4. Brief overview of the risk analysis process by risk category

In this section we present a brief summary of the risk analysis process as it is applied to each of the seven aquaculture risk categories.[4]

4.1 OVERVIEW OF THE PATHOGEN RISK ANALYSIS PROCESS[5]

Pathogen risk analysis (termed "import risk analysis" when international trade is involved) is a structured process for analyzing the disease risks associated with the international and domestic movements of live aquatic animals and their products.

A pathogen risk analysis seeks answers to the following questions:

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

4.1.1 Preliminaries

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

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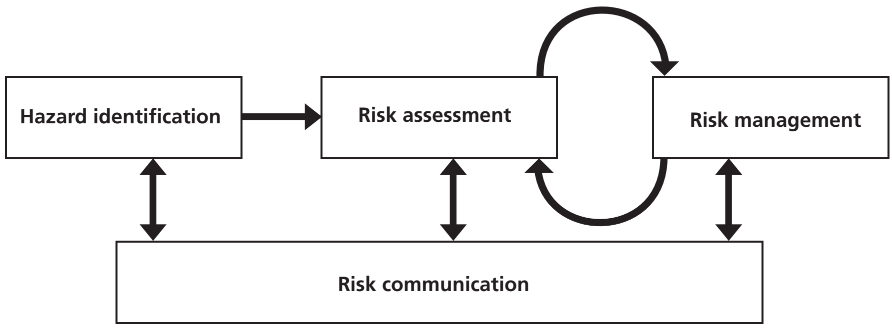
4 Information for each category has been extracted and modified from the relevant review presented in FAO Fisheries and Aquaculture Technical Paper No. 519, *Understanding and applying risk analysis in aquaculture* (Bondad-Reantaso, Arthur and Subasinghe, 2008). In these brief summaries, all references and most figures and tables have been omitted. For more complete information, readers are referred to the original documents.

5 This section is extracted with modifications from Bondad-Reantaso and Arthur (2008).

FIGURE 3
The four components of pathogen analysis



The principal components of the pathogen risk analysis process are illustrated in Figures 3 and 4. They include hazard identification, risk assessment (release, exposure and consequence assessments, which become the basis for risk estimation), risk management (composed of risk evaluation, option evaluation, implementation, and monitoring and review) and risk communication (a continuous activity that takes place throughout the entire process).

4.1.2 Hazard identification

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

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

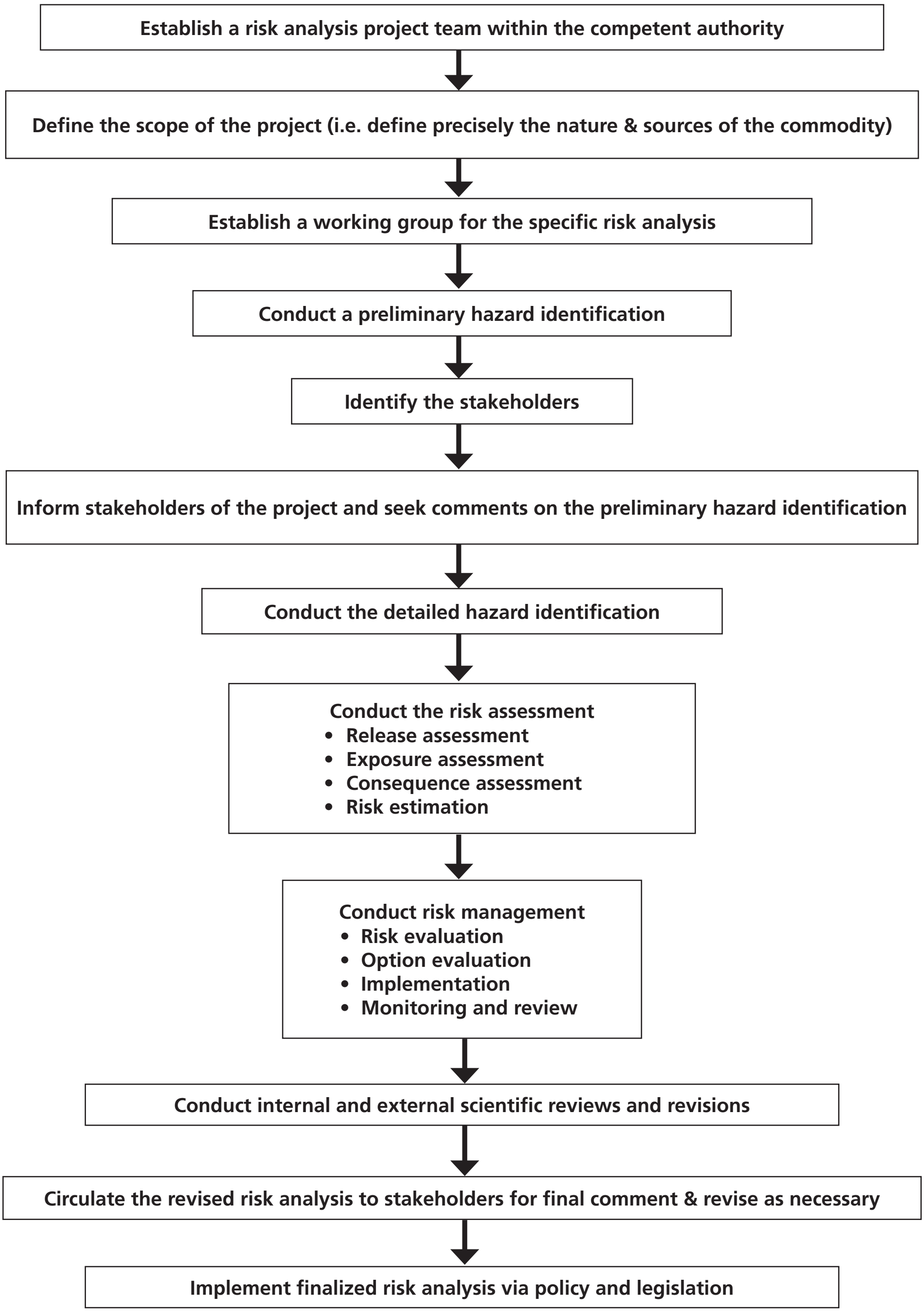
4.1.3 Risk assessment

The actual risk assessment consists of four components:

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

- *Biological factors*: susceptibility (species, life stage), means of transmission (horizontal, vertical), infectivity, virulence, routes of infection, outcomes of infection (sterile immunity, incubatory or convalescent carriers, latent infection), impact of vaccination, testing, treatment and quarantine.

FIGURE 4
A simplified diagram showing the steps in the risk analysis process



Source: Arthur *et al.,* 2004.

- *Country factors:* evaluation of the exporting country's official services in terms of diagnostics, surveillance, and control programmes and zoning systems; incidence and/or prevalence of the pathogen; existence of pathogen-free areas and areas of low prevalence; distribution of aquatic animal population; farming and husbandry practices; geographical and environmental characteristics
- *Commodity factors:* ease of contamination; relevant processes and production methods; effect of processing, storage and transport; quantity of commodity to be imported.

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

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

3. Consequence assessment is the step that identifies the potential biological, environmental and economic consequences expected to result from pathogen introduction. Information required for consequence assessment includes the following:

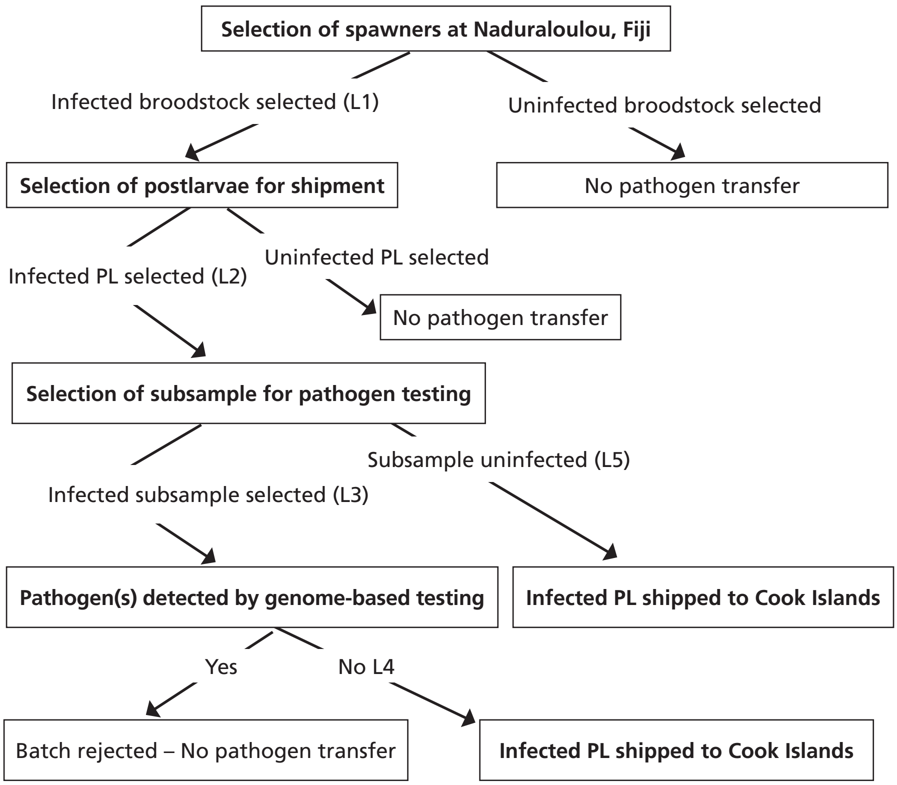
- Potential biological, environmental and economic consequences associated with the entry, establishment and spread:
  - Direct consequences: outcome of infection in domestic and wild animals and their populations (morbidity and mortality, production losses, animal welfare), public health consequences
  - Indirect consequences: economic considerations (control and eradication costs, surveillance costs, potential trade losses (such as embargoes, sanctions and lost market opportunities), environmental considerations (amenity values, social, cultural and aesthetic conditions).

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

In the risk assessment process, the use of pathway analysis and scenario diagrams is very important (an example of a pathogen pathway is shown in Figure 5. They serve as useful tools in identifying possible routes (pathways) and the individual events or steps in each pathway that need to occur for a given pathway to be

FIGURE 5

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



Source: Arthur *et al.*, 2005.

successfully completed. Not only do they provide a logical process by which the critical risk steps (events) leading to pathogen introduction and establishment in an importing country can be identified, they also allow estimation of the probability of each event occurring, thus leading to an overall estimate of the probability of a given pathway being completed. When incorporated unto the pathway analysis, the effectiveness of a risk mitigation measure can be determined, which can then allow the recalculation of the overall risk to see whether the risk can be reduced to an acceptable level. Another advantage of using the pathway/scenario diagram approach is that it allows for sensitivity analysis, whereby the most influential pathway steps that determine the final risk estimate for a particular pathogen can be identified. This greatly assists in targeting risk mitigation measures and in identifying areas where information needs are most critical, particularly in areas where highly sensitive pathway steps are associated with a degree of uncertainty or subjectivity.

4.1.4 Risk management

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

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

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

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

4.1.5 Risk communication

Risk communication is the step whereby information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which results of the risk assessment and proposed risk management measures are communicated to decision-makers and interested parties in the importing and exporting countries. The risk communication process for pathogen risk analysis is similar to the general risk communication process described in Section 3.5.

4.2 OVERVIEW OF THE FOOD SAFETY AND PUBLIC HEALTH RISK ANALYSIS PROCESS[6]

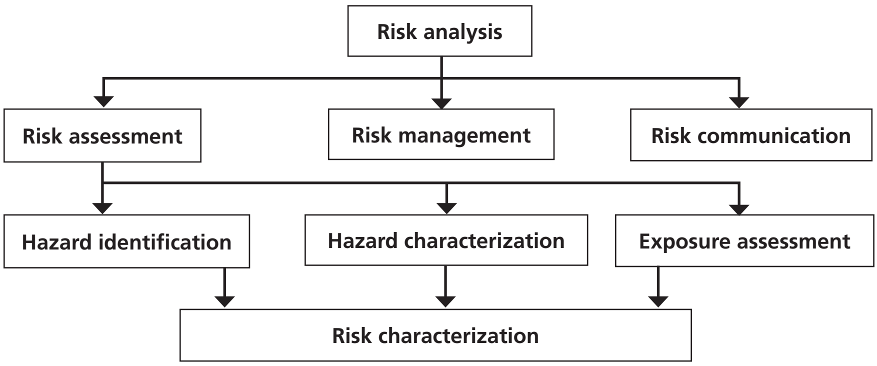
Outbreaks of food-borne illnesses continue to be a major problem worldwide, and international trade in food products is increasing. According to World Health Organization (WHO) estimates, 1.8 million deaths related to contaminated food or water occur every year. Traditionally, food safety programmes have focused on enforcement mechanisms for final products and removal of unsafe food from the market instead of a preventive approach. In such a model, the responsibility for safe food tends to concentrate on the food-processing sector. The FAO is recommending a food-chain approach that encompasses the whole food chain from primary production to final consumption. In such a system, the responsibility for a supply of food that is safe, healthy and nutritious is shared along the entire food chain by all involved in the production, processing, trade and consumption of food. Stakeholders include farmers, fishermen, processors, transport operators (raw and processed material) and consumers, as well as governments obliged to protect public health. The food-chain approach to food safety is based on five important aspects:

- *The three fundamental concepts of risk analysis* – risk assessment, risk management and risk communication – should be incorporated into food safety. There should be an institutional separation of science-based risk assessment from risk management, which is the regulation and control of risk.
- *Traceability f*rom the primary producer (including fish feed) through post-harvest treatments, food processing and distribution to the consumer should be improved.
- *Harmonization of food safety standards* is necessary; this implies increased development and wider use of internationally agreed-upon, scientifically based standards. The Technical Barriers to Trade (TBT) Agreement of WTO tries to achieve this by ensuring that arbitrary standards do not become barriers to international trade.
- *Equivalence of food safety systems* that achieve similar levels of protection against food-borne hazards, whatever means of control are used. This is a requirement under the SPS Agreement.
- *Increased emphasis on risk avoidance or prevention* at source within the whole food chain – from farm or sea to plate – is necessary to complement conventional food safety management based on regulation and control.

Complementing the current emphasis on regulation and control of the food safety system with preventive measures to control the introduction of contamination at source requires the adoption of practices in food production, handling and processing that reduce the risk of microbiological, chemical and physical hazards entering the food chain. There are some hazards such as chemical contaminants and biotoxins in shellfish that cannot be simply removed from foodstuffs. The adoption of sound practices along the food chain based on

6 This section is extracted with modifications from Karunasagar (2008).

FIGURE 6
The risk analysis process as applied to food safety and human health risks



principles defined in good aquaculture practices (GAP) and in-plant control of food processing based on hazard analysis and critical control point (HACCP) analysis is important to prevent such hazards from entering the system. By using a risk-based approach to the management of food safety, food control resources can be directed to those hazards posing the greatest threat to public health and where the potential gains from risk reduction are large relative to the resource use. Establishing risk-based priorities requires sound scientific knowledge and effective systems for reporting the incidence of food-borne diseases.

Guidelines for performing risk analysis have been brought out by the Codex Alimentarius Commission (CAC). According to Codex, risk analysis is a process consisting of risk assessment, risk management and risk communication. The risk analysis process as it is applied in the food safety and human health sector is shown in Figure 6. An example of a food safety risk analysis is presented in Box 3.

