Veterinaria Italiana, **42** (4), 319-336

International trade and the spread of animal diseases: assessing the risks

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Summary

Decisions about managing animal and zoonotic disease risks associated with the international trade in animals and animal products are inevitably made in the face of varying degrees of uncertainty. The risk analysis framework of the Office International des Épizooties (OIE: World organisation for animal health) provides a structured approach that facilitates the identification, assessment, management and communication of these risks. By ensuring that an analysis is transparent and subjected to scientific review, stakeholders and trading partners can be assured that a reasonable level of objectivity is obtained, that the measures adopted are appropriate and that international obligations, outlined in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization, are fulfilled.

Keywords

Consequence assessment, Exposure assessment, Hazard identification, Release assessment, Risk analysis, Risk assessment, Risk communication, Risk estimation, Risk management.

Commercio internazionale e diffusione di malattie animali: valutazione dei rischi

Riassunto

Le decisioni relative alla gestione del rischio nelle malattie animali e delle zoonosi associate al commercio internazionale degli animali e loro prodotti sono state inevitabilmente prese tenendo presenti i vari livelli di incertezza. Il sistema di analisi del rischio dell'OIE (Office International des Épizooties, Organizzazione mondiale per la Sanità Animale) fornisce un approccio strutturato che facilita l'identificazione, la valutazione, la gestione e la comunicazione di questi rischi. Garantita la trasparenza di una analisi e la sua revisione scientifica, tutti i partners commerciali possono essere sicuri che si sia raggiunto un livello ragionevole di soggettività, che le misure adottate siano adeguate e che siano osservati gli accordi internazionali, delineati nell'Accordo sull'Applicazione delle Misure Sanitarie e Fitosanitarie (SPS Agreement) dell'Organizzazione Mondiale del Commercio (WTO).

Parole chiave

Analisi del rischio, Comunicazione del rischio, Gestione del rischio, Identificazione dei pericoli, Valutazione del rischio.

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Introduction

Significant diseases of animals have been and continue to be spread by the international movement of animals and animal products. Some highly infectious diseases capable of extremely rapid spread may lead to explosive outbreaks with devastating consequences. For example, a foot and mouth disease (FMD) outbreak in the United Kingdom (UK) in 1966-1967 was associated with the importation of sheep meat from Argentina (4), an outbreak of classical swine fever (CSF) (hog cholera) in the Netherlands in 1997 was considered to have arisen as a result of the transporting pigs in a lorry that had most likely been contaminated with CSF virus in Germany (1), an outbreak of FMD in the UK in 2001 was thought to be associated with meat or meat products containing or contaminated with FMD virus that was fed to pigs as unprocessed or inadequately processed waste food or the consumption of processed waste food contaminated with such material (5). Other diseases that exhibit a more insidious potential for spread may have become well established before being recognised. Such diseases include Johne's disease, which was introduced into Iceland from sheep imported from Europe in 1933 (11); the varroa bee mite which is likely to have been introduced into the north island of New Zealand sometime in the late 1990s from an unidentified source (10); bovine spongiform encephalopathy (BSE), which was initially spread from the UK through infected cattle and contaminated meat-and-bone meal (2, 3) and has been reported to varying degrees in indigenous cattle in approximately 24 countries (7).

Obviously countries want to prevent the incursion of various diseases and their associated impacts. Both historically and currently, many countries have attempted to achieve this by a policy of avoidance. Where a country has reported a disease, such as FMD or BSE, it may be effectively 'blacklisted'. In such circumstances, the importation of susceptible animals or products derived from them are banned even though internationally agreed and recognised standards, such as those detailed in the *Terrestrial animal health code* (*Code*) of the Office International des Épizooties (OIE: World organisation for animal health) (8), may exist to effectively mitigate against their spread. In other situations, rather than imposing an out-right ban, some countries may apply measures that are much more stringent than relevant international standards. For example, some countries require that specified risk materials be excluded from meat and meat products from cattle of all ages rather than applying the age limits recommended in the *Code* for BSE (9).

According to the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (13) member countries can justifiably employ measures to protect human, animal or plant life or health from diseases likely to be spread through international trade. However, this is not an unfettered right. Measures should not be applied unless it is likely that a disease may enter, establish or spread and lead to unacceptable biological and economic consequences. The basis for determining whether or not this sequence of events is likely for a particular commodity is through a risk assessment. For animals and animal products, the WTO recognises the *Code* as providing the appropriate risk assessment framework.

Rights and obligations for World Trade Organization member countries

While a country can quite reasonably be expected to apply measures to protect the health of its human or animal populations from disease risks

associated with international trade, certain obligations exist, at least for WTO members (6, 13). Measures, which include laws, decrees, regulations, testing protocols, inspection, certification and quarantine, should be based on international standards, guidelines and recommendations, where they exist. However, if there is a scientific justification that these texts do not achieve a level of protection deemed to be appropriate by a country, measures that provide a higher level of protection may be applied. In such circumstances it is important to ensure that measures are applied consistently. For example, it would not be consistent to require that salmon meat from North America be cooked due to concerns about viral haemorrhagic septicaemia while at the same time allowing the unrestricted importation of ornamental marine fish from the same region, given that salmonids and other marine fish are susceptible to this disease.

It is also important to ensure that measures do not constitute a disguised restriction on trade; that they are not applied arbitrarily; that they do not result in discrimination between countries where similar conditions exist; that they are based on scientific principles, in particular risk assessment techniques developed by relevant international organisations such as the OIE; that they be technically and economically feasible and, that they are only applied to the extent that is necessary to effectively manage a disease risk.

