Manual on Risk Analysis for
the Safe Movement of Aquatic Animals (FWG/01/2002)

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Thailand

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Preface

The Asia-Pacific Economic Cooperation (APEC) and the Network of Aquaculture Centres in Asia-Pacific (NACA), in partnership with the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (OIE, the Office International des pizooties), and together with our respective member economies/governments, are pleased to present this Manual on Risk Analysis for the Safe Movement of Aquatic Animals. A major outcome of APEC FWG 01/2002 project "Capacity and Awareness Building on Import Risk Analysis (IRA) for Aquatic Animals", this manual provides a simplified overview of the risk analysis process to assist responsible individuals to formulate national policies and develop approaches to conducting risk analyses for pathogens.

Risk analysis for aquatic animal pathogens has become a major component of global strategies aimed at providing appropriate health management protocols and biosecurity measures that protect national biological, social and economic resources and support economically and environmentally sustainable aquaculture development while, at the same time, facilitating trade. This manual addresses an important policy issue – the responsible conduct and regulation of international and domestic trade in live aquatic animals and their products.

Movement of live aquatic animals and their products is necessary for aquaculture development. However, it is now widely recognized that the introduction and spread of transboundary pathogens due to the imprudent movement of live aquatic animals have resulted in serious adverse consequences to national socio-economic and environmental well being. The countries in the Asia-Pacific, a region highly dependent upon aquaculture production and capture fisheries for food, income and employment, have to various degrees suffered the consequences of exotic aquatic animal disease. APEC and NACA and our partners have therefore initiated this project in order to improve aquatic animal health policies and practices that will contribute to reducing the risks of disease incursions and promote the development of better strategies to prevent such incursions, for higher productivity and smoother trade.

APEC and NACA extend special thanks to the representatives of the economies/governments, agencies, and organizations who took part in this important endeavor, as well as to all individuals who generously devoted their time and contributed information and expertise to the final production of this document.

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Executive Summary

This *Manual on Risk Analysis for the Safe Movement of Aquatic Animals* was prepared as an output of the Asia-Pacific Economic Cooperation (APEC) Fisheries Working Group (FWG) project APEC FWG 01/2002 "Capacity and Awareness Building on Import Risk Analysis (IRA) for Aquatic Animals." The manual specifically addresses the risks associated with spread of aquatic animal pathogens with movement of live aquatic animals and their products.

Risk analysis for pathogens of aquatic animals is a relatively new field, and only a few countries have much experience in this area. The purpose of this manual is to provide a simplified overview of the risk analysis process to assist responsible individuals in developing countries to begin formulating national policies and approaches to conducting risk analyses. This manual should thus be useful to Competent Authorities, senior policy and management staff, and members of the private sector involved in regulating or conducting international and domestic trade in live aquatic animals and their products.

The initial sections of the manual provide information and guidance on how risk analysis facilitates trade while protecting national biological, social and economic resources; a brief review of pertinent international agreements and responsibilities; and a discussion of the issues surrounding the development of national policy and legislation. Following sections then provide a general overview of the process and the mechanisms needed (expertise, procedures, scoping an analysis, etc.) to begin a risk analysis. The individual components are then discussed in detail. These include risk communication, hazard identification, risk assessment and risk management. The remaining sections address some other important considerations, such as the use of "in-house" vs more extensive risk analysis, the importance of good scientific review, qualitative and quantitative approaches to risk analysis, the precautionary approach, developing countries and risk analysis, and the role of politics and science in the risk analysis process. A list of the Literature Cited is given, and finally, two annexes provide a list of Internet resources related to risk analysis for aquatic animals (Annex I) and a list of national agencies with responsibilities for implementing risk analysis and other related aquatic animal health activities within participating Asia-Pacific Economic Cooperation (APEC) Economies and Network of Aquaculture Centres in Asia-Pacific (NACA) and FAO Member Countries (Annex II). Throughout the manual, hypothetical examples of various risk analysis scenarios are presented, with the primary goal of encouraging readers to consider how these scenarios might apply to their particular country situations.

1 INTRODUCTION

1.1 Preparation of this Manual

This *Manual on Risk Analysis for the Safe Movement of Aquatic Animals* was prepared as an output of the Asia-Pacific Economic Cooperation (APEC) Fisheries Working Group (FWG) project APEC FWG 01/2002 "Capacity and Awareness Building on Import Risk Analysis (IRA) for Aquatic Animals." The proposing APEC Member was Thailand, with the co-sponsoring APEC Economies being Australia; Hong Kong, China; Mexico; People' s Republic of China; the Philippines; and the United States of America. The Network of Aquaculture Centres in Asia-Pacific (NACA), Bangkok, administered the project.

Under the project, two training/workshops were successfully conducted, one in Bangkok, Thailand (1-6 April 2002) and the second in Mazatlan, Mexico (12-17 August 2002). A total of 130 participants comprised of regulatory authorities, administrators and aquatic animal health specialists responsible for trade of live aquatic animals attended.

An outline for this manual was developed during the Working Group Sessions held as part of the first workshop in Bangkok, Thailand and after further development, the outline was presented for comment to a second Working Group at the second workshop in Mazatlan, Mexico. A draft manual was then prepared and circulated for comment, first to members of the two Working Groups, and following further revision, to several international experts, leading to production of the final document.

This manual supports the process of risk analysis for aquatic animal pathogens, but does not consider ecological issues that might be associated with the movement of live aquatic animals to new habitats.

1.2 Target Audience and Scope

Risk Analysis (RA) for movement of **aquatic animals** is a relatively new field, and only a few countries have much experience in this area (e.g., among APEC Economies, Australia, Canada, New Zealand and the United States). As there are a number of recent detailed publications (technical proceedings, administrative manuals, etc.) dealing with risk analysis (see AFFA 2001, Rodgers 2001, Murray 2002, OIE 2003a, Biosecurity Australia 2003, Arthur and Bondad-Reantaso 2004), the purpose of this manual is not to provide in-depth technical guidance to the risk analysis process. Rather, its primary goal is to provide a simplified overview of the risk analysis process to assist responsible individuals in developing countries to begin formulating national policies and approaches to conducting risk analyses. This manual should thus be useful to Competent Authorities, senior policy and management staff, and members of the private sector involved in regulating or conducting international and domestic trade in live aquatic animals and **aquatic animal products**.

The members of the Workshop Working Groups strongly believed that proposed **introductions** and **transfers** of live aquatic animals and the movement of **genetically modified aquatic organisms** (GMOs) deserve special consideration and rigorous evaluation by importing countries, because of the potential that ill-conceived introductions and transfers of such aquatic organisms have to cause extensive and often irreversible damage to aquaculture, capture fisheries, natural biodiversity, and the economic and social well-being of individuals and communities dependent upon these resources.

Section 1 provides information on the preparation of this manual, and its target audience and scope, and gives a brief introduction to risk analysis[3]. A glossary[4] of key terms is given in Section 2, while Section 3 provides a list of abbreviations and acronyms. Information and guidance on how risk analysis facilitates trade while protecting national biological, social and economic resources; pertinent international agreements and responsibilities; and issues surrounding the development of national policy and legislation are provided in Section 4. An overview of the risk analysis process is given in Section 5, while setting up the necessary mechanisms (expertise, procedures, scoping an analysis, etc.) to begin a risk analysis is covered in Section 6. The individual components of the risk analysis are discussed in Section 7 (Risk Communication), Section 8 (Hazard Identification), Section 9 (Risk Assessment) and Section 10 (Risk Management). Some other important considerations are discussed in Section 11, including the use of in-house versus more extensive risk analysis, the importance of good scientific review, qualitative and quantitative approaches to risk analysis, the precautionary approach, developing countries and risk analysis, and the role of politics and science in the risk analysis process. The Literature Cited is provided in Section 12. Finally, two annexes provide a list of Internet resources supporting risk analysis for aquatic animals (Annex I) and a list of national agencies responsible for implementing risk analysis and other related aquatic animal health services for those countries/economies participating in APEC FWG 01/ 2002 "Capacity Building on Import Risk Analysis for Aquatic Animals" Training/Workshops held in Bangkok, Thailand in April 2002 and Mazatlan, Mexico in August 2002 (Annex II).

In preparing this manual, it was decided, whenever possible, to develop "hypothetical" examples of various risk analysis scenarios. This was done primarily to encourage readers to consider how these hypothetical scenarios might apply to their particular country situations, as well as to avoid any direct or implied criticism of any individual agency' s or country' s past handling of import or export of live aquatic animals or their products.

1.3 What is Risk Analysis?

Risk analysis is a structured process for analyzing the disease risks associated with movements, both across international borders and domestically, of living organisms and their products.

In general terms, **risk** is the potential for the occurrence of unwanted, adverse consequences associated with some action over a specified time period. For trade in live aquatic animals and their products, a formal risk analysis approach provides objective, repeatable and documented methods for identifying, assessing and considering management options for the risks associated with the export-import process.

In simple terms, **risk analysis** seeks to answer the questions:

- What can go wrong? (**Hazard identification**)[5]
- How is it likely to go wrong? (**Risk assessment: Release assessment** and **Exposure assessment**)
- What would be the consequences of its going wrong? (**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 its going wrong? (Risk management**: Option evaluation, Implementation, Monitoring and review**) (MacDiarmid 1997, OIE 2003a, Rodgers 2004).

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[3] The term "risk analysis" as used in this manual generally refers to analysis of risks due to pathogens ("pathogen risk analysis"). It does not encompass other risks associated with species introductions and transfers, such as those resulting from potential ecological or genetic impacts caused by the introduced aquatic animal itself.

[4] The first use of a term defined in the glossary is given in bold type.

[5] The portions of the risk analysis process addressing these questions are given in bold type in parentheses.

The purpose of risk analysis is to provide a structured, internationally agreed-upon means to assess disease risks objectively and transparently so that (i) the risks that serious pathogens and diseases will be transferred between trading partners are minimized, (ii) applied sanitary measures (e.g., restrictions on species and/or sources of origin, health certification requirements, **quarantine**, treatment, etc.) can be justified; and (iii) restrictions to trade are minimized.

One of the reasons that countries with significant international trade in live aquatic animals and their products are adopting risk analysis is due to the establishment of the World Trade Organization (WTO) and the adoption of the *Agreement on Sanitary and Phytosanitary Measures* (the SPS Agreement) (WTO 1994). The SPS Agreement requires WTO members to remove barriers to trade unless there is a risk to human, animal or plant health, and mandates that the process of risk analysis be used to demonstrate the existence of such risks and justify the imposition of sanitary measures.

Risk analysis is an important tool for liberalizing trade while protecting national human, animal and plant health. The **Competent Authorities** of the **importing** and **exporting countries** both have legal responsibilities for preventing the spread of internationally important disease agents. The importance of risk analysis to importing countries is obvious – it provides a transparent, scientifically based, defensible methodology upon which to base decisions on proposed importations of live aquatic animals and their products. However, it can be equally important to exporting countries, by assisting them to meet importing country standards and to assure trading partners of the safety and quality of their products. Importing countries should use risk analysis procedures when assessing the potential risks posed by the importation of aquatic animal commodities, and when importing species for use in aquaculture or capture fisheries enhancement projects. It is therefore essential that countries cooperate and work together on mutually beneficial solutions. Countries may also want to use risk analysis when considering the domestic movement of aquatic animals, particularly in cases where movements may result in the spread of pathogens into new drainage basins or coastal areas. Indeed, the concept of "zoning" as developed by the World Organisation for Animal Health (OIE or Office International des pizooties) *Aquatic Animal Health Code* (OIE 2003a) necessitates a risk analysis approach, and is equally applicable to within country trade as it is to international commerce (see Hill 2004a).

The risk analysis process need not be overly complicated. It is highly flexible and can be readily adapted to developing country situations. Countries 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. It should also be kept in mind that risk analyses are not universally required. In many situations involving requests to import live aquatic animals or their products, it will be possible to make a decision without resorting to a formal or full risk analysis. Nonetheless, the rationale and supporting scientific information behind any decisions should be documented.

2 GLOSSARY[1]

Appropriate level of protection (also referred to as "Acceptable level of risk"): The level of protection deemed appropriate by the country establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. (modified from WTO 1994)

Acceptable risk: Risk level judged by an importing country to be compatible with the protection of public health, aquatic animal health and terrestrial animal health within the country. (modified from OIE 2003a)

Aquatic animal products: Products from aquatic animals (fish, molluscs, crustaceans) whether they are intended for farming (e.g., eggs, gametes, larvae, etc.), for human consumption, for use in animal feeding or for pharmaceutical, biological, or industrial uses. (from OIE 2003a)

Aquatic animals: Live fish (including eggs and gametes), molluscs and crustaceans from aquaculture establishments or aquatic animals removed from the wild, for farming purposes or for release into the aquatic environment. (from OIE 2003a)

Aquatic Code: The OIE *Aquatic Animal Health Code*. (from OIE 2003a)

Aquatic Manual: The OIE *Manual of Diagnostic Tests for Aquatic Animals*. (from OIE 2003a)

Commodity: Aquatic animals, aquatic animal products, aquatic animal genetic material, feedstuffs, biological products and pathological material. (from OIE 2003a)

Competent Authority: The National Veterinary Services, or other Authority of a country, having the responsibility and competence for ensuring or supervising the implementation of aquatic animal health measures recommended in the Aquatic Code. (modified from OIE 2003a)

Consequence assessment: The process of identifying the potential biological, environmental and economic consequences. (modified from OIE 2003a)

Diseases listed by the OIE: Diseases that fulfill the criteria outlined in Chapter 1.1.2 of the Aquatic Code. (modified from OIE 2003a)

Exporting country: A country from which aquatic animals or aquatic animal products, biological products or pathological material are sent to a destination in another country. (from OIE 2003a)

Exposure assessment: The process of describing the biological pathway(s) necessary for exposure of humans and aquatic and terrestrial animals in the importing country to the hazards and estimating the likelihood of the exposure(s) occurring, and of the spread or establishment of the hazard. (modified from OIE 2003a)

Genetically modified organisms (GMO): An organism in which the genetic material has been altered anthropogenically by means of recombinant DNA technologies. (from ICES 2003)

Hazard: Any pathogen that could produce adverse consequences on the importation of a commodity. (from OIE 2003a)

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[1] Where possible, terms and definitions follow those used in the *Aquatic Animal Health Code*, 6th edition (OIE 2003a).

Hazard identification: The process of identifying the pathogenic agents that could potentially be introduced in the commodity considered for importation. (from OIE 2003a)

Implementation: The process of following through with the risk management decision and ensuring that the risk management measures are in place. (from OIE 2003a)

Importing country: A country that is the final destination to which aquatic animals, aquatic animal products, biological products or pathological material are sent. (from OIE 2003a)

International aquatic animal health certificate: A certificate issued by a member of the personnel of the Competent Authority of the exporting country, certifying the state of health of the aquatic animals, and a declaration that the aquatic animals originate from a source subjected to official health surveillance according to the procedures described in the Aquatic Manual. (modified from OIE 2003a)

Introduction: The intentional or accidental transportation of an aquatic animal into aquatic habitats outside its native range by a human-mediated vector. (modified from ICES 2003)

Mitigated risk estimate (also referred to as "Restricted risk estimate"): The overall measure of risk associated with a hazard (pathogen) taking into account the estimated reduction in risk resulting from potential risk management measures.

Monitoring and review: The ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended. (from OIE 2003a)

National pathogen list: The list of pathogens that are of national importance and that are the subject of control with respect to their entry, establishment and spread within the country and/or the region. The listed pathogens should satisfy at least one of the following criteria: (a) it is the causative agent of a disease listed by the OIE; (b) it is of national and genuine concern to the country; (c) it is the causative agent of a disease whose occurrence would have significant socio-economic impacts; (d) it is either exotic or occurs in limited parts of the country; (e) it can be clearly identified; and (f) it is the causative agent of a disease which is reportable, for example, to the NACA/OIE under a regional reporting scheme.[2]

Option evaluation: The process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the risk associated with an importation in line with an importing country's appropriate level of protection (ALOP). (modified from OIE 2003a)

Precautionary approach: A set of agreed cost-effective measures and actions, including courses of action, that ensures prudent foresight and reduces or avoids risk to resources, the environment, and to people, to the extent possible, taking explicitly into account existing uncertainties and the consequences of being wrong. (from Garcia 1996)

Qualitative risk assessment: An assessment where the conclusions on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as high, medium, low or negligible. (from OIE 2003a)

Quarantine: Maintaining a group of aquatic animals in isolation with no direct or indirect contact with other aquatic animals, in order to undergo observation for a specified length of time and, if appropriate, testing and treatment, including proper treatment of effluent waters. (from OIE 2003a)

Quantitative risk assessment: An assessment where the outputs of the risk assessment are expressed numerically, as probabilities or distributions of probabilities. (from OIE 2003a)

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[2] Note that a national pathogen list is not an inventory of the pathogens occurring in a country.

