Pathogen risk analysis for aquaculture production[1]

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ABSTRACT

In the context of aquatic animal health, pathogen risk analysis (also termed "import risk analysis") is a structured process for analysing the disease risks associated with the international and domestic movements of live aquatic animals and their products. Risk analysis provides a clearly defined framework for a structured, repeatable process, thereby removing to a large extent, ad hoc and arbitrary decision-making with regard to requests to import aquatic animals and their products.

Risk analysis is only one of a large number of components in a national aquatic animal health programme and cannot function effectively unless other components of the national programme have also been developed. In addition to appropriate legislation and policy, and the means to implement them, these other required components include capacity in areas such as diagnostics, quarantine and inspection services; disease surveillance, monitoring and reporting; national pathogen lists; legislation and enforcement; contingency planning; etc.

This paper provides an overview of the pathogen risk analysis process, a list of relevant instruments (treaties and agreements), and examples of actual risk analyses and information sources, as well as a discussion of the way forward, particularly focusing on challenges that will faced by developing countries.

INTRODUCTION

The international trade of live aquatic animals is carried out for various reasons including aquaculture development and sustainment, the ornamental fish industry and

[1] This paper is based primarily on the *Manual on risk analysis for the safe movement of aquatic animals* (Arthur *et al*., 2004) and a paper entitled *Pathogen risk analysis for biosecurity and the management of live aquatic animal movements* (Arthur *et al*., 2008).

the live food fish market. Live fish are also moved across national borders to support the development of capture and sport fisheries, for use as bait, as biological control agents and for research (Arthur, 2004; Subasinghe and Bartley, 2004).

Gametes, fertilized eggs, fry, fingerlings, and spat, as well as broodstock are constantly being moved to support aquaculture development. While the international movement of fertilized eggs and gametes is infrequent in some parts of the world (particularly in Asia), this method is recommended by international codes of practice for species introductions and transfers (e.g. the European Inland Fisheries Advisory Commission [EIFAC] and the International Council for the Exploration of the Sea [ICES], as it generally involves a lower risk of pathogen transfer (Turner, 1988; ICES, 2005).

In Asia and Latin America, immature stages of many species are frequently moved across international borders in large numbers. New industries that are hindered by non-existent or temporarily insufficient national production (e.g. milkfish fry, oyster spat, prawn postlarvae) or industries involving species whose life cycles have not been completed to a commercial level (e.g. groupers, tiger prawn) are associated with these types of movements. Hossain (1997) provides a good example, in Bangladesh, of the magnitude of this trade, estimating an importation level in 1995, of about 50 million nauplii and postlarvae of giant tiger prawn to support the country's developing shrimp culture industry.

Broodstock movement, on the other hand, is less frequent and typically involves only a few animals at a time. Such movements are characteristic for species without closed life cycles at a commercial level (prawns) and for new aquaculture species, in order to avoid delays in aquaculture start up due to the time needed for maturation of juveniles to broodstock.

To support the live food market, fish, crustaceans and molluscs are moved both internationally and domestically. Examples include movement of live oysters from producing countries to consuming countries (e.g. to Europe, North America and South Africa) and the intra-regional trade in Asia involving live finfish and shellfish (e.g. groupers, seabass, shrimp, cockles, etc.) for consumption in seafood restaurants.

The ornamental fish trade is a major industry. Khan *et al.* (1999) and Davenport (2001) reported that the international trade in ornamental fish involves more than 2 000 species and hundreds of millions of fish annually. The culture and trade of aquarium fish is an important source of foreign exchange earnings for some countries. For example, Malaysia, one of the world's main exporters of aquarium fish, produced some 338 million freshwater ornamental aquatic organisms in 2001, including some 293 million freshwater fish belonging to more than 90 species (Latiff, 2004). In 2001, Malaysian production of freshwater ornamental aquatic organisms was valued at over 81 million Malaysian Ringgit (US$21.3 million), a figure which had increased by an average annual rate of 7.5 per cent since 1997.

As a sector, the aquarium fish trade is highly unregulated, involving a high volume of transshipment that often masks the country of origin of individual shipments and species. The complexity of the trade often makes guarantees of the health status difficult, if not impossible. Although ornamental fish diseases have not received the detailed attention they deserve, there is increasing evidence of the presence of a wide variety of pathogens and parasites, some of which are important disease agents of cultured and wild fish or are human pathogens (see references in Arthur *et al.*, 2008). Koi herpesvirus disease is one of the most serious of these diseases and recently caused major losses in wild and cultured common carp (*Cyprinus carpio*), an important food fish in some countries in Asia.

Because of the volume of live aquatic animals traded internationally, the diversity of species being moved, and the many known and potential pathogens that infect aquatic species, countries have often faced great difficulty in trying to find methods that will reduce the risk of spreading transboundary pathogens that could seriously impact their domestic aquaculture industries and aquatic biodiversity. Developing countries, in particular, constantly face this challenge in view of the lack of expertise, capacity, policy, legislation and financial resources necessary to adequately manage transboundary disease risks.

GENERAL PURPOSE OF A PATHOGEN RISK ANALYSIS

Pathogen risk analysis (termed "import risk analysis" when international trade is involved) is a structured process for analysing the disease risks associated with the international and domestic movements of live aquatic animals and their products. "Risk" is the potential that an unwanted, adverse consequence (a serious disease outbreak) will result from the importation or domestic movement of a living aquatic animal or its product (a "commodity") over a given period of time. Risk therefore combines the elements of both likelihood and impact.

A pathogen risk analysis (MacDairmid, 1997; Rodgers, 2004; Arthur *et al*., 2004, 2008; Murray *et al*., 2004; OIE, 2007) seeks answers to the following questions:

1) What serious pathogens could the commodity be carrying?
2) If the commodity is infected by a serious pathogen, what are the chances that it will enter the importing country and that susceptible animals will be exposed to infection?
3) If susceptible animals are exposed, what are the expected biological and socio-economic impacts?
4) If the importation is permitted, then what is the risk associated with each pathogen?
5) Is the risk determined for each pathogen in the risk assessment acceptable to the importing country?
6) If not, can the commodity be imported in such a way that the risk is reduced to an acceptable level?