In certain situations, insufficient scientific evidence may preclude the completion of a risk assessment. While a measure may be provisionally adopted on the basis of available information, additional information should be sought within a reasonable period of time to allow for a more objective assessment. While the so-called *Precautionary principle* has not been written into the SPS Agreement, it finds reflection in Article 5.7. Its status in international law is the subject of debate and considered by some to be more an approach than a principle. Principle 15 of the Rio Declaration on Environment and Development (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'.

Nevertheless, the *Precautionary principle* does not override the requirements of the SPS Agreement that measures must be based on a risk assessment, which takes account of available scientific evidence (15).

Another important obligation relates to the concept of equivalence, which is the capability of different measures to achieve the same outcome. Provided a trading partner can objectively demonstrate that its measures achieve the same level of protection required by an importing country, the measures of the trading partner should be accepted as equivalent.

Whenever a country proposes to introduce a new measure or make changes to an existing measure, particularly where the measure is not substantially the same as an international standard, guideline or recommendation, it is required to notify the other member. Except in urgent circumstances, sufficient time should be allowed for comments to be taken into account, amendments to be introduced and exporters to adapt. Where circumstances are urgent, countries are still required to notify with a brief indication of the objective and the rationale for the measure, including the nature of the urgency, and allow other members to comment and take them into account.

Guidelines for assessing disease risk under the SPS Agreement

The SPS Agreement provides an overview of the basic requirements and factors to take into account when assessing disease risks associated with

international trade. Three steps are involved in a risk assessment (13, 14), as follows:

- identify those diseases that a country wants to prevent from entering, establishing or spreading together with their potential biological and economic consequences
- evaluate the likelihood of entry, establishment or spread and the biological and economic consequences of each disease without any measures being applied
- evaluate the likelihood of entry, establishment or spread of each disease according to the measures that might be applied.

When conducting the risk assessment, a number of factors as outlined in Figure 1 need to be considered. It is important to note that non-disease associated effects, such as the impact of an imported commodity on a domestic industry through increased competition or loss of revenue are not relevant.

Assessing disease risks under the risk analysis framework of the *Code*

Risk analysis provides a structured process designed to determine what can go wrong, how likely it would be for something to go wrong, how serious it would be if something went wrong and what can be done to reduce the likelihood and/or the seriousness of something going wrong. From an import perspective, it broadly consists of two components: the likelihood of an event occurring, such as a disease outbreak following the importation of a commodity; and the likelihood of serious consequences, which include the scale of an outbreak, costs of control and eradication and trade losses (6, 8).

- Available scientific evidence
- Relevant processes and production methods
- Relevant inspection, sampling and testing methods
- Prevalence of specific diseases
- Existence of disease-free areas and areas of low disease prevalence
- Existence of eradication or control programmes
- Relevant ecological and environmental conditions
- Quarantine or other treatment
- Potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a disease
- Costs of control or eradication
- Relative cost-effectiveness of alternative approaches to limiting risks

Figure 1
Factors to consider when conducting a risk assessment (6, 12)

An analysis of disease risks is not a recent development as regulatory veterinarians have generally undertaken some form of analysis prior to approving an importation. However, many have been a 'seat of the pants' or 'back of the envelope' approach without appropriate documentation.

Risk analysis is a tool that uses data, information and expert opinions from many disciplines, including pathology, microbiology, virology, epidemiology and economics (6). It needs to be able to deal with incomplete information, for example disease prevalence and the survival of viruses and bacteria when subjected to freezing, pH changes and cooking are often unknown. It is a blend of critical thinking, deductive reasoning and judgement that requires a good understanding of domestic quarantine law and the SPS Agreement. It requires a range of skills, including epidemiology, statistics, probability modelling and economics. Obviously, it is very unlikely that one person has all these skills, so ideally the analysis should be under-taken by a project team, which, depending on the circumstances, may be comprised of epidemiologists, government regulators, statisticians, mathematical modellers and economists. However, this is not possible in many countries, as limited resources are an inescapable reality, particularly for small countries. In these circumstances, it is worthwhile exploring opportunities for adapting existing risk analyses undertaken by other countries and/or

collaborating with countries that share common concerns.

The *Code* identifies four components for a risk analysis: hazard identification, risk assessment, risk management and risk communication (Fig. 2).

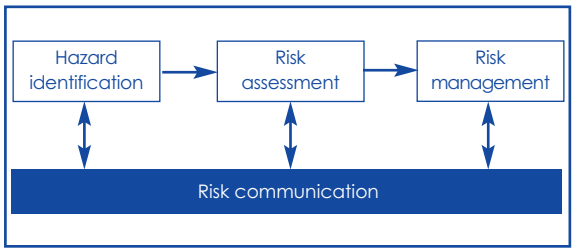

Figure 2
The four components of risk analysis as described in the *Code* (6, 8)

Hazard identification

Hazard identification is an essential step that should be conducted prior to a risk assessment. It involves identifying pathogenic agents associated with an imported commodity that could potentially produce adverse consequences. As defined in the *Code*, a commodity means animals, products of animal origin intended for human consumption, for animal feeding, for pharmaceutical or surgical use or for agricultural or industrial use, semen, embryos/ova, biological products and pathological material.

