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Understanding and applying risk analysis in aquaculture

A manual for decision-makers

Cover photographs:
Left column, top to bottom: fish farmers administering antibiotic treatment to a suspected viral infection of fish (courtesy of M.B. Reantaso).
Middle column, top: Suminoe oyster (*Crassostrea ariakensis*) (courtesy of E. Hallerman); *bottom:* mortalities of common carp in Indonesia due to koi herpes virus (courtesy of A. Sunarto).
Right column: women sorting post-larvae shrimp at an Indian shrimp nursery (courtesy of M.J. Phillips).

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Preparation of this document

The need for a manual for decision-makers on understanding and applying risk analysis in aquaculture was discussed and guidance on its approach and contents formulated by the participants at the FAO/NACA Expert Workshop on Understanding and Applying Risk Analysis in Aquaculture, held from 8 to 11 June 2007 in Rayong, Thailand. The experts attending the Rayong workshop recognized that the aquaculture sector, which is characterized by a high diversity in operating systems, environments and species cultured, faced a wide range of biological, physical, chemical, economic and social risks to its successful and sustainable development. As a consequence, this document was prepared to provide policy-makers and senior managers who must deal with the rapid development of their national aquaculture sectors with a concise overview of risk analysis methodology as applied in seven key risk categories (pathogen, food safety and human health, genetic, environmental, ecological [pests and invasives], financial and social risks) and advice on the application of risk analysis at the national and farm levels can lead to a more sustainable aquaculture industry.

This document will also be of relevance to aquaculture operators, industry organizations, non-governmental organizations (NGOs) and other groups interested in understanding risk analysis and its influences on national aquaculture policy, industry regulation and the management of aquatic resources.

This manual was developed under the technical supervision of Dr Melba B. Reantaso, Fishery Resources Officer, Aquaculture Management and Conservation Service, Fisheries and Aquaculture Management Division, FAO Fisheries and Aquaculture Department. The manual draws heavily on the proceedings of the Rayong workshop (FAO Fisheries and Aquaculture Technical Paper No. 519) and particularly on the review papers of M.G. Bondad-Reantaso and J.R. Arthur (pathogen risks), M.L. Campbell and C.L. Hewitt (environmental pest risks), I. Karunasagar (food safety and public health risks), E. Hallerman (genetic risks), M.J. Phillips and R.P. Subasinghe (environmental risks), K.M.Y. Leung and D. Dudgeon (ecological risks), L.E. Kam and P. Leung (financial risks) and P.B. Bueno (social risks).

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Abstract

Aquaculture is a rapidly expanding sector of the global economy with an average growth rate of 8.8 percent per annum since 1970. This consistent increase in production is a result of expansion of markets, globalization of market access and an increasing market demand for seafood products during a period in which most capture fisheries are stagnating or in decline. Aquaculture is expected to continue to increase its contribution to the world's production of aquatic food and will further strengthen its role in food security and food safety, while also offering opportunities to alleviate poverty, increase employment and community development and reduce overexploitation of natural aquatic resources, thus creating social and generational equity, particularly in developing countries.

This rapid development of the industry under various national and regional jurisdictions has resulted in a diversity of regulatory frameworks. Thus, FAO Members have requested guidance on the application of risk analysis with respect to aquaculture production. The purpose of this manual is to provide an overview of the risk analysis process as applied to aquaculture production and to demonstrate the variety of ways in which risk can manifest in aquaculture operations and management. The intention of this manual is to promote wider understanding and acceptance of the applications and benefits of risk analysis in aquaculture production and management.

This manual is directed towards decisions-makers and senior aquaculture managers in FAO Members States. It includes an introduction to the methodology used to assess the risks posed by aquaculture operations to the environment, socio-political and economic well-being and cultural values, as well as the risks to aquaculture from outside influences, including potential environmental, socio-political, economic and cultural impacts. The manual contains six sections. Section 1 provides a background to the aquaculture sector and an introduction to the concepts of risk analysis. Section 2 presents the operating environment for risk analysis for the aquaculture sector by briefly reviewing the relevant international frameworks applicable to each risk category. Section 3 discusses a general risk analysis process for aquaculture. Section 4 provides brief overviews of the risk analysis process as applied in each of the seven risk categories. Section 5 briefly summarizes actions that need to be taken by FAO Members to promote the wider use of risk analysis for aquaculture development. Finally, Section 6 discusses future challenges to aquaculture and the role risk analysis might play in addressing them.

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Abbreviations and acronyms

ALARA	as low as reasonably achieved (approach)
ALOP	appropriate level of protection
ALOR	acceptable level of risk
ANP	analytic network process
APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of Southeast Asian Nations
BMPs	best management practices
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CCRF	Code of Conduct for Responsible Fisheries
CSR	corporate social responsibility
EIA	environmental impact assessment
EIFAC	European Inland Fisheries Advisory Commission (of the FAO)
ERA	ecological risk assessment; environmental risk assessment
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FSO	food safety objective
GAP	good aquaculture practices
GESAMP	IMO/FAO/UNESCO-LOC/WMO/IAEA/UN/UNEP Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection
GISD	Global Invasive Species Database
GMO	genetically modified organism
HABs	harmful algal blooms
HACCP	Hazard Analysis And Critical Control Point Analysis
ICES	International Council for the Exploration of the Sea
ICPM	Interim Commission on Phytosanitary Measures (of the IPPC)
IPPC	International Plant Protection Convention
IRA	import risk analysis
IRR	internal rate of return
ISO	International Standards Organisation
ISPM	International Standards for Phytosanitary Measures
ISR	International Sanitary Regulations
IUCN	World Conservation Union
LIFDCs	low-income food-deficit countries
MCMD	multicriteria decision-making
MPEDA	Marine Products Export Development Authority (India)
MOTAD	minimization of total absolute deviations
NACA	Network of Aquaculture Centres in Asia and the Pacific

NaCSA	National Centre for Sustainable Aquaculture (India)
NEMESIS	National Exotic Marine and Estuarine Species Information System
NIMPIS	National Introduced Marine Pest Information System
NGO	Non-governmental organization
NPPOs	National Plant Protection Organizations
OIE	World Organisation for Animal Health
ORP	organism risk potential
PAHO	Pan American Health Organization
PRP	pathway risk potential
ROI	return on investment
PRA	pathogen risk analysis
RPPOs	Regional Plant Protection Organizations (of the IPPC)
SEAFDEC	South East Asian Fisheries Development Center
SOPs	standard operating procedures
SPS	Sanitary and Phytosanitary (Agreement) (of the WTO)
SRM	social risk management
TAADs	transboundary aquatic animal diseases
TBT	Agreement on Technical Barriers to Trade (TBT Agreement)
UN	United Nations
UNICLOS	United Nations Convention on the Law of the Sea
USEPA	United States Environmental Protection Agency
WGITMO	Working Group on Introductions and Transfers of Marine Organisms (of ICES)
WHO	World Health Organization
WSD	whitespot syndrome disease
WSSV	whitespot syndrome virus
WTO	World Trade Organization

Glossary

Appropriate level of protection (ALOP)	The level of protection deemed appropriate by a country establishing a sanitary or phytosanitary measure to protect identified or assessed values
Acceptable level of risk (ALOR)	The level of risk a country establishing a sanitary or phytosanitary measure is willing to assume to protect identified or assessed values
Biosecurity	A strategic and integrated approach that encompasses both policy and regulatory frameworks aimed at analyzing and managing the risks of the sectors dealing with food safety, animal life and health, plant life and health and the environment
Consequence	The evaluated impact an event may have on assessed values (environmental, economic, socio-political, cultural)
Consequence assessment	The process of evaluating the impact of an event.
Cultural value	Those aspects of the aquatic environment that represent an iconic or spiritual value, including those that create a sense of local, regional or national identity
Delphi process	A semi-quantitative method from the social sciences that is used to capture stakeholder and/or expert opinions and beliefs
Economic value	Components within an ecosystem that provide a current or potential economic gain or loss
Environmental value	Everything from the biological to physical characteristics of an ecosystem being assessed, excluding extractive (economic) use and aesthetic value
Exposure assessment	The process of describing the mechanism or pathway(s) necessary for an adverse event to occur and estimating the likelihood of that event occurring
Food safety	The process of ensuring that products for human consumption meet or exceed standards of quality to ensure that human consumption will not result in morbidity or mortality

Food security	The protection and management of biological resources for safe and sustainable human consumption
Genetically modified organism (GMO)	An organism in which the genetic material has been altered by human intervention, generally through use of recombinant DNA technologies
Hazard	An organism, action or event that can produce adverse consequences relative to the assessment endpoint
Hazard identification	The process of identifying events, actions or objects that can potentially cause adverse consequences to values
Impact	The alteration or change in value caused by a hazard
Introduction	The intentional or accidental transport and release by humans of any species into an environment outside its present range
Invasive species	An organism that causes negative impact to economic, environmental, socio-political or cultural values due to prolific growth and unmanaged population
Likelihood	Probability of an event occurring, ranging from rare events to likely or frequent events
Non-indigenous species	An organism that has been transferred to a location in which it did not evolve or in which it was not present in its historic range
Pathogen	An infectious agent capable of causing disease
Pest	An organism that causes harm to economic, environmental, socio-political or cultural values
Precautionary approach	An approach to risk management that takes into account the precautionary principle
Precautionary principle	The axiom that "a lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (CBD, 1992)
Quarantine	The isolation of a region, area or group of organisms to contain the spread or prevent the entry of something considered dangerous or likely to cause harm (e.g. a pest or pathogen)
Release assessment	The process of describing the pathway by which a hazard is "released" into the operating environment of the risk analysis and estimating the likelihood of this occurring

Risk	The potential occurrence of unwanted, adverse consequences associated with some action over a specified time period
Risk analysis	A detailed examination including risk assessment, risk evaluation, and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment in order to minimize the risk
Risk assessment	The process of assessing the likelihood and consequence of an event
Risk communication	The act or process of exchanging information concerning risk
Risk management	The pragmatic decision-making process concerned with what to do about risk
Risk mitigation	Actions or controls that, when put in place, will alter, reduce or prevent either the likelihood or the consequence of an event, thus acting to reduce the risk of an event
Socio-political value	The value placed on a location in relation to human use for pleasure, aesthetic or generational values. This value may also include human health and politics. Examples include tourism, family outings, learning and aesthetics
Transfer	The intentional or accidental transport and release of any species within its present range

1. Introduction

1.1 BACKGROUND

As the global population expands to exceed six billion people, ecological security has become a focal point for many national and international bodies (Homer-Dixon, 2001; Degeest and Pirages, 2003; Pirages and Cousins, 2005). Indeed, significant pressures have come to bear on the infrastructure, food security, food safety and natural resources of many nations (McMicheal, 2001). It is estimated that nearly 75 percent of the human population will live within 150 km of a coastline by 2025 (Cohen, 1995; Hinrichsen, 1995), placing significant pressure on ocean and coastal resources.

In order for the current level and rate of economic growth to continue, reliance on aquatic resources to supply food products, specifically protein, will increase (GESAMP, 2008). The current intensive development of aquaculture in many countries is bridging the gap between stagnating yields from many capture fisheries and an increasing demand for fish and fishery products, such that aquaculture now contributes almost 50 percent of the global foodfish supply (FAO, 2007a). As the world's supply of aquatic food will need to increase by at least 40 million tonnes by 2030 to sustain the current per capita consumption level, it is expected that aquaculture's contribution to the world's production of aquatic food will continue to increase. Thus, aquaculture will continue to strengthen its role in contributing to food security and food safety, while also offering opportunities to alleviate poverty, increase employment and community development, and reduce overexploitation of natural aquatic resources, thus creating social and generational equity, particularly in developing countries.

Aquaculture encompasses a very wide range of farming practices with regard to species (seaweeds, molluscs, crustaceans, fish and other aquatic species groups), environments (freshwater, brackishwater and marine) and systems (extensive, semi-intensive and intensive), often with very distinct resource use patterns. This complexity offers a wide range of options for diversification of avenues for enhanced food production and income generation in many rural and peri-urban areas. The majority of the global aquaculture output by weight is produced in developing countries, with a high proportion originating in low-income food-deficit countries (LIFDCs).

The aquaculture industry represents a solution to many of the food security issues facing the growing human population. However, it is also often in direct conflict with other users of aquatic habitats and the adjacent coastal and riparian areas, including economic, environmental and social interests. The aquaculture sector is largely private, with increasing business demands for profitability. As a consequence, the application of risk analysis to aid in identifying the various business, economic, environmental and social risks has become necessary in the management of this growth sector. These include both risks to the environment and society from aquaculture and to aquaculture from the environmental, social and economic settings in which it operates.

1.2 PURPOSE

The purpose of this manual is to provide an overview of the risk analysis process as applied to aquaculture production and to demonstrate the variety of ways in which risk can manifest in aquaculture operations and management. The intention of this document is to promote wider understanding and acceptance of the applications and benefits of risk analysis in aquaculture production and management. Therefore this manual is a high-level guiding document with resources to allow further enquiry.

It is not a recipe book to be followed for instant success. Risk analysis and the resulting guidelines, frequently offered as industry best practice or standard operating procedures (SOPs), are typically developed in an explicit context and require an understanding of the risk fundamentals in order to be adapted to a new situation. To accomplish this, it is necessary that risk analysis capacity and capability in relation to aquaculture operations is developed in Food and Agriculture Organization of the United Nations (FAO) Member States and related to specifically identified outcomes.

1.3 TARGET AUDIENCE

This manual is targeted towards senior managers and policy-makers of FAO Member States to aid in an understanding of the application of risk analysis in this growing sector of the world economy. Therefore the primary focus is on risk issues outside the domain of business, except at a macro-economic level. Policy-level risks, however, may incorporate broad elements relevant to business decisions across an industry base (e.g. prawn farmers, the salmonid industry).

It is likely that some information presented in this manual will be relevant to aquaculture operators, industry organizations, non-governmental organizations (NGOs) and other groups interested in the influences on national policy relating to the aquaculture industry and the management of aquatic resources.

1.4 SCOPE

This manual provides an overview of the considerations for risk analysis in decision making for all forms of aquaculture and includes the impacts of aquaculture operations on environmental, socio-political, economic and cultural values as well as the impacts to aquaculture from outside influences, including environmental, socio-political, economic and cultural influences. For example, hazards (and risks) will flow to production risks from market risks, often incorporating the externalities of environmental and economic factors.

Seven “risk categories” have been identified in previous expert discussions, specifically at the FAO/Network of Aquaculture Centres in Asia-Pacific (NACA)

Workshop on Understanding and Applying Risk Analysis in Aquaculture, held in Rayong, Thailand from 8–11 June 2007, as having relevance. These categories were:

- Pathogen risks
- Food safety and public health risks
- Ecological (pests and invasives) risks
- Genetic risks
- Environmental risks
- Financial risks
- Social risks

In most of the above risk categories the development of methodologies and risk-based policies is well advanced. The first two categories (pathogen risks, food safety and public health risks) are mature as a consequence of risk analysis standards developed under international agreements in application to international trade and food safety. Pathogen risk analysis is covered under the *Aquatic Animal Health Code* of the World Organisation for Animal Health (OIE, 2009) (see Section 2), with attempts to establish consistency across aquatic animal production systems regardless of operating environment. Food safety and public health risk analyses have also been developed in the international community under the *Codex Alimentarius* (see Section 2). Financial risk and social risk analyses have occurred in a variety of sectors, the most relevant of which is the insurance industry (Secretan, 2008). In contrast, ecological, genetic and environmental risk analyses have proceeded along disparate lines, with various sectors developing discrete methodologies and contrasting terminologies. In many instances, there have been limited applications to aquaculture production.

1.5 STRUCTURE OF THE MANUAL

The manual contains six sections. Section 1 provides a background to the aquaculture sector and an introduction to the concepts of risk analysis; Section 2 presents the operating environment for risk analysis for the aquaculture sector by briefly reviewing the relevant international frameworks applicable to each risk category; Section 3 discusses a general risk analysis process for aquaculture; Section 4 provides brief overviews of the risk analysis process as applied in each of the seven risk categories; Section 5 briefly summarizes actions that need to be taken by FAO Member States to promote the wider use of risk analysis for aquaculture development; and Section 6 discusses future challenges to aquaculture and the role risk analysis might play in addressing them.

1.6 CONCEPTS OF RISK ANALYSIS

We live in a complex world, with various and frequently conflicting priorities requiring our attention. In most instances, our ability to make decisions is balanced between these conflicting priorities, and we rarely have all of the information necessary to develop the ideal solution. Instead we must make decisions in the face of uncertainty to ascertain the “best” outcome. Take, for example, the decision to immunize our children against disease. Immunization provides significant human health benefits to individuals and the general population; however, there is the slight potential for immunization to cause significant harm to any individual. We cannot know with certainty whether any one child will experience a negative reaction. In this instance, public health officials have analysed the overall benefits of immunization relative to the risks to the individual and thus support immunization programmes. This assessment is a risk analysis.

