Pathogen Risk Analysis for Biosecurity and the Management of Live Aquatic Animal Movements[1]

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ABSTRACT

This paper presents a brief introduction to the risk analysis process as applied to the transboundary movement of live aquatic animals and experience from some recent risk analyses, and briefly examines some of the current problems and issues. The use of risk analysis as a practical method to assist developing countries in assessing and minimizing pathogen risks associated with proposed introductions and transfers of live aquatic animals is emphasized. Risk analysis for aquatic animal biosecurity is the process of identifying and estimating the level of risk that is posed by a proposed transboundary movement of aquatic animals, and determining the risk management (sanitary) measures that are needed to reduce the risk to a level acceptable to the importing country. Although this is a relatively new field, and only a few countries have much experience in this area, the risk analysis process need not be overly complicated, particularly for developing country situations where expertise and resources may be limited. Countries must determine the risk analysis methods that are most effective and cost efficient for their

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[1] This paper is dedicated to the memory of Chris Baldock, our good friend, colleague and team member.

particular circumstances, taking into consideration that the process needs to be science-based, systematic, iterative, consistent, timely and transparent. The research community plays an essential role in supporting good risk analysis through conducting basic research on the pathogens, parasites and diseases of the main aquatic species cultured and traded, including studies on their taxonomy, life cycles, host and geographic distributions, pathogenicity and epidemiology. Individual risk analyses may show gaps in knowledge that necessitate well-defined, applied research. Scientists should also serve as experts on risk analysis working groups and provide independent expert review of draft risk analyses. They also have a role to play in educating policy-makers as to the potential adverse socio-economic impacts to national aquaculture, fisheries and aquatic biodiversity that may occur due to epizootic transboundary pathogens.

INTRODUCTION

Live aquatic animals are traded internationally for many reasons, the foremost being for the ornamental fish trade, for aquaculture development and sustainment, and for live food markets. They are also less frequently transported across international borders for the development of capture and sport fisheries, for use as bait, as biological control agents and for research (Arthur, 2004; Subasinghe and Bartley, 2004). They may also be moved unintentionally via a number of mechanisms, such as in the ballast water of ships, via water diversion schemes for hydroelectric power and irrigation, and through the release of unused bait by fishermen.

The international trade in ornamental fishes involves more than 2,000 species (Khan *et al*., 1999; Davenport, 2001), and the movement of hundreds of millions of fish annually. For example, the Ornamental Aquatic Trade Association (OATA) reports that approximately 20 coldwater species, up to 1000 tropical freshwater species, and more than 1000 tropical marine species of ornamental aquatic animal are imported annually into the United Kingdom.[2] Malaysia, which is one of the main exporters of aquarium fishes in Asia, produced some 338 million freshwater ornamental aquatic organisms in 2001, including some 293 million freshwater fish belonging to more than 90 species (Latiff, 2004).

Although the top five exporting countries are Singapore, Hong Kong China, the United States, the Netherlands and Germany (Davenport, 2001), freshwater ornamental fish are raised in many countries around the world, often by relatively small-scale producers. The culture and trade of aquarium fishes is an important source of foreign exchange earnings for some countries. For example, 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. In 2003, Singapore exported ornamental fishes worth more than $US 42.3 million (Ling, Kueh and Poh, 2004).

The aquarium fish trade involves a high amount of transshipment, which often masks the country of origin of individual shipments and species. For example, in 1988, 84.3% of

[2] http:\\www.ornamentalfish.com.

Malaysia's total aquarium fish production was exported via Singapore (Siow and Nagaraj, 1989). Of the US$57 million worth of ornamental fishes exported by Singapore in 2003, the country's 68 ornamental fish farms produced less than half of this total (about 44%) (Ling, Kueh and Poh, 2004).

The tropical aquarium fish industry is characterized by a resistance to regulation, and the complexity of the trade often makes guarantees of disease status difficult or impossible. Diseases of ornamental fishes have not received the detailed attention they deserve; however, the few surveys that have been conducted have shown the presence of a wide variety of pathogens and parasites, some of which are of importance as disease agents of cultured and wild fishes or as human pathogens (e.g., Low, Singh and Tan, 1987; Korting, Fuchs and Michel, 1990; Lumanlan *et al*., 1992; Hedrick and McDowell, 1995; Tampieri *et al.,* 1999; Manfrin *et al.,* 2002). The most serious of these is undoubtedly koi herpes virus disease (KHVD), which has recently caused major losses of common carp cultured for food in Japan and Indonesia (Sano *et al.,* 2004, Sunarto *et al.,* 2004, Iida *et al.,* 2005, Sunarto and Cameron, 2005).

Movements of live aquatic animals for aquaculture development involve the shipment of gametes or fertilized eggs; fry, fingerlings or spat; and of broodstock. The movement of eggs and gametes is recommended by international codes of practice for species introductions (e.g., the International Council for the Exploration of the Sea (ICES), and the European Inland Fisheries Advisory Commission (EIFAC)), as it generally involves a lower risk of pathogen transfer (Turner, 1988; ICES, 2004).

Fry, fingerlings and spat of aquatic animals are frequently moved across international borders, particularly in Asia and Latin America. This trade often involves large numbers of an individual species (e.g., prawn postlarvae, oyster spat). Such movements are characteristic of new industries, those hampered 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). An example of the magnitude of this trade is given by Hossain (1997), who estimated that in 1995, 50 million nauplii and postlarvae of giant tiger prawn were imported into Bangladesh, primarily from Thailand, India and Myanmar, to support the country's developing prawn culture industry. Such movements can pose an extremely high risk of pathogen transfer and many serious transboundary pathogens are known or suspected to have been introduced to new geographic areas due to the careless movement of aquatic animals for aquaculture development (Bondad-Reantaso, 2004; Bondad-Reantaso *et al.,* 2005).The international movement of broodstock is less frequent and typically involves only a few animals at a time. Such movements are common in commercial aquaculture of species where there is a high industry dependency on wild-caught broodstock (e.g., prawns), for new aquaculture species, and in circumstances where producers avoid delays in aquaculture start-up due to the time needed for maturation of juveniles to broodstock. These movements often involve a high risk of pathogen transfer.

Examples of fish, crustaceans and molluscs traded to supply live food markets include the movement of live oysters from producing countries to consuming countries (e.g., to Europe, North America, South Africa); and the intra-regional trade in Asia involving live finfish and shellfish (e.g., grouper, seabass, shrimp, cockles, etc.) for consumption in seafood restaurants. Grouper fry, for example, are collected mainly from the wild in developing countries such as Sri Lanka, the Philippines, Thailand and Indonesia (Arthur and Ogawa, 1996). They are shipped to countries such as Singapore, Malaysia and China (Hong Kong) for grow-out in cages. Market-sized fish are then consumed locally or shipped to restaurants in Singapore, Hong Kong, Taiwan and mainland China.

Given the volume of live aquatic animals traded internationally and the diversity of species moved, countries have often found themselves in a difficult position in attempting to find methods that reduce the risk of spreading transboundary pathogens that could seriously impact their domestic aquaculture industries and aquatic biodiversity, while at the same time wanting to increase the benefits of trade in live aquatic species and their products. This is particularly the case for the developing countries in Asia, which often lack the necessary expertise, capacity, policy, legislation and financial resources to adequately manage transboundary disease risks.

THE ROLE OF PATHOGEN RISK ANALYSIS

In the context of aquatic animal health, pathogen risk analysis (also termed "import risk analysis") is a structured process for analyzing 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 encompasses or combines the elements of likelihood and impact.