To classify an agent as a hazard, it must be appropriate to the species being imported, or from which the commodity is derived; it may be present in the exporting country; and, if present in the importing country, it must be subject to control or eradication or be notifiable, which means it is listed by the government authority responsible for animal health, such as a veterinary service, and that, as soon as it is detected or suspected, it is brought to the attention of that authority. When determining if the agent is likely to be present in the exporting country, an evaluation of the veterinary service, surveillance and control programmes and zoning and regionalisation systems are important inputs.

A risk analysis may be concluded if pathogenic agents that qualify as a hazard are not identified. In addition, if an importing country applies the appropriate measures recommended in the *Code*, there may be no need to conduct a full risk analysis, at least as far as international obligations are concerned.

Risk assessment

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

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

Risk management

Risk management is the process of deciding upon and implementing measures to achieve the level of protection considered to be appropriate by an importing country, while at the same time ensuring that negative effects on trade are minimised. The objective is to manage disease risks to the extent that is

necessary by ensuring a balance is achieved between the desire of a country to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import goods and fulfil its obligations under international trade agreements.

Risk communication

Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to decision-makers and stake-holders in both 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.

Practical application of the OIE risk analysis framework to assessing disease risks

In assessing the disease risks associated with international trade there are a number of important steps which must be worked through in a systematic manner (Fig. 3) (6, 8). Each of these will be discussed in turn.

Determining the scope of the risk analysis and stating its purpose clearly and concisely

Before undertaking a risk analysis, it is important to carefully define its scope. It is essential to have a clear understanding of its purpose from the outset. If the scope is defined inadequately, problems arise in interpreting and communicating the results. Consequently, this step requires that the animals or animal products, which are the subject of the analysis, be defined as precisely as possible by considering the nature, source(s) (including country) and intended use(s) of the animals or animal products, the scientific names of the animal species and pathogenic agents, the relevant methods of production, manufacturing, processing or testing that are normally applied, including quality assurance programmes such as the hazard analysis and critical control point (HACCP), and an estimate of the likely annual volume of trade.

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 import measures, ensuring consistency and resource constraints all influence which option is chosen. A risk analysis may be based on a particular

- Determine the scope of the risk analysis and state its purpose clearly and concisely
- Develop a risk communication strategy
- Identify hazard(s) likely to be associated with the commodity
- Conduct a risk assessment
  - Identify biological pathways leading to:
    - the commodity harbouring the hazard(s) at the time of importation
    - susceptible animals and/or humans being exposed to the hazard
    - potential outbreak scenarios
  - Estimate the likelihood of the hazard(s) being imported
  - Estimate the likelihood of susceptible animals or humans being exposed to the hazard(s)
  - Estimate the likelihood of significant biological, environmental or economic consequences arising
  - Decide whether sanitary measures can be justified
- Examine the available risk management options
- Formulate the necessary programme of measures
- Ensure that the risk analysis is transparent
- Consider submitting the analysis to peer review

Figure 3
Steps involved in assessing animal disease risks associated with international trade (6, 8)

commodity, a category of commodities, an animal species or group of similar species, or a particular disease or diseases that share common epidemiological characteristics. The analysis may apply to a particular exporting country (bilateral) or a trading block, such as the European Union (multilateral) or, in some cases it may not apply to any particular country, in which case it is referred to as a generic analysis.

Once the scope of the analysis has been decided, the purpose can be clearly and concisely defined according to the following format:

- 'To assess the likelihood of the hazard(s) spreading or becoming established in (your country) and the likelihood of potential consequences for animal or human health as a result of importing the animals or animal products from the exporting country'
- 'To recommend sanitary measures, if appropriate'.

An example (hypothetical) might be: 'to assess the likelihood of the porcine reproductive and respiratory syndrome (PRRS) virus (Order *Nidovirales* Family *Ateriviridae* Genus *Aterivirus*) spreading or becoming established in New Zealand and its likely consequences as a result of importing chilled or frozen meat derived from domestic pigs (*Sus scrofa domestica*) for human consumption from the United States of America'.

Developing a risk communication strategy

The best outcome of a risk analysis process is one that not only reduces a risk to an acceptable level but minimises disputes and disagreements as well as the measures required to effectively manage risk. Effective risk communication may not resolve all the differences with various stakeholders but may lead to a better understanding of the rationale for a particular decision.

In many countries, there are great expectations from various stakeholder groups (whose interests may be affected by the decisions arising from a risk analysis) that they will be provided with an opportunity for consultation before decisions are made. Members of stakeholder groups now have high levels of education and easier access to an enormous variety and quantity 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 commencement of a risk analysis to ensure that stakeholders are provided with an opportunity to provide comment.

The process of risk communication begins with identifying stakeholders who include the general public; livestock producers, domestic and foreign industry groups, consumer organisations, risk assessors, risk managers, decision-makers, authorities in the exporting country, the SPS committee, the media and academic and scientific institutions. The next step is to determine when to communicate with stakeholders and the most appropriate means. Communication should continue throughout the analysis and be open, interactive, iterative, transparent and timely. It involves an exchange of information and opinions regarding hazards and risks, the results and conclusions of a risk analysis and the proposed measures.