Risk analysis provides a clearly defined framework for a structured, repeatable process, thereby removing to a large extent, ad hoc and arbitrary decision-making with regard to requests to import aquatic animals and their products. Its greatest strength is its flexibility. The process is based on science and is transparent (by having a structured and defined process that is understood by all and by incorporating extensive stakeholder consultation), therefore allowing subjective decisions that enter the process to be recognized. An internationally accepted method, risk analysis provides importing countries with the means to protect themselves against exotic diseases while assuring their trading-partner countries that any disease concerns are justified and are not disguised barriers to trade. It also allows for uncertainty of scientific knowledge. Through the application of the precautionary approach, importing countries are permitted the time needed to address any important information gaps where research is needed to support sound decision-making.

RELEVANT TREATIES AND AGREEMENTS

International trade liberalization resulting from the General Agreement on Tariffs and Trade (GATT) and the creation of the World Trade Organization (WTO) in 1995 consequently brought major changes in the patterns of world trade. With the adoption of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement) in 1994, WTO member countries are now required to use the risk analysis process as a means to justify restrictions on international trade in live aquatic animals or their products based on risk to human, animal or plant health beyond the application of the sanitary measures outlined in the OIE *Aquatic Animal Health Code* (WTO, 1994; Rodgers, 2004; Arthur *et al*., 2004). As a result, risk analysis has become an internationally accepted standard method for deciding whether trade in a particular commodity poses a significant risk to human, animal or plant health, and, if so, what measures, if any can be applied to reduce that risk to an acceptable level.

The World Organisation for Animal Health (OIE, formerly the Office international des Épizooties) is recognized as the international organization responsible for the development and promotion of international animal health standards, guidelines and recommendations affecting trade in live terrestrial and aquatic animals and their products. The OIE's *Aquatic Animal Health Code* (OIE, 2007) outlines the necessary basic steps in the risk analysis process that should be followed; however, decisions as to the details of the process are left to individual member countries.

Risk analysis is only one of a large number of components in a national aquatic animal health programme (FAO/NACA, 2000; Arthur *et al.*, 2004). It cannot function effectively unless other components of the national programme have also been developed, such as appropriate legislation and policy, and the means to implement them; and capacity building in the areas of diagnostics, quarantine and inspection services; disease surveillance, monitoring and reporting; national pathogen lists; legislation and enforcement; contingency planning; etc.

Table 1 provides a list of examples of instruments (treaties and agreements) at different levels (international, regional and national) concerned with aquatic animal health issues.

SCOPING A PATHOGEN RISK ANALYSIS

The preparation of a detailed and accurate commodity description that contains all essential information concerning the proposed importation (e.g. health status of the stock; the number, life cycle stage and age of the animals to be imported; the handling and treatment methods applied before and during shipment; etc.) is an important initial step in the scoping process. Once a decision has been made that a risk analysis is required, the risk analysis team established by the Competent Authority will decide on the type of risk analysis (i.e. qualitative or quantitative) to be conducted. A working group with appropriate expertise that will conduct the actual risk analysis will be formed (Figure 2). The full cooperation of the exporting country in providing such information is essential. Risk assessment methodology may range from the purely

TABLE 1
Examples of instruments at different levels concerned with aquatic animal health issues

International codes/treaties/guidelines	Reference
OIE's *Aquatic Animal Health Code*	OIE (2007)
*Code of Practice on the Introductions and Transfers of Marine Organism*s of the International Council for the Exploration of the Seas (ICES)	ICES (2005)
Code of Conduct for Responsible Fisheries (CCRF) of the Food and Agriculture Organization of the United Nations (FAO)	FAO (1995)
Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO)	WTO (1994)
FAO Technical Guidelines for Responsible Fisheries. No. 5, Suppl. 2 – *Health management for responsible movement of live aquatic animals*	FAO (2007)
Regional guidelines	
Codes of Practice and Manual of Procedures for Consideration of Introductions and Transfers of Marine and Freshwater Organisms of the European Inland Fisheries Advisory Commission (EIFAC)	Turner (1988)
FAO/NACA Asia regional technical guidelines for the responsible movement of live aquatic animals	FAO/NACA (2000)
National strategies	
AQUAPLAN: Australia's National Strategic Plan for Aquatic Animal Health	AFFA (1999)
Canada's National Aquatic Animal Health Programme (NAAHP)	Olivier (2004)
USA's National Aquatic Animal Health Plan	Amos (2004)
Thailand's Strategic Plan for Aquatic Animal Health	Kanchanakhan and Chinabut (2004)

Source: Bondad-Reantaso and Subasinghe, 2008.

qualitative to the purely quantitative. In most cases, a qualitative approach will be simplest, quickest and most cost-effective.

OVERVIEW OF THE RISK ANALYSIS PROCESS

Figure 1 shows the four main components of the OIE risk analysis process and their interrelationships, while Figure 2 outlines the steps in the risk analysis process.

THE STEPS IN THE RISK ANALYSIS PROCESS

The principal components of the risk analysis process, as illustrated above (Figures 1 and 2) are: hazard identification, risk assessment (release, exposure and consequence assessments, which become the basis for risk estimation), risk management (composed of risk evaluation, option evaluation, implementation and monitoring and review) and risk communication (a continuous activity that takes place throughout the entire process).

Hazard identification

The hazard identification step determines what pathogens could plausibly be carried by the commodity. From this initial list of pathogens, those pathogens that pose a serious risk to the importing country will then be determined. Examples of criteria used when considering whether or not a pathogen constitutes a hazard include the following:

- the pathogen must have been reported to infect, or is suspected of being capable of infecting the commodity;
- it must cause significant disease outbreaks and associated losses in susceptible populations; and
- it could plausibly be present in the exporting country.

A list of information sources (disease databases, taxonomic databases, fish databases, abstracting services, internet Web sites) that can be used to obtain information needed to support hazard identification is provided in Table 2.

An example of the process used for hazard identification during a recent risk analysis for the introduction of blue shrimp, *Litopenaeus stylirostris*, from Brunei Darussalam to Fiji (Bondad-Reantaso *et al*., 2005) is provided in Box 1.