A pathogen risk analysis seeks to answer the following questions:

1) What serious pathogens could the commodity be carrying? (Addressed by the **hazard identification** portion of risk analysis, which answers the general question "What can possibly go wrong?");
2) For each pathogen that could potentially be carried by the commodity, what are the chances that the pathogen will enter the importing country and that susceptible animals in natural waters or aquaculture facilities will be exposed to infection? (Addressed by the **release assessment** and **exposure assessment** portions of **risk assessment**, answering the question "How likely is it to go wrong?");
3) For each pathogen, what are the likely biological and socio-economic impacts of susceptible animals in the importing country becoming exposed to the pathogen? (Addressed by the **consequence assessment**, which answers the question "What would be the likely consequences of it going wrong?");
4) If the importation is permitted without restrictions, then what is the overall risk associated with each pathogen? (Addressed by the **risk estimation** portion of the **risk assessment**);
5) Is the risk determined for each pathogen in the risk assessment acceptable to the importing country? (Addressed by the **risk evaluation** section of **risk management**); and

6) Can the commodity be imported in such a way that the risk is reduced to an acceptable level? (Addressed by the **option evaluation**, **implementation, monitoring and review** portions of risk management, which answer the question "What can be done to reduce either the likelihood or the consequences of it going wrong?") (MacDiarmid, 1997; Rodgers, 2004; Arthur *et al*., 2004a; Murray *et al*., 2004; OIE, 2005).

The strength of risk analysis is that it is provides a clearly defined framework for a structured, repeatable process, thereby removing to a large extent, *ad hoc* and arbitrary decision-making with regards to requests to import aquatic animals and their products. An important feature is that the process can make use of pathway analysis. Through scenario diagrams, the possible routes (pathways) and the individual events or steps in each pathway that need to occur for a given pathway to be successfully completed can be identified. This approach assists by providing a logical process by which the critical risk steps (events) leading to pathogen introduction and establishment in an importing country can be identified. This allows for the probability of each event occurring to estimated, leading to an overall estimate of the probability of a given pathway being completed. Further, pathway analysis can be used to gauge the effectiveness of a risk mitigation measure or combinations of measures, as each measure can be incorporated into the pathway analysis, and the overall risk recalculated to see if the risk has been reduced to an acceptable level. Pathway analysis also allows for sensitivity analysis; that is, it allows for identifying those pathway steps that most influence the final risk estimation for a particular pathogen. This can help in targeting risk mitigation measures, as well as in identifying those areas where information needs are most critical, if highly sensitive pathway steps are associated with a degree of uncertainty or subjectivity.

Another strength is that the risk analysis process is based on science and has transparency; thus points where subjective decisions enter the process can be recognized. The transparency comes both from having a structured and defined process that is understood by all, and also from extensive stakeholder consultation, which is an essential component of any risk analysis. Importantly, risk analysis is an internationally accepted method that permits importing countries 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. Finally, risk analysis allows for uncertainty of scientific knowledge; through applying 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.

Risk analysis, of course, is only one of a large number of components in a national aquatic animal health strategy (FAO/NACA, 2000; Arthur *et al.,* 2004a). It cannot function effectively unless other components of the national strategy have also been developed. In addition to appropriate legislation and policy, and the means to implement them, these include capacity in areas such as diagnostics, quarantine and inspection services, disease surveillance and monitoring, reporting, enforcement and contingency planning. One of the major challenges to developing countries is how to develop or have access to these areas of technical capacity.

THE RELATIONSHIP OF PATHOGEN RISK ANALYSIS TO ECOLOGICAL AND GENETIC RISK ANALYSES[3]

Often, an importing country will be confronted with a first request to import a live aquatic animal that is a non-native (exotic) species. In cases where the importation involves the intentional introduction of an exotic species into the natural environment or is for commercial aquaculture development (with perhaps inevitable escape into the wild), the first question that must be asked is "Is the species likely to establish wild populations in the new environment?" and, if so, "What will be the environmental, social and economic impacts of its establishment?" These questions can be explored by conducting an ecological risk analysis, the results of which will provide the Competent Authority with a scientific basis for deciding if an importation should be allowed. Of course, national policy on exotic species will also come into play. Some countries, such as Australia and New Zealand, place a very high priority on protecting natural biodiversity, the integrity of native ecosystems and domestic aquaculture industries from exotic pathogens, and thus treat the introduction of any exotic species with great caution. For various reasons, such as the absence of suitable native species for aquaculture or capture fisheries enhancement, or the prior degradation of native ecosystems, many countries may consider introduction of new species. In the case of requests to import new strains of native or previously introduced aquatic animals, there may be potential for undesirable genetic impacts. In these cases, a genetic risk analysis can be undertaken to help governments evaluate the associated risks (ICES, 2004).

Pathogen risk analysis does not deal with the question of whether or not the introduction of an exotic species, per se, is desirable. Rather, it seeks to answer the question "Does the aquatic animal or its product, as characterized in the commodity description, pose an unacceptably high risk of pathogen introduction?" and if so, "What mitigating measures can be applied that will reduce the risk of pathogen introduction to an acceptable level?"

PATHOGEN RISK ANALYSIS AND INTERNATIONAL TRADE

The past two decades have seen major changes in the patterns of world trade, due primarily to the liberalization of international trade through the General Agreement on Tariffs and Trade (GATT) and the creation of the World Trade Organization (WTO) in 1995. 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 any restriction on international trade based on risk to human, animal or plant health that exceeds those measures allowed by international agreement (e.g., those given in the OIE's *Aquatic Animal Health Code*) (WTO, 1994; Rodgers, 2004, Arthur *et al*., 2004a). As a result, risk analysis has become an internationally accepted

[3] The term "pest risk analysis" is widely applied to encompass analysis of the "pestiness" of the commodity species, including any ecological and genetic risks, as well as the potential for introducing any "hitchhiker" species. "Pathogen risk analysis", of course, includes analysis of pertinent aspects of the pathogen's ecology.

standard method for deciding whether trade in a particular commodity (a live aquatic animal or its product) poses a significant risk to human, animal or plant health, and, if so, what measures could be applied to reduce that risk to an acceptable level.

Under the SPS Agreement, the World Organisation for Animal Health (OIE, 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, 2005), outlines the necessary basic steps in the risk analysis process that should be followed; however, the decisions as to the details of the process are left to individual member countries. The OIE has also established voluntary in-house mechanisms for settling disputes between its 167 Member Countries, avoiding the lengthy and often costly procedures involved in bringing a dispute before the WTO.

Although a veterinary organization, the OIE recognizes that in many cases, particularly in developing countries, the responsibility for aquatic animal health matters (Competent Authority) often lies with the national fisheries agency (Department of Fisheries or similar agency). Thus, the OIE plays a central role in encouraging linkages between the national Competent Authority for aquatic animal health and the national veterinary services. The OIE also plays an important role in assisting countries in the risk analysis process through its international aquatic animal disease reporting system[4] by maintaining, through its collaborating center at the Centre for Environment Fisheries and Aquaculture Science (CEFAS), Weymouth Laboratory, United Kingdom, *The International Database on Aquatic Animal Diseases* (http://www.collabcen.net), and through the OIE *Aquatic Animal Health Code* (OIE, 2005) *and Manual of Diagnostics Tests for Aquatic Animals* (OIE, 2003), as well as publications such as *the Handbook on Import Risk Analysis for Animals and Animal Products* (Murray *et al*., 2004; Murray, 2004).

THE ESSENTIAL OBLIGATIONS OF THE EXPORTING COUNTRY, THE IMPORTING COUNTRY AND THE PROPONENTS OF A PROPOSED IMPORTATION

The risk analysis process is based on the premise that trading-partner countries will deal openly and honestly with each other in providing the information essential to making an accurate risk assessment. For the exporting country, this obligation includes providing the importing country with accurate and timely information, as available, on the national disease status, on the disease status of the specific commodity in question, and on the disease history and status of the particular facility and/or stock under evaluation. The exporting country also has an obligation to provide information to assist the importing country in identifying and evaluating the national Competent Authority, including its diagnostics capability, risk communication procedures, national and provincial legislation and policy, procedures for documenting disease occurrences and archiving of diagnostic, surveillance and monitoring data.

[4] http://www.oie.int/eng/maladies/en_alpha.htm

The importing country has an obligation to deal in a timely and efficient manner with requests to import and, as fundamental components of the risk analysis process, to provide adequate communication with all stakeholders (including the proponents and the exporting country) and transparency of process to ensure trading partners that any sanitary requirements or restrictions placed on trade in the commodity are not disguised barriers to trade.