4.2.1 Hazard identification

This involves identification of biological or chemical agents capable of causing adverse health effects that may be present in a particular food or group of foods. Products of aquaculture include freshwater and marine finfish and shellfish (molluscs and crustaceans). Hazard identification considers epidemiological data linking the food and biological/chemical agent to human illness and the certainty and uncertainty associated with such effects. Data from national surveillance programmes, microbiological and clinical investigations, and process evaluation studies are important. At the hazard identification step, a qualitative evaluation of available information is carried out and documented. The characteristics of the organism/toxin/chemical agent, including its effects on the host and mode of action, are considered. Based on epidemiological evidence, only a few microbial agents are known to be involved in foodborne illnesses; however, only a small number of outbreaks have been adequately investigated. Therefore, limitations

BOX 3

Case study: FAO/WHO risk assessment for choleragenic *Vibrio cholerae* in warmwater shrimp in international trade: example of a risk assessment

Seafood exports are a major source of foreign exchange for many Asian countries. Incidentally cholera is endemic in some Asian countries; and exports are often affected whenever there are reports of cholera in seafood-producing countries. Shrimp constitute the major seafood commodity that is affected. In 2003, there were 4.3 million tonnes of shrimp in international trade, of which 70 percent were warmwater shrimp. Considering the importance of shrimp from warm waters in international trade, FAO/WHO set up an expert committee to perform a risk assessment for *Vibrio cholerae* in warmwater shrimp processed for export.

Vibrio cholerae is a heterogeneous species consisting of over 220 serotypes. The disease cholera is caused only by serotypes O1 and O139, which are also referred to as choleragenic *V. cholerae*. Strains belonging to non-01/non-0139 serotypes of *V. cholerae* are widely distributed in the aquatic environment and are mostly nonpathogenic to humans, although they are occasionally associated with sporadic cases of gastroenteritis. Choleragenic *V. cholerae* are characterized by their ability to produce cholera toxin, which is a complex protein consisting of A and B subunits. Production of cholera toxin is encoded by *ctx*AB genes. The *ctx* gene is present in a filamentous bacteriophage that infects *V. cholerae* through a pilus called toxin co-regulated pilus. Since the *ctx*AB gene is phage encoded and there may be loss of bacteriophage in some environmental strains, it is possible to isolate non-toxigenic *V. cholerae* O1 from the environment and occasionally from seafoods like shrimp. Serotyping alone is inadequate to detect choleragenic *V. cholerae* due to serological cross reactions. Thus use of molecular techniques such as polymerase chain reaction (PCR) or DNA probe hybridization has become important in determining the presence of choleragenic *V. cholerae* in seafood.

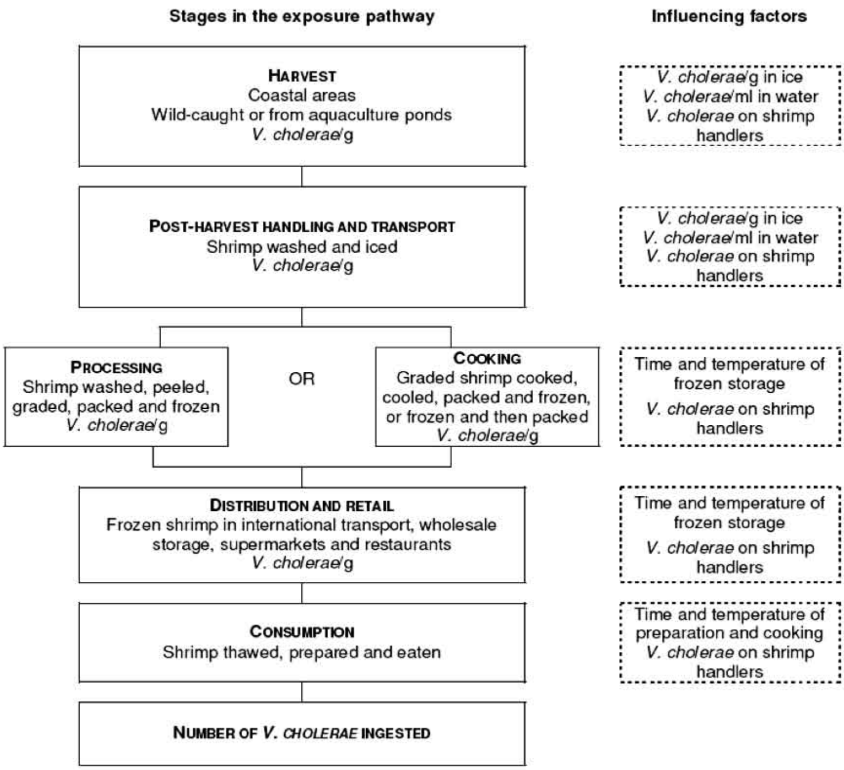
In the aquatic environment, *V. cholerae* may be associated with copepods. But copepods are planktonic organisms while shrimp are demersal and therefore, *V. cholerae* is generally not associated with shrimp in their natural environment. Under an FAO-sponsored shrimp microbiology project during the late 1980s, shrimp surface and gut were tested for the presence of *V. cholerae* in countries such as India, Thailand, Sri Lanka, Indonesia, Malaysia and the Philippines. The data from this study indicated absence of choleragenic *V. cholerae* in association with shrimp. Although one study in the mid-1990s detected *V. cholerae* O1 in tropical shrimp, molecular studies indicated that the isolates were non-toxigenic.

For risk assessment, it is important to consider the prevalence and concentration of choleragenic *V. cholerae* in shrimp during all stages of the farm to fork chain. The model considered in this risk assessment is shown in Figure A. Warmwater shrimp intended for export is handled as per HACCP guidelines, which involve the use of adequate ice to cool shrimp immediately after harvest, use of potable water to make ice, hygienic practices in handling and processing, etc. Studies conducted in Peru during an epidemic of cholera in 1991 have shown that contamination of seafood with *V. cholerae* can be prevented by adopting HACCP procedures.

Freshly harvested shrimp have a bacterial count of about 10^3–10^4 cfu/g, and diverse bacterial groups are present. If contamination with *V. cholerae* occurs in raw shrimp, this organism has to compete with other natural flora on the surface of shrimp. Studies indicate that *V. cholerae* is unable to multiply in raw shrimp. Laboratory studies show that icing and storage in ice for 48 hours can lead to a 2 log reduction in *V. cholerae* levels, if the organism was

BOX 3 (cont.)

FIGURE A
Production to consumption pathway for exposure assessment for choleragenic *Vibrio cholerae* in warmwater shrimp



present on shrimp before icing (Table A). Studies conducted in Argentina show that freezing and frozen storage of shrimp can lead to a 3–6 log reduction in levels of *V. cholerae*. As shrimp are normally consumed after cooking, and as *V. cholerae* is sensitive to heat with a D value of 2.65 min at 60 °C, it can thus be expected that there will be about a 6 log reduction in numbers during cooking of shrimp (Table A).

For risk assessment, dose-response data are important. Data based on human volunteer studies conducted in the United States of America in connection with cholera vaccine trials indicate that the infective dose would range from 10^6–10^8 for different strains of choleragenic *V. cholerae*. Data on the prevalence of choleragenic *V. cholerae* in warmwater shrimp were based on "port of entry testing for *V. cholerae*" at Japan, the United States of America and Denmark. Of 21 857 samples of warmwater shrimp tested, two were positive (0.01 percent) for choleragenic *V. cholerae.* The risk assessments assumed that 90 percent of warmwater shrimp are eaten cooked and 10 percent are eaten raw (as sashimi, etc.). Qualitative risk assessment indicated that the risk to human health is very low. Since the risk of the organism occurring in shrimp is low, the organisms would need to multiply in the product to attain infectious levels, but during the processing of warmwater shrimp (icing, freezing, cooking), significant reductions in level are expected to occur (Table B). Also epidemiological evidence shows no

BOX 3 (cont.)

TABLE A
Effect of processing on levels of choleragenic *Vibrio cholerae* in shrimp

Processing step	Temperature distribution (°C)	Time distribution	Effect on population of *V. cholerae* O1
HARVEST			
Handling time before icing			
Cultured shrimp	15–35	0–1 hour	No effect
Wild-caught shrimp	10–30	0–3 hours	0–1 log increase
WASHING			
Washing and icing of cultured shrimp	0–7	1–4 hours	1 log reduction
Washing in seawater of wild-caught shrimp	0–30	1–4 hours	
ICING			
Icing during transport (including on board fishing vessel for wild-caught shrimp) to processor	0–7	2–16 hours (cultured) 2–48 hours (wild-caught)	2–3 log reduction
WATER USE			
Water use during handling at processing plant	4–10	1–3 hours	No effect
TEMPERATURE			
Temperature during processing before freezing	4–10	2–8 hours	No effect
COOKING			
Cooking at processing plant	>90	0.5–1.0 min (This is the holding time at >90 °C)	>6 log reduction
FREEZING			
Freezing of cooked and raw products, storage, and shipment time	-12 to -20	15–60 days	2–6 log reduction

Source: from FAO/WHO, 2005.

link between imported warmwater shrimp and cholera in importing countries. Semiquantitative risk assessment using Risk Ranger estimated 1–2 cases per decade for Japan, the United States of America and Spain. For other shrimp-importing countries, the estimate was 3–4 cases/century. For a quantitative risk assessment, numerical inputs for a full harvest to consumption model were not available; hence a shortened exposure pathway that began at the port of entry of the importing country was taken (Figure B). The quantitative model estimated that the median risk of acquiring cholera from warmwater shrimp in selected importing countries ranges from 0.009 to 0.9 per year. The prediction of low risk by each of the approaches mentioned above is supported by the absence of epidemiological evidence that warmwater shrimp has ever been incriminated in any cholera outbreak in any developed nation in the world.

BOX 3 (cont.)

FIGURE B

Import to consumption pathway used in quantitative risk assessment

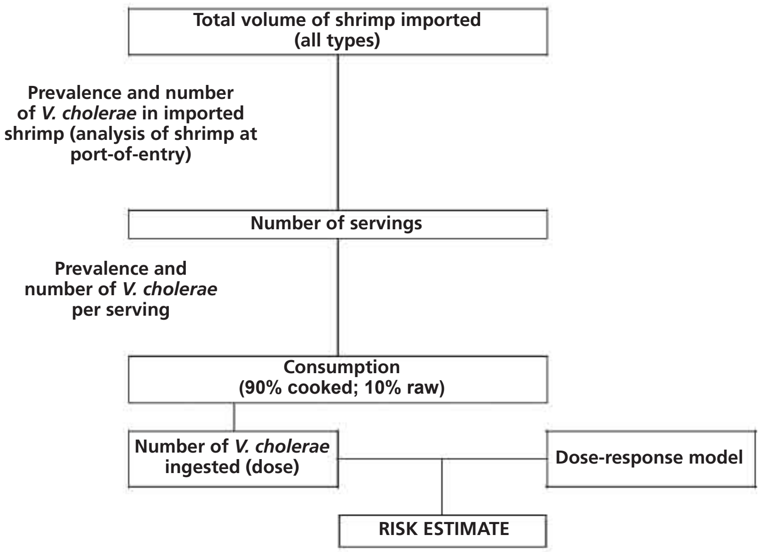


TABLE B

Qualitative risk assessment for choleragenic *Vibrio cholerae* in warmwater shrimp

Product	Identified hazard	Severity[1]	Occurrence risk[2]	Growth[3]	Impact of processing and handling on the hazard	Consumer terminal step[4]	Epidem. link	Risk rating
Raw shrimp	*V. cholerae*	II	Very low	Yes	Level of hazard reduced during washing (0–1 log), icing (2–3 logs), freezing (2–6 logs)	No	No	Low
Shrimp cooked at the plant & eaten without further heat treatment	*V. cholerae*	II	Very low	Yes	Level of hazard reduced during washing (0–1 log), icing (2–3 logs), cooking (>6 logs), freezing (2–6 logs)	No	No	Low
Shrimp cooked immediately before consumption	*V. cholerae*	II	Very low	Yes	Level of hazard reduced during washing (0–1 log), icing (2–3 logs), freezing (2–6 logs), thawing and cooking (>6 logs)	Yes	No	Low

[1] Severity of the hazard classified according to International Commission of Microbiological Specifications for Foods. Level II = serious hazard; incapacitating but not life threatening; sequalae rare; moderate duration.

[2] Very low occurrence of illness – an average of less than one case per ten million population per year based on the data for over a six-year period. This reflects the situation in all countries considered except Japan, which experienced an average of less than one case per million population.

[3] Growth in product required to cause disease.

[4] Cooking, which brings about >6 log reduction in the level of *V. cholerae*.

of hazard identification with respect to biological agents include the expense and difficulty involved in outbreak investigations and the difficulties involved in the isolation and characterization of certain pathogens such as viruses. However, for most chemical agents, clinical and epidemiological data are unlikely to be available. Since the statistical power of most epidemiological investigations is inadequate to detect effects at relatively low levels in human populations, negative epidemiological evidence is difficult to interpret for risk assessment purposes. Where positive epidemiological data are available, consideration should be given to variability in human susceptibility, genetic predisposition, age-related and gender-related susceptibility and the impact of factors such as socio-economic and nutritional status. Due to a paucity of epidemiological data, hazard characterization may have to rely on data derived from animal and *in vitro* studies.

4.2.2 Exposure assessment

At this step, an estimate of the number of bacteria or the level of a biotoxin or a chemical agent consumed through the concerned food is made. This involves documenting the sources of contamination, frequency, concentration and estimation of the probability and the concentration that will be consumed. This requires information on the pathogen (e.g. ecology of the microbial pathogen, distribution, growth, inhibition or inactivation during handling and processing), on the food (food composition – pH, water activity, nutrient content, presence of antimicrobial agents, competing microflora; processing practices; handling at retail and consumer preparation practices), and on the consumer (population demographics, food consumption patterns).

Primarily, exposure assessment is concerned with estimating the likelihood of being exposed to the hazard through consumption of the food under consideration and the amount or dose to which an individual or population is exposed. Microbial hazards are much more dynamic as compared to chemical hazards because of the potential of microorganisms to multiply in foods or their numbers being reduced due to handling, processing or storing (e.g. freezing) of foods and consumer preparation (e.g. cooking) steps that may inactivate them. With respect to microbial toxins, a combination of the microbes' characteristics and the chemical-like effects of the toxin are to be considered. Data on the concentration of the pathogen in the food at the time of consumption are rarely available and therefore, it is necessary to develop models or assumptions to estimate the likely exposure. For bacteria, the growth and death of the organism under the predicted handling and processing conditions of the food are considered in the model, which would take into account the effects on the pathogen due to time, temperature, food chemistry and the presence of competing microflora. However, biological agents like viruses and parasites do not multiply in foods. In these cases, handling, storage and processing conditions may affect their survival.

With respect to chemical hazards, exposure assessment requires information on the consumption of relevant foods and the concentration of the chemical of interest in the foods. Chemical contaminants and pesticides are generally present, if at all, at very low concentrations. Estimation of the dietary intake of chemical contaminants requires information on their distribution in foods that can only be obtained by analyzing representative samples of relevant foods with sufficiently sensitive and reliable methods.

4.2.3 Hazard characterization and dose-response analysis

At this step, a qualitative or quantitative description of the severity and the duration of the adverse health effect that may result from the ingestion of microorganism/toxin/chemical contaminants is made. The virulence characters of the pathogen, effect of food matrix on the organism at the time of consumption (factors of the food such as high fat content that may protect the organism by providing increased resistance to gastric acids), host susceptibility factors and population characteristics are considered. Wherever data are available, a dose response analysis is performed. Data for dose response analysis may come from outbreak investigations, human volunteer studies, vaccine trial studies or animal studies.

4.2.4 Risk characterization

The Codex Alimentarius defines the risk characterization step as the process of determining the qualitative and/or quantitative estimation including attendant uncertainties of the probability of occurrence and the severity of the known or potential adverse health effect in a given population based on hazard identification, exposure assessment and hazard characterization. The output of risk characterization is not a simple qualitative or quantitative statement of risk. Risk characterization should provide insights into the nature of the risk, including a description of the most important factors contributing to the average risk, the largest contributions to uncertainty and variability of the risk estimate and a discussion of gaps in data and knowledge. A comparison of the effectiveness of various methods of risk reduction is also presented.

The output of risk characterization is the risk estimate, which may be qualitative (low, medium, high); semiquantitative (the risk assessors making a ranking, i.e. a number within a range e.g. 0–100); or quantitative (the risk assessors predicting the number of people who are likely to become ill from the pathogen-commodity/product combination). Qualitative risk assessment is performed when data are inadequate to make numerical estimates, but when conditioned by prior expert knowledge and identification of attendant uncertainties, data are sufficient to permit risk ranking or separation into descriptive categories of risk.

