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

[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.