A good risk analysis begins with a clear and accurate picture of the commodity being proposed for importation. Thus, the proponents of a proposed importation have an obligation is to provide the accurate, comprehensive and timely information that is needed on stock history, disease status, etc., so that the importing country has a detailed and accurate commodity description on which to base its risk analysis.

APPROPRIATE LEVEL OF PROTECTION

A country's appropriate level of protection (ALOP) is the level of protection deemed appropriate by the country establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory (WTO, 1994). Determining the ALOP is a political decision made at the highest level of government. In making a decision as to what a country's ALOP should be, politicians must weigh many factors, including the importance its citizens place on 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. It is important to note that the same ALOP must be consistently applied across all commodities – terrestrial animals, aquatic animals and plants. Figure 1 illustrates the concept of ALOP for a country having a very high ALOP (i.e. a very low risk tolerance or Acceptable Level of Risk, ALOR) using a risk estimation matrix combining the likelihood of pathogen entry and exposure with the consequences resulting from entry and exposure.

The importance of ALOP in the risk analysis process is that it is the standard to which the unmitigated risk is compared to determine if the proposed importation poses a risk that is too high (unacceptable to the importing country), and if necessary, the degree to which the risk must be reduced (mitigated risk) in order for importation to occur. The relationship between ALOP and the amount of risk a country is willing to tolerate (the acceptable level of risk) is inverse – the higher the ALOP, the lower the level of risk that is acceptable. Any description of the ALOP, e.g., as being 'very low' or 'moderate', is only relevant to a risk analyst in the context of the framework or method used to measure risk.

From the above, it is clear that, other than perhaps providing occasional advice to senior government officials, a risk analyst has little, if any, role in determining ALOP and indeed, a risk analyst's personal views on the appropriateness of his/her country's ALOP should not have any bearing on the results of a risk analysis.

Consequences of entry and exposure

Likelihood of entry and exposure						
High likelihood	Negligible risk	**Very low risk**	Low risk	Moderate risk	High risk	Extreme risk
Moderate	Negligible risk	**Very low risk**	Low risk	Moderate risk	High risk	Extreme risk
Low	Negligible risk	Negligible risk	**Very low risk**	Low risk	Moderate risk	High risk
Very low	Negligible risk	Negligible risk	Negligible risk	**Very low risk**	Low risk	Moderate risk
Extremely Low	Negligible risk	Negligible risk	Negligible risk	Negligible risk	**Very low risk**	Low risk
Negligible likelihood	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	**Very low risk**
	Negligible impact	***Very low***	***Low***	***Moderate***	***High***	***Extreme impact***

Figure 1. Illustration of ALOP (band of cells marked "very low risk") for a country having a very high level of protection (very low risk tolerance) (modified from Anon., 2001).

OVERVIEW OF THE RISK ANALYSIS PROCESS

The following sections provide only a brief overview of the risk analysis process. More detailed information and guidelines for conducting pathogen risk analyses can be found in MacDiarmid (1997), FAO/NACA (2000, 2001), AFFA (2001), Murray (2002, 2004), Murray *et al.,* (2004), Arthur *et al.,* (2004a), OIE (2005) and the papers contained in Arthur and Bondad-Reantaso (2004). Figure 2 shows the four main components of the OIE risk analysis process and their interrelationships, while Figure 3 outlines the steps in the risk analysis process.

Deciding if a risk analysis is needed

Upon receiving a request to import a specific commodity, the first question the importing country's Competent Authority will ask is "Is a risk analysis needed?" This initial decision will be made taking into account such factors as the nature of the commodity (including any sanitary measures applied), its source, and past knowledge and experience with the commodity, the importing country's competent authority, the source stock and the proponents. In many cases, a similar or identical request to import may have resulted in a risk analysis that has shown the commodity to represent an acceptable risk, and thus approval can be quickly issued. Occasionally, a previous risk analysis may have shown that the commodity represents an unacceptably high level of risk and that the risk mitigation methods available cannot reduce the risk to an acceptable level, so that the request may be

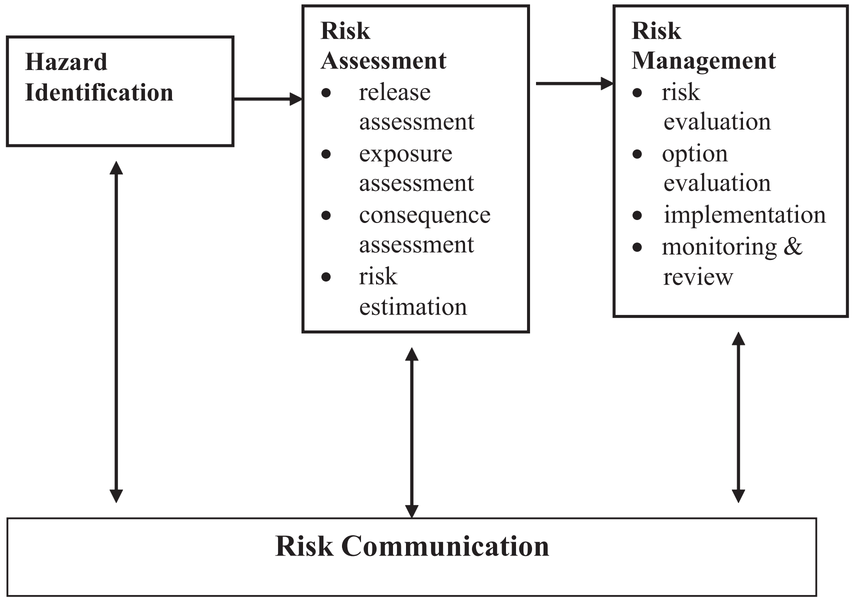

Figure 2. The structure of the OIE risk analysis process (after Murray *et al.*, 2004).

immediately denied. Other requests, such as those involving new species or sources, may require more careful initial evaluation prior to making a decision. In cases where doubt remains as to the level of risk posed by the commodity, a risk analysis is warranted.

Scoping a risk analysis

Having determined that a risk analysis is required, the risk analysis team maintained by the Competent Authority will decide on the type of risk analysis to be conducted and establish a working group with appropriate expertise that will conduct the actual risk analysis. As this decision, and many of those to follow, are based on the commodity description, the importance of a detailed and accurate commodity description cannot be overemphasized. To assist this process, the importing country should provide the exporting country with guidelines and forms for completing a commodity description.