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

Identifying hazards likely to be associated with the commodity

Hazard identification begins with drawing up a list of the pathogens associated with the species from which the commodity is derived. A good place to start is with the OIE listed diseases (www.oie.int). Others can be added as appropriate from various sources of information including: the International Society for Infectious Diseases Promed-mail web site (www.isid.org), the government authority responsible for animal health in the exporting country or in other countries with whom the exporting country trades, text books and scientific literature. Once the list has been developed, the steps outlined in Figure 4 should be worked through to determine if the pathogen can be classified as a hazard. To ensure transparency, the rationale supporting the conclusions reached should be adequately documented.

At this stage, it is worth checking whether the *Code* provides measures for the particular hazard in the commodity under consideration. If it does, a decision may be made to apply these measures. If this is the case, there is no need to conduct a risk assessment, at least as far as international obligations are concerned. If measures are not prescribed in the *Code*, a risk assessment needs to be undertaken.

Conducting a risk assessment

As discussed earlier, the risk assessment process consists of four interrelated steps: release assessment; exposure assessment; consequence assessment; and risk estimation. It begins with identifying the various biological pathways leading to the imported commodity being infected or contaminated with the hazard(s) when imported in the form that it is intended to be used, processed or sold; susceptible animals and/or humans being exposed to the hazard(s); and potential 'outbreak' scenarios. There are a number of important factors that should be considered (Figs 5, 6 and 7). In addition, scenario trees provide a useful conceptual framework to assist in identifying and describing biological pathways (Fig. 8). Figures 9, 10 and 11 provide examples of a series of scenario trees used to describe the biological pathways necessary for chilled or frozen pig meat to become contaminated with PRRS virus in an exporting country and lead to domestic pigs being exposed to the virus in the importing country, as a result of discarded scraps being fed as swill.

- Determine whether the animals or animal products are a potential vehicle for the pathogen
- Determine whether the pathogen is considered to be exotic to your country
  - If it is not known whether the pathogen is present in your country, proceed as if it were not present and conduct surveillance to ascertain its presence or absence
  - If the pathogen is present, it should not be considered, unless it is notifiable, subject to an official control programme, or the local strains have been shown to be less virulent than those reported in the exporting country
- Determine whether the pathogen is likely to be present in the exporting country
  - Do you have sufficient confidence in the capacity and capability of the government authority responsible for animal health in the exporting country?
  - Are there any geographic areas of different animal health status?
  - Is the government authority responsible for animal health able to satisfactorily substantiate any claims regarding disease status?
  - In the case of inadequate information on the presence or absence of a pathogen:
    – contact the government authority responsible for animal health to seek additional information or clarification
    – continue the analysis, taking into account this area of uncertainty and assess its overall importance

Figure 4
Steps to determine if a pathogen is a hazard (6, 8)

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

Country factors
- Evaluation of the government authority responsible for animal health in the exporting country, 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
- Geographic 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 5
Factors to consider when conducting a release assessment (6, 8)

Biological factors
- Means of exposure to, and transmission of the hazard
  - Horizontal exposure and transmission
  – direct (animal to animal contact, airborne spread, ingestion, coitus)
  – indirect (mechanical and biological vectors, intermediate hosts, iatrogenic exposure and transmission, fomites)
  - Vertical exposure and transmission
- Stability, infectivity and virulence of the hazard
- Route of exposure and infection (oral, respiratory, percutaneous, etc.)
- 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 6
Factors to consider when conducting an exposure assessment (6, 8)

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

Note
The consequences may be estimated at four levels; farm/village, district, regional and national. In a qualitative risk assessment, the impact at each level can be described in terms such as 'insignificant', 'of minor significance', 'significant' or 'severe'. When considering the consequences of a disease outbreak, consideration may need to be given to the persistence of its effects

Figure 7
Factors to consider when conducting a consequence assessment (6, 8)

The next step is to estimate the likelihood of the commodity introducing the hazard(s) into the importing country (release assessment); the likelihood of susceptible animals and/or humans being exposed (exposure assessment) to these hazards; and the likelihood of significant biological, environmental or economic consequences arising (consequence assessment). To ensure transparency, it is important to document the relevant factors that that were considered. Ideally, each hazard should be dealt with separately with a reasoned, logical and referenced discussion that supports the likelihood estimates. It is important to note that the risk assessment may be considered as being complete at this point if it is determined that there is a negligible likelihood of the commodity being infected or contaminated with the hazard(s) when it is imported; or of susceptible animals and/or humans being exposed to the hazard(s); or of significant consequences arising.

When undertaking a consequence assessment in the context of assessing animal disease risks, non-disease associated effects (such as the impact of competition from cheaper imported goods on a particular industry) should not be considered. According to the SPS Agreement (13) the economic factors that can be legitimately included are those associated with damage in terms of loss of production or sales in the event of the entry, establishment or spread of a disease, costs of control or eradication and the relative cost-effectiveness of alternative approaches tolimiting risks. In addition, there must be a causal relationship between exposure to a hazard and an adverse effect.

