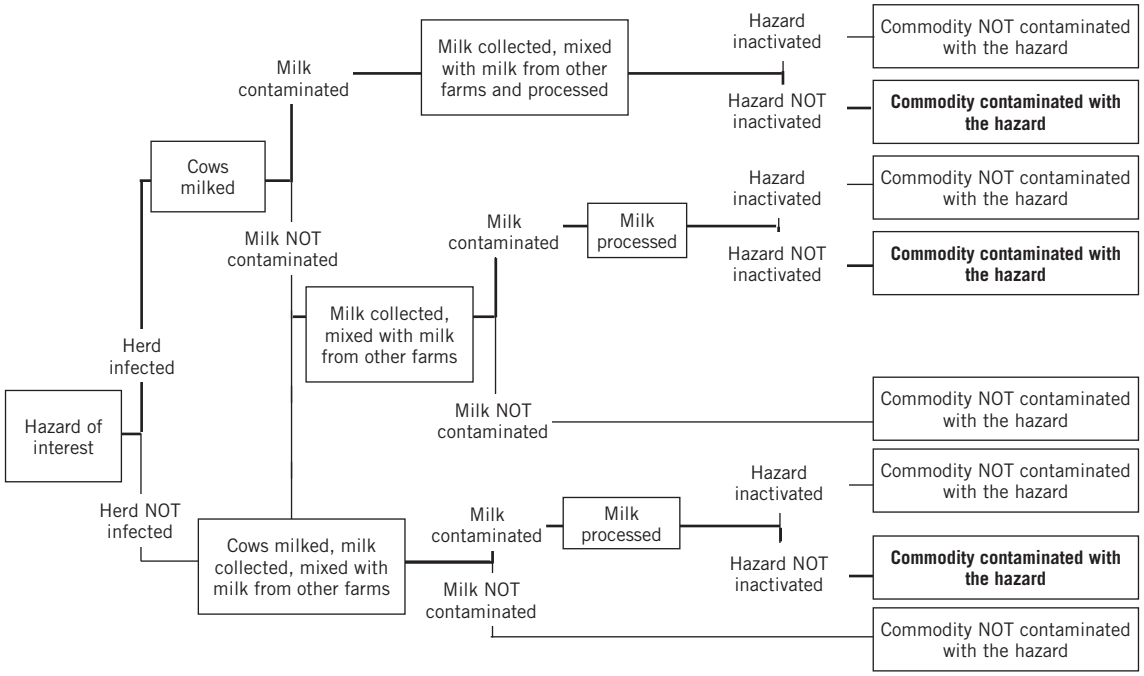

Figure 9 A scenario tree for dairy products outlining some pathways leading to contamination of an imported commodity (entry assessment)

3.7.3. Dealing with uncertainty and variability

Summary

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

Differing uses of the term 'uncertainty' by risk analysts from various disciplines have led to a degree of confusion. In this *Handbook*, uncertainty is defined as 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 (Glossary, page *xi*).

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, then, may be thought of as a measure of the incompleteness of our knowledge or information about a particular thing. 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 might want to predict the likelihood of an outbreak of foot and mouth disease (FMD) 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 might 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 considered carefully. 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 either FMD virus is heat tolerant or there is significant variability in its effectiveness, the impact of these uncertainties becomes much more important.

Where there is significant uncertainty in the estimated risk, a precautionary approach to managing risk may be adopted. However, the measures selected must nevertheless be based on a risk analysis that takes into account the available scientific information. In these circumstances the measures should be reviewed as soon as additional information becomes available,[1] and be consistent with other measures where equivalent uncertainties exist. It is not acceptable simply to conclude that, because there is significant uncertainty, measures will be based on a precautionary approach. The rationale for selecting measures must be made apparent.

Biological pathways considered in the release and exposure assessments must be plausible. As science cannot prove that a particular pathway does not exist, there will always be a degree of uncertainty. In some cases a pathway might be hypothetical rather than plausible. It is not appropriate to consider such pathways in a risk assessment.

3.7.4. Choosing a qualitative or quantitative approach

3.7.4.1. Quantitative methods complement qualitative methods

Summary

A qualitative risk assessment is a reasoned and logical discussion of the relevant commodity, epidemiological and economic factors associated with a hazard, where likelihood estimates are expressed in non-numerical terms such as high, medium, low or negligible. It is suitable for the majority of risk assessments, and is in fact the most common type undertaken for routine decision making. In some situations it may be useful to adopt a quantitative approach as an adjunct to a qualitative assessment to gain further insights, identify critical steps, assess the impact of uncertainty in more detail, or compare risk-mitigation strategies. Quantification, in which a mathematical model is developed that links the various steps in the risk pathway, is a specialised tool. Although both the inputs and outputs (results) are expressed numerically, it is not necessarily more objective or precise than a qualitative approach. In addition, there are invariably significant challenges in describing the model itself, as well as interpreting and communicating the results. Regardless of which approach is chosen, it is essential that the analysis is transparently documented and subjected to peer review.

1 Article 5.7 of the SPS Agreement states that 'a Member may provisionally adopt sanitary … measures' and that 'Members shall seek to obtain additional information … within a reasonable period of time.' Since the plural noun 'Members' is used in reference to seeking additional information, a cooperative arrangement is implied between the importing and exporting country. That is, the onus is not just on the importing country to seek additional information.

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

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

In some circumstances it may be desirable to undertake a quantitative analysis: 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. Choosing an appropriate model structure, which pathways to include or exclude, the level of aggregation or disaggregation, the actual values used for each input variable and the type of distribution applied to them, all involve a degree of subjectivity. In addition, because data are lacking, some models incorporate expert opinion, which by its very nature is subjective. (See the section on elicitation and use of expert opinion in Chapter 6 of Volume 2 of this *Handbook*: OIE, 2004.)

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 documented comprehensively, and the discussion and conclusions must be supported by a reasoned and logical discussion. The analysis should be fully referenced and subjected to peer review.

3.7.4.2. Semi-quantitative methods

Summary

So-called semi-quantitative methods have been promoted by some as being more objective than strictly qualitative techniques. Semi-quantitative methods involve assigning numbers to qualitative estimates, in the form of probability ranges, weights or scores, and combining them by addition, multiplication or other mathematical operations, with the goal of achieving a greater level of objectivity. While semi-quantitative methods are superficially appealing, there are, however, significant problems as the numbers are often assigned and combined arbitrarily without adequate transparency. Inconsistent outcomes frequently arise, and conclusions are reached that may be statistically and logically incorrect. These methods do not offer any advantages over a well-researched, transparent, peer-reviewed qualitative approach.

As discussed in the preceding section, all risk analyses inevitably include a degree of subjectivity. Nevertheless, because many people find numbers seductive and reassuring, some analysts use so-called semi-quantitative methods in the mistaken view that they are somehow more 'objective' than strictly qualitative techniques. The same could be said of quantitative analyses. However, a number of significant problems may arise from adopting a semi-quantitative approach in an import risk analysis. It is sometimes employed as a means of combining various qualitative estimates, by assigning numbers to them, to produce a summary measure or to prioritise risks. The numbers may be in the form of probability ranges or scores, which may be weighted before being combined by addition, multiplication or similar mathematical operations. The numbers, ranges, weights and methods of combination chosen are usually quite arbitrary, and need careful justification to ensure transparency.

It should be recognised that numbers assigned to categories cannot legitimately be manipulated mathematically and statistically. For example, one type of semi-quantitative method that has been used in some risk analyses involves dividing the probability range 0 to 1 into a number of arbitrary intervals (such as, say, 0 to $10^{-6,}$ 10^{-6} to 0.001, 0.001 to 0.05 etc.) and giving each of these a qualitative descriptor such as 'negligible', 'extremely low', 'very low' and so on. The risk assessor uses the qualitative descriptors for the probability of each step of the risk assessment. The probability of the all steps in the pathway occurring is then calculated by multiplying the arbitrary probability intervals ascribed to each qualitative descriptor. Finally the product of this multiplication is converted back to a qualitative descriptor. While it might superficially appear objective, this type of semi-quantitative assessment is flawed, and leads to conclusions that are statistically and logically incorrect (Morris and Cogger, 2006).

In summary, semi-quantitative assessments give a misleading impression of objectivity and precision, and lead to inconsistent outcomes. Assigning numbers to subjective estimates does not result in a more objective assessment, particularly when the numbers chosen and their method of combination are arbitrary. Semi-quantitative methods do not offer any advantage over a well-researched, transparent, peer-reviewed qualitative assessment.

3.7.5. Using appropriate terminology to describe or qualify likelihood

Summary

Since an import risk analysis is essentially concerned with estimating the likelihood of a hazard entering, spreading or becoming established, and the adverse consequences arising, it is important to use appropriate terms to describe or qualify likelihood. For example, it is not sufficient to conclude that there is 'a chance' or 'a possibility' of, or 'potential' for something to happen. Such terms do not enable risk to be placed into perspective. In contrast, concluding that the chance or likelihood or probability of something happening is negligible or highly likely provides both a meaningful estimate and necessary context.

The terminology outlined in the *Codes* 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

must be evaluated, and may be expressed either qualitatively or quantitatively. 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 II gives examples of terms that are acceptable and ones to be avoided. These definitions are taken from the *Concise Oxford Dictionary* (2002), and other dictionaries may give slightly different definitions. It should be noted that the common dictionary definitions for some terms (for example 'possible' and 'possibility' in Table II) may not be precise enough to be useful in a risk analysis.

Some risk analysts categorise likelihoods in terms of 'negligible' and 'non-negligible'. While 'negligible' is a useful term, 'non-negligible' should be avoided. 'Non-negligible' unhelpfully subsumes all likelihoods ranging from 'extremely low' through to 'almost certain' and thus offers no help to the risk manager faced with selecting sanitary measures to insure risks fall below a country's acceptable level.

