Pathogen risk analysis for aquatic animals: experiences from nine case studies

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ABSTRACT

Pathogen risk analysis is an internationally accepted method for deciding whether trade in a particular commodity poses a significant risk to human, animal or plant health, and if so, what measures might be applied to reduce that risk to an acceptable level. This paper provides an overview of the qualitative risk analysis process and briefly examines the results of nine risk analyses that have been undertaken for the Asia and the Pacific Region. The risk analyses examined were conducted by Australia (3), New Zealand (4) and by the Pacific Community (2) and involved the movement of finfishes (5 cases), crustaceans (4 cases) and molluscs (1 case). Two cases involved ornamentals, five cases involved live animals to be moved for aquaculture development and two cases involved non-viable finfish product. It is concluded that although the nine case studies were all hampered by a lack of basic information on aquatic animal pathogens, they were all able to meet the three main objectives of minimizing the risk of transfer of serious pathogens and diseases between trading partners, justifying the application of sanitary measures (e.g. restrictions on species and/or sources of origin, health certification requirements, quarantine, treatment, etc.) and minimizing restrictions to trade. Past experience has shown that serious diseases are often spread through the movement of live aquatic animals and their products, which, coupled with the poor knowledge base that exists for most pathogens of aquatic animals (including information on their identities, life cycles, host specificities, geographical distributions, pathogenicities, etc.) justifies the use of precautionary approaches to minimize the risk of introducing pathogens to new hosts and geographical areas.

Key words: import risk analysis, pathogen risk analysis, risk analysis for aquatic animal movement

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INTRODUCTION

International trade continues to increase in volume due to the expanding human population and technological advancements in transport and communications. Liberalization of international trade has been in part facilitated firstly by establishment of the General Agreement on Tariffs and Trade (GATT) in 1947, followed more recently by the adoption of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement) in 1994 and the creation of the World Trade Organization (WTO) in 1995.

Under the SPS Agreement, WTO Member Countries (counting 153 as of June 2008) may employ sanitary or phytosanitary measures to the extent necessary to protect human, animal and plant health. However, they must base their sanitary measures on international standards, guidelines and recommendations, which in the case of sanitary measures for aquatic animals and their products, is the World Organisation for Animal Health's (OIE) *Aquatic Animal Health Code* (OIE, 2008). WTO members may adopt higher level of standards that those specified in the Code, however, they are required to use the *risk analysis* process as a means to justify these additional restrictions on international trade (see WTO, 1994; Murray, 2002; Rodgers, 2004).

As a result, risk analysis has become recognized internationally as an appropriate method for deciding whether trade in a particular commodity poses a significant risk to human, animal or plant health, and if so, what measures can be applied to reduce that risk to an acceptable level. Besides the SPS Agreement, there are several other international treaties, agreements and memberships that affect international trade in aquatic organisms (Table 1). Some are binding agreements that involve reporting and other requirements, and some are not.

Risk analysis is usually defined either by its components and/or its processes. The Society for Risk Analysis (http://www.sera.org/) defines "risk analysis" in the following ways:

- a detailed examination including risk assessment, risk evaluation and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property or the environment;
- an analytical process to provide information regarding undesirable events; and
- the process of quantification of the probabilities and expected consequences for identified risks.

The risk analysis process has also been simply defined as "science-based decision making" (Arthur, 2008). Risk analysis has characteristics that include consistency of process, transparency of process, emphasis on stakeholder consultation, separation of the objective (scientific fact) from the subjective (opinion), emphasis on the precautionary principle, the concept of an appropriate level of protection (ALOP) (Wilson, 2001), separation of science-based and political decisions, and the concept of unacceptable risk. Risk analysis is now widely applied in many fields that touch our daily lives. These include decisions about risks due to natural disasters, climate change, contaminants in food and water, unemployment, public security, terrorism, safety, insurance, litigation, and so on.

Table 1
Some important international and Asia-regional treaties, agreements and memberships related to international trade in aquatic organisms and their products. Adapted from Arthur *et al.* (2004)

International Law
• SPS Agreement • Convention on Biodiversity (CBD) • Cartagena Protocol on Biosafety • Convention on International Trade in Endangered Species (CITES)
International Memberships
• World Trade Organization (WTO) • World Organisation for Animal Health (OIE) • United Nations (UN) • Various regional inter-governmental associations (e.g. APEC, ASEAN, SEAMEO, SAARC, EU) [1]
Other Non-binding Codes and Agreements
• Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals and the Beijing Consensus and Implementation Strategy (FAO/NACA, 2000) • FAO Code of Conduct for Responsible Fisheries (CCRF; FAO, 1995) • ICES Code of Practice on the Introductions and Transfers of Marine Organisms (ICES, 2005)

[1]APEC – Asia-Pacific Economic Association; ASEAN – Association of South East Asian Nations; FAO – Food and Agriculture Organization of the United Nations; ICES – International Council for the Exploration of the Sea; SEAMEO – Southeast Asian Ministers of Education Organization, SARC – South Asian Association for Regional Cooperation, EU – European Union.

RISK ANALYSIS IN RELATION TO AQUATIC ANIMAL HEALTH AND TRADE IN AQUATIC ANIMALS

In the fields of aquatic animal health and aquaculture, risk analysis has mainly been applied to assess risks to society and the environment posed by hazards created by, or associated with, aquaculture development (Bondad–Reantaso and Arthur, 2008). These include evaluating risk associated with environmental degradation, genetic impacts, introduction and spread of pests and invasive species and introduction and spread of pathogens. While the utility of risk analysis when applied to aquatic animal health is undoubtedly extensive, this paper will concentrate only on pathogen risk analysis (often termed ***import risk analysis*** when applied to international trade). Pathogen risk analysis relates to the analysis of risks of introducing and/or spreading exotic pathogens or strains of pathogens into new geographic areas with the international or domestic movement of aquatic animal commodities (i.e. live aquatic animals and their products).