To assist in evaluating the likelihood of significant, biological, environmental or economic consequences arising, it may be useful to 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 their consequences. For example, in the case of imported live animals, outbreak scenarios might include the following:

- disease does not establish within the exposed population

Whether planning a qualitative or quantitative risk assessment, a graphic depiction of the biological pathways provides a useful conceptual framework. It assists in conveying the range and types of pathways considered in a simple, transparent and meaningful fashion for qualitative assessments. In addition, it is an essential step if a quantitative model is to be developed. Scenario trees are an appropriate and effective way of depicting biological pathways. They provide a useful mind map or visual representation to:

- Identify pathways and variables
- Identify information requirements
- Ensure a logical chain of events in space and time
- Provide a framework for the development of a mathematical model
- Ensure the appropriate estimate is determined
- Assist with communicating the model structure
- Clarify ideas and understanding of the problem

A scenario tree starts with an initial event, for example selecting some animals from a herd which is potentially infected. It then outlines the various pathways that lead to different outcomes, such as accepting animals that are test negative or the outbreak of a disease. By convention, events are described in boxes, while the likelihood or probability of an event is described by a line or arrow emanating from the respective box

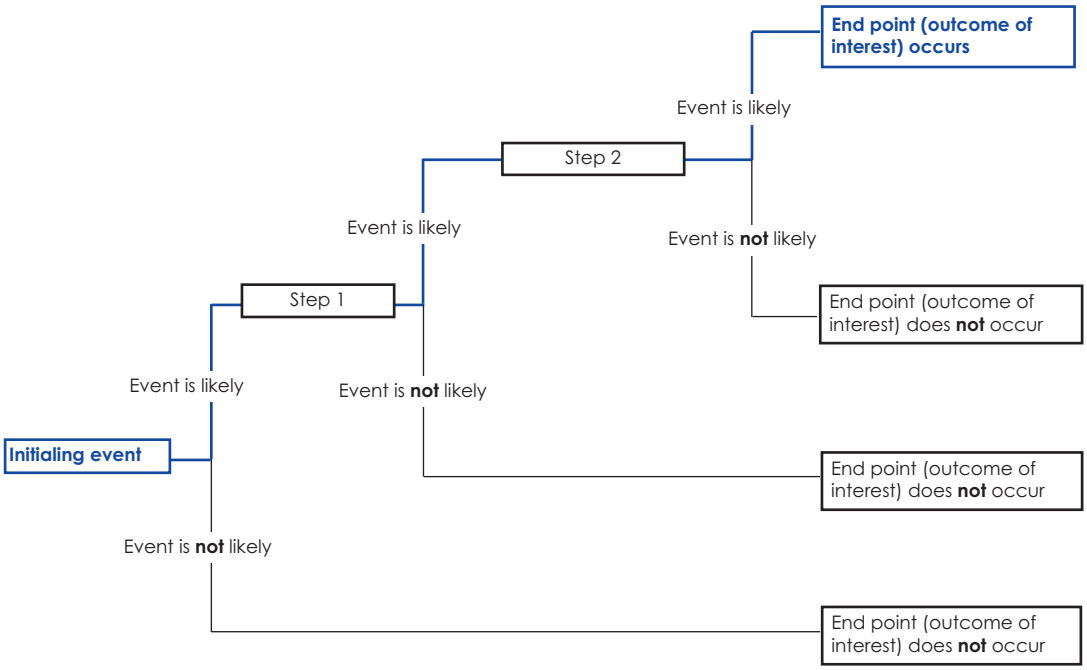

Figure 8
Description of a scenario tree (6)

- 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.

Deciding whether sanitary measures are justified

Each hazard should be dealt with individually, summarising the results and/or conclusions arising from the release, exposure and consequence assessments to estimate the likelihood of the hazard entering the importing country, becoming established or spreading and resulting in adverse consequences. It is not sufficient to conclude that there is a possibility

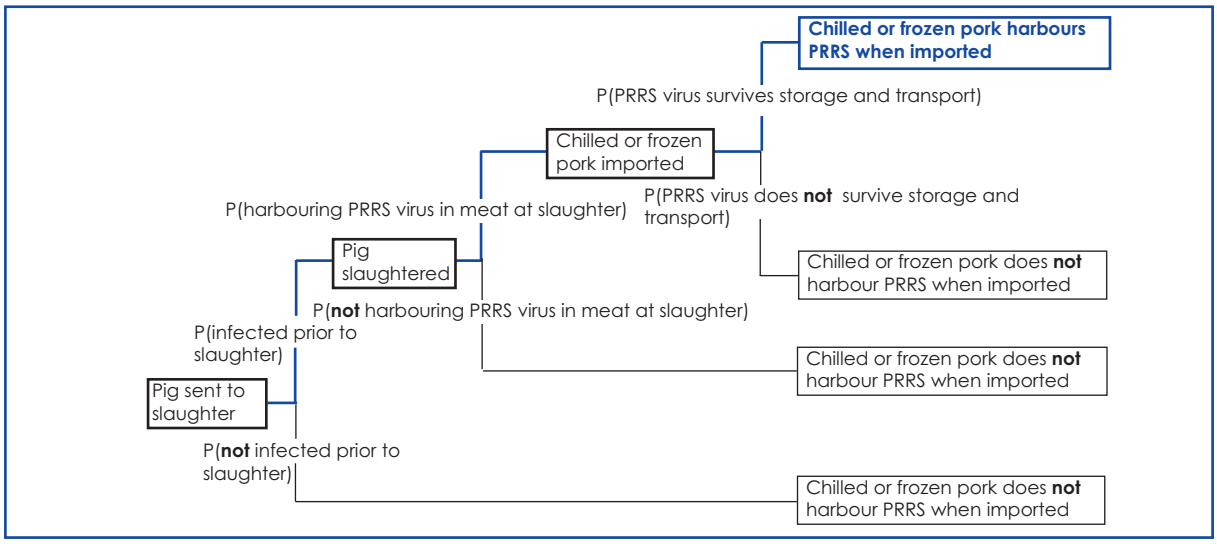

Figure 9
A scenario tree for a release assessment outlining the biological pathways necessary for chilled or frozen pig meat in an exporting country to become contaminated with porcine reproductive and respiratory syndrome (PRRS) virus