Table II Terminology for describing likelihood

Term	**The *Concise Oxford Dictionary* definition**
When expressing likelihood	
1. Terms to avoid:	
Chance	When used in a singular context it indicates a possibility
Could	Past of can, where can means to be potentially capable of
Might	Expressing a possibility based on a condition not fulfilled
Potential	When used as a noun means possibility
Possibility	A thing that may exist or happen
Possible	That is likely to happen; whatever is likely
2. Acceptable terms:	
Chances	In its plural form chance indicates a probability
Likelihood	Probability; the state or fact of being likely
Likely	Probable; such as well might happen or be true; to be reasonably expected
Probability	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
Probable	May be expected to happen or prove true; likely
Would	To express probability (I guess she would be over 50 by now); past of will: expressing a wish, ability, capacity, probability or expectation.
Terms used as adjectives to qualify likelihood estimates	
Average	The usual amount, extent, rate
Extremely	Outermost, furthest from the centre; situated at either end; utmost; the highest or most extreme degree of anything
High	Extending above the normal or average level
Highly	In a high degree
Insignificant	Unimportant; trifling
Low	Less than average, coming below the normal level
Negligible	Not worth considering; insignificant
Significant	Noteworthy; important; consequential
Remote	Slight, faint

Concerns may be raised that because, there is an inevitable degree of subjectivity in estimating and describing the likelihood of an event and its consequences, the conclusions reached in an analysis may be flawed. The best solution to allay such concerns is to ensure that the likelihood estimates and conclusions are supported by a transparently documented risk analysis which is not only well reasoned and logical but has been subjected to peer review.

3.7.6. Entry assessment

Summary[2]

An entry assessment estimates the likelihood of an imported commodity being infected or contaminated with a hazard. It also describes the biological (risk) pathways necessary for that hazard to be introduced into the country. For each step, it lists the relevant biological, country or commodity factors considered. 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.

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

- describe the biological (risk) pathway(s) necessary for the commodity to become infected or contaminated; Note that a scenario tree provides a useful conceptual framework to assist in identifying and describing pathways. Figure 10 provides an example for African horse sickness.
- 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.

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

Biological factors

- susceptibility to the hazard of animals from which the commodity is derived:
  - species and breed
  - age
  - sex
- means of transmission of the hazard:
  - horizontal transmission
  - direct (animal to animal contact, airborne spread, ingestion, coitus)
  - indirect (mechanical and biological vectors, intermediate hosts, iatrogenic transmission, fomites)
  - vertical transmission
- infectivity, virulence and stability of the hazard
- routes of infection (oral, respiratory, percutaneous, etc.)

2 'Entry assessment' was formerly called 'release assessment', a term that had been adopted from environmental risk assessment, where the concern was the release of pollutants into the environment. The authors of this current edition of the *Handbook* consider that 'entry assessment' is a more appropriate term to use in import risk analysis.

- predilection sites of the hazard (for example, muscle, bone, nerve tissue, lymph node etc.)
- outcome of infection (sterile immunity, incubatory or convalescent carrier, latent infection)
- the impact of vaccination, testing, treatment and quarantine.

Country factors

- evaluation of the exporting country's Veterinary Service, surveillance, eradication and control programmes, and zoning systems
- incidence and/or prevalence of disease
- existence of disease-free areas and areas of low disease prevalence
- animal demographics
- farming and husbandry practices
- geographical and environmental characteristics including rainfall and temperature.

Commodity factors

- ease of contamination
- relevant processes and production methods
- effect of processing, storage and transport
- quantity of commodity to be imported.

Figure 10 shows a scenario tree for an entry assessment for the importation of horses potentially infected with AHS virus. Box 5 presents the entry assessment.

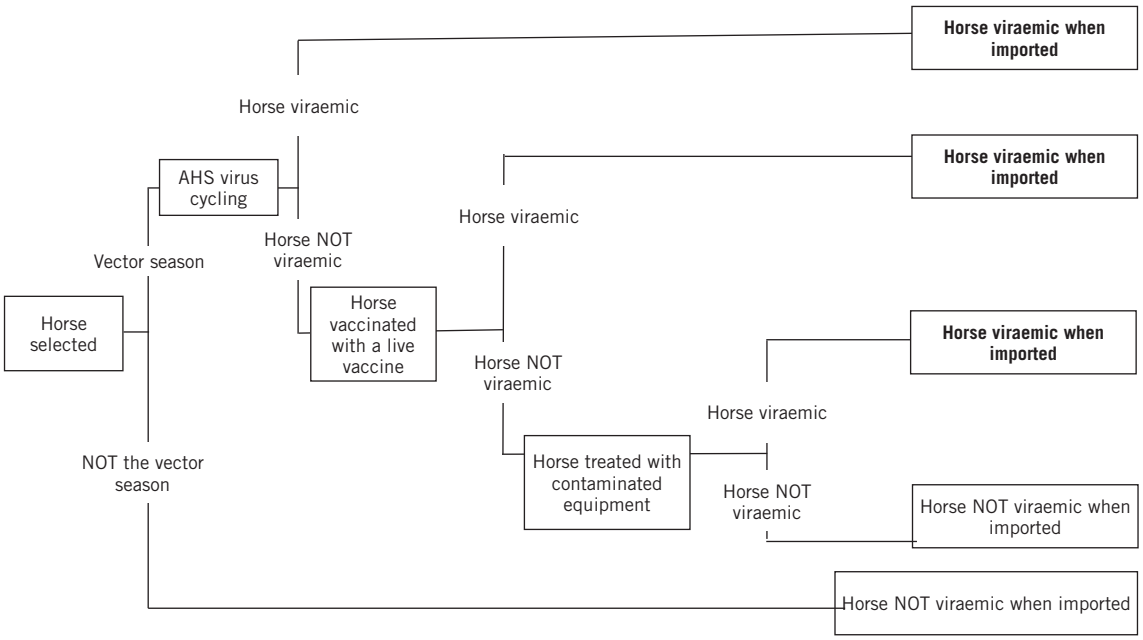

Figure 10 An entry assessment scenario tree illustrating some biological pathways for the introduction of African horse sickness virus through importation of horses

Note: It is assumed in this example that horses are not vaccinated during the non-vector season.

Box 5 Example of a entry assessment for the importation into New Zealand of horses potentially infected with African horse sickness virus

Entry assessment

Since infections occur seasonally in the endemic areas of Africa (Coetzer and Erasmus, 1994; Mellor and Welby, 1998; OIE, 1997), the likelihood of a horse incubating African horse sickness (AHS) or being viraemic when imported increases during summer and autumn. In South Africa, for instance, AHS occurs every summer in the northern provinces, with the first cases occurring in February. The disease spreads southwards over the next few months, with the epidemic stopping abruptly in late April or early May after the first frosts (Coetzer and Erasmus, 1994). There may be several months during the drier or cooler times of the year when vectors are inactive and horses are unlikely to become infected. Provided such periods can be sufficiently well defined, and an allowance is made for the maximum duration of viraemia in horses that become infected late in the season, there may be a window of opportunity when the likelihood of a horse incubating AHS or being viraemic when imported is negligible.

Domestic horses are most likely to be transported to New Zealand by air. Travel times are likely to be short, perhaps less than 24 hours. In such circumstances it is likely that a viraemic horse, particularly one that has been vaccinated or suffering from horse sickness fever, characterised by a low-grade fluctuating fever, or in the pre-clinical incubatory phase of AHS, might be imported into New Zealand.

Conclusion

If a horse is exported to New Zealand from the endemic areas in Africa during the winter and spring months there is a negligible likelihood of it carrying AHS virus. For other times of the year the likelihood of a horse harbouring AHS virus is low.

3.7.7. Exposure assessment

Summary

An exposure assessment describes the biological (risk) pathway(s) necessary for the exposure of susceptible animals and/or humans in the importing country and estimates the likelihood of those exposure(s) occurring. For each step, it should list the relevant biological, country and commodity factors considered. The risk assessment may be concluded at this point if the likelihood of exposure is negligible.

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. Whether it does so depends on both the dose of pathogen and the degree of susceptibility of the host. This relationship is commonly called a dose response. Infection is, strictly speaking, therefore a consequence of exposure.

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

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

- describe the biological pathway(s) necessary for exposure of animals and humans in the importing country. Note: A scenario tree provides a conceptual framework to assist in identifying and describing pathways. Figure 10 is an example for AHS
- estimate the likelihood of these exposure(s) occurring
- estimate the likely dissemination of the hazard and the population exposed.

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

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

Biological factors

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

Country factors

- presence of intermediate hosts or vectors
- human and animal demographics
- farming and husbandry practices
- customs and cultural practices
- geographical and environmental characteristics including rainfall and temperature.

Commodity factors

- intended use of the imported animals or animal products
- waste disposal practices
- quantity of commodity to be imported.

Figure 11 shows a scenario tree for part of an exposure assessment for the importation of horses potentially infected with African horse sickness virus. Similar scenario trees would need to be developed for the other biological pathways. Table III summarises all pathways. Box 6 presents the exposure assessment.

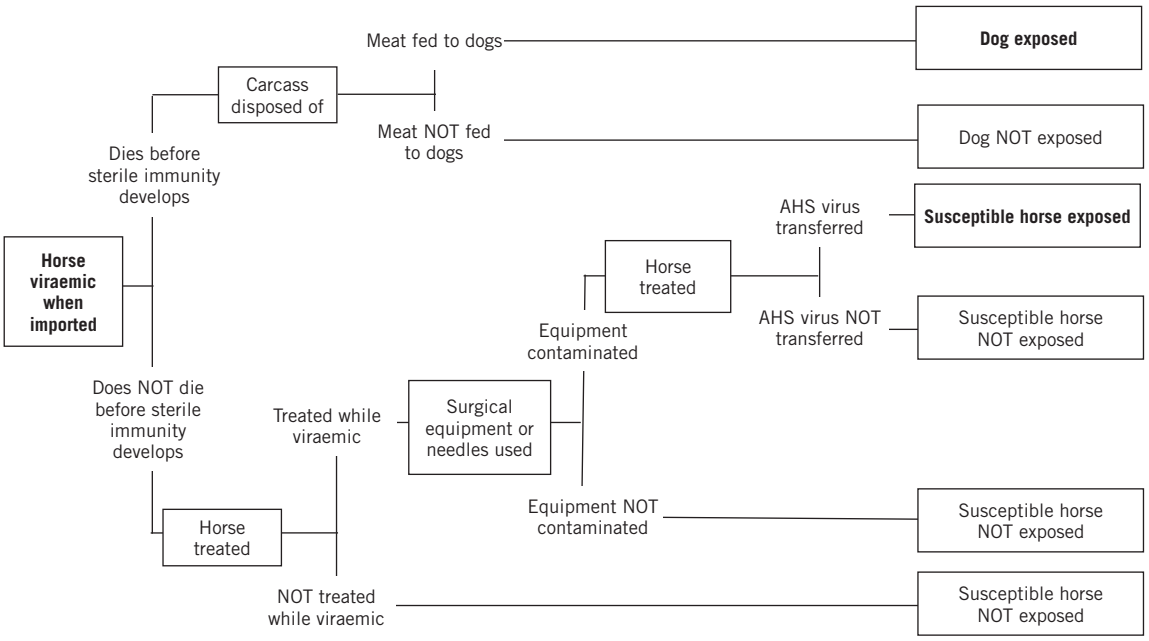

Figure 11 An exposure assessment scenario tree illustrating some biological pathways for the exposure of indigenous animals to African horse sickness virus

Table III A summarised exposure assessment for African horse sickness virus in New Zealand, given that a viraemic horse is imported

Exposure pathway	Likelihood	Explanation
Insect vectors	Negligible*	Competent vectors do not exist in New Zealand
Iatrogenic	Very low	Needle sharing etc. not common
Meat fed to dogs	Very low	Practice of feeding horsemeat to dogs not common
Semen	Negligible*	Stallions would not be used for several weeks after importation

* as the likelihood of this scenario is negligible, it need not be considered further in the risk analysis.