Quantitative risk assessments are based on mathematical models incorporating quantifiable data and emphasize the likelihood of an adverse health effect (e.g. illness, hospitalization, death). These can be further subdivided into deterministic and probabilistic risk assessments. For deterministic risk assessment, single input values that best represent the factors in the system are chosen. The values could represent the most likely value or values that capture a worst-case situation. Deterministic risk assessment does not provide information on the uncertainty of the risk estimate. However, selecting worst-case values and combining worst-case input values across multiple factors affecting food safety performance may be too stringent for most of the industry if risks are associated with extremes of performance. In the case of probabilistic risk assessments, input values are distributions that reflect variability and/or uncertainty. Uncertainty analysis is a method used to estimate the uncertainty associated with models and assumptions used in the risk assessment.

Almost always, risk assessments have a statement specifying that insufficient data were available in one or more areas and, as a result, a certain amount of caution should be attached to the estimate. Caution, as a result of lack of precise information, leads to uncertainty, and it is always important to record the data gaps that lead to uncertainty. Later, if that knowledge becomes available, the level of uncertainty will be reduced so that the risk estimate becomes more accurate. Risk assessment is an iterative process and may need re-evaluation as new data become available. Wherever possible, risk estimates should be reassessed over time by comparison with independent human illness data.

4.2.5 Risk management

Risk management is the process of weighing policy alternatives in the light of the results of risk assessment and if required, selecting and implementing appropriate control options including regulatory measures. According to Codex, risk management should follow a structured approach involving the four elements of risk evaluation, risk management option assessment, implementation of management decision, and monitoring and review.

1. *Risk evaluation* involves identification of a food safety problem, establishment of a risk profile, ranking of hazards for risk assessment and risk management priority, establishment of policy for conduct of risk assessment, commissioning of the risk assessment and consideration of the risk assessment results. Identification of the food safety issue is the entry point for preliminary risk management activities and may come to the attention of the risk manager through disease surveillance data, inquiry from a trading partner or consumer concern. A risk profile comprises a systematic collection of information needed to make a decision. This can include description of the food safety issue, information about the hazard, any unique characteristics of the pathogen/human relationship, information about the exposure to the hazard, possible control measures, feasibility and practicality, information on adverse health effect (type and severity of illness, subset of population at risk) and other information for making risk management decisions. Based on the information generated in the risk profile, the risk manager may be able to make a range of decisions. Where possible and necessary, the risk manager may commission a risk assessment. This would involve defining the scope and purpose of the risk assessment, defining risk assessment policy, interactions during the conduct of the risk assessment and consideration of the outputs of the risk assessment.

2. *The risk option assessment* step consists of identification of available management options, selection of the preferred management option, including consideration of appropriate safety standard, and making the final management decision. Optimization of food control measures in terms of their efficiency, effectiveness, technological feasibility and practicality at different points in the food chain is an important goal. A cost-benefit analysis could be performed at this stage.
3. *Implementation of the risk management decision* will usually involve regulatory food safety measures such as HACCP. There could be flexibility in the measure applied by the industry as long as it can be objectively demonstrated that the programme is able to achieve the stated goals. Ongoing verification of the food safety measure is essential.
4. *Monitoring and review* is the gathering and analyzing of data that gives an overview of food safety and consumer health. Foodborne disease surveillance identifies new food safety problems as they emerge. If the monitoring indicates that the required food safety levels are not being reached, redesign of the measures will be needed.

Protection of human health should be the primary consideration in arriving at any risk management decision. Other considerations (e.g. economic costs, benefits, technical feasibility and societal preferences) may be important in some contexts, particularly in deciding on the measures to be taken. However, these considerations should not be arbitrary and should be made explicit.

In the context of food safety, an appropriate level of protection (ALOP) is a statement of public health protection that is to be achieved by the food safety systems implemented in that country. Most commonly, ALOP is articulated as a statement of disease burden associated with a hazard/food combination and its consumption within the country. ALOP is often framed in the context for continual improvement in relation to disease reduction. For example, if a country has 100 cases of *Vibrio parahaemolyticus* due to consumption of raw oysters per 100 000 population and wants to implement a programme that reduces the incidence, there are two possible approaches in converting this goal into a risk management programme. The first is the articulation of a specific public health goal, i.e. to reduce the number of cases to 10 per 100 000 population. This is based on the assumption that there are practical means of achieving this. The alternate approach is to evaluate the performance of risk management options currently available and select an ALOP based on one or more of these options. This is often referred to as the as low as reasonably achieved (ALARA) approach.

Implementation of a food safety control programme greatly benefits by expression of ALOP in terms of the required level of control of hazard in foods. The concept of food safety objective (FSO) provides a measurable target for producers, consumers and regulatory authorities. FSO has been defined as “the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection”. FSOs are usually used in conjunction with performance criteria and/or performance standards that establish the required level of control of a hazard at other stages in the food chain. A performance criterion is the required outcome of a step or a combination of steps that contribute to assuring that the FSO is met. Performance criteria are established considering the initial level of hazard and changes during production, distribution, storage, preparation and use of the food.

4.2.6 Risk communication

At an international level, organizations like CAC, FAO, WHO and WTO are involved in risk communication. The general subject Codex Committees are involved in risk management such as development of standards, guidelines and other recommendations. Risk assessment information is often provided by the Joint FAO/WHO Expert Committee on Microbiological Risk Assessments. The FAO/WHO Codex Secretariat carries out risk communication through publication of various documents and Internet-based communications. The WTO SPS Committee manages the implementation of the SPS Agreement for WTO member countries; and, through the notification procedure required by the SPS Agreement, it communicates risk management decisions among those member countries.

National governments have the fundamental responsibility of risk communication while managing public health risks, regardless of the management method used. Since industry is responsible for the safety of the food it produces, it has corporate responsibility to communicate information on the risks to the consumers. Food labelling is used as a means of communicating instructions on the safe handling of food as a risk management measure. Consumer organizations can work with government and industry to ensure that risk messages to consumers are appropriately formulated and delivered.

4.3 OVERVIEW OF THE ECOLOGICAL (PESTS AND INVASIVES) RISK ANALYSIS PROCESS[7]

Ecological risk assessment (ERA) is a logical and systematic process for objectively defining the probability of an adverse effect (or impact) on an organism or collection of organisms when challenged with an environmental modification such as habitat destruction, chemical contamination, invasion of exotic species, infection with disease organisms or some other potential stressor. In 1998, the United States Environmental Protection Agency (USEPA) published the Federal Guidelines for ERA (USEPA, 1998), which provides the basic terminology, concepts, assessment framework and step-by-step procedures of ERA, with special emphasis on assessing ecological risks of chemical contamination. In general, ERA includes four key phases:

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[7] Extracted with modifications from Leung and Dudgeon (2008). In this brief summary, only qualitative risk assessment processes are summarized, and we restrict the discussion to ecological risks posed by invasive species and pests, as other sections herein deal with pathogens and diseases (Section 4.1), the genetic risks from escaped organisms (Section 4.4) and the ecological risks associated with pollution from farm wastes and chemicals (Section 4.5).

- problem formulation (i.e. identification of hazards and sensitive receivers);
- parallel analysis of exposure and effect (i.e. pathway and risk analysis);
- risk characterization; and
- risk management and communication.

Ecological risk assessment protocols can be classified into either qualitative or quantitative approaches. The purpose of these assessments is to evaluate the impacts of changes (often human mediated) to organisms, or the environment in which organisms exist, such that the ecological relationships between organisms change in a fashion that is considered undesirable (Byrd and Cothern, 2005). ERA can be used retrospectively or prospectively to identify past or future effects (USEPA, 1998), or to identify the cumulative or synergistic effects of multiple stressors.

4.3.1 Hazard identification

Different operational systems and farming species pose different ecological threats or hazards to the surrounding natural environment, typically referred to as stressors in ERA terminology. These threats include chemical, physical and biological stressors and can be broadly classified into seven categories:

- habitat alteration or destruction;
- organic pollution and eutrophication;
- chemical contamination with pesticides and therapeutics;
- infection with disease organisms;
- genetic risks of escaped culture animals;
- depletion of wild fish stocks to provide food for cultured carnivorous fish, and
- introduction of associated "hitch-hiking" exotic species.

Chemical stressors can have direct or indirect effects, including bioconcentration as the chemical accumulates up the food chain. This bioaccumulation results in the increased concentration and therefore exposure to subsequent predators (including humans). Chemical effects are exhibited at the level of the individual (organism), population (group of individuals of a single species) and community (groups of species). From an aquaculture perspective, chemical stressors include chemicals that enter the farm from outside influence (e.g. fertilizers, chemicals in urban runoff or upstream discharges), or chemicals used as part of farm management (e.g. antibiotics, food additives).

Physical stressors can also result in direct (immediate) and indirect (delayed) impacts and are best described by the frequency and severity of impact across the area affected. These stressors include storm impacts, diversion of water flows, physical alterations to the environment from the placement of aquaculture farms and to waste discharge, including excess feeds.

Biological stressors include the release of cultured organisms through direct loss of stocks or the reproductive output of stocks, the genetic risks posed by released cultured organisms to native populations through genetic introgression, and the release of diseases, parasites and hitch-hiking exotic species into the surrounding environment.

Effective risk assessment processes are needed to identify potentially invasive species and restrict their introduction or use in aquaculture, while encouraging the use of species that have low invasion potential and can provide net economic benefits for the aquaculture industry and society at large. The invasion sequence typically follows five key steps:

- individuals of the target species are collected and transported from their native geographical range to new locations where they do not occur naturally;
- the target species is introduced into the new location where it is an exotic species;
- individuals become established at the point of introduction;
- the established population subsequently grows and spreads to other locations; and
- the invaders become a nuisance and cause ecological and economic impacts (Figure 7).

4.3.2 Risk analysis

The objective is to evaluate the risk of introducing exotic organisms into a new environment via a standardized process, but it may also provide recommendations for appropriate risk management options. The ERA risk analysis process can be applied to invasives and pests and comprises:

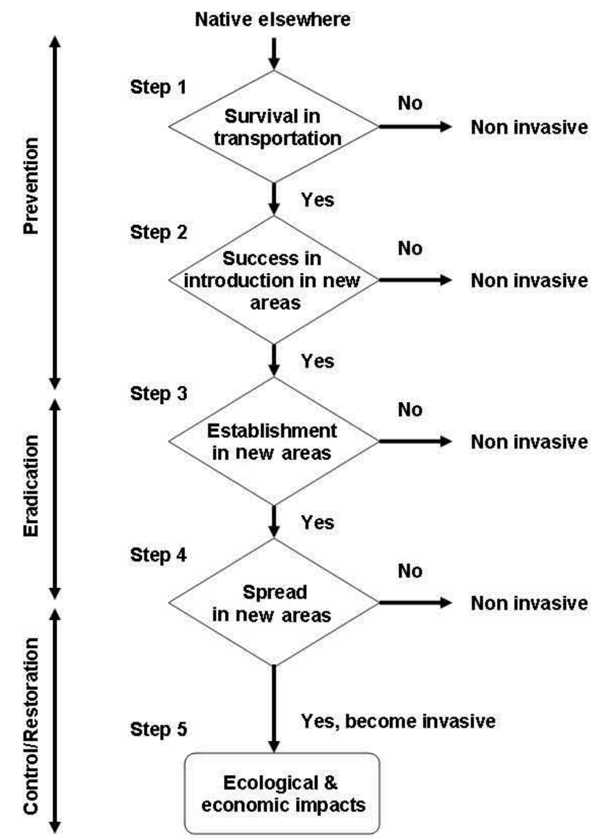
- problem formulation;
- risk analyses (pathway analysis and organism risk assessment; and
- risk characterization.

It is theoretically possible to predict and assess the invasion risk of the candidate species based on the ERA model by way of multiple-level evaluations of the survival probabilities during the transport process (Step 1 in Figure 7), the chance of inoculation into a new region (e.g. accidental escape of cultured organisms, reproduction of cultured organisms in the new region, hitch-hiker release; Step 2 in Figure 7), the chance of establishment in the wild in relation to environmental conditions (e.g. temperature, salinity and food availability; Step 3 in Figure 7), and the likelihood of spread (Step 4 in Figure 7).

1. Problem formulation and assessment framework

Biological invasion risk is a sum of the risks incurred in the transportation, introduction, establishment, spread and impact stages along the sequence of biological invasion (e.g. Carlton, 1985; Hayes and Hewitt, 1998, 2000; Barry *et al.*, 2008; Figure 7). A species-based risk analysis of biological invasions typically comprises two major components, namely a pathway analysis and an organism risk assessment (often referred to as an organism impact assessment (OIA); Figure 8). Initiation of the risk assessment process requires identification of interested parties and other related stakeholders who will provide valuable input and comments on the process (Step 1 in Figure 8). Comprehensive literature reviews on pathway-related matters (e.g. history, ecological risk and mitigation measures) and information on the biology, ecology and invasion history of species of concern are necessary to begin the evaluation (Step 2 in Figure 8). In addition, projected information such as the quantity of individuals, life-history stages and the native and exotic distributions of the organisms are needed for both pathway and organism analyses. Based on all available information, the corresponding probability of each invasion step (i.e. transport, introduction, establishment and spread, as well as ecological and economic impacts) is assessed through a Pathway Analysis and Organism Risk Assessment (Steps 4 and 5 in Figure 8). This process is often conducted with a group of experts and based on the principle of weight-of-evidence. Subsequently, the overall risk of the intended introduction of the exotic species can be characterized using a standardized rating scheme (Step 6 in Figure 8). The results can be used to formulate appropriate mitigation measures and improve risk management (Step 7 in Figure 8).

FIGURE 7
A typical invasion sequence of exotic species, with the corresponding management options (prevention, eradication and control/restoration) at different stages



Source: modified from Kolar and Lodge, 2001; Sakai *et al.*, 2001.

2. Pathway and organism risk analyses

Pathway analysis is largely conducted through collection of relevant information. The following is a generalized list of information required:

- the introduction pathway (intentional vs. unintentional introduction);
- the mechanism and history of the pathway;
- the exact origin(s) of organisms associated with the pathway;
- the numbers of organisms and species travelling with the pathway;
- the intended use of the exotic organisms;
- the history of past experiences and previous risk assessments on the pathway or similar pathways; and
- past and present mitigation actions related to the pathway.