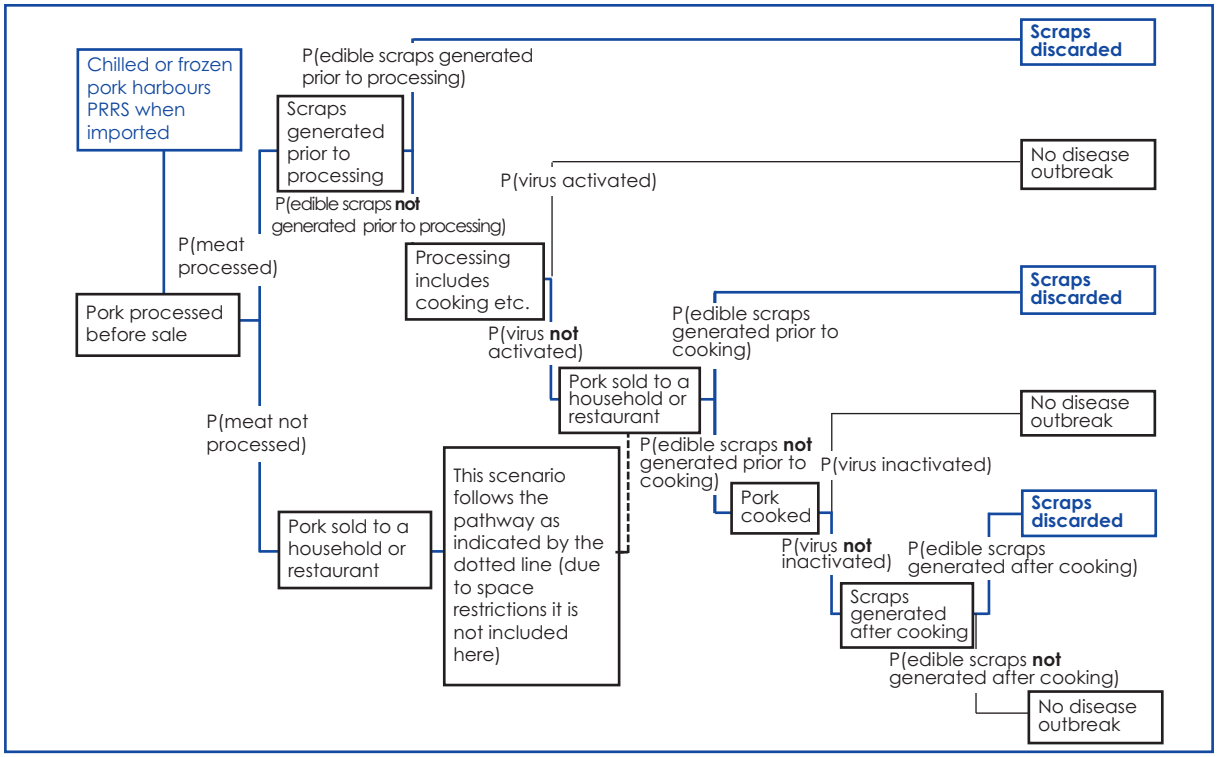

Figure 10
A scenario tree for an exposure assessment outlining the biological pathways leading to infected scraps being discarded as a result of importing chilled or frozen pig meat for human consumption
This could lead to a disease outbreak (Fig. 11)