The main objectives of pathogen risk analysis are:
(i) to minimize risk of transfers of serious pathogens and diseases between trading partners,
(ii) to justify application of sanitary measures (e.g. restrictions on species and/or sources of origin, health certification requirements, quarantine, treatment) and
(iii) to minimize restrictions to trade.

The *Aquatic Animal Health Code* (OIE, 2008) outlines the necessary basic steps in the risk analysis process that should be followed. However, the framework is flexible and decisions as to the details of the process are left to individual member countries.

Governments and the private sector must often make decisions based on incomplete knowledge and a high degree of uncertainty. Because of this, pathogen risk analysis is a structured process within a flexible framework within which the risks of adverse consequences resulting from a course of action can be evaluated in a systematic, science-based manner (MacDiarmid, 1997; Rodgers, 2004). The risk analysis process allows objective and transparent analysis of the risks of disease introduction associated with movements of living organisms and their products across international and domestic borders. Because of the transparent methodology, the risk analysis approach can permit a defendable decision to be reached on whether the risk posed by a particular action or hazard is acceptable or not, and provides the means to evaluate possible ways to reduce risks from unacceptable to acceptable levels.

Components of pathogen risk analysis

The main components of a pathogen risk analysis include hazard identification (i.e. What can go wrong?), risk assessment (How is it likely to go wrong and what would be the resulting consequences?), risk management (What can be done to reduce either the likelihood and/or consequences of it going wrong?) and risk communication (How do we communicate the risk to others in order to generate a change in management, regulation or operation?)

Risk analysis has only recently begun to be used widely to assess the potential risks associated with movements (and proposed movements) of aquatic animals throughout the Asia-Pacific region. Here we examine nine case studies where pathogen risk analysis was applied to movements of fish, crustaceans and mollusks in the Asia-Pacific region. Table 2 presents a summary of the main features of each study. All were based on qualitative analysis of available data, an approach often used when dealing with analyses of aquatic animals due to several factors (Table 3), not the least being the paucity of epidemiological data available, which tends to preclude use of the more involved and costly qualitative analysis method (Murray, 2002). The size and scope of the studies examined varied considerably. Six of the studies examined risks associated with proposed movements of single species (ranging from live and dead fish, to live adult and larval crustaceans, to live mollusks), while the remainder examined risks associated with movements of products from multiple species of salmonids (22 species, Stone *et al.,* 1997) and live ornamental fishes (two studies that encompassed 392

Table 2
Details of nine case studies where pathogen risk analysis was applied to proposed movements of aquatic animals in the Asia-Pacific region.

Risk assessment	Type of translocation	Number of host genera/ species considered	Number of potential hazards in preliminary list	Number of hazards fully assessed	Number of hazards requiring risk management	Risk management methods recommended or required[5]
Salmonids for human consumption (Stone *et. al.*, 1997)	International / between hemispheres	22 species	85	7[1]	0	• Pre-export certification • Commodity headed, gilled and eviscerated • Post-arrival processing at registered premises only
Live ornamental finfish to Australia (AQIS, 1999)	International / between hemispheres	605 genera	104	44	12	• Pre-export inspection and certification • Post-arrival inspection and quarantine (2-3 weeks) • Ad hoc disease testing and/or chemotherapy in quarantine • Safe disposal of wastewater and packaging
Juvenile kingfish (*Seriola* sp.) from Australia to New Zealand for seacage culture (Diggles, 2002)	International / Regional	1 species	42	9[2]	4	• Spatial separation and mortality cut off (5%) in hatchery • High salinity, no external lesions (EUS, parasites) • Virus testing programme (VER/ VNN, aquabirnavirus) • Post-arrival quarantine (4 weeks)
Postlarval blue shrimp (*Litopenaeus stylirostris*) from Brunei to Fiji (Bondad Reantaso *et al*., 2005)[4]	International / between hemispheres	1 species	21	8	8	• Larvae from specific pathogen free (SPF) broodstock • Spatial separation in hatchery • Testing for viruses (BP, HPV, IHHNV, NHP, TSV, WSSV, YHV) and *Vibrio penaeicida* • No shrimp removed from receiving facility without permit

Table 2 *(continued)*
Details of nine case studies where pathogen risk analysis was applied to proposed movements of aquatic animals in the Asia-Pacific region.

Postlarval giant river prawn (*Macrobrachium rosenbergii*) from Fiji to Cook Islands for land-based culture (Arthur *et al.*, 2005)[4]	International / Regional	1 species	61	2	2	• Virus testing programme (WSSV, MrNV, XSV) • No shrimp removed from receiving facility without permit
Ornamental fish and marine invertebrates from all countries to New Zealand (Biosecurity New Zealand, 2005)	International / between hemispheres	394 genera and species	>500	35	13	• Rationalize permitted species to remove high risk hosts • 4 to 6 weeks quarantine • Targeted passive surveillance during quarantine with mortality trigger point (20%) for disease investigation
Adult *Macrobrachium rosenbergii* from Hawaii to New Zealand for land-based culture (Biosecurity New Zealand, 2006)	International/ between hemispheres	1 species	76	6	4	• Virus testing programme (MrNV, WSSV, XSV) • Sourced from waters free of *Aphanomyces astaci* and *Angiostrongylus cantonensis* • No shrimp removed from receiving facility without permit
Menhaden (*Brevoortia* sp.) from USA to Australia for lobster bait (Diggles 2007a)	International/ between hemispheres	1 species	42	1	1	• Pre-export certification with controls on fishing locations • Virus testing (IPN-like Aquabirnavirus) • Post-arrival holding at registered premises, for licensed users only

Table 2 *(continued)*
Details of nine case studies where pathogen risk analysis was applied to proposed movements of aquatic animals in the Asia-Pacific region.