Box 6 Example of an exposure assessment for the importation into New Zealand of horses potentially infected with African horse sickness (AHS) virus

Vectors

AHS virus is probably maintained in an endemic cycle between *Culicoides* midges, principally *C. imicola*, and an as yet unidentified mammalian reservoir host (Mellor and Welby, 1998; OIE, 1997). However, serological evidence indicates that zebras may be the most likely reservoir (Lagreid, 1996; Barnard, 1993). Although the mosquitoes *Aedes aegypti*, *Culex pipiens* and *Anopheles stephensi*, biting flies and the dog tick *Rhipicephalus sanguineus* have been demonstrated to transmit AHS virus experimentally, *C. imicola* is the only recognised natural vector (Coetzer and Erasmus, 1994; OIE, 1995/2002; Radostits, Blood and Gay, 1974). *C. imicola* occurs across Europe and the Mediterranean, but AHS has failed to become established outside Africa despite several outbreaks in the Middle East, Spain and Portugal. These outbreaks were associated with the movement of either infected hosts or vectors

(Lagreid, 1996). Although it is not understood why AHS did not establish in these areas (Lubroth, 1992), likely reasons include the absence of a suitable reservoir host and large-scale vaccination programmes.

Even if a viraemic animal were to be imported, this is not a biologically plausible exposure pathway because *Culicoides* midges, the only known natural vectors, do not occur in New Zealand. Furthermore, evidence suggests that the reservoir host is restricted to Africa, as AHS has never become established elsewhere.

Iatrogenic

Exposure can occur by the parenteral injection of infected blood, particularly by the intravenous route (Coetzer and Erasmus, 1994). This could occur by direct blood transfer during the viraemic period by practices such as needle sharing. However, given the value of imported animals and the ready supply of cheap disposable needles and syringes in New Zealand, such an exposure is very unlikely.

Semen

It is possible that semen collected from a viraemic donor could result in exposure of inseminated mares. Such a scenario is extremely unlikely, as a stallion is normally imported some time before the breeding season to allow it to acclimatise. This period is most likely to be longer than the maximum period of viraemia.

Susceptible species

In addition to solipeds, the vertebrate host range is potentially quite large, with antibodies being recorded in camels, goats, sheep, cattle, buffalo, elephants and dogs (Lubroth, 1992). Apart from dogs, which may contract a fatal form of the disease after ingestion of infected horsemeat, the other species appear to be resistant to the disease (Lagreid, 1996). As *Culicoides* midges do not usually feed on dogs, dogs are unlikely to be exposed to AHS virus by this route. Pigs, cats and monkeys are refractory to infection (Coetzer and Erasmus, 1994). Humans are apparently not susceptible to field strains of the virus, although some vaccine strains can cause encephalitis and retinitis following transnasal infections (OIE, 1996).

Conclusion

There is a negligible likelihood of AHS virus exposure via vectors in New Zealand.

Since any infected animal would be viraemic for only a short period following importation, there are limited opportunities for exposure through iatrogenic transmission, ingestion of horse meat, coitus or artificial insemination. The number of animals likely to be exposed via iatrogenic transmission or the ingestion of horse meat is very small, and the likelihood of exposure is very low. Because of the usual management practices, the likelihood of exposure via semen is negligible.

3.7.8. Consequence assessment

Summary

A consequence assessment identifies the biological, environmental and economic consequences associated with the entry, establishment or spread of the hazard, together with an estimate of their likely magnitude and likelihood of occurrence. An important consideration is that under the provisions of the SPS Agreement, only those consequences directly or indirectly attributable to the hazard may be taken into account. As a result, any positive or negative effects that are not related to the hazard, such as benefits for consumers through the importation of cheaper goods or the impact of these goods on the competitiveness of a particular industry, do not fall within the scope of an import risk analysis for animals and animal products. For each step, the relevant direct and indirect consequences considered are listed. The risk analysis may be concluded at this point if either no consequences are identified or the likelihood for each of the consequences identified is negligible.

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

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

The 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 *Codes* expand 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 domestic industry, should not be taken into consideration. In addition, consequence assessments should 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:

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

Note that a causal relationship must exist between exposure to a hazard and an adverse effect.

The risk analysis may be concluded at this point if either no consequences are identified or the likelihood for each of the consequences identified is negligible.

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

Direct consequences

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

Indirect consequences

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

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

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

Direct and indirect consequences may be estimated at four levels: farm/village, 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.

Box 7 provides an example of a consequence assessment for AHS. A scenario tree illustrating the biological consequences of horses becoming infected with African horse sickness virus is shown in Figure 12, while Table IV summarises the likelihood and significance of the biological, environmental and economic consequences.

Box 7 Example of a consequence assessment for the importation into New Zealand of horses potentially infected with African horse sickness (AHS) virus

Horses and dogs are the only animals likely to be affected by AHS virus in New Zealand. It is not a zoonotic disease and is not likely to become established in this country. Since there are only limited opportunities for exposure there are also limited opportunities for infection and spread. While the number of animals likely to be infected is very small, consequences for the affected animal(s) are likely to be severe.

As neither the natural vector of AHS, *Culicoides imicola*, nor any *Culicoides* spp. is present in New Zealand, any other case would be directly associated with a recently imported animal. The costs of an investigation and any short-term control costs are likely to be minimal.

There are unlikely to be any significant trade implications associated with a case of AHS in New Zealand.

Conclusion

Although the trade implications and costs of control following the introduction of AHS virus in New Zealand are likely to be negligible, there is a high likelihood that animals that become infected would be severely affected. Other biological consequences would be negligible.

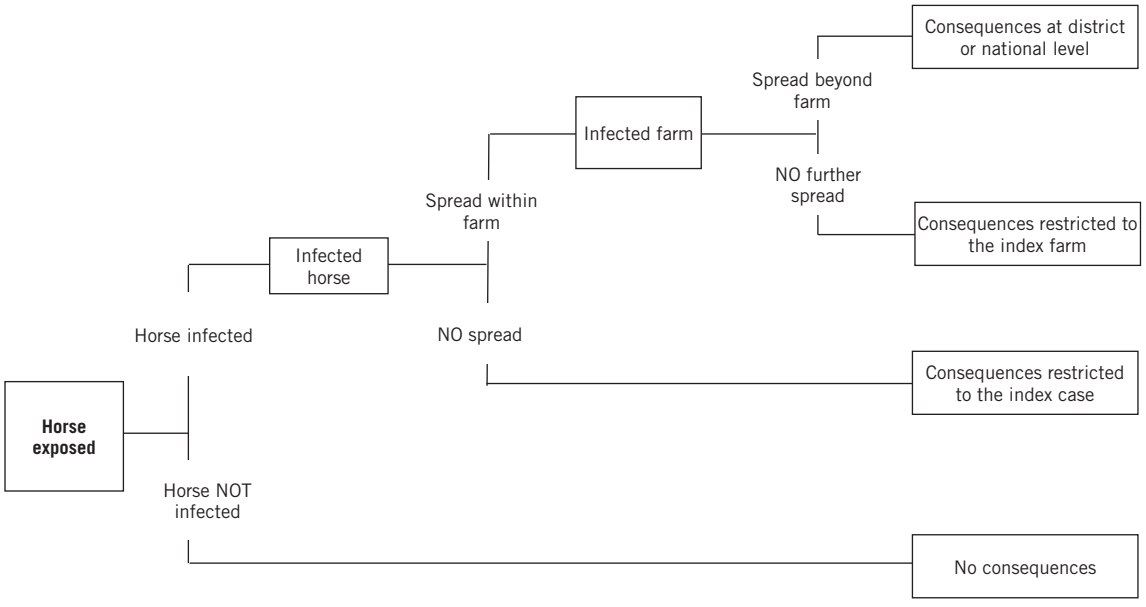

Figure 12 A scenario tree illustrating the biological consequences of local horses being exposed to an imported viraemic horse

Table IV A summarised consequence assessment for the importation into New Zealand of a horse infected with African horse sickness virus

Scenario	Likelihood of scenario	Type of consequence	Likelihood of consequence	Significance of consequence at a national level
No infection of local horses	High	Not applicable as no adverse consequences of scenario		
Infection in one local horse	Very low	Biological	High	Negligible
		Environmental	Negligible	Negligible
		Economic	High	Very low
Spread within index farm	Very low	Biological	High	Low
		Environmental	Negligible	Negligible
		Economic	High	Low
Spread beyond index farm	Negligible	Not taken further as negligible likelihood of scenario		

3.7.9. Risk estimation

Summary

The risk estimation step summarises the results and/or conclusions arising from the release, exposure and consequence assessments. It is a prerequisite step to risk management, which determines whether or not sanitary measures are warranted.

Box 8 Risk estimation decision steps

Entry assessment (likelihood of entry)

Is the likelihood negligible that the commodity is carrying the hazard when it is imported?

a) If the answer is YES, the risk estimate is classified as negligible;

b) If the answer is NO, then conduct an exposure assessment.

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

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

a) If the answer is YES, the risk estimate is classified as negligible;

b) If the answer is NO, then conduct a consequence assessment.

Consequence assessment

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

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

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

Each hazard should be dealt with individually, summarising the results and/or conclusions arising from the entry, exposure, and consequence assessments to estimate the likelihood of the hazard entering the importing country, becoming established or spreading, and resulting in adverse consequences. It is not sufficient to conclude that there is a possibility of entry, establishment or spread, or that there might be consequences. An evaluation of the likelihood of each of these factors must be undertaken. The decision steps outlined in Box 8 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. Box 9 provides an example of a risk estimation for AHS in horses imported into New Zealand.

Box 9 Example of a risk estimation for the importation into New Zealand of horses infected with African horse sickness (AHS) virus

Entry assessment (likelihood of entry)

The likelihood of a horse harbouring AHS virus if it is imported from an AHS endemic area in Africa in the summer and autumn months is low.