Release assessment: The process of describing the biological pathway(s) necessary for an importation activity to ‘ release’ (that is, introduce) a hazard into a particular environment, and estimating the likelihood of that complete process occurring. (modified from OIE 2003a)

Risk: The probability of an adverse event of aquatic animal health, public health or economic importance, such as a disease outbreak, and the magnitude of that event. (from OIE 2003a)

Risk analysis (also termed Import risk analysis): The complete process composed of hazard identification, risk assessment, risk management and risk communication. (from OIE 2003a)

Risk assessment: The processes of identifying and estimating the risks associated with the importation of a commodity and evaluating the consequences of taking those risks. (from OIE 2003a)

Risk communication: The processes of communicating the risk assessment results to the regulators of the import programmes, and to other interested parties, such as industry and the public. (from OIE 2003a)

Risk estimation: The process of integrating the results of the release assessment, exposure assessment, and consequence assessment to produce an overall measure of risks associated with the hazards identified at the outset. (modified from OIE 2003a)

Risk evaluation: The process of comparing the risk estimated in the risk assessment with the importing country’ s appropriate level of protection. (modified from OIE 2003a)

Risk management: The identification, documentation and implementation of the measures that can be applied to reduce risks and their consequences.
(from OIE 2003a)

Stakeholder: Governments, individuals, community or industry groups or organizations, whether within a country or overseas, having an interest in the subject matter and outcome of a risk analysis. (modified from Biosecurity Australia 2003)

Surveillance: A systematic series of investigations of a given population of aquatic animals to detect the occurrence of disease for control purposes, and which may involve testing samples of a population. (from OIE 2003a)

Transfer: The intentional or accidental transport and release of a living aquatic animal within areas of established populations and continuing genetic flow, where it occurs. (modified from ICES 2003)

Transparency: Comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis. (from OIE 2003a)

Unmitigated risk estimate (also referred to as “Unrestricted risk estimate”): The overall measure of risk associated with a hazard (pathogen) before taking into account any reduction in risk resulting from potential risk management measures.

3 LIST OF ABBREVIATIONS AND ACRONYMS

AAHRI	Aquatic Animal Health Research Institute (Bangkok)
AAHSC	Aquatic Animal Health Standards Commission (of the OIE)
ACFS	National Bureau of Agricultural Commodity and Food Standards (Thailand)
AFFA	Agriculture, Fisheries and Forestry of Australia (see also DAFF)
AHID	Animal Health Inspection Department (Vietnam)
ALOP	Appropriate level of protection
AMP	Autoridad Maritima de Panamá
APEC	Asia-Pacific Economic Cooperation
APHIS	Animal and Plant Health Inspection Service (USA)
ASEAN	Association of Southeast Asian Nations
AVA	Agri-Food and Veterinary Authority (Singapore)
BAHA	Belize Agricultural Health Authority
BFAR	Bureau of Fisheries and Aquatic Resources (Philippines)
CBD	Convention on Biological Diversity
CFIA	Canadian Food Inspection Agency
CENDEPESCA	Centro de Desarrollo de la Pesca y Acuicultura (El Salvador)
CITES	Convention on International Trade in Endangered Species
CONAPESCA	Comisión Nacional de Acuacultura y Pesca (Mexico)
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry (formerly AFFA)
DECA	Dirección Ejecutiva de Cuarentena Agropecuaria (Panama)
DFAR	Department of Fisheries and Aquatic Resources (Sri Lanka)
DFO	Department of Fisheries and Oceans (Canada)
DGSAV	Direccion General de Sanidad Animal y Vegetal (El Salvador)
DIGEPESCA	Direccion General de Pesca (Honduras)
DIGERAMA	Direccion General de Recursos Marinos y Costeros (Panama)
DINAAC	Dirección Nacional de Acuicultura (Panama)
DINASA	Dirección Nacional de Salud Animal (Panama)
DOAPH	Department of Animal Production and Health (Sri Lanka)
DoF	Department of Fisheries (Thailand)
EIFAC	European Inland Fisheries Advisory Commission (FAO)
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FRCD	Fisheries Resources Conservation Department (Vietnam)
FWG	Fisheries Working Group (of APEC)
GATT	General Agreement on Tariffs and Trade
GEF	Global Environment Facility
GMOs	Genetically modified organisms
HACCP	Hazard Analysis Critical Control Point
ICES	International Council for the Exploration of the Sea
IMO	International Maritime Organization
INAPESCA	Instituto Nacional de Pesca y Acuicultura (Venezuela)

INP	Instituto Nacional de la Pesca (Mexico)
INPA	Instituto Nacional de Pesca y Acuicultura (Ecuador)
IPA	Instituto de Pesca y Acuacultura (Colombia)
INRENA	Instituto Nacional de Recursos Naturales (Peru)
IRA	Import risk analysis (= risk analysis)
MAGFFOR	Unidad de Sanidad de Acuicola del Departamento de Infeccion y Certificacion HACCP del Ministerio Agropecuario Forestal (Nicaragua)
MALD	Ministry of Agriculture and Livestock Development (Sri Lanka)
MFOR	Ministry of Fisheries and Ocean Resources (Sri Lanka)
MIDA	Ministerio de Desarrollo Agropecuario (Panama)
MINSA	Ministerio de Salud (Panama)
MoFL	Ministry of Fisheries and Livestock (Bangladesh)
MRC	Mekong River Commission
NACA	Network of Aquaculture Centres in Asia-Pacific
NOAA	National Oceanic and Atmospheric Administration (USA)
OIE	Office International des Épizooties (the World Organisation for Animal Health)
PCR	Polymerase Chain Reaction
RA	Risk analysis (= Import risk analysis)
SAARC	South Asian Association for Regional Cooperation
SAGARPA	Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (Mexico)
SEAMEO	Southeast Asia Ministers of Education Organization
SEMARNAT	Secretaría de Medio Ambiente y Recursos Naturales (Mexico)
SENASA	Servicio Nacional de Sanidad Agropecuaria (Honduras)
SENASA	Servicio Nacional de Sanidad Agropecuaria (Peru)
SENASICA	Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (Honduras)
SPC	Secretariat of the Pacific Community
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
TGBCIS	Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Aquatic Animals and the Beijing Consensus and Implementation Strategy
UNEP	United Nations Environment Programme
UNR	Unidad de Normas y Regulaciones (Guatemala)
USDA	United States Department of Agriculture
WTO	World Trade Organization

4 RISK ANALYSIS - FACILITATING FREE TRADE WHILE PROTECTING BIOLOGICAL, SOCIAL AND ECONOMIC RESOURCES

4.1 Protecting National Biological Resources

Risk analysis is an essential component of a national aquatic animal health strategy and provides a science-based, defensible means to estimate the risks posed to national aquatic biodiversity, aquaculture and capture fisheries due to pathogen introduction and, where justified, to justify risk mitigation measures, including import prohibitions or other restrictions on movements. Risk analysis should be used by national authorities to determine domestic movements also, not just international trade.

A formal approach to risk analysis for diseases of aquatic animals should form part of a country' s national policy for dealing with requests for the introduction or transfer of aquatic species (and their products) for use in aquaculture or stocking into the wild, as well as animals not intended for release (e.g., most ornamentals) but whose establishment could cause significant impacts (e.g., requests to import aquatic species that are known to have caused harmful ecological, social or economic impacts elsewhere). Similarly, a formal approach to risk analysis should also be applied to evaluate disease risks posed by a country' s international and domestic trade in aquatic animal products. The process is methodical, iterative, consistent, transparent and science-based.

Risk analysis for responsible movement of live aquatic animals is thus part of a broader science-based approach to assess the likely outcomes of proposed introductions and transfers of aquatic animals. Such an approach addresses concerns about potential negative effects due to:

- ecological impacts, such as competition for food, space or spawning areas, habitat alteration and predation on indigenous organisms;
- genetic impacts that will reduce the survival of local populations; and
- disease impacts, due to the movement of serious pathogens and other accompanying organisms ("fellow travelers") that could affect wild and cultured aquatic organisms in receiving waters and their habitats.

However, as previously indicated, the term "risk analysis" as used in this manual refers to analysis of risks due to aquatic animal pathogens. It does not encompass other risks associated with species introductions and transfers, such as those resulting from potential ecological or genetic impacts caused by the introduced aquatic animal itself.

Over the past several decades, codes of practice for introductions and transfers of live aquatic organisms have been developed by the International Council for the Exploration of the Sea (ICES) and the European Inland Fisheries Advisory Commission (EIFAC) for marine (including brackish water) and freshwater species, respectively (see Turner 1988, ICES 2003). The intent of the ICES and EIFAC Codes is to reduce the risk of unwanted introductions and the adverse effects that can arise from species movement. The codes provide countries with a recommended framework to evaluate new intentional introductions. They also recommend procedures for species that are part of current commercial practice. An outline of the contents of the ICES *Code of Practice on the Introductions and Transfers of Marine Organisms 2003* is given in Box 1, while the full Code can be accessed via the Internet (see ICES 2003). Addition-

ally, appendices to the ICES Code include useful detailed information on procedures to be used in the preparation of a request to introduce or transfer an aquatic species (a "prospectus"), on the risk assessment process, on quarantine and on monitoring.

A recent concern is the use of **genetically modified organisms** (GMOs) in aquaculture and fisheries enhancement. The most recent version of the ICES Code of Practice includes procedures for evaluating proposals to introduce GMOs and procedures to be followed to minimize the potential impacts of their release (see ICES 2003). GMOs are also specifically addressed in the *Cartagena Protocol on Biosafety* (see Section 4.2).

Box 1. The ICES Code of Practice on the Introductions and Transfers of Marine Organisms 2003 (see ICES 2003) includes recommendations related to:

- a strategy for implementation
- steps to take prior to introducing a new species
- steps to take after deciding to proceed with an introduction
- policies for ongoing introductions or transfers that have been an established part of commercial practice
- steps to take prior to releasing genetically modified organisms (GMOs)

At the national level, a few countries have established a National Code on Introductions and Transfers of Aquatic Organisms. An example of such a code that has been adopted by a developed country is that of Canada (Anon. 2003). Such a national code is very useful, as it provides government (both national and state or provincial) and **stakeholders** with a single document outlining national policy and procedures with regard to introductions and transfers. A national code helps to ensure that all proposed introductions or transfers of aquatic species are evaluated fairly, equitably and consistently by all parties, using established scientific criteria. It also helps to clarify the mandates, responsibilities and working relationships of the **Competent Authority**, the various concerned national and state governmental agencies, the private sector and other stakeholders. The national code should reflect existing national and state legislation and policy, as well as regional and international standards and agreements relating to international and domestic trade in live aquatic organisms. The purpose of a national code includes:

- providing a single comprehensive and consistent national framework for the introduction and transfer of aquatic organisms, ensuring a single, standard set of risk assessment and approval procedures that may be applied across a country;
- providing effective procedures that will help minimize the negative impacts of introductions and transfers on fisheries resources, habitat and existing aquaculture, without unduly impeding governmental and private sector activities that depend on the ability to move aquatic organisms from one location to another;
- ensuring that national risk analysis procedures are consistent with international standards and commitments;
- increasing public and private sector awareness of the risks and benefits of introductions and transfers; and
- stimulating research that will improve national capability to evaluate and decide upon the soundness of proposals to introduce and transfer aquatic organisms (see Anon. 2003).

Within a national strategy and/or national code on introductions and transfers, risk analysis is a science-based procedure that helps governments decide if a proposed introduction or transfer of an aquatic organism or the importation of another type of **commodity** poses a significant disease risk, what the impacts are likely to be, and whether or not they can be managed to an acceptable level. In some countries, national risk analysis frameworks are in place (see for example Perera 2004, Hine 2004), while in other countries, risk analysis is increasingly being recognized. The Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Live Aquatic Animals and the Beijing Consensus and Implementation Strategy (TGBCIS; FAO/NACA 2000) strongly recommends incorporating risk analysis as an important component of a National Strategy for Aquatic Animal Health. The relationship of risk analysis to a country' s national strategy for aquatic animal health, its international commitments and

memberships, and other international codes and protocols is described in Box 2 (see also Box 5).
Box 2. The relationship of risk analysis to a country' s national strategy for aquatic animal health and its international memberships, treaties and other responsibilities.

Box 2. The relationship of risk analysis to a country's national strategy for aquatic animal health and its international memberships, treaties and other responsibilities.

International and Regional Level

International Memberships, Treaties and Obligations
- World Trade Organization
- World Organisation for Animal Health
- United Nations
- Other international memberships, treaties and agreements
- Regional memberships and treaties

Other International Players
- Competent Authorities of Exporting Countries
- Stakeholders in Exporting Countries
- International experts

National Level

National Aquatic Animal Health Strategy
- Risk analysis component
- Competent Authority for Risk Analysis
- Risk Analysis Project Team
- Working Groups
- National experts
- Other components of the national strategy (see Box 5)

Other National and Subnational Players
- Competent Authorities for other areas (terrestrial animals, plants, post-harvest products, human health, etc.)
- National agencies concerned with:
- Policy and legislation
- Aquatic animal health: diagnostics, quarantine, monitoring and surveillance, etc.
- Customs and enforcement
- Other stakeholders (aquaculturists, fishery industry, hobbyists, environmentalists, etc.)

4.2 International Agreements and Responsibilities

States have a responsibility, both to their own citizens and to the larger international community, to ensure that serious pathogens are not spread through their international and domestic trade in live aquatic animals and their products.

With the liberalization of international trade through the General Agreement on Tariffs and Trade (GATT), the establishment of the World Trade Organization (WTO) and its *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement), WTO member countries are now required to use the risk analysis process as a means to justify any restrictions on international trade based on risks to human, animal or plant health (see WTO 1994, Rodgers 2004). Risk analysis has thus become an internationally accepted standard method for assessing whether trade in a particular commodity (e.g., a live aquatic animal or its product) poses a significant risk to human, animal or plant health, and if so, what measures could be adopted to reduce that risk to an acceptable level.

Most countries are also signatories of one or more international agreements that include provisions for the protection of biodiversity from the impacts of ill-considered introductions and transfers of aquatic species. Under the 1992 *Convention on Biological Diversity* under the United Nations Environment Programme (UNEP), signatory nations are committed to developing national strategies, plans or programs for the conservation and sustainable use of biological diversity (CBD 1992). *The Cartagena Protocol on Biosafety*, a supplementary agreement to the CBD adopted in 2000, seeks to protect biodiversity from the potential risk posed by GMOs (see Secretariat of the Convention on Biological Diversity 2000). These and other international agreements require that signatories act responsibly when considering the international movement of aquatic organisms and their products.

Box 3. The OIE in-house procedure for settlement of disputes (from OIE 2003a).

The OIE maintains voluntary in-house mechanisms for assisting Member Countries to resolve differences. The following procedures apply:

- Both parties agree to give the OIE a mandate to assist them in resolving their differences.
- If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.
- Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.
- The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.
- The expert or experts should submit a confidential report to the Director General, who will transmit it to both parties.

Most countries are also members of the World Organisation for Animal Health (OIE, the Office International des pizooties). The OIE is an intergovernmental organization whose activities include the preparation of guidelines and standards for health regulations applicable to international trade in live animals and their products (see Hill 2004b). The OIE has developed guidelines for risk analysis (see OIE 2003a). The OIE *Aquatic Animal Health Code* does not provide a detailed description of how a risk analysis is to be carried out; its purpose is simply to outline the necessary basic steps that should be followed – that is, to provide an appropriate standard. Under the SPS Agreement, the OIE is recognized as the international organization responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live terrestrial and aquatic animals and their products. The OIE also maintains mechanisms whereby disputes between OIE Member Countries can be settled internally, without the lengthy and often costly procedures involved in bringing a dispute before the WTO (see Box 3).

There are also a number of international non-binding agreements related to the responsible transboundary movement of live aquatic animals, among them the FAO Code of Conduct for Responsible Fisheries (CCRF) (see FAO 1995), and the FAO/NACA TGBCIS (see FAO/NACA 2000 and Box 4).

A separate issue that must be addressed is how to prevent accidental introductions and transfers of live aquatic organisms through such mechanisms as transit in the ballast water of ships or on their hulls. On an international level, this difficult problem is being addressed by ICES, the International Maritime Organization (IMO) and others (see, for example, the GEF/UNDP/IMO Global Ballast Water Management Programme (GloBallast) http://globallast.imo.org).