Pacific oysters (*Crassostrea gigas*) from Tasmania to New South Wales for on-growing (Diggles, 2007b)	Domestic/ interstate/ inter-island	1 species	18[3]	13	3	• Virus testing (Herpes-like virus OsHV-1) • Chlorine and/or hypoxia treatment for *Carcinus maenas* and *Undaria pinnatifida*

[1]Included in Monte Carlo Simulation Modeling.
[2]Due to lack of knowledge of kingfish diseases in Australia, this analysis considered not only diseases of kingfish but the likelihood that kingfish could be exposed to any of the notifiable diseases of finfish recorded from Australia.
[3]Includes both pests and disease agents.
[4]Analysis considered both ecological and pathogen risks.
[5] BP – *Baculovirus penaei*; EUS – epizootic ulcerative syndrome; HPV – hepatopancreatic parvo-like virus; IHHNV – infectious hypodermal and haematopoietic necrosis virus (IHHNV); IPN – infectious pancreatic necrosis; MrNV – *Macrobrachium rosenbergii* nodavirus; NHP – necrotising hepatopancreatitis; OsHV-1 – ostreid herpesvirus -1; TSV –Taura syndrome virus; VER/VNN – viral encephalopathy and retinopathy/viral nervous necrosis; WSSV – white spot syndrome virus; XSV – extra small virus; YHV – yellow head virus

Table 3
Comparison of features of quantitative and qualitative risk analysis.

Study type	**Quantitative**	**Qualitative**
Approach	Analytical	Pragmatic
Information needs	Comprehensive epidemiological data required	Data gaps acceptable
Expertise	Considerable	Experience preferred
Timeliness	Can take years	Usually months
Cost	Usually expensive	Relatively economical

(AQIS, 1999) and 605 genera (Biosecurity New Zealand, 2005). Only one study examined risks associated with domestic movements of Pacific oysters in Australia (Diggles, 2007b), with the remaining eight studies relating to international movements of fish or crustaceans.

Hazard identification

Hazard identification is the first step in the risk analysis process, and it centers around the process of identifying hazards that could potentially produce consequences. This process attempts to answer the general question "What can possibly go wrong ?" (Arthur *et al.,* 2004).

To be identified as a hazard, a pathogen typically:

- must have been reported to infect or is suspected of being capable of infecting the commodity;
- must cause significant disease outbreaks and associated losses in susceptible populations;
- could plausibly be present in the exporting country; and
- is absent from the importing country or is under an official control or eradication programme.

For the case studies examined here, there were large variations in the number of hazards identified per host species (Table 4). The "hazard:host" ratio varied from as high as 76 potential hazards per host (Biosecurity New Zealand, 2006, proposed movements of adult *Macrobrachium rosenbergii* from Hawaii to New Zealand) to as low as 0.17 hazards per host (AQIS 1999, live ornamental finfish into Australia). There was a general trend whereby the hazard to host ratio was much higher on average (43.3 hazards per host) for the six studies that examined only a single host species, while the studies that examined multiple host species considered on average only 0.67 hazards per host (Table 4). This difference was mainly due to the large numbers of species of ornamental fishes considered in two studies (AQIS, 1999; Biosecurity New Zealand, 2005), together with the paucity of information available on their diseases and pathogens (Corfield *et al.,* 2007, Whittington and Chong 2007). Even so, the risk analysis conducted on live ornamental fishes and invertebrates into New Zealand (Biosecurity New Zealand, 2005) still identified over 500 potential hazards from a host list of 394 genera and species.

Table 4
Hazards identified in the nine case studies.

Risk assessment	Number of host genera and/or species considered	Number of hazards in preliminary list	Hazard: host ratio
Salmonids for human consumption	22 species	85	3.86:1
Live ornamental finfish to Australia	605 genera and species	104	0.17:1
Juvenile kingfish from Australia to New Zealand	1 species	42	42:1
Postlarval blue shrimp from Brunei Darussalam to Fiji	1 species	21	21:1
Postlarval giant river prawn from Fiji to Cook Islands	1 species	61	61:1
Ornamental finfish and marine invertebrates to New Zealand	394 genera and species	>500	1.27:1
Adult giant river prawn from Hawaii to New Zealand	1 species	76	76:1
Menhaden from the United States of America to Australia	1 species	42	42:1
Pacific oysters from Tasmania to New South Wales	1 species	18 (includes pests)	18:1
Mean for single species risk analysis (6 studies)	1 species	43.3 hazards	43.3:1
Mean for multispecies risk analysis (3 studies)	**340 species**	**230 hazards**	**0.67:1**

Risk assessment

The next step in the risk analysis process is the risk assessment. This step is the process of evaluating the likelihood that a potential hazard will be realized, and the potential consequences of that happening. In the context of pathogen risk analysis, this usually means assessing the likelihood that a serious disease outbreak will result from the movement of a commodity over a given period of time, and estimating the likely biological, social and/or economic consequences of the introduction of that disease agent (Arthur *et al.,* 2004).

