Managing Disease Risks Associated With Trade

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ABSTRACT

The importation of animals and animal products involves a degree of disease risk to the importing country. This has been highlighted by the pandemic of white spot disease of shrimp and very recently by the outbreak of disease in koi carp and common carp in Indonesia, suspected to have resulted from imports of live animals. Because of the serious impacts of infectious diseases, particularly in farmed aquatic animals, the process of import risk analyses (IRA) to prevent the entry and spread of unwanted pathogens is assuming increasing importance. The principal aim of IRA is to provide importing countries with an objective and defensible method to assess the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material. It forces a thorough and logical approach to be adopted in considering the likelihood of undesirable events, and identifies gaps in our current knowledge. In undertaking an import risk analysis, a country must be guided by the International Aquatic Animal Health Code (Code) of the Office International des Epizooties (OIE). The OIE Code provides guidelines for national authorities to assist them in addressing the principles laid out in the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures. Facilitating trade while at the same time managing the associated disease risks is a challenge for all those associated with aquatic animal health. The coming years are likely to see an increasing need for skills and experience in this very important area.

INTRODUCTION

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

This has been highlighted by the pandemic of white spot disease of shrimp and very recently by the outbreak of disease in koi carp and common carp in Indonesia, suspected to have resulted from imports of live animals. Because of the serious impacts of infectious diseases, particularly in farmed aquatic animals, the process of import risk analyses (IRA) to prevent the entry and spread of unwanted pathogens is assuming increasing importance.

IRA is based on scientific principles and practices, providing an objective, transparent and defensible method of assessing disease risks associated with imports. It forces a thorough and logical approach to be adopted in considering the likelihood and consequences of undesirable events, and identifies gaps in our current knowledge. The analysis should be transparent. This is necessary so that the exporting country is provided with clear reasons for the imposition of import conditions or refusal to import. Transparency is also essential

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because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

IRA should be flexible enough to deal with the complexity of real life situations. The methods used must be able to accommodate the variety of animal commodities, the multiple hazards that may be identified with an importation and the specificity of each disease, detection and surveillance systems, exposure scenarios and types and amounts of data and information available. As countries place increasing emphasis on IRA, there will be a concomitant increase in the need for more reliable surveillance information in both exporting and importing countries.

Facilitating trade while at the same time managing the associated disease risks is a challenge for all those associated with aquatic animal health. The coming years are likely to see an increasing need for skills and experience in this very important area. This paper briefly describes the process of import risk analysis and highlights the increasing importance of disease surveillance.

IMPORT RISK ANALYSIS IS A FORMAL PROCESS

Countries who are members of the WTO are obliged to abide by the various international multilateral agreements including the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the so-called *SPS Agreement*) (WTO, 1994). The *SPS Agreement* recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines and recommendations affecting trade in live animals and animal products including genetic material and pathological specimens. The OIE *International Aquatic Animal Health Code* (OIE, 2003) provides guidelines for national authorities to assist them in addressing the principles laid out in the WTO's *SPS Agreement.* To this end, Section 1.4 of the OIE *Code* provides a framework for analysing the risks of international transfer of disease with trade. Under the *Code*, risk analysis has four major components: hazard identification; risk assessment; risk management; and risk communication. Risk assessment is further divided into four steps: release assessment; exposure assessment; consequence assessment; and risk estimation. The broad relationships among the components and steps are shown in Fig. 1 below.

Thus, IRA is the process of identifying the pests and diseases (*the hazards*) relevant to an import proposal, assessing the risks (*risk assessment*) posed by them and, if those risks are initially unacceptable (*the unrestricted risk estimate*), determining what measures (*risk management*) can reduce the risks to an acceptable level (*the restricted risk estimate*). Such measures may include processing, testing, treatment and quarantine. Where available measures cannot reduce the risks to an acceptable level, imports should not be permitted. During this process, communication with all stakeholders in the importing and exporting countries needs to be maintained.