There are two major pathways of introducing exotic organisms through aquaculture activities: (i) intentional introduction of exotic species as culture organisms that eventually enter the natural environment (usually via accidental escape of adults or gametes) and (ii) unintentional introduction of hitch-hiking

FIGURE 8

A conceptual framework for a risk analysis for introduction of exotic organisms. (*details of the organism risk assessment are presented in Figure 9)

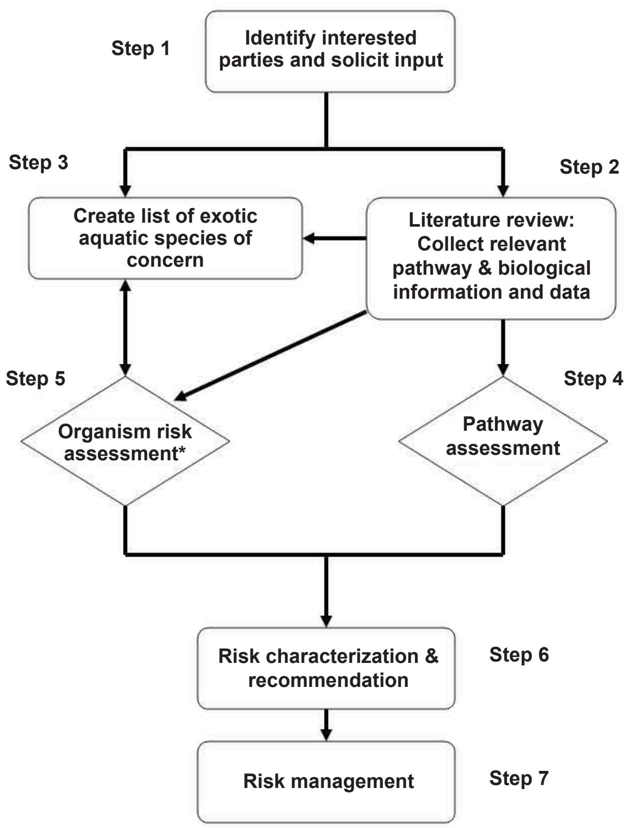


TABLE 7
Classification of native and exotic species according to their characteristics. The priority of concern for each category is also given

Category	Organism characteristics	Concern
1a	A species is exotic and not present in the region or country.	Yes
1b	An exotic species, which has already been present in the region or country, is capable of further expansion.	Yes
1c	An exotic species is currently present in the region or country and has reached probable limits of its range, but is genetically different enough to warrant concern and/or able to harbour another exotic pest.	Yes
1d	An exotic species present in the region or country has reached probable limits of its range, and does not show any of the other characteristics of 1c.	No
2a	A native species but is genetically different enough to warrant concern and/or able to harbour another exotic pest, and/or capable for further expansion.	Yes
2b	Native species is not exhibiting any of the characteristics of 2a.	No

Source: Risk Assessment and Management Committee, 1996.

exotic organisms associated with imported culture organisms or live foods for aquaculture feed. It is important to evaluate the likelihood of escape within the intentional introduction pathway, particularly, in relation to the aquaculture system and facilities. Unintentional introductions have typically been more associated with mollusc aquaculture because of the risk of associated "hitch-hiker" organisms on the external surfaces of the shells. Unintentional introductions have also been identified associated with the movement of aquaculture gear (e.g. ropes, cages, nets) and feeds (e.g. fresh and frozen feeds; Campbell, 2008), as well as the translocation of culture stocks from one facility to another (Culver and Kuris, 2000). Different handling processes can result in very different likelihoods of biological invasion. If the organisms have undergone a quarantine procedure (e.g. isolation, cleaning, depuration) and are transported in reduced density or as larvae, the potential of bringing in hitch-hiking exotic species will be lower.

In Step 3 (Figure 8) a list of exotic species of concern can be developed by identifying the species associated with the pathway (e.g., Hayes and Sliwa, 2003; Hewitt *et al*., 2009) and then classifying them in one of several predefined risk categories according to their characteristics and associated priority of concern (Table 7).

Invasive organisms must be able to pass through all the key stages (Steps 1–5 in Figure 7) along the sequence of successful biological invasion (e.g. Carlton 1985; Hayes and Hewitt 1998, 2000). The organism risk assessment element in Figure 8 (Step 5) is the most important component of the review process used in evaluating and determining the risk associated with a pathway. Leung and Dudgeon (2008) identified the PIES-COM Risk Assessment Model that drives their organism Risk assessment (Figure 9). It has two major parts – the "probability of establishment" and the "consequence of establishment", as described in the equations below:

Invasion risk =
{Probability of establishment} × {Consequence of establishment} (1)

$$\text{Invasion risk} = \{P \times I \times E \times S\} \times \{C \times O \times M\} \quad (2)$$

Where *P* = Estimated probability of the organism being on, with or in the Pathway
I = Estimated probability of the organism surviving in transit and Introduction
E = Estimated probability of the organism colonizing and Establishing a population
S = Estimated probability of the organism Spreading beyond the colonized area
C = Estimated Consequence of all possible ecological impacts if established
O = Estimated Overall perceived impact from social and/or political influences
M = Estimated economic impact (i.e. Money) if established

This risk assessment model contains seven essential elements (i.e. PIES·COM). The probability of establishment is a product of the probabilities of the pathway associated with the particular species (*P*), successful introduction (*I*), successful establishment (*E*) and spread of the species in the new environments (*S*) (Figure 9). The consequence of establishment includes the ecological impact potential (*C*), perceived impact from social and political points of view (*O*) and the economic impact potential (*M*) (Figure 9). The various elements of the PIES·COM model are portrayed as being independent of one another for model simplification, and the order of the elements in the model does not necessarily reflect the order of calculation. Based on the available information and experts' judgment on all relevant considerations (Table 8), a risk rating is given to each element in the model from one of the three levels: low, medium or high. As the certainty of such risk ratings will be influenced considerably by the available information and its quality

FIGURE 9

A schematic diagram illustrating the Organism risk assessment with the seven key elements (i.e. PIES•COM). (VC: very certain, RC: reasonably certain, MC: moderately certain, RU: reasonably uncertain and VU: very uncertain)

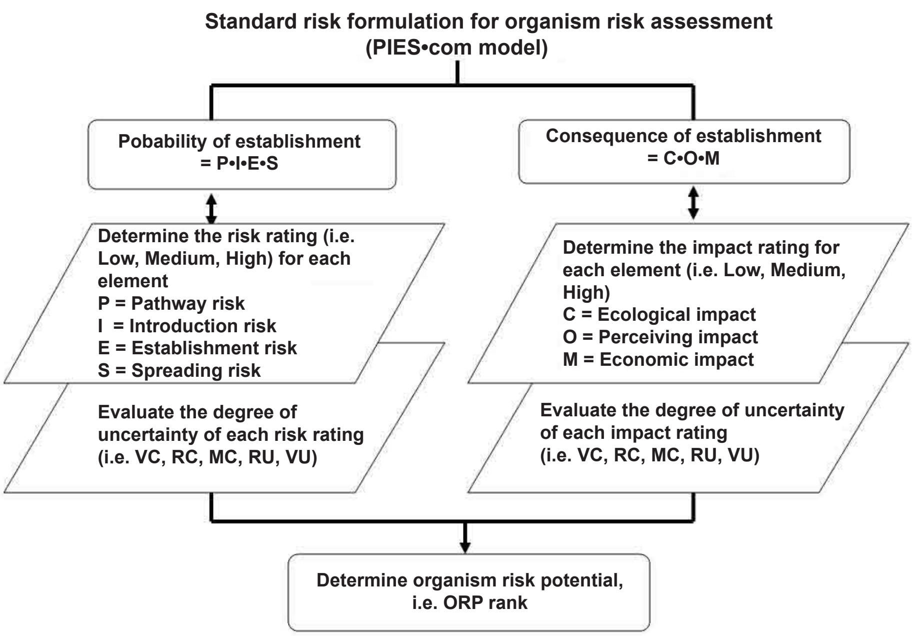


TABLE 8
Characteristics and areas for consideration in the organism risk assessment on the seven key elements (PIES·COM) in the Risk Model (see Figure 9)

Symbol	Element	Characteristics and assessment areas
Probability of establishment		
P	Exotic organisms associated with the pathway	The assessor has to answer whether or not the organisms show a convincing temporal and spatial association with the pathway.
I	Exotic organisms surviving the transit	The assessor should examine the organism's hitchhiking ability in commerce, ability to survive during transit, stage of lifecycle during transit, number of individuals expected to be associated with the pathway or whether it is deliberately introduced.
E	Exotic organisms colonizing, establishing and maintaining a population	The assessor should investigate whether the organisms will come in contact with an adequate food resource, encounter appreciable abiotic and biotic environmental resistance, and have the ability to reproduce in the new environment.
S	Exotic organisms spreading beyond the colonized area	The assessor should evaluate whether the organisms have ability for natural dispersal, ability to use human activity for dispersal, ability to readily develop races or strains, and should estimate the range of probable spread.
Consequence of establishment (CE)[1]		
C	Ecological impact	The assessor should consider the impact on ecosystem destabilization, reduction in biodiversity, reduction or elimination of keystone species, reduction or elimination of endangered/ threatened species, and effects of control measures.
O	Perceived impact	These may include aesthetic damage, consumer concerns and political repercussions.
M	Economic impact	Consideration aspects include economic importance of the aquaculture practitioners, damage to natural resources, effects to subsidiary industries, effects to exports, ad control costs.

[1] Notes: The elements considered under Consequence can also be used to record positive impacts that an exotic organism might have, for example, its importance as a biological control agent, aquatic pet, sport fish, scientific research organism or based on its use in aquaculture. The final risk rating will reflect a balance between the cost, the benefit and the risk of introducing the exotic organisms. When determining the CE score, the three elements are not treated as equal: C and M are given a higher weighting than O.

Source: Risk Assessment and Management Committee, 1996.

and reliability, it is important to record the source of information to support the risk rating and state the degree of uncertainty that the assessor associated with each element. The degree of uncertainty can be classified into:

- Very certain (VC): firm conclusion;
- Reasonably certain (RC): reasonably convinced;
- Moderately certain (MC): more certain than not;
- Reasonably uncertain (RU): reasonably indecisive; or
- Very uncertain (VU): a guess.

For elements with certainty at or below MC, it is important to obtain more data as soon as resources (time, money and efforts) permit. The accuracy of the risk analysis can be greatly improved by minimizing uncertainty.

It is important to stress that the outcome of an Organism Risk Analysis is very likely to be ecosystem specific. Therefore, the risk assessor must consider the potential introduction of the organisms with reference to local conditions such as heterogeneity of aquatic environments, hydrographic parameters, existing biological communities and climate, etc. Biological traits of exotic organisms can be potential predictors indicating whether or not they will be invasive. Although biological traits vary among different stages of invasion and are likely taxon specific, invasive species often display many of the following characteristics:

- high fecundity;
- fast-growth in the establishment stage;
- slow-growth in the spreading stage;
- tolerant of wide ranges of temperature and salinity;
- predatory invaders that eat a range of prey;
- smaller and more eggs;
- a history of invasion;
- exotic taxa distantly related to native species; and
- high number of individuals released and many release events.

3. Risk characterization

The organism risk potential (ORP) is generated from the probability of establishment (PE) and the consequence of establishment (CE): i.e. the risk ratings and impact ratings of the elements in Table 8. The PE is assigned the value of the element (among P, I, E and S) with the lowest risk rating; some examples are shown in Table 9. Such a conservative estimate of the probability of establishment is justified because each of four elements must be present for the organism to become established, and the degree of biological uncertainty for success at each step is often high. For determining the CE score, the three elements (C, O and M) are not treated as equal, the economic impact and ecological impact being given a higher weighting than the perceived impact. The key for obtaining correct CE scores under different impact rating combinations of the three elements is shown in Table 10. It is important to note that the element M (economic impact) can also be positive impacts.

TABLE 9

Examples for derivation of the score for the probability of establishment (PE)

	Pathway	Introduction	Establishment	Spread
Scenario 1				
Risk Rating	High	Low	Medium	Medium
		PE score = low		
Scenario 2				
Risk Rating	Medium	High	High	Medium
		PE score = medium		
Scenario 3				
Risk Rating	High	High	Medium	High
		PE score = medium		

TABLE 10

Key for determination of the final score of the consequence of establishment (CE)

Scenario	Ecological	Economic	Perceived	CE Score
1	H	L,M,H	L,M,H	H
2	L,M,H	H	L,M,H	H
3	M	M	L,M,H	M
4	M	L	L,M,H	M
5	L	M	L,M,H	M
6	L	L	M,H	M
7	L	L	L	L

Legend: Impact rating described as H – high; M – medium; L – low

Source: Risk Assessment and Management Committee, 1996.

After calculation of PE and CE, all seven risk element estimates (P, I, E, S, C, O and M) can be combined into an ORP rating that represents the overall risk of the organisms being assessed. This ORP rating can be determined using the key shown in Table 11. The determination of ORP generally favours environmental protection (following the precautionary principle), as a higher rating is given to borderline cases (cases 2, 4, 6 and 8 in Table 6). This approach is needed to help counteract the high degree of uncertainty usually associated with biological situations.

The overall pathway risk is a sum of pathway-associated risks along the total invasion sequence. The seven risk element ratings of ORP are employed to estimate the combined risk or pathway risk potential (PRP). In practice, results of the rating distribution of the seven elements (e.g. 1 high, 2 medium and 3 low) for deriving the ORP are used to determine the final risk rating of the PRP as shown in Table 12. Thus, the PRP generally reflects the highest ranking ORP.

Once the final rating(s) of ORP and/or PRP have been estimated, the risk characterization is decided following the definition of ratings given in Table 13.

In these risk-characterization procedures, the selection of low, medium and high ratings throughout various levels should mainly be driven by available information such as biological statements under each element. As the low, medium and high ratings of the individual elements cannot be defined or measured, they remain judgmental in nature. The final estimate of ORP or PRP only provides

TABLE 11
Key for determination of the final rating of Organism Risk Potential (ORP)

Case	Probability of establishment	Consequence of establishment	OPR rating
1	High	High	= High
2	Medium	High	= High
3	Low	High	= Medium
4	High	Medium	= High
5	Medium	Medium	= Medium
6	Low	Medium	= Medium
7	High	Low	= Medium
8	Medium	Low	= Medium
9	Low	Low	= Low

Source: Risk Assessment and Management Committee, 1996.

TABLE 12
Key for determination of the pathway risk potential (PRP) based on the rating distribution of the seven elements used for deriving the Organism Risk Potential (ORP)

Characteristics of the rating distribution of the seven elements used for deriving the ORP	PRP rating
1 or more scored with high rating(s) out of the seven	High
5[1] or more scored with medium rating(s) out of the seven	High
1–5[1] scored with medium rating(s) out of the seven	Medium
All scored with low ratings	Low

[1] Note: The number 5 used in this table is arbitrary. The selection of value 4 or 5 is possible when the number of medium-risk organisms reaches a level at which the total risk of the pathway becomes high.

Source: Risk Assessment and Management Committee, 1996.

TABLE 13
Risk characterizations based on the final rating of ORP or PRP

Rating of ORP or PRP	Definition	Actions
Low	Acceptable risk: organism(s) of little concern	• Introduction may be permitted • No mitigation is required
Medium	Unacceptable: organism(s) of moderate concern	• Introduction should be banned or should be controlled via risk management • Mitigation is required
High	Unacceptable: organism(s) of high concern	• Introduction should be banned • Prevention rather than mitigation is mandated, and control measures should be considered.

a summary of the entire risk assessment and some guidance for the decisions about whether or not an exotic species should be introduced, or whether control measures should be in place for introductions that are allowed or whether measures should take place to mitigate the effects of exotic species that have already become established (i.e. retrospective risk assessment). However, the final decision made by the risk assessors should be based on a holistic approach coupled with the weight-of-evidence assessment.

4.3.3 Risk management

Management objectives inevitably depend on the stage of the biological invasion, whether at the prevention (i.e. risk assessment and education), eradication, or control and restoration stages. More attention should be paid to risk prevention, to minimize the chances of an introduction or the necessity for eradication or control measures. Eradication is often impossible when the exotic organism has already established, but the probability of establishment can be minimized if risk analysis is applied consistently. A number of elements would enhance the ability to undertake risk analyses in a more cost-effective and responsive fashion. These include:

- *Database of invasive aquatic organisms*. The development of both global and regional databases of exotic species would greatly help management of introduced organisms. Many such databases currently exist, however these tend to be regionally specific (e.g. Australia – National Introduced Marine Pest Information System (NIMPIS) (www.marinepests.gov.au/nimpis); United States of America – National Exotic Marine and Estuarine Species Information System (NEMESIS) (invasions.si.edu/nemesis); International Union for the Conservation of Nature (IUCN) Invasive Species Specialist Group – Global Invasive Species Database (GISD) (www.issg.org/database).
- *Implementation of Codes of Practice*. Management practices designed to prevent releases of exotic organisms (FAO Code of Conduct; ICES Code of Practice) should be adopted in aquaculture industries.
- *Documentation of the movement of live aquatic organisms.* It is essential to implement a reporting system documenting the details of any import and transportation of exotic organisms.
- *Reporting system for escape.* A reporting system for escapes will be vital for assessing the risk of introduction stage since, if escapes are not reported, the apparent risks of introduction cannot be estimated accurately.