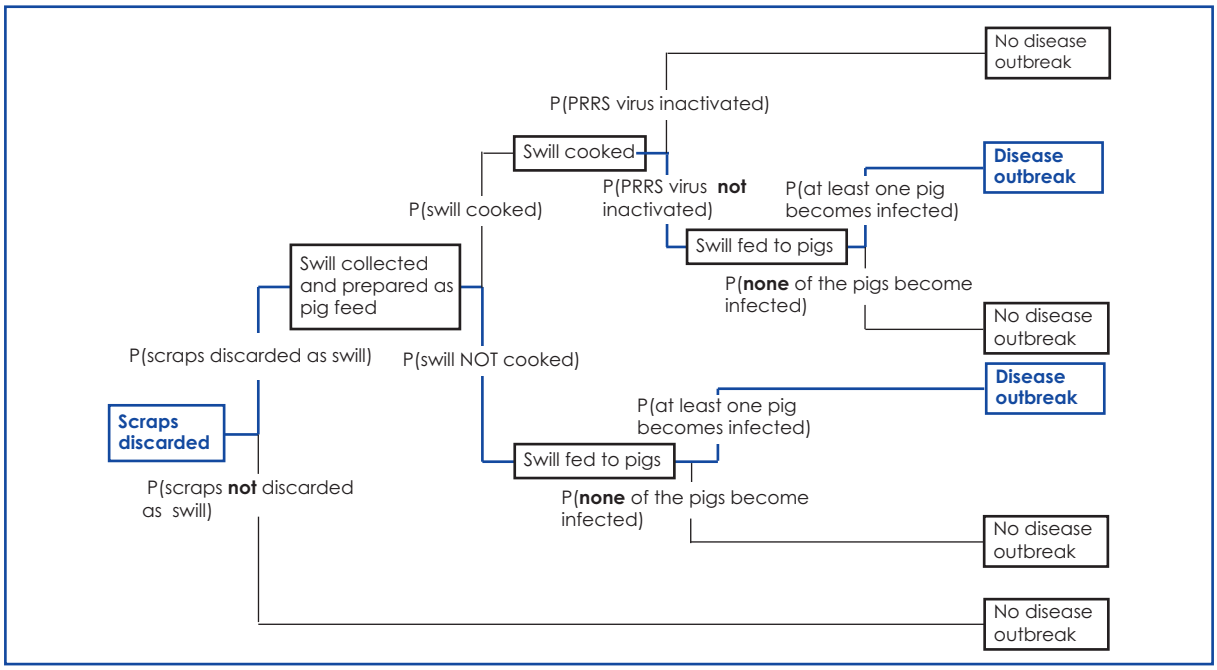

Figure 11
A scenario tree for an exposure assessment outlining the biological pathways necessary for domestic pigs to be exposed to porcine reproductive and respiratory syndrome (PRRS) virus as a result of the introduction of infected scraps and swill feeding

of entry, establishment or spread or that there may be consequences. An evaluation of the likelihood of each of these factors must be undertaken. The decision steps outlined in Figure 12 can be followed to ensure the risk estimate is transparent. If the risk is not estimated to be negligible, the application of measures may be justified.

Examining the available risk management options

Risk management is the process of deciding upon and implementing measures to reduce or eliminate the likelihood of introducing the hazard(s), exposing susceptible animals and/or humans or of significant consequences arising. Each hazard should be dealt

Release assessment (likelihood of entry)
- Is the likelihood that the commodity is carrying the hazard when it is imported negligible?
  - If the answer is YES, the risk estimate is classified as negligible
  - If the answer is NO, then conduct an exposure assessment

Exposure assessment (likelihood of susceptible animals and/or humans becoming exposed)
- Is the likelihood of susceptible animals and/or humans being exposed via any of the exposure pathways negligible?
  - If the answer is YES, the risk estimate is classified as negligible
  - If the answer is NO, then conduct a consequence assessment

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

Figure 12
Risk estimation decision steps (6, 8)

with separately using the guidelines outlined in Figure 13. It is important to note that it is not acceptable to just 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).

Ensuring that the risk analysis is transparent

Transparency is an essential component of any risk analysis. It involves comprehensive documentation of all the data, information, assumptions, uncertainties, references, methods, results and conclusions. Each conclusion should be supported by a reasoned and logical discussion. Transparency facilitates the understanding of a risk analysis as well as consistency in decision-making. It ensures that uncertainties are dealt with appropriately; that the reasons for the conclusions and recommendations are obvious and that interested parties are provided with clear reasons for the imposition of measures or refusal to import.

Submitting the risk analysis to scientific review

Scientific review, also referred to as peer review, is a fundamental component of a risk analysis. It ensures that the analysis is based on the most up-to-date data, information and methods available and that the assumptions are appropriate. It also ensures that the risk analyst has achieved a reasonable level of objectivity and that the analysis will stand up to scrutiny by stakeholders opposed to importation or in favour of unrestricted importation, as well as potential challenge within the WTO dispute settlement system. Ideally, each analysis should be submitted to a review process involving recognised and relevant experts. At the very least, it should be reviewed by staff within the government authority responsible for animal health and, where appropriate, public health. Consideration should also be given to submitting the analysis to selected experts with specialised knowledge in risk analysis and of the diseases under consideration. Since peer review may involve a significant time commitment,

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

Option evaluation
- Identify possible options, including the sanitary measures of the *Code*, where they are available
  - To assist in identifying appropriate option(s), it is worthwhile formulating an objective which states what these option(s) should aim to achieve in order to effectively manage the risks
- Evaluate the likelihood of the release, exposure, establishment or spread of the hazard according to the option(s) that might be applied
- The following guidelines should be taken into account when selecting option(s):
  - ensure that the option(s) are based on scientific principles
  - ensure that the measures of the *Code* are considered where they exist
    - If there is a scientific justification that the *Code* measure(s) do not effectively manage the risks, measures that result in a higher level of protection may be applied. Alternatively, measures less stringent than those recommended in the *Code* may be applied where there is sufficient justification that the risks can be effectively managed using such measures
  - ensure that the option(s) are applied only to the extent necessary to protect human or animal life or health
  - ensure that negative trade effects are minimised
  - ensure that the option(s) are not applied arbitrarily
  - ensure that the option(s) do not result in discrimination between exporting countries where similar conditions exist
  - ensure that the option(s) are feasible by considering the technical, operational and economic factors that might affect their implementation

Figure 13
Guidelines for risk management (6, 8, 12)

particularly for large and/or complex analyses, it is reasonable to expect to pay for the time experts spend. In addition, terms of reference such as those examples outlined in Figure 14 should be provided so that reviewers have a clear idea of what is expected of them.

Choosing between a qualitative or quantitative approach when assessing disease risks

No single method of risk assessment has proven applicable in all situations and different methods may be appropriate in different circumstances. Risks can be evaluated by both qualitative and quantitative methods. A qualitative assessment is essentially a reasoned and logical discussion of the relevant commodity factors and epidemiology of a hazard where 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 suitable for the majority of risk assessments and is, in fact, the most common type of assessment undertaken to support routine decision-making (6).