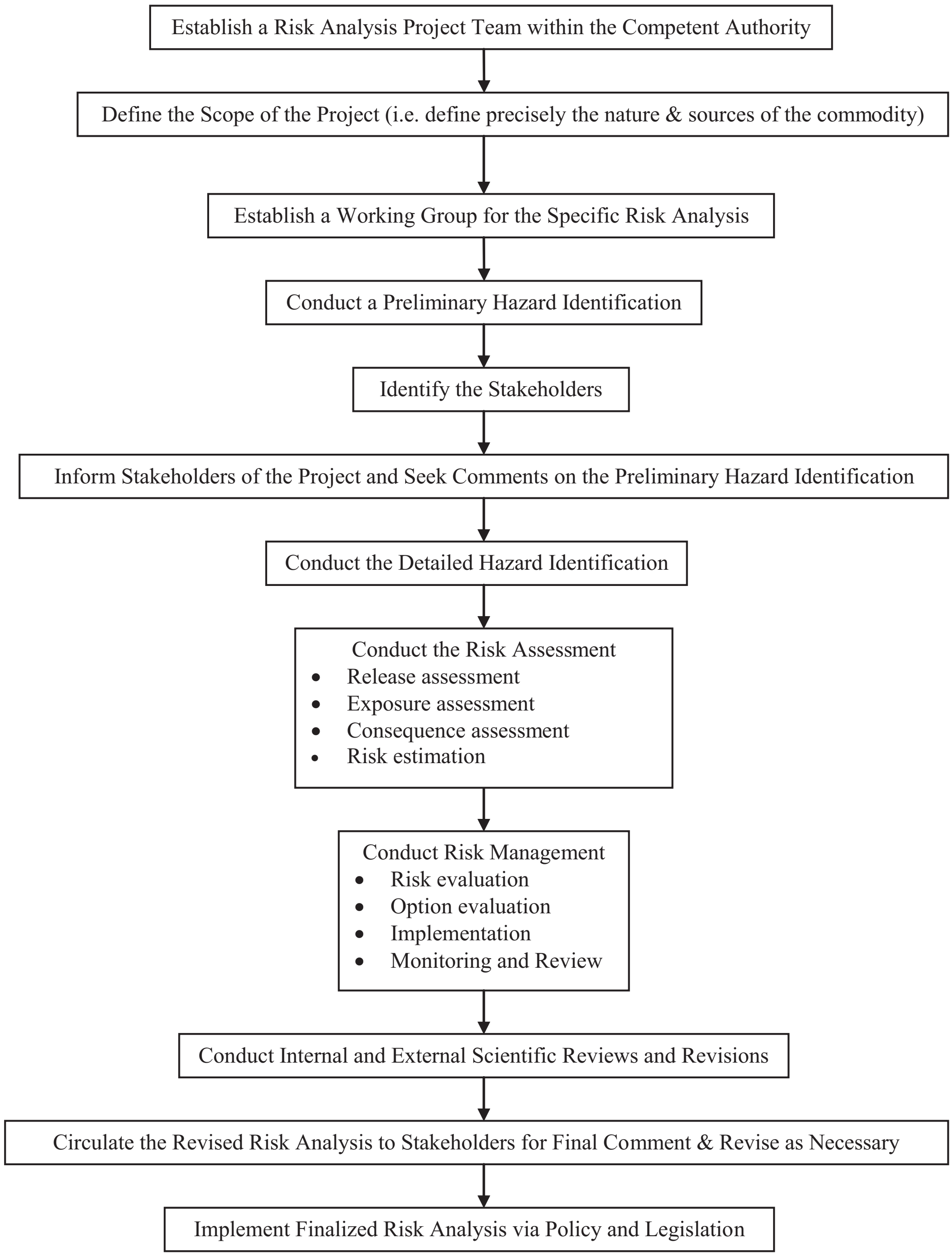

Figure 3. A simplified diagram showing the steps in the Risk Analysis Process (modified from Arthur *et al.*, 2004).

Risk communication

Any risk analysis may involve a large number of agencies, organizations and individuals that have an interest in its outcome. Primary among these will be the proponent, the Competent Authorities in the exporting and importing countries, and the risk analysis team. However, there will be many others 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. An example of a stakeholders list is presented in Box 1. The importance of good risk communication throughout the entire risk analysis process cannot be overstressed.

Box 1. Example of a list of potential stakeholders for a risk analysis involving the importation of a live marine mollusc for aquaculture development. (from Arthur *et al.*, 2004a)

- Oyster farmers
- Oyster traders
- Restaurant owners
- Fish Vendors
- Consumers
- Aquaculturists
- Seafood processors
- Conservationists
- Concerned international, national and local governments and agencies

Deciding on the type of risk analysis to use

In most cases, where the Competent Authority of the importing country has sufficient expertise, the risk analysis will be conducted using a project team drawn internally (an “in-house” risk analysis), often using independent external reviewers from outside the department to maintain quality control and provide additional insights. However, where sufficient internal expertise is lacking, where the risk analysis is likely to generate considerable controversy and thus exceed available manpower, or where the Competent Authority is also the proponent (and thus a real or perceived conflict of interest exists), the use of outside expertise (e.g., a more extensive risk analysis using consultants or other experts) for all or part of the risk analysis process may be desirable.

Risk assessment methodology may range from the purely qualitative to the purely quantitative. In most cases, particularly for developing countries, a qualitative risk analysis will be simplest, quickest and most cost-effective. As will be discussed further below, in conducting a risk assessment, a pathways analysis approach involving the construction of scenario trees to determine the likelihood of a chain of events occurring (for example, the series of events (pathway steps) that need to occur to result in a given shipment of imported fish being infected with a specific pathogen) is useful and preferred approach. Qualitative risk analyses use qualitative estimates of the likelihood of an event happening (e.g., likelihoods can be categorized as being “ low”, “medium” or “high”). These estimates are then combined to give an estimate of the likelihood of a given pathway being completed. Similarly, estimates for successful completion of several pathways are combined to give an overall risk estimate for a given scenario, and scenarios are combined to give a total risk estimate for the individual hazard. Quantitative risk analyses use mathematical probability estimates for events throughout. They can involve a high level of mathematical sophistication and/or computer skills and can be resource intensive in terms of expertise, time and money. However, quantitative risk analyses can help clarify thinking, provide insights into areas where data are lacking, deal with volume of trade issues and improve transparency (Murray, 2002, 2004).

Regardless of the type of risk analysis, a pathways analysis approach to risk assessment and associated construction of pathways diagrams can provide a risk assessment framework that facilitates detailed and transparent examination of the key factors that contribute to the overall risk. While there is a growing body of completed risk analyses for aquatic animals that provide examples of the range of risk analyses from the purely qualitative to the quantitative (see the Annex I of Arthur *et al*., 2004a), there are no universally accepted standards or models. This is probably a good thing, as it allows countries to adapt the risk analysis process to their individual situations, including expertise, manpower and financial resources.

Hazard identification

Hazard identification is the process of determining what pathogens could plausibly be carried by the commodity and then, from this initial list of pathogens, determining those pathogens that pose a serious risk to the importing country. Obviously, the more specific the commodity description and its disease history, and better the knowledge of the disease status of the exporting and importing countries, the easier hazard identification becomes. The most problematic risk analyses involve commodities of unknown health history and status, being exported from countries of poorly known health status to countries of poorly known health status. Unfortunately, this is a situation that often occurs in trade in live aquatic animals and one that may necessitate the application of the precautionary approach. 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;
- it must be plausible that the agent might be present in the exporting country; and
- must be exotic to the importing country (or subject to a control/eradication program in the importing country).

Those OIE-listed diseases that may plausibly be carried by the aquatic animal species proposed for importation present a good starting point in constructing a list of pathogens (hazards) for detailed risk assessment. This list should be augmented with additional disease agents based on nationally and regionally reportable diseases, as well as those diseases described in the scientific literature.

Risk assessment

Risk assessment consists of four components: **release assessment, exposure assessment**, **consequence assessment** and **risk estimation**. In 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, release assessment determines the pathways that a pathogen can move with the commodity from the exporting country to the border of the importing country 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. An example of a hypothetical exposure pathway is presented below (Figure 4). 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 (the unmitigated risk) by combining the likelihood of entry and exposure with the consequences of establishment (Table 1).

Table 1. 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) (from Arthur *et al*., 2004a).

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

Risk Management

Risk management is the process of identifying, selecting and implementing measures that can be applied to reduce the level of risk. In the **risk evaluation** step of risk management, the unmitigated risk estimate for the hazard is compared with the level of risk acceptable to the importing country (based on the national appropriate level of protection (ALOP)). If the 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 risk mitigation measures should be considered. During **option evaluation** possible measures to reduce the risk posed by the hazard 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 at that used during risk assessment, with new scenarios and pathways being constructed that incorporate steps for possible risk mitigation measures