- *Effective quarantine and wastewater sterilization.* In general, aquaculture or other business operations that handle live shellfish require more scrutiny than those handling fresh finfish, as many exotic organisms harboured by the shellfish may enter the new environment unintentionally.
- *Improvement of technology to reduce escape risk.* Management practices and containment facilities could be modified or improved to reduce risks of escapes.
- *Development of artisanal fisheries on escaped exotic species.* The chance of escaped populations of exotic organisms impacting native species may be reduced by allowing local artisanal fishing.

After completion of a risk assessment for an exotic species, risk managers are responsible for determining appropriate management actions. The key elements for risk management and operational requirements during and after a risk assessment are given in Box 4. To evaluate the effectiveness of the implementation of risk management measures, Leung and Dudgeon (2008) recommend that risk analyses should be repeated on a regular basis to ensure that the risk of biological invasion remains low. Such repetition constitutes a form of sensitivity analysis to the initial risk assessment.

4.3.4 Risk communication

Risk communication for ecological risk analysis follows the general principles of risk communication as outlined in Section 3.5.

4.4 OVERVIEW OF THE GENETIC RISK ANALYSIS PROCESS[8]

Aquaculture operations can pose genetic harms to natural populations in the receiving environment. The risk analysis framework is useful for identifying, evaluating and addressing genetic harms posed by escape or release of aquaculture stocks. Direct genetic harms include loss of adaptation, introgressive hybridization, reduction of effective population size and community-level changes; indirect effects upon other species might be mediated by predation or competition. The purpose of a genetic risk analysis is to identify risk pathways, estimate risk probabilities, develop procedures to manage risk and communicate the results to stakeholders, thereby minimizing harm to aquatic and human populations.

4.4.1 Scoping a risk analysis

In a genetic context, a *harm* is defined as gene pool perturbation resulting in negative impacts to a species, a *hazard* is an agent or process that has the potential to produce harm, and a *risk* is the *likelihood* of harm resulting from exposure to the hazard. Risk, R, is estimated as the product of the probability of exposure, $P(E)$, and the conditional probability of harm given that exposure has occurred, $P(H|E)$. That is, $R = P(E) \times P(H|E)$. The steps in risk analysis, then, are to:

- identify potential harms;
- identify hazards that might lead to harms;

[8] This section is extracted with modifications from Hallerman (2008).

BOX 4

Elements of risk management and operational requirements

A. Elements to consider in risk management policy:

- Risk assessments (including uncertainty and quality of data)
- Available mitigation safeguards (i.e. permits, industry standards, prohibition, inspection)
- Resource limitations (i.e. money, time, locating qualified experts, information needed)
- Public perceptions and perceived damage
- Social and political consequences
- Benefits and costs should that be addressed in the analysis

B. Risk management operational steps:

a. ***Maintain communication and input from interested parties*** – Participation of interested parties should be actively solicited as early as possible. All interested parties should be carefully identified because adding additional interested parties late in the assessment or management process can result in revisiting issues already examined and thought to have been brought to closure. They should be periodically brought up-to-date on relevant issues.

b. ***Maintain open communication between risk managers and risk assessors*** – Continuous open communication between the risk managers and the risk assessors is important throughout the writing of the risk assessment report. This is necessary to ensure that the assessment will be policy relevant when completed. Risk managers should be able to provide detailed questions about the issues that they will need to address to the risk assessors before the risk assessment is started. This will allow the assessors to focus the scientific information relevant to the questions or issues that the risk managers will need to address.

c. ***Match the available mitigation options with the identified risks*** – Matching the available mitigation options with the identified risks can sometimes be done by creating a mitigation plan for the organisms, or group of organisms. Where a specific organism or group of organism requires a specific mitigation process (e.g. brine dip of transfers for oysters), the efficacy for control should be recorded. Using this process it will become apparent which mitigation(s) would be needed to reduce the risk to an acceptable level.

d. ***Develop an achievable operational approach*** – Each new operational decision must consider a number of management, agency and biological factors that are unique to any specific organism or pathway. At an operational risk management level, each essential component in the operational sequence (risk assessment, current standard and policy, effective mitigation, feasibility and monitoring) should be examined before approval of the importation or release or action against an exotic organism or pathway is taken. These include the risk assessment, the development of conditions for entry to meet current industry or regulatory standards, effective mitigation of any identified potential exotic aquatic organisms, feasibility of achieving the mitigation requirements and finally, a system of monitoring to ensure that all mitigation requirements are maintained.

Source: Risk Assessment and Management Committee, 1996.

- define what exposure means for an aquaculture stock and assess the likelihood of exposure, $P(E)$;
- quantify the likelihood of harm given that exposure has occurred, $P(H|E)$; and
- multiply the resulting probabilities to yield a quantitative estimate of risk.

Exact probabilities of risk are difficult or impossible to determine for all types of possible harm. Indeed, it is unlikely that all possible harms would be known *a priori*, particularly with respect to any indirect effects. Hence, it may be necessary – based on current knowledge of population genetics, population dynamics, receiving ecological communities and experience with cultured stocks – to classify levels of concern regarding likely genetic impacts posed by cultured stocks into qualitative categories ranging from low to high.

Risk assessment might best be considered as embedded in a three-stage, interactive framework involving the range of stakeholders (Figure 10). Involvement of the full range of stakeholders will bring all existing knowledge into the process, make the process transparent to stakeholders and enhance the understanding and acceptance of the outcome of risk analysis. Stage I involves identifying the problem at hand, engaging stakeholders, identifying possible technical solutions to the problem at hand and identifying potential harms, risk pathways and assessment methods. Stage II is the risk assessment itself, leading to estimating the likelihood that harm will become realized should a proposed action be taken. Upon estimation of that risk, a decision is faced as to whether the risk is acceptable. If it is acceptable, the decision may be made to go forward. If the level of risk is unacceptably high, risk management measures would be identified and residual risk quantified, and the decision of whether to go forward would again be considered. Should the proposed action be implemented, genetic, ecological and social outcomes should be monitored. Because all potential harms and associated pathways cannot be known and precisely predicted *a priori*, it will be necessary to update the risk analysis as knowledge accumulates using an adaptive management approach.

4.4.2 Hazard identification

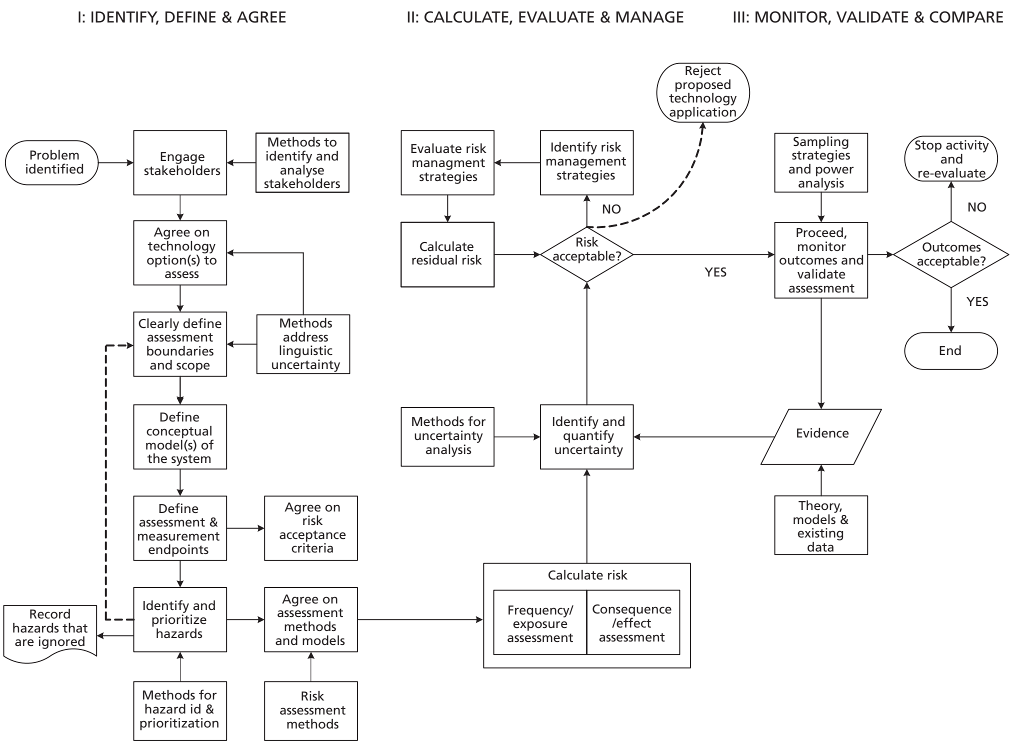
In the context of genetic risk analysis, the hazardous agent is the cultured stock because it is the entity that poses genetic harm to populations in a receiving ecosystem. In the aquaculture context, the hazardous agent may be a non-indigenous species; an interspecific hybrid; or a non-indigenous, selectively bred, triploid or transgenic stock.

4.4.3 Harm identification

The harms posed by the culture of a stock of aquatic organisms relate to chains of events occurring after an escape or release from a culture system. Potential harm must be identified on a case-by-case basis and will depend on the phenotype of the organism, and not *per se* on the genetic manipulation used to produce the stock. Direct genetic harms to wild populations will flow from the cultured

FIGURE 10

Overview of a highly interactive risk assessment framework (Hayes *et al.*, 2007). The framework is divided into three stages. In the first stage, participants agree upon an assessment option, define the scope of the assessment, agree on a conceptual model, identify assessment and measurement endpoints and culminate with an agreed-upon list of prioritized hazard end-points. In the second stage, the risks and uncertainties associated with these hazard end-points are assessed, risks compared to predetermined acceptance criteria and, as appropriate, risk management strategies identified and evaluated. In the third stage, results of monitoring are used to test the predictions of the risk assessment, thereby generating additional data used to reexamine uncertainty in the risk assessment



stock interbreeding with reproductively compatible populations in the receiving ecosystem; examples of types of direct harms include loss of adaptation in natural populations and introgression of new genetic material into species' gene pools through hybridization, which in the extreme case, can lead to loss of locally adapted populations. Indirect effects will flow from competition or predation by the cultured stock on other populations or species in the receiving ecosystem. Indirect genetic harms include the effects of competition or predation, such as reduced abundance of affected populations, resulting in loss of genetic variability, ability to adapt in face of changing selective pressure and an increase the likelihood of inbreeding and extinction. Indirect effects also may be realized through changes in the aquatic community caused by the cultured stocks.

4.4.4 Risk assessment

In the context of genetic risk analysis, risk assessment is an estimation of the likelihood of the occurrence of genetic harm becoming realized following exposure to a genetic hazard. Because realization of harm requires the occurrence of a chain of events, it often is useful to consider risk assessment in terms of the components of the chain. Risk assessment is composed of four components: likelihood of release, likelihood of exposure, consequence assessment and estimation of risk.

1. Likelihood of release – Routine aquaculture operations lose small numbers of cultured animals to the natural environment, with occasional catastrophic losses of larger numbers due to equipment failure, storm damage or flood. The information required for a release assessment in a particular context relates to the biological factors, commodity factors and country factors pertinent to that aquaculture system.

- *Biological factors* relate to the aquatic species at issue, as they affect the likelihood of escape. Finfishes are mobile; in particular the smallest life stages are hard to confine. Crustaceans vary, with many decapods able to escape by crawling or burrowing out of culture systems. Molluscs are easy to confine at the benthic adult stage, but harder to confine at the pelagic juvenile stages; in some cases, the earliest life stages can escape confinement in aerosols.
- *Commodity factors* relate to production methods; that is, different culture systems provide a continuum of confinement, from low to high ranging from extensive production in near-natural systems, to cages and net-pens in oceans and lakes, to intensive production in managed ponds and raceways, to indoor recirculating systems.
- *Country factors* are a consequence of policies and permit systems regulating aspects of siting, culture systems and operations management procedures, as they all affect likelihood of release. In the lack of express or enforced policies,operations of individual farms will vary widely and complicate a release assessment. Especially for developing-country contexts, such a release assessment must assume that cultured stock will escape.

2. Likelihood of exposure – Upon escape or release, for a cultured stock to prove a hazard, it must establish itself in the community long enough to impose harm. Hence, for risk assessment, the critical factor is the likelihood that the cultured stock will become established in the receiving ecosystem. The likelihood of establishment is dependent on three factors: the species' invasiveness, the fitness of the selectively bred stock and the characteristics of the receiving ecosystem. Important aspects in evaluating the likelihood of genetic exposure to a cultured stock are:

- *The species*' invasiveness, i.e. its ability to escape, disperse and become feral in aquatic communities. Many aquaculture species – notably including tilapias, carps and salmonids – exhibit great abilities to disperse and establish themselves in ecosystems in which they are not native.

- *The fitness of the cultured stock in the receiving ecosystem* – Production traits in domesticated aquaculture stocks include improved growth rate, feed conversion efficiency and disease resistance. Traits conferring fitness in culture systems may not be the same as those conferring fitness in the wild. A key question, then, is how genetic improvement might indirectly affect traits determining fitness in the receiving ecosystem, perhaps affecting the likelihood that the cultured stock would become established in the receiving ecosystem. The key issue is change in the net fitness of the selectively bred organism over the entire life cycle. The six net fitness components of an organism's life cycle to be considered are juvenile viability, adult viability, age at sexual maturity, female fecundity, male fertility and mating success.
- *The stability and resilience of the receiving community* – A community is regarded as stable if ecological structure and function indicators return to initial conditions following perturbation. Resilience is the property of how fast the structure or function indicators return to their initial conditions following perturbation. Ecosystems that are most stable will suffer the least harm, with unstable communities suffering the greatest harm. Characterization of community stability and resilience does not generally prove straightforward.

A key caveat for assessing ecological exposure is that it is impossible to limit the spread of an escaped aquaculture stock to a particular receiving ecosystem. Thus, the possibility that a cultured stock may become established in all possible ecosystems to which it can gain access must be considered. If any of these communities is vulnerable, ecological concern would be high. For this reason, precaution suggests that risk should be assessed and managed for the most vulnerable ecosystem into which the escaped or released aquaculture stock is likely to gain access.

3. Consequence assessment – Because of the uniqueness of each cultured stock, culture system and receiving ecosystem, evaluating ecological risk has to be conducted on a case-by-case basis. The likelihood of harm being realized given exposure to a hazard is difficult to quantify, especially with a lack of empirical data for the many kinds of genetic stocks at issue. This linkage is the weakest aspect of current understanding for genetic risk analysis. As a consequence, the risk analyst might often be restricted to evaluating risk qualitatively on the basis of: (1) the species at issue, (2) the effect of genetic background or improvement on the net fitness of the animal in the receiving ecosystem at issue and (3) the stability and resiliency of receiving community. The outcome of such an analysis is likely to be a predication that likelihood of harm given exposure to a genetic hazard is "high", "medium", "low" or "near-zero".

4. Estimation of risk – Rating an overall level of genetic risk posed by a given action then would be based on the product of the three factors, likelihood of release, likelihood of exposure and likelihood of harm given exposure. Because the overall level of genetic risk is a product, if one is negligible, then the overall level of concern would be low. In contrast, genetic improvement that increases fitness of a highly invasive species for introduction into a vulnerable community raises a high level of concern. The estimate of risk might then be compared to a previously set acceptable level of risk (ALOR) to determine whether to go ahead, whether to reconsider the action under conditions of risk management or whether to reject the action at issue.

4.4.5 Risk management

Considering genetic harms in the context of formal risk analysis, it becomes clear that the best approach for minimizing the likelihood of harm being realized is to minimize exposure to the hazard. Four non-mutually exclusive approaches include: (1) geographic location, (2) physically confining the cultured stock on aquaculture facilities, (3) reproductively confining cultured stocks and (4) operations management.