In general terms, **risk** is the potential occurrence of unwanted, adverse consequences associated with some action over a specified time period (e.g. Arthur *et al.,* 2004a)**.** Risk is the possibility that a negative impact will result from an action or decision and the magnitude of that impact.

1.6.1 The risk analysis process

Risk analysis is frequently used by decision-makers and management to direct actions that potentially have large consequences but also have a large uncertainty. Risk analysis[1] is a structured process for determining what events can occur (identifying hazards), analyzing the probability that the event will occur (determining likelihood), assessing the potential impact once it occurs (determining consequence), identifying the potential management options and communicating the elements and magnitude of identified risks.

In simple terms, risk analysis is used to determine the likelihood that an undesired event will occur and the consequences of such an event. This is generally developed in a repeatable and iterative process (MacDiarmid, 1997; Rodgers, 2004; OIE, 2009) where we seek answers to the following questions:

- What can occur? (**Hazard identification**)
- How likely is it to occur? (**Risk assessment:** likelihood assessment through release assessment and exposure assessment)
- What would be the consequences of it occurring? (**Risk assessment:** consequence assessment and risk estimation; **risk management:** risk evaluation); and
- What can be done to reduce either the likelihood or the consequences of it occurring? (**Risk management:** option evaluation, Implementation, Monitoring and review).

The entire process includes **risk communication**, the communication of the risk to others in order to generate a change in management, regulation or operation.

It should be noted that a risk analysis must be “scoped” as the first step. Risk analysis cannot determine the scope of the assessment, the endpoint of the assessment or (in most cases) the acceptable level of risk (ALOR) used to determine management action. These decisions must be made before the analysis,

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[1] It should be noted that *risk analysis* as used by FAO represents the overarching term that includes the activities of hazard identification, risk assessment, risk management and risk communication (e.g. Arthur *et al.,* 2004; GESAMP, 2008; OIE, 2009). In contrast, others (including the World Health Organization, WHO) use the term *Risk Assessment* to represent the overarching term that encompasses hazard identification, risk analysis and risk evaluation (e.g. Aven, 2003; Nash, Burbridge and Volkman, 2005, 2008).

as they influence the operating environment of the risk analysis. The scope of the assessment can limit or restrict the evaluation of impacts. For example, the scope of the assessment may be restricted to economic factors alone, rather than include environmental, social, political or cultural factors. Similarly, the endpoint (literally, where the assessment stops) must be identified, as it will determine the extent of analysis of hazards and impacts that must occur. Lastly, the acceptable level of risk (more often referred to in the opposite: the appropriate level of protection – ALOP) is the level of risk (or protection) deemed acceptable by the authority undertaking the risk analysis and is based upon socio-political perceptions of risk and therefore comprises value judgments within which the risk analysis will proceed. Frequently, neither ALOR nor ALOP are explicitly stated as policy, but they can often be determined from existing standards and practices in protecting human, animal and plant health, ecosystem well-being, and environmental and economic values from external hazards (Wilson, 2001).

1.6.2 Why do we undertake risk analysis?

The purpose of risk analysis is to provide a structured means by which risks to or from a sector can be assessed and communicated in order to guarantee a uniform and transparent process of decision making or regulatory control. It is highly desirable for decision-making to be consistent, repeatable, objective and to provide a clear methodology that makes the information feeding into the decision-making process and its use transparent to others (including stakeholders). The formality of the risk analysis process provides a consistent guide to decision-makers that also establishes a level of surety to stakeholders that the process will meet the desired equitable outcomes.

Often, risk analysis processes are either mandated or suggested under international agreements to meet specific ends. For example, risk analysis procedures have been agreed under the World Trade Organization (WTO) as a means to guarantee that all trading partners are following similar procedures (e.g. WTO's *Agreement on Sanitary and Phytosanitary Measures* – the SPS Agreement). Similarly, a formalized risk analysis can provide equity between competing proponents of a development project or aid regulators in determining the likely outcomes of a proposed activity. Risk outcomes can be codified into "standards of best practice" or "guidelines" by regulatory or industry bodies for congruence. Ultimately, the use of risk analysis is to identify decision options, including risk management options that may eliminate or ameliorate the adverse effects of a decision. Risk management provides a tool that has been successfully employed in numerous industries where the cost of management (e.g. actions ranging from complete prevention to doing nothing) needs to be weighed against the likelihood of an undesired event occurring.

1.6.3 When do we use risk analysis?

Risk analysis is suited to any circumstance where a decision must be made in the face of incomplete information and where the potential for adverse effects exists.

If all were certain, the need for risk analysis would not exist. In some instances, risk analysis may be mandated as a statutory or regulatory requirement as part of international or regional agreements.

Risk analysis need not be an overly complicated process. It can be undertaken as a fully quantitative assessment of probabilities or alternately, can be based on qualitative (categorical) assessments of perceptions (as in socio-political impact analysis). Risk analysis as a process should be considered as a highly flexible tool that can be readily adapted to various situations. As Arthur *et al.* (2004a) have stated, "Countries or industries must determine the best methods that are most effective and cost efficient for their particular circumstances, taking into consideration that the process needs to be science-based, systematic, iterative, consistent and transparent with timely and repeatable outcomes."

1.6.4 The Precautionary Principle

In general, risk analysis should operate under the approach of precaution (e.g. Peel, 2005); however, the use of precautionary approaches in dealing with risk has been the focus of much debate (see FAO, 1996; GESAMP, 2008). The precautionary principle (and its application through the use of precautionary approaches) as agreed in the Convention on Biological Diversity Conference of Parties (UNEP/CBD/COP/6/20) provides that uncertainty associated with the lack of knowledge should not be used to preclude making a decision. It should be noted that in this context, the WTO SPS and CBD positions on precaution are opposed (see Campbell *et al*., 2009). The precautionary principle is widely adopted by the FAO in regards to managing uncertainty in fisheries (and aquaculture) management. The *Code of Conduct for Responsible Fisheries* (FAO, 1995) encourages States to

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

1.6.5 Dealing with uncertainty

Risk analysis provides a systematic and scientifically defensible method of estimating probabilities in the face of uncertainty. Uncertainties come in a variety of types: uncertainty of method, uncertainty of measurement (associated with human error) and uncertainty of knowledge.

Uncertainty of method is typically managed through the iterative process of risk analysis coupled with open and transparent risk communication and feedback from stakeholders. In this fashion, the uncertainty associated with methodology is improved through time as procedural errors are detected or alternate methods are developed.

Uncertainty of measurement is most frequently associated with the quality of the risk analyst, however methods to provide consistency between analysts are increasingly being developed (as part of the process) to reduce human-associated error.

Uncertainty of knowledge remains the greatest and most difficult issue to manage. Typically this is associated with poor or incomplete biological (e.g. how an organism will react to specific stimulus; what impact will an organism have on another organism), economic or socio-political knowledge (e.g. variations in perceptions of impact between cultural groups; regional valuations of aesthetics) where best estimates or judgment must be used. For biological knowledge, the level of uncertainty will vary according to the organism or system being assessed. We will have greater knowledge for a well-known organism or system and therefore less uncertainty about the biological functions or reactions. Social, political and cultural knowledge will vary according to the degree to which prior study has been undertaken. For smaller population groups of homogeneous socio-economic or cultural backgrounds, the level of uncertainty is likely to be much reduced, whereas larger population groups or those with significant variation in socio-economic or cultural backgrounds are likely to be less similar and therefore have greater uncertainty in response outcomes.

In all instances, uncertainty must be quantified or estimated in order to provide the risk analyst the ability to account for uncertainty in the decision-making process. In addition, documenting uncertainty aids in identifying how the risk analysis might be improved through additional information-gathering research.

1.6.6 Application of risk analysis to aquaculture development

Risk analysis has wide applicability to aquaculture (see Arthur *et al.*, 2004a,b; Nash, Burbridge and Volkman, 2005, 2008; GESAMP, 2008) in assessing risks to society (human health) or to the environment due to hazards created through the establishment or operation of aquaculture enterprises (e.g. GESAMP, 2001a, 2008; Nash, Burbridge and Volkman, 2005, 2008). These assessments remain important in the national and local planning process and will continue to provide significant input to policy development. In turn, the aquaculture industry will benefit by reducing its external impact on environmental, economic, social, political and cultural values.

Risk analysis, however, has been less commonly used to achieve successful and sustainable aquaculture production by assessing the risks to aquaculture that are posed by the biological, physical, social and economic environment in which it takes place (GESAMP 2001b, 2008; Arthur, 2008). Issues important to aquaculture proponents such as site selection (e.g. biological risks of pathogen outbreaks, predator impacts, biological introductions) and operational risks (including financial and social impacts) can be managed through a risk analysis approach.

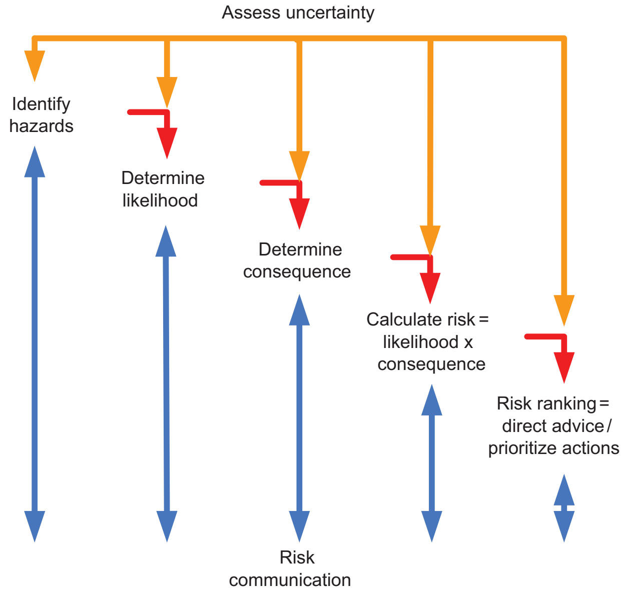
1.7 GENERAL FRAMEWORK OF RISK ANALYSIS

A risk management framework operates by establishing the context (hazard identification); identifying the risk by determining the likelihood of the hazard occurring (generally through release and exposure assessments) and the magnitude of its effect or consequence (i.e. impacts); assessing the risks (analysing and evaluating the risks through the interaction of likelihood and consequence); and managing or treating the risk(s) (i.e. management, mitigation, communication). A measure of risk is derived by multiplying likelihood by consequence. This process is summarized in Figure 1.

Before undertaking a risk analysis, the scope of the risk assessment, including its endpoint, must be determined. The scope of the assessment provides a clear indication of the values that are assessed for impact and includes economic, environmental, social, political, and cultural values. Endpoint selection determines what type of null hypothesis is tested during the risk analysis. Endpoints tend to be either: a) quarantine related – before a barrier control has been breached; or b) impact driven – where the effect/impact/harm of an activity is assessed as the basis of decision making. If a quarantine stance is taken, then consequences after the release are typically classified as "significant" and the likelihood determines risk. If the assessment is impact driven, then both the likelihood and consequence must be determined to derive risk. An impact approach is typically followed when determining if an activity and its broader effect can or should be prevented or managed.

To aid management in prioritizing action in relation to hazards, the real and perceived impacts the hazard will have are examined against the core values (environmental, economic, social and political, and cultural values) in the region that will be directly affected and other regions that may be potentially affected (e.g. Campbell, 2005). The use of core values places management actions into a context of being able to objectively assess hazards across environmental, economic, social

FIGURE 1
Simplified risk analysis process



Source: from Campbell, 2006a.

and political, and cultural issues. The use of core values also ensures that our biases can be accounted for and that the implications of a risk can be assessed across more than just economic concerns. The core values are:

- *Environmental values* – Everything from the biological to the physical characteristics of an ecosystem being assessed, excluding extractive (economic) use and aesthetic value. Examples include floral and faunal biodiversity; habitat; rare, endangered and protected species and marine protected areas.
- *Economic values* – Components within an ecosystem that provide a current or potential economic gain or loss. Examples include the infrastructure associated with ports, marinas and shipping channels; moorings and allocated fisheries areas, including stocks of exploitable living and non-living resources.
- *Social and political values* – The values placed on a location in relation to human use for pleasure, aesthetic and generational values and also including human health and politics. Examples include tourism, family outings and learning.
- *Cultural values* – Those aspects of the environment or location that represent an iconic or spiritual value or provide aesthetically pleasing outcomes for a region, including those that create a sense of local, regional or national identity.

Each core value consists of a variety of different subcomponents that will differ both spatially and temporally. A risk assessment can occur at the level of the core value or at the level of the core-value subcomponents. A risk assessment of the impact a hazard may have on the four core values can be determined through a six-step process, as outlined in Figure 1.

2. Operating environment

2.1 OVERVIEW OF REGULATORY FRAMEWORKS

This section provides an overview of relevant international and regional agreements that should be considered during risk analysis. It is not intended to be an exhaustive list, and the range of agreements, legislation and policy frameworks should be explored prior to the risk analysis process. The relationship between the seven risk categories identified in Section 1.4 and the relevant regulatory agreements is identified in Table 1.

TABLE 1
Relationship between the seven risk categories and relevant frameworks

Framework	**Pathogens**	**Food safety and public health**	**Ecological (pests and invasive species)**	**Genetic**	**Environmental**	**Financial**	**Social**
FAO/WHO *Codex Alimentarius*		X					
Convention on Biodiversity (CBD)	X		X	X	X		X
International Plant Protection Convention (IPPC)	X		X	X	X		
World Health Organization (WHO)	X	X	X				
OIE *Aquatic Animal Health Code*	X		X				
WTO *Agreement on Sanitary and Phytosanitary Measures*	X	X	X	X	X		
FAO *Code of Conduct for Responsible Fisheries* (CCRF)	X	X	X	X	X		
ICES *Code of Practice on the Introductions and Transfers of Marine Organisms*	X	X	X	X	X		

2.1.1 International and regional agreements

Codex Alimentarius

The Codex Alimentarius Commission (CAC) was created in 1963 by FAO and the World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme (www.codexalimentarius.net/web/index_en.jsp). The main purposes of this programme are to protect the health of consumers, ensure fair trade practices in the food trade and promote coordination of all food standards work undertaken by international governmental and non-governmental organizations (NGOs).

The significance of the food code for consumer health protection was underscored in 1985 by the UN Resolution 39/248, whereby guidelines were adopted for use in the elaboration and reinforcement of consumer protection policies. The guidelines advise that "Governments should take into account the need of all consumers for food security and should support and, as far as possible, adopt standards from the *Codex Alimentarius*" of FAO and WHO.

The *Codex Alimentarius* has relevance to the international food trade. With respect to the ever-increasing global market, in particular, the advantages of having universally uniform food standards for the protection of consumers are self-evident. It is not surprising, therefore, that the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement) and the *Agreement on Technical Barriers to Trade* (TBT Agreement) both encourage the international harmonization of food standards. A product of the Uruguay Round of multinational trade negotiations, the SPS Agreement cites Codex standards, guidelines and recommendations as the preferred international measures for facilitating international trade in food. As such, Codex standards have become the benchmarks against which national food measures and regulations are evaluated within the legal parameters of the Uruguay Round Agreements.

The *Codex Alimentarius* has 180 members and has produced over 300 Food Standards that are implemented worldwide.

Convention on Biological Diversity (CBD)

The Convention on Biological Diversity was created in 1992 at Rio de Janeiro to develop consensus on protection of biological diversity at a global scale (CBD, 1992). The CBD, with 191 Parties to the Convention, is not a standards-setting instrument but is rather a facilitating body through which a balance between economic growth (including international trade) and the protection of biological values can be sought. The CBD Conference of Parties recommends non-binding actions to Parties, including Decision VII/5 on marine biological diversity, that recommends Parties and other governments use native species and subspecies in marine aquaculture (paragraph 45(g)), and expresses support for regional and international collaboration to address transboundary impacts of marine aquaculture on biodiversity, such as the spread of disease and invasive alien species (paragraph 51).

The CBD and its supplement, the Cartegena Protocol (CBD, 2000), have relevance to the increasing allocation of riparian and ocean resources to aquaculture and the increasing focus on the use of non-native species for aquaculture development. The Cartegena Protocol is explicitly designed to protect the environment and human health from the effects of modern biotechnology.