Risk assessment

The actual risk assessment consists of four components:
1. Release assessment is the step that determines the pathways whereby a pathogen can move with the commodity from the exporting country to the border of the importing country and the likelihood of this occurring. Information required for release assessment includes the following:

FIGURE 1
The four components of risk analysis

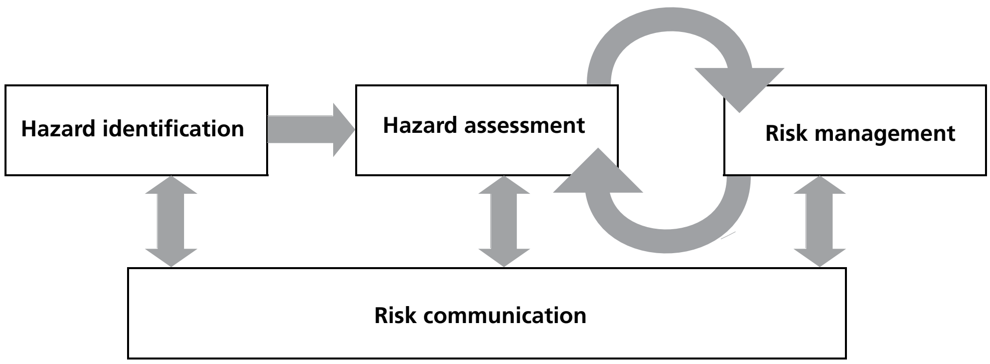
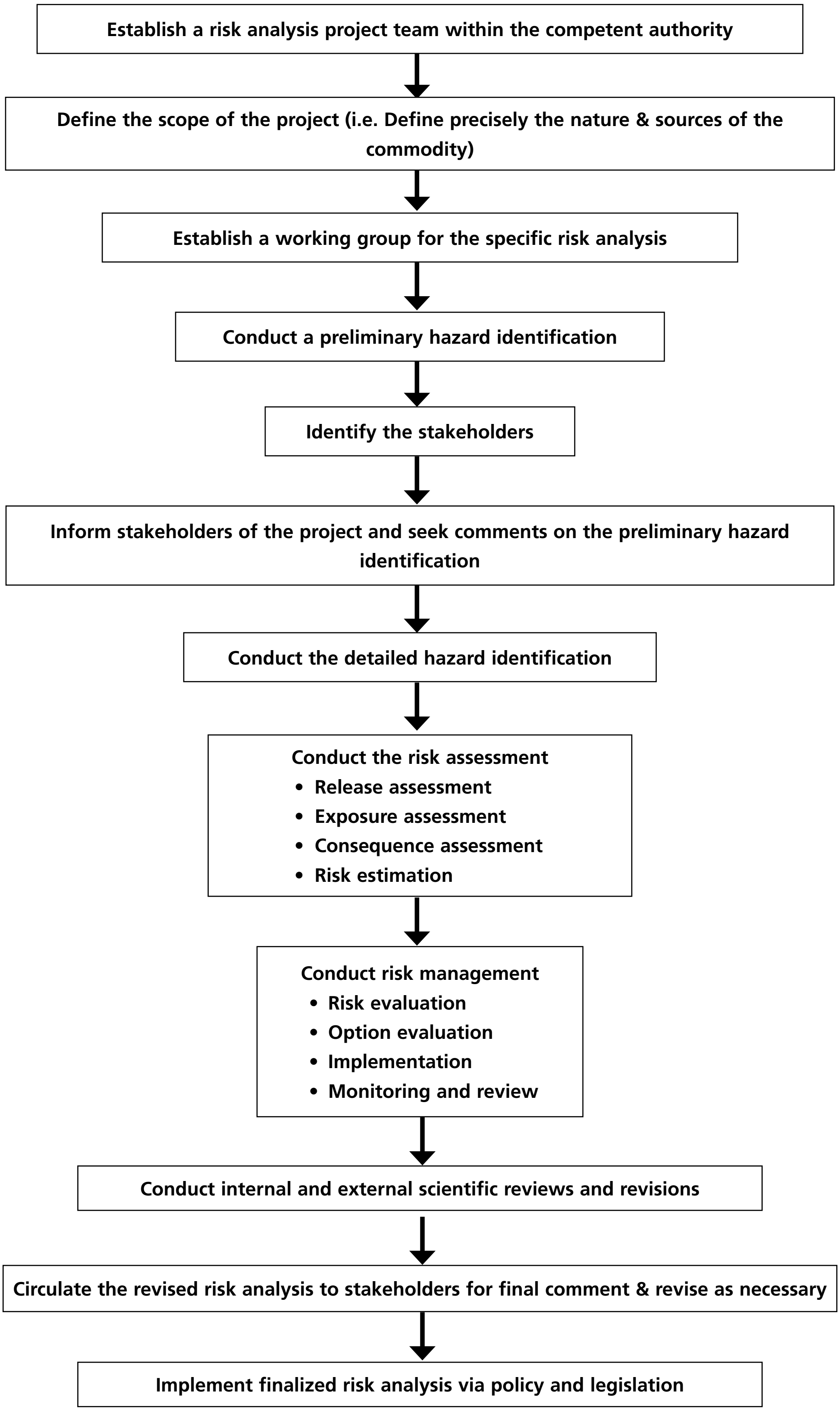


FIGURE 2
A simplified diagram showing the steps in the risk analysis process



Source: Arthur *et al.*, 2004.

TABLE 2

Examples of information resources to support hazard identification

Type of information resources	Access
Scientific and disease databases and abstracting services	
AGRICOLA (Agricultural Online Access)	http://agricola.nal.usda.gov/
Aquatic Animal Pathogen and Quarantine Information System (AAPQIS)	http://www.aapqis.org
Aquatic Science and Fisheries Abstracts (ASFA)	http://www.fao.org/fi/asfa.asfa.asp
Biological Abstracts and BioResearch Index (BIOSIS), database for biological and medical sciences	http://www.biosis.org
Cambridge Scientific Abstracts	http://www.csa.com
Commonwealth Agricultural Bureaux (CAB) Veterinary Sciences/Medicine database	http://www.cabi.org
Food Science and Technology Abstracts database (International Food Information Service)	http://www.ifis.org
INGENTA	http://www.ingenta.com
Northeastern Aquatic Animal Health Directory	http://www.old.umassd.edu/specialprograms/nrac
OIE Collaborating Centre for Information on Aquatic Animal Diseases	http://www.collabcen.net
PubMed, a service of the National Library of Medicine	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi
Science Citation Index, Institute for Science Information (ISI)	http://scientific.thomsonreuters.com/products/sci/

BOX 1

An example of the results of a hazard identification exercise, part of a pathogen risk analysis for the introduction of blue shrimp, *Litopenaeus stylirostris*, from Brunei Darussalam to Fiji

The criteria set for a pathogen or disease to be considered in the preliminary hazard identification were:

- the potential hazard must be an identifiable biological agent or a disease believed to be produced by a single (as yet unidentified) biological agent (thus generalized syndromes are not considered)
- the agent must have been recorded from *L. stylirostris* (any life cycle stage) or it must be listed by the OIE as a serious disease affecting other penaeid shrimp.