What is important to remember is that there is always a risk associated with movements of aquatic animals. In the case of aquatic animal pathogens, any live aquatic animal or animal product that is moved poses some level of risk of carrying a pathogen along with it. Therefore, each and every movement should be treated separately and the risks should be assessed using available scientific data and information. In the event that there is a lack of sufficient scientific data, the **precautionary approach** should be used (FAO 1996). On the other hand, a "zero risk" approach to preventing the introduction of aquatic animal pathogens, which could only be effective by prohibiting the movement of aquatic animals and their products, is no longer practicable. Any SPS restrictions on trade must conform to the international standard or be science-based to be defendable in a WTO dispute. The risk analysis procedure provides the mechanism to develop SPS measures that are consistent with international obligations.

Box 4. Some important international treaties, agreements, and memberships related to international trade in aquatic organisms and their products.

International Law
- SPS Agreement
- Convention on Biodiversity (CBD)
- Cartagena Protocol on Biosafety
- Convention on International Trade in Endangered Species (CITES)

International Memberships
- World Trade Organization (WTO)
- World Organisation for Animal Health (OIE)
- United Nations
- Various regional inter-governmental associations (e.g., APEC, ASEAN, SEAMEO, SARC, EU, etc.)

Non-binding Codes and Agreements
- Technical Guidelines and Beijing Consensus and Implementation Strategy (FAO/NACA 2000)
- Code of Conduct for Responsible Fisheries (CCRF) (FAO 1995)
- ICES Code of Practice on the Introductions and Transfers of Marine Organisms 2003 (ICES 2003)

4.3 National Legislative and Policy Issues

Risk analysis is one of a multitude of activities that should be formulated within the framework of a National Strategy for Aquatic Animal Health. Many countries, particularly those in the Asia-Pacific Region, have formulated such national strategies or are in the process of doing so (see, for example, AFFA 1999, Amos 2004, Bondad-Reantaso 2004a, Kanchanakhan and Chinabut 2004, Olivier 2004). Regional guidelines for the development of national strategies have been formulated and agreed upon by 21 governments in the Asia-Pacific Region under the support of FAO, NACA, OIE, ASEAN and other national agencies (see FAO/NACA 2000, 2001). The essential components of a National Strategy for Aquatic Animal Health are shown in Box 5.

It should be noted that all of the components of a national strategy are inter-related and thus the majority are essential to competent risk analysis. For example, when conducting a specific risk analysis, it will be difficult to determine if a given pathogen is exotic to a country if the country does not have a good

knowledge of the pathogens occurring within its national territory. Thus, targeted and general disease **surveillance** and reporting, based on adequate technical expertise, infrastructure and capacity to diagnose diseases, and leading to establishment of a reliable **national pathogen list** (including detailed information on the host species affected and geographic distribution) are all required (see, for example, Baldock 2004). Similarly, an understanding of health certification and quarantine measures may be essential to developing effective management measures to achieve a **mitigated risk estimate** that is below the risk level specified by a country' s **appropriate level of protection** (ALOP).

Box 5. The components of a National Strategy for Aquatic Animal Health (from FAO/NACA 2000).

- National pathogen list
- Disease diagnostics
- Health certification and quarantine measures
- Disease zoning
- Disease surveillance and reporting
- Contingency planning
- Import risk analysis
- National strategies and policy frameworks
- National and regional capacity building

Clear national policy and supporting legislation are essential to support risk analysis for diseases of aquatic animals. The responsible agencies and individuals must be designated and their mandates and activities clearly defined.

5 OVERVIEW OF THE RISK ANALYSIS PROCESS

"The importation of animals and animal products, whether of aquatic or terrestrial origin, involves a degree of disease risk to the importing country. This risk, which may be to humans or animals, may be represented by one or several diseases not present in the importing country." (OIE 2003a)[3]

5.1 Commodities to be Included in the Risk Analysis Process

For a given country, the importation of any living aquatic animal, or any product derived from any aquatic animal, can represent an unacceptable disease risk. The SPS agreement encourages members of the WTO to base their biosecurity measures on international standards. For aquatic animals, these standards are developed by the OIE. If such standards do not exist, or if a member considers that the standards are inconsistent with its ALOP, further analysis is required. The level of risk associated with a particular commodity and whether it is unacceptable can only be determined by undertaking a risk analysis. The types of commodities falling within the scope of this manual thus include:

- all live aquatic animals, irrespective of their proposed or intended use and destination
- all products derived from aquatic animals, including those intended for:
    - human consumption
    - use in animal feeds
    - use in the pharmaceutical, medical, agricultural, academic or industrial sectors, including research: examples include embryos and gametes (semen and ova), biological products (e.g., vaccines, genetic material) and pathological material (infected tissues, live cultures, etc.)

While the OIE defines aquatic animals as including fish, shellfish and molluscs, the legislation of many countries, particularly those in tropical regions, uses a much broader definition. The risk analysis approach provided here may be used, for example, to cover other aquatic commodities and species, not only finfish, shellfish and molluscs, but also amphibians, reptiles, marine mammals, aquatic invertebrates other than shellfish and molluscs, aquatic plants, etc. that may be important in some countries.

5.2 The Components of a Risk Analysis

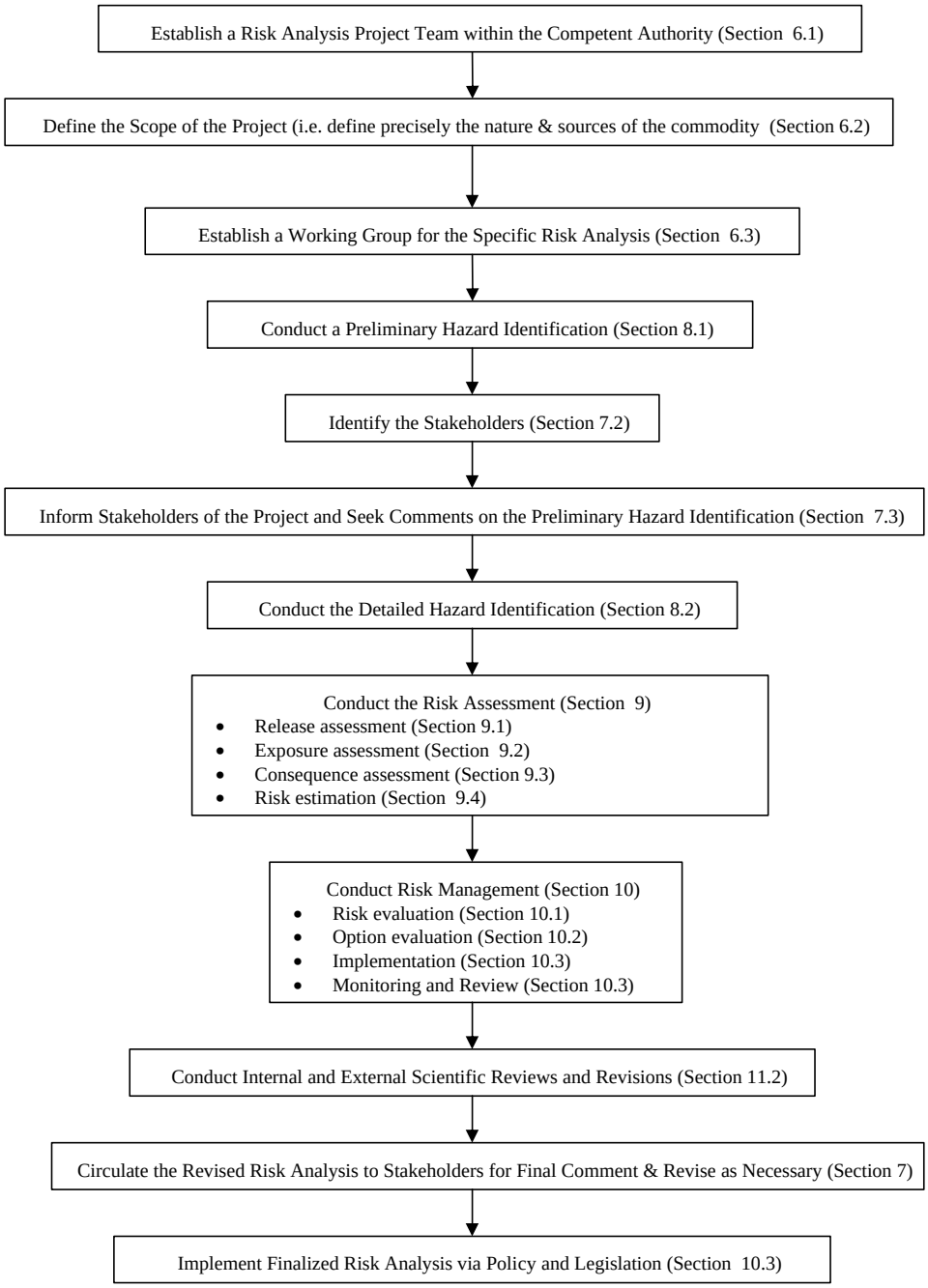
Risk analyses by WTO members must be consistent with the principles of the SPS Agreement. As such, the risk analysis process must be science-based and transparent to produce consistent outcomes. While these principles must be adhered to, the process by which the risk analysis is conducted is the decision of the Competent Authority conducting the analysis. In deciding on the process to be followed, that Competent Authority will consider its own needs, resources and capabilities, as well as the legal and administrative systems in which it operates. A Competent Authority may have significant resources at hand and have the technical capability to undertake the risk analysis completely "in-house". Another Competent Authority may identify the need to engage technical experts in aquatic animal disease and/or risk analysis. Importantly, risk analysis processes need to be flexible to take account of the large number of circumstances that exist and need to be considered. Therefore, the risk analysis process can take many forms,

[3] It should also be noted that the introduction and/or spread of pathogens already present in a country, and subject to control strategies, to a new geographical area represents another significant disease risk.

and each is valid if it stays faithful to the principles of the SPS Agreement.
For instructional purposes, the sequential activities in a hypothetical risk analysis process are represented in the flow diagram given in Figure 1. This hypothetical risk analysis process begins with several preliminary steps:

- Establishing a risk analysis Project Team under the Competent Authority.
- Designating a Working Group for the specific risk analysis under consideration.
- Scoping the risk analysis.
- Conducting a preliminary hazard identification.
- Identifying the stakeholders, informing them of the results of the preliminary hazard identification, and seeking their comments.

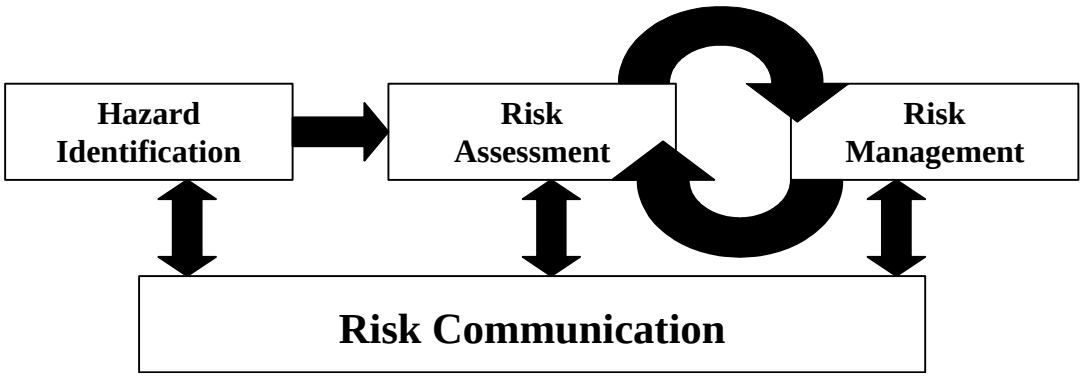
Figure 1. A simplified diagram showing the steps in a hypothetical risk analysis process (Sections of this handbook dealing with each component of the process are given in parentheses).



Once the preliminary steps have been accomplished and the scope of the risk analysis has been well defined, the full risk analysis is conducted. This consists of the four interrelated components whose general relationships are shown in Figure 2:

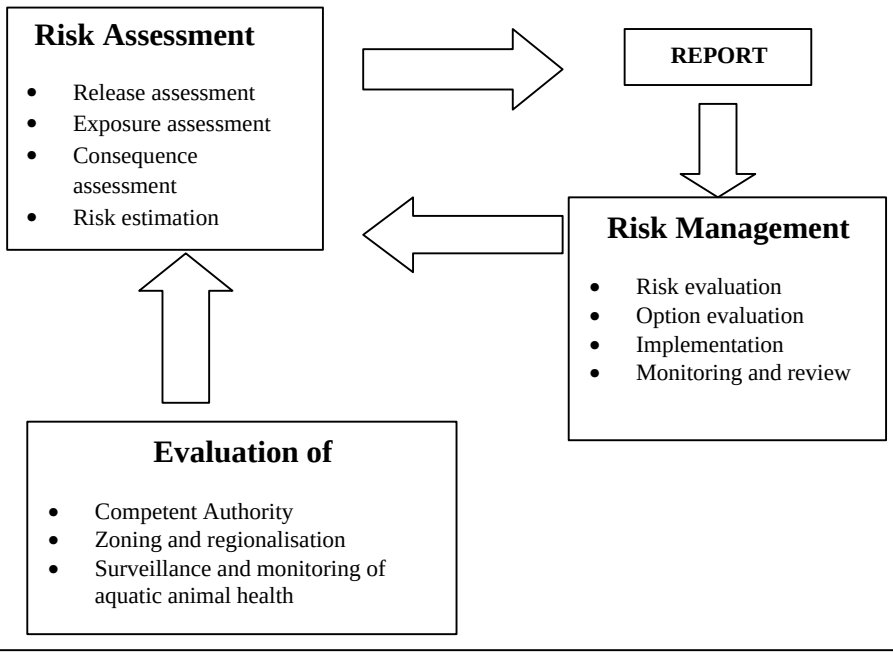
- hazard identification
- risk assessment
- risk management
- **risk communication**

Figure 2. The four components of risk analysis (from OIE 2003a)



Hazard identification, risk assessment and risk management form the core of the risk analysis, while risk communication is a continuous activity that takes place throughout the entire risk analysis process. The relationship between risk assessment and risk management is shown in Box 6.

Box 6. The relationship between risk assessment and risk management processes (modified from OIE 2003a).



Continuing the hypothetical risk analysis process represented in Figure 1, after completion of hazard identification, risk assessment and risk management, the draft risk analysis may be subjected to internal review by the Competent Authority. Following revision, an additional critical review by independent national and international experts may also be warranted. The results of the risk analysis may then be submitted to the broader community of stakeholders for public review and comment. Any stakeholder concerns should be appropriately addressed; then the final risk analysis is implemented by the government through appropriate changes to national and/or state policy and legislation.

Of course, most risk analyses do not proceed through the entire risk analysis process shown in Figure 1. Many requests for importation will be quickly found to involve little risk, since they can often be based on previously conducted risk analyses for the same commodity and source, and will be approved at an early stage; others will be quickly shown to involve a very high risk or be likely to involve risk management measures that are unacceptable to the proponents due to cost or technical complexity, with the result that the request to import is withdrawn or substantially modified at an early stage in the process. In such cases, there should still be **transparency** and thorough documentation of the scientific facts and opinions considered.

The following sections look briefly at the individual steps in the risk analysis process.

6 PREPARING TO CONDUCT RISK ANALYSES

6.1 Establishing a Risk Analysis Project Team

The Competent Authority (typically the Ministry of Fisheries or the national veterinary services) will conduct and/or oversee the risk analysis process. As discussed in Section 5, there are any number of structured processes which may be applied in risk analysis. Under the example structure illustrated in Figure 1, the Competent Authority would establish a permanent Project Team to oversee risk analyses. The function of the Project Team is mainly in the areas of administration, coordination and oversight; it ensures that all components of the risk analysis process are carried out in an efficient, transparent and unbiased manner using the best scientific knowledge available.

The Project Team should be comprised of members with expertise in risk analysis, policy and legislation, administration, project management and the technical aspects of aquatic animal health (Box 7).

Box 7. Composition of a hypothetical Risk Analysis Project Team.

- Team Leader (senior administrator within Competent Authority)
- Risk Analyst 1
- Risk Analyst 2
- Aquatic animal health expert
- Policy and Legislation Expert
- Secretary

The duties of the Project Team would include conducting the preliminary activities of the risk analysis process, such as:

- Receiving and screening requests to import live aquatic animals and their products.
- Determining which import requests should be subjected to full import risk analysis.
- Defining the scope of individual risk analysis projects (i.e., defining precisely the nature and sources of the commodity(ies))
- Establishing the composition of the individual Working Groups for specific commodities. (Note that experts with specialist knowledge of the commodity under consideration, especially diseases affecting that aquatic animal, should be integrally involved in the preparation of risk analysis documents. see Box 8)
- Providing administrative support to the Working Groups charged with conducting specific risk analyses.
- Monitoring and reviewing the schedules and progress made by the individual Working Groups.
- Providing a coordinating function between the Working Groups, the stakeholders and the Competent Authority.
- Identifying the stakeholders for individual risk analysis projects.
- Undertaking preliminary hazard identifications (with the assistance of appropriate technical experts recruited for this purpose).
- Informing the stakeholders of the project and seeking their comments on the preliminary hazard analysis.