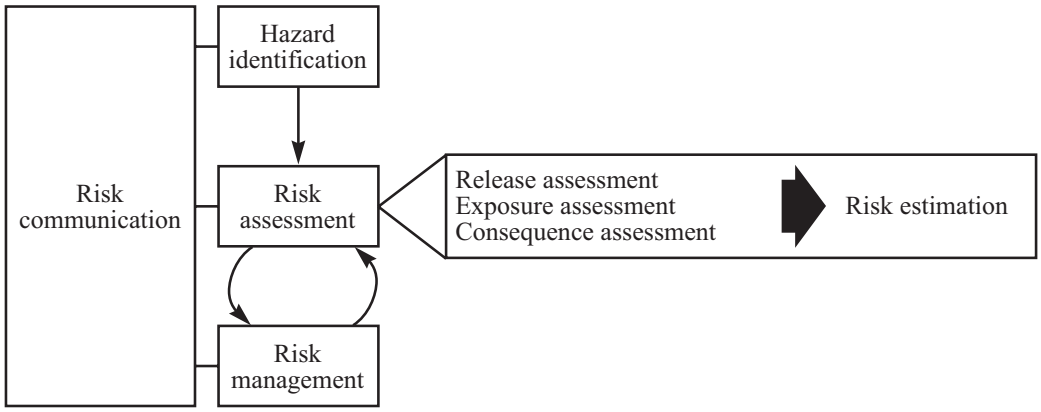

Figure 1. Four IRA components and four risk assessment steps.

HAZARD IDENTIFICATION

Hazard identification leads to a list of the potentially important pathogens to be considered in the risk assessment. Hazard identification is a categorisation step, identifying pathogens dichotomously as potential hazards or not. This step can be reported using a single table, with column headings representing the classification criteria used to decide if a particular agent is a hazard or not. An example is shown in Table 1.

Table 1. Example of how potential hazards might be summarised.

Pathogen	Susceptible species	Exporting country		Importing country		Potential hazard	
		Occurrence	Control measures	Occurrence	Control measures	Yes/No	Reasons

Information on pathogen virulence and transmission routes, host ranges, the evaluation of relevant animal health services, surveillance and control programs and zoning systems are important inputs for assessing the likelihood of hazards being present in aquatic animal populations of the exporting country.

The risk analysis may be concluded if any of the following apply:

- no potential hazards are identified associated with the importation;
- potential hazards are identified which are disease agents listed in the *Code* and the importing country decides to permit the importation using the risk management measures recommended in the *Code*;
- potential hazards are identified, but, because they are not disease agents listed in the *Code*, the importing country decides not to apply risk management measures.

RISK ASSESSMENT

The risk associated with each identified hazard is evaluated in the risk assessment stage, where the risk combines the likelihood of occurrence and the magnitude of the consequences.

A risk assessment may be qualitative (described in words) or quantitative (a numerical value) or a combination of both. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances. Qualitative methods use verbal descriptions while quantitative methods use mathematical terms to describe likelihoods and consequences. Qualitative and quantitative descriptions used to describe the likelihood (probability or chance) of an event occurring are compared in Table 2. A likelihood of 0.000001 shown in the table is a one in one million chance.

Table 2. Comparison of qualitative and quantitative descriptions of likelihoods.

Likelihood statement	**Qualitative description**	**Quantitative range**
Very high	Event would be expected to occur	0.7 - 1
High	Likelihood of event occurring is approximately even	0.3 - 0.7
Moderate	Event is unlikely to occur	0.05 - 0.3
Low	Event would occur rarely	0.001 - 0.05
Very low	Event extremely unlikely to occur	0.000001 - 0.001
Negligible	Likelihood of event occurring is so small that it can be ignored in practical terms	0 - 0.000001

Table 3. A method to combine qualitative likelihood estimates.

		Likelihood 1					
		Very high likelihood	High	Moderate	Low	Very low	Negligible likelihood
Likelihood 2	Very high likelihood	Very high	High	Moderate	Low	Very low	Negligible
	High		Moderate	Moderate	Low	Very low	Negligible
	Moderate			Low	Low	Very low	Negligible
	Low				Very low	Very low	Negligible
	Very low					Negligible	Negligible
	Negligible likelihood						Negligible

Table 3 shows how qualitative likelihoods can be combined (adapted from Wilson and Beckett, 2001). For example, if the likelihood of release of a hazard is **high** and the likelihood of exposure is **low**, then, by reading from the table above, the combined likelihood of release and exposure would be **low**.

The choice of a qualitative or quantitative method will depend on the nature of the hazard, the availability of data and the preference of the risk analyst. In either case, the risk assessment should be based on the best available information that is in accord with current scientific thinking. The assessment should be well documented and supported with references to the scientific literature and other sources, including expert opinion. Consistency in application of risk assessment methods and transparency are essential in order to ensure fairness and rationality, uniformity in decision-making and ease of understanding by all the interested parties. Risk estimates should document the uncertainties, the assumptions made, and the effect of these on the final estimate.