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, to assess the impact of uncertainty or to compare measures. Quantification involves developing a mathematical model to link various aspects of the epidemiology of a disease, which are expressed numerically. It is a specialised discipline that, at the very least, requires a computer, spreadsheet and risk analysis software, mathematical modelling skills and training. The results, which are also expressed numerically, invariably present significant challenges in interpretation and communication. For example, if a risk is assessed as one disease outbreak per 50 000 000 kg of commodity imported, it might be considered that this is an extremely small risk. However, if 10 million kg are imported each year and the risk is re-expressed as one outbreak per five importation years, then it might seem to be rather high, particularly if dealing with a disease like FMD (6). Regardless of whether a qualitative or quantitative assessment is conducted, it is important to appreciate

- 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 measures be easily followed?
- Does the document make clear what are data and what are assumptions?
- Has the literature been cited accurately? Have any important publications been overlooked?
- Are the references cited appropriate? That is, are the critical epidemiological observations based on secondary sources where it would have been preferable to consult primary sources?
- 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?
  - Would every iteration of the model give a biologically plausible output?
  - Is the structure of the model appropriate?
  - Are the data used appropriate?
  - Is the model mathematically sound and are the formulae used appropriate?
  - Are the distributions used appropriate for the data or information being modelled?
  - Are there any data or information that have been overlooked but which might be appropriate in the quantitative assessment?

Figure 14
Some example terms of reference for undertaking scientific (peer) review (6)

that a risk assessment inevitably includes a degree of subjectivity. For qualitative assessments, sources of subjectivity include the personal perceptions of risk analysts, experts and decision-makers. Although a quantitative assessment involves numbers, it is not necessarily more 'objective', nor are the results necessarily more 'precise' than a qualitative assessment. 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 chosen to represent each variable all involve a degree of subjectivity. In addition, because data are lacking, some models incorporate expert opinion, which by its very nature is subjective (6).

Since both types of assessment are inevitably subjective, how can a reasonable level of objectivity be attained? The solution lies not in the method chosen, but in ensuring that the assessment is transparent; that it is based on the best available scientific information, and that it has been subject to a rigorous peer review process (6).

Dealing with incomplete information

Decisions about managing animal disease risks are inevitably made in the face of varying degrees of uncertainty, which reflects a lack of complete knowledge or information. Sources of uncertainty include a lack of understanding of various aspects of the epidemiology of a disease, estimates of disease prevalence and the survival of viruses and bacteria when subjected to freezing, pH changes or cooking. Risk analysis provides a structured approach that enables uncertainties to be acknowledged appropriately and placed in perspective. It can assist in determining the potential impact of various uncertainties on the outcome. For example, suppose a risk assessment is being undertaken to estimate the likelihood of an outbreak of 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' and, finally a susceptible animal ingesting discarded cheese in 'Country A', becoming infected and transmitting the virus to other animals (6).

There may be some very good information on the survival of FMD virus in pasteurised milk, some limited information on the occurrence of FMD in 'Country B' and virtually no information on the likelihood of susceptible animals ingesting cheese scraps in 'Country A'. A prediction in these circumstances will be based on information ranging from poor to excellent. As a result, it may be concluded that there is significant uncertainty in the estimates of the occurrence of FMD in 'Country B' and the exposure of susceptible animals in 'Country A'. The impact of these uncertainties on the overall risk estimate needs to be carefully considered. For instance, the impact is likely to be insignificant if pasteurisation is predicted to effectively kill FMD virus. On the other hand, if pasteurisation cannot be relied upon because of heat tolerant strains, the impact of these uncertainties becomes much more important (6).

Where there is significant uncertainty in the risk estimate, a precautionary approach to managing risk may be adopted. However, the measures selected must nevertheless be based on a risk assessment that takes into account the available scientific information. In these circumstances, the measures should be reviewed as soon as additional information becomes available and be consistent with other measures where equivalent uncertainties exist. 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 apparent (6).

Guiding principles

There are a number of important guiding principles to consider when conducting a risk assessment (6), in particular:

- a risk analysis should be based on the best available scientific information
- risk should be expressed in terms of likelihood or probability either qualitatively or quantitatively, not as a possibility
- although there is inevitably a degree of uncertainty, hypothetical (theoretical) risks should not be considered
- simply identifying a range of measures that might reduce the risks is not acceptable; an evaluation of the likelihood of entry, establishment or spread of a disease according to the measures which might be applied should be undertaken
- there must be a rational relationship between the proposed measure and the risk assessment so that the results of the risk assessment support the measure
- each measure must be evaluated either singly or in combination to determine its relative effectiveness in reducing the overall disease risk
- while each disease should be considered separately, some of the elements of a risk assessment related to one disease might be used as part of the assessment for another disease, so that disease-by-disease assessments may overlap
- as soon as there is a specific assessment for one disease of concern, on which a measure as a whole can be based, there might be no further need to assess the risks related to the other diseases of concern
- a risk analysis should only consider disease associated effects. Non-disease associated effects should not be considered, for example, the impact of an imported commodity on domestic industries through increased competition or loss of revenue
- the assessment should be transparent so that countries are provided with clear reasons for the imposition of import conditions or refusal to import.

Conclusions

Decisions on the management of animal and zoonotic disease risks associated with inter-national trade are obviously made in the face of varying degrees of uncertainty. Risk analysis provides a structured approach that facilitates the identification, assessment, management and communication of these risks. By ensuring that it is transparent and subjected to peer review, stakeholders and trading partners can be assured that a reasonable level of objectivity is obtained and that the sanitary measures adopted are appropriate.

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