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

The likelihood of susceptible animals (horses or dogs) being exposed to AHS virus in New Zealand by pathways involving:

- insect vectors or semen is negligible
- contaminated surgical equipment, needles etc. or the oral ingestion of contaminated horse meat is very low.

Consequence assessment (likelihood of biological, environmental or economic consequences occurring, and their likely magnitude)

While the likelihood of one or a few animals becoming infected is low, it is highly likely that the biological consequences for these animals would be high. The likelihood of a large number of susceptible animals becoming infected with AHS in New Zealand is negligible. The environmental consequences are negligible and the national economic consequences are low or very low.

Risk estimation

Although AHS virus would not become established in New Zealand, the likelihood that a horse imported from an endemic area will be viraemic leading to spread to other horses is very low. The consequences of infection are likely to be severe for infected animals, particularly if they are affected by the pulmonary, cardiac or mixed forms of the disease. As a result, the risk estimate for AHS virus is greater than negligible and sanitary measures may be justified.

3.8. Risk management

Summary

The risk management step examines the animal health options available to effectively manage the risks posed by each hazard in order to achieve the importing country's acceptable risk. An important consideration is that under the provisions of the SPS Agreement, there should essentially be no restrictions (sanitary measures) on international trade in animals and animal products unless it is likely that a disease may enter, establish or spread and lead to unacceptable biological and economic consequences. For this reason, the sanitary measures eventually chosen must:

- be based on the risk analysis, not simply selected arbitrarily
- be applied only to the extent that is necessary to reasonably and effectively manage the overall risk continuum
- not constitute disguised restrictions on trade
- not result in either discrimination between an importing and exporting country, or preferential treatment being granted to one exporting country over another where similar conditions (disease status, control programmes, etc.) are known to exist
- be technically, operationally and economically feasible.

Four components are identified:

1. risk evaluation, where the estimated risk is compared with the importing country's acceptable risk
2. option evaluation, where sanitary measures are identified, evaluated and selected to effectively manage the risks in line with the importing country's acceptable risk
3. implementation, where
   - a scientific peer review of the risk analysis and the chosen sanitary measures is undertaken to ensure that the analysis is technically robust and the measures are both appropriate to the circumstances and consistent with international obligations
   - selected sanitary measures are notified to the WTO as appropriate and applied
4. monitoring and review, where sanitary measures are audited to ensure that they are achieving the results intended.

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

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

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

- risk evaluation
- option evaluation
- implementation
- monitoring and review.

3.8.1. Risk evaluation

Summary

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

An important consideration is that under the provisions of the SPS Agreement, there should essentially be no restrictions (that is, sanitary measures) on international trade in animals and animal products if there is not a significant likelihood that a disease might enter a territory, become established or spread, and lead to unacceptable biological and economic consequences. As a result, if the risk estimate determined in the risk assessment is greater than the importing country's acceptable risk, sanitary measures may be justified. Acceptable risk is the term used to indicate that level of risk judged by each OIE Member Country to be compatible with its aims in protecting animal and public health in that country. The term reflects the balance the country wishes to achieve between its desire to participate in international trade, and the pest and disease risks associated with such trade. The equivalent term used in the SPS Agreement is the 'appropriate level of [sanitary or phytosanitary] protection', which is commonly abbreviated to ALOP. It is also referred to as the 'acceptable level of risk'.

A country's ALOP is a societal or political judgement which needs to be in place before individual decisions on human and animal (and plant) health risks are made. The SPS Agreement recognises each Member Country's right to set its own ALOP, and for this reason, the level of risk considered acceptable may differ between countries. While there is no unique or defined level of acceptable risk applicable to all countries, it is nevertheless essential that within each country, the ALOP is applied consistently across the various risk pathways associated with the range of commodities imported from different countries and their associated hazards. This will ensure that arbitrary distinctions in the level of protection are avoided.

It is not unusual, however, for some interest groups in a society to call for the Competent Authority to adopt a policy of 'zero risk', especially where they believe that the risks associated with a particular hazard cannot be managed effectively, no matter what the situation. In some cases stakeholders may be concerned that the importation of less expensive commodities may subject local producers to significant economic competition. While a zero risk importation policy may have an intuitive appeal for some, the pursuit of such a policy would require either a total prohibition on all imports, or the imposition of an onerous set of measures far out of proportion to the actual level of risk. Even these approaches would not be sufficient to eliminate all risk, because of illegal trade activities and/or natural incursions.

A further complication is that, in the case of live animal imports at least, the benefits of importation may accrue to relatively few citizens, such as the entrepreneurs who import superior genetic stock. The risks, on the other hand, may be borne by many, including the established livestock industry, the public and taxpayers, who might be expected to bear the cost of eradicating any introduced disease. This might mean that a risk that is acceptable to the entrepreneur is unacceptable to the established livestock industries or general public.

Within this context, the role of the risk manager is to decide whether a particular risk exceeds the country's acceptable risk level, and whether sanitary measures need to be applied to reduce the assessed risk to the acceptable level. It is essential that there be a close association between the risk assessors and risk managers, as there must be a rational relationship between the outcome of the risk analysis and the sanitary measures chosen. It is important to clarify the roles of risk assessors and risk managers. For example, what does a risk manager expect from a risk assessment? Is the task to provide an estimate of the risk, to provide a range of options available to manage the risk, or to recommend particular sanitary measures? Who is responsible for identifying, selecting and implementing sanitary measures? Should there be a transparent and interactively documented process between risk managers and assessors? Regardless of the answers to these questions, one of the most important guiding principles is that the risk analysis should precede the decision, rather than being commissioned to support a decision that has already been made.

3.8.2. Option evaluation step

Summary

In the step of evaluating options, sanitary measures are identified, evaluated and selected to effectively manage the risks in line with both the importing country's acceptable risk and WTO obligations. It is essential to ensure that the *Code*'s sanitary measures are considered where they exist; that the measures are based on scientific principles that have been developed through a risk analysis (not chosen or applied arbitrarily); that negative trade effects are minimised by choosing measures that are technically, operationally and economically feasible, and only applied to the extent that is necessary to protect human or animal life or health; and that the measures do not result in discrimination between an importing and exporting country or the granting of preferential treatment to one exporting country over another, where similar conditions exist in the exporting countries.

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

Where sanitary measures are considered, WTO Member Countries must ensure that the measures finally chosen:

- are based on a risk analysis, not simply selected arbitrarily
- are applied only to the extent that is necessary to reasonably and effectively manage the overall risk continuum
- are not disguised restrictions on trade
- do not result in discrimination between an importing and exporting country, or the granting of preferential treatment to one exporting country over another, where similar conditions (disease status, control programmes, etc.) exist in the exporting countries

- are consistently applied across a range of commodities likely to contain the same hazard to avoid situations where different levels of protection arise
- are technically, operationally and economically feasible.

It is clear from the above that a sanitary measure must be justified scientifically, and be based on either a risk analysis or a relevant international standard. The SPS Agreement addresses the situation when the scientific information available is not sufficient to carry out a full risk analysis, by allowing Members to implement provisional measures, provided they seek to obtain the additional information necessary for a more objective risk analysis, and review the sanitary measure accordingly within a reasonable period of time.

A number of important steps, as outlined in Box 10, must be considered when identifying, evaluating and selecting sanitary measures.

An example of risk management appears in Box 11.

3.8.3. Scientific peer review

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

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

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

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:

- 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?
- Does the document make clear what data have been used and where assumptions have been made?
- Has the literature been cited accurately? Have any important publications been overlooked?
- Are the references cited appropriate? For example, are the critical epidemiological observations based on secondary sources where it would have been preferable to consult primary sources?
- Have the relevant international standards been applied appropriately?
- 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?

Box 10 Steps involved in identifying, evaluating and selecting sanitary measures to effectively manage risks in order to achieve an importing country's acceptable risk

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

Box 11 An example of risk management for the importation into New Zealand of horses potentially infected with African horse sickness (AHS) virus

Risk management

Risk evaluation

Since the risk estimate for AHS virus is greater than negligible, sanitary measure(s) need to be employed to achieve New Zealand's acceptable risk.

Option evaluation

Objective

To effectively manage the risks of AHS virus, sanitary measure(s) need to ensure that horses are not viraemic when released into the general population.

Sanitary options available

As the currently available commercial vaccines are unlikely to prevent viraemia, the only means available to ensure that horses are not carrying the virus when released into the general population, is to ensure they are either resident in a free country or free zone, or protected from insect vectors for a period equal to the maximum duration of viraemia plus the incubation period. Since the incubation period may be up to 14 days and viraemia may last up to 21 days, horses need to be protected from insect vectors for up to 35 days. Since the duration of viraemia following vaccination with a live vaccine is likely to be similar to that resulting from a natural challenge, animals need to be vaccinated no less than 35 days prior to being released into the general population.

The *Code* details the accepted standards for defining a free country or free zone, and specifies the conditions for importing domestic horses from a free country or free zone. The requirements specified in the *Code* are consistent with the objective outlined above. Therefore the *Code* provides appropriate measures to mitigate against the risks associated with AHS virus for horses imported from free countries or free zones.

The *Code* specifies the conditions for the importation of domestic horses from an infected country or an infected zone. The requirements are consistent with the objectives outlined above, although a negative test for AHS (as specified in the *Code*) in unvaccinated animals that are protected from vectors is not warranted. A seropositive test in such circumstances indicates past infection, not current infectivity. Apart from the requirement to test unvaccinated animals, the *Code* provides appropriate measures to mitigate the risks associated with AHS virus for horses imported from infected countries or infected zones.

Recommended sanitary measures

Horses must either:

a) originate from an AHS-free country or free zone as specified in the *Code* and satisfy the requirements for the importation of domestic horses from an AHS-free country or free zone, or

b) if from a country or zone considered to be infected with AHS, be protected from insect vectors for 35 days prior to being released into the general population. A live vaccine may be used. However it must be administered at least 35 days prior to release of the horse into the general population.

- 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?
- Has any data or information been overlooked that 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.

The Competent Authority should normally reimburse experts reviewing risk analyses.

3.8.4. Implementation

Summary

In the implementation step, the focus is on reaching a final decision on the sanitary measures to be adopted. The WTO will need to be notified if the measures are not substantially the same as those in the *Code* and are likely to have a significant effect on international trade. Sufficient time (usually 60 days) should be allowed for comments from WTO Members to be taken into account.

The focus of implementation is on reaching a final decision on the sanitary measures to be adopted for the particular commodity under consideration. Once measures have been identified in the option evaluation step, consideration should be given at this stage to:

- identifying clearly who the decision maker is, and transparently documenting the rationale for any decisions made that are not based on or supported by a risk analysis
- notifying the WTO as appropriate.