The risk assessment component of pathogen risk analysis normally consists of four subcomponents. In the release assessment, the biological pathways necessary for an importation activity to “release” (introduce) a hazard into the importing country are defined and the likelihood of that complete process occurring is estimated. Or, more simply stated, the release assessment determines the pathways that a pathogen can move with the commodity from the exporting country to the border of the importing country (Fig. 1) and the likelihood of this occurring. Similarly, exposure assessment determines the pathways by which susceptible populations in the importing country can be exposed to the pathogen and the likelihood of this occurring. Consequence assessment identifies the potential biological, environmental and socio-economic consequences expected to result from pathogen introduction, while risk estimation calculates the overall risk posed by the hazard

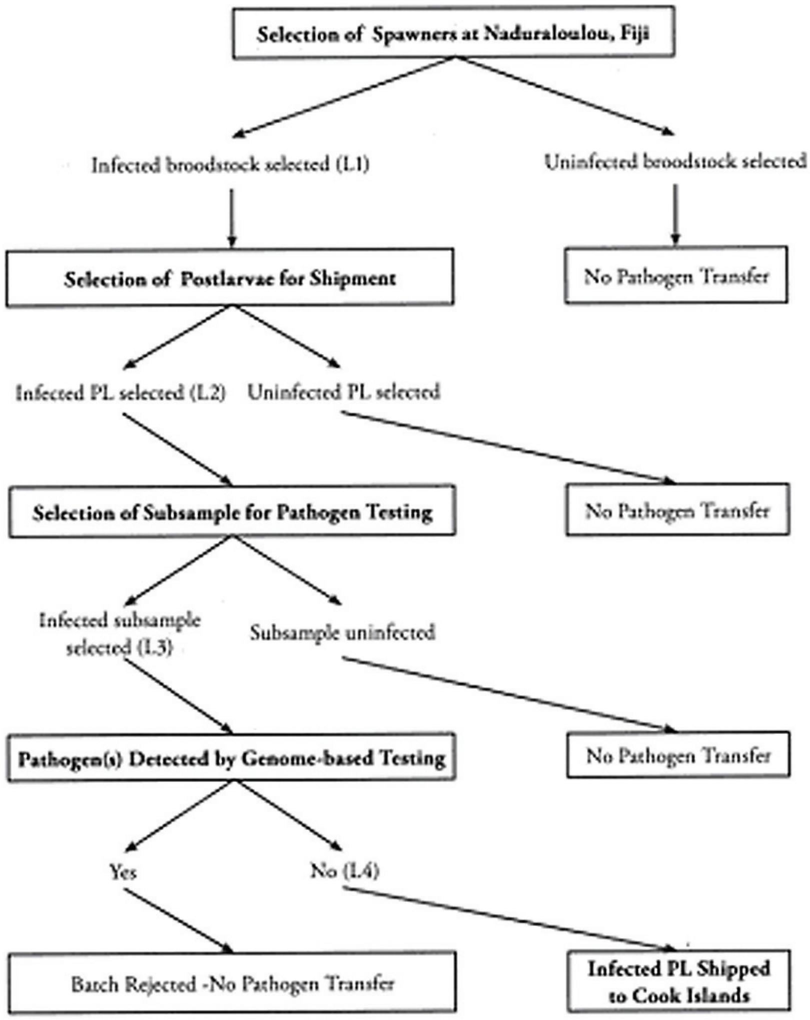

Figure 1. Example of potential exposure pathways for movements of live *Macrobrachium rosenbergii* larvae to the Cook Islands (modified from Arthur *et al.* 2005).

(the unmitigated risk) by combining the likelihood of entry and exposure with the likely consequences of establishment.

To determine whether the risk estimate for each pathogen in the risk assessment is acceptable to the importing country, the concept of a national appropriate level of protection (ALOP) is required. The ALOP (also referred to by its inverse, the “acceptable level of risk”), is the level of protection deemed appropriate by a country establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory (see WTO, 1994). As such, establishing an ALOP is a political, rather than a scientific decision, and must be made at the highest level of government. Where no formal statement of ALOP exists, a country's ALOP can often be defined by review of its import practices for various other (often non-aquatic animal) commodities. In the risk analyses examined, determination of each country's ALOP was often demonstrated using risk estimation matrixes, which can be very useful for rapidly determining whether a country enforces a relatively low ALOP (Table 5) or a relatively high ALOP (Table 6).

Table 5
Risk estimation matrix (low ALOP/high ALOR). The shaded areas indicate situations where the unmitigated risk does not meet the country's ALOP and thus risk management will be required to reduce the risk to an acceptable level.

Estimated Likelihood of Release & Exposure	Estimated Consequences:	Negligible	Low	Moderate	High	Catastrophic
	High	Negligible Risk	Low Risk	Moderate Risk	High Risk	Extreme Risk
	Moderate	Negligible Risk	Low Risk	Moderate Risk	High Risk	Extreme Risk
	Low	Negligible Risk	Very Low Risk	Low Risk	Moderate Risk	High Risk
	Very Low	Negligible Risk	Negligible Risk	Very Low Risk	Low Risk	Moderate Risk
	Negligible	Negligible Risk	Negligible Risk	Negligible Risk	Negligible Risk	Negligible Risk

Table 6
Risk estimation matrix (High ALOP/Low ALOR). The shaded areas indicate situations where the unmitigated risk does not meet the country's ALOP and thus risk management will be required to reduce the risk to an acceptable level.

Estimated Likelihood of Release & Exposure	Estimated Consequences:	Negligible	Low	Moderate	High	Catastrophic
	High	Negligible Risk	Low Risk	Moderate Risk	High Risk	Extreme Risk
	Moderate	Negligible Risk	Low Risk	Moderate Risk	High Risk	Extreme Risk
	Low	Negligible Risk	Very Low Risk	Low Risk	Moderate Risk	High Risk
	Very Low	Negligible Risk	Negligible Risk	Very Low Risk	Low Risk	Moderate Risk
	Negligible	Negligible Risk	Negligible Risk	Negligible Risk	Negligible Risk	Negligible Risk

Risk management

If the country's ALOP is met, the importation can be approved without further action. However, if the risk posed by the commodity exceeds that specified by the ALOP, then additional risk management (otherwise known as risk mitigation) measures are required. For the nine case studies examined here, the risk assessment process determined that the vast majority of potential hazards did not require specific risk management. Only 8.3% of the potential hazards identified in the six single host species risk analyses and 4.6% of the potential hazards identified in the three multi-host species analyses required additional risk management measures to be implemented (Table 7).