The preliminary hazard identification determined that there were 19 pathogens fulfilling the above criteria (Tables 1 and 2).

Another set of criteria was drawn up that needed to be fulfilled in order for a potential hazard be given further consideration (i.e. considered a hazard). These were:

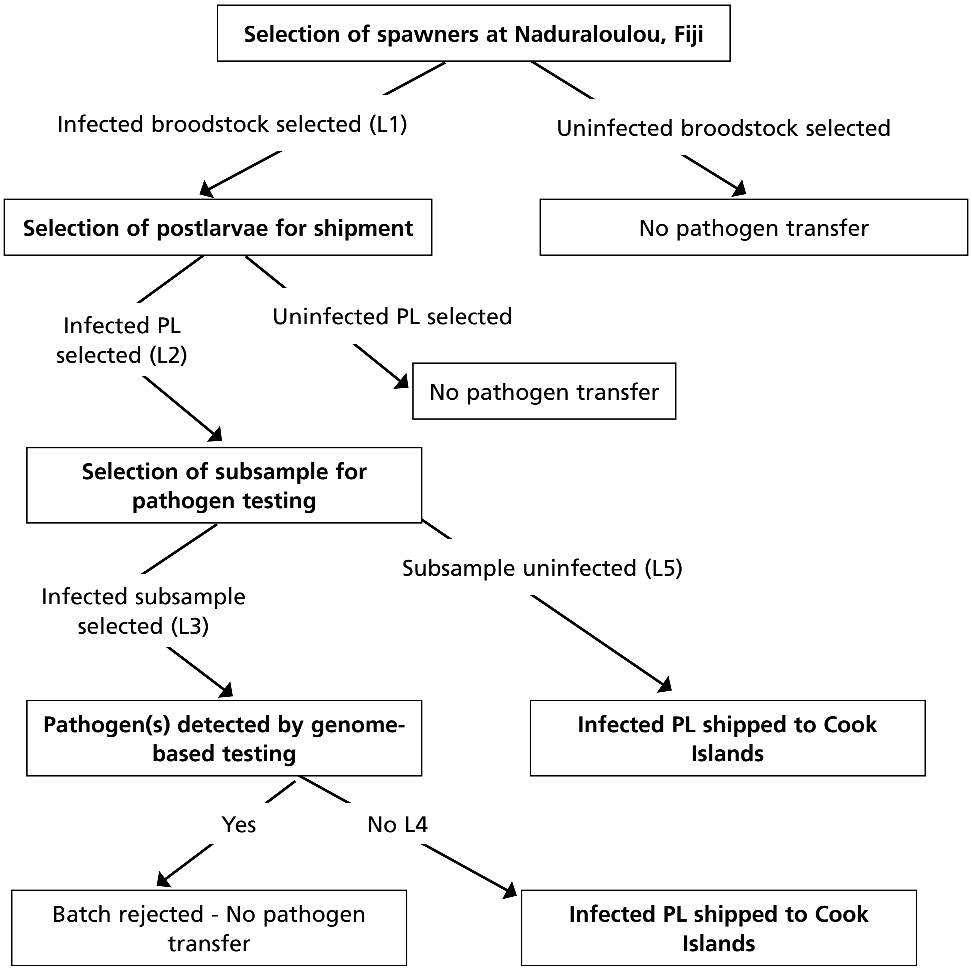
- the pathogen must have been reported to infect, or is suspected of being capable of infecting postlarval *L. stylirostris;*
- the agent must be an obligate pathogen (i.e., it is not ubiqitous free-living organism that is capable of becoming an opportunistic pathogen of *L. stylirostris* under certain environmental or culture conditions);
- the agent must cause significant disease outbreaks and associated losses in populations of *L. stylirostris* or, if not a significant pathogen of *L. stylirostris*, it must cause serious disease outbreaks in populations of other species of penaeid shrimp; and
- it must be plausible that the agent might be present in populations of *L. stylirostris* in Brunei Darussalam.

In the final analysis, some comments and observations were presented as to why some of the pathogens were not given consideration and which of the 19 pathogens were recognized as requiring further consideration. These pathogens became the subject of detailed risk assessment. In this particular case, out of the 19 pathogens, eight were given further consideration (see Box 2).

Source: Bondad-Reantaso *et al.*, 2005.

FIGURE 3

Simplified Pathways Diagram for the release of viral pathogens in *Macrobrachium rosenbergii* postlarvae from Fiji to Cook Islands. Not considered are less probable pathways such as via shipping water or fomites, or failure of the diagnostics tests to detect true positives. In this simplified example, the likelihood that infected PL will be released (LR) can be expressed as LR = (L1 x L2 x L3 x L4) + (L1 x L2 x L3 x L5)



Source: Arthur *et al.,* 2005.

- Biological factors: susceptibility (species, life stage), means of transmission (horizontal, vertical), infectivity, virulence, routes of infection, outcomes of infection (sterile immunity, incubatory or convalescent carriers, latent infection), impact of vaccination, testing, treatment and quarantine
- Country factors: evaluation of the exporting country's official services in terms of diagnostics, surveillance, and control programmes and zoning systems; incidence and/or prevalence of the pathogen; existence of pathogen-free areas and areas of low prevalence; distribution of aquatic animal population; farming and husbandry practices; geographical and environmental characteristics
- Commodity factors: ease of contamination; relevant processes and production methods; effect of processing, storage and transport; quantity of commodity to be imported

2. *Exposure assessment* is the step that determines the pathways by which susceptible populations in the importing country can be exposed to the pathogen and the likelihood of this occurring (Figure 3). Information required for exposure assessment includes the following:

- Biological pathways: description of pathways necessary for exposure of animals and humans to the potential hazards and estimate of the likelihood of exposure
- Relevant factors:
  - Biological factors: susceptibility of animals likely to be exposed (species, life stage), means of transmission (horizontal, vertical), infectivity, virulence and stability of potential hazards, route of infection, outcome of infection
  - Country factors: presence of potential intermediate hosts or vectors, fish and human demographics, farming and husbandry practices, customs and cultural practices, geographical and environmental characteristics
  - Commodity factors: intended use of imported animal, waste disposal practices, quantity of commodity to be imported

3. Consequence assessment is the step that identifies the potential biological, environmental and economic consequences expected to result from pathogen introduction. Information required for consequence assessment include the following:
- Potential biological, environmental and economic consequences associated with the entry, establishment and spread
  - Direct consequences: outcome of infection in domestic and wild animals and their populations (morbidity and mortality, production losses, animal welfare), public health consequences
  - Indirect consequences: economic considerations (control and eradication costs, surveillance costs, potential trade losses [such as embargoes, sanctions and lost market opportunities]), environmental considerations (amenity values, social, cultural and aesthetic conditions)

4. Risk estimation is the step that calculates the overall risk posed by the hazard (the unmitigated risk) by combining the likelihood of entry and exposure with the consequences of establishment (Table 3).

In the risk assessment process, the use of pathway analysis and scenario diagrams is very important. They serve as useful tools in identifying possible routes (pathways) and the individual events or steps in each pathway that need to occur for a given pathway to be successfully completed. Not only do they provide a logical process by which the critical risk steps (events) leading to pathogen introduction and establishment in an importing country can be identified, they also allow estimation of the probability of each event occurring, thus leading to an overall estimate of the probability of a given pathway being completed. When incorporated unto the pathway analysis, the effectiveness of a risk mitigation measure can be determined, which can then allow the recalculation of the overall risk to see whether the risk can be reduced to an acceptable level. Another advantage of using the pathway/scenario diagram approach is that it allows for sensitivity analysis, whereby the most influential pathway steps that

TABLE 3
Example unmitigated risk estimation combining the results of the exposure and consequence assessments for a hypothetical hazard using three qualitative rankings (high, medium and low)

Likelihood of entry and exposure	Consequence of establishment	Unmitigated risk estimate
Low	Low	Low
Low	Medium	Medium
Low	High	Medium
Medium	Low	Medium
Medium	Medium	Medium
Medium	High	High
High	Low	Medium
High	Medium	High
High	High	High

Source: Arthur *et al.*, 2004.

determine the final risk estimate for a particular pathogen can be identified. This greatly assists in targeting risk mitigation measures and in identifying areas where information needs are most critical, particularly in areas where highly sensitive pathway steps are associated with a degree of uncertainty or subjectivity.

Risk management

Risk management is the step in the process whereby measures to reduce the level of risk are identified, selected and implemented. The three steps involved are briefly described below:

- In the *risk evaluation* step, the unmitigated risk estimate for the hazard is compared with the level of risk acceptable (the acceptable level of risk, ALOR) to the importing country. If the estimated risk is within the ALOR, the importation can be approved. However, if the risk posed by the commodity exceeds the ALOR, then risk mitigation measures should be considered.
- During *option evaluation* possible measures to reduce the risk are identified and evaluated for efficacy and feasibility, and the least restrictive measure(s) found to reduce the risk to an acceptable level are selected. The process is essentially the same as that used during risk assessment, with new scenarios and pathways being constructed that incorporate steps for possible risk mitigation measures to determine their ability to reduce the overall risk (now the mitigated risk estimate) to an acceptable level.
- During *implementation and monitoring and review,* the requirements for importation, including any mitigation measures, are presented to the proponent and the importation process is monitored and reviewed by the importing country's Competent Authority to assure that all conditions for importation are met.

During the risk management step, it is important to keep in mind several important principles of the SPS Agreement related to the risk management process. These are:

- Risk management measures must be applied in the least trade restrictive manner possible – *principle of least restrictiveness.*
- The concept of equivalence allows the exporting country the opportunity to prove that its own risk mitigation measures lower the risk to within the importing country's ALOR – *principle of equivalence of mitigation measures*.
- The importing country must apply the same ALOR (i.e. accept the same level of risk) at both external (international) and internal (national) borders, and the ALOR must be applied consistently across the range of commodities in which the country trades, without prejudice as to the country of origin – *principle of consistency in application*.

An important concept that needs to be understood in the risk management step is what is called the "acceptable level of risk" or "ALOR".[2] ALOR is the level of risk that can be tolerated by a country when importing live aquatic animals or their products. It is the standard to which the results of a hazard analysis are compared (the unmitigated risk estimate) to determine if an importation should be approved, as well as the standard to be applied in determining whether risk mitigation measures can be effective in reducing risk to an acceptable level (the mitigated risk).

Many factors need to be carefully weighed by politicians when establishing the ALOR. These include the importance of protecting national biodiversity and natural ecosystems, the availability of species for aquaculture and capture fisheries development, the need for social and economic development, and past trading practices, including those in the plant and livestock sectors.

[2] The "appropriate level of protection" or "ALOP", which can be thought of as the inverse of ALOR, is often used in stating a country's level of risk tolerance.

Examples of a conclusion of a pathogen risk analysis and the associated risk management measures identified and recommended as an outcome of the risk analysis process are given in Box 2.

Risk communication

Risk communication is the step whereby information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which results of the risk assessment and proposed risk management measures are communicated to decision-makers and interested parties in the importing and exporting countries. Risk communication is a multidimensional and iterative process, ideally beginning at the start of the risk analysis and continuing throughout the whole process. It is the stage that provides over-all system integrity. In order to achieve such integrity, a clear communication strategy is required (i.e. what kind of message, the medium, to whom and the frequency of iteration, mechanism for seeking input/ feedback, etc.). An effective risk communication has the following key components: transparency, consensus building, stakeholder cooperation and consultation.

As the risk analysis process may involve a large number of agencies, organizations and individuals that have an interest in its outcome, key stakeholders should be identified early in the process. The primary stakeholders in a risk analysis process are the proponents, the Competent Authorities of the exporting and importing countries, and the risk analysis team. Many other stakeholders will be interested in the outcome of a risk analysis; the precise agencies, organizations and individuals will vary depending on the commodity being considered and its intended use. To give an example, a risk analysis involving the importation of a live marine mollusc for aquaculture development may include the following potential stakeholders: oyster farmers, oyster traders, restaurant owners, fish vendors, consumers, aquaculturists, seafood processors, conservationists, and concerned international, national and local governments and agencies.