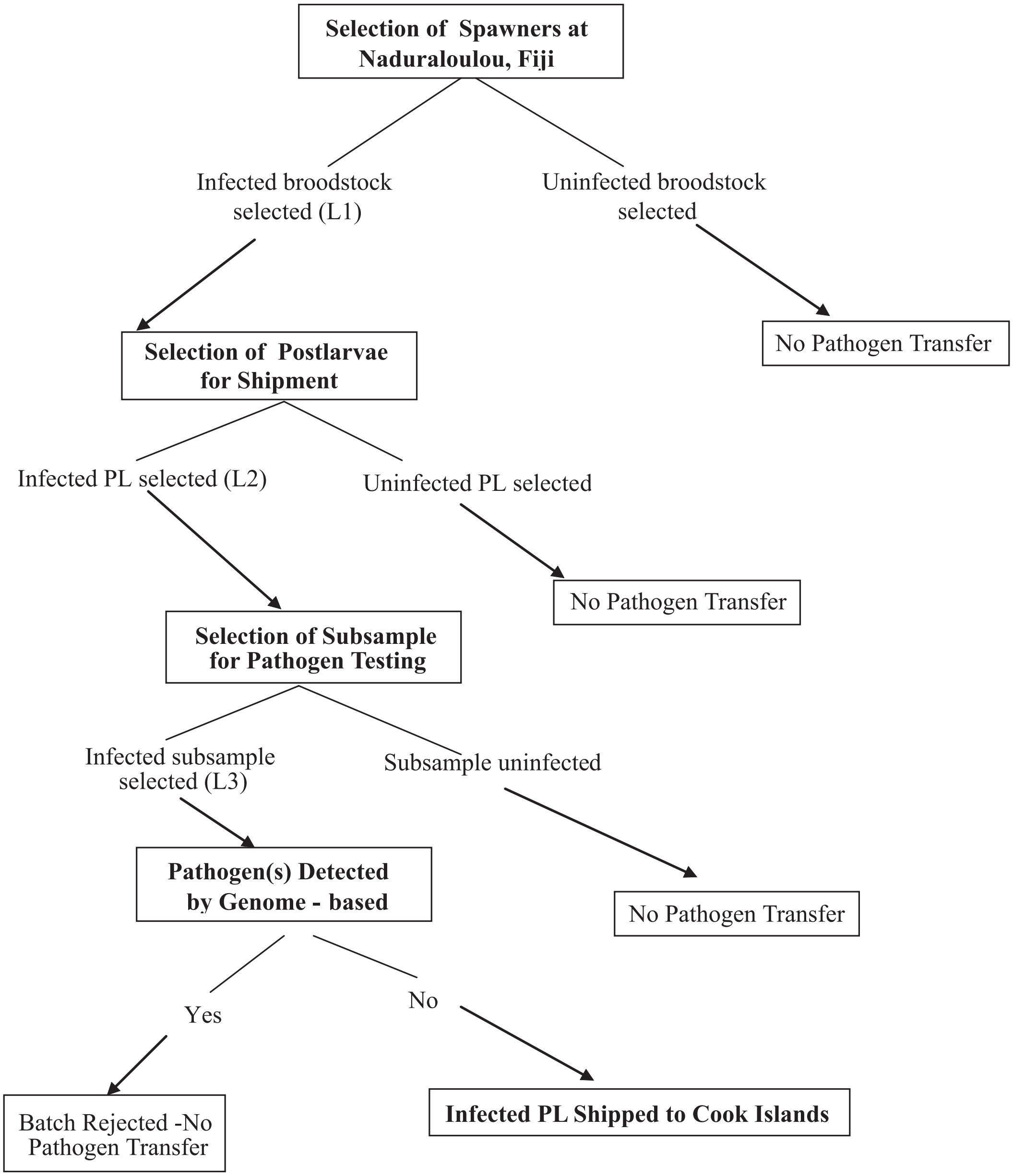

Figure 4. Simplified Pathways Diagram for the release of viral pathogens in *Macrobrachium rosenbergii* postlarvae from Fiji to Cook Islands. Not considered are less probable pathways such as via shipping water or fomites, or failure of the diagnostics tests to detect true positives. In this simplified example, the likelihood that infected PL will be released (LR) is the product of the individual likelihood's = L1 x L2 x L3 x L4. (from Arthur *et al.*, 2004b).

to determine their ability to reduce the overall risk (now the mitigated risk estimate) to an acceptable level. Once effective risk mitigation measures have been identified, the next phase is **implementation, monitoring and review**. In this phase, the requirements for importation, including any mitigation measures, are presented to the Competent Authority of the exporting country (and 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.

Several important principles of the SPS Agreement related to the risk management process are important to keep in mind:

- *Least restrictiveness* - Risk management measures must be applied in the least trade restrictive manner possible. Thus if there are several risk management options that will allow the proponent to meet the importing country's ALOP, the proponent should be able to chose the least burdensome (least trade restrictive) method. .
- *Equivalence of mitigation measures* -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 ALOP.
- *Consistency in application* - The importing country must apply the same ALOP (i.e. accept the same level of risk at both external (international) and internal (national) borders; and the ALOP must be applied consistently across the range of commodities in which the country trades, without prejudice as to the country of origin.

THE PRECAUTIONARY APPROACH

The precautionary approach is widely used in fisheries management and elsewhere where governments must take action based on incomplete knowledge. FAO's *Code of Conduct for Responsible Fisheries* (FAO, 1995) 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."

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

The risk analysis process has at least three points where the precautionary approach may come into play (Figure 5):

- 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.

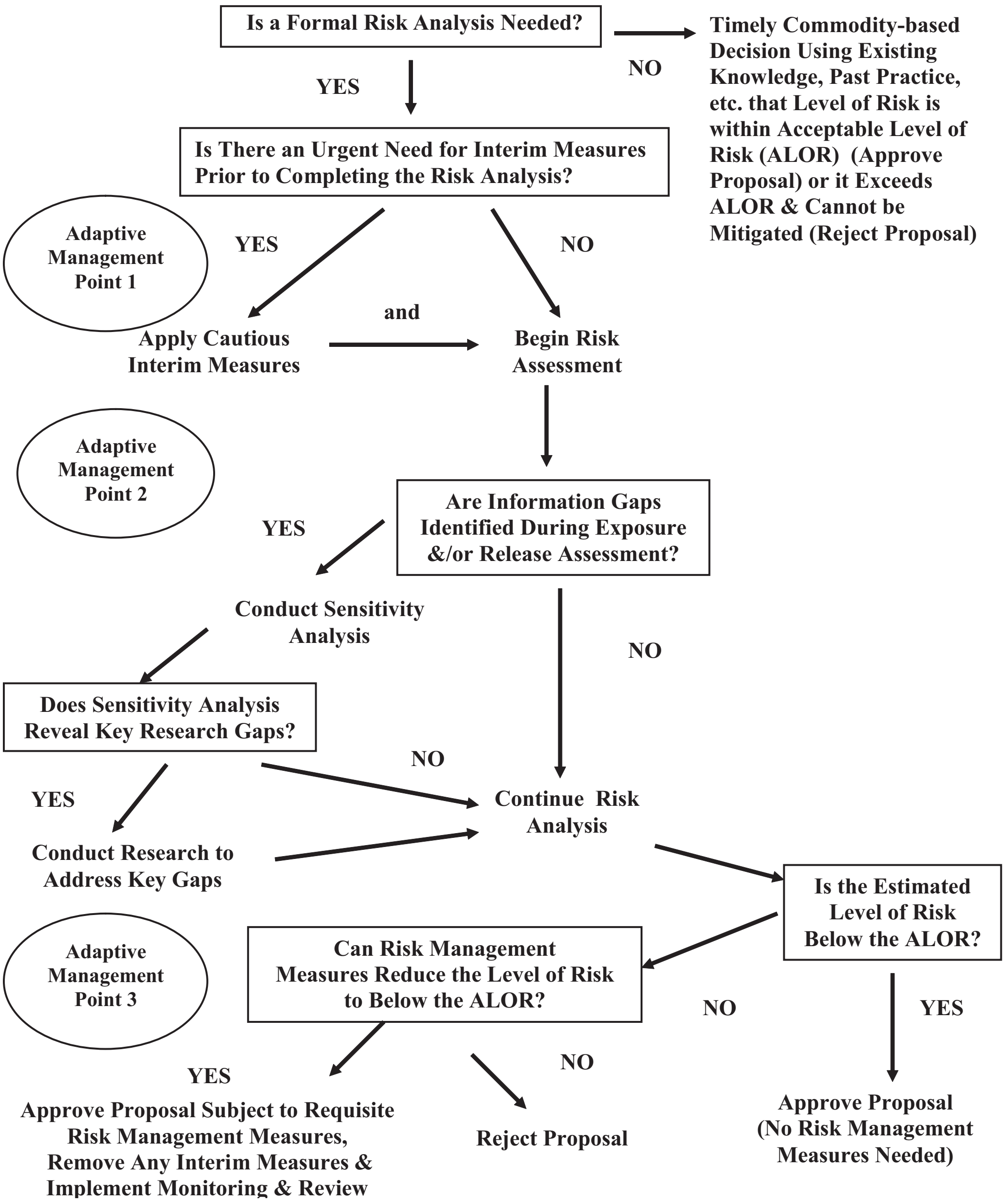

Figure 5. Decision tree for assessment of a proposal to import a commodity showing the use of the precautionary approach through adaptive management.