Box 8. Example of a possible Working Group for a risk analysis involving the importation of a marine mollusc for aquaculture.

- Chairperson (expert in RA)
- Risk Analyst 1(general expertise in RA)
- Risk Analyst 2 (expertise in RA for molluscs)
- Molluscan Biology/Disease Expert

Following completion of a risk analysis by an individual Working Group, the Project Team would be responsible for such activities as:

- Coordinating internal and external scientific reviews.
- Assuring that the Working Group has adequately addressed the criticisms of the reviewers.
- Circulating the draft final revision of the risk analysis to the stakeholders and ensuring that all stakeholders have adequate opportunity to comment on the analysis.
- Ensuring that the concerns expressed by stakeholders are adequately addressed by the Working Group.
- Reviewing the final risk analysis provided by the Working Group and submitting the results of the analysis to the Competent Authority for implementation into policy and legislation.

6.2 Scoping a Risk Analysis

Before a risk analysis is begun, it is important to define clearly the nature and extent (boundaries) of the analysis (i.e., its scope). Scoping will involve defining the terms of the specific risk analysis to be undertaken as precisely as possible. The scope of the risk analysis will determine many of the subsequent decisions to follow, such as the expertise and resource requirements, the time frame, the stakeholder community and the type of risk analysis (qualitative or quantitative) that will be undertaken. It is essential that participants and stakeholders have a clear understanding of the purpose of the analysis from the outset.

In general, the scoping of a risk analysis involves developing:

- a clear statement of the purpose of the risk analysis;
- a description of the commodity, its origin(s), and the relevant methods of production, manufacturing and processing; and
- an estimate of the likely annual volume of trade.

Important criteria that assist in scoping a risk analysis, and which must be provided by the proponents of the proposed importation include:

For living aquatic animals:

- The scientific name of the species involved.
- The life cycle stage (e.g., eggs, larvae, fry, juveniles, adults)
- Their origin (hatchery or origin; collection locality, if wild, etc.)
- The extent of knowledge of their health status and the status of the stock(s) from which they originate.
- The quantities (number of animals, volume of product, etc.) to be imported.
- The proposed date(s) of importation.
- Any risk management measures that the proponents propose to undertake.

For other commodities:

- The commodity to be imported (including the scientific name of the species involved).
- The exact nature of the product (including a description of any treatment processes).
- Its origin (original source of the biological material, processing plant, manufacturer).
- The extent of knowledge of the health status of the stock(s) of origin.
- The nature of production and processing.
- The quantities (number of animals, volume of product, etc.) to be imported.
- The proposed dates of importation (e.g., will this analysis involve a single shipment or will there be a continuous trade?).
- Any risk management measures that the proponents propose to undertake.

Since much of the information necessary for scoping a risk analysis will be provided by the proponents of the proposed importation, it is essential that the Competent Authority develops a clear and detailed application form and associated guidelines for the information to be provided. Box 9 provides an example of the type of information that may be required. Note that in this example, the required information supports the analysis of risks associated with aquatic animal pathogens, and ecological aspects, the latter being also relevant to many introductions (more detailed information can be found in Appendix III of Anon. 2003 and in ICES 2003).

Box 9. Example of the types of information required from the proponents of a proposed introduction or transfer (see Anon. 2003).

- *Executive summary*
- *Introduction*: including information on species, history of use, rationale for the proposed introduction, alternate strategies, geographic area of the proposed introduction, numbers of organisms to be introduced, source(s), etc.
- *Life history information for the species to be introduced or transferred*: description of native and present range, previous introductions and their effects, factors limiting native range, physiological tolerances, habitat preferences and tolerances, reproductive biology, migratory behavior, food preferences for each life history stage, growth rate and life span, known pathogens and parasites, behavioral characteristics.
- *Interaction with native species*: including information on potential for survival and establishment of escapees, habitat(s) likely to be occupied and overlaps with any vulnerable, threatened or endangered species; overlaps with native species, food habits in receiving environment and estimates of adverse impacts due to predation; likelihood of survival and reproduction (including need for annual stocking); introductions elsewhere and their positive and negative impacts; potential impacts on habitat or water quality.
- *Receiving environment and contiguous watershed*: including information on the physical parameters of the receiving environment and contiguous waterbodies and whether these match the requirements and preferences of the species; species composition (major aquatic vertebrates, invertebrates and plants) of the receiving waters and their known susceptibility to the parasites and diseases of the introduced species in its native range; habitat in the area of introduction, including contiguous waters; natural or man-made barriers that should prevent the movement of the introduced species to adjacent waters.
- *Monitoring*: including a description of the plans for follow-up assessments of the proposed introduced species' success in meeting/breaking the assessed risks of negative impacts on native species and their habitats.
- *Precautions and management plan*: including a detailed description of the management plan for the proposed introduction, the precautions to be taken to prevent accidental escape of any aquatic organisms and their pathogens and their establishment in non-target ecosystems; contingency plans to be followed; information on any fishery that will be created.
- *Business data:* including information on the company and the licenses it holds; indication of the economic viability of the proposed project.
- *References:* including a detailed bibliography of all references cited in the risk assessment and a list of scientific authorities consulted and/or listed.

An analysis that is poorly scoped has the potential to create many problems in conducting the risk analysis and in interpreting and communicating the results. Thus it is important to achieve the best project definition (scope) possible.

Box 10 shows a list of useful guiding questions to consider during a risk analysis process for a proposed introduction of a marine mollusc for use in aquaculture. Box 11 shows the results of a hypothetical scoping exercise for such an importation.

Box 10. List of useful guiding questions to consider for a scoping exercise for a proposed introduction of marine mollusc for use in aquaculture.

- Why is the translocation of stock taking place?
- What is the source of the stock concerned?
- What numbers and what developmental stages are involved?
- Is the time of year important?
- Does the exporting country have a good scientific database, which may form the basis of an risk analysis?
- What are the potential hazards?
- What are the pathways by which they may become established?
- Are there good data on the species in question in the scientific literature?
- Who in the Competent Authority of the exporting country has sufficient experience to certify the stock for export?
- Can the stock for export be held in quarantine before export?
- In what ways may risk be mitigated?
- Can the shells be cleaned of any fouling organisms before export?
- How will the molluscs be transported?
- What holding/quarantine facilities are there near the point of entry?
- Do susceptible hosts live near the point of entry and the destination?
- How will the water in which the stocks travelled be disposed of?
- Are there any likely vectors in the vicinity of the holding facility?
- How long should the animals be kept in containment before being released to the importer?

Box 11. Results of a scoping exercise for importation of a marine mollusc for use in aquaculture.

- **Purpose**: To analyze the risks of introducing diseases from a hatchery in France to an oyster farm in Baja California, Mexico during a proposed importation of 6-month-old Japanese cupped oysters, *Crassostrea gigas*, for aquaculture.
- **Commodity Description:**
- **Species:** Japanese cupped oyster (*C. gigas*)
- **Origin:** Hatchery in France
- **Volume:** 80 kg for approximately 100,000 units
- **Use:** On-growing in culture conditions in an oyster farm in Baja California, Mexico.
- **Reason for importation:** Poor natural spat collection linked to environmental conditions (El Nino) and low production of national hatcheries in Baja California, Mexico. Importer can get very good prices from a hatchery located in France.
- **Preliminary Hazard Identification:** Two hazards were identified: (a) *Haplosporidium nelsoni* and (b) Herpes virus of oysters.
- **Examples of risk management measures that the proponents propose to undertake**:

For *H. nelsoni:*

- Health certificate to be provided
- PCR test to be undertaken from representative samples before departure and upon arrival
- Treatment of transport water

For herpes virus of oysters:

- Certification of the batch
- Quarantine
- PCR and *in-situ* hybridization tests on arrival
- Treatment of transport water
- Imported animals not be to be used as broodstock

7 RISK COMMUNICATION

"Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision makers and interested parties in the importing and exporting countries. It is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue through out." (OIE 2003a)

Risk communication is a continuous interactive process between all parties concerned or likely to be affected by a specific risk analysis. Within the Competent Authority, this of course includes any teams or groups formed, and senior staff of the Competent Authority outside these groups. More broadly, it also includes all other agencies, organizations and individuals with a real or potential interest or involvement in the results of the risk analysis. This can include the proponent, other governmental agencies (e.g., those responsible for legislation, enforcement, trade, social programs, human health, wildlife management, etc.), non-governmental organizations (both grass roots and international), organizations for commercial fishermen, sport fishermen, aquaculturists, ornamental fish traders, hobbyists, etc., and concerned members of the general public. An example of a potential list of stakeholders for a risk analysis involving the importation of a live marine mollusc for aquaculture development is given in Box 12.

Box 12. Example of a list of potential stakeholders for a risk analysis involving the importation of a live marine mollusc for aquaculture development.

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

The key components of effective risk communication are:

- transparency,
- consensus building,
- information exchange so that all available relevant information is fed into the process,
- stakeholder cooperation, and
- stakeholder consultation throughout the various stages of the entire risk analysis process.

The principles of risk communication as outlined by the OIE are given in Box 13.

Box 13. Principles of risk communication (from OIE 2003a).

- Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision makers and interested parties in the importing and exporting countries. It is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout.
- A risk communication strategy should be put in place at the start of each risk analysis.
- The communication of risk should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.
- The principal participants in risk communication include the authorities in the exporting country and other stakeholders such as domestic aquaculturists, recreational and commercial fishermen, conservation and wildlife groups, consumer groups, and domestic and foreign industry groups. The assumptions and uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated.
- Peer review of risk analyses is an essential component of risk communication for obtaining a scientific critique aimed at ensuring that the data, information, methods and assumptions are the best available.

7.1 Transparency

Transparency throughout the entire risk analysis process is absolutely essential, as it provides the exporting country and potential domestic importers with a clear justification and the logic as to why a particular commodity is subject to import conditions or is prohibited. Alternatively, other stakeholders in the importing country may perceive that the risk management measures, or lack there of, are not sufficiently stringent to address the disease risk. It can be expected that some stakeholders will not like or agree with the results of a given risk analysis; however, they should have the feeling that they understand the process and logic by which the decision was reached, and are able to distinguish between the components of the risk analysis that are based on scientific fact and those that are based on value judgments or policy. They should also feel that the risk analysis process was fair and that they were given sufficient opportunity to comment on the process and results.

7.2 Identification of Stakeholders

The process of stakeholder identification should begin at a very early stage in the risk analysis. As soon as the scope of the risk analysis has been determined and a preliminary hazard identification completed, a preliminary notification should be made available to potential stakeholders advising them of the scope of the risk analysis and the risk analysis pathway that will be followed.

A stakeholder list should be established and maintained to inform them that a specific risk analysis is being undertaken. Additional stakeholders will be identified during the risk communication process (e.g., by announcements in the media and during the holding of public meetings). These new stakeholders can be added to the list and be consulted during future risk analyses.

7.3 Means of Risk Communication

There are many ways that risk communication can be accomplished, and developing countries must determine and develop communication strategies and methods that are most effective and cost efficient for their particular circumstances. Information can be distributed and feedback received by such means as:

- electronic communication (e-mail and websites)
- printed material (reports and announcements in newspapers and trade journals, printed notices such as brochures or fact-sheets, mailings to potential stakeholders, etc.)
- telephone
- public information and review meetings
- mass media (e.g., television, newspapers, magazines)
- mail surveys
- outreach and extension channels

8 HAZARD IDENTIFICATION

"Hazard identification involves identifying the pathogenic agents that could potentially produce adverse consequences associated with the importation of a commodity." (OIE 2003a)

During the risk analysis process, two types of hazard identification will be conducted. The first of these is the preliminary hazard identification, which is used to make an initial assessment as to whether importation of the commodity (a living aquatic animal or its product) is likely to involve a significant **hazard**, a hazard being any pathogen that could produce adverse consequences resulting from importation of the commodity. The second process is the detailed hazard identification, which will take an exhaustive look at the hazards involved.

To classify an agent as a potential hazard, the following criteria (see Box 14) need to be fulfilled (Murray 2004):

- The agent must be appropriate to the species being imported, or from which the commodity is derived.
- It may be present in the exporting country.
- If present in the importing country, it should be a reportable disease or subject to control or eradication.

Box 14. Steps to determine if an organism is a potential hazard (modified from Murray 2002).

1) Is the commodity a potential vehicle for the organism?
   - If YES, proceed to step 2;
   - If NO, the organism is not a potential hazard.

2) Is the organism exotic to the importing country but likely to be present in the exporting country?
   - If YES, it is classified as a potential hazard;
   - If NO, proceed to step 3

Note: An exporting country' s Veterinary Service, surveillance and control programs and zoning and regionalization systems are important factors to consider when assessing the likelihood of hazards being present in the animal population of the exporting country. They enable the exporting country to substantiate claims of disease status and the importing country to establish and maintain confidence in such claims.

If a country claims that it is free of a particular hazard, supporting evidence must be documented. In such cases the appropriate sanitary measure to be applied is certification from the Veterinary Authority in the exporting country that is free of hazard.

3) For an organism reported in both the exporting and importing countries, EITHER IF:

(a) there are free zones or zones of low prevalence in the importing country that are established under a national or regional pest management strategy or small-scale program and where the movement of animals and/or animal products into the zone is under statutory control;
OR IF

(b) it is listed on the unwanted organisms register as a reportable organism; OR IF

(c) there is a more virulent strain in the exporting country.

THEN the organism is classified as a potential hazard.

It is important to remember that in both types of hazard identification, only pathogens that are relevant to the host species should be considered. However, it is possible that while some pathogens will show strict physiological host specificity (i.e., infecting only a single host species), many more will be more broadly host specific, capable of infecting all species in a given genus or family. Some others will show only ecological specificity, infecting all hosts in a given environment. Thus, for example, in considering the hazards that might be associated with the importation of live Nile tilapia (*Oreochromis niloticus*) from a stock of unknown health status, it might be wise to consider all pathogens reported from species of the genus *Oreochromis*, or even all those recorded from all African members of the family Cichlidae.

Good hazard identification requires considerable technical expertise and experience. Thus, personnel with adequate skills in such areas as pathology, epidemiology, parasitology, bacteriology, virology and mycology, as well as the broader areas of the biology and ecology of the aquatic animal species in question, must be integrally involved in the risk analysis, e.g., in a Working Group. Hazard identification also takes into consideration potential pathways, transit/transshipment risks and hazards that may result from water changes, and so on.

An evaluation of the Competent Authority in the exporting country, any disease surveillance and control programs that are in place, and any zoning systems is important in assessing the likelihood of hazards being present in the aquatic animals present in the exporting country. Information on the disease status of the exporting country and on the status of the specific aquatic animal and the individual source of origin (hatchery, stock, population, etc.) is also required. For OIE-listed diseases, country status information can be obtained from the OIE' s International Database for Aquatic Animal Diseases (http://www.collabcen.net/toWeb/aq2.asp). Additional information can often be obtained from the Competent Authority in the exporting country, from national experts at government and university laboratories, from the scientific literature and from websites such as the Aquatic Animal Pathogen and Quarantine Information System (AAPQIS) (http://www.aapqis.org) and the NACA/OIE Quarterly Aquatic Animal Disease Report (Asia and Pacific Region) series (see Annex I or reports available at www.enaca.org). However, in many cases, adequate information may be lacking.

8.1 Preliminary Hazard Identification

The preliminary hazard identification is used to make a rough estimation of the unmitigated risk (i.e., the risk associated with importation unimpeded by any risk management measures) and decide whether a full risk analysis is required for a given commodity). This process would also help to determine the complexity of the issues surrounding the proposed importation and the type of risk analysis needed (e.g., an "in-house" risk analysis, or a risk analysis involving the participation of external experts, with more extensive analysis, documentation and review).

The information required and the approach taken is much the same as that outlined below under Detailed Hazard Identification (Section 8.2). However, the search for pathogens is less extensive, particularly in cases where potentially serious hazards are quickly identified. In such cases, the decision can be easily made to conduct a full risk analysis, and to commence a detailed hazard identification.

8.2 Detailed Hazard Identification

Detailed hazard identification involves a more exhaustive and comprehensive search for information on the potential hazards that the commodity may be carrying. This often requires knowledge of not only the potential pathogens for the commodity in the country of origin, but also knowledge of its pathogens on a world-wide basis. This is because the health status of the commodity in the exporting country will often

be poorly known, and that specific diseases are often difficult to detect due to an absence of a reliable diagnostic test or their low prevalence in the population.

The process of identifying hazards may include such activities as:

- Conducting extensive literature searches for the pathogens reported for the commodity.
- Consulting electronic databases, such as those maintained by OIE and the FAO.
- Use of risk analyses performed by other countries.
- Contacting the Competent Authority in the country where the commodity is produced or traded to obtain unpublished information.
- Contacting individual experts for information and their opinion.