Table 7
Results of risk assessment in the nine case studies. Note that the proportion of potential hazards that required risk management was very low.

Risk assessment	No. of hazards in preliminary list	No. of hazards assessed	No. of hazards requiring risk management
Mean for single species risk analyses (6 studies)	43.3 hazards	6.5	3.6 (8.3%)
Mean for multi-species risk analyses (3 studies)	230 hazards	26.3	10.6 (4.6%)

The option evaluation component of the risk mitigation process identifies the efficacy and feasibility of various possible measures available to reduce risks posed by the hazard. Generally, the least restrictive measure(s) found to reduce the risk to an acceptable level are selected.

During option evaluation, the risk analyst attempts to answer the question "What can be done to reduce either the likelihood or the consequences of it going wrong?" (Arthur *et al*., 2004). The process is essentially the same at 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.

For pathogen risk analysis, a wide variety of risk mitigation measures are potentially available to be used singly or in combination. These include pre-export health certification, quarantine (at various levels of stringency, see Arthur *et al.,* 2008), inspection, post-arrival diagnostic testing, vaccination, prophylactic treatments, use of alternate sources (e.g. specific pathogen free stocks, hatchery stocks of known health status), use of different life-cycle stages (e.g. eggs rather than juveniles or adults), or use of various treatments (e.g. cooking or other types of post-harvest processing) that reduce the risk of pathogen transfer to an acceptable level. In the nine case studies examined here, eight of the nine required pre-export disease certification or other similar conditions and seven of nine specified post-arrival quarantine or other restrictions on post-arrival movements, in no instances did the analysts determine that movements of the commodities were impossible

(Table 8). The specific risk mitigation measures recommended understandably varied on a case-by-case basis (Table 2), depending on a wide variety of commodity and country-related factors.

Table 8
Risk management recommendations from the nine case studies

Condition	Frequency of use
Pre-export certification and conditions	8 of 9 studies
Viral testing	6 of 9 studies
Post-arrival conditions/quarantine	7 of 9 studies
No movements possible	0 of 9 studies

Risk communication

One important aspect of the pathogen risk analysis procedure is risk communication, which is the process by which stakeholders are consulted, information and opinions gathered, and risk analysis results and management measures communicated. Risk communication is an essential component of any risk analysis that is conducted or commissioned by a public-sector agency (e.g. Competent Authority) and where multiple stakeholders may be involved. Such risk analyses may involve or have potential impacts upon the mandates and current and/or potential activities of a large number of agencies, organizations and individuals.

For any pathogen risk analysis, primary among the stakeholders that need to be included in communication strategies will be the proponent, the Competent Authorities in the exporting and importing countries, and the risk analysis team. However, there are usually many other entities with an interest in the outcome, the precise agencies, organizations and individuals varying depending on the commodity being considered and its intended use. Key stakeholders should be identified early in the risk analysis process and methods of advising them and seeking input established. The importance of good risk communication throughout the entire risk analysis process cannot be overstressed (Box 1).

Benefits of pathogen risk analyses

In practice, the nine pathogen risk analyses examined in this study proved to be indispensable for identifying potential disease threats, and greatly assisted with development of strategies for managing these risks, generally without undue restriction on the proposed movements of the commodities. In most cases, the risk analysis process also delivered additional benefits, such as highlighting priorities for research in those cases where data were absent or incomplete.

Although the risk analysis process is not science, it is science-based. Well qualified risk analysts are typically scientists who have considerable research experience, and high quality risk analyses utilize large amounts of supporting scientific information based on high-quality research. In many cases drafts of the analyses examined in this study were peer reviewed.

BOX 1

Risk communication case study (Biosecurity New Zealand)

Biosecurity New Zealand recently updated its risk analysis procedures (http://www.biosecurity.govt.nz/files/pests/surv-mgmt/surv/review/revision-to-risk-analysis-procedures-10oct07.pdf). Risk analyses are now released for consultation as *drafts* – with *option*(s) for different levels of intervention and related measures as opposed to *recommended* measures. Feedback will be sought from stakeholders on these options. Risk analyses will then be finalized following this consultation and will present options – refined if appropriate –for the import health standard process to consider. (Measures will only be *recommended* to the Chief Technical Officer for decision once the import health standard process is complete.) Draft and final risk analyses will be signed off by a committee chaired by the Manager of the Risk Analysis team with the Manager, International Co-ordination and Manager of Standards as the other members of the team. Decisions will be made by consensus – if this is not possible then differences will be escalated to the Director Policy and Risk and Director Standards for resolution. Decisions about the content and measures outlined in draft and final risk analyses should be guided by the Decision Making Framework – process and principles – as endorsed by the Biosecurity New Zealand Executive Management Team in March 2007 as well as our domestic and international obligations.

The scientific information used is mainly obtained from the published scientific literature, but unpublished information obtained from colleagues, as well as expert opinion was also used in some instances.

Constraints of pathogen risk analyses for aquatic animals

Of course, the risk analysis process is not perfect. The main constraints to the risk analysis process for aquatic animal pathogens in the studies examined here included:

- a lack of baseline data for hazard identification;
- scarce data on pathogen inactivation and epidemiology;
- uncertainty regarding the ecological consequences of pathogen introduction;
- uncertainty regarding the financial consequences of pathogen introduction;
- inconsistent evaluation of risk between different commodities and analysts;
- inconsistency regarding the appropriate level of protection (ALOP) between different commodities in the same country; and
- regulatory issues, especially in developing countries – (e.g. lack of disease surveillance, lack of competent authority or competent authority lacking expertise and/or diagnostic capacity in the field of aquatic animal health)

A key reason for the large amount of uncertainty that is seen during many risk analyses is the general lack of basic knowledge on the epidemiology and pathogens of aquatic animals, particularly for ornamental fishes and less commonly traded species, and especially for commodities originating from developing countries.