International Plant Protection Convention (IPPC)

The International Plant Protection Convention is an international treaty to secure action to prevent the introduction and spread of pests of plants and plant products and to promote appropriate measures for their control (www.ippc.int/

IPP/En/default.jsp). The IPPC was placed within the Agriculture Directorate of the Director-General of the FAO since its initial adoption by the Conference of FAO at its Sixth Session in 1951. It is governed by the Interim Commission on Phytosanitary Measures (ICPM), which adopts International Standards for Phytosanitary Measures (ISPMs). The Secretariat of the IPPC was established in 1992 by FAO in recognition of the increasing role of the IPPC in international standard setting. It coordinates the activities of the IPPC and is hosted by FAO. As part of the organization, there are Regional Plant Protection Organizations (RPPOs) – intergovernmental organizations functioning on a regional basis as coordinating bodies for National Plant Protection Organizations (NPPOs). The Secretariat is responsible for coordinating the IPPC work programme, which involves three main activities:

- developing International Standards for Phytosanitary Measures (ISPM);
- providing information required by the IPPC and facilitating information exchange between contracting parties; and
- providing technical assistance, especially for capacity building, to facilitate the implementation of the IPPC.

As of May 2009, there are 170 governments that are currently Parties to the Convention. The authority that the IPPC holds is that afforded to it by the SPS agreement in Article 3 paragraph 1, which relates to the requirement that members base their SPS measures on international standards, guidelines or recommendations, where they exist.

World Health Organization (WHO)

Established on 7 April 1948, the World Health Organization is the UN's specialized agency for human health (www.who.int/en/). WHO's objective, as set out in its constitution, is the attainment by all peoples of the highest possible level of health, health being defined as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

The WHO has 193 Member States. All countries that are Members of the UN may become members of WHO by accepting its constitution. Other countries may be admitted as members when their application has been approved by a simple majority vote of the World Health Assembly. Territories that are not responsible for the conduct of their international relations may be admitted as Associate Members upon application made on their behalf by the Member or other authority responsible for their international relations. Members of WHO are grouped according to regional distribution.

The authority that WHO has is through the authority of the UN. WHO is governed through the World Health Assembly, which is composed of representatives from WHO's Member States. The main tasks of the World Health Assembly are to approve the WHO programme and the budget for the following biennium and to decide major policy questions

The purpose of the International Health Regulations is to ensure the maximum security against the international spread of diseases with minimum interference with world traffic. Its origins date back to the mid-nineteenth century when cholera epidemics overran Europe between 1830 and 1847. These epidemics were catalysts for intensive infectious disease diplomacy and multilateral cooperation in public health, starting with the first International Sanitary Conference in Paris in 1851.

Between 1851 and the end of the century, eight conventions on the spread of infectious diseases across national boundaries were negotiated. The beginning of the twentieth century saw multilateral institutions established to enforce these conventions, including the precursor of the present Pan American Health Organization (PAHO).

In 1948, the WHO constitution came into force and in 1951, WHO Member States adopted the International Sanitary Regulations, which were renamed the International Health Regulations in 1969. The regulations were modified in 1973 and 1981. The International Health Regulations were originally intended to help monitor and control six serious infectious diseases: cholera, plague, yellow fever, smallpox, relapsing fever and typhus. Today, only cholera, plague and yellow fever are notifiable diseases.

The WHO continues to monitor and disseminate information on harmful algal blooms (HABs) that cause significant human morbidity or mortality associated with seafood poisonings.

World Organisation for Animal Health (OIE)

The World Organisation for Animal Health is an intergovernmental organization that was created on 25 January 1924 as the Office international des épizooties (OIE) and is based in Paris (www.oie.int/eng/en_index.htm). In April 2009, the OIE had 172 Member Countries and Territories. Its objectives are to ensure transparency in the global animal disease and zoonosis situation by each member country undertaking to report the animal diseases that it detects on its territory. The OIE then disseminates the information to other countries, which can take the necessary preventive actions. This information also includes diseases transmissible to humans and the intentional introduction of pathogens. Information is sent out immediately or periodically depending on the seriousness of the disease.

The OIE collects and analyses the latest scientific information on animal disease control. This information is then made available to the member countries to help them to improve the methods used to control and eradicate these diseases. The OIE also provides technical support to member countries requesting assistance with animal disease control and eradication operations, including diseases transmissible to humans. The OIE notably offers expertise to the poorest countries to help them control animal diseases that cause livestock losses, present a risk to public health and threaten other Member Countries.

The OIE develops guidelines relating to animal health that member countries can use in establishing rules to protect themselves from the introduction of diseases and pathogens without setting up unjustified sanitary barriers. The OIE risk analysis framework allows for the assessment of all potential diseases that may be associated with a particular commodity. The release and exposure assessments include the risk of transfer to both indigenous and domestic animals and humans, and the consequence assessment also includes consequences of exotic diseases that may enter on that pathway, to indigenous wildlife (alongside consequences to the economy and human health). The OIE risk analysis framework can also be used for assessment of risks from new pests and diseases. With regard to aquatic animal diseases, the main normative works produced by the OIE are the *Aquatic Animal Health Code* (OIE, 2009) and the *Manual of Diagnostic Tests for Aquatic Animals* (OIE, 2006). OIE standards are recognized by the World Trade Organization (WTO) as reference international sanitary rules.

World Trade Organization (WTO) – SPS Agreement

The *Agreement on the Application of Sanitary and Phytosanitary Measures* (the "SPS Agreement") entered into force with the establishment of the World Trade Organization on 1 January 1995. It concerns the application of food safety and animal and plant health regulations, and it sets out the basic rules for food safety and animal and plant health standards. For the purposes of the SPS Agreement, sanitary and phytosanitary measures are defined as any measures applied:

- to protect human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in their food;
- to protect human life from plant- or animal-carried diseases;
- to protect animal or plant life from pests, diseases, or disease-causing organisms; and
- to prevent or limit other damage to a country from the entry, establishment or spread of pests.

Measures for environmental protection (other than as defined above) are a specific aspect of the SPS Agreement. Any environmental protection or benefits are as a result of measures taken to meet the objectives of the above, so are not identified as solely for "environmental protection".

The process for development of international standards, guidelines and recommendations is through expert advice by leading scientists in the field and governmental experts on health protection and is subject to international scrutiny and review. Most of the WTO's member governments participate in the development of these standards by other international bodies; the WTO itself is not a standard-setting body.

Member countries are encouraged to use international standards, guidelines and recommendations where they exist. International standards are often higher than the national requirements of many countries, including developed countries, but the SPS Agreement explicitly permits governments to choose not to use the international standards. However, when members use measures that result in higher standards than those specified in international agreements, these must be based on appropriate assessment of risks so that the approach taken is consistent and not arbitrary. They should be applied only to the extent necessary to protect human, animal or plant life or health and should be implemented impartially to all countries and regions where identical or similar conditions prevail. The agreement still allows countries to use different standards and different methods of inspecting products. If the national requirement results in a greater restriction of trade, a country may be asked to provide scientific justification, demonstrating that the relevant international standard would not result in the level of health protection the country considered appropriate.

As of 23 July 2008, there are 153 member governments belonging to the WTO. By accepting the WTO Agreement, governments have agreed to be bound by the rules in all of the multilateral trade agreements attached to it, including the SPS Agreement. In the case of a trade dispute, the WTO's dispute settlement procedures encourage the governments involved to find a mutually acceptable bilateral solution through formal consultations. If the governments cannot resolve their dispute, they can choose to follow any of several means of dispute settlement, including good offices, conciliation, mediation and arbitration. Alternatively, a government can request that an impartial panel of trade experts be established to hear all sides of the dispute and to make recommendations.

2.1.2 Voluntary frameworks

Numerous voluntary frameworks exist that have influence over aquaculture production. Here we outline two that have explicit relevance to aquaculture.

FAO Code of Conduct for Responsible Fisheries (CCRF)

The FAO's *Code of Conduct for Responsible Fisheries* (CCRF) (FAO, 1995) is a best-practice guide to the management and maintenance of capture fisheries and aquaculture enterprises and has been promoted by FAO and other international instruments, resulting in numerous follow-up initiatives towards improving the sustainability of capture fisheries and aquaculture practices. Article 9 of the Code deals with Aquaculture Development, with Articles 9.2 and 9.3 explicitly identifying the introduction of alien species as requiring additional evaluation to minimize or prevent impacts to native ecosystems, including transboundary contexts.

Of particular relevance to assessing and managing risks in aquaculture development, to support implementation of the CCRF, the FAO has developed the *FAO Technical Guidelines for Responsible Fisheries,* a series of guidelines providing more detailed guidance to member countries on the application of the CCRF. Technical Guidelines No. 2 *Precautionary approach to capture fisheries and species introductions* (FAO, 1996) concerns the application of the precautionary principle with respect to capture fisheries and species introductions (including introductions for aquaculture development), highlighting the need for risk evaluation and the use of precaution. Technical Guidelines No. 5 *Aquaculture development* (FAO, 1997) is explicit to aquaculture development and discusses each CCRF Article in Section 9 in further detail. Of these articles:

- Article 9.1.2 identifies the potential genetic impacts of released species through introgression and competition with native stocks.

- Article 9.2.3 explicitly discusses the need for consultation with neighbouring states when considering the introduction of alien species into a transboundary aquatic system. This discussion includes the need to identify or establish a regional body for consideration of applications and the sharing of information relevant to the introduction.
- Article 9.3 (and all sub-articles) identifies the need to minimize the adverse effects of alien species to genetic resources and ecosystem integrity and encourages the use of native species whenever possible, the application of standard quarantine procedures and the establishment (or adoption) of codes of practice for approvals and management of introduced species.

Additionally, to further support Technical Guidelines No. 5 on *Aquaculture development*, Supplement 2 of the series (FAO, 2007c) deals with *Health management for the responsible movement of live aquatic animals,* stresses the need for countries to use risk analysis procedures as the basis for preventing the introduction and spread of transboundary aquatic animal diseases (TAADs) and the application of a precautionary approach in cases where insufficient knowledge exists.

The ICES Code of Practice

As a fishery-oriented intergovernmental organization, the International Council for the Exploration of the Sea (ICES) was confronted early on with issues related to the introduction of non-indigenous species, in particular the potential for the spread of diseases and parasites via the international movement of live fish and shellfish for stocking, ranching, aquaculture development and fresh-fish markets. During the late 1960s and early 1970s, the need to assess the risks associated with deliberate introductions and transfers of species was primarily of concern. While great successes have been achieved by these activities, leading to the creation of new and important fishery and aquaculture resources, three challenges have surfaced over the past several decades relative to the global translocation (introduction or transfer) of species to new regions. These include:

- The potential ecological and environmental impacts of translocated species, especially those that may escape the confines of aquaculture facilities and become established in the natural environment, with possible negative impacts on native species.
- The potential genetic impact of introduced and transferred species relative to the mixing of farmed and wild stocks, as well as to the release of genetically modified organisms (GMOs).
- The inadvertent coincident movement of harmful organisms associated with the movement of the target species, resulting in the spread of pests and pathogens to new geographic areas where they may negatively impact the development and growth of new fishery resources (including aquaculture) and native fisheries.

ICES, through its Working Group on Introductions and Transfers of Marine Organisms (WGITMO) and its cooperation with other ICES Working Groups and with FAO, has addressed these three levels of concern since 1973 through publication of a series of successive Codes. These Codes represent a risk management framework for operational implementation to provide surety to neighbouring coastal states that intentional introductions follow acceptable guidelines. The most recent version of the *ICES Code of Practice on the Introductions and Transfers of Marine Organisms* (ICES, 2005) provides guidance for assessing the ecological, genetic and pathogen risks posed by a proposed introduction or transfer of an aquatic animal and provides decision-makers with a formal mechanism for deciding if a proposed translocation should proceed.

2.2 OVERVIEW OF THE KEY RISK CATEGORIES

For the purposes of this manual, the potential areas of risk, and therefore application of risk analysis, have been summarized in seven risk categories. Within these broad categories, it is impossible to outline all possible types of hazards that may be encountered during aquaculture development or even, given the wide range of risk analysis models that have been recommended and/or legislated for the seven risk categories, to recommend a single risk analysis model to be followed. Instead we provide a starting point for understanding the approaches and methodologies that are applied in the analysis of risk in the various categories. Below we outline the seven risk categories and provide for each, a short description and linkage to the relevant guidance and the international agreements that inform risk analyses within these categories. A brief summary of the risk analysis process as applied in each of the seven risk categories is presented in Section 4.

2.2.1 Pathogen risks

The movement of live aquatic biota (animals and plants), their products and the water they are in has the potential to transfer pathogens from one country or region to another where the pathogens may not currently exist. Risks associated with the uncontrolled movements of aquaculture species, gear and feeds are well known (e.g. Sindermann, 1986, 1991; Arthur *et al*., 2004a; Bondad-Reantaso *et al.,* 2005; OIE, 2006, 2009). Pathogen risks have largely been managed from the perspective of international importation, but several countries and regional economic communities have internal quarantine borders (e.g. Australia, Canada, the United States of America and the European Union (EU); Bondad-Reantaso and Arthur, 2008). Pathogen risk analysis (PRA) (often termed import risk analysis (IRA) when applied to international movements) is a structured process used in many countries to analyse the disease risks associated with the international or domestic transport of live animals and their products. The endpoint of the risk analysis is the outbreak of a serious disease in managed or wild stocks of the receiving country or region. PRA represents only one aspect of a larger national biosecurity strategy (also typically known as a national aquatic animal health strategy) (Arthur *et al.,* 2004a).

In order to protect human, animal and plant health, the member countries have signed the *Agreement on Sanitary and Phytosanitary Measures* (the SPS

Agreement) (WTO, 1994). Under this agreement, member countries are required to use the risk analysis process as a means to justify restrictions on international trade in live animals or animal products based on their risk to human, animal or plant health. For aquatic animals this includes the application of sanitary measures beyond those outlined in the OIE *Aquatic Animal Health Code* (WTO, 1994; Rodgers, 2004; Arthur *et al.*, 2004a). Section 1.4 of the *Aquatic Animal Health Code* (OIE, 2009) provides a framework and general guidelines for the IRA process, but leaves significant leeway for member countries to adapt the details of the process to their individual needs and situations. More recent advice on the methods for application of risk analysis to pathogen risks can be found in Arthur *et al.* (2004a), ICES (2005), Bondad-Reantaso and Arthur (2008) and Copp *et al.* (2008).

The OIE Code provides for both qualitative and quantitative assessments of risk. Under specific agreement, the OIE maintains a list of reportable diseases that present a suite of internationally agreed levels of unacceptable impact. These include pathogens of aquatic organisms affecting fish, crustaceans, molluscs and amphibians (Table 2).

TABLE 2
List of aquatic animal diseases notifiable to the OIE (from OIE, 2009)

Affected taxon	OIE-listed Disease
Fish	Epizootic haematopoietic necrosis
	Infectious haematopoietic necrosis
	Spring viraemia of carp
	Viral haemorrhagic septicaemia
	Infectious salmon anaemia
	Epizootic ulcerative syndrome
	Gyrodactylosis (*Gyrodactylus salaris*)
	Red sea bream iridoviral disease
	Koi herpesvirus disease
Crustacea	Taura syndrome
	White spot disease
	Yellowhead disease
	Tetrahedral baculovirosis (*Baculovirus penaei*)
	Spherical baculovirosis (*Penaeus monodon*-type baculovirus)
	Infectious hypodermal and haematopoietic necrosis
	Crayfish plague (*Aphanomyces astaci*)
	Infectious myonecrosis
	White tail disease
Mollusc	Infection with *Bonamia ostreae*
	Infection with *Bonamia exitiosa*
	Infection with *Marteilia refringens*
	Infection with *Perkinsus marinus*
	Infection with *Perkinsus olseni*
	Infection with *Xenohaliotis californiensis*
	Abalone viral mortality
Amphibia	Infection with *Batrachochytrium dendrobatidis*
	Infection with ranavirus

Pathogen risks associated with aquaculture include the importation of live organisms as food, feed products, fry, fingerlings, spat, and broodstock, as well as uncooked products. Commodities include live invertebrates (e.g. molluscs, arthropods) and vertebrates (e.g. finfish, amphibians) in various life-cycle stages and their products (e.g. gametes, non-viable chilled aquatic animals (whole, or in various forms) for human food, feed products, etc.) that can potentially transfer pathogens into cultured and wild stocks in the receiving country.

2.2.2 Food safety and public health risks

Outbreaks of food-borne illness continue to be a major problem worldwide, with a significant number of deaths relating to contaminated food and drinking water (Karunasagar, 2008). In order to protect public health and facilitate safe international trade in food products, the member countries of the World Trade Organization (WTO) have signed the *Agreement on Sanitary and Phytosanitary Measures* (the SPS Agreement; WTO, 1994). Under this agreement, member countries are encouraged to apply internationally negotiated standards; however, member countries have a right to adopt higher standards than internationally agreed, but only if they are based upon strict risk analysis guidelines (produced by the Codex Alimentarius Commission, CAC) and are not deemed to be arbitrary or used as an excuse to protect domestic markets.

The CAC guidelines provide for both qualitative and quantitative assessments of risk and include both chemical and biological hazards capable of causing adverse human health effects. The detailed knowledge of the majority of hazards in this risk category allows for significant sophistication in the risk analysis process. Hazard characterization may include dosage and temporal exposure effects, influences of target physiological condition (e.g. fat content, age, gender, race) and population characteristics.