EXAMPLES OF RECENT RISK ANALYSES FOR AQUATIC ANIMALS

The following section looks briefly at two recent risk analyses conducted by developing countries for the international movement of aquatic species for aquaculture development. The most high profile trade dispute involving risk analyses for an aquatic animal commodity, the Canada-Australia SPS dispute on importations of raw salmon product into Australia that was taken to the World Trade Organization, has been discussed from the perspectives of a risk analyst and a third-party country by Beers (2004) and Amos (2004), respectively. On-line sources for additional risk analyses undertaken by the governments of Australia and New Zealand can be found in Annex I of Arthur *et al.*, (2004a).

Thailand's Risk Analysis for Importation of White Shrimp

Thailand is one of the world's leaders in production of farmed shrimp (estimated production of 300,000 tonnes in 2003; Briggs *et al.*, 2004), and until recently its shrimp aquaculture industry has been based on the culture of the black tiger shrimp (*Penaeus monodon*), a native Asian species. The Thai shrimp culture industry has faced serious problems due to transboundary diseases, environmental degradation and a scarcity of quality broodstock that has affected production capacity. As a result, importation of white shrimp (*Litopenaeus vannamei*) into Thailand for use in aquaculture began in March 2002, and production of this exotic species has increased rapidly, such that during the year 2002-2003, white shrimp contributed an estimated 120,000 tonnes, or approximately 40 percent of the total national shrimp production (Kanchanakhan, 2004). While some importations of broodstock were sourced from specific pathogen free (SPF) stocks in the United States and imported to registered hatcheries under the approval of the Thai Department of Fisheries (DOF), others have involved illegal movement of animals from neighboring countries in the region. As a result of these illegal importations, Thailand experienced it first outbreak of Taura syndrome virus (TSV) in 2003, leading to the drafting of a contingency plan for eradication of the virus (Kanchanakhan, 2004). These developments caused the DOF to become concerned that the existing procedures regulating the importation of postlarvae and broodstock were only partially effective, and would lead to further introductions of TSV and other serious pathogens that could have major negative impacts on the Thai shrimp culture industry.

To determine a course of action, the DOF contracted a group of scientists with expertise in shrimp pathology, shrimp aquaculture, aquatic ecology, economics and trade to prepare a detailed review of legislation, standards and importation regulations for *L. vannamei* in Thailand and abroad, to estimate the various positive and negative impacts of importation and cultivation of this species in Thailand and to provide a summary and recommendations. In a second study also funded by the DOF, the Centex Shrimp, Mahidol University and the Aquatic Animal Health Center, Prince Songkla University conducted a study on the impact of white shrimp importation into Thailand and a pathogen risk analysis, respectively, which included as part of its hazard identification, a survey of the viral and bacterial diseases present in Thai hatcheries and in both domestically produced and imported white shrimp broodstock. The risk analysis also included susceptibility testing of various native crustaceans to viral pathogens using extracts taken from infected white shrimp. Based on these studies, the risk analysis concluded that there was a high risk posed by imported white shrimp due to Taura syndrome virus (TSV), white spot syndrome virus (WSSV) and infectious hypodermal and haematopoietic necrosis virus (IHHNV).

The DOF then convened a series of public meetings at which the experts presented facts and options on the pros and cons of banning further introductions and of permitting continued importations, although with more stringent controls, so that the policy makers and stakeholders could decide what to do. The DOF's goal was clearly to "clean up" a pre-existing situation that was considered "risky", primarily from the standpoint of possible pathogen introductions, and it was generally understood that the goal was to introduce new regulations that would legalize importations under conditions that would reduce the associated risks due to pathogens to an acceptable level.

The recommendations presented by the experts have been partially implemented, including:

- Organizing a DOF/industry group to travel to the United States to visit producers of specific pathogen free (SPF) *L. vannamei* and to select from these, a list of acceptable sources for permitted importation of broodstock to Thailand with limited quarantine procedures. The current list includes six producers whose broodstock are all believed traceable to the SPF stocks developed by the Oceanic Institute's program (the Oceanic Institute sells only to US producers). This has now been in effect for over one year.
- Making all other sources illegal.

Recommendations made to DOF (that have not yet been implemented) also included the following:

- The period of continuous importation from the approved producers was to last only for approximately one year, until local nucleus breeding centers (NBC) could be set up with more strictly quarantined stocks.
- Once this had been achieved, all continuous imports are to stop and any new introductions are to follow the same strict quarantine protocol leading to establishment of local NBC only.
- Postlarvae and broodstock originating from the local NBC are to be accompanied by certification documents that will be backed up by DNA microsatellite records.
- Policing is to be carried out by random checks at all levels of production and any shrimp not conforming to accepted microsatellites are to be immediately destroyed according to the Animal Epidemic Law.

DOF intends to follow this program once the biosecure hatcheries and farms are established and functioning (S. Chinabut, AAHRI, pers. comm.).

So far, two private companies are dedicated to setting up local NBC for *L. vannamei.* As the details of their operations are not open to the public, it is unknown how much actual progress they have achieved towards setting up and operating local NBC with genetic selection programs. Thus, although the approach followed by the DOF to this difficult problem is quite promising, more time will be needed before its success or failure will be known.

The SPC's ecological and pathogen risk analysis for the importation of giant river prawn from Fiji to the Cook Islands

The Secretariat of the Pacific Community (SPC), an intergovernmental agency assisting Pacific Island Countries and Territories (PICTs) with headquarters in Noumea, New Caledonia, has recently begun assisting its member countries to develop risk analysis methods for the importation of live aquatic animals for aquaculture development. As part of this initiative, in 2004, the SPC commissioned risk analyses for the transboundary movements of blue shrimp (*Litopenaeus stylirostris*) and giant river prawn (*Macrobrachium rosenbergii*). The terms of reference were to conduct ecological and pathogen risk analyses for these proposed importations that could serve as models for subsequent risk analyses for other commodities whose importation was being contemplated by SPC member countries (see Arthur et al., 2004b; Bondad-Reantaso *et al.*, 2004). This paper presents a brief case history of the risk analysis for the importation of giant river prawn from Fiji to the Cook Islands.

A project team was formed consisting of two Australian experts on crustacean ecology (P.B. Mather and D. Hurwood), a local aquatic ecologist (E.R. Lovell), and two experts on aquatic animal pathology and risk analysis (J.R. Arthur and M.G. Bondad-Reantaso). On-site visits to the proposed source hatchery in Fiji and the site of the proposed aquaculture facility at Rarotonga, Cook Islands were made and meetings with the proponent and key staff of the Ministry of Marine Resources (MMR) in the Cook Islands, and staff of the source hatchery and the Ministry of Fisheries and Forestry (MFF) in Fiji, as well as with other potential stakeholders, such as the veterinary services, Chief Veterinary Officer, airport quarantine officers and environmental services.

The proponent of this proposed importation was a private entrepreneur who wished to establish a backyard integrated hydroponic production facility for giant river prawn to serve the local tourist market in the Cook Islands. In making arrangements for importation, he was assisted by the MMR. The commodity to be imported was postlarval *M. rosenbergii* originating from the MFF Aquaculture Center at Naduruloulou, Fiji. In this instance, the commodity description was prepared by the consultant with the full cooperation and assistance of the proponent and the staff of the supplying hatchery.

The ecological risk analysis was based on a literature review of the species life cycle and ecology, history in the importing and receiving countries, and ecological impacts in other countries. In broad terms, the assessment examined:

- the risk of escape,
- the potential for *M. rosenbergii* to establish sustaining local populations,
- the potential for widespread dispersal, and
- the possible effects on native species should a population of *M. rosenbergii* become established in the wild.