The four sequential steps in the risk assessment describe the events necessary for the identified potential risk(s) to occur, and facilitate understanding and evaluation of the outputs. The product is the risk assessment report, which is used in risk communication and risk management. The first three steps of the risk assessment leading to risk estimation are illustrated in Fig. 2. Pathways of entry into the importing country and exposure of susceptible animals are developed in the release and exposure assessments respectively, while outbreak scenarios are frequently used to assist in estimating the consequences.

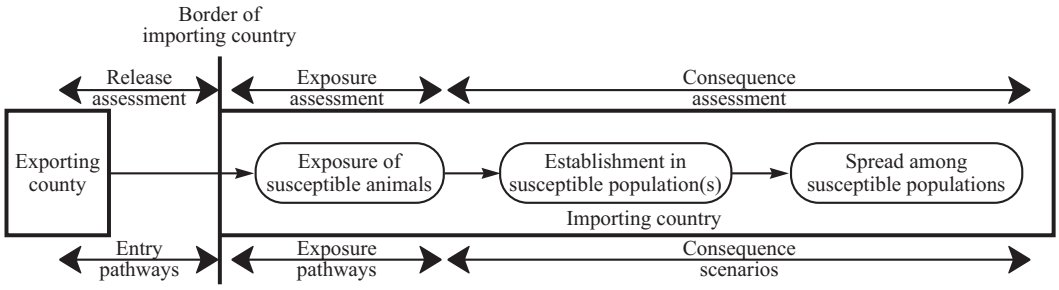

Figure 2. The three steps or risk assessment leading to the final step of risk estimation.

Diagrams can be used to show the different paths that may lead to a pathogen being transported from one country to another and leading to exposure of susceptible animals. Fig. 3 provides an example. Two further points need to be made on likelihood estimation. First, it is important to appreciate that when estimating likelihoods, the time period of interest must be stated. In the case of IRA, the period is usually one year which accommodates seasonal variations but does not require long range forecasts of such things as changes in trading practices, production factors and disease epidemiology. Second, since the likelihood of release of (introduction) and exposure to a hazard increases with increasing volume of the commodity imported, the risk assessment should be amenable to updating when additional information becomes available. Both of these points need to be addressed in the risk assessment and combined, they represent the trade intensity.

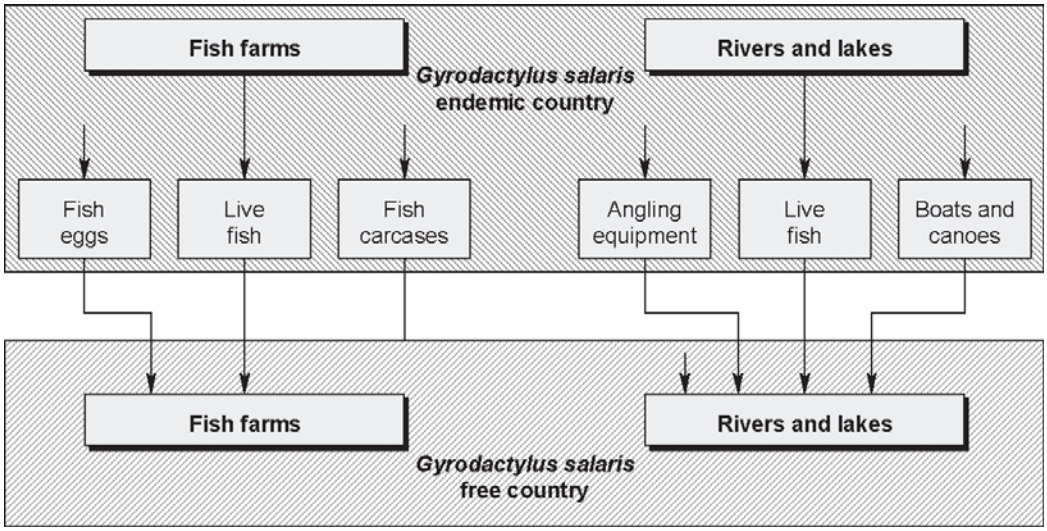

Figure 3. Possible paths for *Gyrodactylus salaris* to move from an endemically infected country to a free country (release) and cause infection in susceptible animals (exposure).

If the release and/or exposure assessments demonstrate a negligible likelihood, then the risk assessment can usually be concluded at this stage.