It should be noted that food safety and public health risk analyses are highly pro-active, anticipating the information needs. As a consequence, dose-response assessments are conducted from outbreak assessments, volunteer studies and/or animal studies.

Food safety and public health risk analyses within the aquaculture production sector include assessments to allow international trade (e.g. development of import health standards, generally via Import Risk Assessments), industry-wide closures due to pathogen outbreaks and detection of tainted products on importation or in the marketplace. These assessments are largely restricted to the presence of a hazard (i.e. a viral, microbial or chemical agent), the dosage necessary to cause human morbidity (generally as a percentage of population), and the food handling and food preparation opportunities to reduce or eliminate the harm. As a consequence, risk management options are outlined that follow a structured approach to meet appropriate levels of protection (ALOP).

Other public health risks associated with aquaculture production include worker safety, public safety and externalities on the community (e.g. impacts on drinking water). Worker safety is generally managed under public safety legislation covering occupational health and safety (variously called occupational safety and health, occupational safety, health and environment) and is not discussed further here.

Public safety may be affected through the unintentional access of untrained personnel to the farm site or through interactions between the aquaculture facility and competing stakeholder uses (e.g. swimmers, recreational and commercial fishers, boaters, coastal navigation). The evaluation and management of these risks is generally the authority of coastal planning agencies (GESAMP, 2001a). The potential for aquaculture to release waste effluents into coastal waterways and thereby increase the likelihood of harmful algal blooms (HAB) has been discussed by Yin, Harrison and Black (2008).

2.2.3 Ecological (pests and invasives) risks

Ecological risks both to and from aquaculture are here restricted to the human-mediated introduction of non-native species to regions where they did not evolve or did not historically exist. Such introductions have had significant impacts to environmental, economic, social and political, and cultural values on a global scale (Campbell and Hewitt, 2008; Leung and Dudgeon, 2008). Non-native (also termed exotic or introduced) species are now considered to be one of the top five threats to native biodiversity in the world's oceans (Carlton, 2001; Hewitt, 2003a). Non-native species may cause harm through both direct and indirect avenues such as predation on and competition with native species, habitat alteration, and toxic effects on humans and native animals and plants (Hewitt, 2003b).

The increasing use of non-native species for aquaculture development is of significant concern, as subsequent escapes of these species and their associated pathogens pose a serious threat to native biodiversity, economic value and ecosystem function, particularly in regions rich in endemic species (Cook *et al.*, 2008). Aquaculture-associated introductions have contributed as much as 20 percent of the total introduced fauna and flora to many regions, both through movement of the intentional target species and through inadvertent movement of "hitch-hikers" (pests and pathogens) that live on, in or with the target species (Hewitt *et al.*, 2004; Weigle *et al.*, 2005; Casal, 2006). The contribution of non-native species to the growth of the global aquaculture industry and the economic benefits that they have brought to many developed and developing countries, however, cannot be underestimated (see FAO, 2007a).

Currently no international instrument explicitly addresses the use of non-native species for establishing new aquaculture industries or capture fisheries. Hewitt, Campbell and Gollasch (2006) review the international agreements and codes associated with the use of non-native species in aquaculture. The United Nations Convention on the Law of the Seas (UNCLOS, 1982) created the legal basis for subsequent marine legal regimes. UNCLOS explicitly places a general requirement for Parties to take measures "to prevent, reduce and control pollution of the marine environment" and includes all activities involving the development of economic resources, as does the Convention on Biological Diversity (see Section 2).

Several codes have been developed as voluntary guidelines on these issues, such as the ICES *Code of Practice for the Introductions and Transfers of Marine Organisms* (ICES, 2005) and FAO's *Code of Conduct for Responsible Fisheries* (CCRF), whose Article 9 addresses *Aquaculture Development* (FAO, 1995) (see Section 2.1.2 for details).

Ecological risks to aquaculture from non-native species and invasive native species also remain significant. Species introduced via other transport vectors such as international shipping, intentional movements for fisheries stocking or other aquaculture activities (e.g. Ruiz *et al.*, 1997; Carlton, 2001) can have significant impacts on aquaculture operations. These impacts can include predation; competition; the fouling of nets resulting in reduced water flow, oxygen depletion and scarification of gills; algal blooms and associated biotoxins; and loss or reduction of food stocks (e.g. Hewitt, 2003b).

Ecological risk analyses can be either qualitative or quantitative and can contribute to import health standards or organism impact assessments after the species has been introduced (Campbell, 2005, 2006a,b, 2008). The processes and methodologies used for these risk analyses follow similar steps to those in other risk categories.

2.2.4 Genetic risks

The development and application of molecular and genetic techniques will play an important role in the future development of aquaculture (Hallerman, 2008), with contributions to improved quality of genetic stocks (Dunham, 2004; Gjedrem, 2005) and the concomitant increase in production levels and efficiencies (ADB, 2005). Cross (2000) described the genetic improvement of aquaculture species as an economic imperative and without it, the industry would find it impossible to compete. For example, coho salmon (*Oncorhynchus kisutch*) with introduced growth hormone genes from chinook salmon (*O. tshawytscha*) demonstrated much faster growth compared to the control group (Devlin *et al.,* 1994). This increased attention to and use of genetic methods for the improvement of stocks has led to direct genetic harm to natural populations, including loss of local adaptation and introgression of new genetic material (e.g. Mooney and Cleland, 2001; Arnaud-Haond *et al.,* 2004).

The potential for aquaculture to affect the genetic integrity of natural populations is recognized in a number of international agreements, guidelines and codes of conduct; however, these vary widely in their approaches (Hallerman, 2008). The CBD (1992) addresses the use of genetically modified organisms (GMOs) for research and commercial activity and provides implementation policies (CBD, 2000). However policies for aquatic GMOs are still under development. The release of genetically distinct stocks from aquaculture facilities into native populations is considered as an introduction of non-native species under the CBD, FAO's CCRF and the ICES Code of Practice.

The use of risk analysis in relation to genetic risks from aquaculture has notably been used in assessing triploid oyster impacts (Dew, Berkson and Hallerman, 2003;

NRC, 2004) and transgenic fishes (OAB, 1990; Hallerman and Kapuscinski, 1995); however, it has had limited application elsewhere (Hallerman, 2008). Recently, GESAMP (2008) developed a risk analysis methodology for environmental risks that incorporated the impacts of genetic introgression of farmed stocks on wild populations (Davies, Greathead and Black, 2008).

2.2.5 Environmental risks

The development of aquaculture poses several potential threats to the natural environment, including (but not limited to) increased organic and inorganic loading, residual heavy metals, residual therapeutants, physical interactions with marine life of gear and escapes, use of wild juveniles for grow-out, use of wild stocks for fish feed and degradation or replacement of habitat (Nash, Burbridge and Volkman, 2005, 2008; GESAMP, 2008).

It has been noted that the effects of environmental risks can be subtle and cumulative, leading to difficulties in prediction and management (Phillips and Subasinghe, 2008). Indeed, environmental impacts from aquaculture are highly diverse, leading to no single international or regional agreement that provides insights to appropriate management. As previously mentioned under Ecological risks (Section 2.2.4), UNCLOS and the Convention on Biological Diversity (CBD) (see Section 2) create obligations on Parties to prevent the pollution of the marine environment. Many environmental impacts occur at some distance from the source (aquaculture farm) and may result in transboundary effects. Similarly, impacts to locations of high value may be covered under a number of international agreements such as the World Heritage Convention (UNESCO, 1972), the Ramsar Convention (Convention on Wetlands, 1971) or other site-specific agreements. In addition, the FAO's CCRF provides guidance on the need to manage the environmental impacts of fishing and aquaculture activities.

The use of risk analysis to aid in management of environmental risks to and from aquaculture is limited. Nash, Burbridge and Volkman (2005, 2008) provide guidelines for ecological risk assessment[2] of marine fish aquaculture. They identify the standard risk process and provide ten environmental impacts (hazards) as having greatest importance. Environmental risk assessment (ERA) is noted to rely on information with significant uncertainty and often deals with effects that are not clearly quantifiable. As a result, the ERA process is typically qualitative or semi-quantitative in form. This is particularly the case when impacts are assessed based on environmental, social and cultural values.

The Joint Group of Experts on Scientific Aspects of the Marine Environmental Protection (GESAMP) Working Group 31 has recently completed the report on *Assessment and communication of environmental risks in coastal aquaculture* (GESAMP, 2008). This document provides advice on the potential environmental impacts of coastal aquaculture and identifies mechanisms to maintain consistency in assessment and communication of risks from coastal aquaculture. The report

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[2] It should be noted that the terms environmental risk assessment and ecological risk assessment are frequently used interchangeably.

provides a clear and concise methodology with examples across a number of environmental effects, including impacts on primary producers and changes in trophic resources and in habitat.

2.2.6 Financial risks

Financial risk in aquaculture refers primarily to investment risk associated with individual farms or facilities (Kam and Leung, 2008). While these risks are likely to be of primary concern to individual farmers, shareholders, enterprises or financial institutions providing finance or insurance (Secretan, 2008), the impacts of financial loss across a large sector of an economy can create macro-economic market fluctuations that must be considered at the national policy level or even at the international level, as seen by the increase in global salmon prices following the recent severe disease outbreaks in Chilean salmon farming. Agriculture (including aquaculture) activities have been deemed inherently risky ventures by some (Goodwin and Mishra, 2000).

Kam and Leung (2008) suggest that financial risk is largely broken into production threats and market threats. Production threats result in financial loss due to reduced yield. These impacts can be realized based on adverse environmental conditions, equipment failure, poor quality stock, disease or pest infestation, and others. Many of these external factors can be ameliorated by knowledgeable staff; hence, employee management (social risks) may lead to significant production failures.

In contrast, market threats include price fluctuations and the impacts of the regulatory environment (Jorion, 2007). Competition, either domestically or internationally, will add to the volatility of market prices and hence to profit margins. In contrast, the regulatory environment may create additional cost burdens at the national level that are equally shared across the industry, but create significant financial risks on the international market.

Analyses of financial risk are typically quantitative in their approach because financial risk generally implies monetary loss (Jorion, 2007). Analyses can be applied at the level of an individual enterprise (farm) or across a sector at the national or regional level. No specific international or regional agreements exist that provide guidance on financial risk analysis, and as Kam and Leung (2008) state, few examples of financial risk analysis exist that would be comparable to analyses conducted for other risk categories.

2.2.7 Social risks

Much like financial risks, social risks are widely associated with the corporate sphere and have had limited application in national policy planning for the aquaculture industry (Bueno, 2008). Social risk analysis is widely used as part of project planning; however, there has been recent application to address poverty alleviation and social welfare in developing economies (Holzmann, 2001; ADB, 2003). Social risks incorporate business practices that adversely impact human welfare and development, working conditions and industrial relations. As Bueno

(2008) states, "Social risks in aquaculture are challenges by society to the practices of the sector, industry, company or farm over the perceived or real impacts of these practices on issues related to human welfare."

Many social risks can be found in other risk categories; however, the explicit impact of aquaculture business practice on local human welfare requires special attention to developing this area at a national policy level. The development or expansion of an aquaculture sector can have significant impacts on native access rights, artisanal fisheries, traditional values or earning potentials. In some instances the use of offshore (e.g. non-domestic) labour may reduce the social benefit to local communities from establishing the aquaculture industry in the first place.

3. A risk analysis process for aquaculture

This section presents an outline of a generic risk analysis process for aquaculture (brief summaries of the risk analysis processes specific to the seven risk categories can be found in Section 4, with detailed reviews given in Bondad-Reantaso, Arthur and Subasinghe, 2008). The general process, shown in Figure 2, consists of a preliminary step – scoping the risk analysis, and four major components: (i) hazard identification, (ii) risk assessment, (iii) risk management and (iv) risk communication. The following sections briefly discuss some of the important aspects of each of these activities.

3.1 DETERMINING THE SCOPE OF THE RISK ANALYSIS

3.1.1 Define the objectives of the risk analysis

At the outset of a risk analysis, it is imperative to understand what is to be achieved. The objective must be clearly stated and will generally define the scale and scope of the analysis along with the measurement endpoints and desired outcomes.

To accomplish this, a risk analyst needs to answer a number of questions about the purpose and nature of the risk analysis that will ultimately set the objectives and boundaries (the “scope”) of the analysis. The precise questions will vary depending on the risk category. As an example, some useful questions that help define the scope of an ecological or environmental risk analysis are given in Box 1.

The analyst must also delineate the endpoint(s) of the risk analysis, which will provide guidance as to what hazards the assessment is trying to prevent, what outcomes it is trying to achieve and/or what values it is trying to protect. The endpoints will also be formed by examining exposure to the hazard and can be explored by asking appropriate questions.

3.1.2 Agree upon a risk analysis methodology and approach

With each of the seven risk categories, numerous risk analysis methodologies exist (qualitative, semi-quantitative or quantitative) to meet a variety of objectives. In many cases, risk analysis need not be complicated; however, choosing the methodology most appropriate to the problem that is being addressed will make the decision-making process easier. Considerations for selecting a risk analysis method include the quality and availability of data, the uncertainty surrounding the data, the available budget (including human resources) and the time available to undertake the assessment. It is also important to determine the linguistic level of approach, e.g. is it for seasoned risk analysis specialists, well-educated non-risk specialists or less well educated stakeholders? If a detailed analysis is required and

BOX 1

Some useful questions that help define the scope of an ecological or environmental risk analysis

Questions that help define the purpose and nature of the risk analysis and provide information that will guide it include:

- What is the scale of the risk assessment?
- What are the critical ecological endpoints and ecosystem receptor characteristics?
- How likely is recovery and how long will it take?
- What is the nature of the problem?
- What is the current knowledge of the problem?
- What data and data analyses are available and appropriate?
- What are the potential constraints?

Questions that establish the ecosystem boundaries include:

- What are the geographic boundaries?
- How do the geographic boundaries relate to the functional characteristics of the ecosystem?
- What are the key abiotic factors influencing the ecosystem?
- Where and how are functional characteristics driving the ecosystem?
- What are the structural characteristics of the ecosystem?
- What habitat types are present?
- How do these characteristics influence the susceptibility of the ecosystem to the stressor(s)?
- Are there unique features that are particularly valued?
- What is the landscape context within which the ecosystem occurs?
- What are the type and extent of available ecological effects information?
- Given the nature of the stressor, which effects are expected to be elicited by the stressor?
- Under what circumstances will effects occur?

Questions related to the stressor and its source include:

- What is the source of the hazard? (Is it anthropocentric, natural, point source or diffuse nonpoint?)
- What type of stressor is it? (Is it chemical, physical or biological?)
- What is the intensity of the stressor?
- With what frequency does a stressor event occur?
- What is the stressor event's duration? (How long does the stressor persist in the environment?)
- What is the timing of exposure? (When does it occur in relation to critical organism life cycles or ecosystem events?)
- What is the spatial scale of exposure? (Is the extent or influence of the stressor local, regional, global, habitat-specific or ecosystem-wide?)
- What is the distribution? (How does the stressor move through the environment?)
- What is the mode of action? (How does the stressor act on organisms or ecosystem functions?)

there is ample budget and no time constraints, then a fully quantitative analysis may be desired. However if a rapid decision must be made in the face of poor data availability or a limited budget, then a qualitative assessment may be more feasible.

Qualitative or even semi-quantitative risk analysis can often provide the level of information sufficient for use by a decision-maker in a rapid fashion; however, these analyses often require a number of assumptions to be made due to poor data quality or cost-saving measures that may result in increased uncertainty (see Section 3.3.4). As a consequence, qualitative and semi-quantitative risk analyses may occasionally be considered too subjective and lacking in scientific rigor. Alternately, fully quantitative risk analyses can be costly and time-intensive; however, they are often perceived as being more objective and scientifically defensible.

3.1.3 Identify the stakeholders

Identification of responsible agencies is fundamental to understanding the resourcing (both human and financial) and decision-making responsibility. If there is more than one responsible agency, a clear and concise statement of roles and responsibilities should be developed in advance to guarantee success. The early identification of non-statutory stakeholders will aid in the development of risk communication strategies, as well as in the gathering and exchange of information throughout the analysis.