Results from the literature review were summarized and tabulated using a modification of the method promoted by the *ICES Code of Practice on the Introductions and Transfers of Marine Organisms 2003*. Additionally, a slightly modified version of the decision model proposed by Kohler (1992) for the *Environmental risk management of introduced* *aquatic organisms in aquaculture* was used as a decision-making tool to assess the level of risk relative to the potential benefits of introduction. A major modification to the ICES procedure was to assume that escapes from aquaculture facilities in the Cook Islands would inevitably occur and rather than rejecting the importation based on the likelihood of escape (as called for in the ICES protocol), to look at the probability of escaped animals establishing populations in the wild and the likely impacts, both negative and positive, that would occur.

The pathogen risk analysis was more problematic due to the large number of uncertainties involved. These included the poorly known health status of the stock of origin, the poorly known health history of the facility of origin, the poorly known pathogen status of the country of origin, and the poorly known pathogen status of the importing country.

Due to the absence of any information on the diseases of *M. rosenbergii* in the proposed stock of origin, or in populations of wild and cultured crustaceans in general in either Fiji or the Cook Islands, the preliminary hazard identification included all pathogens and parasites reported from this species throughout its world-wide distribution. The criteria for consideration during preliminary hazard identification was thus the following:

- 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 were not considered).
- The agent must have been recorded from *Macrobrachium rosenbergii.* Pathogens reported for any life cycle stage and any geographical locality were included.

From the list of over 60 potential pathogens identified during the preliminary hazard identification, one crustacean virus listed as reportable to the OIE and one other disease associated with concurrent infections by two non-OIE listed viruses were identified as requiring further consideration:

- White spot syndrome virus (WSSV)
- White tail disease (WTD), due to *Macrobrachium rosenbergii* nodavirus (MrNV) and/or Extra small virus (XSV)

The criteria used to select a pathogen for further consideration in the detailed hazard identification were:

- The pathogen was reported to infect, or suspected of being capable of infecting postlarval *M. rosenbergii*;
- It was obligate pathogen (i.e., it is not a ubiquitous free-living organism capable of becoming an opportunistic pathogen of *M. rosenbergii* under certain environmental or culture conditions);
- It causes significant disease outbreaks and associated losses in populations of *M. rosenbergii* or, if not a significant pathogen of *M. rosenbergii*, it causes serious disease outbreaks in populations of other species of aquatic organisms; and
- It was plausible that the agent might be present in populations of *M. rosenbergii* in Fiji.

Based on past practices and trading partners, it was recommended that the Cook Islands adopt an appropriate level of protection (ALOP) that is “very conservative”, and a risk tolerance (acceptable level of risk) that is “very low”.

Both the pathogen and ecological risk analyses were characterized by a high level of uncertainty. For the former, this was due to an absence of information on the health history and current health status of the Fijian stock of *Macrobrachium* to be introduced, and the general lack of any aquatic animal health information for both Fiji and the Cook Islands; while for the latter, it was due to a general lack of information on the ecology of *M. rosenbergii* and of follow up studies from previous introductions of this species to other countries. It was concluded that if the Cook Islands wished to act very conservatively, it could apply the precautionary approach until such a time as data on health status of the parent stock and on important ecological issues, such as potential interactions of *M. rosenbergii* with native *Macrobrachium* spp. were obtained.

Although there is a general paucity of country-specific and species-specific data to support the analyses, the ecological risk analysis suggested that the benefits of introduction appeared to outweigh the potential negative effects.

The pathogen risk analysis concluded that the proposed introduction could be accomplished within the recommended ALOP if appropriate disease mitigation measures were adopted to minimize the risk of the imported postlarvae (PL) being infected with whitespot syndrome virus (WSSV) and white tail disease (WTD). These included that:

- statistically appropriate samples of the PL to be introduced would be tested for WSSV using the methods specified by the Office International des Épizooties, and for *Macrobrachium rosenbergii* nodavirus (MrNV) and extra small virus (XSV) using the genome-based methods cited in the report;
- no animals would be removed from the receiving facility without prior permission from the Ministry of Marine Resources (MMR);
- the operator would keep detailed records of mortalities and would report any occurrences of serious disease outbreak or mortality to MMR; and
- a contingency plan would be developed requiring that in the event of serious disease outbreak or mortality, all animals would be destroyed and disposed of using an approved sanitary method, and the facility fully disinfected.

The main lesson learned from this risk analysis is that it is very difficult to assess risks when there is a high level of uncertainty present in many key areas. In such cases, general precautionary and sanitary methods such as those outlined by the OIE, ICES and other regional and international bodies are recommended. The analysis also revealed the need for basic diagnostic capability and the development of history of stock health status of cultured species in the exporting country.

While a similar case study for the risk analysis for importation of blue shrimp from Brunei to Fiji (Bondad-Reantaso *et al.*, 2004) will not be presented here, it is worth noting that the uncertainties encountered by the risk analysis team were quite similar, that importations that appeared to be highly risky had already occurred and were continuing, and that the supplier of the postlarvae in the exporting country and the Competent Authority were not forthcoming in supplying essential information such that preparing a commodity description was very difficult. One recommendation of the risk analysis was that such lack of responsiveness on the part of the exporting country and/or supplier should be considered sufficient reason to deny the request to import, particularly, as in the present case, where other sources of postlarvae of known health history were readily available.

SOME ISSUES RELATED TO RISK ANALYSES AND THE RISK ANALYSIS PROCESS

Within the context of the Sanitary and Phytosanitary Agreement (SPS), risk analysis for aquatic animals has evolved from the past experience with terrestrial animals and plants, historically well established and studied agricultural commodities. As a result, certain issues such as how to deal with rapidly emerging diseases, the importance of trade in wild-caught commodities, the more frequent occurrence of uncertainties and knowledge gaps, and the use of the precautionary approach have greater relevance in aquatic animal risk assessment. There is an urgent need for standards-setting bodies such as the OIE and the FAO to address these and other issues. This section looks briefly at some of the issues and problems encountered by the authors during the risk analyses that they have conducted and suggests some possible solutions.

Problems with the Risk Analysis Process

- *How to apply the concept of Appropriate Level of Protection (ALOP)* - An important and still unresolved question is "How should an importing country apply the concept of ALOP?" Currently, with respect to a particular pathogen, a risk analyst would apply the ALOP in terms of the risk posed by a specific commodity. However, should the total risk associated with a given pathogen be measured in terms of the sum of risks presented by all commodities that are capable of introducing that pathogen into a country? A related issue, particularly in quantitative risk analyses, is how to take into account the volume of trade in the commodity or commodities, which of course, can greatly increase the risk of pathogen introduction.
- *Consistency in applying ALOP.* Another important question is "How can national governments ensure that the ALOP is consistently applied, both for risk analyses involving commodities of a similar nature (e.g., aquatic animals, aquatic animal products) and across widely differing commodities (e.g., across risk analyses conducted for aquatic animals, terrestrial animals and plants)?"
- *Consistency in applying the Precautionary Approach* - As with ALOP, how countries apply the precautionary approach, both for commodities of similar nature and across commodities, can be quite subjective. Developing countries, in particular, need scientifically based guidance and examples of what is reasonable precaution, and what is not.
- *Standardization of risk assessment methodologies*. At least at the country level, and preferably among countries conducting frequent trade in aquatic animals, there is a need to standardize risk assessment methods. There are no "fundamental truths" with respect to risk assessment outcomes, but rather all determinations are dependent

on the declared (ALOP), and this can only be appreciated in the context of the assessment methodology applied. Thus, standardization and consistent application of methodology is perhaps the most important aspect of good risk assessment and decision-making. A risk analysis template should be developed that countries can adopt and, if necessary, adapt to their individual situations. Compared to risk assessments for plant and terrestrial animal commodities, those for pathogens of aquatic animals are often very subjective, due to associated environmental complexities, the wide range of pathogen and host species involved and the many unknowns that must be taken into account. Technical guidelines to assist risk analysts in minimizing the level of subjectivity in their risk analyses are thus needed.