At the same time, the sources of information should be documented extensively. Moreover, preliminary information that will be needed for the risk assessment and risk management steps that will likely follow would normally be noted and collected to increase efficiency.

It should be remembered that the absence of reported hazards for a given commodity (particularly when the commodity is a live aquatic animal species) does not indicate a real absence of potential hazards. Often the risk analyst will find that the species of aquatic animal of concern has been little studied, such that there is little or no information available on the pathogens that it might carry. Of course this uncertainty must be considered during the process of risk management and a precautionary approach (see Section 11.4) may come into play.

However, if either the preliminary hazard analysis or the detailed hazard analysis determines that the commodity, due to its nature, origin, the processing methods used or another factor, contains no hazards, then the risk analysis process is terminated because the risk has been found to be negligible.

The end result of the hazard identification process will be a list of hazards (pathogens) of concern. This list will then be used in the next step in the risk analysis process, risk assessment, to determine the level of risk that each hazard represents to the importing country. An example of the results of a hypothetical hazard identification exercise for the importation of a live oyster (*Crassostrea gigas*) is given in Box 15.

Box 15. Results of a hypothetical hazard identification exercise and additional disease information required for it in a risk analysis involving the proposed importation of *Crassostrea gigas* for aquaculture.

OIE listed and other significant pathogens of concern for *Crassostrea gigas* and/or *Crassostrea* spp. are identified as follows:

- *Haplosporidium nelsoni*
- *Perkinsus marinus*
- *Perkinsus olseni*
- *Bonamia ostreae*
- Herpes virus
- Oyster velar virus disease
- Other diseases considered to be significant to the importing country which are present in the exporting country and not present in the importing country, or if present, subjected to disease control measures

Additional disease information:

- Diseases recorded from *C. gigas* and/or *Crassostrea* spp. from the exporting country
- Diseases recorded from *C. gigas* and/or *Crassostrea* spp. from the importing country
- Significant diseases of *Crassostrea* spp.
- Other diseases listed by the importing country
- Other diseases significant to the importing country

9 RISK ASSESSMENT

Risk assessment is..." the processes of identifying and estimating the risks associated with the importation of a commodity and evaluating the consequences of taking those risks." (OIE 2003a)

Once the potential hazards associated with the importation of a particular commodity have been identified, the next step is to estimate, for each hazard (pathogen), the likelihood of entry, establishment and spread, as well as the likely biological and economic consequences that would result.

In simple terms, risk assessment tries to answer the questions:

(i) How likely is it that a particular pathogen will enter, become established and spread in an importing country through trade in a given commodity? and

(ii) How serious will the consequences be if this happens?

Risk assessment is comprised of four components:

- Release assessment
- Exposure assessment
- Consequence assessment
- Risk estimation

When conducting a risk assessment, it is important to clearly define the terms used to describe the probability of an event occurring and its consequences. The number and complexity of such terms may vary depending on the individual risk analysis and the preferences of the Competent Authority and personnel working on the risk analysis. An example of a set of terms used by AQIS (1999) in a recent qualitative risk analysis is given below:

- High: Event would be expected to occur
- Moderate: There is less than an even chance of an event occurring
- Low: Event would be unlikely to occur
- Very low: Event would rarely occur
- Extremely low: Event would occur very rarely
- Negligible: Chance of event occurring is so small it can be ignored in practical terms

The principles of risk assessment, as outlined in the **Aquatic Code** (OIE 2003a) are given in Box 16.

Box 16. OIE's principles of risk assessment (from OIE 2003a).

- Risk assessment should be flexible in order to deal with the complexity of real-life situations. No single method is applicable in all cases. Risk assessment must be able to accommodate the variety of animal commodities, the multiple hazards that may be identified with an importation and the specificity of each disease, detection and surveillance systems, exposure scenarios and types and amounts of data and information.
- Both qualitative and quantitative risk assessment methods are valid. Although quantitative analysis is recognized to provide deeper insights into a particular problem, qualitative methods may be more relevant when available data are limited as is often the case with aquatic species.
- The risk assessment should be based on the best available information that is in accord with current scientific thinking. The assessment should be well documented and supported with references to the scientific literature and other sources, including expert opinion.
- Consistency in risk assessment methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.
- Risk assessments should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate.
- Risk increases with increasing volume of commodity imported.
- The risk assessment should be amenable to updating when additional information becomes available.

9.1 Release assessment

"Release assessment consists of describing the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) a hazard into a particular environment, and estimating the likelihood of that complete process occurring." (OIE 2003a)[4]

For each identified hazard, the range of factors that will affect the likelihood of that particular hazard being imported into the country with the commodity must be assessed. These factors include the biology of the host and the pathogen, country specific factors, and commodity factors. For example, it is important to consider the occurrence of the pathogen; i.e., its prevalence in different lifestages of susceptible species in the exporting country, and any seasonal variations. Moreover, if dealing with a product derived from an aquatic animal, the likelihood of inactivation of the pathogen during typical processing procedures is an important consideration (e.g., many parasites will be inactivated or killed by freezing).

Figure 3 provides a simplified scenario tree for release assessment of a pathogen in a batch of live aquatic animals.

The results of a hypothetical release assessment for two identified hazards associated with the importation of a live marine mollusc imported for aquaculture development is shown in Box 17.

In addition to the expertise required in hazard identification, a release assessment for a given commodity/pathogen combination may require the input of experts who specialize in the specific pathogen (e.g., a microbiologist, parasitologist, virologist, etc.) and commodity (e.g., someone with specific post-harvest and processing expertise).

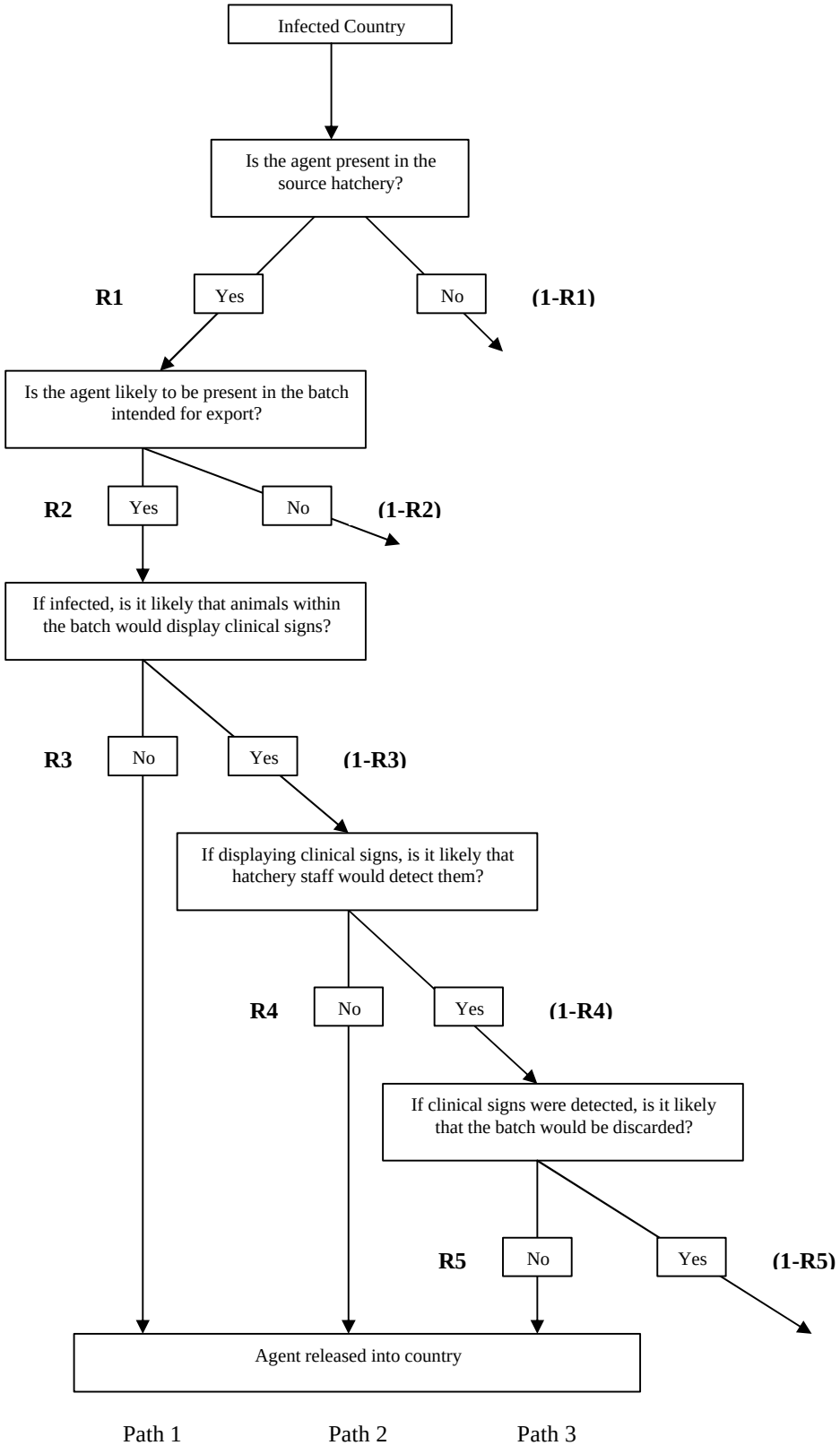
Box 17. Results of a hypothetical release assessment for two identified hazards involving the importation of live marine molluscs for aquaculture development.

(a) *Haplosporidium nelsoni*
- **Natural hosts**: *Crassostrea virginica, C. gigas*
- **Global distribution**: USA, Japan, Korea and France
- **Occurrence:** Reported from exporting country; not reported from importing country.
- **Release assessment**: low (with good confidence); juveniles originating from indoor facility where life cycle is not known to be fulfilled; pathogen occurring at a very low level of prevalence in exporting country (< 1%); pathogen reported from adults but never from juveniles.

(b) Herpes virus of oyster
- **Natural hosts:** *C. virginica, C. gigas, Ostrea edulis, O. angasi, Tiostrea chilensis*
- **Global distribution**: reported from France, New Zealand and Australia.
- **Occurrence:** Reported from exporting country; not officially reported from importing country.
- **Release assessment**: high (reasonably certain); agent initially described from hatching facilities; recurrent report from exporting country monitoring in oysters.

[4] This OIE definition implies that release assessment estimates the probability of the hazard getting into the environment of the importing country, making it difficult to ascertain where the "release" ends and the "exposure" begins in terms of developing pathways. In practice, most countries consider that the "release" pathways terminate and the "exposure" pathways begin at the importing country' s border.

Figure 3. Scenario tree for the release of an infectious agent that infects hatchery-produced larvae of an aquatic animal. In this simplified example, the release likelihood (RL) would be equivalent to the product of the likelihoods at each branch, i.e., RL = path1+ path2+ path3= (R1* R2* R3)+ (R1* R2(1-R3)* R4)+ (R1* R2* (1-R3)* (1-R4)* R5).



9.2 Exposure assessment

"Exposure assessment consists of describing the biological pathway(s) necessary for exposure of humans and aquatic and terrestrial animals in the importing country to the hazards and estimating the likelihood of the exposure(s) occurring, and of the spread or establishment of the hazard." (OIE 2003a)

Exposure assessment can be visualized by a pathways diagram for each hazard. The diagram should show all the various pathways that the commodity could take following its importation, identify those that entail a risk of exposure, estimate the risk of exposure of susceptible animals (e.g., low, medium or high risk) and the probability that once exposure occurs, that the pathogen will become established. Figure 4 provides a very simple example of a scenario tree for a hypothetical exposure assessment for a batch of live aquatic animals.

It is important to note that actual exposure pathway diagrams will usually be significantly more detailed than is indicated in Figure 4. For example, the question of whether an aquatic animal, or its progeny or products from it, or media or vessels with which it has had contact, may enter the aquatic environment will require thorough assessment of many issues. These may include *inter alia* seafood or pet industry practices, retail practices, aquaculture industry practices, consumer preferences and demographics, and cultural issues. There are several actual exposure assessment scenario trees for aquatic animals which may serve as complex examples (see Kahn *et al.* 1999 for one example). On the other hand, in the case of imported broodstock for aquaculture, it is clear-cut that the stock or its progeny will enter an aquatic environment.

In the case where the hazard may pose a health risk to humans or terrestrial animals, these additional pathways must also be considered. Exposure assessment may therefore also need to draw on the experience of people with expertise in, for example, waste disposal practices and cultural and social practices (e.g., for a fish-transmitted food-borne zoonoses, cooking practices used by rural populations in the country, the tendency of citizens to eat raw or undercooked fish, local human waste disposal practices, etc.).

9.3 Consequence assessment

"Consequence assessment consists of identifying the potential biological, environmental and economic consequences. A causal process must exist by which exposures to a hazard result in adverse, health, environmental or socio-economic consequences." (OIE 2003a)

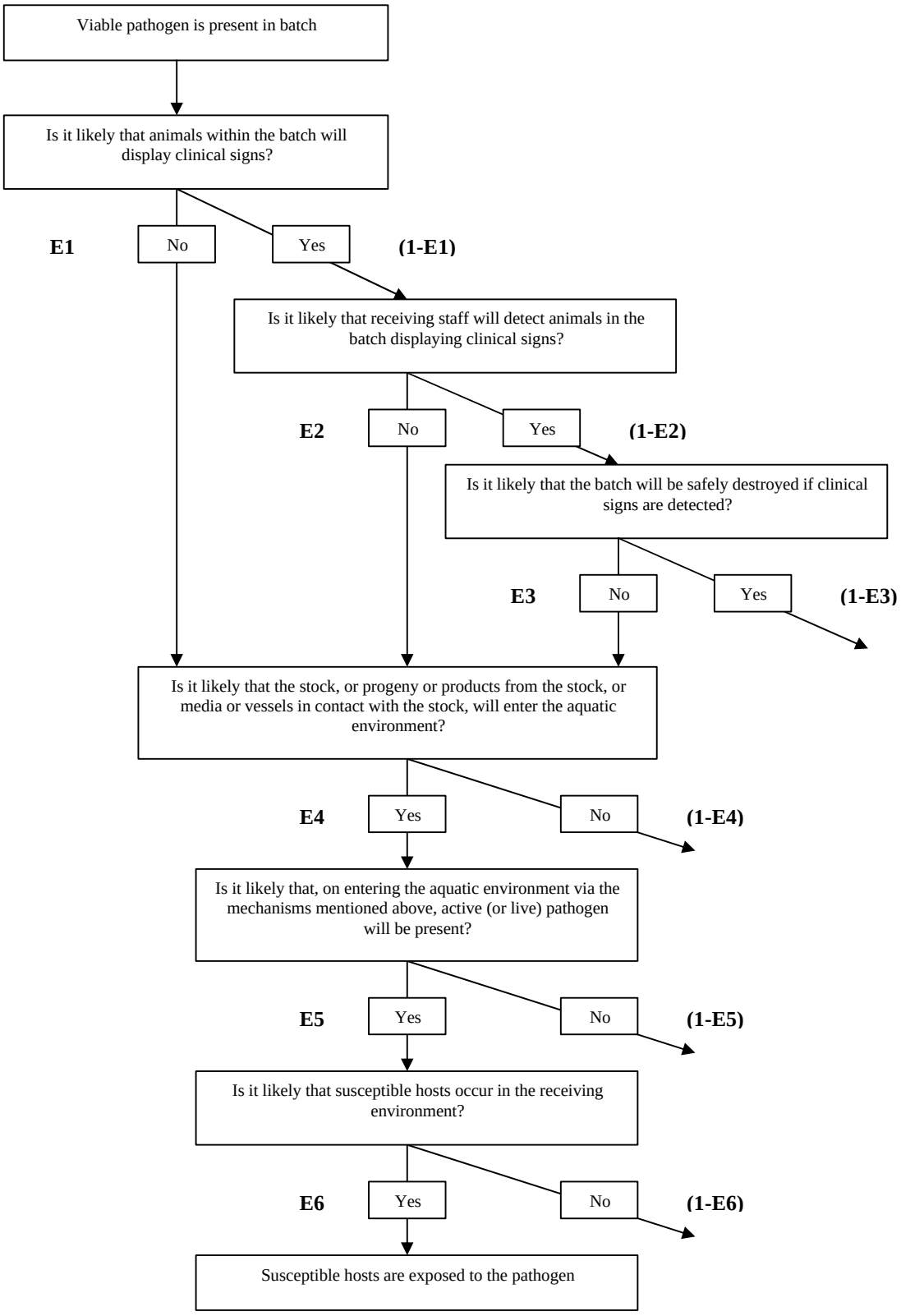
Consequence assessment should take into consideration the biological, economic and social value of such direct and indirect impacts as:

- Loss of production to fisheries and aquaculture.
- Loss of jobs in the fishing or aquaculture industries and in secondary industries.
- Environmental damages.
- Social impacts (e.g., loss of wages and sources of nutrition to rural families and the poor).
- Effects on international and domestic trade.
- Costs of surveillance, control and eradication programs.
- Public health consequences.
- Costs of compensation programs.