3.2 HAZARD IDENTIFICATION

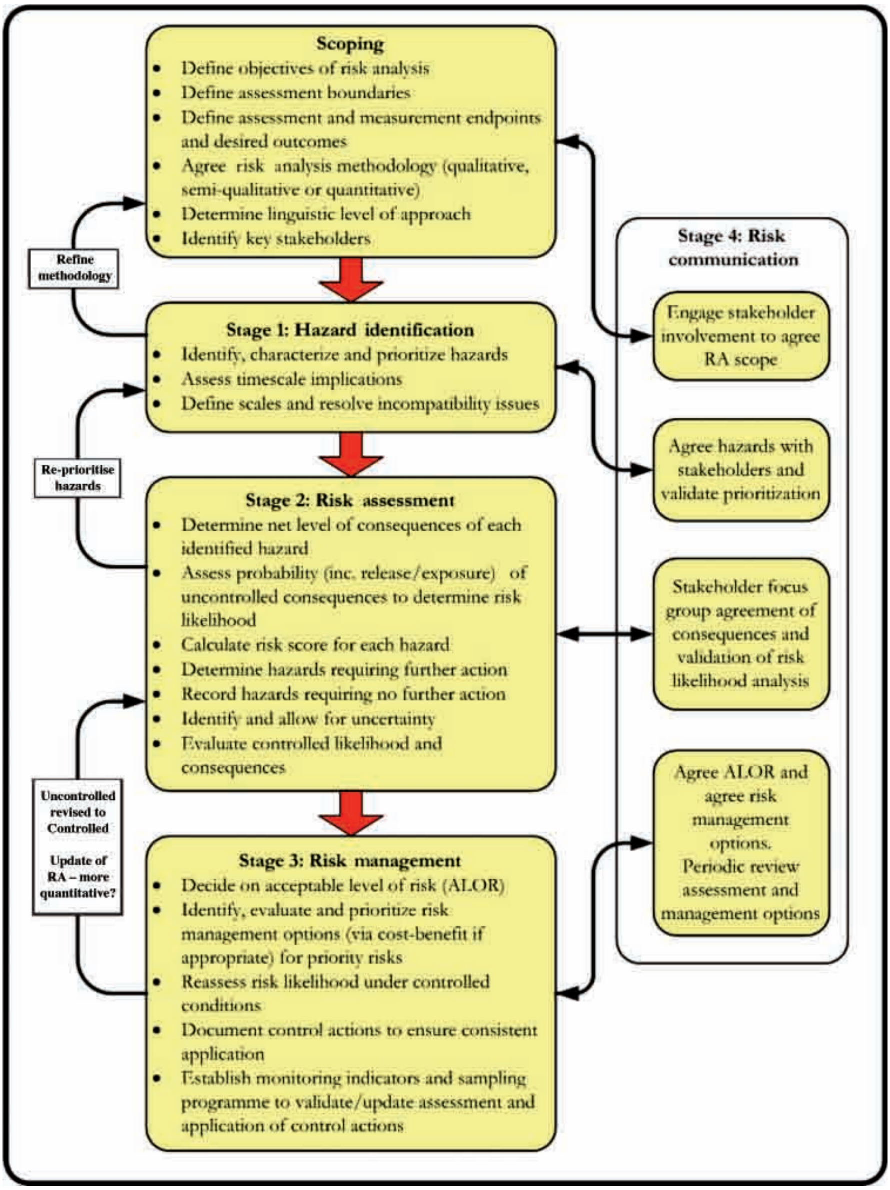
3.2.1 Identify, characterize and prioritize hazards

In simple terms, a hazard is something (an action, an organism, a physical condition, a piece of legislation, etc.) that may cause harm and therefore potentially create risk. A hazard may act synergistically to increase risk or may cause cascade events that lead to hazard migration (i.e. the action of one hazard creates additional hazards that result in increased likelihood and consequence). For example, caged finfish culture in shallow water increases the nutrient input to the system, frequently leading to eutrophication and accumulation of feces and excess feed on the substrate. This accumulation of organic material will lead to anoxia (reduced oxygen levels) in the sediments and have consequential impacts on infaunal organisms.

Hazard identification may proceed in a variety of ways, including via a Delphi process using expert opinion or by a more formalized assessment such as fault tree analysis (Hayes, 1997). For pathogen risk analysis, Arthur *et al.* (2004a) outline a multistage hazard identification process based on collation of prior knowledge (exhaustive literature review) and expert assessment to reduce the number of potential hazards. This process is useful for situations where significant prior knowledge exists, such as for pathogen risks, food safety and public health risks, financial risks and to a lesser extent, social risks.

In contrast, fault-tree analysis has been used to identify the chain of events leading to a hazardous occurrence in ecological, genetic and environmental risk analyses. Fault trees provide a rigorous mechanism to identify logical relationships and situations leading to hazardous situations. Hayes and Hewitt (1998, 2000, 2001) provide an explicit example of fault tree analysis in the context of marine biosecurity where the fault-tree analysis identified taxonomic hazards in donor ports and a number of subtle (and less tractable) hazards within the ballast water introduction cycle.

FIGURE 2
Overview of the risk analysis methodology



With regard to aquaculture, hazards can either affect the success of aquaculture operations, or the aquaculture activities themselves can be hazards (Table 3). These can vary across all core values (environmental, economic, socio-political and cultural) and can be represented within multiple risk categories.

3.2.2 Assess timescales

Hazards vary in their spatial extent and in the timing of presence. Some hazards are always present (e.g. tidal flow), whereas others may only occur at specific times (e.g. storm events). As a consequence, hazards may create windows of opportunity for impacts to occur. The temporal component of a hazard will vary depending on the stressor itself, the length of time that a stressor event occurs (short, medium or long term) and the length of time the hazard persists in the environment. For example, a disease outbreak may involve a vagile species that can persist for a long period of time, thus posing a greater risk than a disease that is caused by a

TABLE 3
Examples of hazards to and from aquaculture associated with the seven risk categories

Risk category	Hazard to aquaculture	Hazard from aquaculture
Pathogen risks	Disease outbreak causing loss of stock OIE-listed disease Food safety and public health concern Loss of consumer confidence	Disease outbreak in wild populations OIE -listed disease Food safety and public health concern
Food safety and public health risks	Bacteria Viruses Parasites Residual therapeutants Biotoxins (HABs)	Transfer of pathogen from aquaculture facility to wild Residual therapeutants
Ecological (pests and invasives) risks	Pest outbreak causing fouling Pest outbreak competing for space Pest outbreak predating on adult or juvenile stock	Escape of adult or juvenile stock into wild Release of non-target hitch-hiker into wild Release of species as /or associated with feed stock (e.g. microalgae, pathogens)
Genetic risks	Not applicable	Genetic introgression Loss of local adaptation Loss of locally adapted populations
Environmental risks	storm activity (including flooding) Predation Competition for food	Organic loading Inorganic loading Residual heavy metals Residual therapeutants Physical interaction with marine life Physical impact on marine habitat
Financial risks	Changing production costs Reduced production Equipment failure Poor quality broodstock Market demand fluctuations Increased regulatory costs	Volatility in the aquaculture industry affecting economy Global market instability Changes in transport costs due to "carbon-miles"
Social risks	Industrial action Skill shortage Civil unrest Excessive regulation	Poor workplace conditions Use of technology that replaces labour Pollution from farm Poor quality product Loss of resource access due to farm site

pathogen that is fragile outside of its host and will perish after mere minutes of exposure to the aquatic environment. Persistence in the environment may also be increased by the presence of an encystment life history stage of a hazardous species. Some harmful algal blooms are good examples of species that can persist for decades based on a dimorphic life history phase that involves cysts.

3.3 RISK ASSESSMENT

3.3.1 Determine the likelihood of the hazard being realized

Likelihood is typically described as the probability of an event (impact, incursion, release, exposure, etc.) occurring, ranging from rare events to likely or frequent events. There is no universal set of categorical likelihood descriptors, both the number of descriptors used and their definitions (descriptions) varying between and within risk categories. An example of a set qualitative likelihood descriptors used in a risk assessment is presented in Table 4. Qualitative and/or quantitative data can be used to assess likelihood.

3.3.2 Determine the consequences of the hazard being realized

Consequence is the outcome, generally negative, of an event (hazard) occurring. For each hazard there is at least one consequence that occurs (there may be more than one consequence from an event), which may range from positive to negative. Consequence may be expressed qualitatively or quantitatively. Consequences must identify the intensity or degree of impact, the geographical extent of impact and the permanence or duration of impact.

Consequences fall into four broad categories:

- Environmental impacts – Examples include loss of biodiversity, loss of habitats, disease in target and non-target species, and alterations to trophic interactions.
- Social and political impacts – Examples include altered employment rates, altered tourism, significant change to artisanal resources, international economic sanctions and loss of international trade.
- Cultural impacts – Examples include alteration to aesthetics, connection to the aquatic environment and religious beliefs.
- Economic impacts – Examples include loss of domestic and international trade, loss of current and potential resource(s), loss of consumer confidence, loss of production (e.g. poor food quality, disease, predation, escapes) and loss of business viability.

TABLE 4

An example of a set of categorical likelihood descriptor

Descriptor	Description
Rare	Event will only occur in exceptional circumstances
Very Low	Event could occur but is not expected
Low	Event could occur
Moderate	Event will probably occur in most circumstances
High	Event is expected to occur in most circumstances

Often there are limited data relating to the consequences of an event being realized. In such circumstances, the risk analyst can either:

- *State that the risk assessment cannot be completed due to data deficiencies.* If consequences are defined as data deficient, then the risk assessment process cannot proceed and risk management must decide whether to classify data-deficient records as high risk (conservative approach) or low risk (non-conservative approach). A risk averse decision-maker would classify all data deficient decisions as high risk and might employ a precautionary approach until essential data can be obtained; *or*
- *Undertake a Delphi process to fill data gaps.* The Delphi process fills data gaps by asking experts their opinion and beliefs about a hazard. Expert opinion must be drawn from all four consequence categories to ensure that each category (environmental, social and political, cultural and economic impacts) is thoroughly considered in the light of potential data. The Delphi process creates a statistical population of beliefs that can then be evaluated using classic statistics and can acknowledge uncertainty. A simplified example of a consequence matrix for an ecological risk analysis that was established via expert opinion is provided in Table 5. Within this table, note that threshold values (represented by percent values) are used to delineate levels within the matrix. These threshold values were also determined via the Delphi process.

TABLE 5
Example consequence matrix: economy as defined by primary and secondary industry, tourism, education and intrinsic value

Descriptor	Economic impacts
Insignificant	Reduction in national income from introduced species impact shows no discernible change No discernable change in strength of economic activities If the introduced species was removed, recovery is expected in days
Minor	Reduction in national income from introduced species impact is <1% Reduction of strength in individual economic activities is <1% Economic activity is reduced to 99% of its original area (spatial context) within a defined area If the introduced species was removed, recovery is expected in days to months; no loss of any economic industry
Moderate	Reduction in national income from introduced species impact is 1–5% Reduction of strength in individual economic activities is 1–5% Economic activity is reduced to less than 95% of its original area (spatial context) within a defined area If the introduced species was removed, recovery is expected in less than a year with the loss of at least one economic activity
Major	Reduction in national income from introduced species impact is 5–10% Reduction of strength in individual economic activities is 5–10% Economic activity is reduced to less than 90% of its original area (spatial context) within a defined area If the introduced species was removed, recovery is expected in less than a decade with the loss of at least one economic activity
Catastrophic	Reduction in national income from introduced species impact is >10% Reduction of strength in individual economic activities is >10% Economic activity is reduced to less than 90% of its original area (spatial context) within a defined area If the introduced species was removed, recovery is not expected with the loss of multiple economic activities

Source: modified from Campbell, 2005.

TABLE 6

A typical risk matrix, where risk is denoted by: N = negligible, L = low, M = moderate, H = high, E = extreme

	Consequence				
Likelihood	**Insignificant**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Rare	N	L	L	M	M
Very low	N	L	M	H	H
Low	N	L	H	H	E
Moderate	N	M	H	E	E
High	N	M	E	E	E

3.3.3 Calculate the risk of consequence realization

For each hazard that was identified, a measure of risk must be derived by multiplying likelihood by consequence. A risk matrix (Table 6) is used to derive this measure of risk. Again, the exact nature of the matrix may vary depending on the risk category and the individual risk analysis.

3.3.4 Identify uncertainty

As previously discussed, uncertainty can occur for a number of different reasons. Byrd and Cothern (2005) suggest nine different categories of uncertainty:

1) *Subjective judgment* – This is typical of the Delphi approach, where data are absent, partly absent or conflicting, and hence a poll of expert opinion is used to ascertain the missing information. Because it is based on opinion, the result is subject to error or uncertainty.
2) *Linguistic imprecision* – Words can have different meanings in different situations, or multiple meanings. Thus, when defining uncertainty in qualitative terms people can easily misunderstand what was meant. For example, the word "old" may have a different meaning to different people based on their perceptions (to a five-year-old child, 30 may seem very old, but to a 70-year-old pensioner, 30 may seem young). To avoid this, terms should be fully and accurately defined or quantitative measures of uncertainty should be used, where possible.
3) *Statistical variation* – Standard deviation is a common method to express statistical variation. If experimental data exist, then statistical variation can be expressed.
4) *Sampling* – Sampling bias may result in an incorrectly represented trend in results, which in turn may lead to an identified level of uncertainty. Sampling for impact needs to consider resource constraints but more importantly, the statistical robustness of the sampling programme to ensure that an accurate answer can be reached.
5) *Inherent randomness* – The world is an extremely dynamic and inherently variable place that humans have a limited capacity to measure. This limitation due to the randomness results in uncertainty.
6) *Mathematical modeling* – Model uncertainty occurs because it is difficult to fit mathematical models or equations to environmental data. Models are imperfect because of the inherent randomness in the environment and our lack of ability to accurately measure the cause of many events.

7) *Causality* – Relationships (correlations) between cause and effects are often captured via epidemiological data. Yet a correlation does not demonstrate causality. To scientifically demonstrate cause is difficult and when combined with the dynamic nature of the world, it often precludes us from knowing the exact cause of an event.
8) *Lack of data or information* – For most risk analyses, data are lacking. If data are missing, this must be stated up-front. If missing data are compensated for by extrapolating existing data or by using a Delphic approach, then this must also be stated up-front, as these become assumptions of the risk assessment that can affect the risk manager's decisions.
9) *Problem formulation* – It is important to solve the correct problem. A risk can be misunderstood and consequently, the wrong problem can be "solved".

For the risk assessment to proceed, the types of uncertainty associated with the assessment should be identified and stated up-front, thus allowing stakeholders to understand the assumptions that are made within the evaluation. By stating these assumptions up-front, risk managers can then allow for the uncertainty in their decision-making.

3.4 RISK MANAGEMENT

3.4.1 Determine the Acceptable Level of Risk

Acceptable level of risk (ALOR) is based on social and political perspectives. Risk perception can be shaped by culture (Byrd and Cothern, 2005; Slimak and Deitz, 2006), context, control (if you can control the risk is the threat lower?) and benefit (a willingness to accept risk if the benefit is sufficiently high). It will also depend on the stakeholder's needs, issues and knowledge. For example, poorly informed stakeholders might perceive a greater or lesser risk than what actually exists. Also, stakeholders may examine risk from different perspectives (e.g. pathogens, environmental issues, introduced species, etc.) and will be informed based on different statutory obligations.

In some risk categories having well-defined frameworks (i.e. pathogen risk analysis, food safety and public health risk analysis), determining the appropriate level of protection (ALOP), and consequently, the ALOR, is explicitly not a part of the risk analysis process. For these sectors, ALOR is typically a national standard that is explicitly or implicitly set by political decision, legislation and/or past practice that are outside the framework of an individual risk analysis (for example, for import risk analysis, the ALOP is typically a political decision that is made at the national level and is applicable across the plant, terrestrial animal and aquatic animal biosecurity subsectors). In other cases (such as genetic, social and financial risk analyses), a predetermined ALOR does not exist, and what constitutes "unacceptable risk" must be determined on a case by case basis by expert opinion and stakeholder consultation. In these cases, the risk assessment process needs to integrate the divergent views, subjective rationalities and preferences of experts and stakeholders to establish an effective ALOR. This can be done via a Delphic approach, which allows discussion and the opportunity to compromise and/or seek consensus. Through this process, ambiguities or conflicts can be resolved.

In either case, once the ALOR has been established and the estimated risk for the hazard being assessed has been determined, the risk analyst compares the two values to determine if the risk is "acceptable" or "unacceptable" (significant). If the risk is acceptable, then the risk assessment for the particular hazard is completed, and the risk analyst can either approve the proposed action (if there is only a single hazard being assessed) or move on to assessing the next hazard posed by the action being proposed. If the risk posed by the hazard is found to be unacceptable, then risk management options can be considered.

3.4.2 Identify, evaluate and prioritize risk management options

Where a risk assessment has determined that a hazard poses a significant risk, the risk analyst may attempt to identify possible management options (i.e. mitigation options) and assess their effectiveness in lowering the risk posed by the hazard by reducing either the likelihood or consequences of its realization. Trade-offs between different mitigation options must be assessed, hence application of cost-benefit analyses may be essential to some risk categories (e.g. financial risk analysis) to prioritize the risks.

Risk management typically follows a four-step process:

- Determine the options for mitigation;
- Re-calculate the level of risk under each option;
- Compare the new risk estimate with the ALOR to see if the risk mitigation option is likely to be effective in reducing risk to an acceptable level; and
- Evaluate other synergistic and interacting information. This typically involves cost-benefit, risk-risk, and risk-benefit analyses; assessing technical feasibility; determining social acceptability, legal conformance and regulatory objectives, and political perceptions; and assessing enforceability.