Table 4 provides a list of the pathogen risk analyses for aquatic animals that have been conducted or are currently in progress;

The precautionary approach

The large amount of uncertainty that is seen during many risk analyses is due to the general lack of basic knowledge and information that is needed in the process. In fisheries management and elsewhere where governments must take decisions based on incomplete knowledge, the "precautionary approach" is widely used. FAO's *Code of Conduct for Responsible Fisheries* states that:

"States should apply the precautionary approach widely to conservation, management and exploitation of living aquatic resources in order to protect them and preserve the aquatic environment. The absence of adequate scientific information should not be used as a reason for postponing or failing to take conservation and management measures." (FAO, 1995).

A "precautionary approach", within the context of risk analysis for aquatic animals, would be that both importing and exporting nations act responsibly and conservatively to avoid the spread of serious pathogens (Arthur *et al*., 2004).

There are at least three points whereby the precautionary approach may come into play within the context of risk analysis for aquatic animal movement:

- throughout the risk analysis process, when "*cautious interim measures*" are considered necessary to ban or restrict trade until a sound risk analysis can be completed;
- during the pathways scenario portion of the risk assessment process, when sensitivity analysis reveals key information gaps that must be addressed by targeted research; and
- during risk management, when risk mitigation measures are identified to reduce the risk to an acceptable level.

BOX 2

Example of conclusions from a pathogen risk analysis (PRA) for the introduction of blue shrimp, *Litopenaeus stylirostris*, from Brunei Darussalam to Fiji and risk management measures identified and recommended as an outcome of this PRA

Conclusions of the pathogen risk analysis

Both Fiji and Brunei Darussalam, as members of the World Trade Organization (WTO), and Brunei. as a member of the Office international des épizooties (OIE) are bound to fulfill their obligations as WTO/OIE members, particularly in implementing new agreements such as the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the "SPS Agreement"). The principal objective of the SPS Agreement is to ensure that governments do not use food safety and quarantine requirements as unjustified trade barriers to protect their domestic agricultural industries from competitive imports. The SPS agreement also ensures that governments can give health protection priority over trade.

The absence of historical and current information on the health status of the stock of origin, and the lack of responsiveness of the exporter and Government of Brunei to provide information necessitate the application of the precautionary approach. ***Because of the high risk of introducing serious pathogens, further importations from this source should not be permitted until adequate information to assess risk is provided by Brunei.*** The Government of Fiji is urged make an official request to the Government of Brunei, both directly and through the offices of the SPC and OIE, to obtain this crucial information, which should be carefully evaluated prior to making a final decision as to whether or not to permit these introductions to continue. Fiji and Brunei should cooperate fully in order to address the critical information gaps in a timely and transparent manner.

Based on the preliminary hazard identification, six viruses and two bacteria were recognized as potentially serious hazards associated with the importation of PL of *Litopenaeus stylirostris* from Brunei Darussalam:

- White spot syndrome virus (WSSV)
- Infectious hypodermal and haematopoietic necrosis virus (IHHNV)
- Taura syndrome virus (TSV)
- Yellow head virus (YHV)
- Baculovirus penaei (BP)
- Hepatopancreatic parvo-like virus (HPV)
- Necrotising hepatopancreatitis (NHP)
- *Vibrio penaeicida*

Four of the six viruses (WSSV, IHHNV, TSV and YHV) are among the most serious pathogens of both cultured and wild shrimp. These pathogens have been introduced and spread on a global scale due to the irresponsible movement of shrimp broodstock and PL for aquaculture development, and perhaps through other means, such as via aquaculture products (e.g. frozen shrimp), other animal carriers (reservoir hosts, passive carriers) and other abiotic factors.

The associated levels of risk (release, exposure and consequence) for these pathogens exceed the appropriate level of protection (ALOP) recommended for Fiji (see Table 1). From an economic, social and biological perspective, it is well worth the cost and effort to protect Fiji, as far as possible, from the potential irreversible impacts of these pathogens.

BOX 2 (continued)

TABLE 1
Summary of the results of assessment of unmitigated risk for eight potential hazards

Pathogen[1]	Likelihood of Release	Likelihood of Escape	Probable Consequence
IHHNV	moderate	moderate	moderate
TSV	moderate	moderate	low
WSSV	moderate	moderate	moderate
YHV	moderate	moderate	moderate
BP	moderate	moderate	low
HPV	moderate	moderate	moderate
NHP	low	low	low
V. penaeicida	low	low	low

1 Infectious hypodermal and haematopoietic necrosis virus (IHHNV), Taura syndrome virus (TSV), white spot syndrome virus (WSSV), yellow head virus (YHV), *Baculovirus penaei* (BP), hepatopancreatic parvo-like virus (HPV), necrotising hepatopancreatitis (NHP).

Mitigation measures are available that can be applied to reduce the risk associated with all hazards to below that specified by the ALOP. The most important of these are:

- All shipments of PL to be imported into Fiji should be of "high health" status and should originate from a facility certified as using specific pathogen free (SPF) broodstock *L. stylirostris.* The facility must demonstrate a proven track record of producing PL free of the specific diseases through a documented history of pathogen surveillance, evidence of adherence to strict biosecurity protocols and an over-all health management plan. The facility must provide sufficient guarantees as to the health status and history of its stock. An on-site inspection visit to the production facility by an internationally recognized shrimp health expert on behalf of the Government of Fiji should be made to assure that the protocols, diagnostic procedures, security, etc. are adequate to validate guarantees of health status.[1,2]
- The production facility in the exporting country should also meet the following pre-border requirements:
  - The batch of PL destined for export should be separated as early as possible from other stocks reared in the facility of origin and should be maintained in tanks separate from the rest of the stocks;
  - Detailed records should kept of the health status and mortality rates of each batch of *L. stylirostris*. Such records should be made available to the Competent Authority responsible for health certification;
  - A statistically appropriate sample taken from the batch intended for export should be tested for the eight pathogens using the recommended methods (for OIE listed diseases, these are the methods specified by OIE (2003));
  - Should a batch of PL test positive for any of the eight hazards, the batch will be rejected and future importations from the infected production facility prohibited until such a time that freedom of the facility from disease can be clearly demonstrated.