1. *Geographic location* – Context is key; the ease or difficulty of managing risk will depend greatly on the geographic location of an aquaculture facility. Sites subject to flooding, violent storms or wave action are poorly suited for confinement of production stocks.
2. *Physical confinement* – Physical confinement of cultured aquatic organisms will require a combination of measures in order to prove effective. Virtually all physical confinement systems will include mechanical and/or physical/chemical barriers to prevent the escape of cultured organisms from the culture site. The set of barriers must prevent escape of the hardest-to-retain life-stage held at the aquaculture operation, usually the smallest life-stage. Because no barrier is 100 percent effective at all times, each possible escape path from the aquaculture facility should have redundant barriers to escape of cultured organisms. Barriers also must prevent access of predators that can carry cultured organisms off-site (e.g. birds) or damage ponds (e.g. muskrats), allowing escape of cultured organisms.
3. *Reproductive confinement* is a key element of many risk management strategies, especially for cases where physical confinement alone is unlikely to prove effective. Two approaches, culture of monosex or sterile stocks, might be applied singly or in combination. Other approaches for reproductive confinement may become available in the future, including the possibility of reversible sterility through transgenesis.
4. *Operations management* is a key, though often overlooked, aspect of a confinement system. Measures are needed to: (1) ensure that normal activities of workers at the aquaculture operation are consistent with the goal of effective confinement, (2) prevent unauthorized human access to the site and (3) ensure regular inspection and maintenance of physical confinement systems. Effective supervision of project personnel is critical for operations management. Materials transfer agreements may prove important for limiting ill-considered distribution of aquaculture

stocks. Operations management must consider biosecurity after cultured organisms are removed purposefully from the culture site, that is, through the marketing process.

To achieve effective risk management, combinations of risk management measures are advisable so that failure of any one measure will not necessarily lead to escape of confined stocks. Many critical unknowns complicate risk assessment and risk management for aquaculture stocks. The adaptive management approach is based on recognition that knowledge of the environmental and social systems into which the aquaculture stocks would enter is always incomplete. Management should evolve as knowledge of these systems increases. Management cannot adapt if it realized by a only single passage through breeding, decision of whether and how to distribute the stocks and implementation of the distribution programme. Instead, adaptive management would include risk assessment for candidate areas for distribution, incorporation of risk management in the distribution programme and capacity building as appropriate to meet programme goals. Once the aquaculture stocks are distributed, culture operations and receiving ecosystems would be monitored for indicators of ecological and social conditions. Should monitoring indicate that benefits are being realized without harms occurring, then few if any adjustments to programme implementation are required. However, should monitoring indicate that production of cultured stocks is not contributing to the nutritional and economic well-being of farmers or that the stocks are escaping and impacting receiving ecosystems, then it will prove necessary to redefine goals, revise implementation and continue monitoring.

4.4.6 Risk communication

The principles and methods for communication of genetic risks are similar to those outlined in Section 3.5. In particular, pre-agreed contingency plans are useful in risk communication and for achieving agreement on what to do if things go wrong, or well. Genetic risk analysis is an emerging area in aquaculture science. While genetic hazards are well known, the associated risks are not well quantified. Genetic risk management, while widely applied at the research scale, is not widely applied at commercial aquaculture operations. Hence, we do not yet have a body of case studies to exemplify effective communication of genetic risk management.

Communication strategies for genetic risk analysis involve crafting the message appropriate to the case at hand and its effective delivery to target audiences. Two sorts of message are at issue – general explanation of risk analysis as applied to genetic harms and information about applications of risk analysis to specific genetic issues facing the aquaculture community.

4.5 OVERVIEW OF THE ENVIRONMENTAL RISK ANALYSIS PROCESS[9]

The use of risk analysis to identify hazards and to assess and manage environmental risks associated with aquaculture development is relatively recent. In most countries,

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[9] This section is extracted with modifications from Phillips and Subasinghe (2008).

environmental impact assessment (EIA) is the main existing and legally required assessment tool, and many of the elements of risk analysis are already included in the EIA process, although associated with somewhat different terminology. Risk analysis should therefore be part of EIA and strategic environmental assessment, rather than considered as a separate or even parallel process. It is also emphasized that the risk analysis process (as for EIA) needs to be related to management. The analysis is of limited practical use if there is no management framework suitable for addressing the most significant environmental risks associated with aquaculture development.

Traditionally, environmental risk analysis has dealt primarily with the human health concerns of various anthropogenic activities, but this approach has now been broadened to encompass a wide range of environmental concerns. Numerous protocols exist for estimating the human health risks associated with various hazards, and there are an increasing number for the analysis of environmental risks arising as a result of human activity. On a global scale, the major areas of environmental concerns for aquaculture are now well identified and include the following:

- wetland and habitat utilization and damage to ecosystem functions;
- abstraction of water;
- sediment deposition and benthic impacts;
- effluent discharge, hypernutrification and eutrophication;
- environmental contamination and human health risks associated with veterinary drugs;
- human health concerns related to chemical, biological and physical food safety hazards;
- ground water contamination;
- exotic species introduction;
- genetic impacts on wild populations;
- introduction of aquatic animal pathogens and pests;
- other wildlife and biodiversity impacts; and
- social issues related to resource utilization and access.

Although the concerns are highly diverse and are farming species/system and site specific, there are some common characteristics to be taken into account if improved environmental management is to be achieved:

- Many of the impacts are subtle and cumulative – often insignificant in relation to a single farm but potentially highly significant for a large number of farms producing over a long period of time, particularly if crowded in relation to limited resources.
- Some of the impacts may be highly dispersed through space and time, depending on seasonality, farm management, stocking practices and other factors.
- There is a high level of uncertainty and lack of understanding associated with many potential impacts of aquaculture. This argues for more extensive use of the precautionary approach to aquaculture but makes gathering and analysis of risk analysis data problematic.

The risk analysis framework is useful for identifying, evaluating and addressing environmental hazards associated with aquaculture; however, it should be noted that the potential hazards from aquaculture and their impacts depend upon the species, culture system and operations management practices, and other non-technical factors such as human and institutional capacities.

4.5.1 Preliminaries – Scoping, hazard identification and end-points

The wide range of environmental hazards in aquaculture and sometimes, the costs of risk analysis, make it necessary at the outset to carefully determine the scope of the risk assessment. Decisions need to be made and clearly articulated on the specific objectives and scope of the risk assessment (e.g. qualitative or quantitative analysis of a single or multiple threats to a single or multiple environmental asset(s); determination of spatial and temporal scale). These decisions will guide the type of data and information that need to be gathered and help to identify knowledge gaps. At this "problem formulation and hazard identification" stage, existing information typically needs to be compiled for the following:

- the environment of interest, particularly its most important assets (and their values), or at least those that need to be protected or are potentially at risk;
- the hazard(s) to which the environmental assets are, or may be, exposed; and
- the types of effects that the hazard(s) may have on the environmental assets.

The synthesis of such information should be done in consultation with stakeholders through an agreed-upon process. For example, the assigning of the "values" of ecological aspects in particular requires consultation to determine their significance for society and local communities.

End-points are the environmental values that are to be protected, operationally defined by an ecological entity and its attributes. For example, salmon are valued ecological entities; reproduction and age class structure are some of their important attributes. Together "salmon reproduction and age class structure" could form an assessment end-point. In other cases, ecological characteristics such as the abundance of some sensitive species could be considered. Ecological end-points should be ecologically, socially and politically relevant, sensitive to the potential stressors, amenable to measurement and relevant to the management goals.

The specific undesirable end-points that need to be managed may be identified in a variety of ways. Some of the end-points are the result of legislative mandates or international agreements. Others may be derived from special socio-economic concerns and may be identified through community consultations. Legislation and policies of the national or regional authority may identify some end-points that need to be managed. The IMO/FAO/UNESCO-IOC/WMO/WHO/IAEA/UN/UNEP Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP) notes five broad categories of environmental effects or end-points commonly raised as concerns by society in relation to temperate coastal marine aquaculture:

- changes in primary producers:
  - abundance (i.e. of macroalgae and marine angiosperms);
  - composition (i.e. harmful microalgae);
- changes in survival of wild populations due to genetic change, disease or competition from escaped aquatic animals and plants from aquaculture facilities;
- changes in composition and distribution of macrobenthic populations;
- changes in trophic resources; and
- changes in habitat (physical and chemical).

However, the actual end-points associated with the wide range of potential hazards in aquaculture will vary and will be site specific. Prior to initiating a risk analysis, it is important to identify the "end-point(s)".

4.5.2 Risk assessment

Risk assessment is a process for evaluating the likelihood of adverse environmental effects arising from the hazard. This phase incorporates the release assessment, exposure (likelihood) assessment and consequences (effects) assessment. The most pertinent information sources and techniques should be used, although these will vary depending on the assessment.

1. *Release assessment* consists of describing the probability of release, as well as the quantity, timing and distribution of a hazard in an environment. If the release assessment demonstrates no significant probability of release, the risk assessment need not continue. For example, a release assessment associated with a hazard such as discharge of nutrients from an intensive aquaculture farm would examine the probability of nutrient release, amounts of the nutrients of interest, timing and distribution into the receiving environment. The term "release assessment" is less relevant to some hazards associated with aquaculture, such as the siting of farms and habitat conversion. Some ecological assessments therefore do not consider this part of the risk assessment.
2. *Exposure assessment* determines the likelihood of the effects of an undesirable event (identified in the hazard identification and release assessment stages). Data on the effects of a hazard provide little useful information without knowledge on the actual level of exposure of the end-point to the hazard. Thus exposure assessment aims to determine the likelihood that the environmental asset(s) of concern will be exposed to the hazard and therefore, that an effect will be realized. For a biological hazard, such as an invasive species, exposure assessment might involve integrating information on the source of the species, the potential route of entry into the ecosystem of interest, rate of spread, habitat preferences and associated distribution. Existing information (e.g. remotely sensed imagery) or habitat suitability modeling can be used for such purposes. If the exposure assessment demonstrates no significant likelihood of significant exposure, the risk assessment may conclude at this step.

The outputs of the exposure assessment should involve and be crosschecked with stakeholders to ensure that data and information were used and interpreted appropriately. The assessment should also be iterative. Information that is obtained throughout the process should allow for reassessment of an earlier step. In particular, discoveries during the analysis stage may encourage a shift in emphasis. Rather than being considered a failure of initial planning, this constant reassessment enables environmental risk assessment to be a dynamic process well suited to ecological study.

3. *Consequence Assessment* aims to determine and characterize the impacts or consequences of the release on the measurement end-points selected during problem formulation. For example, reduced water quality (for whatever reason) might impact aquatic ecosystems as measured by reduced species diversity and abundance of macroinvertebrate and/or fish communities. It is desirable to quantify the magnitude of impact to the extent possible. The process of risk assessment associated with the theoretical release of solid organic material from a marine fish farm is summarized in Table 14.

TABLE 14
Risk assessment approach applied to solid organic material from an intensive marine fish farm

Risk analysis step	Description	Methods
Potential hazard	Discharge of organic fish farm waste	Consultation, analysis
End-point	Benthic macrofauna diversity and species retained	Scientific, legal review and public consultation
Release assessment	Assess amounts, patterns and types of organic wastes released from fish farm (uneaten food, faeces, displaced fouling organisms)	Review of scientific data, management information
Exposure assessment	Assess organic material settling on the benthos (i.e. being exposed to solid organic waste)	Benthic models (relating current, depth and settling velocity of sold waste), site assessments
Consequence assessment	Assess how benthic macrofauna diversity and species are impacted by organic material accumulation rates	Review of scientific literature, site assessments
Risk estimation	Estimate consequences; the probability and extent that benthic macrofauna diversity and species will be impacted	Risk evaluation matrix method

4.5.3 Risk estimation

This step integrates the outcomes of the effects (consequences) and exposure (likelihood) assessments in order to determine the level of risk (i.e. consequences × likelihood) to environmental values (end-points).

In general, there are three levels at which this analysis of risks can be undertaken: qualitative, semiquantitative and quantitative. Often, risk assessments are undertaken in a tiered manner, with initial screening-level qualitative or semiquantitative analyses being done prior to more detailed quantitative analyses. This approach can be used to first rank the threats and associated hazards so that more effort can be allocated to quantitative risk analyses for the most important (i.e. highest priority) hazards. Quantitative risk assessment methods are becoming more widely used. They include decision or logic trees, probabilistic methods, predictive models, dynamic simulation models and Bayesian networks.

GESAMP has attempted to develop a "logic model" to explore and illustrate the complex causal chain between hazard and ecological end-points. The "release-exposure" model is rather limited and difficult to apply to many aquaculture-associated hazards (it was developed originally in relation to simple toxic chemical release and exposure of organisms). GESAMP has therefore built up causal models with information on the probability of a causal effect, the uncertainty (lack of knowledge or unpredictability) associated with the relationship and the severity of the effect (intensity, extent, duration). This approach may serve as a useful tool to: a) analyse the nature and overall significance of the risk; b) communicate and exchange knowledge and perspective on the various relationships and associated risks/uncertainties; and c) focus further work on key areas where probability, severity and uncertainty are all high, and where research can significantly reduce uncertainty. There are also many variations on this in the form of networks, trees, matrices and associated scoring systems that can be used to explore alternative outcomes and/or the likely benefit to be derived from specific management interventions.

The wide range of environmental issues in aquaculture therefore requires a wide range of tools and approaches. The complexities of environmental risk assessment in aquaculture will also be influenced by a complex interaction of different factors related to the sector, such as:

- the variability associated with technology, farming and management systems, and the capacity of farmers to manage technology;
- the variability associated with location (i.e. climatic, water, sediment and biological features), the suitability of the environment for the cultured animals and the environmental conditions under which animals and plants are cultured;
- the financial and economic feasibility and investment, such as the amount invested in proper farm infrastructure, short versus long-term economic viability of farming operations, investment and market incentives or disincentives, and the marketability of products;
- the socio-cultural aspects, such as the intensity of resource use, population pressures and social and cultural values and aptitudes in relation to aquaculture; social conflicts and increasingly, consumer perceptions, all play an important role; and
- institutional and political factors such as government policy and the legal framework, political interventions, plus the scale and quality of technical extension support and other institutional and non-institutional factors that are also influential in determining the risks, possibilities for management and the success with which the risk analysis approach can be applied.

The risk analysis approach however can also be used to explore the risks associated with different technologies and indeed, to use such information to develop industry codes of practice.

4.5.4 The role of social aspects

The social aspects of environmental risk analysis for aquaculture deserve special attention. Economic, political, legal and social concerns play important roles throughout the assessment, evaluation and decision-making stages of risk management. Ensuring dialogue between interested parties at all stages requires an understanding of the social aspects of risk along with an appreciation of the mechanisms by which stakeholders can be actively engaged in the process.

The evaluation of risk entails a judgment about how significant the risk is to the receiving environment and to those concerned with, or affected by, the decision. In conjunction with formal scientific input, this requires the examination of public and political judgments about risks alongside the measurable costs and benefits of the activity in question. The precise knowledge required for an objective evaluation is often lacking for environmental risk assessment and an element of judgment is therefore usually needed. Furthermore, environmental quality involves both scientific and social elements. There is, therefore, a need to carefully consider the social dimensions of a risk as a part of the decision-making process.

Society is increasingly conscious of the harm that its activities can cause to the environment and the harm to people or the loss of quality of life that can result from environmental degradation. Decisions about environmental risks should, therefore, take social issues into account. In conjunction with the assessment of a risk, it is important that the decision-maker asks whether the risk is likely to be acceptable to those concerned with, or affected by, the risk or consequent management decision.

4.5.5 Risk management

Risk management is the design, selection and implementation of a programme of actions to reduce risk to an acceptable level. Risk management measures may also include monitoring, the outcomes of which should be used to re-assess risk as well as to determine or modify the success of risk management measures.

Risk management measures to address environmental issues in aquaculture are now being used in several countries following risk assessment. An example is in the State of South Australia, where the type and level of environmental management and reporting requirements for effluents from inland aquaculture farms are varied depending on the risk classification from the assessment phase. Higher risk farms require additional parameters and increased frequency of sampling.

4.5.6 Risk communication

The purpose of risk communication in environmental risk analysis is to supply planners, managers, industry experts, environmental agencies and laypeople with the information that they need to make informed, independent judgments about risks to their health, about the safety of the operation under consideration and about the potential environmental effects, as well as concerning the economic and social risks associated with the development. Risk communication is widely recognized as a critical component of the ERA process. Communication about environmental risks can be used either as a tool to provide information, explain and warn, or to encourage collective partnership approaches to decision-making through greater public participation in the risk management process. The risk communication process for ERA is similar to the general risk communication process described in Section 3.5.