At the end of the risk management process, decisions can be made that modify risk. This is referred to as risk treatment and includes:

- *Risk avoidance* – A risk manager decides not to become involved in a risk situation or takes action to withdraw from a risk situation (Aven, 2003). An example, may be to halt importation of the Pacific white shrimp (*Litopenaeus vannamei*) into regions where it is not native if native shrimp populations may be seriously affected.
- *Risk optimization* – This is accomplished by undertaking a process that minimizes the negative and maximizes the positive consequences and their respective probabilities. For example, the importation of Pacific white shrimp may lead to economic growth and greatly improve the livelihoods of farmers directly involved in this activity (positive consequences). This aspect is played up, while the loss of natural biodiversity and the potential spread of pathogens (negative consequences) may be played-down.[3]

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[3] Note, however, that in pathogen risk analysis, consideration of the potential benefits resulting from the cross border movement of an aquatic animal commodity is specifically excluded.

- *Risk transfer* – This involves the sharing of the benefit of gain or burden of impact from a risk with another party. Typically, this occurs via insurance or other agreements. For example, a government may agree to provide “insurance” against the potential for transfer of pathogens associated with the importation of Pacific white shrimp. This insurance would cover farmers of other shrimp species that would be adversely affected by a pathogen imported with Pacific white shrimp.
- *Risk retention* – This involves the acceptance of the benefit of gain and/or burden of loss from a risk. It also includes the acceptance of risks that have not been identified but does not include treatments that include risk transfer.

3.4.3 Reassess risk likelihood under controlled conditions

Once a risk management strategy or control option has been identified, it is necessary to reassess the likelihood and consequences arising from a hazard under the new management regime. It is imperative to determine whether the risk reduction achieved under the management option achieves the ALOR in a cost-efficient fashion, and whether it is an effective strategy. Efficiency includes an assessment of whether the management option requires a long-term management action and who will be responsible for the action. Effectiveness may include an assessment of the level of risk reduction that is achieved relative to costs and whether the risk will return if management is reduced or removed. These considerations must be taken into account when considering long-term decisions.

3.4.4 Document management actions

Once a risk manager has identified risk mitigation actions, it is important that these are implemented. The management action, how it was implemented and the realized outcomes need to be recorded accurately and assessed against expected outcomes. By doing so, the performance of the management action can be monitored and improved if it fails to meet expected goals. Documenting the performance of actions allows iterative improvements to be made and provides future risk managers with consistent data on attempted mitigation measures that can be used to establish principles for subsequent decision-making. If the outcomes of risk management actions are not recorded and communicated, then it is impossible to know if an action is worthy for future attempts.

3.4.5 Establish monitoring indicators and a sampling programme

Risk management actions should be monitored in both space and time to ensure that the expected outcomes are being met or if alterations to the actions need to occur. Typically, management actions are monitored using indicators and a robust sampling programme. These need to be established prior to, during and after the control actions have been established. For example, when using a biological control agent to control a weed (such as alligator weed infestations in waterways), the population of the weed and the biological control are monitored over time and along the infestation and control regions to provide a statistically robust picture of how the biological control is impacting upon the weed. If the biological control is having no effect, then another control action can be attempted. Without monitoring the action, the risk manager may be under the false impression that a control effort was successful in mitigating a risk when in actuality the control action had had no effect.

While monitoring programmes are intrinsic to evaluating management outcomes, they are typically at significant risk of delivery failure due to issues such as continued long-term funding, availability of appropriately trained personnel, continued access to monitoring sites and the political will to continue a long-term programme. Prior to establishing long-term monitoring programmes, the risk manager needs to ensure that the duration of the programme is sufficient to achieve the desired outcomes and to secure political and financial support for this period.

3.5 RISK COMMUNICATION

3.5.1 Engaging stakeholders and building consensus

Risk communication is the process of explaining risk and communicating the process and outcomes of the risk analysis. Its aim is to inform people that are "outside" of the formal risk analysis process, so that they can understand the risk assessment that is being conducted and equally important, provide information to the process. Stakeholders can provide vital information, including relevant aid in determining hazards and in outlining standard operating procedures (SOPs) that may create hazards or more importantly, provide risk management options. Risk communication also aims to aid people in accepting risk management decisions while also providing risk managers with an insight into stakeholder concerns. Risk communicators must engage both the general community and the stakeholders to understand how the public views risk (risk perception).

As an operating principle, risk communicators must engage truthfully and openly with stakeholders, accepting information and advice as it is offered. Risk communication most frequently fails when the stakeholders feel that they have been ignored or that their opinions are discounted. By maintaining an open policy of communication, many of these stakeholder concerns will be avoided.

3.5.2 Identifying stakeholders

Stakeholders are derived from a variety of sources, including sectoral interests (those directly associated with the industry being regulated) and external interests (those who have an interest in the outcomes of the risk assessment and who may be secondarily affected). It is the risk communicator who must decide which stakeholders need to be engaged in the risk analysis process and how and when they should be engaged in order to achieve the best outcome of the risk analysis process.

Stakeholders within the aquaculture sector being assessed (e.g. finfish farmers, oyster farmers, prawn farmers) will have a direct and immediate interest in any risk analysis being undertaken. They will have a significant interest in the intended outcomes, but are also likely to have information vital to conducting the risk assessment. Communicating the risk analysis approach, results and outcomes and the future consultation programme to stakeholders within the aquaculture sector (including communities, fishers, etc.) is imperative to achieve the ultimate goal of effective risk management.

Each risk analysis will have a unique set of external stakeholders, which can include, for example, other aquaculture sectors, concerned scientists, NGOs and government agencies. Similarly, public stakeholders, including adjacent landowners, recreational users, native or indigenous communities, and transboundary interests of adjacent countries will provide a broad external stakeholder base for consideration. These stakeholders may or may not have information of vital interest to the risk analysis, depending on the scope of the analysis. In some instances, such as transboundary interests, engagement is mandated under several international agreements. Regardless, it is imperative that communicating the risk analysis results, outcomes and future consultation programme to stakeholders both within and outside the aquaculture sector occur throughout the process.

3.5.3 Stakeholder contributions to the risk analysis process

Effective stakeholder consultation throughout the entire risk analysis process is essential to information gathering, consensus building, acceptance of the conclusions of the risk analysis by those who will be most affected, and successful implementation of risk management measures. For example, during hazard identification, the participation of stakeholders can lead to increased identification of potential hazards. By accessing stakeholder information, the risk analyst not only increases information flow but also improves communication with the stakeholder community. Once relevant hazards are identified, appropriate stakeholders must be engaged to validate and provide a reference for each specific hazard (or hazard grouping). Stakeholder composition may vary between hazards. For example, stakeholders that are interested in introduced marine species may not be interested in or knowledgeable about animal pathogens. Stakeholders that may be of importance at this stage include farmers, scientists, the interested public and product marketers.

Different stakeholders may be approached during the risk assessment process. This is particularly important when consequences across environmental, social and political, cultural and economic impacts are assessed. Stakeholders must have relevant background knowledge and experience to ensure that accurate data are collected; thus each of the consequence groups should be represented by stakeholders during the risk assessment process. Examples of relevant stakeholders include communities, fishers, agriculture farmers, government officials, economists, natural scientists, social scientists and cultural groups (e.g. indigenous groups).

During risk management, stakeholder communication is directed towards two groups: those who will be affected by the management actions (the public) and those who are legislating and regulating to help mitigate the risk (government officials). Regardless of the decision, some stakeholders are likely to be adversely affected by the outcomes of the risk analysis. As a consequence, the need to provide opportunities for public consultation on risk management outcomes is emphasized. For some sectors, stakeholders may also participate in setting the ALOR to be applied during the risk analysis process.

3.5.4 Dissemination of results and outcomes

The dissemination of the risk assessment results and risk management considerations and outcomes is essential to gain stakeholder understanding and support. Frequently a report is prepared to provide a formal outcome of the risk analysis process. A model template for a risk analysis report is presented in Box 2.

BOX 2

Model template for the contents of a risk analysis report

- Describe the preliminary risk analysis objectives and plans.
- Describe the scale and scope of the risk analysis (e.g. environmental setting of the planned aquaculture development).
- Describe the operational context of the project/system to be assessed.
- Review the risk analysis process and agreed endpoints with a statement of ALOP.
- Discuss the primary data sources or experts and methods used for data collection and analysis.
- Describe the identified hazards with risk profiles (likelihood and consequence assessments) for each hazard; include a summary of uncertainty in each risk profile.
- Identify risk management options for each risk profile and provide advice on the extent to which the risk is reduced by the management option.

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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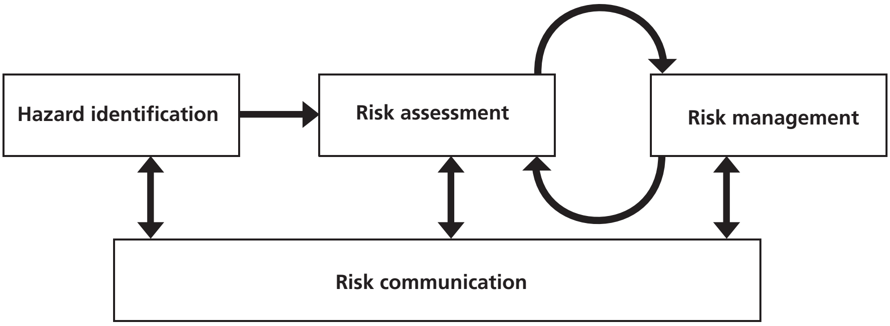
[4] Information for each category has been extracted and modified from the relevant review presented in FAO Fisheries and Aquaculture Technical Paper No. 519, *Understanding and applying risk analysis in aquaculture* (Bondad-Reantaso, Arthur and Subasinghe, 2008). In these brief summaries, all references 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.

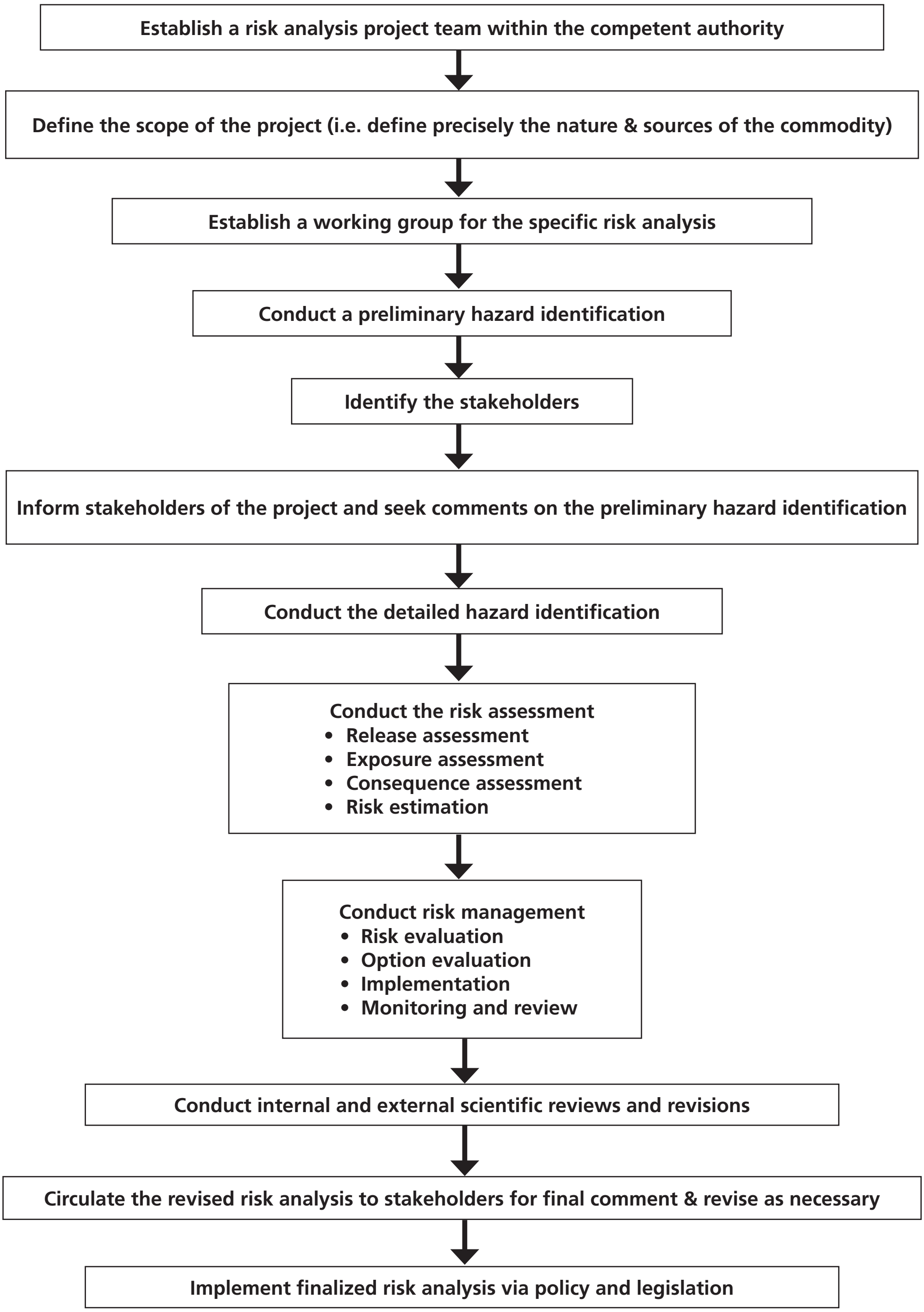
4.1.3 Risk assessment

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:

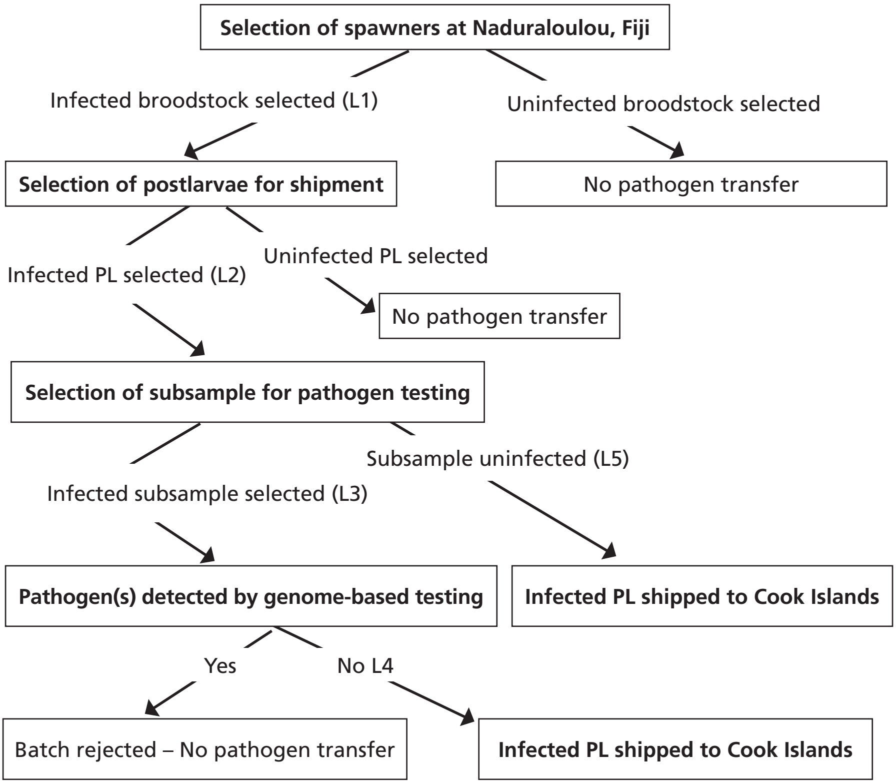
- Potential biological, environmental and economic consequences associated with the entry, establishment and spread:
  - Direct consequences: outcome of infection in domestic and wild animals and their populations (morbidity and mortality, production losses, animal welfare), public health consequences
  - 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

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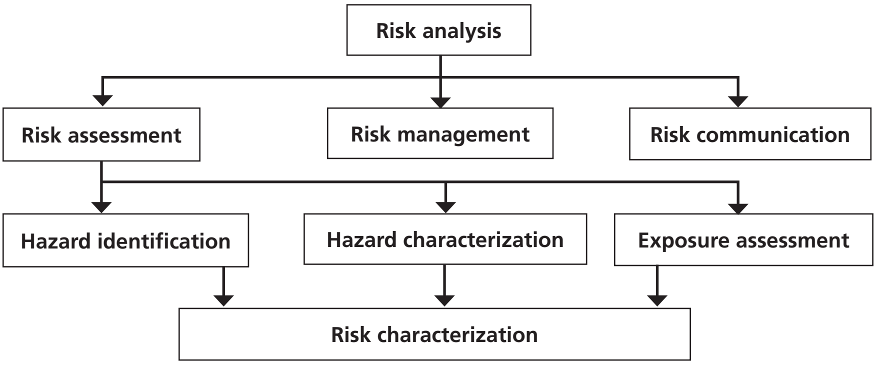
[6] This section is extracted with modifications from Karunasagar (2008).