1 SPF is a concept that is generally poorly understood (see Carr 1996, Lotz 1997). Once broodstock or PL produced by an SPF facility leave that facility, they are no longer considered to have SPF status for the specific pathogens indicated, because the level of biosecurity under which they are being maintained is now decreased. When transferred to a commercial hatchery or grow-out facility having adequate, albeit lower level health security, they and any nauplii and PL derived from them may be referred to as 'high health' shrimp. Because their health status is now less certain, a new historical record for that facility must be established.

2 An alternate approach, and one that would provide a higher level of protection from exotic disease, would be a single importation of a limited number of SPF broodstock *L. stylirostris* that would be used to establish a breeding program in a biosecure facility in Fiji.

- The importing country should implement the following post-border requirements:
  - The receiving facility should meet minimum requirements with regard to its design and operation such that the risk of pathogen exposure is minimized. (see Annex I).
  - A health monitoring system should be in place at the receiving facility so that a new historical record of health and mortality status can be established.
  - No animals are to be removed from the receiving facility without prior permission from the Ministry of Fisheries and Forestry (MFF), Fiji;
  - The operators must report any occurrences of serious mortalities or disease outbreak; and
  - A farm level contingency plan should be developed requiring that in the event of a serious disease outbreak or mortality, all animals will be destroyed and disposed of in an approved sanitary method, and the facility fully disinfected before restocking (see Annex II).
- Importations from countries with a known history of occurrence of serious shrimp pathogens should be avoided unless the production facility is able to clearly demonstrate freedom from serious pathogens. Ideally, the country of origin should have capable veterinary or aquatic animal health services (an evaluation of the Competent Authority may be necessary) and an established program of disease surveillance and control in place to manage the disease.
- The stock of *Litopenaeus stylirostris* currently being cultured in Fiji is considered to represent a high risk to the national disease status. To reduce this risk, the following risk management measures are recommended:
  - No animals should to be moved from the receiving facility (Gulf Seafood Fiji Ltd.) without prior permission from the Ministry of Fisheries and Forestry (MFF);
  - The operators should be required to report any occurrences of serious mortalities or disease outbreak.
  - The production facility should meet minimum standards of construction and operation so as to minimize the possibility that pathogens will gain access to natural waters through escapes, exposure of potential carriers, transfer by birds and other vectors, and release of virus into natural waters. Suggested standards are given in Annex I.
  - A contingency plan should be developed requiring that in the event of a serious disease outbreak or mortality, all animals will be destroyed and disposed of in an approved sanitary method, and the facility fully disinfected before restocking. The components of such a contingency plan are given in Annex II.

THE WAY FORWARD

Developing countries face many challenges in undertaking pathogen risk analysis. Combining national expertise with the risk analysis expertise available in neighbouring countries through regional approaches may be the most cost-effective way for many countries to conduct risk analyses involving common and shared aquatic species. This approach will also involve sharing of databases and other sources of information. Particularly for introductions involving shared waterways, the sharing of risk analysis approaches and associated costs will be a practical action.

Regional efforts to establish hatcheries and stocks with known health history, e.g. specific pathogen free (SPF) stocks, for the most frequently traded species (e.g. tilapia, marine shrimp, giant freshwater prawn, oysters) should be strongly considered by developing countries. Accepting risks inherent in importing live aquatic animals of uncertain health status is not justified.

The risk analysis process is science-based and as such requires adequate supporting scientific information based on high quality research obtained from published

TABLE 4
Examples of pathogen risk analyses for aquatic animals

Title	Agency	Authors/ Date
Current import risk analysis: non-viable bivalve molluscs.	Australian Department of Aquaculture, Fisheries and Forestry (AQIS)	In progress[1]
Current import risk analysis: freshwater crayfish	AQIS	In progress
Current import risk analysis: prawns and prawn products	AQIS	In progress
Current import risk analysis: freshwater finfish	AQIS	In progress
Import risk analysis: frozen, skinless and boneless fillet meat of *Oreochromis* spp. from China and Brazil for human consumption.	MAF Biosecurity New Zealand	Johnson (2007)
Import risk analysis: Freshwater prawns (*Macrobrachium rosenbergii*) from Hawaii	New Zealand Ministry of Agriculture and Fisheries (MAF)	MAF (2006)
Pathogen and ecological risk analysis for the introduction of the Blue Shrimp, *Litopenaeus stylirostris*, from Brunei Darussalam to Fiji	Secretariat of the Pacific Community (SPC)	Bondad-Reantaso *et al.* (2005)
Pathogen and ecological risk analysis for the introduction of giant river prawn, *Macrobrachium rosenbergii*, from Fiji to the Cook Islands	SPC	Arthur *et al.* (2005)
Import risk assessment: juvenile yellowtail kingfish (*Seriola lalandi*) from Spencer Gulf Aquaculture, South Australia	Island Aquafarms, Ltd. and NIWA, New Zealand	Diggles (2002)
Import risk analysis on live ornamental fish	AQIS	Kahn *et al.* (1999)
Import risk analysis on non-viable salmonids and non-salmonid marine finfish	AQIS	AQIS (1999)
Supplementary import risk analysis – head-on gill-in Australian salmonids for human consumption.	Biosecurity Authority, MAF	MAF (1999)
Import health risk analysis: salmonids for human consumption	Ministry of Agriculture Regulatory Authority, New Zealand	Stone, MacDiarmid and Pharo (1997)

[1] Information on animal risk analyses in progress can be accessed at: http://www.daff.gov.au/ba/ira/current-animal

scientific literature. Nonetheless, unpublished information obtained from colleagues as well as expert opinion can also be used. Scientists having considerable research experience can make a valuable contribution to the risk analysis process. In addition to scientific information and input from experts, an individual risk analysis may also require specific targeted research to address critical information gaps identified during sensitivity testing.

Greater attention should be given to generating information and knowledge essential to risk analysis. There is thus a need to establish the appropriate research capacity and to conduct targeted studies. Examples of essential research areas include pathogen studies, information on trade and most importantly, studies on biological pathways for the introduction (release assessment), establishment (exposure assessment) and spread (consequence assessment) of a pathogen. Other important areas of research include studies on host susceptibility; modes of transmission; infectivity, virulence and stability; intermediate hosts and vectors; and effects of processing, storage and transport. For newly emerging diseases as well as some diseases in poorly studied aquatic animal species, basic studies on their pathology and methods for rapid and accurate diagnosis are essential to facilitate accurate risk assessment and biosecurity management. Increased surveillance of wild fish to detect significant disease problems at an early stage is also needed (Bondad-Reantaso *et al*., 2005).