Consequence assessment consists of describing the relationship between specified exposures to a biological agent (hazard) 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 potential consequences of a given exposure, establishment and spread of a disease agent and estimates the probability of them occurring. Again, this estimate may be either qualitative or quantitative. Outbreak scenarios may be used to illustrate the range of possible consequences that could be experienced in the importing country and to provide quantitative biological data for economic analyses where these are considered necessary.

Examples of consequences include:

- production losses from disease
- public health effects
- surveillance and control costs
- compensation costs
- potential trade losses
- adverse impacts on the environment.

An example of how different levels of impact of consequences might be described is shown below. A particular country may wish to define the different levels of significance of consequences in a totally different manner. However, it is important for any particular IRA to define the terms used and also to be consistent with other IRAs undertaken for similar commodities and hazards.

- A **very high** (also called **catastrophic or extreme**) impact is associated with the establishment of diseases that would be expected to significantly harm economic performance at a national level, or cause serious, irreversible harm to the environment.

- A **high** impact is associated with the establishment of diseases that would have serious biological consequences (e.g., high mortality or high morbidity and significant pathological changes in affected animals) over a prolonged period and are not amenable to control or eradication. Such diseases would be expected to significantly harm economic performance at an industry or national level. Alternatively or in addition, they may cause serious harm to the environment.
- A **moderate** impact is associated with the establishment of diseases that either have less pronounced biological consequences or would harm economic performance significantly at an enterprise/regional level. Such diseases would not be expected to significantly harm economic performance at the industry/national level. These diseases may be amenable to control or eradication, at a significant cost or their effects may be temporary. They may affect the environment, but such effects would not be serious or may be reversible.
- A **low** impact is associated with the establishment of diseases that have mild biological consequences and would normally be amenable to control or eradication. Such diseases would be expected to affect economic performance at the enterprise/regional level but to have only minor significance at the industry or national level. Effects on the environment would be minor or, if more pronounced, would be temporary.
- A **very low** impact is associated with the establishment of diseases that have very mild biological consequences and/or are readily amenable to control or eradication. Though there may be moderate economic effects at an enterprise level, there would be little impact at an industry or national level. Effects on the environment would be minor and transient.
- A **negligible** impact is associated with the establishment of diseases that have no significant biological consequences, may be transient and/or that are readily amenable to control or eradication. The economic effects would be expected to be low at an individual enterprise level, and insignificant at an industry or national level. Effects on the environment would be negligible.

If the consequence assessment demonstrates a negligible impact, then the risk assessment can usually be concluded at this stage although this will depend on the importing country's acceptable level of protection (ALOP), which is explained later.

The final step in the risk assessment, namely risk estimation, consists of integrating the findings from the release assessment, exposure assessment and consequence assessment to produce overall measures of risk associated with each individual hazard identified at the outset. Thus risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome.

A relatively straightforward way to qualitatively combine the likelihood of introduction and establishment with the impact of the consequences for each identified hazard is to use a risk estimation matrix. An example is shown in Table 4. The cells of this matrix describe the product of likelihood and consequences which are the different levels of 'risk'. When interpreting the risk estimation matrix it should be remembered that although the descriptors for each axis are similar ('low', 'moderate', 'high', etc.), the vertical axis refers to *likelihood*

and the horizontal axis refers to *consequences*. One implication of this is that a 'negligible' probability combined with 'very high' consequences, is not the same as a 'very high' probability combined with 'negligible' consequences, that is, the matrix is not symmetrical. Another implication is that 'risk' is expressed in the same units as are used to estimate consequences. Thus, 'risk' is not a likelihood in IRA.

RISK MANAGEMENT

Risk management is the process of deciding upon and implementing measures to achieve the Member Country's appropriate level of protection (ALOP), whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage risk appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood of disease incursions and their consequences and its desire to import goods and fulfil its obligations under international trade agreements. Each Member Country has the right to set its own ALOP which is consistent with the animal health status of that country and which is consistent with the principles of the *SPS Agreement*. Thus, different countries will have different ALOPs. It is important to note that the *SPS Agreement* does not require a country to have a scientific basis for its ALOP determination.

The risk estimation matrix shown in Table 3 can be used to visualise a country's ALOP. For example, a country may be willing to accept only a very low risk or less for all hazards. However, the ALOP must be consistent for all imports. For example, it would not be acceptable to permit the import of a particular commodity for use as fishing bait while at the same time refusing the import of a similar commodity for human consumption from the same country.

For those hazards where the risk exceeds a country's ALOP prior to the application of risk management measures (the 'unrestricted' risk), the risk can be reassessed in the light of the different options for management. The selected option should be that which brings the risk to the ALOP value and no lower (the 'restricted' risk).