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.

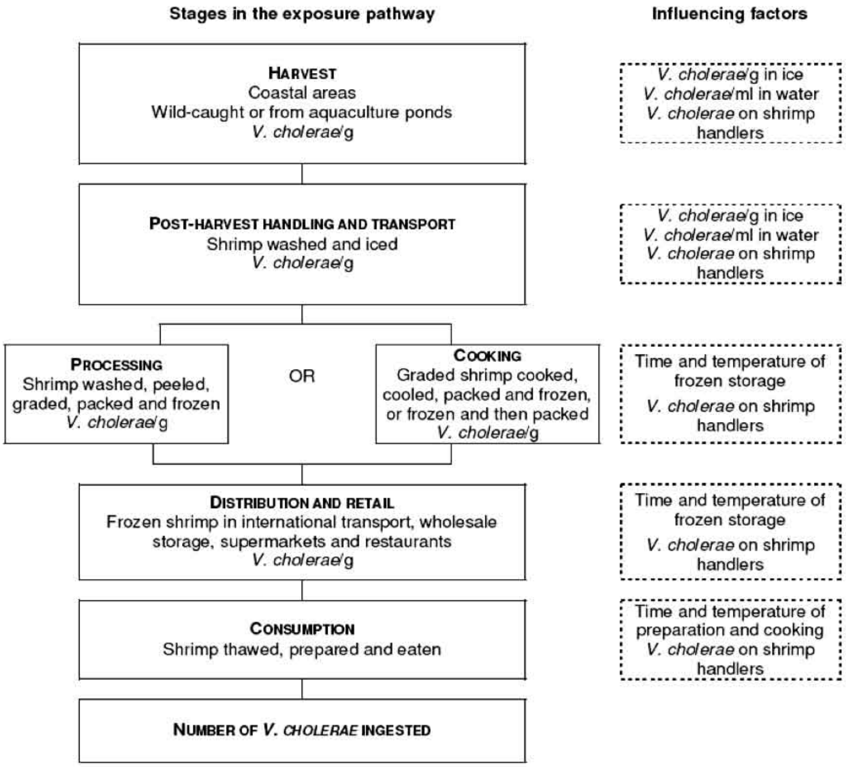
For risk assessment, it is important to consider the prevalence and concentration of choleragenic *V. cholerae* in shrimp during all stages of the farm to fork chain. The model considered in this risk assessment is shown in Figure A. Warmwater shrimp intended for export is handled as per HACCP guidelines, 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

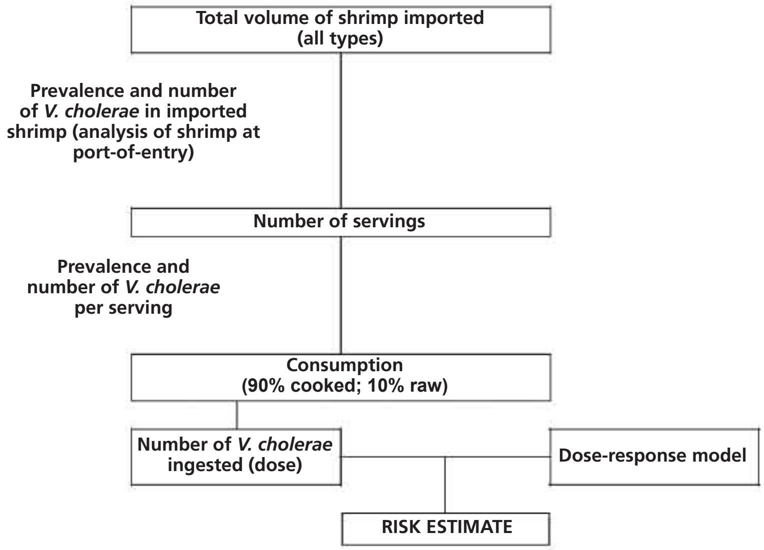


TABLE B

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.

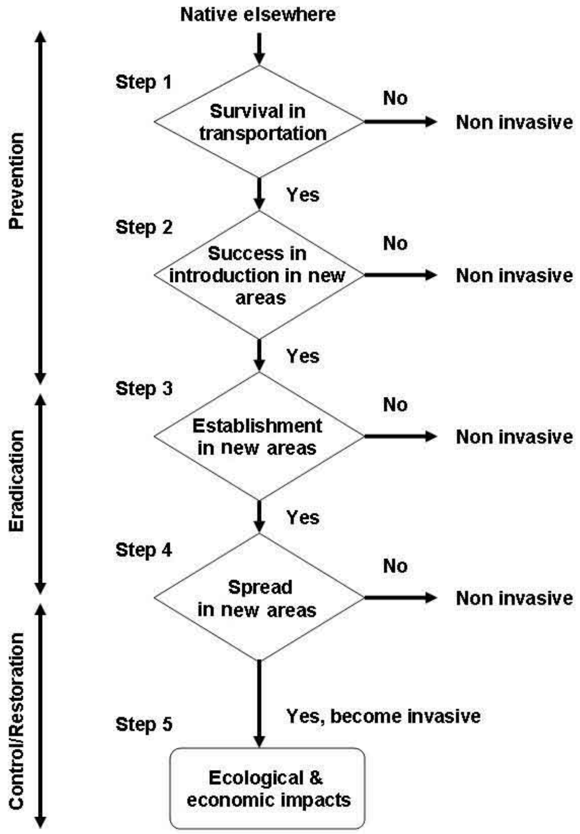
It is theoretically possible to predict and assess the invasion risk of the candidate species based on the ERA model by way of multiple-level evaluations of the survival probabilities during the transport process (Step 1 in Figure 7), the chance of inoculation into a new region (e.g. accidental escape 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)

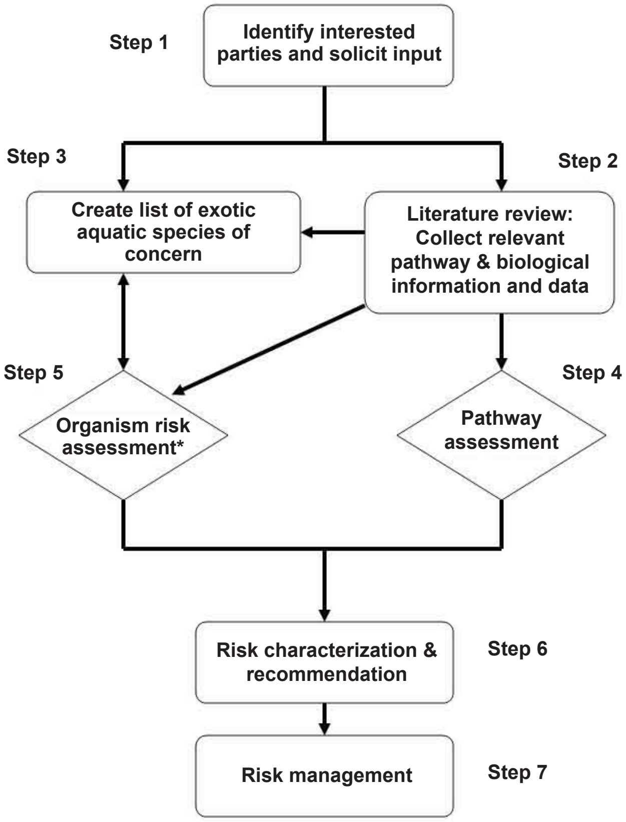


TABLE 7
Classification of native and exotic species according to their characteristics. The priority of concern for each category is also given

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:

$$\text{Invasion risk} = \{\text{Probability of establishment}\} \times \{\text{Consequence of establishment}\} \quad (1)$$

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

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)

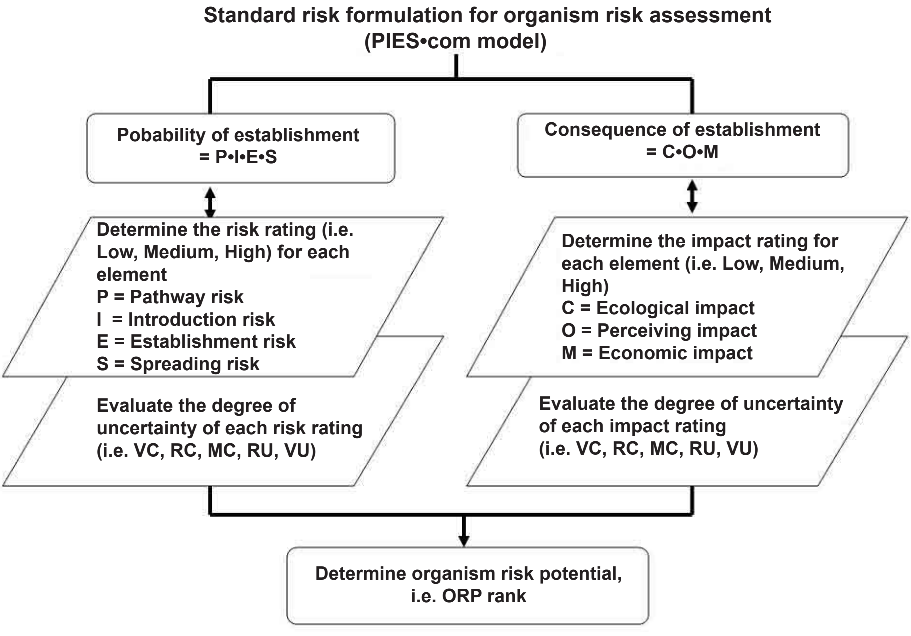


TABLE 8

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;

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[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

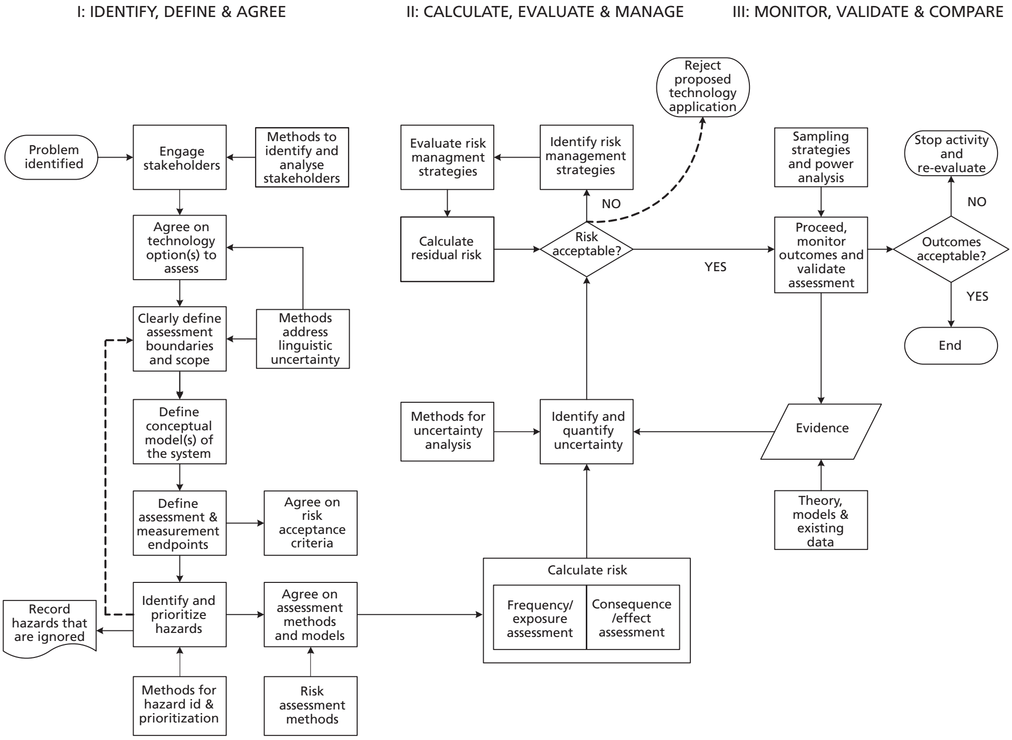
In the context of genetic risk analysis, the hazardous agent is the cultured stock because it is the entity that poses genetic harm to populations in a receiving ecosystem. In the aquaculture context, the hazardous agent may be a non-indigenous species; an interspecific hybrid; or a non-indigenous, selectively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

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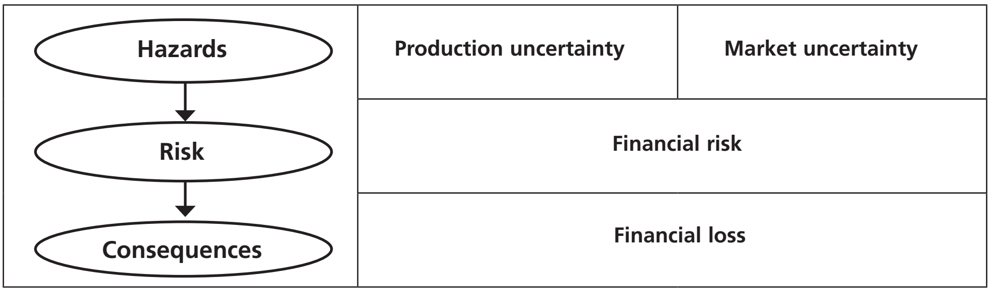
[10] Extracted with modification from Kam and Leung (2008).

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

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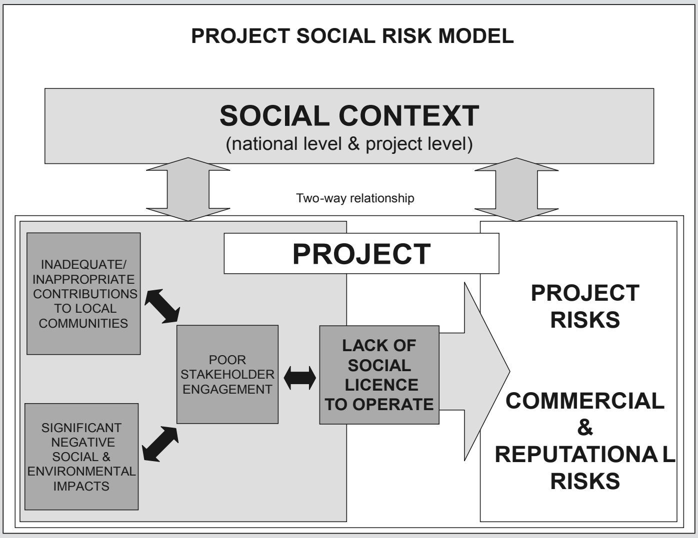
[11] Extracted with modifications from Bueno (2008), who examined social risks from the perspective of risks posed to aquaculture from society.

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.

5. Implementation of risk analysis in aquaculture

The effective implementation of risk analysis methods in the aquaculture sector is contingent upon actions by government at the national policy level, by the private sector at the farm operational level and by international collaboration to build capacity for its wider application.

5.1 NATIONAL POLICY LEVEL

Actions required at the national policy level include:

- *Adoption of risk analysis in national policy* – The case for adoption of the risk analysis approach in aquaculture can be strengthened by including the method in national policies for aquaculture development. In doing so, the approach applied to aquaculture should be consistent with policies for other sectors and should be applied to the aquaculture industry in a balanced manner, *vis-a-vis* other natural resources activities and environmental policies and legislation.
- *Identification of a responsible agency* – In most national systems, the aquaculture industry is not represented by a single champion to promote multisectoral coordination of aquaculture's challenges into overall national development policy. Indeed, aquaculture is frequently managed under a variety of environmental, resource allocation and economic systems, some with primary relationships in the fisheries sector. The relationship between aquaculture and wild capture fisheries may provide some benefits, such as in development of international agreements; however, the benefits can be outweighed by the negatives. In many countries, the economic importance of the aquaculture sector is such that improved and higher profile institutional arrangements are necessary for its management. Aquaculture stakeholders desire a single and clear point of contact with government, and centralized communication benefits the industry (e.g. via reduced transactional costs and increased transparency and information exchange). This may, however, not be feasible in many countries under present institutional arrangements. Although development of a strong national strategy that provides risk-based decision-making and which also meets the needs for regional harmonization of aquaculture regulation will ideally require a single responsible agency responsible for coordinating all aspects of aquaculture policy, one should not be discouraged by not having such an arrangement to implement risk analysis and establish national strategies. Efforts must be made to streamline institutional arrangements, reduce transaction costs to farmers and harmonize administrative procedures within national policy and legal frameworks.

