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.

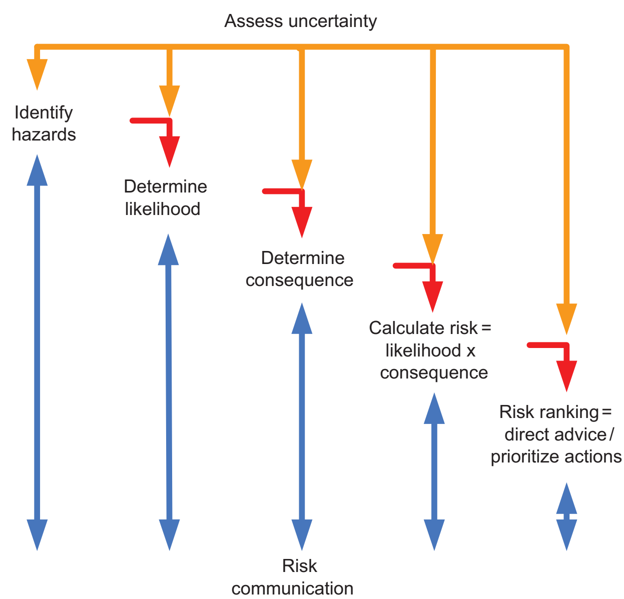
1.7 GENERAL FRAMEWORK OF RISK ANALYSIS

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.