For example, say a particular country was considering a proposal to import live goldfish and had identified goldfish haematopoietic necrosis virus (GFHNV) as a hazard. Suppose the risk assessment had resulted in estimates for the likelihood of release and exposure as low and consequences of establishment and spread as high. Reference to the risk estimation matrix in Table 3 shows that the qualitative unrestricted risk for GFHNV based on these estimates is low. Suppose also, that the importing country has a conservative ALOP and only accepts risks that are very low or lower. For the GFHNV example, the unrestricted risk, assessed as low, exceeds the importing country's ALOP and risk management measures are required. The types of measures which might be considered include certification of the health status of the source populations, inspection prior to export and after arrival, and observation in a post-entry quarantine facility. If it could be shown that these measures would reduce the risk to the level of very low (the restricted risk estimate), then the imports could proceed with the appropriate management measures in place for GFHNV.

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. The results of the risk assessment and proposed risk management measures are then 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.

IMPORTANCE OF SURVEILLANCE TO IRA

An ongoing problem for trade is that the disease situation in both exporting and importing countries is never static. Rather, it is dynamic - it is undergoing continuous change and this change needs to be continuously evaluated as part of the overall IRA process. Clearly, hazard identifications and risk assessments can only be meaningful when based on an understanding of the health status of relevant aquatic animal populations in both importing and exporting countries. Such an understanding can only be derived from a comprehensive surveillance program.

Increasing trade in aquatic animal commodities has resulted in increasing scrutiny of the risk of international spread of disease. As a result there has been a growing interest in developing better systems for investigating and reporting of animal diseases. Reliable evidence for freedom from particular diseases and confidence that exporting countries have reliable systems in place for the early detection of emerging diseases are also becoming issues of major interest. It is therefore vital to have a highly sensitive and effective means of identifying and continuously tracking diseases and their effects to enable wise decisions to be made with regard to early preventive or remedial action.

Thus, disease surveillance should be an integral and key component of all government aquatic animal health services. This is important for early warning of diseases, planning and monitoring of disease control programs; provision of sound aquatic animal health advice to farmers; certification of exports; international reporting and verification of freedom from diseases as well as providing a sound basis for IRAs.

In the broadest sense, surveillance is a mechanism to collect and interpret data on the health of aquatic animal populations to the benefit of all stakeholders. The primary purpose of aquatic animal disease surveillance is to provide cost-effective information for assessing and managing risks associated with trade in aquatic animals and products, animal production efficiency and public health. This statement of purpose is consistent with the OIE Code and international perceptions of what surveillance is meant to achieve.

The disease focus of a country's surveillance program should be based on the OIE listed diseases, any national list of notifiable diseases and other diseases of special concern to the particular country. The recommended statements to precisely articulate the objectives of a country's overall surveillance efforts are:

1. rapidly detect new and exotic infectious diseases in aquatic animals;
2. provide evidence of freedom from diseases relevant to domestic and international movement of aquatic animals and products;

3. describe the distribution and occurrence of diseases relevant to disease control and domestic and international movement of aquatic animals and products; and
4. assess progress in control or eradication of selected diseases and pathogens.

As written, the above objectives are unambiguous and clearly set boundaries on what surveillance is meant to achieve, whether the activity be undertaking a survey to describe the distribution and prevalence of an important disease, collecting information to ensure that disease zones are maintained or providing information to a trading part as part of the IRA process.

At present, results from multiple surveillance activities undertaken by a country are combined in an informal process to arrive at an overall opinion on a country's status for a particular disease. This process is neither transparent nor reliably reproducible and this poses difficulties under the *SPS Agreement*. However, rapid progress is likely to be made over the next five years in developing more scientific methods to combine different data sources to produce an overall estimate of a country's animal health status. This will be most useful for demonstrating freedom from specified diseases. It is likely that a number of quantitative methods will be used in combination such as scenario-trees, Bayesian probability estimation, stochastic modelling and time-effect modeling.

CONCLUSIONS

Many countries are still coming to grips with the concept of IRA. The formal process of import risk analysis described in the OIE *Code* provides a framework to achieve more objective decisions by relevant competent authorities using qualitative, quantitative or a combination of both methods.

The realization that IRAs are underpinned by reliable surveillance information, which is often simply not available, is leading to increasing interest in different methods of surveillance as well as methods to formally and transparently combine surveillance data from different sources within a particular country.

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