3.8.4.1. Decision making

While a risk analysis provides recommendations on whether or nor sanitary measures can be justified, and if they are, the type of measures required to achieve an importing country's acceptable level of risk, other factors may be taken into account in reaching a final decision. If this is done, what factors have been considered? Have non-disease associated effects been considered? If so, how have they been taken into account? It is also important to clarify who makes the decision. Is it, for example, the Chief Veterinary Officer or another official in the Competent Authority, or is the decision made at the political level? To ensure transparency, it is essential that where the final decision is not based on or supported by a risk analysis, the decision maker adequately documents the rationale for their decision.

3.8.4.2. WTO notification

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

- measure(s) where an international standard, guideline or recommendation does not exist

- 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.

To determine whether there is likely to be a significant effect on trade, the following elements need to be considered:

- the value or other importance of imports in respect of the importing and/or exporting Members concerned, whether from other Members individually or collectively
- the potential development of such imports
- difficulties for producers in other Member Countries in complying with the measure.

The concept of a significant effect on trade of other Members should include both import-enhancing and import-reducing effects. This concept should be interpreted broadly, and Members should be notified of sanitary measures if there is any doubt whether this is necessary.

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 60 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.

3.8.5. Monitoring and review of sanitary measures

Summary

In the monitoring and review step, sanitary measures are audited to ensure that they are achieving the results intended through, for example an audit of the sanitary measures and certification requirements implemented in both the exporting and importing countries. As new information or the results from the audit become available the measures themselves or the underlying risk analysis may need to be reviewed.

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

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

Factors of such significance that they may need to be reassessed immediately include changes in the animal disease status of the exporting country, neighbouring countries or regions. Other important events that may require the updating of a risk analysis include major political changes affecting officials responsible for the export process, natural

disasters which affect the animal health infrastructure, decreases in social stability such as labour shortages, which could impact the availability of personnel responsible for key activities, significant changes in economic status, and the completion of a new risk analysis involving a related animal commodity or product.

Specific factors that may need to be monitored periodically can be identified through the process of risk analysis. Those steps in the importation process that incorporate the greatest uncertainty or have the greatest impact on the risk estimate should be monitored. Through this monitoring, additional information can be collected, which will help to show whether these steps need to be revised.

Because risk increases with the increasing volume of a commodity that is imported, in some cases importation may be permitted provided a specified volume of the commodity is not exceeded in any specified unit of time. In such cases, the volume of the commodity imported should be monitored to ensure that the levels of the anticipated volumes are not exceeded. Should volumes of imports exceed that estimated in the risk assessment additional sanitary measures may be required. Less obvious, but equally important, is the monitoring of the sanitary measures that were incorporated into the importation process to reduce risk to an acceptable level. Especially if these steps were new, or required a change in a normal production or trade process within the exporting or importing country, periodic affirmation that these measures are being implemented appropriately may be needed.

Officials in charge of animal health programmes in the countries participating in the proposed export/import have a responsibility to ensure that open and honest communication occurs routinely between the organisations involved and their staff. This communication includes a timely response to requests for information necessary to complete and update the requested risk analysis, and periodic reports on the status of the risk analysis.

4. Presenting the results in a risk analysis report

4.1. Transparency

Summary

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

The *Codes* define 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 that:

- fairness and rationality are used in the analysis
- there is consistency in decision making
- all interested parties can understand the approach taken
- assumptions are documented
- uncertainties are dealt with appropriately
- the reasons for conclusions and recommendations are clear
- stakeholders are given clear reasons for the imposition of sanitary measures or a refusal to import.

4.2. Information to include in the import risk analysis report

Box 12 provides a template for an import risk analysis report.

This section provides detailed guidelines that are necessary to facilitate communication of the results of the analysis. It is important to:

- Restate the question that has been asked;
- Explain the risk analysis structure clearly, with the aid of appropriate diagrams, such as a scenario tree;
- Focus on information directly relevant to the logic chain of the analysis:
  - 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 sanitary options;
  - it is not necessary to offer detailed descriptions of clinical syndromes, pathology, treatments etc., unless these have a direct bearing on the likelihood of detecting diseased animals or managing disease risks;
  - for some commodities, as soon as a risk assessment has been completed for a particular hazard and the sanitary measure(s) have been proposed, for example a form of processing such as cooking, there may be no need to undertake a full risk analysis for the other potential hazards, because the measure proposed for the first hazard would also address the risks posed by the other hazards. In these circumstances, an assessment of the efficacy of the proposed measure(s) on the other potential hazards might be all that is required;
- Document all the evidence, data and assumptions, including their references;
- Use clearly labelled, uncluttered graphs, where appropriate;
- When a quantitative analysis has been made, avoid reporting results to more than one or two decimal places, as reporting results to several decimal places implies a level of precision that is usually unattainable. Consider reporting the results to the nearest order of magnitude only;
- Ensure the report is as focused and as uncluttered as possible;
- Keep any statistics to a minimum;

Box 12 A template for an import risk analysis report

1. **Date**:
2. **Title**: Determined from the scoping step by considering the nature, source(s) (including country of origin) and intended use(s) of the animals or animal products; the scientific names of the animal species involved; the relevant methods of production, manufacturing, processing or testing that are normally applied and quality assurance programmes (such as HACCP); and, an estimate of the likely annual volume of trade if possible.
3. **Context**: Provide a brief description of the request.
4. **Purpose**: Clearly state the purpose, for example, 'To identify and assess the likelihood of [*the hazard(s)*] being introduced and spreading or becoming established in [*the importing country*] together with the likelihood of and the likely magnitude of their potential consequences for animal or human health as a result of importing [*the animals or animal products*]; to recommend sanitary measures as appropriate.'
5. **Risk communication strategy**: Provide an overview of who was consulted and when/how they were consulted.
6. **Executive summary**: Should be simple, concise, complete and contain all the elements needed by the decision maker.
7. **Hazard identification**: List the hazards together with the supporting rationale.
8. **Sanitary measures in the OIE *Code***: Indicate whether OIE measures are available, and whether or not they will be applied, together with any supporting rationale.
9. **Risk assessment**
   a) Entry assessment: Describe the biological (risk) pathways necessary for each hazard to be introduced into the country. Provide details of the relevant biological, country or commodity factors that have been considered and that support the overall conclusions reached. (Include details of how uncertainty was taken into account and of any assumptions that have been made.)
   b) Exposure assessment: Describe the biological (risk) pathways necessary for the exposure of susceptible animals and/or humans in the country to each hazard. Provide details of the relevant biological, country or commodity factors that have been considered and that support the overall conclusion reached. (Include details of how uncertainty was taken into account and of any assumptions that have been made.)
   c) Consequence assessment: Describe the biological, environmental and economic consequences associated with the entry, establishment or spread of each hazard. Provide details of the relevant direct and indirect consequences that have been considered and that support the overall conclusions reached. (Include details of how uncertainty was taken into account and of any assumptions that have been made.)
   d) Risk estimation: Provide a summary of the results and/or conclusions arising from release, exposure, and consequence assessments.
10. **Risk management**: Discuss the rationale for selecting the chosen animal health options, together with how recommendations from a scientific peer review and feedback from stakeholder consultation have been taken into account.
11. **Conclusions and recommendations**: List the main findings, and include a summary of the sources of uncertainty and of the assumptions that have been made.
12. **References**: List all sources of information used.

- Communicate the results verbally whenever this is reasonably practicable. Verbal communication ensures a better understanding of the problem and the outcome of the risk analysis.

In the interests of transparency, the risk analysis must be well documented and supported with references to the scientific literature and other sources, including expert opinion, where used. The analysis must also provide a reasoned and logical discussion to support the conclusions and recommendations. There must be comprehensive documentation of all data, information, assumptions, methods, results, and uncertainties. Because risk analysis is based in science, risk analyses should be written in a style that reflects this science-based approach. They should be subjected to a process of peer review.

Critical epidemiological observations that are the key to the analytical process should be attributed to primary sources. Where a number of references are cited in support of a particular point, the analyst should ensure that they are all based on independent studies. In other words, the analyst should not cite several references that are based on the same, single primary source.

Where expert opinion has been used to estimate key inputs into a risk assessment, the methods used to elicit that expert opinion should be documented (see Chapter 6 of Volume 2 of this *Handbook,* OIE, 2004).

Box 13 Guidelines for writing an import risk analysis

It is recommended that import risk analyses are written, as far as is practicable, according to the guidelines offered to authors submitting manuscripts to the *Scientific and Technical Review* of the OIE. The following guidelines are adapted from the *Scientific and Technical Review* guidelines to authors:

1. Title, names and addresses of the Competent Authority

The title should describe adequately the commodities covered by the risk analysis. An import risk analysis should be attributed to the Competent Authority that commissioned it. Attributing an official risk analysis to individuals is not appropriate, although some Competent Authorities may consider that the names of the individuals carrying out the analysis should be recorded in an acknowledgements section.

2. Summary

A summary of appropriate length should describe the methodology, principal conclusions and recommendations of the risk analysis. Abbreviations used for the first time should be preceded by the expression in full.

3. Text

Unlike manuscripts submitted for publication in the OIE's *Scientific and Technical Review*, reports of import risk analyses may be large documents. It is not appropriate to recommend a particular length for an import risk analysis; the length should be appropriate to the scope of the analysis. In the interests of meeting the obligation for transparency, the analysis may be quite long. However, analysts should use appendices for explanatory detail not directly essential to the understanding of the main conclusions of the analysis. Unnecessarily long paragraphs should be avoided.

Analysts should make every effort to write clearly and concisely.

Units of measurement should be expressed using the metric system, and where appropriate SI units.

Diagnostic methods should be described and referenced.

Veterinary drugs, reagents and laboratory materials should be referred to in the text by their generic name (give their commercial name only if necessary).

Abbreviations and acronyms should be defined the first time they are used and collated in a table.

4. References

References may be placed in footnotes, as a bibliography at the end of each chapter, or at the end of the risk analysis as a whole. The decision on placement of references may be based on the size of the analysis and the preference of the Competent Authority commissioning the analysis. Where a bibliography appears at the end of each chapter or at the end of the analysis as a whole, the numbered references (optional) should be listed in alphabetical order of authors. In the text, references to the literature should be made by number and enclosed in brackets.

By preference, the names of journals and reviews should be given in full. Unpublished data and personal communications should be referred to in the body of the text or as footnotes, and not be included in the list of references. All unpublished data and personal communications should be available as hard copy on file, to be made available should the risk analysis be challenged.