Are the objectives of pathogen risk analysis being met in the real world?
From the case studies reviewed here, we consider that the answer to this question is Yes, most of the time. The three main objectives of pathogen risk analysis are to minimize risk of transfers of serious pathogens and diseases between trading partners, to justify application of sanitary measures (e.g. restrictions on species and/or sources of origin, health certification requirements, quarantine, treatment) and to minimize restrictions to trade. As none of the studies examined here determined that the proposed movements of the commodities were impossible, the key criteria of minimizing restrictions to trade would appear to have been achieved. However, there have been suggestions by some authors that implementation of a precautionary approach in some instances may result in adoption of more restrictive sanitary (risk mitigation) measures that may not be justifiable in the absence of additional epidemiological information (mainly related to exposure pathways) for some commodities, such as commodity shrimp (see Flegel, 2009). However, there is also ample evidence that while the risk of transfer of serious pathogens tends to be reduced by the risk analysis process, in some cases they have not been minimized to levels consistent with the high ALOP enforced by some countries (such as Australia and New Zealand) for other commodities such as plants and terrestrial animals (Biosecurity Australia, 2009).

The precautionary principle was defined in Principle 15 of the Rio Declaration (1992) as follows:

Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.

We consider that there is sufficient evidence to warrant use of the precautionary principle during pathogen risk analysis for aquatic animals. This is particularly justifiable for hazard identification and selection of risk mitigation measures, as experience has shown that hazards can still occur even in the absence of disease identification (Gaughan, 2002). A classic example of the latter problem is the emergence of a novel herpesvirus that caused massive epizootics in Australian pilchards (*Sardinops sagax*) in 1995 and 1998 (Whittington *et al*., 1997, Hyatt *et al.,* 1997). Both epizootics extended over 7 700 km of coastline (Murray *et al.* 2003), radiating outwards from a 250 km stretch of coastline where intensive tuna ranching operations were feeding many thousands of tonnes of imported frozen baitfish (including *Sardinops* sp.) annually. Strong association of the disease outbreaks with the tuna farming process is suggested by the fact that the statistical likelihood of both epizootics randomly originating within the same 250 km stretch is 0.001 (Gaughan, 2002). Available evidence now suggests that the pilchard herpesvirus was a novel exotic pathogen that is now endemic in Australia (Whittington *et al.,* 2008), having been introduced into the country via importation of frozen baitfish for use as aquaculture feed (Gaughan, 2002).

A precautionary approach to the hazard identification process also might have prevented a potential incursion of exotic disease with proposed movements of juvenile kingfish (*Seriola lalandi*) from Australia to New Zealand (Diggles, 2002). While nodavirus infections had never been recorded in the literature from *Seriola* spp., the precautionary approach to the hazard identification process used in that risk assessment considered that hatchery-reared juvenile kingfish may be susceptible to nodavirus strains (as well as other viruses) endemic to Australia (Diggles, 2002). Polymerase chain reaction (PCR) testing for nodavirus was subsequently included as part of the import health standard for movements of juvenile kingfish from Australia to New Zealand, and positive test results for nodavirus (Australian bass strain) were subsequently obtained from several pools of fish sampled from the proposed shipment (Crane, 2004), halting the translocation. From this, it appears that possible introduction of a pathogen previously unrecorded from New Zealand, and most significantly, also previously unrecorded from kingfish, was avoided mainly due to use of a precautionary approach to hazard identification and risk mitigation during the risk analysis process.

Further evidence that the precautionary principal is justifiable during selection of risk mitigation measures comes directly from another of the risk analyses examined in this paper (live ornamental fishes into Australia, AQIS, 1999). There is proof that despite the recommendations of that analysis, the pre-export conditions, border protection and post-arrival quarantine procedures used for live ornamental fishes in Australia remain inadequate (Whittington and Chong, 2007) and do not meet Australias ALOP (Biosecurity Australia, 2009). This has been evidenced by documentation of arrival of diseased fish into quarantine, escape of exotic pathogens from quarantine into the ornamental fish retail sector (Humphrey, 1995a, 1995b; Evans and Lester, 2001; Go *et al.,* 2005; Chong and Whittington, 2005; Go and Whittington, 2006; Corfield *et al.,* 2007) and establishment in the wild of many exotic freshwater fishes (together with their parasites and pathogens) in many parts of Australia (Humphrey and Ashburner, 1993; Lintermans, 2004; Corfield *et al.,* 2007).

CONCLUSION

Risk analysis allows for uncertainty of scientific knowledge, and for pathogen risk analyses for aquatic animals in particular, we consider that the use of the precautionary principle can be justified. This is because in most instances, critical epidemiological information is either scarce or simply not available. There are at least four points where the precautionary principle may come into play:

- during the hazard identification process;
- throughout the risk analysis process, when "cautious interim measures" are needed 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 may reveal 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.

Through applying the precautionary principle, importing countries are permitted the time needed to address any important information gaps where research is needed to support sound decision-making. For the latter course of action, the risk analysis process itself also provides other important benefits, such as highlighting priorities for research in those cases where data are absent or incomplete.

REFERENCES

AQIS. 1999. Import risk analysis on live ornamental finfish. Australian Quarantine and Inspection Service, July 1999. Canberra, 172 pp.

Arthur, J.R. 2008. General principles of the risk analysis process and its application to aquaculture, pp. 3-8. *In* Bondad-Reantaso, M.G., Arthur J.R., and Subasinghe, R.P. (eds.). Understanding and applying risk analysis in aquaculture. *FAO Fisheries Technical Paper* No. 519, Rome, FAO.