Again, these potential impacts can be assessed qualitatively and an overall assessment given.

To achieve an accurate consequence assessment, the knowledge of experts in such areas as economics, public health and social studies may be required.

Figure 4. Scenario tree for assessment of the likelihood that susceptible hosts would be exposed to a pathogen present in an imported batch of an aquatic animal. In this simplified example, the exposure likelihood (EL) would be equivalent to the product of the likelihoods at each branch, i.e., EL = (E1* E4* E5* E6)+ ((1-E1)* E2* E4* E5* E6)+ ((1-E1)* (1-E2)* E3* E4* E5* E6).



9.4 Risk Estimation

"Risk estimation consists of integrating the results of the release assessment, exposure assessment and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset." (OIE 2003a)

Risk estimation is the final step in the risk assessment exercise. The result for each hazard being evaluated will take into consideration the **unmitigated risk estimate** and the estimate of the consequences of the hazard becoming established in the country. Two different methodologies for estimating risk are provided in Box 18 and Table 1. The steps involved in risk estimation are outlined in Box 18. In a **qualitative risk assessment**, the various possibilities for each hazard can be visualized as a matrix (see Table 1).

Box 18. An outline of the steps involved in risk estimation (modified from Murray 2002).

1. Release assessment (likelihood of entry)

Is there a non-negligible likelihood that the commodity is carrying the potential hazard when imported?

- If NO – the risk estimate is classified as negligible.
- If YES – proceed to step 2.

2. Exposure assessment (likelihood of susceptible animals and/or humans being exposed)

- If NO – the risk estimate is classified as negligible.
- If YES – proceed to step 3.

3. Consequence assessment (successful exposure results in infection that may spread with or without establishment)

3.1 If there is a non-negligible likelihood of the potential hazard spreading but not becoming established, are there further significant potential consequences?

- If NO – the risk estimate is classified as negligible.
- If YES – Is there a non-negligible likelihood of at least one of these potential consequences occurring?
- If NO – the risk estimate is classified as negligible.
- If YES – the risk estimate is classified as non-negligible.

3.2 If there is a non-negligible likelihood of the potential hazard becoming established, are there further significant potential consequences?

- If NO – the risk estimate is classified as negligible.
- If YES – the risk estimate is classified as non-negligible

Table 1. Unmitigated risk estimation combining the results of the exposure and consequence assessments for a hypothetical hazard using three qualitative rankings (high, medium and low).

Likelihood of Entry and Exposure	Consequence of Establishment	Unmitigated Risk Estimate
Low	Low	Low
Low	Medium	Medium
Low	High	Medium
Medium	Low	Medium
Medium	Medium	Medium
Medium	High	High
High	Low	Medium
High	Medium	High
High	High	High

10 RISK MANAGEMENT

Risk management is... "the process of identifying, selecting and implementing measures that can be applied to reduce the level of risk." (OIE 2003a)

Risk management consists of four components:

Risk evaluation
Option evaluation
Implementation
Monitoring and review

The principles of risk management as outlined by the Aquatic Code (OIE 2003a) are given in Box 19. The SPS Agreement provides that if a measure conforms to the relevant international standard it is deemed to be consistent with international obligations.

Box 19. Principles of risk management (from OIE 2003a).

- Risk management is the process of deciding upon and implementing measures to achieve the Member Country' s appropriate level of protection, while at the same time ensuring that negative effects on trade are minimized. The objective is to manage risk appropriately to ensure that a balance is achieved between a country' s desire to minimize the likelihood or frequency of disease incursions and their consequences and its desire to import commodities and fulfill its obligations under international trade agreements.
- The international standards of the OIE are the preferred choice of sanitary measures for risk management. The application of these sanitary measures should be in accordance with the intentions of the standards or other recommendations of the SPS Agreement.

10.1 Risk evaluation

Risk evaluation is the process of comparing the unmitigated risk as estimated in the risk assessment with the importing country's appropriate level of protection (ALOP).

An example of a hypothetical risk evaluation is given in Table 2.

Table 2. Unmitigated risk estimation combining the results of exposure and consequence assessments for a hypothetical hazard using three qualitative rankings (high, medium and low). The risk evaluation decision is based on "low" as the appropriate level of protection (ALOP).

Likelihood of Entry and Exposure	Consequence of Establishment	Unmitigated Risk Estimate	Risk Evaluation Decision
Low	Low	Low	Approve
Low	Medium	Medium	Proceed to option evaluation
Low	High	Medium	Proceed to option evaluation
Medium	Low	Medium	Proceed to option evaluation
Medium	Medium	Medium	Proceed to option evaluation
Medium	High	High	Proceed to option evaluation
High	Low	Medium	Proceed to option evaluation
High	Medium	High	Proceed to option evaluation
High	High	High	Proceed to option evaluation

The unmitigated risk estimate for each hazard is then compared with the ALOP, which is the level or risk considered acceptable to the country. The ALOP is determined by political decision and is based on national policy with regard to many factors and priorities (see Section 11.6).

Two outcomes are possible:

(i) The unmitigated level of risk for all hazards is within the ALOP, or
(ii) The unmitigated level of risk for one or more of the hazards is above the ALOP.

In the first case, the risk analysis procedure would be terminated and the request to import would be approved. In implementing the findings, the Competent Authority should ensure that the product allowed importation is as specified in the risk analysis, i.e., taking into account risk management measures that were included in the commodity specification/scope of the risk analysis.

In the second case, the risk analysis would continue, and potential ways that the risk could be reduced to an acceptable level for all hazards would be examined. This process is called option evaluation.

10.2 Option evaluation

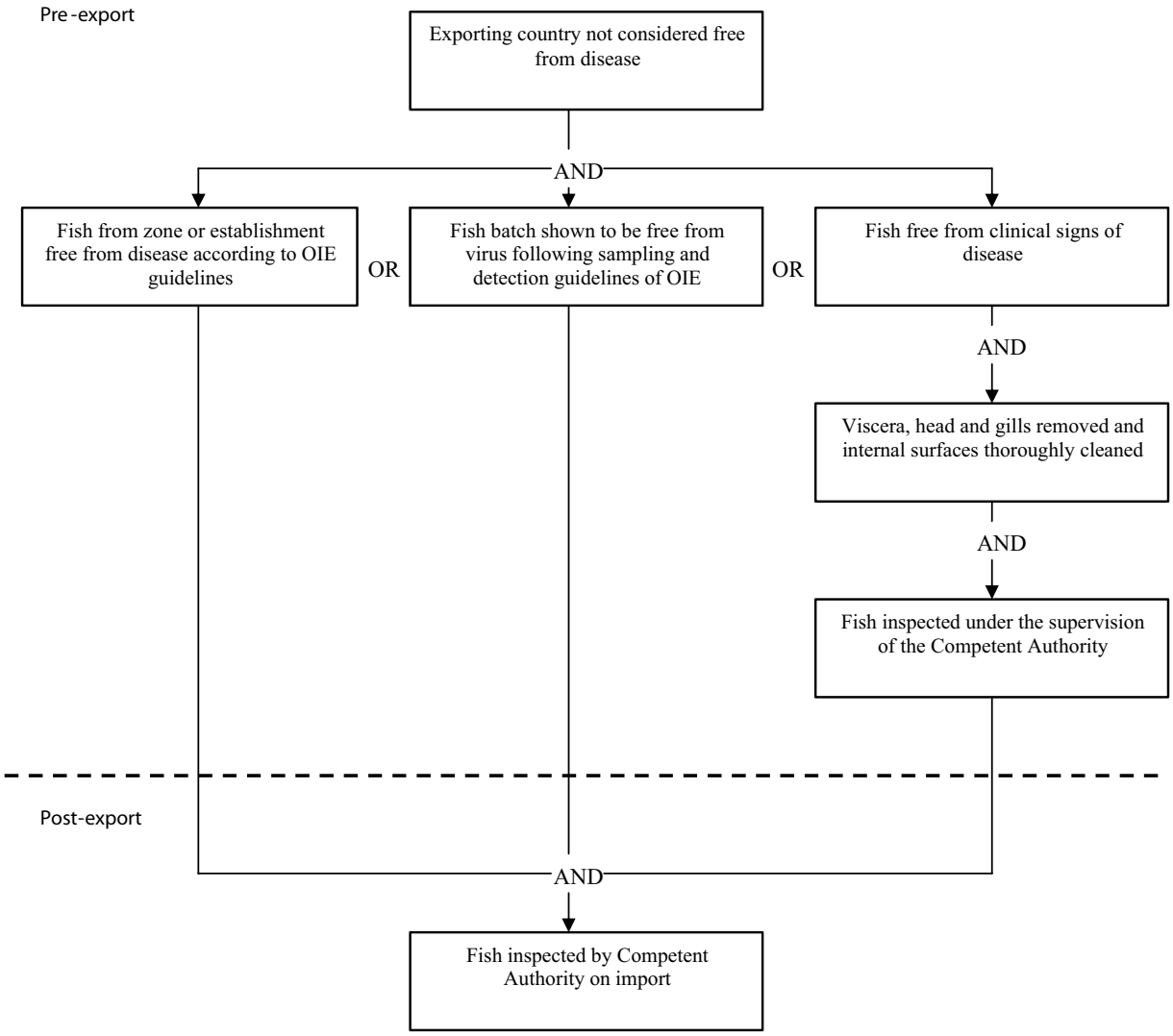
Option evaluation is the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the risk associated with an importation to below the importing country's ALOP. (modified from OIE 2003a)

In cases where the risk assessment has determined that the level of risk associated with the commodity exceeds the ALOP, ways to reduce the risk to an acceptable level are considered. The possible options for risk management will vary depending on the nature of the commodity and the individual hazard. Additional expertise in disease diagnostics, quarantine, disease treatment, post harvest processing, etc., may be consulted. Some examples of risk management measures for importations of living aquatic animals include:

- Sourcing from stocks of known disease status, including the use of specific pathogen free (SPF) stocks
- Importing eggs only
- Requiring quarantine and inspection in the country of origin
- Requiring quarantine and testing within the receiving country
- Use of International Council for the Exploration of the Sea (ICES) and OIE protocols
- Requiring the use of specific diagnostic tests and standards
- Requiring preshipment and/or postshipment treatments

The management options for each hazard must be carefully evaluated as to their likely effectiveness, and the risk presented by the hazard reassessed based on the expected results. Figure 5 shows an example of a summary of possible risk management steps recommended by the risk assessment for movement of live cultured juvenile fish from Country X to Country Y. The recommended measures generally apply to all exotic disease agents/parasites that may be identified during hazard identification.

Figure 5. Summary of the risk management steps recommended for viral haemorrhagic septicaemia in a hypothetical risk analysis for the movement of dead fish from Country X to Country Y.



In the end, two possible outcomes based on the likelihood of establishment of the hazard in the importing country and the probable consequences to the importing country (i.e., the mitigated risk estimation) may arise:

(i) The estimated mitigated risk for all hazards may now be below the ALOP, in which case the importation is allowed to proceed under the conditions that are required to meet the appropriate level of protection.

(ii) Effective management may be impossible for one or more hazards, so that the estimated mitigated risk remains above the ALOP. In this case, the importation will not be allowed.

An example of a hypothetical final risk evaluation taking into consideration the likely results of option evaluation is given in Table 3.

Table 3. Mitigated risk evaluation combining the results of exposure and consequence assessments for a hypothetical hazard using three qualitative rankings (high, medium and low). The risk evaluation decision is based on "low" as the appropriate level of protection (ALOP).

Likelihood of Entry and Exposure	Consequence of Establishment	Mitigated Risk Estimate	Risk Evaluation Decision
Low	Low	Low	Approve
Low	Medium	Medium	Reject
Low	High	Medium	Reject
Medium	Low	Medium	Reject
Medium	Medium	Medium	Reject
Medium	High	High	Reject
High	Low	Medium	Reject
High	Medium	High	Reject
High	High	High	Reject

It is important to note here several key principles of the SPS Agreement. Firstly, risk management must be applied in a least trade restrictive manner. In other words, if there are several different measures that will lower the risk to an acceptable level, then the least trade restrictive of those measures must be applied. Moreover, the SPS Agreement recognizes the concept of equivalence, where an exporting country has the opportunity to prove that its own measures are sufficient to lower the risk to meet the ALOP of the importing country. Finally, possibly the most important principle is consistency in application of the ALOP. Importing countries must apply the same ALOP, i.e., accept the same level of risk, at both external (international) and internal (national) borders. Moreover, ALOP must be applied consistently across the range of commodities in which that country deals, whether it be aquatic animals, other livestock, vegetables, and so on, without prejudice as to the country of origin. (Note that issues pertaining to the country of origin, such as disease occurrence, will be considered in determining the unmitigated risk estimate.)

10.3 Implementation and Monitoring and Review

Implementation is "the process of following through with the risk management decision and ensuring that the risk management measures are in place", while monitoring and review is "the ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended." (OIE 2003a)

In the case where the mitigated risk for all identified potential hazards is found to be below the ALOP and the importation is allowed to proceed, the Competent Authority has the duty to ensure that the importer fully complies with all conditions specified as essential to reduce the risk to below the ALOP. If there is serious non-compliance by the importer at any point in the risk mitigation process, or if a serious and untreatable disease is discovered in the imported stock, then the import permit may be revoked, the commodity destroyed and appropriate sanitary measures taken to ensure destruction of any pathogens.

11 OTHER IMPORTANT CONSIDERATIONS

11.1 "In house" vs More Extensive Risk Analysis

Developing countries, in particular, have serious constraints in terms of resources and expertise that can be devoted to risk analysis, and it is thus very important to identify the most important problems so that limited resources can be focused on them. After a few years of experience, a database of risk analyses for the commonly traded commodities will accumulate that will begin to allow quick separation of those requests to import that are likely to pose an **acceptable risk** as opposed to those that may involve a high risk or, in the case of requests to import new commodities, an unknown level of risk. Requests to import commodities that are variations on previously approved requests can usually be handled "in-house" and without proceeding through the full risk analysis procedure (once the risk is determined to be acceptable, the risk analysis stops).

In the case where a full risk analysis is required, and the importing country lacks the necessary expertise, outside expertise (e.g., national and international consultants) may be engaged to assist with the analysis. Donor agencies are increasingly recognizing the importance of good risk analysis procedures to assisting developing countries in promoting trade while protecting biodiversity and the social and economic well being of people depending on existing aquaculture and capture fisheries. Countries lacking the necessary resources or expertise to conduct an important risk analysis should thus consider seeking external funding support.

11.2 The Importance of Good Scientific Review

The importance of good, balanced scientific review of the technical aspects of the risk analysis cannot be over emphasized. This should include both:

- scientific review by experts selected for their specialized knowledge of aquatic animal diseases, and
- scientific review by experts selected for their specialized knowledge of risk analysis (see Rodgers 2004).

To ensure impartial scientific review, at least some reviewers should be drawn from experts outside the Competent Authority. As the documents produced by risk analysis are often lengthy and their critical evaluation can be quite time consuming, the Competent Authority should expect to pay external reviewers for their time and expertise.

Good external review also requires that the reviewers be provided with clear and adequate Terms of Reference.

11.3 Qualitative and Quantitative Approaches to Risk Analysis

A risk analysis may involve a risk assessment that is "qualitative" or "quantitative". In a qualitative risk assessment, the likelihood of a serious adverse outcome happening, or the magnitude of the negative consequences, is expressed in relative terms, such as "high", "medium" or "low". In a **quantitative risk assessment**, the likelihood is expressed in non-relative terms, such as "one disease introduction in 100

years of trade" or "failure to correctly identify one diseased establishment out of 100" or "any one salmonid would need to eat 400 kg of salmon scraps to be 50% certain of receiving an infective dose" (see Rodgers 2004).

Both qualitative and quantitative approaches to risk assessment are valid and, in practice, every risk assessment is first carried out qualitatively. Only if further insight is required is it necessary to attempt to quantify the risk.

Quantitative risk assessments can be used to:

- clarify thinking,
- provide insights into areas where data are lacking,
- deal with volume of trade issues,
- improve transparency,
- build upon qualitative risk assessments in complex or poorly understood cases, and
- investigate how effective a proposed risk reduction measure might be in reducing risk (sensitivity analysis).

Quantitative risk assessments require considerable specialized expertise and are often very time and resource consuming. Developing countries will find that a qualitative assessment will generally meet their needs for the vast majority of risk analyses.