4.6 OVERVIEW OF THE FINANCIAL RISK ANALYSIS PROCESS[10]

Financial risk refers to the potential loss associated with an aquaculture investment. Aquaculture investments may be public or private and made on behalf of stakeholders, including individual farmers, shareholders, farm enterprises, financial institutions and/or government institutions.

A variety of quantitative methods are used for financial risk assessment. Financial analysis methods (capital budgeting, enterprise budgets, cash flow analysis, financial performance ratios, partial budget analysis, etc.) are necessary. Numerous examples from aquaculture research illustrate methods for probabilistic risk estimation (probability trees, Bayesian networks and stochastic simulation) and non-probabilistic risk estimation (what-if/scenario-based analysis, sensitivity analysis and break-even analysis). Evaluation methods based on decision analysis principles are well-established in financial risk analysis. Examples for assessing financial risk in aquaculture include the use of decision trees and Bayesian decision networks, risk programming (e.g. E-V efficiency and MOTAD), stochastic efficiency and multiple criteria/trade-off analysis (e.g. MCDM and AHP/ANP).

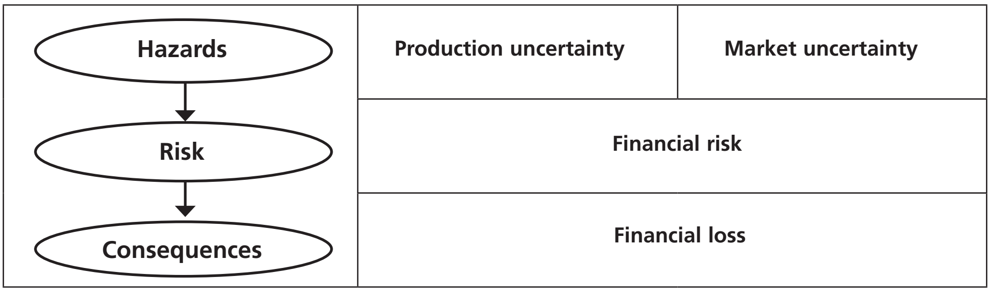
While many studies and techniques are available to analyse financial risk in aquaculture, the methods are not necessarily linked to the traditional components of a risk assessment (i.e. release assessment, exposure assessment, consequence assessment and risk characterization). Financial risk analysis requires a background in financial analysis methods and the assistance of risk analysis tools. Although commercial software packages are becoming easier to use, farmers and policy-makers may require the assistance of risk analysts/modelers to decompose their financial risk concerns. Without the available resources or assistance, practitioners may not view these evaluation methods as practical or may find existing models unusable. Education, software accessibility, training and assistance will be needed in order for financial risk analysis to be widely adopted in aquaculture. Financial risk analysis methods must be integrated in the early phases of hazard identification and risk assessment in order to truly manage financial risk in aquaculture.

4.6.1 Hazard identification

Financial hazards can be broadly classified as production threats or market (or economic) threats. Financial risk represents the likelihood of a hazardous event occurring and the potential financial loss that could result. Figure 11 illustrates how financial risk links hazards to financial loss. The presence of hazards affecting production and market conditions (e.g. price, demand) can bring about financial loss.

[10] Extracted with modification from Kam and Leung (2008).

FIGURE 11
Market and production uncertainty are commonly viewed as sources of risks that lead to financial losses



- *Production threats* have a negative impact on saleable yield, resulting in a financial loss. Threats to production include unfavourable environmental conditions, equipment or other asset failure, poor-quality seedstock and broodstock, disease and pest infestation. The success of an aquaculture enterprise often depends on the tacit knowledge of a few experienced farmers and managers. Consequently, employee loss or disability creates financial risk because production may be disrupted.
- *Market threats* exist in the form of product prices and regulations. Industry competition or reduced demand can lead to decreasing sale prices of aquaculture products. In either case, decreasing market prices will reduce revenue associated with sale of aquaculture products. Escalating prices of production inputs also pose a market threat because they decrease producer profit. Likewise, producers are exposed to risk due to limited supply of inputs.
- *Government policies and other institutional threats* affect the aquaculture business climate by influencing interest rates and imposing tax incentives, trade restrictions and environmental policies. Government regulations contribute to risk because they can become increasingly demanding, costly to satisfy over time and may be subject to change.

A variety of resources should be consulted to identify the hazards that contribute to financial risk. Stakeholders whose investments are at risk may provide significant insight when identifying hazards. When the hazards contributing to financial risk are not well defined, anecdotal reports are helpful in identifying hazards. Industry experts and the farmers themselves are typical secondary sources used to identify the pertinent production and market threats.

4.6.2 Risk assessment

A risk assessment refers to the process of identifying, estimating and evaluating the consequences of exposure to a hazard or a source of risk. It consists of (i) release assessment; (ii) exposure assessment; (iii) consequence assessment; and (iv) risk characterization.

1. Release assessment

After production and market threats have been identified, a release assessment is needed to determine the extent to which potential hazards exist. The practice of risk assessment presumes that it is possible to estimate the uncertainty of the hazard existing. Quantitatively, uncertainty can be estimated in the form of probabilities (or probability distributions). When probabilities are difficult to estimate, a range of values can reflect uncertainty in the form of scenarios (e.g. best case, most likely and worst case). For biological production threats, a release assessment will generally rely on a pathway analysis to trace the method by which a pathogen reaches the production site.

In contrast to biological threats that pose financial risk, many other production threats are not biological in nature and consequently, a pathway analysis is not necessary for a risk assessment. Production threats that originate on the farm-site are a distinct departure from biological threats traditionally traced by risk assessment methods. Potential hazards that are farm-specific such as growth variation can be estimated using expert input or based on farm historical data. Other on-site risks include equipment failure, which can be quantified using expert estimates or farm data on downtime for repairs and services.

For market threats, a hazard can include the potential decrease in sale prices or demand. Hazards also come in the form of increases in the price of production inputs (e.g. cost of seedstock, broodstock, feed, water) or demand of products. Industry data are a good resource for identifying fluctuations in the volumes and prices of products sold, as well as input prices.

2. Exposure assessment

In contrast to release assessments that describe the extent to which the hazard exists in the environment, exposure assessments are specific to the investor(s) (or stakeholders). In financial risk analysis, exposure assessment involves an estimate of the probability that a hazard will affect a farm, entire industry or other unit of analysis. In studying an aquaculture industry, a hazard may affect each farm differently. Just as some populations are more resilient to biological hazards, some farms are more resilient to financial hazards. Their resilience or susceptibility to the threat will depend on production technologies, business strategies, site characteristics and other risk-mitigating practices. Differences between farm characteristics and practices and their association with financial risk allude to potential financial risk management strategies.

Determining the financial risk factors for a farm is often based on tacit knowledge. An exposure assessment helps to illuminate the factors contributing to financial risk and fosters risk communication. General perceptions of a farm's level of exposure in comparison to other farms can underscore the characteristics and strategies that lower a farm's financial risk. Financial risk factors that expose farms to hazards can also be determined from farm performance measures.

3. Consequence assessment:

Consequences refer to outcomes, usually a loss such as monetary loss, production loss or socioeconomic loss. The consequences can represent a single aquaculture enterprise, entire industry representing multiple enterprises or a regional economy. They include:

- *Financial consequences* – Since many of the principles underlying a financial risk assessment are based on financial analysis, a basic understanding of financial analysis methods is highly recommended. Financial risk analyses focus primarily on profitability indicators. Financial profitability can be measured in a variety of ways, including profit (net revenue or net income), return on production inputs (e.g. capital, water, land and labour), profit margin, return on investment (ROI) and internal rate of return (IRR). In order to measure profitability, a careful accounting of the costs is needed. When estimating the financial cost of a hazard, it is necessary to identify the fixed costs and variable costs. Costs that vary with production are called "variable costs" (also called operating costs). In contrast, fixed costs are costs that are incurred regardless of production activity (sometimes referred to as overhead or ownership costs). Fixed costs associated with a hazard can include the one-time expenses associated with the realized financial threat. These costs can include additional clean-up costs, preventive control measures (disease control), fines, equipment repair or enhancements. Many fixed costs require additional supporting information to identify depreciation costs and interest levels that may change on an annual basis. An example of a financial analysis based on an enterprise budget for a Pacific threadfin hatchery is given in Box 5.
- *Economic consequences* – Financial risk can be viewed as a contributing factor to economic risk. The economic impact on an industry reflects the cumulative financial consequences experienced by industry members. When examining economic consequences, or "economic risk," we are also concerned with the impact on other industries within a region or between regions of interest, generally with less concern for the individual farm financial details. An input-output model, for example, considers relationships between different industry sectors. An input-output model defines how output from one industry becomes input of another industry among different sectors for a cross-section of the economy. Based on the structure of the economy as it relates to product consumption, the impact of policies could be projected for a regional economy or national economy. A more detailed analysis could also include welfare assessments (i.e. consumer and producer surpluses) using econometric and welfare analyses.
- *Other consequences* – Socio-economic consequences may also be considered when evaluating financial risk. Environmental damages, social impacts (e.g. employment and income distribution issues), and the effects on international and domestic trade are also valid measures to consider. Industry performance measures (e.g. proportion of farmers experiencing a loss or farmers receiving

BOX 5

Classifying costs to calculate profitability: a financial analysis of a Pacific threadfin hatchery

A spreadsheet model was developed to determine the viable scale for a commercial Pacific threadfin (*Polydactylus sexfilis*) hatchery in Hawaii (Kam *et al.*, 2002). The production scheme was modeled after state-of-the-art practices performed at the oceanic Institute in Waimanalo, Hawaii. For a hatchery enterprise producing 1.2 million fry per year, the cost associated with raising one 40-day old 1.00 g fry is estimated at US$0.2201 (Table 7). The largest variable costs are in labour and supplies, which comprise 49 and 9 percent of the total production cost, respectively. The combined annualized fixed cost for development and equipment is approximately 12 percent of total production cost. Based on a 20-year statement of cash flows for fry sold at US$0.25, the 20-year internal rate of return (IRR) was 30.63 percent. In comparison to the US$0.2201 unit cost for 1.2 million fry production, analyses of smaller enterprises producing 900 000 and 600 000 fry per year reflected significant size diseconomies, with unit costs of US$0.2741 and US$0.3882, respectively (Figure 4).

Demand to support a large-scale Pacific threadfin commercial hatchery was uncertain. Since smaller-scale commercial hatcheries may not be economically feasible, facilities may seek to outsource live feed production modules or pursue multiproduct and multiphase approaches to production. An analysis of the production period length, for example, indicated that the cost for producing a day-25 0.05 g fry is US$ 17.25 before tax and suggested the financial implications of transferring the responsibility of the nursery stage to grow-out farmers (Figure 5). Evaluation of the benefits gained from changes in nursery length, however, must also consider changes in facility requirements, mortality and shipping costs associated with transit, and the growout performance of and market demand for different size fry.

Additional analyses can be found in the original study, which estimated the potential cost savings associated with the elimination of rotifer, microalgae and enriched artemia production. Managerial decisions, however, would also consider the quality and associated production efficiencies of substitutes.

return on labour that is lower than the wage rate) may be useful measures when considering regional socio-economic agendas. Principles of utility and methods for defining evaluation criteria can help to consolidate social, economic and financial considerations.

The results of a release assessment, exposure assessment and consequence assessment are combined to form a risk characterization for a hazard (or multiple hazards). Financial consequences signify the difference between financial risk characterization from other forms of risk characterization. A financial risk analysis can be conducted for any hazard that contributes to a financial loss.

4. Risk characterization

The process of risk characterization produces a risk estimate that reflects the consequences and likelihood of a hazard affecting a farm. Consequently, a risk estimate integrates the results of the release assessment, exposure assessment and consequence assessment. Financial risk characterizations quantify the relative impact of hazards in comparison to a baseline – ideal situation – where no hazard exists. When no baseline is available, the consequences associated with different hazards are often compared when making risk management decisions.

Financial risk cannot be measured by budgets or performance ratios because they are based on average values and do not account for uncertainty. Consequently, principles of financial analysis are a necessary first step in financial risk assessment. Since risk is a relative measure, a financial analysis is usually conducted first as the reference point for subsequent risk analysis. For risk analysis, methods for integrating aspects of uncertainty are needed. When characterizing financial risk, decision analysis methods allow us to consider uncertainty that affects the financial measures of interest.

Decision analysis refers to the body of methods used to rationalize and assist choices under uncertainty. In addition to providing managerial decision support, decision analysis techniques encourage transparency of the problem, which is essential for risk communication. From a decision analysis perspective, there are two approaches to estimating uncertainty: probabilistic and non-probabilistic estimation. In probabilistic estimation, likelihood estimates and probability distributions are used to quantify uncertainty. In non-probabilistic estimation, uncertain events – for which the likelihood of occurring is not specified – are portrayed as scenarios. Common methods for probabilistic estimation include probability trees, Bayesian networks and stochastic simulation, while those for non-probabilistic estimation include what-if (scenario-based) analysis, sensitivity analysis and break-even analysis.

Like a bioeconomic model, financial risk characterization links production and financial (economic) parameters. When the relationships between a hazard and its financial consequences are formalized in a risk characterization, it is possible to systematically compare alternative strategies. These linkages are generally specified during the financial risk assessment (release assessment, exposure assessment and consequence assessment).

4.6.3 Risk management

Risk assessments inform risk management, the process of evaluating and reducing risks. Risk reduction will depend on the risk management evaluation criteria or financial objectives. Financial risk management implies that something can be done to reduce risk with respect to the financial risk objective. The basic process of financial risk management includes:

- defining the risk management objective(s);
- specifying the decisions that may reduce or remove the hazards; and
- selecting an evaluation and monitoring method.

Risk management objectives – Risk management evaluation criteria are usually based on the outcome measures identified in the consequence assessment. Financial risk assessment objectives are usually based on measures of profitability.

- *Expected utility maximization* – The emphasis of the consequences or the evaluation criteria considered thus far has been monetary in nature. In decision analysis, the criteria can be a single attribute such as profit or represent multiple attributes. One common method for combining or converting values into a general measure of utility is through the use of an additive weighting scheme. According to the principle of rational choice, we prefer alternatives that maximize our expected utility. The expected utility maximization principle is conventionally used in decision analysis.
- *Risk aversion* – When a decision-maker is assumed to have a risk-neutral attitude, a simple additive weighting scheme is used. Risk-aversion and risk-seeking attitudes require that risk be embedded into the weighting scheme. Utility is a flexible measure that can incorporate monetary and subjective criteria. Risk attitudes, for example, can be used to adjust traditional profit-maximizing analyses to reflect risk-averse behaviour. For example, when faced with greater risk, risk aversion may increase and our investment level will decrease.
- *Precautionary principle:* The precautionary principle reflects a preventive approach to risk management. The precautionary principle can be contrasted with "monitor-response" regulatory frameworks, which can be viewed as a weak approach since the damage will have already been done. At the surface, the precautionary principle could appear to reduce our confidence in methods highly regarded as having scientific rigor. Yet, by taking into account the precautionary principle, it is still necessary to identify cost-effective measures to prevent irreversible damage. Therefore, from the precautionary principle perspective, risk management methods will not seek to determine *if* any preventive measures should be taken, but rather *which* preventive measures should be carried out.
- *The safety-first rule:* The "safety-first approach" is a form of lexicographic utility that is commonly used in risk analysis. As an alternative to expected utility maximization rules, the approach specifies that decisions must preserve the safety of a firm's activities, followed by a profit-oriented objective.

Management decisions – Risk management explores alternative strategies that potentially reduce consequences, examines the feasibility of implementing measures and involves periodic review of the effectiveness of policies implemented. The alternative strategies can be classified as action decisions and information decisions. Action decisions remove or reduce hazards to reduce risk – the potential for negative consequences. Test decisions gather evidence to inform action decisions. This perspective of risk management is referred to as the "test-action" risk framework. Most risk assessment frameworks do not permit a systematic comparison between different kinds of intervention and existing farmer/fisher activities. However, the test-action risk framework has been demonstrated to be general enough to compare the effectiveness of different risk management strategies and compare the relative risk between hazards.