Each reference should list the surnames followed by the initials of all authors, the year of publication, full title, journal, volume, issue and page numbers, as shown in the examples below. Papers by the same author should be listed in chronological order (placing works by a single author first, followed by those written with co-authors).

Article from a journal or review

#. Douglas B., Moffat L., Russell V. & Coulton P. (1982). – Study on the persistence of foot and mouth disease antibodies in calves born of vaccinated dams. *Rev. sci. tech. Off. int. Epiz.*, **1** (2), 875–892.

Article in press

#. Douglas B., Moffat L. & Russell V. (2000). – A study on foot and mouth disease antibody production in cattle with protein deficiency. *Rev. sci. tech. Off. int. Epiz.* (in press).

Chapter of a book or conference report

#. Read P., Cousins C. & Murray R. (1992). – Assessment of the immunogenicity of different strains of *Bacteroides nodosus. In* Proc. 4th Symposium on sheep diseases (P. Morris & G. Roberts, eds). 12–14 February 1991, Paris. Vigier, Paris, 894–897.

Electronic documents

#. Read P., Cousins C. & Murray R. (1992). – Assessment of the immunogenicity of different strains of *Bacteroides nodosus.* Available at: www.websiteaddress.org/detailed_address (accessed on 6 April 2010).

Electronic documents (CD-ROMs and documents available on the web) may be cited (giving the full web address and the date accessed), but the Competent Authority should ensure that paper copies of web-based documents are retained on file, as websites are subject to review and change. In the event of a challenge to the import risk analysis, the Competent Authority should be able to provide copies of any document cited in the analysis.

Reference should be made to specific documents on the web, and not to the home pages of organisations.

5. Tables and figures

Tables and figures should be numbered and given titles that are self-explanatory, so that the need to refer back to the text is minimised. All columns, rows and axes should be labelled. It may be appropriate to give data either as individual values, or as mean values and standard deviations or other appropriate distribution parameters. Notes, comments or explanations relating to numerical values should be indicated using superscript letters (e.g. $^{(a)}$, $^{(b)}$, $^{(c)}$, $^{(d)}$) linked to notes placed immediately below the table. Abbreviations that are not widely used should be explained. Tables and figures should illustrate, not duplicate, information in the text.

Chapter 3
Risk communication

1. Introduction

As defined in the *Codes*, risk communication is a process involving an open, interactive, iterative and transparent exchange of information on hazards and their associated risks, together with proposed mitigation measures. Risk communication is conducted among risk assessors, risk managers and potentially affected and/or interested parties (stakeholders) in both importing and exporting countries.

With any risk issue, the best outcome is one that reduces the risk to an acceptable level, while at the same time minimising disputes, disagreements and the measures required to effectively manage the risk. Risk communication may not resolve all differences with stakeholders, but may lead to a better understanding of the rationale for a particular decision. Stakeholders who have been involved in the decision-making process from the outset are less likely to challenge the outcome, especially if their concerns have been adequately addressed.

2. Those involved in the risk communication process

The participants in the risk communication process are all the potentially affected and/or interested parties (stakeholders) in both the importing and exporting countries. These participants are often referred to as stakeholders, and include the Competent Authorities in both the importing and exporting countries, the WTO and OIE, importers and exporters, producer, farmer and consumer organisations, academia and scientific institutions, and the media. To ensure meaningful dialogue, all stakeholders need to acknowledge that, while they have a right to propose a contrary view, they have an obligation to provide a reasoned argument that is relevant to the analysis. In addition to this basic right and obligation, stakeholders have the specific roles and responsibilities noted below.

2.1. Competent Authority

The Competent Authority of a country has the responsibility of developing and implementing a risk communication strategy that provides stakeholders with the opportunity to become involved. It also needs to ensure that the level of complexity of the information provided is appropriate to particular stakeholder groups, and that the legitimate concerns of stakeholders are addressed adequately and in a timely manner.

2.2. International organisations

The OIE is responsible for the development and publication of international standards to ensure safe trade in animals and animal products, and for collating and reporting information on specified animal diseases and zoonoses.

The WTO SPS Committee, comprising WTO Members, manages the implementation of the SPS Agreement. As required by the SPS Agreement's notification procedure, it communicates risk management decisions among Members.

2.3. Importers and exporters

Importers and exporters may be significant sources of information for the risk assessment and risk management steps because of specialist knowledge they may have on methods of production and processing of various commodities. In some circumstances, this information may be commercially sensitive, and they may be reluctant to share it with the Competent Authority unless confidentiality can be assured.

2.4. Producer, farmer and consumer organisations

Producer, farmer and consumer organisations can play a valuable role in disseminating information and presenting the concerns and opinions of their members to the Competent Authority. Including them in the risk analysis process from the outset will help to ensure that the concerns of their members are adequately addressed, and will facilitate their understanding of the basis for risk management decisions.

2.5. Academic and scientific institutions

Members of the academic and scientific community may play an important role by contributing expertise on animal diseases and by assisting in the hazard identification, risk assessment and risk management steps. They may be asked by the media or other stakeholders to comment on risk analyses undertaken by, and the decisions of, the Competent Authority. They often have a high degree of credibility with the public and the media, and may serve as independent sources of information. Experts in risk perception or risk communication may also provide advice on communication approaches and strategies to the Competent Authority.

2.6. Media

The media can play an important role, as a significant amount of information that the public receives on animal health risks is likely to come from them. They may transmit the message, or they may create or interpret it. The media are seldom restricted to official sources of information, and their messages often reflect the concerns of particular stakeholders. They can be an extremely valuable partner in the risk communication process, and can facilitate an interactive and transparent exchange of information, opinions and concerns amongst the various stakeholders.

3. When the risk communication process should begin

Ideally, the risk communication process should begin at the start of each risk analysis to ensure that stakeholders are provided with an opportunity to become involved from the outset. Increasingly, stakeholders expect that they will be provided with an opportunity for consultation before decisions are made. They are likely to have easy access to a variety of information, and are less reliant on the scientific community or government evaluating risks and making decisions on their behalf.

Once a decision is made by the Competent Authority to undertake an import risk analysis for a particular commodity, a risk communication strategy should be developed. Stakeholders should be identified, with the aim of being inclusive rather than exclusive. Providing stakeholders with information on the scope of the proposed analysis and a preliminary list of hazards enables them to offer comment and share relevant information with the Competent Authority from the outset.

4. 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 sanitary measures to effectively manage the risks posed by the hazards, and the final decision. Stakeholders should be provided with an opportunity to engage in a two-way dialogue with the Competent Authority to ensure that their legitimate concerns and comments are addressed adequately. The following factors should be considered.

4.1. Identifying stakeholders

In most circumstances the Competent Authority will be able to identify key stakeholder groups such as producer, farmer and consumer organisations. Since it is important to be inclusive, various ways of identifying other potential stakeholders should be explored so that as complete a list as possible is developed. For example, official publications, web pages and public notices in newspapers provide opportunities to assist in identifying potentially affected or interested parties and inviting them to register as stakeholders.

4.2. Providing stakeholders with the opportunity to participate

Once stakeholders have been identified, the most appropriate and cost-effective means of providing them with the necessary information should be explored. Options include direct mail-outs, official publications, web pages, public notices and/or advertisements in newspapers, press releases and meetings with specific groups. In addition, mechanisms to facilitate feedback should be considered, including submissions by letter, e-mail or the web.

4.3. Providing information to stakeholders

The nature and type of information provided to different stakeholders is likely to vary, depending on their needs and technical understanding. For this reason, it is important to provide several options from which stakeholders can choose, ranging from a dossier providing all the technical details, to a summary of that dossier, explanatory leaflets and press releases.

4.4. Establishing expertise in risk communication

Successful risk communication requires skills that facilitate interaction with stakeholders and the preparation of suitable information and messages for specific stakeholder groups. People with suitable training and expertise in risk communication should be involved as early as possible, particularly if the risk analysis is likely to be contentious.

5. The goals of risk communication

The goals of an effective risk communication strategy are:

- to exchange information freely by undertaking an interactive and iterative (two-way) dialogue with stakeholders from the outset of a risk analysis
- to maximise the effectiveness and efficiency of the risk analysis process by providing

stakeholders with the opportunity to share information that might not otherwise be available to:
– risk assessors during the hazard identification and risk assessment steps
– risk managers when they are identifying and evaluating available sanitary measures

- to provide information that is meaningful, relevant, accurate, clear and targeted to specific stakeholder groups
- to promote an awareness and understanding of specific issues
- 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
- to provide stakeholders with an assurance that their legitimate concerns will be addressed and that feedback will be timely
- to strengthen working relationships and mutual respect among all participants in the risk analysis process
- to enhance public trust and confidence in the safety of imported commodities.

6. Barriers to effective risk communication

6.1. Lack of credibility

Information from a credible source is more likely to be taken seriously than information from sources that lack credibility. Credibility is influenced by beliefs in competence or expertise, trustworthiness, fairness, and lack of bias. Trust and credibility can easily be lost and are difficult to regain. Studies have shown that mistrust and low credibility are products of exaggeration, distortion and perceived vested interests.

6.2. Lack of participation

Lack of participation in the risk analysis process by stakeholders who are likely to have a significant interest in the outcome can create significant problems. Inviting stakeholders to participate in the process from the outset and providing them with opportunities to comment and raise their concerns are essential and effective means of overcoming this barrier. In some circumstances stakeholders may be reluctant to participate because the information they are asked to provide is commercially sensitive. They will need to be assured by the Competent Authority that confidentiality can be maintained.

6.3. Risk comparisons

Comparing the estimated level of risk associated with the hazard(s) under investigation with more familiar risks can create problems if it appears that the comparison has intentionally been chosen to make the risk seem more acceptable. In general, risk comparisons should be avoided unless:

- both (or all) risk estimates are equally sound
- both (or all) risk estimates are relevant to the specific audience
- the degree of uncertainty in both (or all) risk estimates is similar

- stakeholders' concerns are acknowledged and addressed
- the commodities, products or activities themselves are directly comparable, including the concept of voluntary and involuntary exposure.

6.4. Differences in perceptions of risk

Individuals may perceive the risk from the same hazard(s) very differently. Once attitudes and perceptions are formed, they are difficult to change. People tend to accept information that supports the beliefs they already hold, and discount information that does not. This is especially true when people are presented with conflicting information.