A detailed treatment of quantitative risk assessment is beyond the scope of this manual. Readers seeking more information should refer to specialized texts such as that by Murray (2002) for guidance.

11.4 The Precautionary Approach

*"States should apply the precautionary approach widely to conservation, management and exploitation of living aquatic resources in order to protect them and preserve the aquatic environment. The absence of adequate scientific information should not be used as a reason for postponing or failing to take conservation and management measures." (**Code of Conduct for Responsible Fisheries, Section 7.5.1)***

The concept of the precautionary approach is widely used in fisheries management and elsewhere where governments must take action based on incomplete knowledge. Within the context of risk analysis for aquatic animals, a precautionary approach would be that both importing and exporting nations act responsibly and conservatively to avoid the spread of serious pathogens.

There is often a severe lack of data on pathogens and their life cycles, pathogenicities, prevalences, host specificities, geographical distributions, epidemiology, etc. to support risk analyses, particularly for countries in the developing world. Nevertheless, governments must often work with these uncertainties.

There are many cases where the application of the precautionary approach could have prevented the irreversible introduction of serious pathogens and the resulting severe socio-economic and/or ecological impacts (see for example, Bondad-Reantaso 2004b). Thus, the precautionary approach is an important approach that should be considered to prevent potential damage where data is lacking and evidence of a serious risk exists. However, the precautionary approach must be applied responsibly, and when applied, it should be used only as a temporary measure permitting the importing country the time necessary to collect and analyze the data needed to undertake a more objective risk analysis.

11.5 Developing Countries, Capacity Building and Risk Analysis

At first glance, the risk analysis process may appear complicated, particularly in light of the few high profile trade disputes involving aquatic animals and their products that have reached the World Trade Organization for settlement. However, developing countries should not be intimidated by the apparent complexity of the risk analyses that have been conducted by some developed nations. The risk analysis process is highly flexible and can be readily adapted to developing country situations with limited resources. Moreover, there are often a large number of circumstances that exist and a wide range of issues that need to be addressed. Therefore, it is strongly recommended that risk analyses be undertaken in a flexible manner. It is important to stress the need for certainty about the process: of what will be assessed (the scope of the risk analysis), of the key issues, of the consistency of the outcome, of equivalence and of the need to develop experience and a good understanding of the whole process.

For developing countries, the greatest struggle will be to obtain adequate information (both quantity and quality), to develop the capacity of staff, to implement disease surveillance to demonstrate country/regional freedom from specific disease agents, to implement effective legislation and to determine what constitutes an acceptable risk. It is extremely important to note that these difficulties do not force developing countries to accept a high level of risk.

Assistance from APEC, FAO, NACA, and OIE has been made available to assist developing countries in understanding the risk analysis process and in developing appropriate national expertise. Further assistance by these and other agencies in training and capacity building can be made available as the need arises. In particular, strengthening national sanitary and phytosanitary regulations and risk analysis capacities, enhancing national diagnostic laboratories and surveillance resources and linking these to regional and international aquatic health information systems, and developing and enhancing linkages of resources (information exchange, technical assistance, bilateral assistance, etc.) between developing and developed trading partners are key priority areas. Additionally, developing countries that become involved in international trade disputes should not hesitate to approach international and bilateral donors for assistance in conducting risk analyses for aquatic animals and their products.

Developing countries can also place much of the responsibility for conducting and/or funding many of the risk assessment activities on the would-be importers. This can include the hiring of private consultants to undertake the risk assessment.

The Competent Authority must, of course, maintain control of the entire risk analysis process, including the selection of any external consultants to maintain impartiality. The Competent Authority will set the detailed terms of reference (TOR) for any required technical support, will closely monitor the consultant's progress and will assess the comprehensiveness and accuracy of their results. It will also retain all responsibility for communication with stakeholders.

11.6 Politics and Science in the Risk Analysis Process

As previously mentioned, one of the most difficult problems faced by decision makers is that of deciding what constitutes an acceptable risk. Decisions have to be made in the presence of a great deal of complexity, significant variability, large uncertainties and multiple management goals. Deciding the ALOP for a country is a political decision, and will be made at the highest levels of government. ALOP, which applies to all animal and plant health and the environment, is a societal value judgment about how much a

community is willing to pay for protection against incursions, in forgone trade versus the benefits of trade. In determining the ALOP in aquatic animal movement, the government will take into consideration many factors, including the economic and social value of existing aquaculture and capture fisheries, the perceived value of natural biodiversity, and the likely economic and social benefits to be gained by trade in live aquatic animals and their products.

In the risk analysis process, the steps involving hazard identification and risk assessment represent the objective and scientific portion, while risk management constitutes the value-laden, politically contentious segment. The distinction between these two segments is one of focus and content, rather than of form. Despite this quite clear distinction, controversies and disputes still exist over many risk assessments performed well before any risk management decision-making has begun.

As noted by Rodgers (2004), risk analyses for aquatic animals often involve a high degree of subjectivity, due to the fact that there is often little data available to support hazard identification, risk assessment, risk management, etc. Thus risk analysts, either consciously or unconsciously, are often forced to make value judgements. Indeed this is unavoidable when, for example, assessing the probable consequences of a pathogen being introduced into a country. However, the risk analyst needs to be constantly aware of this subjectivity, and wherever possible, clearly indicate those interpretations and conclusions that are subjective in nature. It is important that the risk analysis be used to reach a decision, rather than to support a decision that has already been made.

Because a risk analysis can never be fully "objective", transparency in how decisions are reached is essential to encourage stakeholder support for the risk analysis decision. For a given risk analysis, there will usually be a wide range of stakeholders who will be affected to a greater or lesser extent, either negatively or positively by the risk analysis decision. Thus there will usually be disagreement among stakeholders about what constitutes an acceptable risk. Although stakeholders may disagree with a specific decision regarding a proposed importation, they should be able to see clearly how the decision was reached. Thus involving all stakeholders early in the process and within a structured time-table to ensure credibility of the process is necessary. A better understanding and acceptance of risk assessment by stakeholders can be achieved by a proactive risk communication strategy. Building trust among stakeholders is an important and long term-goal that needs to be achieved.

12 LITERATURE CITED

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ANNEXES

Annex I

Computer-based Resources Supporting Risk Analysis for Aquatic Animals

Discussion Groups/E-mail Fora

- Aquahealth: E-mail aquahealthLAC-L@mailserv.fao.org
- AquaVetmedNews: http://www.fishdoc.net/asac_ signup.html# AnchorAquaVetMe-22663 or e-mail to: DScarfe@avma.org
- International Society for Aquatic Animal Epidemiology, ISAAE list server: http://lists.upei.ca/mailman/listinfo/isaae.
- International Society for Infectious Diseases, Pro-Med-mail post: http://www.promedmail.org
- Marine Pathology: Contact majordomo@back.vims.edu
- Molluscan Health: e-mail: MolluscHealthOne-L@mailserv.fao.org
- Monogenean Discussion Group: monos-1@bio.ufpr.br; Contact: wboeger@bio.ufpr.br
- Parafish: http://www.anicca.net/parafish
- *Perkinsus* Identification: E-mail: perkid@ifremer.fr
- Shrimp One List: shrimp@onelist.com

Inter-governmental and Other Organizations:

- Asia-Pacific Economic Cooperation (APEC): http://www.apecsec.org.sg/
- Association of Southeast Asian Nations (ASEAN): http://www.aseansec.org/home.htm
- Food and Agriculture Organization of the United Nations (FAO): http://www.fao.org
- Global Aquaculture Alliance (GAA) http://gaalliance.org/
- International Center for Living Aquatic Resources Management (ICLARM): http://www.dec.ctu.edu.vn/cdrom/cd6/projects/iclarm_ 1197/index-1.htm
- World Organisation for Animal Health (OIE) http://www.oie.int
- Network of Aquaculture Centres in Asia-Pacific (NACA): http://www.enaca.org
- Secretariat of the Pacific Community (SPC): http://www.spc.org.nc/
- Southeast Asian Fisheries Development Center (SEAFDEC): http://www.seafdec.org
- World Fish Centre http://www.worldfishcenter.org/
- World Trade Organization (WTO) http://www.wto.org

International/Regional Agreements/Treaties

- Asia Regional Technical Guidelines on Health Management for the Responsible Movement of Aquatic Animals and the Beijing Consensus and Implementation Strategy: http://www.enaca.org/NACAPublications/AsiaRegionalTechnicalGuidelines.pdf
- Convention on Biodiversity http://www.biodiv.org/convention/articles.asp
- Cartagena Protocol on Biosafety: Text of the Protocol (http://www.biodiv.org/biosafety/protocol.asp)
- Food and Agriculture Organization of the United Nations, Code of Conduct for Responsible Fisheries (http://www.fao.org/fi/agreem/codecond/codecon.asp)
- International Council for the Exploration of the Sea (ICES) Code of Practice on Introductions and Transfers of Marine Organisms http://www.ices.dk/reports/general/2003/Codemarineintroductions2003.pdf
- Office International des pizooties, Aquatic Animal Health Code: http://www.oie.int/eng/normes/fcode/a_ summry.htm
- World Trade Organization Sanitary and Phytosanitary Agreement: http://www.wto.org/english/tratop_ e/sps_ e/spsagr_ e.htm)

Electronic Newsletters:

- Aquatic Animal Health Subprogram Newsletter: http://www.frdc.com.au/research/programs/aah/news.htm
- APHIS Aquaculture Industry Report/USDA Animal and Plant Health Inspection Service http://www.aphis.usda.gov/vs/aqua/aquaindu.html
- EdOp Net http://pdacrsp.oregonstate.edu/edops/edop.html
- FAO Fisheries and Aquaculture Newsletter (FAN): http://www.fao.org/fi/eims_search/advanced_s_result.asp?NO_IN_SERIEAN* &lang= en&sortorder= 3&form_c= AND
- Fish Health Section of the American Fisheries Society: http://www.fisheries.org/fhs/newslett.htm
- Fish Health Section of the Asian Fisheries Society: http://afs-fhs.seafdec.org.ph
- National Shellfisheries Association http://shellfish.org/pubs/qnl.htm
- The Crest (VIMS Newsletter): http://www.vims.edu/vimsnews/

National Strategies on Aquatic Animal Health

- Department of Fisheries and Oceans, Canada – National Code on Introductions and Transfers of Aquatic Organisms. September, 2003: http://www.dfo-mpo.gc.ca/science/aquaculture/code/Code2003_e.pdf
- Aquaplan – Australia's national strategic plan for aquatic animal health: http://affa.gov.au/outputs/animalplanthealth.html

Professional Societies

- Fish Health Section, Asian Fisheries Society: http://afs-fhs.seafdec.org.ph/
- Fish Health Section, American Fisheries Society http://www.fisheries.org/fhs/
- European Society of Fish Pathologists: http://www.ifremer.fr/eafp
- International Association for Aquatic Animal Medicine http://www.iaaam.org
- International Society for Infectious Diseases: http://www.isid.org
- International Society for Aquatic Animal Epidemiology http://www.ncsu.edu/project/cvm_ISAAE/
- Japanese Society for Fish Pathology: Contact hirono@s.kaiyodai.ac.jp
- National Shellfisheries Association http://shellfish.org/

Risk Analysis

- Aquaculture, Fisheries and Forestry – Australia (AFFA): http://www.affa.gov.au/content/publications.cfm
    - Current import risk analysis: freshwater crayfish: http://www.affa.gov.au/content/publications.cfm?Category= Biosecurity%20Australia&ObjectID= 104993BA-243A-4014-8F5DCE881F4DFA78
    - Current import risk analysis: freshwater finfish: http://www.affa.gov.au/content/publications.cfm?Category= Biosecurity%20Australia&ObjectID= FF33C2C8-3E16-41CE-8E770ABDD800BA28
    - Current import risk analysis: non-viable bivalve molluscs: http://www.affa.gov.au/content/publications.cfm?Category= Biosecurity%20Australia&ObjectID= 9A1BF387-33DB-4FAF-8C73AE1BD779ACFF
    - Current import risk analysis: prawns and prawn products: http://www.affa.gov.au/content/publications.cfm?Category= Biosecurity%20Australia&ObjectID= 27B461A7-E098-4522-B4B00184796DBEE3
    - Draft import risk analysis framework: http://www.affa.gov.au/content/publications.cfm?Category= Biosecurity%20Australia&ObjectID= DE0391E7-FF71-47DC-A77E3D5F73D0BE80

    - Draft import risk analysis guidelines: http://www.affa.gov.au/content/publications.cfm?Category= Biosecurity%20Australia&ObjectID= 85B98CC3-86DE-48AE-8A76D4A40F33245A
- David Vose Consultancy Ltd: http://www.risk-modelling.com
- Joint Institute for Food Safety and Applied Nutrition (JIFSAN) Food Safety Risk Analysis Clearinghouse. (Examples of worked risk assessments and a database of useful data (both published and otherwise) which could be used in a risk assessment process): http://www.foodriskclearinghouse.umd.edu
- New Zealand Ministry of Agriculture and Forestry (MAF)
    - MAF Biosecurity Authority: http://www.maf.govt.nz/biosecurity/
    - Import health risk analysis: salmonids for human consumption: http://www.maf.govt.nz/biosecurity/pests-diseases/animals/risk/salmonids-ra.pdf
    - Supplementary import risk analysis – head-on, gill-in Australian salmonids for human consumption.: http://www.maf.govt.nz/biosecurity/pests-diseases/animals/risk/salmonids-supplementary.pdf
    - MacDiarmid, S.C. 2000. Process for conducting import risk analyses for animals and animal products. (extract from Biosecurity, Issue 21, 8 August 2000) http://www.maf.govt.nz/biosecurity/pests-diseases/animals/risk/risk-analysis-process.pdf
    - MAF. 1996. Risk analysis. Opening the way for safety in agricultural trade. http://www.maf.govt.nz/biosecurity/pests-diseases/animals/risk/risk-analysis/index.htm
- Risk World (covers news and views on risk assessment and management) http://www.riskworld.com
- Society for Risk Analysis (provides a list of risk-related sites): http://www.sra.org/related.htm
- South Pacific Islands: http://www.spc.int/rahs/riskanalysis/framework.htm
- United States of America
    - Department of Environmental Health, Safety and Risk Management, University of Wisconsin: http://www.uwm.edu/People/rjg/ehslinks/ehslinks.html
    - US Department of Agriculture Animal Plant Health Inspection Service (USDA APHIS). Centers for Epidemiology and Animal Health (CEAH): http://www.aphis.usda.gov/vs/ceah/
    - US Department of the Environment http://www.em.doe.gov/irm/question.html
    - US Environment Protection Agency (EPA), National Center for Environmental Assessment (NCEA): http://www.epa.gov/ncea/ecorsk.htm
    - US Food and Drug Administration (FDA). Antibiotic risk assessment: http://www.fda.gov/cvm/antimicrobial/antimicrobial.html
    - US National Agricultural Library (contains information on HACCP, training courses and resources): http://www.nalusda.gov

Scientific and Disease Databases and Abstracting Services

- AGRICOLA (Agricultural Online Access): http://www.nal.usda.gov/ag98/ag98.html
- Aquatic Animal Pathogen and Quarantine Information System (AAPQIS): (http://www.aapqis.org)
- Aquatic Sciences and Fisheries Abstracts (ASFA): http://www.fao.org/fi/asfa/asfa.asp
- Biological Abstracts and BioResearch Index (BIOSIS), database for biological and biomedical sciences: http://www.biosis.org
- Cambridge Scientific Abstracts (e.g., ASFA): http://www.csa.com
- Commonwealth Agricultural Bureaux (CAB) Veterinary Sciences/Medicine database: http://www.cabi.org
- Food Science and Technology Abstracts database (International Food Information Service): http://www.ifis.org
- INGENTA http://www.ingenta.com/
- Northeastern Aquatic Animal Health Directory http://www.old.umassd.edu/specialprograms/nrac/
- OIE Collaborating Centre for Information on Aquatic Animal Diseases http://www.collabcen.net/
- PubMed, a service of the National Library of Medicine http://www.ncbi.nlm.nih.gov/entrez/query.fcgi
- Science Citation Index, Institute for Science Information (ISI):

http://www.isinet.com/isi/products/citations/sci/

- Science Direct: http://www.sciencedirect.com science?_ob= AbstractDB ListURI&_btn= Y&_acct= C 000050221&_version= 1&_userid= 10&md5= edd67229ef9df021dc88bc667b7ffd71
- Scirus http://www.scirus.com/srsapp/