- *Actions to remove or reduce hazards* – Farm enterprises can reduce financial risk in a number of ways. Farmers can reduce production threats by diversifying their product mix, changing their scale of production and re-allocating resources. The financial structure of the farm can be adjusted to combat market threats (e.g. a change in financial leverage will cause a change in the debt to equity ratio). Yield insurance is a preventive means of mitigating financial risk. In exchange for a fixed insurance premium, producers will receive protection from uncertain but potentially large losses.
- *Tests to gather information* – Tests are performed to gather information that is used to inform decisions. In risk assessment, an informative test result can reduce uncertainty and be used to revise release and exposure estimates and the expected utilities of subsequent decisions. Based on the revised expected utilities, a decision-maker might proceed with a management plan that reduces potential financial loss. Test information is not usually free. Monitoring, biosurveillance, forecasts and laboratory analyses are examples of test decisions. Test decisions might incur expenses associated with labour, materials or revenue foregone. Ideally, the cost of a test will not exceed the potential financial benefit.

Evaluation methods – As in risk characterization, where a number of decision analysis methods can be employed, a range of decision analytic methods are available for evaluating financial risk management decisions (see Kam and Leung [2008] for details). These include:
- decision trees and Bayesian decision networks;
- risk programming (expected value-variation efficiency [E-V or mean-variation efficiency], MOTAD (minimization of total absolute deviations) and scheduling);
- stochastic efficiency; and
- multiple criteria (trade-offs) analysis (multicriteria decision making [MCDM] and the analytic network process [ANP]).

4.6.4 Risk communication

Risk communication occurs throughout risk analysis, such that information and the opinions of stakeholders are incorporated throughout the risk analysis, results of the risk assessment and proposed risk management measures are communicated to decision-makers and stakeholders, and relevant feedback is used to revise the risk assessment.

Financial ratios can be a useful communication tool. However, some financial ratios are complex and difficult for wide audiences to interpret. Since the results of a risk analysis are meant to inform decision-makers, interpretable results and a transparent process are necessary. Risk analysts should strive to use the simplest financial measures that can communicate the major issues.

Spreadsheets continue to grow in popularity and can be used by non-programmers. A number of sophisticated add-ins have been developed for Excel that can be used to analyse risk. The spreadsheet interface and add-in features assist in visualizing model uncertainty. Risk analysis results presented as probability distributions, cumulative probability distribution graphs and decision trees are helpful in communicating risk and comparing scenarios to wide audiences.

The decision analysis methods require that a problem be decomposed. The process of decomposition creates transparency and fosters communication. Many decision analysis software packages used in risk analysis are equipped with visual aids. Probability trees, decision trees, Bayesian networks and Bayesian decision networks, for example, illustrate causal relationships that can help to communicate the risk problem and results of the analysis. Consequently, in addition to the analytical benefits of software packages, the software packages also enable communication and promote risk understanding.

4.7 OVERVIEW OF THE SOCIAL RISK ANALYSIS PROCESS[11]

Social risks are challenges by stakeholders to companies' business practices due to real or perceived business impacts on a broad range of issues related to human welfare. The consequences may include brand and reputation damage, heightened regulatory pressure, legal action, consumer boycotts and operational stoppages – jeopardizing short- and long-term shareholder value.

In terms of risk management, the difference between social risks and technical risks such as pathogens is that the latter focuses on point solutions (i.e. specific actions to mitigate particular sources or impacts of risk). On the other hand, the approach to social risk, because of its complex origins and impacts, is integrated management. This is probably one of the reasons for the lack of any standardized, widely accepted method, guidance or manual on social risk analysis, apart from those developed for project risk analysis in which social risk is incorporated. There is as yet no formal guideline or agreement issued or arrived at by the FAO, Asia-Pacific Economic Cooperation (APEC) or other organization, on social risk analysis that is comparable to those on food safety, pathogen, environmental and ecological risks.

The broad and usually interlinked social and economic impacts of risks include loss of livelihood, loss of income, loss of market, loss of assets and loss of capacity to work productively. From this perspective, just about any hazard has the potential to translate into a risk that has social impact. Civil unrest, threats to peace and order and widespread poverty and social inequalities are by themselves social hazards. But these are not results of socially or environmentally irresponsible practices of aquaculture. A farm or a company deciding to locate in an area considered high-risk because of social unrest is expected to make a decision analysis on the basis of an already known hazard that could threaten the viability of its operations. Similarly, farms or enterprises located in an area where risks of a social nature or origin are imminent or suddenly occur would need to weigh management options, i.e. pull out and avoid the risk or stay and initiate risk

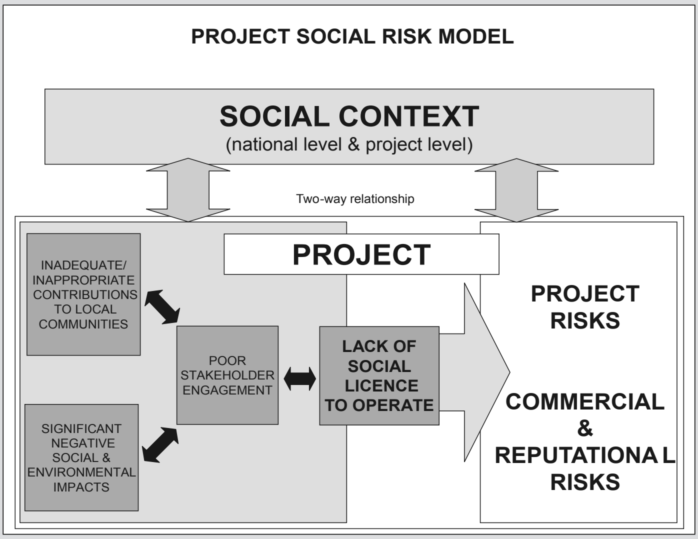
[11] Extracted with modifications from Bueno (2008), who examined social risks from the perspective of risks posed to aquaculture from society.

management actions. This falls under project risk management. But it is relevant – project risk assessments include a social risk assessment, which could be a useful method to adopt for analysis of risks to aquaculture. A model for social risk assessment and management for projects is given in Box 6.

BOX 6

A model for social risk assessment and management for projects

Projects located and run in unstable environments could inadvertently trigger or sustain violence or become the focus of resentment. Violent conflict represents a threat to life, security, growth and prosperity for affected communities. Conflict also undermines decades of economic development and destroys the social harmony of a locality, country or region. In the context of a project (such as establishing a mining operations), social risks and opportunities are essentially related to a project's local stakeholders and their perceptions and interactions with the project and the organizations delivering it (i.e. the client and their contractors). Social risk can often be visualized as the gap between the boundary of responsibility that these organizations acknowledge and that perceived by their stakeholders. A project social risk assessment model (from Anon., 2006) that could be adapted for aquaculture is illustrated below:



The two-way interactions between a project and the economic, political, socio-cultural and security context in which it is constructed and operated will shape the social risks facing that project: just as a project will be affected by the local and national context, the project itself will also have an impact on this context. To understand and identify social risks, it is important to first understand the context and this two-way relationship. The model outlines how the interactions between a project and its context and stakeholders may generate social risk and opportunities for the project. The diagram provides a basic model of these interactions. In particular, it highlights the link between a lack of "social licence to operate" and the generation of risks to the project that would impact on its commercial viability as well as reputation.

4.7.1 Hazard identification

Any action within the aquaculture sector that tarnishes its reputation for social responsibility has the potential to provoke challenges from society. The process of identifying hazards with social consequence includes posing the critical question "What challenges to the industry can be expected from society or certain stakeholders if something went wrong?" Codes of conduct and practices; certification schemes (especially ecolabeling); and standards of food safety, chemical use and labour are useful guides to identifying hazards that could turn into social risks. These instruments can be used to identify hazards, i.e. to assess what could go wrong. Beyond this, aquaculture needs to know what challenges can be expected from any sector of society if something goes wrong. For example, introduced species that become pests or that carry pathogens have in some cases caused the collapse of fisheries and aquaculture operations, resulting in massive losses in revenue and severe implications for farmers, fishers, post-harvest industries and human health. The risk analysis methodologies used for alien or introduced species are well established and the methodology to evaluate their economic, environmental and social impacts has been developed. It is the likely challenges to aquaculture as a whole (or, for example, the ornamental fish industry, if it were the source of the alien) that their impact would incite that need to be identified, assessed and mitigated.

The hazards that could provoke challenges from industries in other countries are those with potential impacts from a country's policies (i.e. subsidies) or a sector's targets (i.e. species and production targets) and marketing practices (e.g. dumping). Subsidies, as well as protectionism, could cause harm to a similar industry and its workers in another country. Overproduction and flooding the market thus depressing prices would hurt competitors in poorer areas or countries, and dumping can create a lot of economic backlash on an industry or commodity sector.

4.7.2 Risk assessment

Assessing the likelihood of a hazard turning into a social risk may or may not follow the stepwise release, exposure, consequence and estimation procedure designed for pathogen risk analysis. Risk assessment of introduction of species would follow exactly the standard procedure up to assessment of its social, environmental and economic consequences. To then assess its social risk, key questions would be:

- What is the likelihood that a challenge is provoked from adversely affected parties or groups taking up their cause?
- What kind of challenge could be expected, from whom or which interest group(s)? and
- What are the likely consequences of a challenge to the aquaculture sector or the industry?

The critical question is what would be the most serious consequence from the challenge? Would it be simply an annoyance, would it breed resentment from the community, would it provoke hostile action such as a blockade against the farm or destruction of its structures and equipment, would it result in loss of market, or would it lead to the closure of a farm or an industry?

A negative report or public criticism in the local or national media from some person or group would at first glance seem a mild reaction that can be responded to by a media release or a public relations campaign. However, this could readily escalate into (a) a greater issue, say, of human rights, environmental irresponsibility or anti-poor, or (b) a suite of interlinked issues that could be more intractable and expensive to respond to, or (c) a class action. For example, what started as public criticism from an environmentalist in India on a single issue – water abstraction – ended in the Supreme Court ordering the closure of brackishwater shrimp aquaculture.

Consequence scenario

The complexity of origins, the relationships between risks or among several risks, and the many possible consequences of a social risk make it extremely difficult to establish a social risk consequence scenario. Other challenges such as consumer boycotts and resistance are difficult to assess, although an indication that such challenge might be mounted could be gauged from the severity and visibility of the impact. For example, food poisoning, discovered and widely reported drug residue in a shipment and its being burned, mass lay off of workers, massive pollution and massive mortality of cultured and wild fish are unmistakable signals of severity that can catch the industry off guard. On the other hand, importing country actions such as bans, return or destruction of shipment, and trade sanctions are essentially notified and, because of specific provisions in World Trade Organization (WTO) or bilateral trade agreements, could be anticipated.

The following steps could be followed in risk assessment with the ultimate aim of determining the likelihood of a issue being realized and the seriousness of its consequences. For several issues, the exercise would aim at ranking their relative seriousness so that responses could be prepared and set into priorities.

1. Assessment – To provide an example of an assessment matrix for social risks, we pick the farm worker and the "community" as resources under threat. A column on modifying factors, i.e. what could reduce or aggravate the risk, is introduced (Table 15).

2. Quantification of social risks allows proper comparison and prioritization against perhaps more easily quantifiable technical risks. It also allows a proper decision as to which risk or set of risks justify and are amenable to more detailed analysis and evaluation. For aquaculture, a risk evaluation matrix could be developed using a qualitative rating system for the severity of the consequence of a challenge and its likelihood of occurrence. The information on severity of impact and likelihood of the risk happening could be derived from historical experiences and expert views.

TABLE 15
An example of an assessment matrix for social risks

"Resource" under threat	Threats to resource	Causes	Consequences	Modifying factors (reduce (–) or aggravate (+) risk)
farm labour	• Displacement • Injury or illness	• Labour-saving technology • Unsafe, unsanitary working condition, lack of protection; lack of knowledge of safety measures	• Lawsuit • Bad press • Community resentment • Strike	• Skills training (–) • Cutting corners on employee safety (+) • Investment in training and safety devices (–)
Community goodwill or cooperation	• Pollution of water bodies, croplands • Perceived exploitative practice	• Leaks, spills, discharge of effluent • Unfair labour terms or unethical hiring practices	• Community hostile action • Lawsuit • Bad press	• Water treatment system (+) • Forced labor (+) • Child labour(+) • Illegal wage structure (+)

3. Descriptors of likelihood of occurrence are developed (for example, likelihood could be described as "remote", "rare", "unlikely", "possible", "occasional" or "likely").

4. Ranking – The result enables a ranking of risks so that responses could also be prioritized.

5. Developing a risk table – The next step is to rank the issues. This can be accomplished by developing a matrix of likelihood and consequence, assigning an issue according to its rank under one of the categories and developing a risk table. This process should be completed for each of the identified issues with a risk ranking developed and the rationale for assigning these rankings recorded. The actual risk assessment is not just the scores generated during the assessment process. It should include the appropriate level of documentation and justification for the categories selected.

4.7.3 Risk management

Social risk management (SMR) consists of three strategies: prevention, mitigation and coping.

1. Prevention strategies are those that reduce the probability of the risk occurring. Measures that could apply to aquaculture include:

- skills training or job function improvement to reduce the risk of unemployment, under-employment or low wages;
- optimizing macroeconomic policies to reduce the shocks of financial crisis, such as oil price surges or unpredictable market moves on currencies;
- for natural disasters and environmental degradation, deploying a networked pre-warning system or sustainable, renewable and environmentally friendly ecosystem management strategies and practices to minimize the impact of the consequences, such as flooding, earthquakes, drought, global warming and soil acidity or salinity;

- in human and animal health care, focus on preventing epidemics and the introduction of pathogens by awareness and educational programmes, responsible movement of live animals, quarantine, certification, etc.; and
- for social security, establishing a farm mutual to compensate for loss of assets, disability or chronic illness.

2. Mitigation strategies focus on reducing the impact of a future risk event. Common practices include:

- diversifying to a reasonable level that is commensurate to the resources and management skills of the farmer, to spread the risk as well as reduce shock from a crop wipeout;
- microfinancing to smallholders; and
- insurance.

3. Coping strategies are designed to relieve the impact of the risk event once it has occurred. Usual measures are:

- issuing government relief and rehabilitation funds for very serious risks such as disasters and epidemics;
- immediate compensation schemes for serious damages to crops and assets caused by intentional or accidental pollution or acts that result in extensive damage; and
- alternative and emergency employment such as work-for-food programmes.

The complexity of impacts and difficult-to-pinpoint origins of social risks reinforce the need for integrated approaches to strategic risk management. Strategic risks can scale rapidly in geographic terms: what looks like a local public relations issue could turn from a one-time cost and simple response into an issue involving a sector's, industry's, company's or farm's reputation. For strategic risks, in contrast with traditional compliance or hazard risks, risk and opportunity are often two sides of the same coin. A strategic risk that is anticipated early and mitigated well can be converted into a new market, a competitive advantage, a stock of goodwill or a strategic relationship.

4.7.4 Risk communication

The aim of social risk communication usually is to avoid or correct misperceptions of a risk. One important arm of "corporate social responsibility" (CSR) is a public affairs or public relations unit with the capabilities and expertise to manage strategic risks stemming from social (and environmental) issues. In the aquaculture sector, with the obvious absence of a CSR body for small, widespread or independent farms, the alternatives have included organizing into associations, federations and alliances that include suppliers of inputs and processors/exporters.

In the context of communicating social risk, a "CSR" action (whether by the industry itself or in cooperation with development organizations) contributes through two means: (i) providing intelligence, awareness and insight about what those risks are; and (ii) offering an effective means to respond to them. A process for internal and external risk sensing, reporting and monitoring should be employed. By partnering with other social actors including civil society organizations, the aquaculture sector can also improve the conditions that pose emerging risks for them in the first place.