It has been shown that the way people perceive risk is affected by whether or not:

- those assessing the risk are seen as trustworthy;
- hazards are unknown, unfamiliar (exotic) or rare, as opposed to well known or common;
- risks are controlled by 'others', rather than those being in the control of the stakeholder(s);
- a risk is memorable. More memorable risks are likely to be perceived as being more serious;
- risks are estimated to be unlikely to occur but would have a significant impact. People take the worst case more seriously;
- risks have a significant scientific uncertainty, or there is open controversy among experts as to the probability and severity of the risk. People focus on the worst case;
- risks raise moral or ethical questions, such as the fairness of the distribution of risks and benefits, or put the rights of one group in society at risk. For example, the risks and benefits associated with importation of animals may not be shared equally among all stakeholders. The benefits may accrue to a relatively small number of importers while the risks (the introduction of exotic diseases) may be borne by the majority of livestock owners;
- the risk assessment and decision-making process is considered by stakeholders to be unresponsive, unknown, non-transparent or incomplete.

7. Explaining the results

There are often significant challenges in communicating the results of a risk analysis, particularly when the probability estimate is very small. Most people find it difficult to conceptualise very small numbers. Information that contains a lot of scientific terminology may make it difficult for stakeholders to differentiate between facts, assumptions and uncertainties. As a result, they may not be in a position to understand the basis for the conclusions of a risk analysis and the decisions reached. The information provided to stakeholders needs to be targeted to their needs and likely level of understanding of scientific terminology.

8. The media

Relatively few reporters have the appropriate experience to enable them to deal with the complex scientific and policy issues associated with a risk analysis. This makes it difficult

for them to prepare a story, especially under the pressure of tight deadlines. Sometimes they may convey the information inaccurately. Because of this, it is important that risk assessors, risk managers and those involved in risk communication undertake training in media skills. This will assist them to work with reporters to enhance the quality and accuracy of media reports. They should also work to establish long-term partnerships with individuals working in the media.

While the media have their own goals and reporters make their own judgements on what is newsworthy, in those situations where an item is not considered newsworthy, consideration should be given to paying for advertisements or public notices.

Appendix 1
An animal health import risk analysis template

Summary

Steps involved in an animal health import risk analysis:

1. Determine the scope of the risk analysis;
2. State clearly the purpose of the risk analysis;
3. Develop a risk communication strategy;
4. Identify sources of information for the risk analysis;
5. Identify the hazards likely to be associated with the commodity under consideration;
6. Determine whether or not the *Codes* provide sanitary measures for the hazard in the commodity under consideration;
7. Conduct a risk assessment for each hazard:
   - 7.1. Identify the populations of interest;
   - 7.2 Draw a scenario tree to identify the various biological (risk) pathways leading to the commodity harbouring the hazard when imported, animals that are susceptible and/or exposed, and potential outbreak scenarios;
   - 7.3. Conduct an entry assessment to estimate the likelihood of the commodity introducing the hazard into the country;
   - 7.4 Conduct an exposure assessment to estimate the likelihood of susceptible animals and/or humans being exposed to the hazard;
   - 7.5 Conduct a consequence assessment to estimate the likely magnitude of potential biological, environmental and economic consequences associated with the entry, establishment or spread of the hazard, and the likelihood of their occurrence;
   - 7.6 Summarise the conclusions of the release, exposure and consequence assessments to provide an overall estimate of the risk (risk estimation);
8. Determine whether sanitary measures are warranted (risk management);
   - 8.1 Evaluate the risk to determine whether the risk estimate is greater than the county's acceptable risk level;
   - 8.2 Evaluate the animal health options to effectively manage the risks posed by each hazard and ensure that the options chosen are consistent with the country's obligations under the SPS Agreement;
   - 8.3 Undertake a scientific peer review of the risk analysis;
   - 8.4 Implement the sanitary options by notifying the WTO as appropriate and making a final decision on the measures selected;
   - 8.5 Monitor and review factors that could impact on the conclusions of the risk analysis and/or the implementation of the sanitary measures.

1. Determine the scope of the risk analysis

Define as precisely as possible the animals or animal products that are the subject of the risk analysis by taking account of:

- the nature, source(s) (including country) and intended use(s) of the animals or animal products
- the scientific names of the animal species
- the relevant methods of production, manufacturing, processing or testing that are normally applied and quality assurance programmes (such as HACCP)
- the likely annual volume of trade (if possible).

Draft a suitable title for the risk analysis (based on the above).

2. State clearly the purpose of the risk analysis

The purpose of the risk analysis should be stated in an appropriate form, for example:

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

3. Develop a risk communication strategy

The risk communication strategy should:

- identify interested parties
- determine when you need to communicate with them
- determine the appropriate means of communication.

4. Identify sources of information for the risk analysis

Information to assist in identifying hazards, assessing risks and exploring options to manage risk can be found in a variety of sources including:

- the OIE website (www.oie.int)
- import risk analyses carried out in other countries
- scientific journals and textbooks
- websites devoted to diseases of livestock, aquatic animals, wildlife and zoo animals
- the Competent Authority in the exporting country.

Assistance and advice can also be sought from a variety of specialists, including epidemiologists, veterinary pathologists, virologists, microbiologists, parasitologists, laboratory diagnosticians, wildlife specialists, biologists, ecologists, risk analysts, biostatisticians, livestock industry specialists, agricultural economists, field veterinarians and product specialists.

5. Identify the hazards likely to be associated with the commodity

Draw up a list of the pathogens associated with the species from which the commodity is derived, and based on the following criteria, determine whether or not they can be classified as a hazard for further consideration in a risk assessment:

5.1. Taking account of the methods of production, manufacturing or processing is the commodity under consideration a potential vehicle for the pathogenic agent?

a) If the answer is YES proceed to Step 5.2; otherwise the pathogenic agent is not a hazard.

5.2. Is the pathogenic agent present in the exporting country?

a) If the answer is YES proceed to Step 5.3.

b) If the answer is NO, is there sufficient confidence in the capacity and capability of the exporting country's Competent Authority to satisfactorily substantiate a claim that the pathogenic agent is absent?[1]
- If the answer is YES, the pathogenic agent is not a hazard.
- If the answer is NO, contact the Competent Authority to seek additional information or clarification and proceed to Step 5.4, assuming that, until otherwise demonstrated, the pathogenic agent is likely to be present in the exporting country.

5.3. Are there zones or compartments from which the commodity will be derived within the exporting country that are free of the pathogenic agent?

a) If the answer is YES, is there sufficient confidence in the capacity and capability of the exporting country's Competent Authority to satisfactorily substantiate a claim that the pathogenic agent is absent from, and ensure that the commodity is only derived from, these zones or compartments?[1]
- If the answer is YES, the pathogenic agent is not a hazard.
- If the answer is NO, contact the Competent Authority to seek additional information or clarification and proceed to Step 5.4, assuming that, until otherwise demonstrated, either the pathogenic agent is likely to be present in these zones or compartments, or the commodity is likely to be derived from other areas in the exporting country.

b) If the answer is NO, proceed to Step 5.4.

5.4. Is the pathogenic agent present in the country?

a) If the answer is YES, proceed to Step 5.5.

b) If the answer is NO, is the Competent Authority of the country able to satisfactorily substantiate a claim that it is absent?
- If the answer is YES, the pathogenic agent is classified as a hazard.
- If the answer is NO, proceed to Step 5.5, assuming that the pathogenic agent is present, and explore options within a reasonable period of time to ascertain its presence or absence with a sufficient level of confidence.

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

5.5. For a pathogenic agent reported in both the exporting and the importing country, if
a) it is subject to an official control programme in the importing country, OR
b) there are zones or compartments of different animal health status, OR
c) local strains are likely to be less virulent than those reported internationally or in the exporting country
THEN the pathogenic agent might be classified as a hazard. Proceed to Step 6.

Note: A risk analysis may be concluded at this stage if none of the pathogenic agents considered are classified as potential hazards.

6. Check whether the *Codes* provide sanitary measures for the hazard in the commodity under consideration

a) If the answer is YES, is it a requirement by legislation, policy or other considerations within the country to undertake a complete risk analysis?

– If the answer is YES, proceed to Step 7 and conduct a risk assessment.

– If the answer is NO, consider applying the sanitary measures prescribed in the *Code,* as a risk assessment to fulfil WTO obligations is not necessary.

b) If the answer is NO or it is decided to adopt a higher level of protection than that provided by the measures in the *Code*, proceed to Step 7 and conduct a risk assessment.

7. Conduct a risk assessment for each hazard

7.1 Identify the populations of interest. Potentially susceptible species need to be identified to ensure that all the appropriate biological pathways are considered in the risk assessment. Susceptible species include terrestrial and aquatic animals that are reared on farm or in captivity or are in the wild, as well as humans if the hazard has zoonotic potential.

7.2 Draw a scenario tree to identify the various biological (risk) pathways leading to:
- the commodity harbouring the hazard when imported
- susceptible animals and/or humans being exposed
- potential 'outbreak' scenarios.

7.3 Conduct an entry assessment to estimate the likelihood of the commodity introducing the hazard into the country.

List the relevant biological, country and animals or animal product factors considered in each step.

Is the likelihood negligible that the commodity is carrying the hazard when imported?

– If the answer is YES, the risk estimate (Step 6) is classified as negligible, and the risk analysis may be concluded at this point.

– If the answer is NO, proceed to Step 7.4.

7.4 Conduct an exposure assessment to estimate the likelihood of susceptible animals and/or humans being exposed to the hazard.

List the relevant biological, country and animals or animal product factors considered in each step.

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

– If the answer is YES, the risk estimate (Step 7.6) is classified as negligible, and the risk analysis may be concluded at this point.

– If the answer is NO, proceed to Step 7.5.

7.5 Conduct a consequence assessment to estimate the likely magnitude of potential biological, environmental and economic consequences associated with the entry, establishment or spread of the hazard, and the likelihood of their occurrence.

List the relevant direct and indirect consequences considered.

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

– If the answer is YES, the risk estimate (Step 7.6) is classified as negligible, and the risk analysis may be concluded at this point.

– If the answer is NO, proceed to Step 7.6.

7.6 Risk estimation: summarise the results and/or conclusions arising from the release, exposure and consequence assessments and proceed to Step 8.

8. Risk management

8.1 Risk evaluation:

Is the risk estimate greater than the country's acceptable risk level?

– If the answer is YES, proceed to Step 8.2.

– If the answer is NO, the sanitary options cannot be justified and the risk analysis may be concluded at this point.

8.2 Option evaluation:

Formulate an objective that clearly states the intended outcome of the sanitary measure(s) by taking into account the risk pathways leading from the likelihood of the hazard being introduced, to the exposure of susceptible animals and/or humans, and significant consequences arising.

Identify possible sanitary measures, including those specified in the *Code:*

– If there is a scientific justification that the measure(s) specified in the *Code* will not achieve the acceptable risk of the importing country, measures that result in a higher level of protection may be applied provided they are based on a risk assessment.