Arthur, J.R., Bondad-Reantaso, M.G., Baldock, F.C., Rodgers, C.J. and Edgerton, B.F. 2004. Manual on risk analysis for the safe movement of aquatic animals (FWG/01/2002). APEC/DoF/NACA/FAO, APEC Publ. No. APEC#203-FS-03, 159 pp. (available at: http://www.apec.org/content/apec/publications/free_downloads/2004.html).

Arthur J.R., Bondad-Reantaso, M.G. and Subasinghe, R. 2008. Procedures for the quarantine of live aquatic animals. A manual. *FAO Fisheries Technical Paper* No. 502, Rome, FAO, 74 pp. (available at: http://www.fao.org/docrep/010/i0095e/i0095e00.htm)

Arthur, J.R., Hurwood, D., Lovell, E.R., Bondad-Reantaso, M.G. and Mather, P.B. 2005. Pathogen and ecological risk analysis for the introduction of giant river prawn, *Macrobrachium rosenbergii*, from Fiji to the Cook Islands. SPC Aquaculture Technical Papers. Secretariat of the Pacific Community, Aquaculture Section, Noumea Cedex, New Caledonia, August 2004, 58 pp. (available at: http://www.spc.int/aquaculture/site/publications/documents/MacrobrachiumRosenbergii1.pdf).

Biosecurity Australia. 2009. Importation of freshwater ornamental fish: review of the biosecurity risks associated with gourami iridovirus and related viruses. Draft import risk analysis report, March 2009. Biosecurity Australia, Canberra, Australia. Available at: http://www.daff.gov.au/__data/assets/pdf_file/0019/1056511/2009-06a_Ornamental_finfish_draft_report.pdf

Biosecurity New Zealand. 2005. Import risk analysis: Ornamental fish and marine invertebrates from all countries to New Zealand. Biosecurity NZ, Ministry of Agriculture and Forestry, Wellington, 264 pp.

Biosecurity New Zelaand. 2006. Import risk analysis: Freshwater prawns *Macrobrachium rosenbergii* from Hawaii. Biosecurity NZ, Ministry of Agriculture and Forestry, Wellington, 63 pp. (available at: http://www.biosecurity.govt.nz/pests-diseases/animals/risk/prawns-ra.htm).

Bondad-Reantaso, M.G. and Arthur, J.R. 2008 Pathogen risk analysis in aquaculture production. *In* Bondad-Reantaso, M.G. Arthur, J.R. and Subasinghe, R.P. (eds.). Understanding and applying risk analysis in aquaculture. *FAO Fisheries Technical Paper* No. 519, Rome, FAO, 304 pp. (available at: http://www.fao.org/docrep/011/i0490e/i0490e00.htm)

Bondad-Reantaso, M.G., Lovell, E.R., Arthur, J.R., Hurwood, D. and Mather, P.B. 2005. Pathogen and ecological risk analysis for the introduction of blue shrimp, *Litopenaeus stylirostris* from Brunei Darussalam to Fiji. SPC Aquaculture Technical Papers. Secretariat of the Pacific Community, Aquaculture Section, Noumea Cedex, New Caledonia, August 2004, 80 pp. (available at: http://www.spc.int/aquaculture/site/publications/documents/Stylirostris_BruneiFiji.pdf).

Chong, R. and Whittington, R.J. 2005. A review of Australian ornamental fish import risk management for the period 1999-2004. A report to the National Aquatic Animal Health Technical Working Group (NAAH-TWG) August 2005, 106 pp. (available at: http://www.scahls.org.au/NAAH-TWG/docs/ornimental_fish-risk.pdf).

Corfield, J., Diggles, B., Jubb, C., McDowall, R.M., Moore, A., Richards, A. and Rowe, D.K. 2007. Draft final report for the project 'Review of the impacts of introduced aquarium fish species that have established wild populations in Australia'. Prepared for the Australian Government Department of the Environment and Water Resources, 278 pp. (available at: http://www.environment.gov.au/biodiversity/invasive/publications/pubs/wild-aquarium-fish.pdf).

Crane, M. 2004. Diagnostic Specimen Testing Report SAN: 04-3116. Virology (IPNV and RSIV exclusion) for export certification of *Seriola lalandi* to New Zealand, including VNN PCR. Australian Animal Health Laboratory (AAHL) report. 9 November 2004. 2 pgs. Report available from BKD upon request.

Diggles, B.K. 2002. Import risk assessment: Juvenile yellowtail kingfish (*Seriola lalandi*) from Spencer Gulf Aquaculture, South Australia. NIWA Client report WLG 2001/03, July 2002. Prepared for Island Aquafarms Ltd., 54 pp. (available at: http://www.maf.govt.nz/biosecurity/pests-diseases/animals/risk/yellowtail-kingfish-ra.pdf).

Diggles, B.K. 2007a. Scientific submission to AQIS supporting an application for an import permit allowing entry of whole, round menhaden (*Brevoortia tyrannus*) for use as lobster bait. DigsFish Services Client Report DF07-01. January 2007, 39 pp.

Diggles, B.K. 2007b. Risk assessment for translocation of Pacific oyster (*Crassostrea gigas*) seed spat from shellfish culture sites in Tasmania into NSW. DigsFish Services Client Report DF07-09. August 2007, 37 pp. Confidential client report, contact BKD for details.

Evans, B.B. and Lester, R.J.G. 2001. Parasites of ornamental fish imported into Australia. *Bulletin of the European Association of Fish Pathology,* 21:51-55.