Special Interest Websites

- Aquaculture Department of the Southeast Asian Fisheries Development Research Center: http://www.seafdec.org.ph/training/aquahealth.html; http://www.seafdec.org.ph/training/aquahealthonline.html
- Aquatic Animal Health Subprogram (Australia's FRDC): http://www.frdc.com.au/research/programs/aah/
- Aquaculture Health Page: http://www.geocities.com/CapeCanavera/Lab/7490/index.html
- American Library of Congress: http://www.lcweb.loc.gov/
- Aquatic Animal Health Commission (of the OIE): http://www.oie.int/fdc/eng/en_fdc.htm
- Aquatic Animal Health Research Institute (AAHRI): http://www.agri-aqua.ait.ac.th/aahri/seaadcp/AAHRI/aahri.htm
- Auburn University, Department of Fisheries and Allied Aquaculture: http://www.ag.auburn.edu/faa.faa1.html/
- Australian Centre for International Agricultural Research: http://www.aciar.gov.au/
- Ausvet Animal Health Services: http://www.ausvet.com.au/
- Bacterial Taxonomy and Nomenclature: http://www.uct.ac.za/depts/mmi/lectures/bactax/ppframe.html
- Centers for Epidemiology & Animal Health: An OIE Collaborating Center: http://www.aphis.usda.gov/vs/ceah/
- Centro Nacional de Acuicultura e Investigaciones Marinas, CENAIM: http://www.cenaim.espol.edu.ec/organizacion/japon.html
- CSIRO Animal Health Page: http://www.csiro.au
- Crayfish Disease: http://us.geocities.com/crayfishdisease/
- Dave Gibson's Home-Page: http://wwwdialspace.dial.pipex.com/town/plaza/aan18//
- DFO-Canada: http://www.pac.dfo-mpo.gc.ca/sci/shelldis/toc_e.htm
- *Gyrodactylus salaris* Page: http:// www.toyen.uio.no/gyrodactylus/
- International Committee on Taxonomy of Viruses: http://www.ncbi.nlm.nih.gov/ICTV/intro_to_universal/virus_nomenclature.html
- Index Virum: http://life.anu.edu.au/viruses/Ictv/fr-index.htm
- International Registry of Aquatic Pathology (at CEFAS): http://www.cefas.co.uk/products/Pathology.htm
- Internet Biodiversity Service: http://ibs.uel.ac.uk/ibs/
- Laboratoire de Genetique et Pathologie Home Page: http://www.ifremer.fr/latremblade/
- National Center for Biotechnology Information: http://www3.ncbi.nlm.nih.gov/Taxonomy/taxonomyhome.html
- Network of Aquaculture Centres in Asia-Pacific, Health Publications: http://www.enaca.org/modules/mydownloads/viewcat.php?cid= 5
- Oxford Marine Library - http://mrl.cofc.edu/oxford/
- The Disease Group, Institute of Aquaculture, University of Stirling: http://www.stir.uk/aqua/Disease/DisHome.html/
- The Sealice Website: http://www.ecoserve.ie/projects/sealice/
- The University of Arizona Aquaculture Pathology Home Page: http://microvet.arizona.edu/research/aquapath/index.htm/
- The University of Maryland Aquatic Pathobiology Center: http://www.som1.ab.umd/aquaticpath/
- The Whirling Disease Foundation: http://whirlingdisease.org/
- Unidad Mazatl n en Acuicultura y manejo Ambiental del Centro de Investigaci n en Alimentaci n y Desarrollo (CIAD): http://www.ciad.mx/mazatlan/ciadmaze.htm

Annex II

List of National Agencies Responsible for Implementing Risk Analysis and Other Related Aquatic Animal Health Services.[5]

Country	Agency	Remarks
Australia	• Department of Agriculture, Fisheries and Forestry (AFFA), Australian Quarantine and Inspection Service (AQIS) and Biosecurity Australia (BA) • Environment Australia, Department of Environment and Heritage	• AQIS has operational responsibility for animal and plant health with regard to import and export matters. • BA has responsibility for developing biosecurity policies (including the conduct of RA), negotiating export protocols for animal and plant health, and for assessing foreign Competent Authorities. • Environment Australia has responsibility for environmental protection and biodiversity conservation issues relating to the import and export of live animals and plants.
Bangladesh	• Ministry of Fisheries and Livestock (MoFL), Department of Fisheries and Department of Livestock • Ministry of Commerce	• Department of Fisheries is responsible for quality control. • Department of Livestock is responsible for animals. • Ministry of Commerce is responsible for ornamental fish.
Belize	• Ministry of Agriculture and Fisheries, Belize Fisheries Department and Belize Agricultural Health Authority (BAHA)	• Implementation of RA is mandated to BAHA, which is thus the lead agency for farmed animals, but works in conjunction with the Fisheries Department for wild marine animals and freshwater aquatic animals. • Both agencies work along with the Coastal Zone Management Authority and Institute for the National Plan of Aquaculture, which includes aquaculture policy development.
Cambodia	• Ministry of Industry • Ministry of Health, Department of Veterinary and Animal Production	These agencies: • Control quality standards of all food products including fisheries and aquaculture products. • Issue issuance for quarantine service. • Control sanitation of aquatic animals and provide certificates.
Canada	• Department of Fisheries and Oceans Canada (DFO) • Canadian Food Inspection Agency (CFIA)	RA is a shared responsibility between DFO and CFIA. • CFIA is the lead agency for RA on terrestrial animals and their products. • DFO is the lead for RA on aquatic animals and their products.
Chile	Chilean National Fisheries Service (Servicio Nacional de Pesca de Chile)	• Competent Authority for aquatic animal health and sanitary quality of fisheries products for export. • Responsible for controlling aquatic animal diseases and pharmaceutical product residues. • Responsible for the sanitary control and certification of fisheries products for export.

[5]The economies/governments listed are those that participated in the APEC FWG 01/2002 "Capacity Building on Import Risk Analysis for Aquatic Animals" Training/Workshops held in Bangkok, Thailand in April 2002 and Mazatlan, Mexico in August 2002. The information presented here was provided by participants during the workshops.

Country	Agency	Remarks
Colombia	Institute of Fisheries and Aquaculture (INPA - Instituto de Pesca y Acuacultura)	
Cuba	• Fisheries Industry Ministry (Ministerio de la Industria Pesquera) • National Civil Defense (Defensa Civil Nacional) • Ministry of Agriculture (Ministerio de Agricultura), Institute of Veterinary Medicine (Instituto de Medicina Veterinaria)	• Civil Defense identifies and evaluates the factors related to hazards, vulnerability and risk and determines the planning necessary for the protection from all types of catastrophes. • The Ministry of Agriculture, in coordination with the Ministry of Fisheries, organizes and carries out actions for the protection of aquatic animals of economic interest and, with the participation of the Institute of Veterinary Medicine, establishes all health regulations designed to protect the country from the entry of exotic diseases that could affect aquatic resources. • The Institute of Veterinary Medicine is the Competent Authority for animal health, epizootiological surveillance, quarantine, etc.
Ecuador	Instituto Nacional de Pesca y Acuicultura (INPA) (National Institute of Fisheries and Aquaculture)	• Responsible for implementing all policies, research, quality control and regulations related to fisheries and aquaculture.
El Salvador	• Fisheries and Aquaculture Development Center (CENDEPESCA – Centro de Desarrollo de la Pesca y Acuicultura). Directorate General of Animal and Plant Health (Direccion General de Sanidad Animal y Vegetal - DGSAV).	• CENDEPESCA is responsible for regulations concerning fisheries and aquaculture. • DGSAV is responsible for live animal health.
Guatemala	Standards and Regulations Unit (UNR – Unidad de Normas y Regulaciones)	UNR belongs to the Agriculture Livestock and Food Ministry (MAGA) and is responsible for implementing RA for aquatic animals. However, the Fishery and Aquaculture Management Unit (UNIPESCA), which belongs to MAGA, is the technical adviser on aquaculture topics. Both agencies work together through the Working Group on Pathology (GTT – Grupos de Technicos de Trabajos in Pathology) with the participation of universities, producers and governmental institutions. The Aquaculture Health Management program includes RA as one of the identified topics.
Honduras	Secretariat of Agriculture and Livestock (SAG) • DIGEPESCA (Direccion General de Pesca) (Directorate General of Fisheries and Aquaculture) • SENASA (Servicio Nacional de Sanidad Agropecuaria) (National Service for Agriculture and	• DIGEPESCA is responsible for legislation for fishing and aquaculture that includes research, capture fisheries, processing and marketing; achieving the sustainable development of aquaculture and fishing; working in coordination with other private, governmental and international organizations in areas that affect aquaculture and the control and inspection of certain fiscal obligations related to the fishing and aquaculture sectors. • SENASA is responsible for safeguarding the protection and health of plants and animals, and conservation of their products and by-products against pests and diseases of economic importance or that require quarantine and affect humans; strengthening phytozoosanitation, mainly for diagnosis and epidemiological surveillance, agricultural quarantine and control of agricultural supplies, control of products of

Country	Agency	Remarks
		animal and plant origin, programs and phytozoosanitary control campaigns and the mechanisms of national and international harmonization and coordination; and planning, developing and evaluating joint activities with the public and private sectors, as well as national and international entities having a relationship with agricultural health.
Hong Kong, China	Agriculture, Fisheries and Conservation Department	
Indonesia	Ministry of Marine Affairs and Fisheries (MMAF): • Directorate of Fish Health and Environment (DFHE) • Centre for Fish Quarantine (CFQ)	• DFHE is responsibile for developing policy, rules and regulations on fish health management and environmental protection, including RA. • CFQ has operational responsibility for fish health with regard to import and export matters, including implementation of RA.
Mexico	Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA - Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación) • National Service of Health, Food Security and Quality of Plant and Animal Products (SENASICA - Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria)National Commission of Aquaculture and Fisheries (CONAPESCA - Comisión Nacional de Acuacultura y Pesca) • National Fishery Institute (INP - Instituto Nacional de la Pesca)	• Implementing RA is a shared responsibility between SENASICA, CONAPESCA and INP. SENASICA is the lead agency for RA on plants and animals and their products, supported by CONAPESCA and INP for RA on aquatic animals and their products. • SENASICA has operational responsibility for animal, plant, fisheries and aquaculture health and their products, as well as their food safety. • SENASICA has operational responsibility for animal, plant, fisheries and aquaculture with regard to import and export matters, through quarantine, biosecurity and food safety programs. CONAPESCA and INP support the activity on aquatic animals. • SENASICA approves operational programs for health and food security of plants, animals, and fishery and aquaculture products being imported and exported by the private sector. • CONAPESCA and INP support SENASICA in developing biosecurity policies (including the conduct of RA) and negotiating export and import protocols for aquatic animals. • SEMARNAT (Secretaría de Medio Ambiente y Recursos Naturales) has responsibility for environmental protection and biodiversity conservation issues relating to the import and export of live animals and plants.
Myanmar	Ministry of Livestock and Fisheries, Department of Fisheries	
Nepal	Ministry of Agriculture and Co-operative Department of Agriculture • Directorate of Plant Protection • Directorate of Fisheries Development Department of Livestock Services • Directorate of Animal Health	• Plant Quarantine Section of the Directorate of Plant Protection is responsible for implementing RA for plants, seeds and other agricultural related products. • Livestock Quarantine Section of the Directorate of Animal Health is responsible for implementing RA for livestock, fish and fisheries and livestock products. • Directorate of Fisheries Development is a focal technical wing at the policy level and coordinates with concerned institutions in implementing RA in the fisheries subsector.
Nicaragua	Aquatic Animal Health Unit of the Inspection and HACCP Certification	MAGFOR, through the Directorate General of Agricultural Health (DGPSA), and the Directorate of

Country	Agency	Remarks
	Department of the Ministry of Agriculture and Forestry (MAG-FOR - Unidad de Sanidad de Acuicola del Departamento de Infeccion y Certificacion HACCP del Ministerio Agropecuario Forestal)	Animal Health, is authorized to: • Prevent, promote the control of, and organize eradication campaigns for pests and diseases of animals and plants, avoid their spread, and promote the integrated management of pests in plants and vegetables. • Establish sanitary and phytosanitary measures to facilitate, prohibit or restrict the movement, exportation and importation of plants and animals, as well as the products and by-products of agriculture, aquaculture, fishing, forestry and agroforestry. • Create the DGPSA, as the authority for coordination, production, execution and consultation for the programs and policy of MAG-FOR, in order to facilitate, promote standards and regulate sanitary and phytosanitary policy leading to the planning and coordination of all the national activities linked to health in agriculture, aquaculture, fishing, forestry and agroforestry. The Directorate of Animal Health, through the Inspection and HACCP Certification Department: • Forms and regulates the HACCP group, which is responsible for monitoring and control of the functioning of the system. • Carries out and verifies sanitary inspections in establishments authorized to slaughter animals for internal consumption and exportation. • Produces sanitary standards in order to implement them in any industrial, livestock, aquaculture and fishing activities that have no regulation. • Controls the movement of animals, products and their by-products, pharmaceuticals, biological and feed products for animals, as well as the establishments concerned with internal sanitary barriers, quarantine, isolation and animal sacrifice.
Panama	Livestock and Agriculture Development Ministry (MIDA - Ministerio de Desarrollo Agropecuario) • Aquaculture National Directorate (DINAAC - Dirección Nacional de Acuicultura) • Animal Health National Directorate (DINASA - Dirección Nacional de Salud Animal) • Livestock and Agriculture Quarantine Executive Directorate (DECA - Dirección Ejecutiva de Cuarentena Agropecuaria) Panama Maritime Authority (AMP - Autoridad Maritima de Panamá) General Directorate of Marine and Coastal (Shore) Resources (DIGERAMA – Direccion General de Recursos Marinos y Costeros)	• MIDA-DINAAC is responsible for policy concerning aquaculture and the utilization of aquaculture resources in marine, coastal and continental areas, in coordination with related institutions (DINASA-DECA). • MIDA-DINASA is responsible for diagnostics, surveillance, epidemiology, and the control of products of animal origin. • MIDA-DECA is responsible for quarantine for the control of raw materials from livestock and agriculture, including products from animal and plant sources. • AMP-DIGERAMA is responsible for regulations concerning the extraction and utilization of marine fishery resources. • MINSA-DPA is responsible for the organization and implementation of actions for the management and control of raw materials, products, and by-products from animals.

Country	Agency	Remarks
	Health Ministry (MINSA - Ministerio de Salud), Food Protection Department (DAP - Departamento de Protecció n de Alimentos)	
Philippines	Department of Agriculture, Bureau of Fisheries and Aquatic Resources (BFAR)	
Peru	• Vice Ministry of Fisheries (Vice Ministerio de Pesqueria) • National Service of Agricultural Health (SENASA - Servicio Nacional de Sanidad Agriaria) • National Institute of Natural Resources (INRENA - Instituto Nacional de Recursos Naturales)	• The Vice-Ministry of Fisheries is responsible for policy, research, quality control and regulations related to fisheries and aquaculture. • SENASA is the lead agency for prevention and control of the sanitary security of terrestrial animals and plants. • INRENA is the lead agency for the management of natural resources and the environment.
Singapore	Ministry of National Development, Agri-Food & Veterinary Authority of Singapore (AVA)	
Sri Lanka	• Ministry of Fisheries & Ocean Resources (MOFOR), Department of Fisheries and Aquatic Resources (DOF) • Ministry of Agriculture and Livestock Development (MOALD), Department of Animal Production & Health (DOAPH)	• Implementation of RA is a shared responsibility between MOFOR and MOALD. • Other agencies involved include the National Aquatic Resources Research & Development Agency (NARA) and the National Aquaculture Development Authority of Sri Lanka (NAQDA)
Thailand	Ministry of Agriculture and Cooperative • National Bureau of Agricultural Commodity and Food Standards (ACFS) • Department of Fisheries • Department of Agriculture • Department of Livestock Development	• One bureau and three departments under the Ministry of Agriculture and Cooperative share responsibility for implementation of RA for agricultural products.
United States of America	• United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) • Department of Commerce, National Oceanic and Atmospheric Administration (NOAA) • Department of the Interior, Fish and Wildlife Service	• Implementation of RA is a shared responsibility between three federal agencies - USDA/APHIS, Commerce/NOAA Fisheries, and Interior/Fish and Wildlife Service. • APHIS is the lead agency for farmed animals, NOAA for wild marine animals, and the Fish and Wildlife Service for freshwater aquatic animals.
Venezuela	National Institute for Fisheries and Aquaculture (INAPESCA - Instituto Nacional de Pesca y Acuicultura)	• Responsible for the National Plan of Aquaculture, which includes aquaculture policy development and the introduction of exotic organisms into the country.
Vietnam	• Ministry of Fisheries, Fisheries Resources Conversation Department (FRCD) • Ministry of Agriculture and Rural Development, Animal Health Inspection Department (AHID)	• FRCD, in cooperation with the Research Institute for Aquaculture No. 1 (RIA1), RIA2, RIA3, the Research Institute of Marine Products (RIMP) and universities and colleges related to fisheries conduct research before extension to broader users. • AHID is responsible only for fish species listed by CITES.