- *Formation of stakeholder groupings* – Identification and formalization of regional, national and subnational stakeholder groupings would aid the consultation and risk management process. The aquaculture industry is comprised of many disparate subsectors with differing operations resulting in different hazards. Yet these subsectors are often the least coordinated due to significant communication and competitive constraints. The establishment of "peak" bodies, such as democratically organized farmer associations, could provide a better basis for coordinated engagement at the national policy level and for better stakeholder communication. Harmonization or even joint development within similar biogeographic regions could also provide an improved investment climate and a mechanism for increased harmonization through development of industry-based voluntary guidelines, Codes of Practice and best management practices (BMPs). Risk analysis processes can be used to develop such guidelines and management practices.
- *Information acquisition and management* – At the national level, access to the information necessary to undertake comprehensive risk planning for the aquaculture sector (or even for other sectors) is problematic. Information may be gathered under national or international statutory obligations, but due to the multi-agency management of aquaculture, it is rarely available. Harmonization of information needs at the national and regional levels could greatly enhance information acquisition and management. This is likely to require regional agreements with clearly specified use agreements in place, such as through regional aquatic animal disease reporting.
- *Capacity building* – Many nations face significant capacity issues (both in terms of number of people and skill availability) at the national policy development and regulatory implementation levels. Conducting a risk analysis, while not a difficult skill to acquire, can be relegated to a lesser status unless it has a clear relationship with outcomes. Capacity-building needs at the national and sectoral levels must be assessed relative to risk analysis skills across the seven risk categories. FAO and regional bodies and programmes (e.g. the Network of Aquaculture Centres in Asia and the Pacific [NACA], the Southeast Asian Fisheries Development Center [SEAFDEC]), the Asia Pacific Economic Cooperation [APEC], the Association of Southeast Asian Nations [ASEAN] and South-South Cooperation arrangements provide significant opportunities for training and capacity building. The multidisciplinary knowledge base, access to information and on-going risk management skills should be identified in-house, and cross-linkages made with like-minded nations or regional partnerships to facilitate both capacity and capability enhancement. In support of this process, there should be ongoing efforts to share experiences and risk analysis tools and to develop simple manuals. There are presently limited experiences and case studies associated with some applications, such as complex ecological risk analyses and genetic risk analyses as applied to aquaculture. Case studies and sharing of experiences are needed. The understanding of some key issues (e.g. risks

associated with aquaculture and ecosystem functions, use of trash fish) is still limited, and research is required to develop understanding and practical tools. The need to develop and demonstrate cost-effective systems for small aquaculture operations is also apparent.

5.1.2 Farm operational level

Actions required at the farm operational level include:

- *Initial business planning* – The most fundamental and effective approach to risk management at the farm level is to integrate risk analysis into business planning when first establishing up an aquaculture farm. The proposed development plan should generally require analysis of the environmental impacts and will provide the opportunity to assess a number of risk categories at the outset. This will in turn give information on the implications of siting (e.g. environmental impacts), including the influence of prevailing weather and should include pathogen and pest information from the region. A business plan should incorporate analysis of possible financial risks and social risks associated with staffing strategies (e.g. social impacts) and the economic performance of the farm. In order to address the importance of application of risk analysis at the farm level, particularly during the planning stage, appropriate simple planning tools are required. Such tools are currently scarce; it is important that their development clearly addresses the requirements of small-scale farmers.
- *Ongoing management planning* – Once a farm is operational, the business plan should be updated to incorporate up-to-date risk analyses as new challenges emerge or the farm changes in terms of business strategy (e.g. new species and sites) or operation (i.e. staffing and resource management). For larger farms, this should be integrated into an annual risk audit for ongoing insurance purposes (see below). Any changes to farm operations, including those due to significant regulatory shifts, should trigger a reassessment of the risks. It is also important to address the issue within the context of small-scale farmers and farming systems. At the small-scale level, annual audits may not be feasible; however, organizing farmers into societies or farm/farmer clusters may assist in meeting such requirements. Organizing farmers into clusters for better management of the sector must be given due consideration during the planning process.
- *Insurance* – Insurance can be seen as a way of identifying and managing risk (see Secretan, 2008). It has traditionally been limited to larger farming operations with a formal, more stable production and management structure. However with the development of farming clusters adhering to common best practice guidelines and sharing common resources (e.g. feeds, markets, etc.), it may be possible to extend insurance coverage to small-scale operations within the cluster. For small-scale farmers, one necessary step is the establishment of mutual insurance groups that understand aquaculture and are able to spread risk appropriately in order to make insurance coverage feasible (see Box 7).

BOX 7

Case study: example of the application of risk analysis to small-scale rural aquaculture in Indian shrimp farming

This case study, summarized from Umesh *et al.* (2008), provides an example of how risk analysis can be informally applied to assist the development of sustainable small-scale rural aquaculture. The project, which was implemented by NACA in association with the Marine Products Export Development Authority (MPEDA) of India, was formulated to develop strategies for reducing the risk of shrimp disease outbreaks and improve farm productivity through formation of "aquaclubs" (cluster, farmer self-help groups) to tackle shrimp disease problems more effectively. Although the initial work was not formally planned to follow a risk analysis approach, the experiences provide valuable lessons in the application of risk analysis in small-scale aquaculture.

The project's demonstration programmes successfully organized small-scale farmers into self-help groups for adoption of best management practices (BMPs). The demonstration of risk management practices in cluster farms gave promising results, with improvements in both profits and productivity. In farms adopting better shrimp health management recommendations, returns shifted from a loss in 80 percent of the ponds to a profit in 80 percent of the ponds, a good indication of the viability of the management measures resulting from the study.

Hazard identification and risk assessment

The project began with a longitudinal epidemiological study to identify hazards (disease: horizontal and vertical transmission of diseases in selected shrimp farming areas, including investigation of hatcheries and broodstock, food safety, social, environmental and financial aspects) and assess risks of key hazards in small-scale shrimp farms during 2000–2001. The epidemiological study, which covered a total of 385 ponds in two districts of Andhra Pradesh, identified the farm-level hazards as (a) shrimp disease outbreaks and (b) low pond productivity, for further analysis. The risk associated with these hazards was then analysed using an epidemiological approach, and a range of risk factors were identified (e.g. presence of whitespot syndrome virus (WSSV) in shrimp seed, shrimp pond depth, soil conditions, etc.) that were significantly associated with these outcomes. Using epidemiological analysis, these "risk factors" provided an understanding of white spot disease (WSD) causation and possible risk management options for reducing the likelihood of disease outbreaks and low pond productivity.

In aquaculture systems, a risk factor is a crop-related factor that simply increases or decreases the probability of occurrence of an adverse event happening during a specified time period. For example, WSD is an adverse event during the shrimp-cropping period. If a high prevalence of WSSV in seed batches stocked in ponds increases the probability of occurrence of WSD, then the high prevalence of WSSV in seed batches is called a risk factor to WSD. Epidemiology investigates the statistical and biological significance of the relationship between the adverse event and the hypothesized risk factor to determine whether the hypothesized risk factor is a risk factor or not. The risk factor study of the project considered shrimp disease outbreak and poor production as adverse crop events for the epidemiological analyses.

In total, the study covered 365 ponds in the state of Andhra Pradesh. The ponds were selected randomly. WSSV has been established as the "necessary cause" of WSD. However, presence of the necessary cause alone will not lead to a WSD outbreak in a pond. In a farm situation, a number of "component causes" (risk factors) along with the "necessary cause"

BOX 7 (cont.)

might become “sufficient cause” to produce WSD outbreaks. The study clearly showed that WSD is not caused by any one factor. Rather a number of risk factors influence the occurrence of WSD in the farm. These risk factors occur throughout the shrimp cropping cycle and in general terms, fall into the following categories during the different stages of the crop cycle: season of stocking; pond preparation; pond filling and water preparation; seed quality and screening; water management; pond bottom management; feed management; and disease treatments.

It was concluded that:

- A WSD outbreak is the end result of a series of actions or changes from healthy shrimp through to disease outbreak.
- At each stage of the cropping cycle, a number of factors influence the development of the disease in individual animals and also in the population of shrimp in each pond.
- WSSV can enter the shrimp and pond through different routes, including shrimp seed, water, carrier animals and transfer of infected animals and farm equipment from one farm to another.
- Adverse environmental factors combined with a high prevalence of infected shrimp among the pond population are necessary for a mass disease outbreak to occur.

Management factors can be used to control environmental factors and reduce risks of WSD occurring in the pond. To be successful in controlling shrimp disease, one has to manage all potential risks at different stages of the cropping cycle.

The results from the shrimp disease risk factor study clearly showed a number of significant factors that influence shrimp disease outbreaks and shrimp yields at the pond level, many of which can be managed at the farm level. The risk factor study clearly demonstrated that WSD is not caused by any one factor but by a number of factors that interact and influence the occurrence of the disease. Thus, an integrated management and extension approach is necessary to deal with the key factors that contribute to disease occurrence.

The findings provided a strong foundation for reducing shrimp disease losses to farmers, improving farm-level capacities and skills in shrimp health management, minimizing the risks of spread of shrimp diseases to other areas and improving shrimp farm productivity and profitability.

Risk management

The risk management objective was to develop practical measures for containing/preventing shrimp disease outbreaks that should include identification of shrimp disease risk factors, diagnosis of problems and management strategies to control disease in farms. The results of the epidemiological study provided the basis for the project team to work closely with farmers and scientists to identify practical farm-level risk management interventions. Eventually two key areas were identified:

- BMPs that are practical farm-level interventions to address the key “risk factors”. These were subsequently expanded to include all relevant shrimp disease risk factors, plus food safety and environmental risks.
- Farmer organization/self-help groups/clusters to address social and financial risks associated with farming and allow effective dissemination of the BMPs among group members.

The BMPs used were good pond preparation, good quality seed selection, water quality management, feed management, health monitoring, pond bottom monitoring, disease

BOX 7 (cont.)

management, emergency harvest, harvest and post-harvest, food safety and environmental awareness. The BMPs were disseminated through communication channels involving farmer meetings, regular pond visits, training of extension workers and publication of ten brochures on steps of BMP adoption and booklets on shrimp health management and extension.

The BMPs were implemented through farmer groups and clusters, a cluster being a group of interdependent shrimp ponds situated in a specified geographical locality and typically being comprised of the farmers whose ponds are dependent on the same water source. The cluster concept makes it practical to communicate risks and risk management to farmers more effectively to reduce risks and maximize returns.

Risk communication

Risk communication involved conducting training and demonstration of appropriate disease control measures, which especially included demonstration of efficient farm management practices for containing diseases in selected farms through cooperation and self-help among shrimp farmers in affected areas.

A village demonstration programme for effective communication of risks, promoting adoption of BMPs and capacity building of farmers was started in Mogalthur Village of Andhra Pradesh in 2002 and has been very successful in forming a participatory movement of farmers across the country. The demonstration programmes were successful in organizing small-scale farmers into self-help groups for adoption of BMPs. The success of this programme generated considerable enthusiasm among the aquaculture farming community, and there are now requests for conducting such programmes in the different regions of India. As a result, aquaclubs/aquaculture societies have been established in the maritime states for community management with a participatory approach. In order to continue the work initiated by the MPEDA-NACA project and to provide the much needed thrust through institutional and policy changes to the extension work in coastal aquaculture development, MPEDA has established a separate agency, the National Centre for Sustainable Aquaculture (NaCSA), with the approval of the Government of India.

6. Future challenges

In 2007, the global aquaculture production reached 65.1 million tonnes, worth US$95 billion and accounting for nearly half (45 percent of world seafood production. It has experienced average annual growth rates of 8.8 percent per year since 1970 (FAO, 2007a, 2007b) and it exceeded wild capture fisheries in Asia in 2002 (FAO, 2008). Aquaculture as an industry now faces significant challenges in its growth and development over the next several decades. In order to meet the growing demand for food products and aquatic-based protein, aquaculture expansion is a real imperative for many economies. The use of risk analysis for decision-making can enhance the ability of decision-makers in the aquaculture sector to identify risks and strategies to meet challenges, particularly at the level of national policy development.

In the short- to medium-term, political governance and institutional capacity present significant challenges to achieving consistency in management of aquaculture across national and regional boundaries. In the longer term, three challenges present themselves as having the propensity to significantly impact on aquaculture sustainability.

Firstly, globalization and trade are increasingly part of the macro-economy. Aquaculture development has largely benefitted from globalization and the ability to create new trading markets for high-quality, highly desirable products. Globalization has also facilitated exchange of technologies, experiences and services and further facilitated development of aquaculture.

Secondly, in both the medium and long term, limitations in natural resources will increasingly challenge human populations and economic growth. Many aquaculture activities compete for natural resources, such as water and land, that are needed by other sectors, and aquaculture will have to adapt and become a more efficient user of increasingly limited resources.

Thirdly, climate change is likely to have significant impacts on aquaculture operations, influencing risk patterns both from and to aquaculture.

In many instances, the risk analysis methods outlined in this manual can assist governments and the private sector in addressing the major challenges the industry faces in trying to realize its full potential as a contributor to world food supplies and national social and economic wellbeing, including poverty alleviation and employment generation in rural areas. In applying risk analysis in aquaculture, the following also need to be considered:

- *Improving governance and planning* – Weak governance at the local or national levels can increase operational risks through poor sectoral planning and integration, as well as fragmented social and community management structures. A lack of harmonization across national boundaries can lead to significant shifts in aquaculture operations to areas of decreased regulatory management or reduced production costs. Poor sectoral planning can also increase the adverse impacts of aquaculture operations to the environment, or create other social and financial risks if land or coastal allocations are in areas unsuitable for the proposed operation or if the capacities, policies or institutions are not in place for effective sectoral governance.

- *Improving institutional coordination* – At the national level, aquaculture as a sector has rarely been incorporated into the issues of wider economic development. National policies dealing with aquaculture are generally restricted to impacts on human and animal health, fisheries regulation, quarantine and sometimes resource access. Aquaculture is generally overshadowed by capture fisheries and its regulation is commonly subsumed within fisheries legislation. In many nations, the aquaculture industry faces multiple regulatory and management agencies with involvement in risk management to capture its potential environmental, economic and social impacts. As a result, the transactional costs for development of aquaculture are often significant. This perceived overregulation is balanced with significant underregulation in some aspects and in some regions. In order to achieve an appropriate balance, national governments are encouraged to review the interagency responsibilities towards aquaculture development and management with the intent to ensure appropriate lead and cooperating agencies for key regulatory functions.
- *Addressing issues associated with globalization and free trade* – The increasing competition in the global market place creates stronger incentives for both binding and voluntary harmonization of standards. There have been several international trade restrictions based on non-compliance with certain trading standards, particularly those related to fish health and food safety issues. In turn, these restrictions create additional burdens on competent authorities and regulatory pressures in some economies, resulting in an unbalanced market place. This results in increased financial and social risks, and as profit margins are reduced, can result in decreased safety margins in the production line and overcrowding of stocks, which may increase pathogen, food safety and public health and genetic risks through loss of stock and environmental impacts.
- *Improving the use of limited natural resources* – Many of the resources on which aquaculture depends (e.g. water, land, fishmeals and oils) are finite. As aquaculture inevitably expands, competition for these resources – from both within the sector and outside – will increase. This will inevitably increase the level of environmental risk and make risk analysis, both at the national and at the farm level, increasingly necessary and yet more complex. The implications of resource limitations to aquaculture are increased production costs that automatically lead to increased financial and social risks. Aquaculture operations will of necessity seek to make more efficient use of resources, such as reducing the use of scarce resources, increasing production per unit resource or recycling, all of which may have financial, environmental, social and other implications

- *Dealing with the social and biological impacts of climate change* – Climate change is having a steady but profound effect on the riparian and coastal systems in which many aquaculture operations occur. Aquaculture farms in coastal areas may be vulnerable to sea level rise, increased incidence of storm surges and land-based run-off, including extreme weather events that result in flooding and drought, as well as environmental perturbations such as a rise in sea temperature. Climate change remains highly unpredictable; however, the incidence of storm events resulting in loss of stocks and infrastructure is likely to increase, resulting in higher financial, genetic and social risks. Increased temperatures may lead to greater likelihood of pathogen, food safety and public health and ecological risks. Better analysis of risk and climate change in the aquaculture sector would provide a basis for advising industry and governments on appropriate management strategies.

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Aquaculture is a rapidly expanding sector of the global economy with an average growth rate of 8.8 percent per year since 1970. Development of the industry under various national and regional jurisdictions has resulted in a diversity of regulatory frameworks. This manual has been produced in response to a request from FAO Members for guidance on the application of risk analysis with respect to aquaculture production. Aimed at decision-makers and senior managers involved in the sector in FAO Member States, this manual provides an overview of the considerations for risk analysis in decision-making for all types of aquaculture, including the impacts of aquaculture operations on environmental, socio-political, economic and cultural values as well as the impacts to aquaculture from outside influences. This manual is expected to promote wider understanding and acceptance of the applications and benefits of risk analysis in aquaculture.

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