FAO. 1995. Code of conduct for responsible fisheries. Rome, FAO, 41 pp. (available at: ftp://ftp.fao.org/docrep/fao/005/v9878e/v9878e00.pdf).

FAO/NACA. 2000. The Asia regional technical guidelines on health management for the responsible movement of live aquatic animals and the Beijing consensus and implementation strategy. FAO Fisheries Technical Paper No. 402, Rome, FAO, 53 pp. (available at: http://www.fao.org/DOCREP/005/X8485E/X8485E00.HTM).

Flegel, T.W. 2009. Review of disease transmission risks from prawn products exported for human consumption. *Aquaculture,* 290:179-326.

Gaughan, D.J. 2002. Disease-translocation across geographic boundaries must be recognized as a risk even in the absence of disease identification: the case with Australian *Sardinops*. *Reviews in Fish Biology and Fisheries,* 11:113-123.

Go, J., Lancaster, M., Deece, K., Dhungyel, O. and Whittington, R.J. 2005. Molecular epidemiology of iridovirus infection in Murray cod and ornamental fish. Abstract, FRDC Aquatic Animal Health Subprogram Scientific Conference Proceedings, Cairns, 26-28 July, 2005.

Go, J. and Whittington, R. 2006. Experimental transmission and virulence of a megalocytivirus (family Iridoviridae) of dwarf gourami (*Colisa lalia*) from Asia in Murray cod (*Maccullochella peelii peelii*) in Australia. *Aquaculture* 258:140-149.

Humphrey, J.D. 1995a. Australian quarantine policies and practices for aquatic animals and their products: a review for the Scientific Working Party on Aquatic Animal Quarantine, Part 1: Review and Annexes, Bureau of Resource Sciences, Canberra.

Humphrey, J.D. 1995b. Australian quarantine policies and practices for aquatic animals and their products: a review for the Scientific Working Party on Aquatic Animal Quarantine, Part 2: Appendices. Bureau of Resource Sciences, Canberra.

Humphrey, J.D. and Ashburner, L.D. 1993. Spread of the bacterial fish pathogen *Aeromonas salmonicida* after importation of infected goldfish, *Carassius auratus*, into Australia. *Australian Veterinary Journal,* 70:453–454.

Hyatt A.D., Hine P.M., Jones, J.B., Whittington, R., Kearns, G., Wise, T.G., Crane, M.S. and Williams, I.M. 1997. Epizootic mortality in pilchards *Sardinops sagax neopilchardus* in Australia and New Zealand in 1995. II. Identification of a herpesvirus in the gill epithelium. *Diseases of Aquatic Organisms* 28:17-29.

ICES. 2005. ICES code of practice for the introductions and transfers of marine organisms 2005. International Council for the Exploration of the Sea, Copenhagen, 30 pp. (available at: http://www.ices.dk/reports/general/2004/ICES%20Code%20of%20Practice%202005.pdf).

Lintermans, M. 2004. Human-assisted dispersal of alien freshwater fish in Australia. *New Zealand Journal of Marine and Freshwater Research* 38:481-501

MacDiarmid, S.C. 1997. Risk analysis, international trade, and animal health. p. 377-387. In Fundamentals of risk analysis and risk management. CRC Lewis Publ., Boca Raton.

Murray, N. 2002. Import Risk Analysis. Animals and animal products. New Zealand Ministry of Agriculture and Forestry, Wellington, 183 pp.

Murray, A.G., O'Callaghan, M. and Jones, J.B. 2003. A model of spatially evolving herpesvirus epidemics causing mass mortality in Australian pilchard *Sardinops sagax*. *Diseases of Aquatic Organisms* 54:1-14.

OIE. 2008. *Aquatic animal health code*, Section 1.4, Risk analysis. (available at: http://www.oie.int/eng/normes/fcode/a_summry.htm).

Rio Declaration. 1992. United Nations Conference on Environment and Development, Rio, 1992.

Rodgers, C.J. 2004. Risk analysis in aquaculture and aquatic animal health. p. 59-64. *In* Arthur, J.R. and Bondad-Reantaso, M.G. (eds.) Capacity and awareness building on import risk analysis (IRA) for aquatic animals. Proceedings of the Workshops held 1-6 April 2002 in Bangkok, Thailand and 12-17 August 2002 in Mazatlan, Mexico. APEC FWG 01/2002, NACA, Bangkok.

Stone, M.A.B, MacDiarmid, S.C. and Pharo, H.J. 1997. Import health risk analysis: salmonids for human consumption. Ministry of Agriculture Regulatory Authority, New Zealand, Wellington, 269 pp.
Whittington, R.J. and Chong, R. 2007. Global trade in ornamental fish from an Australian perspective: The case for revised import risk analysis and management strategies. *Preventative Veterinary Medicine,* 81:92-116.
Whittington, R.J., Crockford, M., Jordan, D. and Jones, J.B. 2008. Herpesvirus that caused epizootic mortality in 1995 and 1998 in pilchard, *Sardinops sagax neopilchardus* (Steindachner), in Australia is now endemic. *Journal of Fish Diseases*, 31:97-105.
Whittington, R.J., Jones, J.B., Hine, P.M. and Hyatt, A.D. 1997. Epizootic mortality in pilchards *Sardinops sagax neopilchardus* in Australia and New Zealand in 1995. Pathology and epizootiology. *Diseases of Aquatic Organisms,* 28:1-16.
Wilson, D. 2001. The appropriate level of protection. p. 159-164. *In* Quarantine and market access – playing by the WTO rules, a forum held in Canberra, 6-7 September 2000. Canberra, Australia.
WTO. 1994. Agreement on the application of sanitary and phytosanitary measures. p. 69-84. In The results of the Uruguay Round of multilateral trade negotiations: the legal texts. General Agreement on Tariffs and Trade (GATT), World Trade Organization, Geneva.