– Less stringent measures than those recommended in the *Code* may be applied where there is sufficient justification that they will achieve the importing country's acceptable risk level.

Select an option or combination of options that will achieve the acceptable risk of the importing country by ensuring that:

- option(s) are not chosen or applied arbitrarily but are based on scientific principles and a risk analysis:
  – Evaluate the likelihood of the entry, exposure, establishment or spread of the hazard, and estimate the likelihood of occurrence and likely magnitude

of biological, environmental and economic consequences according to the measure(s) that might be applied;

- negative trade effects are minimised:
  - Choose measures that are technically, operationally and economically feasible;
  - Apply measures only to the extent that is necessary to protect human or animal life or health;
  - Avoid situations where some parts of a risk pathway are overmanaged;
  - Consider each measure from the overall perspective of the entire risk pathway, not in isolation;
  - Take into account that if the contribution of a particular measure to the overall reduction in risk is insignificant or negligible, it is effectively redundant and should not be included. It is not defensible to include a redundant measure, and its inclusion could create unnecessary and unjustifiable technical and/or operational challenges, and lead to an unwarranted inflation in costs;
  - It is unlikely to be necessary to apply a sanitary measure at each and every step in the risk pathway in order to achieve the acceptable risk for an importing country;
  - Ensure that the option(s) do not result in either discrimination between an importing and exporting country or preferential treatment being granted to one exporting country over another where similar conditions, such as disease status or control programmes, are known to exist in each country.

8.3 Scientific peer review

Commission a scientific peer review to ensure that the risk analysis is technically robust and that the sanitary measures chosen are appropriate to the circumstances and consistent with international obligations under the SPS Agreement.

8.4 Implementation

Undertake a scientific peer review to ensure that the risk analysis is technically robust and that the sanitary measures chosen are appropriate to the circumstances and consistent with international obligations under the SPS Agreement.

Notify the WTO of measure(s):

- where an international standard, guideline or recommendation does not exist
- 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.

Make the final decision and implement the sanitary measure(s).

8.5 Monitoring and review

Monitor factors that may have an immediate impact on the risk, for example:

- changes in the animal disease status of the exporting or importing country, neighbouring countries, or regions
- major political changes affecting officials responsible for the export process
- natural disasters which affect animal health infrastructure.

Monitor factors associated with each risk analysis that may need to be reviewed periodically as updated and/or new information becomes available, for example:

- those steps in the importation process that incorporate the greatest uncertainty or have the greatest impact on the risk estimate
- the volume of commodity imported, particularly where a threshold has been established, that if exceeded could impact on the acceptable risk of the importing country.

Monitor the implementation of sanitary measures, especially if they are new, or required a change in a normal production or trade process within the exporting or importing country, to ensure they are achieving the results intended through periodic audits of the Veterinary Services, disease control programmes, production and processing practices, certification requirements and so on.

Appendix 2
Assessment of the risk of introduction of epizootic haematopoietic necrosis virus (EHNV) to the United Kingdom via imports of live carp from Australia

Epizootic haematopoietic necrosis (EHN) virus is a member of the genus *Ranavirus* in the family *Iridoviridae* (Eaton, Hyatt and Hengstberger, 1991). It has been isolated only from fish in Australia (Langdon *et al.,* 1986) and it is considered to be exotic to other parts of the world. EHN virus causes outbreaks of mortality in redfin perch (*Perca fluviatilis*) and to a lesser extent rainbow trout (*Oncorhynchus mykiss*) (Langdon and Humphrey, 1987). EHN is listed in the *Aquatic Code* (OIE, 2009).

Pathways of introduction of EHNV to the United Kingdom

Potential routes of introduction were identified as the importation of:

i) fish carcasses (rainbow trout or redfin perch)
ii) live susceptible species (rainbow trout or redfin perch)
iii) other live fish species (which may be unrecognised susceptible species or mechanical vectors).

Importation of fish carcasses

No trade in rainbow trout or perch carcasses has been reported. However, eviscerated fish (chilled or frozen) packaged for direct retail trade are considered by the OIE to be safe commodities and are not subject to trade restrictions (OIE, 2009). This route therefore need not be considered further.

Importation of susceptible species of fish

European Council Directive 2006/88/EC lists EHN as an exotic disease, hence the importation of live susceptible species (rainbow trout and redfin perch) from Australia would not be permitted.

Importation of fish species which may be unrecognized susceptible species or may be mechanical vectors

Importations of other live fish species may present a risk of introduction. The species might be capable of becoming subclinically infected (but not have been identified as a susceptible species). Also, the virus might be introduced mechanically either through contamination of the animals (e.g. gut content, skin, mucus), or in the transport water.

Subclinical infection

Evaluation of the evidence that the species could not become infected (clinically or subclinically) would be required before introduction of a species of fish not recognised as a susceptible species for EHNV. Experimental work to investigate the range of species

susceptibility was undertaken by Langdon (1989), who investigated a total of 14 species of fish, mainly Australian species.

Mechanical transmission

The potential for mechanical transmission of the virus via piscivorous birds has been demonstrated (Whittington et al., 1996). Any live aquatic animal imported from Australia might potentially act as mechanical vector for EHNV.

Assessment

The likelihood of EHNV introduction and establishment is assessed for the following theoretical consignment: importation of 30 live adult carp of mixed sex and sourced from a river catchment and where EHNV is endemic, and shipped directly to the United Kingdom for release into on-line still-water recreational fisheries.

A thorough literature review was used to collect the data needed to complete the risk assessment (e.g. biophysical properties of the virus, species susceptibility, mortality and morbidity, routes of spread, factors associated with disease outbreaks, mapping of waters in UK, water temperature, distribution of perch and rainbow trout populations, within Australia geographic distribution of the virus and susceptible species).

The scenario tree for the introduction of EHNV with the importation of carp was developed and identified 11 steps.

Entry assessment

1. Susceptible species (present in the source catchment) are infected with the hazard

In this case, the carp are sourced from a river where both susceptible species and the hazard are present. EHNV is known to persist within perch and rainbow trout populations. During the period between outbreaks the virus probably persists at a low prevalence. The likelihood that susceptible species are infected was estimated to be high.

2. Susceptible species shed the hazard

During outbreaks of EHN in perch, high levels of morbidity and mortality occur, resulting in a high numbers of virus particles being shed from clinically infected individuals. During the period between outbreaks the proportion of the population shedding virus is likely to be very low to negligible. Outbreaks in rainbow trout cause considerably lower morbidity and mortality. The likelihood of susceptible species shedding the hazard was estimated to be low.

3. Effective contact is made between the carp (potential vector) and the susceptible species

Effective contact results in transmission of the agent from the susceptible species to the potential vector species. Transmission will depend on the amount of virus shed, its survival and the physical proximity between the aquatic animal and the susceptible species. Perch are generally found in still water or slow-moving lower reaches of rivers, where carp will

also be found. Carp are benthic foragers and are likely to be exposed to EHNV in the environment. There are no experimental studies to support this contention; hence this step carries a high level of uncertainty. The likelihood of effective contact was estimated to be medium.

4. EHNV is present in carp selected for shipment

The likelihood that carp selected for shipment are contaminated by the hazard will depend on the prevalence or degree of contamination and the size of the consignment. There is a 95% probability of selecting at least one contaminated carp if 30 are randomly selected from a population where the prevalence is at least 10%. No data exist on which to estimate the prevalence of contamination; this step carries a high level of uncertainty. The likelihood of EHNV-contaminated animals being present in the consignment was estimated to be high.

5. EHNV survives transport

EHNV is robust and there is a high probability that the virus would survive transport to the United Kingdom. The likelihood of EHNV surviving transport was estimated to be high.

Exposure and establishment assessment

6. Imported carp/transport water released into the environment with the susceptible species

Perch are indigenous to the south-eastern part of the United Kingdom (Maitland and Campbell, 1992). Perch are not farmed in the United Kingdom and wild populations are self-sustaining. Perch are likely to be present in still-water fisheries into which the carp are introduced, and present in the river into which water from on-line fisheries flow. Rainbow trout are occasionally stocked in lakes with carp, and will be found in rivers where they have been stocked or escaped from fish farms. The likelihood that the susceptible species will be present was estimated to be high.

7. EHNV released from the carp/transport water into the environment

During transport, contaminated animals are likely to shed the virus, e.g. from the gut or skin, into the transport water. The amount of virus released into the environment will depend on whether the transport water is also deposited with the fish or disposed of safely. For the purposes of this example it is assumed that transport water enters the environment with the carp. The likelihood of EHNV is released to the environment was estimated to be high.

8. Susceptible species exposed to EHNV

Whether rainbow trout or perch are exposed to the virus depends on:

- the population density where the virus is released
- the amount of virus released
- the survival of the virus in the environment.

The fish population density will vary considerably, but will be moderately high in still-water fisheries where carp are most likely to be released. The amount of virus released is likely to be low, but the virus is known to survive well in the environment. The likelihood of susceptible species being exposed to EHNV was estimated to be high.

9. Susceptible species become infected

The susceptibility of rainbow trout and perch populations in the United Kingdom has not been tested. However, they are genetically related to the populations in Australia, and are therefore highly likely to be very susceptible. From experimental data, establishment requires exposure of perch when water temperatures are higher than 12°C, which on average in the south of the United Kingdom happens, in at least some parts of the river, for intervals of 18 consecutive weeks per year. The period will be shorter in other parts of the United Kingdom. Only a low level of challenge is likely from exposure to aquatic animals acting as mechanical vectors. However, perch can be infected by bath challenge with extremely low levels of infective EHNV. There is a high level of uncertainty associated with this step since no evidence exists on which to assess the level of virus introduced with a consignment of carp. The likelihood of susceptible species becoming infected was estimated to be low.

10. Susceptible species become infective

Infection in perch is highly likely to result in clinical disease, excretion of the virus and mortality. The likelihood of infected species being infectious was estimated to be high.

11. More than one individual becomes infected per case

For EHNV to establish, the basic reproductive ratio (R_0) must exceed 1. Perch are highly susceptible to low infectious doses of EHNV, and they frequently exhibit shoaling behaviour, favouring contact between individuals. The likelihood of $R_0>1$ was estimated to be high.

Risk estimation

The risk of mechanical introduction, exposure and establishment of EHNV via the introduction of a consignment of 30 carp (acting as mechanical vectors) was estimated to be very low, with a high level of uncertainty at three of the 11 steps.

Acknowledgement

Adapted from Peeler *et al.* (2009).

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