Problems with Individual Risk Analyses

- *Failure of trading partners to respond adequately to requests for information.* The reluctance of the proponents of a proposed importation or of the Competent Authority of the exporting country to cooperate fully with requests for information should immediately raise a warning flag with the Competent Authority of the importing country. Such lack of cooperation should be sufficient reason to deny importation. The importing country may recommend that the proponents seek another source for the commodity.
- *Undefined national ALOP* many developing countries have no formally stated ALOP or level of acceptable risk. In order to facilitate risk analysis across all sectors and commodities and to advise trading partners, such countries should begin the process of defining a national ALOP.
- *Inaccurate/inadequate information provided in the commodity description. In most cases, it is the proponent's responsibility to develop the commodity description.* However, the importing country must provide the proponents with detailed instructions on the information required (typically, via guidelines and standardized forms for commodity description), and then review the description and return it to the proponents for any corrections or elaboration. The Competent Authority should make it clear from the very beginning that further action is contingent upon approval of an acceptable commodity description.
- *Inadequate coordination/communication between national agencies.* Few countries have good coordination mechanism between the various “stakeholder” agencies (biosecurity, quarantine, environment, fisheries, veterinary services, human health, customs, legal services, etc.) whose mandates touch on the importation of aquatic animals and their products. This lack of coordination and communication can make it difficult to conduct risk analyses in an efficient and timely manner.
- *Inadequate external review.* The importance of good external scientific review cannot be overstressed. Such review lends credence to the risk analysis process and will assure trading partners and other stakeholders that the conclusions of the risk analysis are well supported.
- *Potential conflicts of interest.* A potential conflict of interest arises when the proponent and the Competent Authority of the importing country are one and the

same. In such cases, to avoid real and apparent conflict of interest, and the appearance of "rubber stamping", transparency is highly important, and the risk analysis should be conducted and/or reviewed by independent outside experts.

- *Lack of scientific information.* Lack on scientific information on pathogens affecting a species, their pathogenicities, life cycles, distributions etc. can create a high level of uncertainty such that the results of an importation cannot be predicted. Where this occurs, the precautionary approach should be applied and research into critical areas conducted.
- *Improperly constituted risk analysis team.* Occasionally a poor quality risk analysis has resulted due to an improperly constituted risk analysis team. Good risk analysis requires appropriate expertise, including specialist knowledge on pathogens, on the commodity, and on conducting risk analyses, and more general knowledge on the local receiving environment. Thus the risk analysis team should typically include both specialists and general fisheries biologists having local knowledge.
- *Inordinate haste.* Private aquaculturists, national and state government agencies and internationally funded projects for aquaculture and fisheries enhancement that involve the use of exotic species or strains of aquatic animals often do not take into consideration the need to allow adequate time and resources for risk analysis and the risk mitigation measures (such as diagnostics testing and extended quarantine periods) that may be required. There is thus a tendency in developing countries for importation to occur without adequate risk assessment and disease prevention, and for questions of ecological and/or pathogen risk to be raised only after importation has already occurred. This of course drastically reduces the possibility of preventing adverse ecological and pathogen impacts from occurring and may make the risk analysis process a rather futile one.
- *Research loopholes.* National fisheries agencies and staff at universities have often imported aquatic species for research or trial in aquaculture and fisheries development projects. Despite the perception that these importations are for research and therefore represent "little risk", the exotic organisms often end up being released into the natural environment. Requests for importations for research purposes need to be more closely monitored. Ecological and pathogen risk analyses should be mandatory for those requests that are likely to result in release into natural environments, while approval of those involving requests for animals strictly for use in laboratory research should require that all stock be kept under stringent quarantine isolation and that they be destroyed at the end of the study.

DEVELOPING COUNTRIES AND RISK ANALYSIS

Although some the risk analyses undertaken by developed nations (particularly those few high profile trade disputes involving aquatic animals and their products that have reached the World Trade Organization) appear to be highly complex, developing countries should not be intimidated, as the risk analysis process is both highly flexible and readily adapted to developing country situations.

A key issue for developing countries is how to find the expertise and financial resources needed to conduct a risk analysis. However, there are many sources of support and assistance. International and bilateral donor agencies such as the Food and Agriculture Organization of the United Nations (FAO), the Network of Aquaculture Centres in Asia-Pacific (NACA), and the World Animal Health Organisation (OIE) have provided assistance to developing countries in Asia and Latin America understanding the risk analysis process and in developing appropriate national expertise. In the South Pacific, the Secretariat of the Pacific Community is playing a lead role by assisting its member countries to develop risk analysis capacity and to undertake risk analyses for the most urgent proposals to introduce exotic species. Further assistance by these and other agencies in training and capacity building will certainly be made available as the need arises.

Developing countries can also place much of the responsibility for conducting and/or funding many of the risk assessment activities on the would-be importers. This can include the hiring of private consultants to undertake the risk assessment. As risk analyses are conducted, a growing level of national and regional expertise and experience will be developed that can be tapped by developing countries.

CONCLUSIONS

Clearly, the most cost-effective way for many developing countries to conduct risk analyses is through combining national expertise with the risk analysis expertise available in neighboring countries through regional approaches to shared problems. This includes the sharing of databases and other sources of information, and particularly for introductions involving shared waterways, the sharing of risk analysis approaches and associated costs.

Small countries, such as the Pacific Island Countries and Territories (PICTs), typically have small populations, and thus very limited manpower and specialized expertise within their Competent Authorities. As the number of risk analyses such countries are likely to undertake is quite limited, it makes little sense for individual countries to attempt to develop extensive expertise and capacity for aquatic animal risk analysis. A better approach is for each country to have one or two staff members that have a general familiarity with the risk analysis process and an in-depth knowledge of local aquaculture, fisheries, environmental and socio-economic issues, etc. When a specific risk analysis is needed, these staff can be assisted by appropriate specialists, including outside consultants. The SPC is currently developing a regional project to assist member countries in developing this basic knowledge and capacity for risk analysis and is undertaking ecological and pathogen risk analyses on several key exotic species whose importation is of broad interest to member countries. The project will also promote linkages between risk analysts in the various PICTS, provide training, establish shared databases on pathogens, develop shared approaches and promote linkages and communication between Competent Authorities in the plant, livestock and aquatic animal sectors and between aquatic animal risk analysts and experts concerned with the broader issue of invasive aquatic species.

As previously mentioned, risk analyses involving trade between developing countries often involve a great deal of uncertainty in many key areas, making accurate risk estimation difficult. A key reason for this is the general lack of basic knowledge on the ecology and pathogens of aquatic animals in developing countries. There is thus a need to establish the appropriate research capacity and to conduct targeted studies. For example, research to support aquaculture biosecurity should focus on the pathways of pathogen spread, methods for inactivation of infectivity, "barrier" vaccination strategies, etc. Epidemiological research should include investigation of biological factors (identification of at-risk populations, hazards, pathways, pattern of spread, incubation period, nature of the pathogen); risk factors; interventions and methodologies (e.g., surveillance techniques, disease outbreak modeling, use of geographic information systems), etc. Risk analysis information/knowledge requirements should be given high priority. Essential research areas, for example, include pathogen studies, information on trade and most importantly, 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 (including standardization, validation and inter-calibration) are essential to facilitate accurate risk assessment and biosecurity management. Increased surveillance of wild fish to detect significant disease problems at an early stage will also be required.

Developing countries such as those in the South Pacific and in Southeast Asia should consider a regional effort to establish hatcheries and stocks of known health history (ideally, specific pathogen free (SPF) stocks) for the most frequently traded species (e.g., ,tilapia, marine shrimp, giant freshwater prawn, oysters, etc.). There is little justification for importing countries to continue to accept the risks inherent in importing live aquatic animals of uncertain health status.

Finally, in aquatic animal risk analysis, Murphy's Law *"If anything can go wrong, it will."* and its corollary *"Left to themselves, things tend to go from bad to worse"* apply. Occasionally, and despite the best risk analysis and risk mitigation measures, serious pathogens will be introduced and cause major disease problems. This is because of limitations in diagnostics 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. Therefore, good disease surveillance, monitoring and reporting and well-designed emergency plans are essential back ups to detect and contain or eradicate new diseases.

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