Occasionally, despite the best risk analysis and risk mitigation measures, serious pathogens will be introduced and cause major disease problems. This is due to limitations in diagnostic techniques, the existence of cryptic pathogens and the ability of benign organisms (normally non-pathogenic parasites, bacteria, viruses, fungi, etc.) to become pathogenic when introduced to new hosts and environments. Good disease surveillance and reporting as well as well-designed contingency plans will be necessary.

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ANNEX I

TABLE 1
Results of the preliminary hazard identification (note: for all pathogens,there is no information available as to occurrence in either the exporting or the importing country) Y=Yes, N=No, P=Plausible, ?=Uncertain

Pathogen	Infects PL stage	Causes significant disease	Further consideration required	Comments
Viruses				
White spot syndrome virus (WSSV)	Y	Y	Y	Significant pathogen of penaeid shrimp; global distribution; wide host range; experimental infections lethal to *Litopenaeus stylirostris.*
Infectious hypodermal and haematopoietic necrosis virus (IHHNV)	Y	Y	Y	Significant pathogen of penaeid shrimp; infects a wide range of penaeids; occurs both in wild and cultured shrimp; a major pathogen of *L. stylirostris.*
Taura syndrome virus (TSV)	Y	Y	Y	Significant pathogen of penaeid shrimp; *L. stylirostris* recently found to be susceptible.
Yellow head virus (YHV)	Y	Y	Y	Natural infections in *Penaeus monodon*, lethal experimental infections in *L. stylirostris* and other species.
Viruses				
Baculovirus penaei (BP)	Y	Y	Y	Causes serious disease in *Farfantepenaeus duorarum, F. aztecus, L. vannamei* and *P. marginatus.*
Hepatopancreatic parvo-like virus (HPV)	Y	Y	Y	Natural infection in *P. monodon, Fenneropenaeus merguiensis, P. semisulcatus* and *L. stylirostris.*
Lymphoid organ vacuolization virus (LOVV)	Y	N	N	Identical histopathology occasionally observed in L. *stylirostris.*
Rhabdovirus of penaeid shrimp (RPS)	Y	N	N	Uncertain if a true pathogen of penaeid shrimp.
Bacteria				
Necrotising hepatopancreatitis (NHP)	Y	Y	Y	Reported only from American penaeids *(L. vannamei, F. aztecus, L. stylirostris, L. setiferus* and *F. californiensis).*
Vibrio harveyi	Y	Y	N	Vibriosis affects all penaeid species; mortality ranges from inconsequential to 100%; worldwide distribution.
V. vulnificus	Y	Y	N	
V. parahaemolyticus	Y	Y	N	
V. penaeicida	Y	Y	Y	Reported from New Caledonia; a significant pathogen of *Marsupenaeus japonicus.*
Shrimp tuberculosis (*Mycobacterium marinum, M. fortuitum* and *Mycobacterium* sp.)	?	N	N	Ubiquitous; potentially infectious to all penaeids
Rickettsia-like organisms	P	N	N	*L. stylirostris* experimentally infected by rickettsia of *P. marginatus.*
Parasites				
Haplosporidium sp.	?	N	N	In cultured and wild penaeid shrimp including *L. stylirostris.*
Fungi				
Lagenidium spp.	Y	N	N	Affects all penaeids
Sirolpidium spp.	Y	N	N	Affects all penaeids
Fusarium solani	P	N	N	Opportunistic pathogen; isolated form both cultured and wild crustaceans. All penaeids probably susceptible; *L. stylirostris* moderately susceptible.

Source: Bondad-Reantaso *et al.*, 2005[1]

[1] References column has been deleted from this table (see Bondad-Reantaso *et al.,* 2005).

ANNEX II

TABLE 2

Known or probable infectivity of important pathogens in *Litopenaeus stylirostris* and seven penaeid species reported to occur in Fiji. (Y=Yes, N=No, P=Plausible, NI=No Information)

Pathogen[1]	*Litopenaeus stylirostris*	*Penaeus monodon*	*P. canaliculatus*	*P. semisulcatus*	*P. latisulcatus*	*Fenneropenaeus merguiensis*[2]	*Metapenaeus anchistus*	*M. elegans*
Viruses								
IHHNV	Y	Y	NI	Y	NI	N	NI	NI
TSV	Y	Y	NI	NI	NI	Y	NI	NI
WSSV	Y	Y	NI	Y	NI	Y	NI	NI
YHV	Y	Y	NI	NI	NI	Y	NI	NI
BP	Y	N	NI	NI	NI	NI	NI	NI
HPV	Y	Y	NI	Y	NI	Y	NI	NI
LOVV	Y	Y	NI	NI	NI	NI	NI	NI
RPS	Y	NI	NI	NI	NI	NI	NI	NI
Bacteria								
NHP	Y	NI	NI	NI	NI	NI	NI	NI
Vibrio spp.	P	P	P	P	P	P	P	P
V. penaeicida	Y	NI	NI	NI	NI	NI	NI	NI
Mycobacterium spp.	P	P	P	P	P	P	P	P
Rickettsia-like organisms	Y	NI	NI	NI	NI	Y	NI	NI
Parasites								
Haplosporidium sp.	Y	NI	NI	NI	NI	NI	NI	NI
Fungi								
Lagenidium spp.	P	P	P	P	P	P	P	P
Sirolpidium spp.	P	P	P	P	P	P	P	P
Fusarium solani	Y	N	NI	NI	NI	N	NI	NI

[1] Infectious hypodermal and haematopoietic necrosis virus (IHHNV), Taura syndrome virus (TSV), white spot syndrome virus (WSSV), yellow head virus (YHV), Baculovirus penaei (BP), hepatopancreatic parvo-like virus (HPV), lymphoid organ vacuolization virus (LOVV), rhabdovirus of penaeid shrimp (RPS), necrotising hepatopancreatitis (NHP).

[2] Established exotic species.

Source: Bondad-Reantaso *et al.*, 2004.